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Nóirín O'Herlihy MB MICGP MPH

Technology-enhanced learning and proficiency based progression to investigate and mitigate 'wrong blood in tube (WBIT)s' in our hospitals; can we improve patient safety and reduce resource wastage?

Thesis submitted to the College of Medicine and Health,

National University of Ireland, Cork

For the degree of Doctor of Medicine (MD)

February 2020

The Department of Medicine, University College Cork

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Dedication

I dedicate this thesis to my family and to frontline healthcare workers.

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Table of Contents

DEDICATION 2
ACKNOWLEDGEMENTS 3
LIST OF TABLES 11
LIST OF FIGURES 12
LIST OF ABBREVIATIONS 12
DISSEMINATION OF THE RESEARCH 13
Conference Presentations *13*
Other Presentations *14*
Papers in relation to thesis provisionally accepted for publication 18/02/2020 ..... *14*
Paper prepared for submission to the International Journal of Laboratory Haematology *14*
DECLARATION 15

THESIS ABSTRACT AND SUMMARY 16
INTRODUCTION 18
RESEARCH SETTING AND DATA SOURCES 19
ICM and APEX information systems for Haematology Blood Samples 19
Blood Forms and APEX information system for Blood Transfusion Samples 19
OVERALL AIMS AND OBJECTIVES 19
Aim of the Study *19*
Specific Objectives 20
METHODS 20
STUDY DESIGN 22
THESIS OUTLINE 22

CHAPTER ONE: BACKGROUND 24
QUALITY IN LABORATORY MEDICINE 24
Quality in the Irish healthcare system *24*
Quality in medical laboratories in the Irish healthcare system *24*
Accreditation of medical laboratories in Ireland 24
National Haemovigilance Office reports 25
Are electronic identification systems invariably safer: NHO report on BloodTrack 25
Audit of blood transfusion errors at Cork University Hospital *26*
Total testing process *26*
Pre-analytical laboratory errors 27
Quality indicators in the total testing process 27
Factors leading to pre-analytical errors *28*
Table 1.2 Factors leading to pre-analytical errors *28*
Interventions to reduce pre-analytical errors *28*
Phlebotomy standards *31*
Wrong blood in tube (WBIT) *32*
Definition of WBIT 32
Incidence of WBIT 32
Incidence of WBIT errors leading to harm 33
Detection of WBIT 34
Factors contributing to WBIT 34
Human error 34
Patient registration and wrist bands 34
Labelling remote from the patient 34

Failure to use positive patient identification 35
Staff group at greatest risk of error 36
Patient using another person's identity 36
Consequences pre-analytical errors and WBIT 36
Death 36
Inappropriate treatment 36
Lack of appropriate treatment 36
Misdiagnosis 37
Delay 37
Reputational issues 37
How often does WBIT result in harm? 37
Further clinical examples of harm 37
The majority of WBITS are likely to go undetected 37
Audit and reporting: the opportunity to learn and redesign 37
Recommendations to reduce WBIT identified in previous studies 38
Organisational policies and protocols 38
Zero tolerance policy 38
Labels used immediately and correctly 38
Education and training 38
Audit and feedback 39
Electronic barcode scanning systems 39
A group check sample policy 39
Two healthcare practitioners to sign the blood specimen 39
Multiple interventions applied together at different risk points in the sampling process 40
Minimum standards for blood sample labelling at Cork University Hospital 40
Standard operating procedure (SOP) for performing bloods at Cork University Hospital 41
iClinical Manager (ICM) 42
Retrospective analysis of blood transfusion and haematology laboratory WBIT events in 2015 and 2016 42
Example of reference event: Near-miss WBIT at CUH Emergency Department 43
Approaches to analysing safety in healthcare 44
Safety 1: Ensure as few events as possible go wrong 44
Safety 2: Ensure as many events as possible go right 44
Improving pre-analytical errors at Cork University Hospital: the case for proficiency-based progression training 45
Why change is needed 45
PROFICIENCY-BASED PROGRESSION TRAINING 45
Proficiency-based progression training versus traditional training in previously validated settings 45
Skill development – relevant educational research 46
Metrics – relevance and development 47
Metric validation 47
Proficiency standard 47
Proximate feedback 48
Evidence for proficiency-based progression training 48
Conclusion 49
CHAPTER TWO: METRIC DEVELOPMENT AND VALIDATION 51
BACKGROUND 51
METHODS 52
Metric Development 52
Background of the process of procedure characterisation 52

PROCEDURE CHARACTERISATION TO DEVELOP METRICS FOR THE PERFORMANCE OF PHLEBOTOMY AT CORK UNIVERSITY HOSPITAL. 53
First metric-development meeting, February 4th, 2017 54
Second metric-development meeting, February 16th, 2017 54
Third metric-development meeting, March 2nd, 2017 56
Fourth metric-development meeting, March 9th, 2017 58
Fifth metric development meeting, March 23rd, 2017 59
Background of stress-testing the metric 59
Stress-testing of the phlebotomy metric, April 6th, 2017 60
Table 2.1. Metric version four before stress testing took place 60
Background of the Delphi method 65
Background: Delphi vs modified Delphi 65
Delphi consensus panel for phlebotomy metric 65
Report from Delphi meeting, May 12th, 2017 66
Results of metric development and stress-testing the metric 66
Results of Delphi consensus panel 67
Modification to the metric included: 67
Background of validity and reliability 79
Construct validity: phlebotomy metric 79
Results of Construct Validity Study 81
Background of proficiency benchmark 83
Setting the proficiency benchmark for WBIT proficiency-based progression training in CUH 83
DISCUSSION 83
LIMITATIONS 84
CONCLUSION 85
MAIN MESSAGES 85
CHAPTER 3: PROFICIENCY-BASED PROGRESSION (PBP) INTERN TRAINING MITIGATES CRITICAL BLOOD SAMPLING ERRORS, INCLUDING 'WRONG BLOOD IN TUBE' 86
ABSTRACT 86
INTRODUCTION 86
METHODS 88
Study Design 88
Phase 2: Controlled Trial 88
Methods- accessing the data 94
Haematology laboratory 94
Transfusion laboratory 95
RESULTS 95
BACKGROUND RATES OF THE PRIMARY OUTCOME WBIT IN THE HOSPITAL BEFORE AND DURING THE STUDY 95
Results: haematology department 97
Results: Blood transfusion department 100
Primary outcome 100
2016 100
2017 100
2018 100
DISCUSSION 102
KEY FINDINGS OF THE STUDY 102

Comparison with other studies *103*
Strengths of the study *104*
Weaknesses of the study *104*
Sample size 104
Inconsistent use of login details by doctors using the ICM system 104
Influence of untrained medical staff 104
Environmental factors 104
Detection bias 105
CONCLUSION 105

CHAPTER 4: OBSERVATION OF ASSESSMENT OF CLINICAL PERFORMANCE TO DETERMINE FACTORS CONTRIBUTING TO COMMON BLOOD SAMPLING ERRORS IDENTIFIED DURING REAL-TIME MENTORING PHASE OF PROFICIENCY-BASED PROGRESSION TRAINING IN CORK UNIVERSITY HOSPITAL – BARRIERS TO IMPLEMENTATION OF EVIDENCE-BASED TRAINING 106
INTRODUCTION 106
OBSERVATION FOR ASSESSMENT OF CLINICAL PERFORMANCE 107
CONCEPTUAL FRAMEWORK TO ANALYSE INTERN VERBAL FEEDBACK 108
METHOD 110
Setting *110*
STUDY SAMPLE 111
Study design *111*
Topic guide for semi-structured interview at end of mentorship on the wards *113*
Ethical approval *113*
Data collection and analysis *113*
RESULTS 113
DATA ANALYSIS 116
DISCUSSION 117
Key findings of the study *117*
Variable time taken 117
Equipment not curated/available 117
Butterfly vs Vacuette System 118
Patient not available 118
Computers and printers in short supply/not working 118
Task disturbance 118
Poor requesting practice 118
Patients lacking wristbands 118
Environmental/social factors 118
ECONOMIC CONSIDERATIONS TO ADDRESS THE DOCUMENTED BARRIERS TO PERFORMING PHLEBOTOMY ACCORDING TO THE METRIC 118
Comparison with other research *119*
Limitations *120*
WHAT IMPROVEMENTS ARE REQUIRED IN CUH TO ADDRESS THE FINDINGS IN THIS STUDY . 121
Conclusion *121*

CHAPTER 5: OVERALL DISCUSSION 122
INTRODUCTION 122
SUMMARY OF MAIN FINDINGS 122
The problem of pre-analytical errors and WBIT *122*
Pre-analytical errors and WBIT at Cork University Hospital *123*

Evidence for PBP training for transfer of knowledge in procedural skills *123*
Development of the PBP training programme in phlebotomy for CUH *123*
Controlled trial to determine the effect of PBP training in phlebotomy on the rate of blood sampling and labelling errors (including WBIT) at CUH *124*
Observation of assessment of clinical performance to determine factors contributing to common blood sampling errors identified during real time mentoring phase of PBP training in CUH – barriers to implementation of evidence-based training *125*
Strengths and limitations of thesis *126*
Health services research and policy implications *127*
Future research recommendations *128*
CONCLUSION 128

REFERENCES 130

APPENDIX 139
APPENDIX A. ETHICAL CONSENT 139
APPENDIX B: SENIOR PHLEBOTOMIST POST (TRAINING AND DEVELOPMENT) DEVELOPED AS AN OUTPUT OF THE STUDY 142
APPENDIX C: OTHER RESEARCH POSTER PRESENTATIONS RELATING TO THE PROJECT 146
APPENDIX D: EXAMPLE FEEDBACK LETTER TO INTERNS 147
APPENDIX E: PHOTOGRAPH OF INTERN INSTRUCTIONS FOR JOBS WHILE ON-CALL 149
APPENDIX F: HSE REPORT 150

REVIEW OF MISLABELLING ERRORS DURING BLOOD SAMPLE COLLECTION AT CORK UNIVERSITY HOSPITAL- 150

A REPORT FOR EXECUTIVE MANAGEMENT BOARD (EMB) 150

List of Tables

Table 1.1. Annual report National Haemovigilance Office, Serious adverse events involving transfused patient in 2016/2017
Table 1.2. Factors leading to pre-analytical errors
Table 1.3. Summary of studies which have examined the effectiveness of interventions to reduce pre-analytical errors
Table 1.4. International incidence of WBIT
Table 1.5 Trends in WBIT rates across sites in haematology and blood transfusion in 2015/2016
Table 1.6 Evidence for PBP training
Table 2.1. Metric version four before stress testing took place
Table 2.2 Members of the modified Delphi panel
Table 2.3 Modifications to the phlebotomy metric at modified Delphi procedure
Table 2.4 Phases of the phlebotomy metric and critical errors, if any, in each phase
Table 2.5 Description of the 11 phases in the final phlebotomy metric
Table 2.6 Final Metrics for Phlebotomy at CUH (version created May17, 2017)
Table 2.7 Construct validity: frequent errors which occurred in the novice group (n=5)
Table 2.8 Construct validity: frequent errors which occurred in the expert group (n=7)
Table 3.1 Baseline characteristics 2017 pilot study and 2018 follow-on study groups.
Table 3.2 Mean number of blood tests collected by interns
Table 3.3. Errors by interns in the haematology department in a three-month period from commencement of employment
Table 3.4 Logistic regression analysis of the probability of a blood test rejection in the haematology laboratory for July 2017 and July 2018 in comparison to July 2016
Table 3.5 Logistic regression analysis of the probability of a blood test rejection in the transfusion laboratory for year July 2017 and July 2018 in comparison to 2016
Table 3.6 Comparison of blood transfusion error rates between the three years for a two-month period from commencement of work by interns in July 2016, 2017, 2018
Table 3.7 Reason for rejection of blood sample in the blood transfusion laboratory for a two-month period from commencement of work by interns in July 2016, 2017, 2018
Table 4.1 Theoretical domain framework
Table 4.2 Standard form completed by the medical researcher following mentorship of interns on the wards
Table 4.3 Topic guide for intern interviews on the wards
Table 4.4. Baseline characteristics of 40 interns observed on the wards
Table 4.5. Number of bloods performed since commencement of employment up until PBP mentorship in phlebotomy
Table 4.6. Equipment difficult to find on the ward/missing from the ward essential to performance of phlebotomy
Table 4.7. Interruptions noted during phlebotomy on the wards
Table 4.8. Real world data on common deviations from the metric on the wards by interns

List of Figures

Figure 1.1 Blood sample labelling errors in the blood transfusion laboratory in 2010
Figure 1.2. Criteria for rejecting and accepting samples in biochemistry, haematology, microbiology and pathology laboratory in Cork University Hospital
Figure 1.3 Total number of WBITs compared across 2015 and 2016 in CUH and UHK
Figure 1.4. Ordinal differentiation between different levels of performance by Dreyfus and Dreyfus
Figure 2.1 Description of the varieties of human work which take place in the workplace
Figure 2.2. Description of current practice of phlebotomy at CUH in early 2017
Figure 2.3 Go-Pro camera worn by the participant (first person perspective) during video recordings of phlebotomy on the wards at CUH
Figure 2.4 Comparison of errors and critical errors performed by novice and expert groups
Figure 3.1 Bloody Excellence eLearning Programme, instruction to take blood
Figure 3.2 Bloods Excellence eLearning Programme, decontaminate the procedure tray
Figure 3.3. Bloody Excellence eLearning Programme, how to use the iCM software system
Figure 3.4 The phlebotomy simulation ward
Figure 3.5 Computers and label printers on the phlebotomy simulation ward
Figure 3.6 Interns training on the phlebotomy simulation ward
Figure 3.7 Model IV Arms used in the simulation ward to practice phlebotomy
Figure 3.8 Background rate of haematology WBIT in the hospital (trained and non-trained healthcare practitioners) in the haematology laboratory from October 2016 to December 2018.
Figure 3.9 Description of the background rate of WBIT in transfusion department in the hospital from 2013 to 2017.
Figure 3.10 Flow diagram of interns and blood samples analysed in 2016 control group, 2017 pilot study group and 2018 follow-on study group.

List of Abbreviations

BEST	Biomedical Excellence for Safer Transfusion
CUH	Cork University Hospital
CUMH	Cork University Maternity Hospital
FBC	Full blood count
GP41 -guide	Clinical Laboratories Standards Institute GP41 guideline
INAB	Irish National Accreditation Board
IRR	Inter-rater reliability
MedLIS	National Medical Laboratory Information System
NHO	National Haemovigilance Office
SFA	Superficial femoral artery
SHOT	Serious Hazards of Transfusion
STEP	Surgical training for endoscopic proficiency

ToT	Transfer of training
UHK	University Hospital Kerry
WBIT	Wrong blood in tube

Dissemination of the Research

Conference Presentations

Title/ Presentation type/ Date	Conference / Venue
Validation of phlebotomy performance metrics developed as part of a proficiency-based progression training initiative to mitigate wrong blood in tube. October 2017 (Poster)	Haematology Association of Ireland Annual Meeting, Belfast
Clinical Trial of Proficiency Based Progression (PBP) Intern Training to Mitigate Blood Sampling Errors including Wrong Blood in Tube (WBIT). November 2018 (Poster)	Haematology Association of Ireland Annual Meeting, Cork
Preliminary Results of a Clinical Trial of Proficiency Based Progression Training in Phlebotomy at a Large University Teaching Hospital to Reduce Blood Sampling Errors November 2018 (Poster)	Haematology Association of Ireland Annual Meeting, Cork
Qualitative Analysis of Factors Contributing to Common Blood Sampling Errors identified during Real Time Mentoring Phase of PBP training in CUH- Barriers to Implementation of Evidence-Based Training. (*Presentation on main stage - awarded recognition prize)*	Haematology Association of Ireland Annual Meeting, Cork. .
Clinical Trial of Proficiency Based Progression (PBP) Intern Training to Mitigate Blood Sampling Errors including Wrong Blood in Tube (WBIT). February 2019 (Poster)	Faculty of Pathology Annual Symposium 2019, Royal College of Physicians, Dublin.
Preliminary Results of a Clinical Trial of Proficiency Based Progression Training in Phlebotomy at a Large University Teaching Hospital to Reduce Blood Sampling Errors February 2019 (Poster)	Faculty of Pathology Annual Symposium 2019, Royal College of Physicians, Dublin

Other Presentations

Title/Date	Venue
Presentation of the Preliminary Results of a Clinical trial of PBP Training in Phlebotomy at a Large University Teaching Hospital to Reduce Blood Sampling Errors. 21st February 2017.	Laboratory Scientist lunchtime meeting CUH
WBIT: A Discussion of the Effectiveness of the PBP Training Programme in Phlebotomy. !8th September 2018.	Haematology Journal Club CUH
PBP phlebotomy training to mitigate blood sampling errors including WBIT	Teaching session with doctors in training in the Emergency Department at CUH
Keeping patients safe in CUH. Learning from Excellence. Wrong Blood in Tube. January 23rd, 2019.	Grand Rounds CUH

Papers in relation to thesis provisionally accepted for publication 20/11/2021

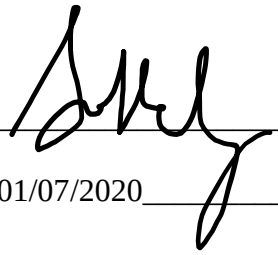
Validation of Phlebotomy Performance Metrics Developed as Part of a Proficiency-Based Progression Initiative to Mitigate Wrong Blood in Tube	Accepted by Postgraduate Medical Journal June 12th 2020.

Paper accepted by HRB open

Proficiency-Based Progression Intern Training to Reduce Critical Blood Sampling Errors including Wrong Blood in Tube	Version 1 – 2 peer reviews and accepted with reservations, awaiting review of version 2

DECLARATION

I declare that this thesis has not been submitted for another degree at this or at any other University. The work, upon which this thesis is based, was carried out in collaboration with a team of researchers and supervisors who are duly acknowledged in the text of the thesis. The Library may lend or copy this thesis upon request.

Signed: 

Date: ____01/07/2020_____

Thesis Abstract and Summary

Abstract

Background

Blood sampling errors are a frequent occurrence in healthcare. Wrong Blood in Tube (WBIT) errors are a serious blood sampling error that occur when the blood in the tube is not that of the person on the tube label. WBIT can lead to serious consequences including ABO incompatible blood transfusion with a risk of mortality, inappropriate diagnosis and inappropriate treatment of patients. Blood sampling errors are recognised globally. In Cork University Hospital (CUH), to maintain INAB accreditation at the laboratory, tracking and trending of blood sampling errors including WBIT is required. Since 2010, a steady incidence of WBIT errors was identified with a peak in incidence with the intake of new doctors to the hospital each July. Teaching by the medical school on phlebotomy, awareness campaigns and efforts by the haemovigilance team in the hospital failed to reduce the incidence of WBIT at CUH.

Aim

The aim of this study is to develop a novel proficiency-based progression (PBP) training programme in phlebotomy, specific for CUH to reduce the incidence of blood sampling errors, especially WBIT.

Objective

1. Engage with stakeholders in the process of phlebotomy at CUH and with experts in the field of PBP to develop metrics to define the procedure of phlebotomy at CUH.
2. Develop a PBP training programme in phlebotomy, specifically for interns commencing work in the hospital consisting of 1) Online module 2) Face-to-face training on a simulated ward 3) Mentorship of the doctors performing phlebotomy on real patients according to the metric.
3. Perform a controlled clinical trial to determine if the introduction of the training programme resulted in a reduction in blood sampling errors including WBITs in comparison to blood sampling errors in a retrospective control group in 2016 before the study commenced.
4. An observational study took place on the wards to identify the barriers and facilitators to implementation of the instructions provided in the metric.

Findings

A validated metric for performing phlebotomy at CUH was developed and used to develop a PBP training programme in phlebotomy.

In the haematology laboratory, 43 interns in 2016 control group had an error rate of 2.4% compared to 44 interns in the 2017 pilot study, who had an error rate of 1.2% (OR=0.50, 95% CI 0.36-0.70 p-value<0.01). 46 interns in the 2018 follow-on group had an error rate 1.9% (OR=0.89, 95% CI 0.65-1.21 p-value=0.46). There were three WBITs in 2016 and 2017 and five WBITs in 2018.

In the transfusion laboratory, there was a reduction in overall error rates with the introduction PBP training, but the reduction was not statistically significant. There was no blood transfusion WBIT in 2016, there was one blood transfusion WBIT in 2017, and no blood transfusion WBIT in 2018.

During observations of interns performing phlebotomy on the wards, phlebotomy was found to take a median of 20 minutes (minimum 10 minutes, maximum 45 minutes). There were often poor practices promoted by difficulty locating patients, task disturbance, poor requesting practices acting as a barrier to positive patient identification, patients not wearing wristbands to identify them, and environmental factors such as stress and lack of safety culture.

Conclusion

The effect of the PBP training programme in phlebotomy on the primary outcome WBIT was difficult to determine due to the rare occurrence of WBIT. There was not sufficient sample size to reach a statistically significant conclusion. Blood sampling errors appeared to be improving, but the effect size was smaller in the second year of the study possibly due to a reduction in the number of tutors available per group on the simulation ward and confounding. Observation of phlebotomy on the wards identified numerous barriers to key elements including positive patient identification, poor access to essential equipment and task prioritisation by busy doctors. Introducing bedside label printers and promoting a culture of safety are critical factors to improve the safety and reduce WBIT errors.

Summary

Introduction

This thesis systematically examines a global problem present in our hospitals and carrying with it much potential for patient harm, monetary and time costs in detection and remediation and a steady global rate suggesting universal difficulty in addressing the underlying issues.
Laboratory testing is a fundamental diagnostic tool for supporting medical decisions. Laboratory test results influence up to 70% of clinical decisions. Approximately 80% of clinical guidelines aimed at establishing a diagnosis or managing disease, require laboratory data. Errors in testing are under-recognised. The Institute of Medicine's landmark publication 'To Err is Human: Building a Safer Health System' asserts that medical errors occur due to good people working within bad health systems which need to be made safer. Laboratory errors are most common in the pre-analytical phase of laboratory testing. The most serious pre-analytical error is 'wrong blood in tube' (WBIT), an error that occurs when the blood in the tube (bottle) is not that of the patient identified on tubes label. Adverse consequences include harm to the patient and waste of resources. This error results from failure to identify the correct patient or failure to accurately label the tube. In this thesis, it accords with the WBIT acronym. Training and medical education have shown to reduce the occurrence of WBIT, but a significant and unacceptable level of error remains, with approximately 1.1 WBITs occurring per 1000 samples performed.
Having described the background to these pre-analytical errors in a busy academic hospital, the thesis describes the development of a bespoke, novel validated technology-enhanced learning approach using proficiency-based progression (PBP) in phlebotomy to reduce blood sampling errors, with a particular emphasis on labelling errors, including wrong blood in tube.
This training was then implemented in the form of two clinical trials of the training intervention. Outcomes were reliably measured by the laboratory and enhanced recording of details of mislabelling allowed for errors performed by the doctors to be followed-up and a learning feedback loop was instigated.
A qualitative study was also conducted which was very revealing of the environment in which the trials were conducted.

This thesis addresses the null hypothesis that the implementation of a multidisciplinary PBP training programme in sampling, labelling and phlebotomy in a busy teaching hospital – CUH- would have no effect on reducing errors (WBIT and other errors) in blood sampling as detected by the laboratory.
PBP has already proven successful in clinical training in orthopaedics and cardiology settings, leading to a reduction in error of 40% to 69%. The training programme produced could then be applied in other healthcare institutions, nationally and globally.

Research setting and data sources

ICM and APEX information systems for Haematology Blood Samples

The research took place in a busy teaching hospital at Cork University Hospital (CUH) with 800 in-patient beds. The hospital uses an electronic ordering system, 'iSoft clinical manager' (ICM). Using ICM software, the healthcare practitioner can order a blood test on the system and then print a label for the patient, which is affixed to the blood tube. The label is scanned in the laboratory, so the laboratory scientist knows which test is ordered without the need for a blood form. The ICM system records the person who orders the test and the person who prints the label after taking the blood test.
The laboratory uses an information system called APEX. This system has capability to record all the samples which are 'rejected" by the laboratory (a specimen is rejected if it fail to meet safe sampling and labelling standards as outlined in the laboratory handbook). Samples are rejected if they do not meet the minimum labelling criteria or if the sample cannot be tested due to problems such as insufficient blood sample, incorrect tube or haemolysis. All rejected samples and the reason for rejection are recorded on the APEX system.

Blood Forms and APEX information system for Blood Transfusion Samples

At the time of the study, the hospital did not allow the use of electronically generated labels in the transfusion laboratory, but these labels were accepted in the haematology, biochemistry and microbiology laboratories. The greatest danger of patient harm arises from mislabelling of samples which might be used to crossmatch a unit of blood for administration to a patient. Therefore, all blood transfusion samples were hand labelled and accompanied by a hand-labelled request form.
As a consequence of this policy, data collection in the transfusion laboratory required, the researcher to manually search each blood form. Examples of data required included 'requesting doctor' as it was important to determine if an intern (the subject of my intervention in this study) had performed the transfusion test requested.

The laboratory scientists record details of samples requested and reasons for rejection in the APEX software system. For the purpose of this MD, data on the samples rejected were extracted from APEX, using Cognos Impromptu software, and exported to Excel for analysis.

Overall aims and objectives

Aim of the Study

The study aimed to investigate and characterise behaviours and environment around the blood sampling procedure and followed with the identification, development, operational definition and then validation of phlebotomy performance metrics to characterise the optimal performance of healthcare practitioners' execution of phlebotomy. These validated metrics served as an educational and training tool to improve and quality assure phlebotomy training. The validated metrics were used to produce validated metric-based

simulations that establish a training benchmark based on experienced clinicians' performance and to underpin deliberate practice in phlebotomy.
By training healthcare professionals to a proficiency standard in phlebotomy, we aimed to reduce pre-analytical errors, with a focus on reducing WBIT errors. My research examined in detail the implementation of this training, its success, feasibility and sustainability, including barriers to implementation.

Specific Objectives

1. To establish the metrics (operational definitions) required to characterise and examine the phlebotomy procedure utilised by doctors in training, commencing with the instruction to take blood until the dispatch of the blood sample to the laboratory at CUH.
2. To characterise the hospital phlebotomy environments in which interns work while sampling.
3. To seek consensus from experts on the appropriateness of the steps and errors identified using a modified Delphi panel method. The hypothesis was that face and content validity for the step and error metrics derived from task deconstruction of phlebotomy procedure would not be demonstrated.
4. To determine construct validity of the metrics identified.
5. To develop and implement a PBP training programme in phlebotomy using a validated metric in phlebotomy specific for CUH.
6. To examine the pre-analytical errors in sampling and labelling that occurred among interns who commenced work in CUH in July 2016, over a three-month period (control group).
7. To determine the effectiveness of the PBP training programme in phlebotomy by performing a clinical trial to compare the blood-sampling errors of interns commencing work in 2017 and 2018, who had undergone PBP training in phlebotomy, and compare their errors to historical controls in 2016, when interns received no additional training in phlebotomy.
8. To perform a qualitative process evaluation during mentorship of doctors in training on the wards to inform further training.
9. To study the feasibility, sustainability and barriers to successful implementation of PBP training in phlebotomy in a busy hospital "real world" setting.

Methods

Historical data: examination of 'wrong blood in tube' and other pre-analytical errors occurring in the historical control group.
We examined the rate of pre-analytical errors occurring in interns who commenced work in the hospital in July 2016, over a three-month period. This group did not receive any

additional training and worked in the hospital prior to the commencement of the trial. Labelling errors in the Blood Transfusion and Haematology departments were identified and data on other pre-analytical errors which led to rejection of the blood test were collected. By examining how many blood tests were taken by the interns alone in the Haematology and Transfusion departments, a rate of error was calculated.

Procedure characterisation process: metric identification and validation. Meetings with practitioners who regularly undertook phlebotomy functioned to consolidate investigator understanding and planning of the research to be undertaken.

Metric identification and definition meetings with procedure 'experts' (e.g., investigators) and a technical advisor from laboratory and phlebotomy. This involved several meetings to comprehensively break down the component steps and characterise the process of phlebotomy.

Metrics stress testing and definition verification coupled with reliability. Stress testing the metric comprises two to three experts in phlebotomy, watching a video of a healthcare professional performing phlebotomy and scoring the performance using the metric. This serves to stress test the applied, practical usage of the metrics and their operational definitions. If ambiguities become apparent, the metrics are redefined to improve clarity.

Delphi meeting for the assessment of face and content validity of the procedure metrics. A consensus of experts from multiple backgrounds was reached on whether the metrics and their operational definitions appropriately characterised the reference procedure in question and provided the basis for identification of errors. The Delphi panel agreed on errors and their severity.

Construct validity assessment (at one individual site to a common protocol). Metrics retained as part of the procedure characterisation from the Delphi meeting were then used to establish the construct validity at distinguishing between the objectively assessed performance of experienced operators and novice operators.

Proficiency assessment and definition (face-to-face meeting)
On demonstration of construct validity for the metrics, investigators met to reach a consensus on which metrics or groups of metrics are required to be performed correctly so that proficiency in the procedure is clearly and quantitatively defined.

Proficiency-based progression training
The metrics and proficiency benchmarks were used to construct a proficiency-based progression education and training curriculum, which was delivered to the doctors in training on commencement of employment in the hospital in July 2017 and July 2018. The training comprised 1)an eLearning module, 2)PBP training on a simulated ward where the interns were expected to perform phlebotomy according to the correct process outlined in the PBP phlebotomy metric 3)mentorship of the interns while they were observed performing phlebotomy in their clinical environment on the wards in CUH.

Observation of Assessment of Clinical Performance to determine factors contributing to common blood sampling errors identified during real time mentoring phase of Proficiency

Based Progression Training in Cork University Hospital – Barriers to Implementation of Evidence Based Training

The final stage of PBP training in phlebotomy in 2017 was comprised of mentorship of the interns in their clinical environment. Observational notes were taken to record the performance of the interns and the barriers and facilitators to implementation of the correct process of performing phlebotomy as recommended by the metric. A short interview took place with the interns to gain an insight into their experience of the training and of performing phlebotomy on the wards. A theoretical domain framework was used to analyse their responses.

Study Design

Following initial scoping of the problem, analysis of historical data and its potential harm, a controlled trial was designed to compare the pre-analytical errors of doctors in training commencing work in the hospital in July 2016, who did not receive additional PBP training in phlebotomy (historical controls), to doctors in training commencing work in July 2017 and separately in July 2018, for a three-month period, who were provided with the PBP training programme in phlebotomy. The study protocol is registered with the National Institutes of Health (ClinicalTrials.gov) before initiation of the investigation and ethical approval was granted by the University College Cork Clinical Research and Ethics Committee.

Thesis Outline

The thesis is divided into chapters on the background (Ch 1), the development and validation of the novel training from scratch including the electronic component of the training (Ch 2), the clinical trials (Ch 3), the qualitative study (Ch 4) and the summary (Ch 5).

The thesis contains two papers assessing the specific objectives outlined above.

Chapter One outlines the current risk of laboratory errors, including WBIT. Pre-analytical errors, including WBIT, are defined. The incidence of WBIT nationally and internationally, the consequences of these serious events, and the evidence for interventions to reduce WBIT are outlined. The thesis portrays strategies by the World Health Organisation and other parties to improve positive patient identification and phlebotomy. A scoping of the literature on patient safety and underlying factors leading to WBIT occurs. The current trend of pre-analytical errors in CUH is illustrated, including a description of the risk factors leading to WBIT in the busy clinical workplace and the pre-intervention measures that had been in place to mitigate these errors.
Chapter One also provides the evidence for the effectiveness of PBP training use for medical and surgical procedures

Chapter Two addresses objectives one to three. Metrics (operational definitions) of the phlebotomy procedure are developed and stress tested using videos of phlebotomy being performed in CUH. The metrics are validated using a modified Delphi method to seek face validity and content validity. Construct validity is assessed. A proficiency benchmark is set, which is used in the PBP training programme.

Chapter Three describes how objectives four to six were executed. It details the implementation of the PBP training programme in 2017 and 2018, and data collection and analysis to compare retrospective data on the 2016 control group and the intervention groups in 2017 and 2018 to determine if the programme can effectively reduce blood sampling errors.

Chapter Four details a qualitative process evaluation during mentorship on the wards, which investigates the barriers and facilitators to embedding the PBP training programme in phlebotomy in the hospital culture.

Chapter Five provides an overall discussion of the main findings, the strengths and limitations of this thesis, and suggestions for future research.

The Appendix includes a report on the development and implementation of the training, produced specifically for the Health Service Executive to help disseminate the findings of the study.

Chapter One: Background

Quality in Laboratory Medicine

Quality in the Irish healthcare system

The Irish healthcare system continually aims to improve the quality of care provided to its health service users [1]. The Department of Health Statement of Strategy 2016-2019 states its objective to 'deliver high quality services' [2]. In Ireland, quality standards have been developed using an extensive process involving a review of the international and national evidence, in consultation with key stakeholders, and the establishment of an advisory group. Quality has been defined by the four quality dimensions set out in the Safer Better Healthcare Standard [3]. The four dimensions of quality are:

1. Person-centred: care that is respectful and responsive to an individual's needs and values and partners with them in designing and delivering that care
2. Effective: care that is delivered according to the best evidence as to what is clinically effective in improving an individual's health outcomes
3. Safe: care that avoids, prevents and minimises harm to patients and learns from things that go wrong
4. Better health and wellbeing: care that seeks to identify and take opportunities to support patients in improving their own health and wellbeing.

Quality in medical laboratories in the Irish healthcare system

Accreditation of medical laboratories in Ireland

Medical laboratories can demonstrate the quality of their service through accreditation, which can be attained in Ireland by applying to the Irish National Accreditation Board (INAB). The INAB uses the ISO 15189 Medical Laboratories: Requirements for Quality and Competence' Standard [4]. Irish Legislation (SI No 360 of 2005 and SI 547 of 2006) published as a result of the European Directives on the quality and safety of blood and blood products, requires blood bank laboratories to operate to ISO 15189 [5]. Blood transfusion laboratories can be closed by INAB inspectors if found in major non-compliance in clinically critical areas. To meet the standard required for accreditation, laboratories must demonstrate provision of advisory services to clinicians, collection of patient samples, provision of testing in a medical emergency, and the contribution of medical laboratory service to patient care, amongst other requirements. Additionally, blood transfusion laboratories must illustrate compliance with blood traceability standards and haemovigilance (notification of serious adverse reactions and events).

It is mandatory for all hospitals in Ireland to report serious adverse events relating to collection, testing, processing, storage, and distribution of blood and blood components to the National Haemovigilance Office (NHO). Since 2010, it has been mandatory for all hospitals to report all near-miss serious adverse events occurring in the hospital blood bank under Directive 2005/61/EC. These events are reported to the NHO, which reports to the

Health Protection Regulatory Authority, which, in turn, submits an annual report to the European Commission. Until 2019, these near-miss events did not include WBIT events. However, following an audit of performance on the incidents of WBIT, conducted by the NHO in 2017, since March 4th, 2019, it has been mandatory to report WBIT events in Ireland. This is an important step as reporting of near-miss events will allow for the recognition and analysis of errors, determination of patterns of errors, and monitoring for changes in frequency after corrective action is implemented as previously demonstrated [6]. Against this changing regulatory and reporting environment, the data in this thesis is timely and relevant. This data had been collected in Ireland ,in a survey in 2011 [7], and again in 2017 and 2018 [8]. The surveys had response rates averaging 50%.

National Haemovigilance Office reports

The NHO produce annual reports to describe the incidence of serious adverse events (table 1.1). In 2017, the NHO conducted a survey to establish Irish data on sample rejection in transfusion and WBIT rates [8]. This allowed the NHO to benchmark WBIT rates in Ireland against national and international rates and to compare the rate with a previous survey that was carried out in Ireland in 2011.
According to the NHO report for 2016 and 2017 [9], there were 23 unnecessary transfusions, of which two were due to sampling errors. Human error accounted for all 23 unnecessary transfusions. The reason for the human errors included 16 cases of failure to adhere to hospital policies or procedures, seven cases of lack of knowledge, six cases of poor coordination and communication, five verification errors (there was more than one cause in some cases)[9].

Table 1.1. Annual report National Haemovigilance Office, Serious adverse events involving transfused patient in 2016/2017 [9]

	2016	2017
Transfusion incorrectly labelled unit	10	16
Inappropriate / unnecessary transfusion	13	10
Blood or blood product to wrong patient (if no reaction)	2	1

Are electronic identification systems invariably safer: NHO report on BloodTrack

In 2011, some Irish hospitals began using BloodTrack, phase three, an electronic bar code system used for bedside transfusion sampling and administration practice. The 2017 survey aimed to determine if this had led to a reduction in rejection and WBIT rates in these hospitals. The survey identified that hospitals using this system had a higher incidence of WBIT and rejected samples in blood transfusion compared to hospitals which did not use BloodTrack phase three. To investigate further, a second survey was conducted in 2018. The 2018 report investigated the WBIT rates and the effect of BloodTrack phase three and the second sample rule, which had been implemented in some hospitals in Ireland. 97% of hospitals surveyed (51% response rate) had a standard operating procedure on sample acceptance and rejection criteria, 50% of hospitals had a zero-tolerance policy, and 46% hospitals had implemented the British Society of Haematology second sample recommendation [10]. Between all 39 sites, there were a total of 430,336 samples taken in

2017. There were 18,460 samples rejected in total, giving a rejection rate of 4.3%. Rejection rates were higher in sites using the BloodTrack system (rejection rate of 3.8% ranging from 1.1 to 20.5%) compared to sites who were hand-labelling the samples (rejection rate of 3.7%, ranging from 2.2 to 7.4%). One in 23 samples were rejected in 2018 compared to 2011, when one in 24 samples were rejected. Doctors were the healthcare professionals implicated in the highest number of WBITs, followed by nurses. The 2017 Irish WBIT rate (which does not correct for undetected WBITs) is 0.0137% (14 per 1,000 samples) [8]. The increase in WBIT events following the introduction of BloodTrack was disappointing and highlighted that the introduction of an electronic system does not guarantee an error-proof process. Correctly linking the sample to the patient with positive patient identification remains fundamental to the process and staff must be adequately educated and trained on how to use barcoding systems if they are to successfully reduce the incidence of WBIT.

Audit of blood transfusion errors at Cork University Hospital

Accreditation first began at the CUH Haematology and Blood Transfusion laboratories in 2010. As a consequence of this, an audit in the blood transfusion laboratory in 2010 – which examined 14,480 specimens received from CUH and Cork University Maternity Hospital (CUMH) and 13,375 specimens received from general practitioners – showed a peak of labelling errors in July and a small peak in January. This reflects the timing of the commencement of new doctors in training in the hospital, as illustrated in figure 1.2. Of the specimens, 983 (6.8%) of those received from CUH/CUMH were incorrectly labelled and 255 (1.9%) received from GPs were incorrectly labelled.

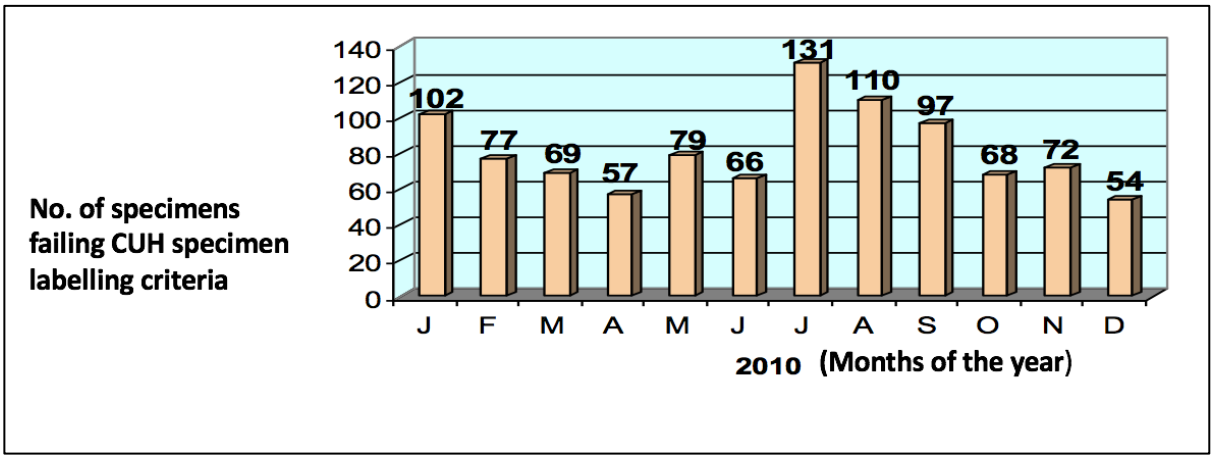


Figure 1.1 Blood sample labelling errors in the blood transfusion laboratory in 2010

Total testing process

Accreditation in the laboratory requires laboratories to examine each step in the total testing process, beginning with the test order prior to phlebotomy and ending with the timely return of an accurate result and interpretation to the requester. The total testing process is comprised of the pre-analytical, analytical, and post analytical phases [11]. Lundberg describes a virtual loop in the total testing process with a 'brain to brain cycle' comprised of

nine phases: ordering, collection, identification (at several stages), transportation, separation (or preparation), analysis, reporting, interpretation, and action [12]. In Ireland, the national accreditation process, compliant with ISO standards, requires laboratories to track each of these phases (except clinical action) for errors and to introduce quality-improvement initiatives where required. Quality in laboratory medicine requires action both within and outside the laboratory.

Pre-analytical laboratory errors

The pre-analytical phase of blood testing is the first phase in the total testing process of blood samples and comprises the process from deciding to perform the blood test to the arrival of the blood sample in the laboratory for analysis. Between 60% and 70% of laboratory errors occur in the pre-analytical phase of testing [13]. The most common pre-analytical errors identified include; incorrect blood to anticoagulant ratios for coagulation testing, patient identification errors, incorrect blood tubes, empty blood tubes, contradictory demographic information (cases where the tube and request do not match exactly) and sample dilution with an intravenous infusion solution, clotted samples, haemolysed samples [14].

Pre-analytical errors are costly. Detection and correction consume time and resources. They have been estimated to represent on average between 0.23% and 1.2% of total hospital operating costs [15].

During an observational study in 12 European countries, inadequate patient identification in the pre-analytical phase was identified in 16% of venous blood collections [16]. Patient identification and tube labelling were identified as the steps in phlebotomy with the highest risk occurrence. In 30% of cases where tubes were labelled following phlebotomy, i.e. labelling did not take place in the presence of the patient.

Quality indicators in the total testing process

Quality indicators have been developed to monitor and evaluate performance during each step of the total testing process and are a requirement for accreditation [17]. Quality indicators are described as tools which enable the user to quantify the quality of a selected aspect of care [18] and are used to audit standards in the laboratory to determine the level of compliance.

Examples of quality indicators in the pre-analytic phase of testing include [19]:

- standards for sample labelling (such as incorrect patient identification and unlabelled specimens)
- use of the correct blood tubes,
- under-filling or overfilling of the blood tube,
- haemolysed sample and
- clotted sample.

These quality indicators are tracked and characterized and should be monitored in medical laboratories to meet standards required for accreditation. The quality indicators encourage patient safety and minimise errors by allowing continual measurement of the level of error.

Factors leading to pre-analytical errors

Table 1.2 Factors leading to pre-analytical errors

Variability in phlebotomy performance by healthcare practitioners
Phlebotomy performed by healthcare professional other than a phlebotomist [20] [22, 23]
Poor positive patient identification practices [21]
Not allowing antiseptic solution to dry [21]
Rapid removal of tourniquet before blood starts to flow[21]
Poor calibre veins [21]
Lack of laboratory audit of identification errors [22]

Variability in the phlebotomy performance of healthcare practitioners has been identified as a possible source of pre-analytical errors. A study of nurses performing phlebotomy showed that some practitioners had poor practices, which included active and passive patient identification; not allowing antiseptic solution drying time; and rapid removal of tourniquet when blood started flowing [21]. Non-modifiable factors such as poor-calibre veins and instances when blood-drawing was difficult led to an increased risk of pre-analytical errors [21].

Samples collected by trained phlebotomists show reduced rates of haemolysis and contaminated EDTA samples and lower rejection rates in the laboratory [23] [24].

Laboratories that check computer orders against requisitions before tests are verified are better able to correct identification errors before results leave the laboratory. Post-verification error rates are lower at laboratories that monitor identification errors, suggesting that monitoring may be a useful method for heightening awareness about identification errors and promoting their detection before results are released [22].

Interventions to reduce pre-analytical errors

The following table (1.2) provides an overview of studies examining the effect of various interventions on pre-analytical errors.

Table 1.2. Summary of studies which have examined various intervention on pre-analytical blood sampling errors

Intervention	**Effect**
A systematic approach to identify and analyse the root causes of the problem was applied using quality tools such as a process flowchart and a fish-bone diagram. The Model for Improvement was used and several PDSA (Plan, Do, Study, Act) cycles were run to test interventions	A 25% reduction in errors during the pre-analytical stage.

which aimed to prevent laboratory processing errors and mistakes [25]	
Educational sessions provided to primary-care nursing staff [26]	According to the type of pre-analytical error, the incidents of pre-analytical errors were compared before and after the intervention. Compared incidences were: missed samples, 4.8% vs. 3.8%, p<0.001; haemolysed samples, 1.97% vs. 3.9%, p<0.001; coagulated samples, 0.54% vs. 0.25%, p<0.001; incorrect samples, 0.15% vs. 0.19% p=0.08; and other errors, 0.3% vs. 0.42%, p<0.001. This study concluded that one intervention does not appear to be effective enough.
Two separate short interventions consisting of educational posters and educational screensavers in the hospital [27]	There was no change in error rate or error type at the intervention site(s) compared with the control(s).
Educational program for nursing staff **Custom label system** **Detection, identification, and monitoring of the error and implementing strategies to improve pre-analytical quality [28]**	The educational program for nursing personnel decreased sample errors. The custom label system minimised the potential oversight of forgetting to draw a tube, which happens frequently when operating without appointments, by printing the labels according to requested tests. Detection, identification, and monitoring of the error and implementing strategies to improve pre-analytical quality reduces error numbers and thereby improves patient safety and health-system outcomes.
Retrospective study investigating multiple interventions [29] including: **1) restrictive specimen acceptance** **2) computer-assisted barcode positive patient identification system** **3) automated sample labelling combined with electronic identification systems**	There was a 97% relative reduction in patient-identification errors following introduction of the serial interventions.

Retrospective study analysing the effects of two interventions [30]: **1) one-on-one specimen collection education** **2) removal of an electronic option that allowed registered nurses to bypass the barcode safety function**	There was a 90% reduction in specimen labelling errors after introduction of the intervention i.e. rate of error of 0.131% reduced to rate of error of 0.014%
Multiple educational training activities were provided to hospital nursing staff and nursing students primarily responsible for blood collection, on a regular basis from 2008 to 2015	There was a significant reduction in rejected samples from 0.29% in 2007 to 0.07% in 2015, resulting in an improvement of 75.86% (*P* <0.050). In particular, specimen identification errors decreased by 0.056%, with a 96.55% improvement [31].
Education and training program covering the topics of method of blood sample collection, reinforcement of the knowledge on standardised blood sample collection procedures, causes of analytical interference, and methods for sample storage and transport.	Rates of pre-analytical errors decreased from 0.42% in the pre-intervention period to 0.32% in the post-intervention period [32].
Introduction of an laboratory information system and electronically generated laboratory orders and labels for the blood tube.	The total number of the top 4 preanalytical errors decreased significantly, from 3.20 per 1000 specimens pre-implementation to 1.93 per 1000 specimens post-implementation (*P* ≤.001). There was a significant decrease in mislabelled, unlabelled, and no specimen received errors (*P* = .0004, *P* = .001, and *P* = .000001, respectively), with no mislabelled or unlabelled specimens post implementation [33].
Systematic review of the effectiveness of venepuncture training on haemolysis rates [34]	There are no RCTS on the effectiveness of venepuncture training for reducing haemolysis rates, and findings from the existing uncontrolled studies are unclear [34].
Educational intervention delivered in primary healthcare centres in Sweden [35]	several significant improvements on phlebotomists' self-reported adherence to venous blood specimen sampling practices with attendance at the educational intervention including patient identification and blood sample labelling [35].

Phlebotomy standards

Venous blood sampling is one of the most common procedures performed in healthcare. At least three international standards agree on positive patient identification and bedside labelling in front of the patient. Surprisingly the HSE own guidelines (Guiding Framework for the Education, Training and Competence Validation in Venepuncture and Peripheral Intravenous Cannulation for Nurses and Midwives (2017) [36] do not mandate this. In the context of improving WBIT in the HSE, these guidelines fail to provide necessary 'local' support for an essential safety step. However, the standard operating procedure for performing phlebotomy in CUH clearly instructs healthcare professionals to positively identify patients and to label in the presence of the patient at the bedside (see Standard operating procedure (SOP) for performing bloods at Cork University Hospital).

International guidelines to ensure standardisation of phlebotomy procedure, include
i) Clinical Laboratories Standards Institute GP41 guideline [37]
ii) World Health Organisation guideline on drawing blood [38]
iii) British Committee for Standards in Haematology (BCSH) [10].

The Clinical Laboratories Standards Institute GP41 guide requires the healthcare practitioner to ask the patient their name and date of birth and if the patient is unconscious then a nurse or relative is required to give this detail. End-of-bed charts or other identification near the bedside are not adequate for identification purpose as these can be misplaced. The GP41 guide mandates that all tubes must be labelled **only when filled and whilst still in the presence of the patient**. Use of pre-labelled tubes is unacceptable; they are easily misplaced and mixed up with tubes collected from another patient [40].

The WHO provides instruction on the procedure to be followed when taking bloods. Regarding positive patient identification, it advises asking the patient's full name and then checking the request form against the patient details. It does not specify the requirement to check two patient identifiers a key element of the process as it frequently occurs that there might be two patients on the same ward with the same name. The guide advises on labelling the blood tube and checking it's accuracy after the blood sample is taken but does not clearly indicate that this process should be performed in the presence of the patient.

The British Committee for Standards in Haematology guidance provides recommendations specifically for blood transfusion sample collection [39].
Key recommendations include:

- Positive patient identification, where the healthcare practitioner asks the patient his or her name and date of birth. If the patient is unconscious, then a nurse or relative is required to give this detail. End-of-bed charts or other identification near the bedside are not adequate for identification purpose.

- All tubes must be labelled and filled whilst in the presence of the patient; taking the sample and labelling the tube should be a continuous, uninterrupted process undertaken by a single healthcare practitioner in the presence of the patient.
- Tubes should be hand-labelled in the presence of the patient, unless bedside label printers are available that can be used in the presence of the patient.
- Laboratories should have a policy on acceptance and rejection criteria of blood samples and should provide request forms that include acceptable labelling requirements and actions to be taken if the minimum criteria are not met.

Wrong blood in tube (WBIT)

Definition of WBIT

The most serious type of pre-analytical error, 'wrong blood in tube,' occurs when the blood in the tube in not that of the person identified on the label [40]. WBITs are an important patient safety issue. WBIT can lead to serious patient harm such as the cross match and transfusion of an incorrect blood group. This has been highlighted by the Canadian Patient Safety Institute who have listed avoidance of ABO-incompatible transfusions as one of five 'never events' [41].

The UK SHOT scheme, an independent, professionally led haemovigilance scheme that has been monitoring adverse events in blood transfusion in the UK since 1966, defines WBIT as events where:
1) Blood is taken from the wrong patient and is labelled with the intended patient's details (in other schemes 'mis-collected').
2) Blood is taken from the intended patient, but labelled with another patient's details (in other schemes 'mislabelled', but the term 'mislabelled' could include missing core identifiers or other errors which are not WBIT in SHOT).

Incidence of WBIT

In the transfusion literature, WBITs have been estimated to occur at a rate of between one in 1,303 to one in 2,717. The variation is due to differences in the definition of a WBIT and whether a correction factor is used to include undetected WBITs [40]. Table 1.3 illustrates the rates of WBITs [40].

Table 1.3. International incidence of WBIT

Location	Rate of WBIT	Definition	Correction factor	References
UK, 27 hospitals	1 in 1,303	Blood group not matching previous record	1·418	[42]
International, 10 countries, 71 hospitals	1 in 1,986	Blood group not matching previous record	1·6	[43]
International, 122 institutions (95·1% USA)	1 in 2,500	Blood group not matching previous record	None	[44]
USA single centre over five years	1 in 2,283	Blood group not matching previous record, clinical service notification, and others	None	[45]
North East England, 15 hospitals over 12 months	1 in 2,717	Blood group not matching previous record notifications from clinical areas	1·418	[46]
UK, national postal survey of 400 laboratories: 245 respondents	Estimated 1 in 6,000 red cell units issued	Self-reported by 20 respondents	None	[47]
France, five-year study, single blood bank for 35 hospitals	1 in 3448	Blood group not matching previous record	None	[48]
Spain, single-centre study over six months	1 in 2243	Detected by comparison with past samples	1·4388	[49]

Incidence of WBIT errors leading to harm

Identification errors which are detectible are usually noted in the laboratory before the result is released to the doctor and in this case harm is prevented. In a study comprising more than 120 laboratories in the US, over 85% of identification errors were detected by the laboratory before verification occurred and results were therefore not authorised to the doctors. However, 55 in 1,000,000 blood tests performed were unwittingly released from the laboratory although the results were, in fact, WBIT events and provided incorrect results. Adverse events resulted from one in every 18 identification errors that were not picked up by the laboratory. More than 70% of the adverse events due to the identification

errors resulted in significant patient inconvenience (for example attendance for repeat phlebotomy) with no known change in treatment or outcome [22].

Detection of WBIT

The WBIT rate is not necessarily indicative of a hospital's quality of practice, as it is strongly affected by the hospital's ability to detect such an error [50]. WBITs are detected in blood transfusion when the patient has a historical blood group performed and recorded by the laboratory that is different from the result from the new sample. Outside of blood transfusion, haematology or biochemistry laboratories may detect the error when there is a discrepancy in the result compared to previous results, for example a sharp fall or rise in the haemoglobin level or creatinine where there is no history of recent bleeding, transfusion or nephrotoxic event. In some cases, the WBIT may be identified due to a realisation by the healthcare practitioner that an error occurred, or when red blood cells were crossmatched for a patient who did not have a blood test or who did not require a blood transfusion. In other cases, the failure to receive an expected result may alert the clinician that another patients details were erroneously written on the sample tube. Sharing historical data on patients between hospitals can lead to improved detection rates of WBIT [51] as it allows for a greater chance of detecting a mismatch between a historical sample that may have been tested at a different laboratory. This currently occurs in the South/ Southwest Hospital Group between CUH, University Hospital Kerry, Bantry General Hospital, Mallow General Hospital, Mercy University Hospital and South Infirmary Victoria University Hospital. This will be achievable on a wider geographical area in Ireland once the National Medical Laboratory Information System (MedLIS) programme becomes available, which will provide an integrated nationwide hospital laboratory information system.

Factors contributing to WBIT

Human error

Contributory factors to WBIT are related to human errors. These are slips and lapses, taking short cuts, distractions, and omission of essential steps. These 'human factors' are widely recognised and have been highlighted by SHOT and the NHO [52] [9].

Patient registration and wrist bands

Risk factors leading to an increased incidence of WBIT include incorrect patient registration, patients wearing incorrect wristband identification, or wristbands changed or removed during admission. Wristband error rates in hospitals occur in approximately 7.4 % of cases. Missing wristbands account for 71.6 % of errors, with others including wrong wristbands, illegible wristbands, erroneous ID information, and missing ID information [53]. Hospitals with the lowest wristband error rates (under 1%) recommend that phlebotomists should refuse to perform phlebotomy on a patient when a wristband error is detected [53].

Labelling remote from the patient

Labelling samples away from the patient has been shown in studies to be responsible for up to 44% of misidentification errors [46]. Pre-labelling tubes is not advisable, as the tubes could be mixed up with those of another patient or misplaced. After taking the blood, labelling the bloods away from the patient is error prone, as it does not allow for the opportunity to

verify with the patient that the correct details have been applied to the tube and the bloods could easily be mixed up with another patient consequently. Once the healthcare professional moves away from the bedside, they are at risk of being distracted with other work and this could lead to inadvertent mistakes when labelling. This practice is against international guidelines (see Phlebotomy Standards).

Failure to use positive patient identification

Failure to use positive patient identification can result in WBIT, as well as other errors including medication errors, wrong person procedures, and the discharge of infants to the wrong family. Positive patient identification should be performed by asking the conscious patient to state his/her name and date of birth, rather than simply agreeing with a stated name provided by staff [40].

Misidentification has been identified as a root cause of many errors by the Joint Commission in the United States of America, which has listed improving identification accuracy as the first of its National Patient Safety Goals since 2003 [54]. To avoid identification errors, the commission recommends using at least two ways to identify the patients e.g. patient's name and date of birth. The World Health Organisation emphasises the importance of having systems in place, including informing healthcare workers of their responsibility to ensure the correct care matches the correct patient, and encouraging the use of at least two patient identifiers to identify a patient, neither of which should be a room number. Standardising the approach to patient identification among facilities within a health care system, introducing clear protocols for identifying patients who lack identification and distinguishing patients with the same name, promoting labelling of patient specimens in the presence of the patient, and encouraging active patient participation throughout the process are all desirable.

Healthcare providers should operate to clear protocols for maintaining the integrity of the patient identification of a sample throughout the total testing process. Promoting clear protocols for questioning results that are not consistent with the patient's history is an important way that WBITS can be identified outside the laboratory once results return to the clinical team. A safety culture that promotes questioning and provides time for reflecting on results, is necessary to facilitate this. Organisations should incorporate training for verifying and checking a patient's identity during staff orientation, continue professional education for healthcare workers, and educate patients on the importance of positive patient identification in a positive manner [55].

The WHO has identified barriers to the correct identification of the patient. These include [55]:

i) Individual behaviour change
ii) Process variation
iii) Costs
iv) Increase in workload
v) Erroneous ordering
vi) Cultural issues

My thesis has examined these barriers, starting with addressing difficulty in achieving individual behaviour change to comply with recommendations in the intern cohort in CUH.

I looked at this and following WHO guidance, identified issues as applied to practice in CUH; short cuts and workarounds, process variation around hospital systems within a geographical area, process variation where there may be practitioners employed in more than one hospital (e.g. colour coding may have different meanings in different hospitals), costs associated with potential solutions, perception that process affects the patient relationship due to repeated verification procedures, increase in workloads and time spent away from the patient, typing and errors when entering patient details on the computer system, and cultural issues such as perceived stigma of wearing a patient identity bracelet [55].

Staff group at greatest risk of error

Doctors are the staff group most likely to make errors [46] and phlebotomists have the lowest risk of making an error. It has been noted that doctors are often not educated on how to correctly perform positive patient identification and this could make this group more prone to error. Institutional safety culture, teamwork, feedback processes, and physical environment (for example, ease of access to the materials and equipment to perform phlebotomy) increase the risk of error [40]. In the SHOT conference report 2016, 77.7% of WBIT errors were attributed to human factors [56]. The report highlighted the importance of work-related factors such as short staffing, long shifts and multi-tasking as contributors to errors [56]. Qualitative research shows that doctor behaviour that deviates from institutional protocols has become accepted practice and that vigilance levels in blood-sample collection among doctors is low [57].

Patient using another person's identity

A WBIT can occur when a patient deliberately uses another person's identification, for example, an individual not entitled to healthcare using a family member's identity [40].

Consequences pre-analytical errors and WBIT

Death

WBIT errors can result in ABO-incompatible blood transfusions. In 2017, there was one ABO-incompatible blood transfusion noted in the UK, which occurred due to an administrative error. A survey performed by the NHO in Ireland in 2018 noted that 37% WBIT events, involving 10 sites, would have led to an ABO-incompatible transfusion if the error had not been detected [8]. Eleven percent of all transfusion deaths occur as a result of the healthcare practitioner not properly identifying the patient or mislabelling a tube of blood [58].

Inappropriate treatment

WBIT can lead to inappropriate treatments or investigation. For example, in the case of a full blood count sample it could lead to inappropriate transfusion, while on a biochemistry sample it could lead to an inappropriate life-threatening intervention such as inappropriate electrolyte or insulin administration.

Lack of appropriate treatment

WBIT's affect two individuals; the person whose name is on the tube and the person whose blood is in the tube. Clearly, if one patient is at risk of getting inappropriate treatment – e.g.

a potassium infusion, the patient who actually needs it is at risk of not receiving necessary treatment.

Misdiagnosis

Patients could be misdiagnosed. They can then be referred inappropriately. This may lead to anxiety, waste of time and resource and delay in appropriate referral/diagnosis for the correct patient.

Delay

WBIT may delay results and treatment as patients need to be re-tested when a WBIT event is detected.

Reputational issues

Loss of confidence in the healthcare provider and the laboratory can occur.

How often does WBIT result in harm?

Due to the many safety check points along the total testing process pathway, in the laboratory, and between the release of laboratory information, the decision-making process, and the final action on the patient, it seems likely that only a small proportion of laboratory errors result in actual patient harm. In a review of the impact of errors in laboratory medicine on patient outcomes, the risk of an error leading to an effect on patient care was 24.4% to 30%, [59] however the risk of an adverse event occurring as a result of a clinical decision made due to laboratory errors ranges from 2.7% to 12% . This is still a substantial and preventable cause of patient harm.

Further clinical examples of harm

Examples of clinical decisions taken as a result of a laboratory error include admission to critical care units, and adjustments to digoxin or heparin infusion doses [59]. Laboratory errors lead to further inappropriate investigations which, although not harmful, cause discomfort to the patient and are costly.

The majority of WBITS are likely to go undetected

Unnoticed WBIT events, such as those that occur when there is a clinically undetectable quantitative difference between the samples, can result in **underestimation of actual error** rates, for example, a specimen-identification error that leads to the transposition of one normal FBC result for another. This is unlikely to result in patient harm but will lead to loss of the opportunity for root-cause analysis [60].

Audit and reporting: the opportunity to learn and redesign

Although not all errors lead to harm, it is important to monitor and report mistakes, as they can indicate a weakness or pressure in the process and the potential for adverse consequences if not dealt with appropriately. Audit and reporting and use of WBIT as a quality indicator should provide the opportunity for healthcare practitioners and management to learn from mistakes. The process should be examined carefully to facilitate

the introduction of quality-improvement initiatives to continually improve the safety of our patients. Redesigning systems so that it is difficult for healthcare practitioners to make a mistake is an important approach identified [59].

Recommendations to reduce WBIT identified in previous studies

Organisational policies and protocols

A systematic review recommends improved communication and collaboration between laboratory and healthcare professionals with the formation of a multidisciplinary team approach [61]. This would include actions such as the development of standardised organisational policies and protocols that emphasise the importance of positive patient identification (building on the current HSE policy but adding the important points emphasised by international guidelines).
For example, development of new organisational policies and protocols might include the following: requirement of unique patient identifiers on specimen labels, implementation of zero-tolerance policy, staff performance assessment, availability of adequate number of qualified personnel to perform specimen collection, and reinforcement of specimen labelling at the bedside.

Zero tolerance policy

SHOT recommends a 'zero tolerance' policy for the labelling of all blood samples, not just those for transfusion. This approach drives up standards for all samples and recognises the potential connection between for example, an erroneous Hb due to WBIT and a possible unnecessary transfusion. Each sample must be labelled with the minimum required core identifiers of the patient's first name, family name, date of birth, and unique identification number [40]. If these minimum criteria are not met the sample is rejected.

Labels used immediately and correctly

Previous studies recommend that blood sampling and labelling should take place as a continuous process in the presence of the patient [10]. If printed labels are used, procedures should be in place to ensure labels are printed immediately prior to use and that there is a safety-net system to ensure that the labels used are correct. Patients should be encouraged to participate in the labelling process and patients should be made aware of why this process is of importance [40 55].

Education and training

Education and training in phlebotomy procedures can reduce the incidence of WBIT [40 61 62]. However, a systematic review concluded that the numbers included in the studies analysed were small [61] and considered the level of evidence insufficient to make a recommendation. Further research on novel techniques is recommended [40]. These data encourage trials of novel teaching methods such as PBP training [63].

Audit and feedback

Audit and feedback have been evaluated as an intervention to reduce WBIT and have shown a moderate decrease in specimen labelling errors; however, the strength of the evidence was deemed insufficient to make a recommendation in a systematic review [61 62].

Electronic barcode scanning systems

Electronic barcode scanning systems have been recommended for the prevention of WBIT, particularly for transfusion medicine, to mitigate adverse effects of mislabelling the tube which can be life-threatening [64]. A recent retrospective analysis demonstrated that the introduction of an electronic barcode system could reduce the incidence of WBIT up to fivefold [65]; however, an audit performed by the NHO in Ireland 2017 and 2018 did not demonstrate an improvement in the incidence in hospitals where the electronic system was introduced [8]. On investigation of the errors which had led to the WBIT events using the electronic system the reasons for the error included a)printing issue with label caused a WBIT event, b)system used incorrectly leading to WBIT event, c)wrong patient ID scanned resulting in WBIT event, and d) the system was used correctly but the WBIT still occurred. The NHO concluded that the barcode system was a positive measure in reducing blood sampling errors but is only effective if healthcare workers utilising the system are provided with sufficient education and training on how to use the system safely and ensure positive patient identification and label printing at the patient bedside always occurs. (*National Haemovigilance Office reports).*

In contrast, the Biomedical Excellence for Safer Transfusion (BEST) collaboration, using retrospective data, compared pre-transfusion sample WBIT rates at hospitals using manual patient identification with those at hospitals using electronic patient identification for some or all samples and found that the unadjusted WBIT rate at sites using patient identification was 1: 10,110 versus 1: 35,806 for sites using electronic identification ($p<000.1$)[65] . The effectiveness of the electronic labelling system in other districts suggests better safety culture and training on the importance of positive patient identification and labelling in the presence of the patient, to support the electronic barcode system.

A group check sample policy

A group check sample policy means that patients who may need a transfusion have their blood group measured twice on two independent samples. This policy has been recommended as a valuable tool to safety net for instances of WBIT and can prevent ABO-incompatible blood transfusions [65 66]. It cannot of course apply in the emergency situation.

Two healthcare practitioners to sign the blood specimen

If an electronic barcode system is not available, the incidence of WBIT can be reduced by asking two healthcare practitioners to sign the blood specimen, indicating that the patient identification details are correct [67]. This extra check point helps to raise awareness of the importance of correct labelling of the bottle and ensures that this point in the process is performed correctly and not overlooked.

Multiple interventions applied together at different risk points in the sampling process

A systematic review concluded that, although there is some evidence that all the interventions reduced WBIT, data collection has been insufficient to demonstrate sustainability. Multiple interventions and feedback is likely the most effective approach to reduce errors and improve patient safety [62]. As an example of this, SHOT in the UK has had a multi-faceted approach to reducing WBIT and this has resulted in a decline in ABO-incompatible transfusions [52]

Minimum standards for blood sample labelling at Cork University Hospital

Data has shown that samples that fail to meet the criteria for acceptance of the sample are 40 times more likely to have a blood-group discrepancy [68]. To ensure patient safety and reduce the incidence of WBIT, a minimum standard of blood sample labelling is required as recommended by WHO. The transfusion laboratory in CUH has a zero tolerance approach and applies the criteria strictly.

The pathology handbook at CUH indicates the following requirements for correct identification of blood transfusion samples [69]:

- Blood transfusion samples may only be taken by doctors or specially trained nurses/midwives working in the hospital.
- Request forms and samples for blood transfusion laboratory requests from all users of the service must be handwritten.
- Essential information required on both samples and forms must include:
  -Patient's forename
  -Patient's surname
  -Patient identification number (in the case of samples taken in general practice where there is no patient identification number available, the address is to be used)
  - Date of birth
  - Identity of person taking the sample (doctor/dedicated nurse) including bleep/contact number. Ideally, doctors should include their medical council registration number. Nurses/midwives should include their an Bord Altranais personal identification number.
  - Date and time that the sample was taken.
- Unconscious patients admitted to the emergency department should be identified using the system as agreed with the blood transfusion laboratory, CUH, as detailed in local instructions.

The transfusion laboratory operates a zero-tolerance approach and if the criteria are not met, the specimen will not be processed. In this case, one of the healthcare practitioners caring for the patient is contacted to ensure another sample can be arranged. Of note, the group check sample policy is not in use in CUH but is introduced in some other hospitals in the South Southwest Hospital Group.

Biochemistry, Haematology, Microbiology, Pathology		
Labelling Requirements*	Essential Information	Desirable Information
Request Form	Patients full name or proper coded identifier** D.O.B. and/or Patient's Medical Record Number (MRN/RID) Patient's location or destination for report or patient's consultant or GP Specific requirements of individual departments: Biochemistry: - Date and time of specimen collection - Clinical details - Note: - Certain analytes may not be processed if mandatory fields are incomplete - Request must come from a Qualified Healthcare Professional. Haematology /Microbiology: Test Request Pathology/Cytopathology Requesting Clinician, Patient's address, Patient's location,	Patient's address Patient's sex Clinical details, relevant therapy and foreign travel (antibiotic treatment important for Microbiology), travel and prophylaxis history for Malaria Date and time of specimen collection (timing in relation to antibiotic dose **essential** for Antibiotic Assays and for some Chemical Pathology tests) Pathology: Date and time specimen taken. Previous relevant Histopathology Numbers (CUH/MUH) if applicable). Signature of clinician / nursing staff (pp) Clinician's bleep number Clinical Information

Figure 1.2. Criteria for sampling and labelling in biochemistry, haematology, microbiology and histopathology laboratory in Cork University Hospital [69].

Standard operating procedure (SOP) for performing bloods at Cork University Hospital

The SOP on routine venepuncture and specimen handling at CUH provides the following guidance:

- Proper work practice procedures: Healthcare practitioners should have a professional appearance, relate well to patients, be capable of adapting to change, willing to adhere to rules, display open disclosure of errors, and have good working relations with staff.
- Staff safety and infection control measures are required.
- Equipment required is listed.
- Patient safety measures: patient is positioned so they will not fall if they faint, no more than two attempts should be taken, tourniquet released before removing needle, patient to apply pressure rather than bending the arm, dispose of sharps safely, do not draw blood from indwelling lines or cannulas unless trained and authorised.
- Actions to be taken if there are patient problems such as accidentally entering an artery, patient faint/nausea/convulsion/objection to test.
- Patient preparation

- Patient identification: Proper patient identification is mandatory. If an inpatient is able to respond, ask for a full name and always check the armband for confirmation. The SOP advises not to draw blood if the armband is missing. Outpatients must provide identification, rather than a verbal statement of a name, and the healthcare practitioner should ask the patient to provide additional information, such as date of birth.
- Requesting laboratory tests and electronic requests through the ICM software system.
- Order of draw (as per manufacturer instructions)
- Venepuncture including selection of vein, choice of device, procedure, butterfly safety system
- Labelling the sample, which should take place in the presence of the patient.
- Advice on troubleshooting issues such as if the blood stops flowing in the tube, incomplete collection, or no blood obtained.

iClinical Manager (ICM)

iClinical Manager (ICM) is one of the electronic patient records used in CUH. It is the main record used throughout hospital departments. Due to the lack of a national standardised record, many departments – such as radiotherapy, renal medicine and cancers services – use their own patient record in addition. ICM provides order communications for biochemistry, autoimmune serology, haematology, or microbiology departments from the wards and accident and emergency, but not in the outpatient department. Instructions on how to use the ICM system are provided in the pathology user handbook. The staff member must first login to the ICM system using his or her personal ID and password. On logging into the system, it displays a list of patients in a current area, e.g. ward 4A, or the search icon can be used to search for a patient using the patient's Medical Record Number (MRN), surname and/or date of birth. Users are instructed to take the specimen before printing the label, as the time on the label helps to laboratory to decide the useful life of the sample. Users are instructed to ensure that labels printed match the details of the patient identified for phlebotomy, that labels are affixed to correct bottles (without covering specimen blood volume or container 'fill to' marks, which the laboratory need to be able to see), and that the specimen type on label matches the specimen type on bottle. The ICM system records the person who was logged into the computer when the test was ordered and when the label for the blood bottle is printed. The label contains a code, which is then scanned when the specimen arrives in the laboratory so the system will know which test is required without the need for further data entry.

Retrospective analysis of blood transfusion and haematology laboratory WBIT events in 2015 and 2016

As background work, data from WBIT events at CUH were compared to UHK for the years 2015 and 2016. The trends in WBIT rates in both hospitals in the haematology and blood transfusion laboratories in 2015 and 2016 are shown in Table 1.4. In all, 211 WBITs were

identified from 2,877,603 samples processed in the two hospitals. Samples in the CUH haematology laboratory were labelled using the electronic ordering system, ICM, while samples in the CUH transfusion laboratory were hand labelled. All samples in UHK (haematology and blood transfusion) were hand labelled. Rates of WBIT in CUH (9/100,000) were treble that in UHK (3/100,000). Transfusion error rates were higher than haematology WBIT rates in both hospitals, but this is likely related to increased detection rates in the transfusion laboratory. The number of WBITs appeared to be decreasing from 2015 to 2016.

This retrospective analysis of WBIT events at CUH and University Hospital Kerry (UHK) took place as part of work undertaken for the purposes of a Final Medicine Research project and was supervised by me (N.O'H).

Table 1.4 Trends in WBIT rates across sites in haematology and blood transfusion in 2015/2016

	Haematology	**Transfusion**
Cork University Hospital	Electronic 0.87 per 10,000 samples	Hand-labelled 2.27 per 10,000 samples
University Hospital Kerry	Hand-labelled 0.27 per 10,000 samples	Hand-labelled 1.56 per 10,000 samples

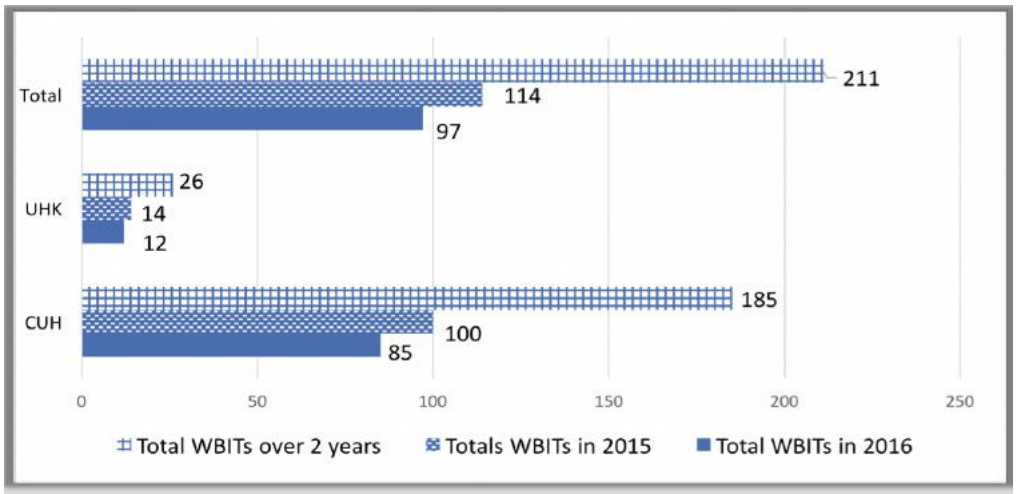


Figure 1.3 Total number of WBITs compared across 2015 and 2016 in CUH and UHK

Example of reference event: Near-miss WBIT at CUH Emergency Department

In July 2015 a 44-year-old male patient attended the emergency department at CUH and was diagnosed with a fractured neck of femur. A group and hold sample was taken by the

specialist registrar in the emergency department. This returned with the following result: Group B RhD positive. There was no previous blood group result available for the patient. The patient's pre-operative haemoglobin was 13.1 g/dL but following surgery his post-operative haemoglobin dropped to 8.8 g/dL. The patient was not transfused but would have been transfused with B RhD Positive blood components if required.

In April 2018 the same patient was admitted to CUH and diagnosed with a second fractured neck of femur. A group and hold blood sample was taken in the emergency department. The blood result returned with A RhD Positive, which was confirmed by repeat specimen to be the correct blood group. The 2015 group was incorrect and it was too late to identify the correct patient whose sample this actually was.

This near miss was particularly serious as, were it not for good medical/surgical care and a judicious hemovigilance transfusion minimisation policy, the patient might have been transfused and died.

Approaches to analysing safety in healthcare

Against the backdrop of a significant, prevalent and hard to detect problem, I will review approaches to safety in health care. Safety scientists adopt different methodologies when investigating issues of safety in healthcare and in other fields. Safety 1 and Safety 2 approaches have both been used to look at the issue of blood sample mislabelling in hospitals. Both approaches are important when investigating and developing solutions to patient safety.

Safety 1: Ensure as few events as possible go wrong

Safety 1 highlights adverse outcomes and seeks to retrospectively investigate the causes of specific incidents where harm occurred and, following this, remove the sources of harm. Safety 1 presumes that things go wrong due to a specific component malfunctioning, e.g. technology, procedure, human worker. Humans are the most variable component in the environment and are viewed as a liability or hazard. Accident investigation in safety 1 determines the cause for an adverse event, while risk assessment aims to determine the likelihood of an adverse event occurring.

Safety 2: Ensure as many events as possible go right

Safety 2 investigates how performance of staff adapts to the variations in the environment the healthcare worker is working within, and how this can lead to things going either right or wrong on any given occasion. It aims to gain a realistic insight into the clinical environment and looks at how normal routine performance usually leads to safe outcomes [70]. This highlights the need to understand routine clinical practice and how work is actually done in the clinical environment, which is often contrary to the guidance provided by standard operating procedures, training, and education.

This study utilise the concepts of safety 1 and safety 2 when engaging with stakeholders in the process of phlebotomy during meetings to develop a metric in phlebotomy that would

be used to train interns. The meetings included interviews with various health personnel to consider the current process, and errors that were occurring. The videos involved the doctors wearing a GoPro camera and recorded the process from the instruction to collect blood to the dispatch of the sample to the laboratory on the wards in CUH. By observing videos of both novices and experts in phlebotomy, this helped to determine what is done well and what practices leave the health care practitioner more susceptible to error.

Improving pre-analytical errors at Cork University Hospital: the case for proficiency-based progression training

Why change is needed

Quality in the pre-analytical phase of blood testing is essential to ensure reliable results that assist clinicians with key decisions when caring for their patients. As reviewed above, errors are common. WBIT is the most serious pre-analytical error and occurs rarely. However, due to its seriousness, and lack of detection in many cases, prevention of WBIT is the optimal strategy.

Since 2010, audit at CUH consistently shows that doctors in training are at risk of WBIT and other sampling and labelling errors, especially on commencing employment in the hospital. The electronic system of labelling the blood specimens appears to increase the risk of a WBIT event occurring compared to hand-labelling the blood specimens at University Hospital Kerry. By improving education, training, and awareness of the pitfalls that can result in pre-analytical errors, most especially WBIT, this project hopes to reduce the error rates at CUH using the principles of proficiency-based progression (PBP) training [63].

In 2016/7 UCC was pioneering technology enhanced learning in its ASSERT centre by developing Simulation Based Training and Virtual Reality Based Training in its state-of-the-art healthcare training facilities with the aim of improving patient safety and patient outcomes.

A novel, practical educational programme, we considered PBP training to help solve the issues with the frequently performed, basic procedure – phlebotomy.

In this thesis, I describe how the programme was developed specifically for use with interns taking up post in CUH taking careful consideration of how to perform the procedure in the safest, most effective manner. However, the educational tool could be easily adapted for use in other healthcare institutions and settings, nationally and globally.

Proficiency-based progression Training

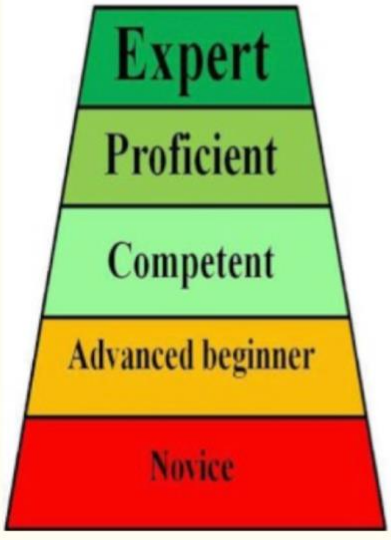
Proficiency-based progression training versus traditional training in previously validated settings

Medical education has traditionally relied on the apprenticeship style model, first described by Dr. William Stewart Halsted at the Johns Hopkins Hospital, Baltimore, USA [71]. This involves the ‘see one, do one, teach one’ approach to training. However, an awareness of

high error rates and a reduction in working hours has resulted in a paradigm shift, especially within the training of surgical skills in recent years. Those involved in the development of surgical training curriculum have recognised the value of simulation and training to a proficiency benchmark [72]. Improvements in surgical-simulator technology permits students to spend less time observing and more time doing. The transfer of skills in a simulated environment ensures doctors avoid learning skills on patients. Previous studies have highlighted the value of teaching advanced surgical skills such as intracorporeal suturing, knot tying and laparoscopic and endovascular surgery in a simulated environment [73-75]. However, for simulation training to be successful, it must be systematically integrated into a well-thought-out education and training program that objectively assesses technical skills improvement proximate to the learning experience [76].

Skill development – relevant educational research

To objectively assess any skill, it is essential to determine the standard required to say the student has progressed to a proficient level. Stages of skill development have been described by Dreyfus and Dreyfus to allow for ordinal differentiation between different levels of performance, i.e. novice, advanced beginner, competent, proficient, expert [77]. The ability of an assessment to determine whether a student has reached proficiency can be examined from multiple viewpoints. Construct validity investigates the ability of a test of a particular skill to differentiate between experts and novices. Concurrent validity looks at whether persons who perform well in the assessment of a particular task also perform well on similar or related tasks. Predictive validity examines whether performing well in the assessment predicts future good performance [78].



STAGE	PERFORMANCE CHARACTERISTICS
Expert	• Source of knowledge and information for others • Continually looks for better methods • Work primarily from intuition • Being forced to follow rules degrades performance
Proficient	• Seeks to understand larger context • Frustrated by oversimplification • Can self-correct performance • Can learn from experience of others
Competent	• Can troubleshoot problems on his/her own • Seeks out expert user advice • Develops conceptual models
Advanced beginner	• Starts trying tasks on his/her own • Has difficulty troubleshooting • Begins to formulate principles, but without holistic understanding
Novice	• Has little or no previous experience • Doesn't know how to respond to mistakes • Needs rules to function

Figure 1.4. Ordinal differentiation between different levels of performance by Dreyfus and Dreyfus [77].

Metrics – relevance and development

To objectively assess performance in a quantitative manner metrics are required. Metrics consists of operational definitions of the procedure to be taught. The level of skill can be quantitatively defined in metric units of task execution [78]. The metric comprehensively defines each step required to complete the procedure (steps). The metrics also include, for each procedure step, what should not be done, thus characterising performance that deviates from optimal performance (or errors) [79]. The metrics give a clear instruction of what needs to be done and what should not be done to perform the task. The metrics must unambiguously 'define' rather than 'describe' each step or error, to facilitate reliable scoring of the metric and proximal feedback in training. Metrics must be validated, a process which has been described for procedures including closed reduction and fixation of a 31A2 per-trochanteric fracture [80], superficial femoral artery angioplasty [81], central venous catheterisation [82], flexible endoscopy training, i.e. surgical training for endoscopic proficiency (STEP) [83], tracheostomy suctioning [84], robotic assisted training [85], acute surgical wound dressing procedure [86], virtual reality simulation for mechanical thrombectomy in ischaemic stroke [87], and ultrasound guided brachial plexus block . The metrics can be used as a tool to develop a simulation training programme and allow for meaningful performance assessment [88].

Metric validation

Once developed, validation of the metrics is required. Content validity is assessed using a modified Delphi method. The assessment of construct validity occurs by using the metrics to score novice and expert performers of the procedure. If construct validity is attained, then the metrics can reliably distinguish between expert and novice performers. The construct validity assessment also informs the setting of a proficiency benchmark for the procedure through analysis of the performance of each group [78]. This step ensures that any subsequent questioning of the metrics by training or trained practitioners can be answered with relevant local evidence. This is especially important given data on lack of agreement and adherence to best practice in phlebotomy – especially by medical staff [16].

Proficiency standard

PBP provides an outcome-based approach to assessment, - ideal for mitigation of WBIT- which is essential when determining if trainees can be certified as meeting a proficient standard before graduating to independent professional practice. Despite similar levels of experience, some doctors may continue to perform outside of standard practice.
In a study that examined the skills of 100 experienced surgeons, 1-5% of the doctors' performance was significantly below their colleagues. This lower 5% of surgeons made significantly fewer correct incisions (mean = 7 (SD = 2) versus 19.42 (SD = 4.6), $P < 0.0001$) and a greater proportion of incorrect incisions (mean = 45.71 (SD = 10.48) versus 5.25 (SD = 6.6), $P < 0.0001$) [89]. PBP training provides an effective solution. Validated metric-based simulations can serve as a benchmarking device to demonstrate proficiency and to detect practitioners that require more assistance in performing a procedure [78]. By analysing the average scores of experts at performing the procedure clinically, the training pass level in training is defined.
Until students can reach this proficient standard in the simulated environment on at least two consecutive occasions, progression from the PBP programme is not permitted.

Graduation from the programme is reliant on the trainee's performance and is objectively assessed by the trainer.
Because PBP studies published to date have largely been carried out in controlled surgical environments and phlebotomy is carried out in diverse locations throughout busy hospitals we also incorporated a post training component.

Proximate feedback

PBP training with validated metrics provides a unique opportunity to provide proximate feedback to the student while performing the procedure. Feedback can be provided in real time on the correct order of the procedure and critical steps and errors to be performed or avoided. This facilitates learning due to deliberate practice [78] compared to the traditional style of learning, where a student's ability to learn was variable and depended on opportunistic occasions of repeated practice, during which training advice may or may not have been provided. For our clinical trial we incorporated feedback on errors in a real world setting post training.

Evidence for proficiency-based progression training

PBP training is effective in improving the performance of doctors in several areas as listed in Table 1.5. These results illustrate the value of PBP training as an effective tool to teach technical as well as communication skills.

Table 1.5. Published studies showing evidence of efficacy for PBP training

PBP training provided	**Improvement demonstrated**
Epidural catheter placement for pain relief in labour	Epidural failure was reduced by 54% with PBP training [90]
Arthroscopic Bankart repair	A PBP training curriculum and protocol coupled with the use of a shoulder model simulator and previously validated metrics produces a superior arthroscopic Bankart skill set when compared with traditional and simulator-enhanced training methods [91].
Arthroscopic knot-tying skills	PBP-trained doctors had a reduced knot failure rate compared to those not trained by PBP training [92].
Proficiency-based virtual reality training for laparoscopic cholecystectomies	VR-trained group consistently made significantly fewer errors (P=0.0037). Residents in the control group made, on average, three times as many errors and used 58% longer surgical time [93].
Virtual reality simulation training for laparoscopic skill acquisition.	Experienced laparoscopic surgeons and novices who trained on the simulator performed significantly better than their controls, thus demonstrating transfer of training [94].
Superficial femoral artery (SFA) angioplasty	Simulation-trained trainees scored higher than the controls on the procedural scale [86.8 (5.4) vs. 67.6 (6), *P* = 0.001] and the global rating scale [37.2 (4.1) vs. 24.4 (5.3), *P* = 0.003]. Basic endovascular skills acquired using proficiency-based simulation training in SFA angioplasty translate to an improvement in real-world performance [81].

Proficiency-based suturing and knot-tying for medical students	A proficiency-based suturing and knot-tying curriculum taught early in the fourth year results in improved performance compared with no training or a traditional 'boot camp' program [95].
Proficiency-based progression full-physics virtual reality simulator training for learning carotid artery angiography by very experienced operators	Experienced interventional cardiologists trained on the VR simulator performed significantly better than their equally experienced controls, showing a significantly lower rate of objectively assessed intraoperative errors in coronary angiography. Performance showed 17–49% transfer of training (ToT) from the VR to the in vivo index case [96].
Clinical communication for the deteriorating patient [97]	Students were trained using an eLearning programme with PBP training (E+ PBP group), an eLearning programme with standard simulation training (E +S group) or an eLearning programme only (E group). 6.9% (2/29) of the E group and 13% (3/23) of the E+S group demonstrated proficiency in comparison to 60% (15/25) of the E+PBP group. The difference between the E and the E+S groups was not statistically significant (χ^2=0.55, 99% CI 0.63 to 0.66, p=0.63) but was significant for the difference between the E and the E+PBP groups (χ^2=22.25, CI 0.00 to 0.00, p<0.000) and between the E+S and the E+PBP groups (χ^2=11.04, CI 0.00 to 0.00, p=0.001).
Ultrasound-guided peripheral nerve block [98]	Compared with novices who self-guided their practice using metrics, those who undertook expert-supervised deliberate practice using metrics made fewer errors immediately after practice (median [range], 0 [0-0] vs. 5 [3-8], p < 0.0001) and 24 h later, (0 [0-3] vs. 6.5 [3-8], p < 0.0001 and 0 [0-3] vs. 4 [2-7], p < 0.0001).

Conclusion

This chapter discussed the culture of quality control that exists in our medical laboratories and that is validated by yearly accreditation inspections by INAB to document adherence to standards and to ensure patient safety.

The prevalence of pre-analytical errors arising outside the laboratory, but detected within the laboratory, is significant and requires action. Putting quality controlled actions and processes in the day to day clinical environment to mitigate risk is challenging. There is a contrast between the relatively highly controlled laboratory and the clinical environment outside the laboratory. Despite educational campaigns run by the laboratory over a decade, audit and feedback, and efforts from haemovigilance within the hospital, the problem of pre-analytical errors and the critical error WBIT remains.

With the introduction of technology enhanced learning and proficiency based progression in the medical school in UCC, the opportunity to put these skills into place to address the clinical problems posed by WBIT arose. This study proposes proficiency-based progression training as a solution. We developed a bespoke PBP training programme in phlebotomy which studied and considered the error-prone pressure points when performing phlebotomy, particularly pertaining to WBIT.

PBP training has strong evidence supporting its ability to improve healthcare practitioners' performance of medical procedures. It helps us to move away from the traditional apprenticeship-style model of 'see one, do one, teach one'. Instead, learning takes place in the simulated environment, following metrics which have been carefully described and validated to ensure the process is safe and the optimal methods are agreed. The students receive proximate feedback during training to encourage deliberate practice. The students must reach a proficiency benchmark before they are allowed to proceed to perform the task in the clinical environment on real patients. The proficiency benchmark (which the trainees must reach before graduating from the training) is usually described as the mean performance of experts in the field. This novel teaching style avoids the concept of practicing on patients and uses rigorous methods to ensure transfer of learning is demonstrated.

Despite the considerable challenges of the busy clinical environment, we chose to trial PBP in the clinical environment of newly qualified interns in CUH in 2017/8. In the following chapters I explore the development, application, results and qualitative factors relevant to the implementation of this methodology on a previously difficult-to-solve issue of importance to patient safety.

Chapter Two: Metric Development and Validation

Abstract:

Aims:
The purpose of this study was to 1) characterise the procedure of phlebotomy, deconstruct it into its constituent parts and develop a performance metric for the purpose of training healthcare professionals in a large teaching hospital, 2) evaluate the construct validity of the phlebotomy metric and establish a proficiency benchmark.

Method: By engaging with a multidisciplinary team with a wide range of experience of pre-analytical errors in phlebotomy and observing video recordings of the procedure performed in the actual working environment, we defined a performance metric. This was brought to a modified Delphi meeting, where consensus was reached by an expert panel. To demonstrate construct validity, we used the metric to objectively assess the performance of novices and expert practitioners.

Results: A phlebotomy metric consisting of 11 phases and 77 steps was developed. The mean inter-rater reliability was 0.91 (min 0.83, max 0.95). The expert group completed more steps of the procedure (72 Vs 69), made fewer errors (19 vs 13, p = 0.014) and fewer critical errors (1 Vs 4, p = 0.002) than the novice Group.

Conclusions: The metrics demonstrated construct validity and the proficiency benchmark was established with a minimum observation of 69 steps, with no critical errors and no more than 13 errors in total.

Background

Medical error is a serious patient safety issue [99] and is reported as the third leading cause of death in the USA [100]. Errors by doctors during the pre-analytical phase of blood testing, i.e. before the sample is analysed in the laboratory, form a large proportion of the diagnostic errors occurring in practice [101]. Blood sampling is a frequently performed procedure which is prone to mistakes at several phases. These include; identifying the patient, communicating with the patient, selecting the correct puncture site [102 103]. Wrong Blood in Tube (WBIT), which occurs when the blood in the bottle is not that of the patient identified on the label [40], is a critical error for patients and should be a 'never event' [41]. Previous research has shown that 79% of doctors report the undesirable practice of not always using wristbands for patient identification, leading to a serious risk of misidentifying patients [104]. Quality control in the phlebotomy process is essential. An increase in the error rate at our teaching hospital (CUH) led to a concern regarding the safety for patients of doctors commencing phlebotomy without adequate training. As discussed in Chapter 1, this increase had been noted both after the introduction of the isoft clinical management (ICM) system to electronically order bloods and following a new intake of doctors in training in the hospital in July. Traditionally, doctors were trained according to the 'apprenticeship' model, with a large portion of their learning taking place on sick patients. A PBP training programme using simulation and metric-based feedback was chosen. This approach has been demonstrated to be a more effective approach to training than traditional models [73 91 105], and ensures that a large element of a doctor's learning experience takes place in a simulated environment, prior to learning with patients. The doctors must reach proficiency in the simulated environment before progressing to performing the procedure on patients.

To develop a bespoke PBP training programme for UCC interns in CUH, we needed operational definitions (metrics) defined and scorable as well as agreed proficiency benchmarks which interns would be expected to reach.
In order to achieve this, we characterised optimal and suboptimal performance of phlebotomy to design a metric. Metrics are units used to measure performance and to break down the procedure into its constituent parts. They define how a procedure should be performed and also provide a method for performance assessment [91]. The metric aims to allow an individual without prior experience of the procedure to have a set of validated instructive steps to follow. Metrics-based performance characterisation can be used to establish a proficiency benchmark which trainees must demonstrate before PBP training progression [78]. The metric has similarities with the "Surgical Safety Checklist" developed by Atul Gawande and colleagues which demonstrated a reduction in the rates of death and complications when the checklist was implemented. The study illustrated that the 'Surgical Safety Checklist' program can improve the safety of surgical patients in diverse clinical and economic environments [106].

The purpose of this study was to establish the metrics required to characterise a phlebotomy procedure in doctors in training, from the instruction to take blood to dispatch of the blood sample to the laboratory, and to seek consensus from experts on the appropriateness of the steps and errors identified. The null hypothesis was that face and content validity for the step and error metrics derived from task deconstruction of phlebotomy procedure would not be demonstrated.

Methods

Metric Development

Background of the process of procedure characterisation

Metric development is procedure-specific and requires breaking down a task into its essential components (task deconstruction) and tightly defining what differentiates optimal from suboptimal performance [63]. It entails clear and detailed identification of what is to be measured and then careful definition of the behaviours in a manner that facilitate their reliable measurement. Task analysis is used to identify the specific behaviours required in the performance of the procedure and to break down a complex sequence of behaviours into their component parts. It occurs most easily by observing people who perform the task well and those who perform the task poorly, e.g. comparing a phlebotomist to a newly qualified doctor to highlight what the experts do well and the trainees do badly and therefore clearly distinguish the two groups [63]. Video and audio recordings of the procedure allow for careful observation of the procedure by expert reviewers, with the ability to replay the performance to ensure any subtle behaviours during the procedure performance are not missed. Videos are scored, task by task.
The task analysis team should include more than one subject expert and a task-analysis expert (behavioural scientist). The behavioural scientist leads the task-analysis team and

translates the larger goals that the experts and other team members have identified into concrete steps and discrete units of behaviour.

I assembled a task analysis team adhering to recommended selection criteria which include: they all speak the same language; they have relatively good group social skills, e.g. not too argumentative, opinionated or shy; and they are able to genuinely participate in a group discussion and come to a consensus decision that does not necessarily represent 100% of their opinion (92). It is important the resultant units of performance (metrics) are discrete and observable and the order of sequence of these behaviours needs to be specified as this may be of critical or minor importance. One example might be that, during phlebotomy, it is critically important to dispose of the needle directly into the sharps bin immediately after use. The goal of the task-analysis team should be to identify this and other crucial aspects of performance that contribute to both optimal and suboptimal performance, taking account of the tasks that the healthcare practitioner does or does not do. This process results in a shortlist of performance characteristics that typify a good candidates for metric definition. Clear metric definition is a key outcome of the process, as it is not sufficient to describe the behaviours in general terms – each step must be explicitly defined to minimise vagueness and maximise specificity. Definitions must be unambiguous and objective, so that, if they are tested by independent observers, the results are reproducible in a reliable fashion. Operational definitions must meet three criteria: objectivity, clarity, and completeness. The metrics are used to develop an effective metric-based assessment of the phlebotomy performance that can be reliably assessed.

Procedure characterisation to develop metrics for the performance of phlebotomy at Cork University Hospital.

For the purpose of this study, procedure characterisation was performed in early 2017 over a three-month period. I assembled a multidisciplinary team for metric-development group consisting of a clinical professor in haematology, a haematology consultant, medical scientists, laboratory management, laboratory information system leader, education experts, a behavioural science expert, and members of the clinical haematology team. Each member of the team provided insights into their experience of phlebotomy in the hospital and highlighted points in the process prone to error. The group held four face-to face meetings to develop a metric to measure the performance of the procedure of phlebotomy.

Following this full-length videos demonstrating novice (intern) practitioners with less than one year's experience in phlebotomy and expert practitioners with more than five years' experience in performance of the phlebotomy procedure assisted in the creation and stress-testing of the metrics. The patients and healthcare practitioners gave informed consent. They were aware that anonymity could not be assured as positive patient identification is a key step in the process. The videos were recorded with assistance from ASSERT staff using a GoPro camera, worn on a headset by the person performing the procedure. Each participant was observed performing blood on real patients in their normal clinical environment.

Once recorded, the procedure was deconstructed and comprehensively characterised into constituent, essential, and elemental tasks necessary for the safe and effective completion of a reference approach to the performance of taking blood for laboratory testing. Particular attention was paid to the ergonomics of the procedure, preparation, patient identification

and sample labelling, and use of the computer software, which the interns would not have practiced previously.

First metric-development meeting, February 4th, 2017

These meeting were convened and moderated by NO'H using scientific frameworks available such as models for Delphi preparation, Shorrock's framework, WHO guidance and the principles of PBP metric development [63].
The meeting was attended by Professor M.R. C, Professor A.G. G, two interns working on the haematology team (J.O'S., S.O'S.) and a senior house officer from the haematology team (A.D).
The project background was summarised and the example of procedure characterisation for the surgical treatment of a per-trochanteric fracture was shared. Metric characterisation commenced with the first four phases of the phlebotomy metric identified as follows:

1. Identify requirement to take blood
2. Prepare equipment to take the sample
3. Identify the patient
4. Procedure

Second metric-development meeting, February 16th, 2017

The meeting was attended by Professor A.G. G, Professor M.R. C, a senior house officer from the haematology team (A.D), an intern (S O'S) , a specialist registrar in haematology (S.G.), the medically qualified researcher (NO'H), the chief medical scientist from the haematology laboratory, and a laboratory scientist working in the information technology section (B'OM).

An initial discussion of current issues pertaining to the performance of phlebotomy in CUH was led by the doctors in training working on the wards in CUH in February 2017. We then focused on ,the process for interns when using the ICM system to label the blood bottle.

Issues doctors in training raised included the following:

- The induction process for interns when commenting work at CUH was poor in relation to providing information on phlebotomy. The interns tended to pick up habits from other doctors but had no formal introduction to the correct process of performing a blood test or on how to use the ICM system. The interns had received training in phlebotomy during medical school. Those students who had attended UCC had received traditional phlebotomy training as medical students in their third year on two occasions and once in the final year of medical school, comprising a phlebotomy guide, training videos, and a practical training session in the clinical skills laboratory.
- There is a lack of printers at the patient bedsides.
- The access to computers and to label printers is poor, with one computer being used for multiple tasks, including discharges and viewing reports, and being shared amongst multiple doctors.

- Printers are often out of order or out of label-printing paper.
- If the doctors in the hospital are unsure of what bottles to use, they are inclined to print labels from the ICM first, because the system automatically tells the doctor how many bottles and which bottle type is required to perform each particular blood test. However, in cases where labels are printed before performing the blood test, there is a higher risk of WBIT.
- The wards and emergency department often have no transport bags available for samples.
- If the healthcare practitioner forgets to log out of the ICM system, this can lead to labels printing on the incorrect ward. For example, if a doctor fails to log out of the computer on ward 1A, when the doctor then attempts to print labels on ward 2b the labels will print off on ward 1A incorrectly.
- There is a glitch on the ICM system, so that, through no fault to the doctor, incorrect labels sometimes print from the system. If the doctor is not checking the label before affixing it to the bottle, then there is a risk of a WBIT event.
- Doctors were unsure of how many supplies should be taken to the bedside and said they discard items not used.

During the meeting, the laboratory provided information regarding current issues with blood samples received in the laboratory.
The laboratory issues included

- A recurrent problem of incorrect placement of labels on the tubes. If labels are placed on the tube incorrectly, then the laboratory staff have to unpeel the label and correctly align it so the machine can scan the label.
- Failure to leave a viewing space for the scientist to see how full the bottle is, particularly in the case of coagulation samples
- The healthcare practitioner needs to ensure the correct label is placed on the correct bottle. The ICM system prints one label for the serum bottle and a different label for the EDTA bottle and if the wrong label is put on the bottle then the sample will be rejected.
- Clinical details need to be included in the space provided on the ICM system when ordering the blood samples, especially if the sample is taken out of hours, as this helps the laboratory staff to prioritise their work.
- The doctors need to mark the appropriate sample as urgent with ‘stat’ on the ICM system.
- The laboratory often has to reject samples as the sample is taken in the incorrect bottle to perform the test.
- Healthcare practitioners often request a haematinic blood test but do not include a serum bottle, which is needed to correctly perform the test.

- In the blood bank, blood samples are often rejected due to incorrect handwritten details on the bottle or if the handwritten label is missing details which are required as per hospital policy.

The IT expert mentioned the need to be aware of technical issues with the ICM system:

- The ICM system can sometimes flick back to the first patient on the system. If this happens without the doctor noticing it, the system could print the label belonging to the wrong patient. If the doctor does not check the label before putting it on the bottle, this may lead to a WBIT event.

Solutions proposed by the team

- Teach doctors how to replace the paper in the label printers.
- Consider having trolleys on wards for doctors to use, which contain the equipment required, including label printers, similar to those already in place for phlebotomists.

Points for research which were noted

- There is an underreporting of mislabelling issues in the laboratory – these issues are not being reported, but the laboratory staff, instead of rejecting the samples, are fixing the labels themselves, leading to increased workload and inefficiencies.

Following this meetings we recognised that PBT alone could not address all the issues raised. The IT issues and other infrastructure were raised in the appropriate hospital fora.

During the meeting the phlebotomy metric was edited. At the end of the meeting the phlebotomy metric consisted of 43 steps in six phases as follows:

1. Request to take blood
2. Identify patient
3. Preparation of sample
4. Procedure
5. Label bottles
6. Transport

Third metric-development meeting, March 2nd, 2017

Meeting attended by Professor M.R.C, Professor A.G.G., the chief medical scientist in Haematology (M.F.R.), a registrar in haematology (SG),), two interns (J.O' S. and S O' S.), a researcher (N.O'H), a lecturer in medicine (P.H.)

Each of the steps developed for the metric during the previous meeting were discussed. Definitions were modified to improve clarity and a discussion took place with the multidisciplinary team to ensure the process developed would avoid errors as much as possible.

- The team discussed how to identify the correct patient. Two patient identifiers needed to be provided to the person taking the test if positive patient identification could occur correctly.
- If a test was taken on an incorrect patient this was a critical error.
- The team recommended producing a standard checklist for the wards that could be used to instruct interns and would prompt the requestor to provide two patient identifiers.
- The hospital policy on positive patient identification in cases where the patient is unconscious was referred to.
- Providing advice to the interns on what to do if asked to take bloods on a patient who did not have a wristband would be given during the face-to-face training but was not included in the metric.
- The team decided to seek advice from the infection control team on hand hygiene.
- The ergonomics of the procedure were discussed. Phlebotomists are provided with trollies however, doctors had to use a tray and there was no specific space to place the tray at the beside which was often unsafe.

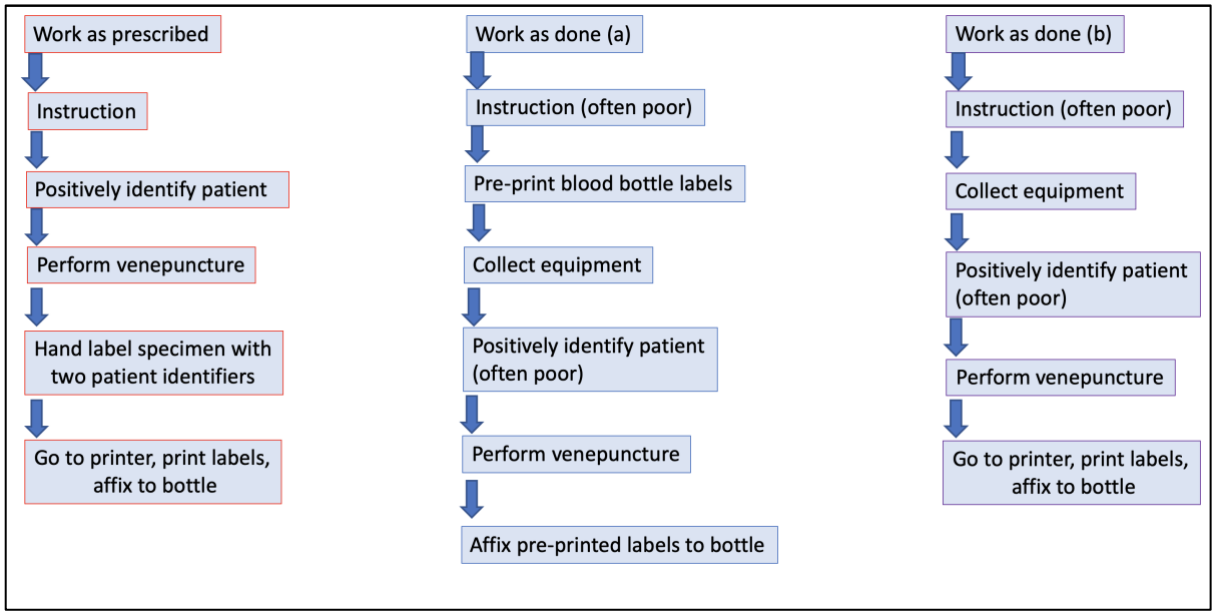
At the end of this meeting the metric consisted of 40 steps with the following phases:

1. Request to take blood
2. Identify patient
3. Preparation of Sample
4. Procedure
5. Label bottles
6. Transport

The meetings with the stakeholders highlighted the current practices of taking bloods in the hospital. Shorrock's framework of the variety of human work which takes place, as seen in figure 2.1 [107] illustrates the structure of the discussion which took place. The 'work as described' at CUH was defined by the standard operating procedure for phlebotomy and by the phlebotomy department. 'Work as done' describes the insight into the process of performing blood samples at CUH as provided by the doctors in training (figure 2.2). Our aim was to move the green oval ('work as done') to maximal overlap with the blue oval ('work as prescribed').



Figure 2.1 Description of the varieties of human work which take place in the workplace



Work as prescribed = Standard operating procedure for phlebotomy at CUH
Work as done (a), Work as done (b)= following interviews with healthcare workers performing phlebotomy this is the process followed by most doctors in the hospital.

Figure 2.2. Description of current practice of phlebotomy at CUH in early 2017.

Fourth metric-development meeting, March 9th, 2017

Meeting attended by Professor M.R. C, Professor A.G. G, consultant haematologist (M.R.), a clinical director at University College Cork (R.G.), a registrar in haematology (SG), a senior house officer in haematology (A.D), two interns in haematology (O.D., S. O'S), a researcher (NO'H), a representative from the laboratory IT department (B.O'M.), the chief medical

scientist (M.F. R.) from the microbiology department (S.C), a representative from the biochemistry department (N.G.) .

- The order of draw for the phlebotomy procedure was discussed with reference to the instructions provided by the manufacturer of the blood bottles used in the hospital and international guidance [38] [108].
- The angle for venepuncture was discussed, with reference to the WHO guidelines on venepuncture [38].
- Components of the programme to be delivered in the didactic teaching on the simulation training day were identified, including the need to ask for help after attempting to take blood on two occasions. A video recording of how to use the ICM system needed to be delivered online before the training.
- Metric phases and steps were adjusted accordingly

At the end of the fourth meeting version four of the metric consisted of sixty two steps and six phases as follows:

1. Request to take blood
2. Identify patient
3. Preparation of sample
4. Procedure
5. Label bottles
6. Transport

Fifth metric development meeting, March 23rd, 2017

Attendees included Professor M.R. C, Professor A.G. G., a consultant haematologist (M.R.), a registrar in haematology (S.G), a director of clinical skills (R.G), a lecture from the medical school (P.H.) and a researcher (N. O'H.).

- The barriers to patient identification were again discussed. Interns were frequently asked to take bloods from patients by the nurses. The message was often relayed by the nurses by leaving a handwritten list of intern jobs on the ward. Often, the patient's name and bed number were included but the list did not include a date of birth or medical record number for the patient, which made positive patient identification difficult (see Appendix E).

No modifications to the metric took place at this meeting.

Background of stress-testing the metric

Once the operational definitions have been arrived at, then the usefulness, validity, and reliability needs to be assessed. Stress-testing the metric [63] is a process involving a few members of the task analysis team. The team members view video recordings of the procedure (phlebotomy) and apply the metric in the assessment of the performance,

independent of their peers. If the team members are unable to score the performance reliably, then it is unlikely that someone outside the task analysis team could do so. Any scoring disagreements among the members of the group are discussed, and modifications are made to the metric definition based on this discussion and agreement by the group.

Stress-testing of the phlebotomy metric, April 6th, 2017

Table 2.1. Metric version four before stress testing took place

Phase I	REQUEST TO TAKE BLOOD	DEFINITIONS
1	Verify right test, right time. Examples: verbal call to registrar, intern list of jobs, talk to nurses, check notes, check previous bloods, check to see if ordered in ICM at a particular time	Ensure not repeating a test unnecessarily
2	For the right patient	Identify from notes or jobs list the patients name and MRN or DOB
	Triage time, determine urgency	
	Balancing requests with other priorities	
	Hand hygiene before approaching the patient	
Phase II	**IDENTIFY PATIENT**	
3	Locate patient	
4	Meet patient	Before collecting items for phlebotomy
5	Introduction,	
6	Confirm identity,	
7	Explanation,	
8	Consent,	
9	Inform of impending procedure	
10	Identify patient	Patient verbalises name and dob on request Cross check with wrist band

11	Ask name	
12	Date of birth	Verify with staff at the bedside and check wristband
	Consider hand hygiene if touched patient or the patient's surroundings	
Phase III	**PREPARATION OF SAMPLE**	
13	Gather equipment:	
14	Tray and sharps bin Clean tray inside and outside	
	Consider hand hygiene if had to clean the tray	
15	alcohol swab,	
16	Needles,	
17	Tourniquet	
18	Cotton wool	
19	Gauze	
20	Plaster	
21	Gloves	
22	Pen	
23	Forms,	
24	Printer if available,	
25	Test tubes ensure in date	
26	Identify site, verify that can take bloods (same assumed); ensure non pulsatile vessel	
27	Determine if line/ TPN/ blood transfusion will affect where taking sample from? How long you need to stop if	
28	Ensure no contraindications e.g., lymphedema, renal fistula, heparin	Ask patient opinion regarding particularly good vein or arm
	PROCEDURE	
29	Wash hands before approach patient	

30	Expose /Move	
31	Position patient. Comfortable, ideally sitting or lying, ask if comfortable, Not standing	
	Place tray at bedside within arm's reach and open lid	
32	Ensure equipment within arm reach	Environmental findings
	Assemble vacuette	
	Hand hygiene before putting on the gloves	
33	Put on tourniquet correctly Correct procedure – describe attend to knot teach about non-tourniquet samples Optimal technique	*4-5 finger widths above. Use quick release method to apply tourniquet*
34	Gloves well fitting & intact	Snug with no overhang
35	Clean area with alcohol wipe and allow to dry Clean hands and put on gloves	
36	Puncture vein – angle – 30 or less… If subcutaneous tissue large: may require larger angle	
	? Traction on skin Lean on patients arm to anchor hand Hold vacuette to steady it while inserting tube with dominant hand	
37	Exact fill Allow sufficient time to fill, not for longer than 2 minutes	Half bottle with biochemistry usually enough
38	Confirm in vein: blood in tube	
	Remove tube from vacuette before removing tourniquet ?	
39	Remove tourniquet before needle removed, using quick release method Changing hands to hold vacuette with dominant hand	
40	Not for longer than 2 minutes	i.e. tourniquet not to be left on for longer than two minutes
41	Order of draw- Coagulation, Biochemistry, FBC	
	Activate safety device after moving the vacuette and needle away from you and the patient	
42	Dispose of sharps safely directly to sharps bin	

43	Apply cotton wool or gauze, until bleeding stopped, - patient or doctor finger	
	Remove gloves in a manner that will catch cotton wool	
44	Invert tubes	
45	Apply Plaster unless allergy	
	Hand hygiene	
46	If no access ok to attempt on 2/3 occasions, ? switch limb, recognize if not able to take the blood sample - Help needed .Consider patient view and urgency.	
IV	**LABEL BOTTLES**	
47	If printer available at beside print label, if no printer available at bedside label each bottle at bedside with MRN , First name and Surname	Need teaching on how to use ICM. YouTube video + assessment at the end? Add stat or routine in ICM so clear to lab if sample urgent or routine If using a form write urgent,
48	Add label, check label first to ensure appropriate label to each blood tube (Print Check, Add->is the ideal)	Check with wristband at bedside or with bottles if printing labels away from the patient.
49	Labels printed correctly so that details readable (reprint label if not)	
50	Labels aligned correctly to bottle – (perpendicular), allowing lab scientist space to view specimen	
51	One label per bottle	If need to request another test after printing use add on forms. (not always available on the wards)
52	Check if label correct:	
53	Correct patient	
54	& correct label for each bottle	
55	Check label with bottle ? this metric repeating above	
56	Fully Label manually EG. if label printer not available or if required for blood bank request	

57	Date/time/ location	Will be on ICM sticker but needs to be filled on the forms,
58	Forms: put sample in forms bags or if using ICM can put in one bag , if no label write forms, or if transfusion sample write forms ICM no forms	
V	**TRANSPORT**	
59	Contact porter? Delegate. Formless bags suitable for transport for ICM samples	
60	Use pod	Not always reliable
61	Walk to lab	E.g. urgent cross match ,
62	Reception of sample	If put with GP samples and then would not be done

To stress test the phlebotomy metric, it was subjected to an assessment of how reliably it could score a phlebotomy procedure. In a meeting with Professor M.R.C., Professor. A.G.G., Consultant Haematologists Dr M.R. and a medical education expert (R.G.), the metric was used to independently score two videos of phlebotomy performance. Each metric was scored in a binary fashion, with 'yes' indicating the metric occurred correctly or 'no' indicating it did not occur or occurred incorrectly. After each video, differences in the scoring of each metric were reviewed and discussed. If required, operational definitions were modified, deleted, or added. This process continued until the metric development group was satisfied that the metrics accurately and unambiguously characterised the specifics of the phlebotomy procedure with particular attention to blood sample labelling.

At the end of this meeting the metric consisted of 67 steps and 10 phases as follows:

1. Instruction
2. If group and hold / crossmatch needed
3. Goes to patient
4. Goes to room equipment kept
5. Returns to patient and ergonomics of procedure
6. Prepares equipment
7. Takes blood
8. Gets ready to remove needle
9. Fixes patient up after procedure
10. Tidies up and sends bloods off

Background of the Delphi method

The Delphi method, developed by Dalkey and Helmer (1963) and the Rand Corporation in the 1960s, is a widely used and accepted method for gathering data and opinion from respondents within their domain of expertise. It is designed as a group communication process with goal-specific discussion led by one individual or chair [109].
The purpose of the Delphi method is to obtain the most reliable consensus of a group of experts [110]. It provides face validity and content validity. Face validity is achieved when a group of experts review the contents of a test and see if it seems appropriate. Content validity is an estimate of the validity of a test based on a detailed examination of the contents of the test items. Establishing content validity is a largely subjective measure and is reliant on experts reviewing each element of the test to determine the relevance of the materials included [63]. It structures a group communication process so that the process is effective in allowing a group of individuals as a whole to deal with a complex problem [111]. Structured communication is achieved by issuing the members of the Delphi panel with structured questionnaires with intermittent controlled opinion feedback, with the advantage of avoiding confrontation between the experts. Rounds continue until consensus is reached. This controlled feedback promotes independent thought on the part of the experts and aids them in the gradual formation of a considered opinion [110].

Background: Delphi vs modified Delphi

Delphi participants are polled individually, usually via self-administered questionnaires, with no physical meeting over two or more rounds [109]. A modified Delphi includes a face-to-face meeting of the panel members [63]. This is a more efficient process, as feedback is immediate and response rates are usually complete, and it allows for a face-to-face exchange of information, such as clarification of reasons for disagreements. However, it contradicts one of the basic rules of a Delphi procedure, which is to avoid a situation where one of the panel members might dominate the consensus process. This was avoided by tight chairing to ensure all present got to speak and contributions were not excessively lengthy.

Delphi consensus panel for phlebotomy metric

An important step in designing a Delphi study is choosing the expert panel. It requires qualified experts who have a deep understanding of the issue [112]. Panel members should reflect the full range of stakeholders who have an interest in the results of the study [113]. In this case, six relevant categories of experts were deemed to have important and valuable knowledge about phlebotomy specific to the process at CUH, with additional representation from UHK. These categories included nursing, phlebotomy, hospital consultant, non-consultant hospital doctor, academic teacher of clinical skills, and a behavioural scientist who was a professor of technology assisted simulation. A total of 16 experts were identified and asked to join the panel and 11 attended the meeting.

Report from Delphi meeting, May 12th, 2017

At a modified Delphi meeting, an overview of the project objectives and aims was presented. Delphi panel members comprised senior staff members from multiple centres roles in haematology, emergency medicine, phlebotomy, and nursing management. An explanation of PBP training was given, outlining the methods and evidence behind the approach. Local and national short- and long-term goals regarding improving phlebotomy proficiency to reduce incidence of WBIT were outlined.

Table 2.2 Members of the modified Delphi panel

Martin	**Boyd**	**Emergency Medicine Consultant, UHK**
Mary R.	Cahill	Professor, Haematology CUH
Aine	Connolly	IV Nurse Specialist CUH
Brid	Fitzgibbon	Phlebotomist, CUH
Robert	Gaffney	School of Medicine, UCC
Tony	Gallagher	ASSERT Centre, UCC
Sarah	Griffin	Non-Consultant Hospital Doctor, Haematology, CUH
Ailish	Normoyle	Phlebotomist, CUH
Claire	O'Brien	Clinical Director, UHK
Mary T.	Ring	Nurse Tutor, UHK
Mary F.	Ryan	Locum Consultant Haematology, CUH

For the purposes of Delphi discussion, the metric was presented in 10 phases. During the panel deliberations, each step was discussed, and each phase was voted upon. Consensus required unanimous agreement for each step and phase. Following presentation of each phase, an opportunity was given for critical evaluation and discussion. Delphi panel members voted on whether the metric was acceptable as presented. If consensus could not be reached, the metric definition was revised, and a new vote conducted until a unanimous verdict was reached.

Results of metric development and stress-testing the metric

Each step in the metric was designed to be precise and unambiguous. Definitions are designed to be objective and quantitative. An effort was made to ‘define‘ rather than ‘describe‘ the performance. Steps were further characterised as ‘errors‘ or ‘critical errors‘ if they were omitted or performed incorrectly.
The initial 67-step metric that resulted from the four ‘metric development meetings’ and the final ‘stress testing the metric meeting’ was divided into 10 phases. The procedure was characterised in its entirety. Beginning from the receipt of the order to perform phlebotomy, the procedure was defined by individual steps up to delivery of the sample to the laboratory.

The ten phases consisted of:

1. Introduction
2. If Group and Hold / Crossmatch needed
3. Goes to patient

4. Goes to room equipment is kept
5. Returns to patient and ergonomics of procedure
6. Prepares equipment
7. Takes blood
8. Gets ready to remove needle
9. Fixes patient up after procedure
10. Tidies up and sends off blood

Results of Delphi consensus panel

A panel of 11 experts convened in University College Cork in May 2017. The panel was comprised of an emergency medicine consultant, an intravenous nurse specialist, two phlebotomists, a director of clinical skills, a professor of technology enhanced learning, a non-consultant hospital doctor, a hospital clinical director, a nurse tutor, and two consultant haematologists.
At the commencement of the Delphi meeting, the project and concepts of the PBP training were explained and the procedure metrics for the phlebotomy procedure in CUH was presented. Each phase and step were discussed. The proposed metric was edited in real time and a vote was taken on the agreed consensus statement. Voting was unanimous. Consensus was reached on all phases that the metric reflected the steps necessary for safe performance of the procedure. No mandatory or essential steps had been omitted. This defined a 77-step process for safe phlebotomy, focusing on critical steps to prevent WBIT.

Modification to the metric included:

- Three steps deleted.
- 13 additions, including the formation of a new phase, computer'. This was noted to be vital, as labels were commonly being printed prior to phlebotomy, leading to errors, including mislabelling.
- 38 wording modifications for exactness or to avoid ambiguity.
- Six modifications in the order of the metric.

The detail of each modification to the metric is described in Table 2.3.

Table 2.3 Modifications to the phlebotomy metric at modified Delphi procedure

Detail of Modification	**Summary of the modifications agreed and voted on by the Delphi panel to the procedure steps and procedure errors of the reference approach to phlebotomy procedure**	
	New Value	**Old Value**
	Instructions	**Instructions**

definition modified	Confirms patient's name and MRN OR patient's name and DOB	Looks for patient's MRN from HCP
order modified	*Change in the order of the procedure – goes and gathers equipment before going to patient*	
	Goes to room where equipment is kept	**Goes to room where equipment is kept**
definition modified	**Decontaminate** procedures tray	Cleans procedures tray
definition modified	Places closed **(but not locked)** sharps bin on tray (if not already done so)	Places sharps bin on tray (if not already done so)
definition modified	**Sterile gauze** or cotton wool ball **from pack of five**	Cotton wool ball or gauze
definition modified	**Correct** blood tubes and **spare if using butterfly**	Blood tubes
definition modified	Vacuette needle and holder **and** butterfly	Vacuette needle and holder or butterfly
definition modified	**Disposable single-use** tourniquet	Tourniquet
definition modified	WHO hand hygiene moment: changed position	Performs hand hygiene
	Goes to patient	**Goes to patient**
definition modified	Introduces self u sing full name and **'Doctor'**	Introduces self using full name and **'Junior Doctor'**
definition modified	WHO hand hygiene moment: performs hand hygiene **entering patient space**	Performs hand hygiene using technique approved by WHO hand hygiene guidelines
definition modified	Asks patient's name **and DOB with patient if compos mentis or with nurse if in doubt**	Asks patient's name
definition modified	**Ergonomics of procedure**	**Returns to patient and Ergonomics of procedure**
addition	Ensure enough light to see veins	
definition modified	Asks patient if there is any particularly suitable vein and if one of their arms is unsuitable for venepuncture	Asks patient if there is any particularly suitable vein and palpates to verify vein is present
addition	Ensures that none of the following are present: Thrombophlebitis, Lymphoedema, PICC line,	

	renal fistula or a running IV infusion/TPN/blood transfusion	
definition modified	**Supports** patient's arm if necessary (e.g. with pillow)	Puts pillow underneath arm to support it with slight bend
addition	**Puts on tourniquet using a loop for quick release**	
deleted		Positions patient – if in bed, sitting up at least 30 degrees:
addition	Palpates to verify vein is present	
definition modified	Cleans skin thoroughly **for 30 seconds** using antiseptic swab	Cleans skin thoroughly using antiseptic swab
addition	Releases the tourniquet and allows skin to dry	
	Prepares equipment	**Prepares equipment**
addition	WHO Hand hygiene moment: performs hand hygiene (hand moment number 2 before an aseptic procedure – opening equipment) (**INSERTED AFTER ENSURES SHARPS BIN IS OPEN)**	
	Takes blood	**Takes blood**
addition	WHO Hand hygiene moment: performs hand hygiene **as part of aseptic procedure (Moment 2)**	
order modified		Gloves are snug-fitting with no overhang and are intact
definition modified	Puts on gloves **(gloves are snug-fitting with no overhang and are intact)**	
definition modified	Puts on tourniquet **to ensure quick release**	Applies tourniquet at least two finger breadths above the chosen site for venepuncture
order modified	Tourniquet at least two finger breadths above site	
definition modified	If using butterfly system – holds up wings **to insert needle**	If using butterfly system – holds up wings

definition modified	Puts traction on skin pulling in opposite direction to needle insertion **with non-dominant hand**	Puts traction on skin pulling in opposite direction to needle insertion
definition modified	**Anchors** the device effectively using non-dominant hand	Steadies needle effectively using non-dominant hand
order modified		Puts on tourniquet using a loop for quick release
order modified		Puts on gloves
definition modified	Connects blood tubes in the correct order (After discard blood tube) (**i.e.** Coag first)	Connects blood tubes in the correct order (After discard blood tube) (e.g. Coag first)
definition modified	Invert each tube at least three times **as they are taken** (except Biochem sample)	Invert tubes at least three times (except Biochem sample)
	GETS READY TO REMOVE NEEDLE	**GETS READY TO REMOVE NEEDLE**
definition modified	**Release** tourniquet while last blood tube is filling before removing needle from arm	Opens tourniquet before removing needle from arm
deleted		Swaps hand holding needle back to dominant hand to prepare for removal
definition modified	**Prepares** cotton wool ball	Readies cotton wool ball in non-dominant hand
definition modified	Removes needle and puts pressure over puncture site with cotton wool ball	Removes needle and puts pressure over puncture site with cotton wool ball
definition modified	OR If using Vacuette holder and needle – activates safety device immediately following removal	OR If using Vacuette holder and needle – activates immediately after removal **using index finger of hand** holding the device
definition modified	**FIXES PATIENT UP AFTER PROCEDURE and LABELLING OF BLOOD TUBE**	**FIXES PATIENT UP AFTER PROCEDURE**
definition modified	Removes gloves at bedside, catching cotton wool ball inside glove	Removes gloves at bedside, catching cotton wool ball inside glove
addition	WHO Hand hygiene moment: performs hand hygiene	

definition modified	Tapes down cotton wool ball OR puts plaster on patient	Tapes down cotton wool ball OR puts plaster on patient
addition	If using a butterfly system – activates the safety device during the removal process by holding down wing and compressing sides	
addition	OR If using Vacuette® holder and needle – activates safety device immediately following removal	
definition modified	Writes down patient's name **and DOB** or MRN onto the blood tubes using a pen before leaving bedside	Writes down patient's name and MRN onto the blood tubes before leaving bedside
definition modified	In case of a group and hold/crossmatch sample, completes all patients details by hand-writing on the tube **before leaving bedside**	In case of a group and hold/crossmatch sample, completes all patients details by hand-writing on the tube
deleted		Removes pillow from under arm **DELETED**
addition	Puts closed **(but not locked)** sharps bin back where found	Puts sharps bin back where found
addition	WHO hand hygiene moment: performs hand hygiene	
addition	**COMPUTER**	
definition modified	If **mobile** patient label printer available at bedside, prints and checks against wrist band (see steps for Computer below - steps 68-73)	If patient label printer available at bedside, prints and checks against wrist band
definition modified	Prints off patient's labels for blood tubes after blood collection. Decision to define this as a critical error.	Prints off patient's labels for blood tubes (if not already printed)
definition modified	Checks name and DOB/MRN on labels against patient's details written on blood tubes if applicable	Checks name and MRN on labels against patient's details written on blood tubes

order modified		Labels aligned correctly to blood tube (parallel and over label on tube)
definition modified	Puts labels on blood tubes aligned correctly to blood tube (parallel and over label on tube)	Puts labels on blood tubes
	Tidies up and sends off blood	**Tidies up and sends off blood**
definition modified	Puts blood tubes into sealed transport bags	Puts blood tubes into the haematology and biochemistry forms
definition modified	Dispatches to lab by usual means	Dispatches to lab by any means
definition modified	Dispatches to lab **in** accordance with local protocol	Dispatches to lab by usual means

Table 2.4 Phases of the phlebotomy metric and critical errors, if any, in each phase

Phases	*Phlebotomy Metric*	*Critical Errors*
I	Instruction to take blood	
II	Blood transfusion form completed	Completes all shaded areas of form
III	Collects equipment	Places closed (but not locked) sharps bin on tray
IV	Attends correct patient	Requests permission to take blood Checks name, MRN on ID wrist band against the written instructions (or against group and hold/crossmatch form if applicable)
V	Ergonomics of procedure	Asks patient if there is any particularly suitable vein and if one of their arms is unsuitable for venepuncture and ensures that none of the following are present: thrombophlebitis, lymphedema, PICC line, renal fistula or a running IV infusion /TPN/ blood transfusion
VI	Prepares equipment	
VII	Takes blood	Puts on gloves

VIII	Gets ready to remove needle	Release tourniquet while last blood tube is filling before removing needle from arm Once all blood tubes collected – disconnects last blood tube before removing needle
IX	Completes procedure and labels blood tube	Writes down patient's name and DOB or unique patient identifier number onto the blood tubes using a pen before leaving bedside If mobile patient label printer available at bedside, prints and checks label against wrist band
X	Computer	Prints off patient's labels for blood tubes after blood collection Checks name and DOB/MRN on labels against patient's details written on blood tubes if applicable
XI	Dispatch to laboratory	

The final metric instrument consisted of 11 procedure phases and 77 procedure steps which start from the instruction to take bloods and are completed with the dispatch of the sample(s) to the laboratory (Table 2.6). The more serious 'critical' errors were defined as those expected to either a) result in breach of patient or healthcare worker safety during the procedure itself, e.g. disposes of needle directly into the sharps bin, or b) potentially lead to a blood sampling error or WBIT event, e.g. checks name and patient identity number on ID wrist band against the written instruction.

Table 2.*5* Description of the 11 phases in the final phlebotomy metric

Phase number	**Procedure phase**	**Phase begins & ends**	**Definition of step at beginning/end of the phase**
I	Introduction	Begins	Confirms patient's name and patient ID number OR patient's name and DOB
		Ends	Writes down instructions including patient name, Patient ID number, Location and types of bloods to be done and brings written instruction to bedside
II	If crossmatch required	Begins	Completes form using handwriting (not patient label)

		Ends	Completes section regarding reason for group and hold/crossmatch
III	Goes to room where equipment is kept	Begins	Decontaminate procedures tray
		Ends	Puts last piece of equipment on tray
IV	Goes to patient	Begins	Performs hand hygiene entering patient space using technique approved by WHO hand hygiene guidelines
		Ends	Checks name, patient ID number on ID wrist band against the written instructions (or against group and hold/crossmatch form if applicable)
V	Ergonomics of procedure	Begins	Ensure enough light to see veins
		Ends	Releases the tourniquet and allows skin to dry
VI	Prepares equipment	Begins	Positions procedure tray with sharps bin within arm's reach
		Ends	Assembles Vacuettte needle and holder with safety device off to side of black dot unless using butterfly device
VII	Takes blood	Begins	Arm is positioned so that the chosen vein is pointing towards belly button of doctor (i.e. not awkward)
		Ends	Invert each tube at least three times as they are taken
VIII	Gets ready to remove needle	Begins	Release tourniquet while last blood tube is filling before removing needle from arm
		Ends	Disposes of needle directly into sharps bin
IX	Fixes patient up after procedure and labelling of blood tube	Begins	Confirms patient is not allergic to adhesive material
		Ends	Performs hand hygiene
X	Computer	Begins	Goes to computer, logs in and opens ICM system
		Ends	Logs out of ICM system
XI	Tidies up and sends bloods off	Begins	Puts blood tubes into sealed transport bags
		Ends	Dispatches to laboratory in accordance with local protocol

Table 2.6 Final Metrics for Phlebotomy at CUH (version created May 17th 2017)

LOP – lack of progress

(B) Beginning of onset of step

(E) End of completion of step

S – step

E – error
CE – critical error

Procedure start: Operator requested to take blood
Procedure end: Operator completed the dispatch of the sample to the lab

The following steps are critical errors if omitted or performed in the incorrect order: steps 5, 9, 19, 22, 24, 31, 39, 50, 51, 60, 61, 72, and 73.

Phase	Step	Definition	Step	Error	CE
I		**INSTRUCTIONS (Usually given patient name, location (e.g. Room 19 Bed 2) and types of bloods to be collected**			
	1	Confirms patient's name and Patient ID number OR patient's name and DOB			
	2	If given verbal instruction – repeats back to HCP including patient name, patient ID number, location and types of bloods to be done			
	3	Writes down instructions including patient name, patient ID number, location and types of bloods to be done and brings written instruction to bedside			
II		**If group and hold/crossmatch needed:**			
	4	Completes form using hand-writing (not patient label)			
	5	Completes all shaded areas of the form			
	6	Answers questions regarding blood groups and previous transfusions			
	7	Completes section regarding reason for group and hold/crossmatch			
III		**Goes to room where equipment is kept**			
	8	Decontaminate procedures tray			
	9	Places closed (but not locked) sharps bin on tray (if not already done so)			
		Puts all equipment on the tray			
	10	Non-sterile gloves			
	11	Disposable single use tourniquet			
	12	Antiseptic swab			
	13	Vacuette needle and holder and butterfly			
	14	Correct blood tubes and spare if using butterfly			
	15	Sterile gauze or cotton wool ball from pack of five			
	16	Plaster / Tape			
IV		**Goes to patient**			
	17	Performs hand hygiene entering patient space using technique approved by WHO hand hygiene guidelines			
	18	Introduces self using full name and 'Doctor'			

	19	Requests permission to take blood			
	20	Asks patient's name and DOB with patient if compos mentis or with nurse if in doubt			
	21	Explains procedure and gets verbal consent to take blood			
	22	Checks name, patient ID number on ID wrist band against the written instructions (or against group and hold/crossmatch form if applicable)			
V		**Ergonomics of procedure**			
	23	Ensure enough light to see veins			
	24	Asks patient if there is any particularly suitable vein and if one of their arms is unsuitable for venepuncture			
		Ensures that none of the following are present: Thrombophlebitis, Lymphoedema, PICC line, renal fistula or a running IV infusion /TPN/ blood transfusion			
	25	Supports patient's arm it if necessary (e.g. with pillow)			
	26	Puts on tourniquet using a loop for quick release			
	27	Tourniquet at least two finger breadths above site			
	28	Palpates to verify vein is present			
	29	Cleans skin thoroughly for 30 seconds using antiseptic swab			
	30	Releases the tourniquet and allows skin to dry			

VI		**Prepares equipment**			
	31	Positions procedures tray with sharps bin within arm's reach			
	32	Ensures top of sharps bin is fully open			
	33	Performs hand hygiene (hand moment number 2 before an aseptic procedure – opening equipment)			
	34	Opens all packaging			
	35	Assembles Vacuettte needle and holder with safety device off to side of black dot unless using butterfly device			
VII		**TAKES BLOOD**			
	36	Arm is positioned so that the chosen vein is pointing towards belly button of doctor (i.e. not awkward)			
	37	Puts on tourniquet to ensure quick release			
	38	Performs hand hygiene as part of aseptic procedure (Moment 2)			
	39	Puts on gloves (Gloves are snug-fitting with no overhang and are intact)			
	40	Puts traction on skin pulling in opposite direction to needle insertion with non-dominant hand			
	41	Inserts needle at less than 30 degrees using dominant hand			
	42	If using butterfly system – holds up wings to insert needle			
	43	Anchors the device effectively using non-dominant hand			
	44	Connects blood tubes using dominant hand			
	45	Blood fills tube confirming needle has been correctly inserted to correct depth in vein			
	46	Allow sufficient time for blood tube to fill			
	47	If using butterfly system discards first blood tube			
	48	Connects blood tubes in the correct order (After discard blood tube) (i.e. Coagulation sample first)			
	49	Invert each tube at least three times as they are taken			

VIII		**GETS READY TO REMOVE NEEDLE**			
	50	Release tourniquet while last blood tube is filling before removing needle from arm			
	51	Once all blood tubes collected – disconnects last blood tube before removing needle			
	52	Prepares cotton wool ball			
	53	Removes needle and puts pressure over puncture site with cotton wool ball			
	54a	If using a butterfly system – activates the safety device during the removal process by holding down wing and compressing sides			
	54b	**OR** If using Vacuette® holder and needle – activates safety device immediately following removal			
	55	Disposes of needle directly into sharps bin			
IX		**FIXES PATIENT UP AFTER PROCEDURE and LABELLING OF BLOOD TUBE**			
	56	Confirms patient is not allergic to adhesive material			
	57	Tapes down cotton wool ball OR puts plaster on patient			
	58	Removes gloves at bedside, catching cotton wool ball inside glove			
	59	Performs hand hygiene			
	60	Writes down patient's name and DOB or patient ID number onto the blood tubes using a pen before leaving bedside			
	61	If mobile patient label printer available at bedside, prints and checks against wrist band (see steps for Computer below – steps 68-73)			
	62	In case of a group and hold/crossmatch sample, completes all patients details by hand-writing on the tube **before leaving bedside**			
	63	Places group and hold blood tube into form and seals			
	64	Asks patient if they are comfortable and thanks patient			
	65	Collects all waste including tourniquet onto tray			
	66	Disposes of waste			
	67	Performs hand hygiene leaving bedside			
	68	Puts closed (but not locked) sharps bin back where found			
	69	Cleans procedures tray			
	70	Performs hand hygiene			

X		**COMPUTER**			
	71	Goes to computer, logs in and opens ICM system			
	72	Prints off patient's labels for blood tubes **after blood collection**			
	73	Checks name and DOB/patient ID number on labels against patient's details written on blood tubes if applicable			
	74	Puts labels on blood tubes aligned correctly to blood tube (parallel and over label on tube)			
		Not more than one label attached to each blood tube			
	75	Logs out of ICM system			
XI		**TIDIES UP AND SENDS BLOODS OFF**			
	76	Puts blood tubes into sealed transport bags			
	77	Dispatches to lab in accordance with local protocol			

Background of validity and reliability

A number of methods have been developed to assess the validity of testing instruments, including face, content, construct, concurrent, discriminate, and predictive validity. Face and content validity have already been described (here). Construct validity is defined as a set of procedures for evaluating a testing instrument based on the degree to which the test items identify the quality, ability, or trait it was designed to measure. A common measure is the ability of a test or tool to differentiate between an expert or novice performing a given task [63] and this is one of the most important types of validity to demonstrate when developing a PBP training programme.

Testing tools must also demonstrate reliability. Reliability is a generic term to cover all aspects of the dependability of a measurement device or test. It is the concept of consistency or the extent to which the assessment tool yields the same results when used repeatedly under similar conditions. The reliability coefficient can be used to determine the reliability of a test[63].

One of the objectives of this study was to examine previously developed performance and error metrics of phlebotomy performance in CUH for construct validity and to measure the inter-rater reliability (IRR) of the novel metrics-based assessment tool in a clinical setting.

Construct validity: phlebotomy metric

To establish construct validity, two groups were compared in their performance of phlebotomy. Sampling aimed to recruit at least six novices and six experts working in various specialities in the hospital, including phlebotomy, nursing, and medical specialities. All novices were intern doctors in training, as the metric was primarily developed for doctors. All participants were working in CUH at the time of the study. The expert group consisted of two phlebotomists, two haematology nurse specialists, and two senior doctors in training. The expert healthcare professionals performed the procedure consistently in practice and were cognisant of the potential for error during blood sampling. The 'novice'

group consisted of five intern doctors. Each group was instructed to perform a venepuncture on a patient. The procedure was video recorded using a Go-Pro camera worn by the participant (first-person perspective).



Fig 2.3 Go-Pro camera worn by the participant (first-person perspective) during video recordings of phlebotomy on the wards at CUH

Video recording began with the instruction to take blood and ended with dispatch of the blood sample to the laboratory. A score of 77 would indicate that all 77 steps of the procedure had been performed correctly. If a step was missed, then this was marked as an error. There were 13 critical errors that could occur as indicated in Table 2.4 and the full metric is illustrated in Table 2.6.

The video recordings were scored by two reviewers: a director of clinical skills (RG) and a medically qualified researcher (N.O'H.) Reviewer training consisted of a one-hour meeting, during which the metric was discussed in detail. The definition of a 'step,' 'error,' and 'critical error' and how scoring should occur was clearly outlined. A full-length example video was viewed and scored. Any differences in scoring methods were discussed. Finally, the reviewers scored each of the videos separately. The reviewers were blinded to group status when scoring the videos. Each video was scored for 'steps,' 'errors,' and 'critical errors'.

For each of the 77 steps of the procedure, the numbers of 'steps,' 'errors,' and 'critical errors' were tabulated in an Excel sheet and the scores of the two reviewers were compared. The number of 'agreements' were tabulated (either both reviewers documented that a step was performed or both scored the step as not being completed). In addition, the number of 'disagreements' in scoring steps was tabulated (one reviewer scored the step had been completed and the second reviewer scored that it had not been completed). The inter-rate reliability (IRR) for the steps was calculated according to the following formula: Number of agreements/Number of agreements + Number of disagreements. An acceptable IRR is defined as equal to or greater than 0.80 [114]. Performance differences were compared for statistical significance with a one-way ANOVA, using SPSS statistical package (V.24). We estimated a 26%-42% difference between the experienced and novice groups based on previous studies [94].

Results of Construct Validity Study

5 interns (novices) were observed performing phlebotomy on video. 6 experts were observed performing phlebotomy comprising 2 phlebotomists, 2 nurses, 2 senior doctors in training (one doctor was observed twice). Of the 12 videos that were scored, the mean inter-rater reliability was 0.91 (min 0.83, max 0.95). The expert group completed more steps of the procedure (72 Vs 69), made 46% fewer errors (19 vs 13, p = 0.014) and had 300% fewer critical errors (1 Vs 4, p = 0.002) than the novice group. This is illustrated in Figure 2.3. A list of the frequent errors occurring in each group is displayed in tables 2.5 and 2.6

Table 2.7 Construct validity: frequent errors which occurred in the novice group (n=5)

Number of videos where Novices performed the Error(n=5)	**Step Number**	**Description**
5	2	If given verbal instruction repeats back to HCP including patient name, patient ID number, location and types of blood to be done
5	22	Checks name, patient ID number on ID wrist band against the written instructions (Critical Error)
5	30	Releases tourniquet to allow skin to dry
5	38	Performs hand hygiene before procedure
5	47	If using butterfly system discards the first blood tube (Critical Error)
5	56	Confirms patient is not allergic to adhesive material
5	60	Writes down patient name and DOB or patient ID number onto the blood tubes using a pen before leaving the patient
5	68	Puts closed but not locked sharps bin back where found

Table 2.8 Construct validity: frequent errors which occurred in the expert group

Number videos where experts performed an error (n=7)	Step number	Description
7	30	Releases tourniquet to allow to skin to dry
6	69	Cleans procedure tray after use
6	70	Performs hand hygiene after cleaning tray
5	56	Confirms patient is not allergic to adhesive material
5	75	Logs out of iCM System
4	17	Performs hand hygiene entering the patient space
4	49	Invert each tube after taking blood
4	68	Puts closed but not locked sharps bin back where it was found.

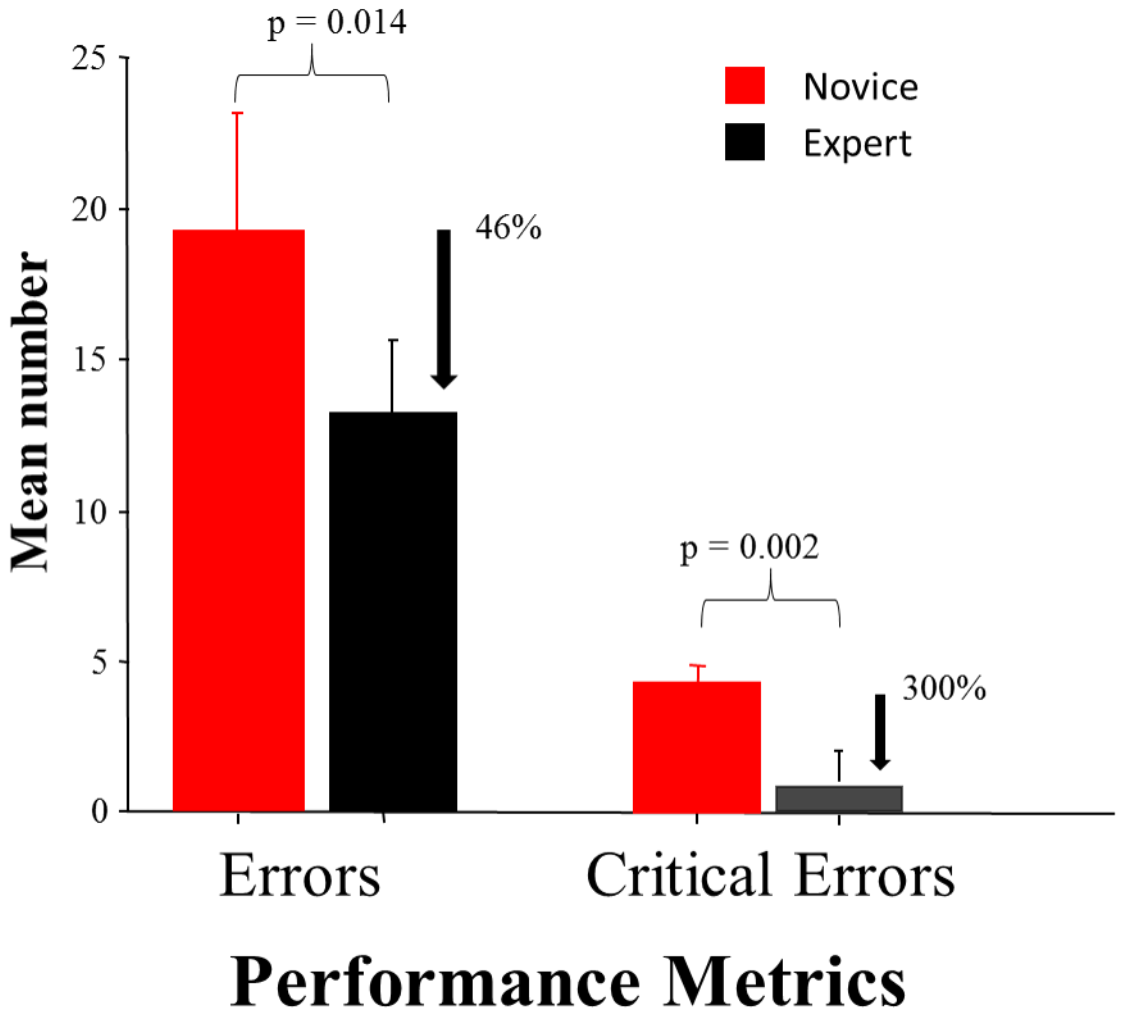


Figure 2.4 Comparison of errors and critical errors performed by novice and expert groups

Background of proficiency benchmark

One of the key concepts of PBP training is that trainees graduate from the programme only when they reach a proficient – as distinct from competent – standard. Competency is a level where doctors have 'enough' skill to complete a task; proficiency is when the person begins to act autonomously, while remaining cognisant of ways to improve their performance [63]. A proficiency benchmark can be defined as 'what proficient individuals do' [63]. To set the proficiency benchmark, the mean performance of the expert group is chosen. This means that trainees who reach the benchmark criterion have the same or better level of performance as 50% of the expert group on which the benchmark was established. In previous studies on developing PBP training programmes, it is required that the trainees reach the proficiency benchmark on at least two consecutive occasions before graduating from the programme [105]. The proficiency benchmark is an indicator of skill rather than competency and is a robust method of assessing the trainees.

Setting the proficiency benchmark for WBIT proficiency-based progression training in CUH

The proficiency benchmark was decided at a meeting of experts including a professor of haematology (M.R. C) , a professor of technology-enhanced learning (A.G. G.), a laboratory information systems leader (BO'M), and the medically qualified researcher (NO'H). The experts had a mean of 13 errors during video recording and had completed a minimum of 69 steps. It was decided that, to reach proficiency, the training programme would require the interns to perform phlebotomy according to the metric with at least 69 steps completed and less than 13 errors. Given the importance of avoiding any critical errors, it was decided that no critical errors should be allowed for the interns to reach proficiency. This decision differed from other cases of PBP training and set a high bar for the implementation side of this research.

Discussion

Phlebotomy is a widely used procedure that healthcare professionals are expected to perform proficiently from the first day of work. However, due to a lack of practical skills training at an undergraduate level, often interns do not feel adequately prepared for clinical practice on commencement of work [115].

With the use of example videos demonstrating novice and proficient practitioners in their usual working environment, and the contribution of a multidisciplinary team, we developed a performance metric. This was stress-tested and reviewed by a modified Delphi meeting, which accepted the metric and provided face and content validity for the metric.
The study demonstrates strong evidence of construct validity for the use of the phlebotomy metric in scoring performance of healthcare practitioners while performing phlebotomy on patients. The phlebotomy metric was shown to have a high inter-rater reliability, indicating that it provides a precise description of the procedure with consistent and reliable results when used by different reviewers. The tool can accurately distinguish between novice and expert performers of phlebotomy as the expert group had fewer errors and, more

importantly, fewer critical errors. Previous studies have used a phlebotomy metric or checklist to evaluate the effectiveness of VR simulation training compared to mannequin arm training, but, evidence of construct validity for the instrument used was not clear [116-118]. As discussed in Chapter 1, guidelines exist on the correct procedure to be followed when performing phlebotomy and were developed following literature review and expert consensus alone [37 38 36] . The construct validity of VR simulator 'CathSim' to distinguish between expert and novice groups has been established [119]; however, the simulator does not focus on the eradication of labelling errors and there is a lack evidence of concurrent validity (the closeness of the assessment to the real life environment). Our assessment tool is comprehensive, outlining 11 phases and 77 steps in phlebotomy in an effort to reduce pre-analytical errors, including mislabelling and WBIT errors, which can be detrimental to patient safety.

Limitations

My study has a number of limitations. Recording videos in the clinical setting using real patients is time consuming and difficult so the number of videos analysed is small. Seven expert and five novice videos were reviewed. The validity and proficiency benchmark for training programme may need to be confirmed with a larger sample size before using the tool for high stakes evaluation. The expert panel had no special qualification to determine them as experts, but had longer years of experience in taking bloods and were aware of pitfalls in mislabelling and previous campaigns to reduce this. Only one episode of phlebotomy was observed per video recording. The results may have differed if more than one procedure was observed, but this was restricted by time constraints and the difficulty in recruiting subjects.

The metric is developed especially for the hospital with specific hardware including the ICM system, however, ICM is a standard order communication system with many similar systems in use elsewhere.

The phlebotomy metric will require modification to adapt according to changing best practice within phlebotomy and changes to the process in the hospital. European guidance in 2018 recommends that the tourniquet be released once the blood starts to flow into the tube first to avoid haemolysis and clotting of the sample [120 121] and printing labels and labelling at the bedside in the presence of the patient [122]. The definitions provided in the metric were agreed by Delphi but in retrospect could have been clarified further. For example, under the section "Tidies up and sends off blood", the title could be better defined. Further detail which could have been considered in this phase include the following:

a. ensures haemostasis - patient applies pressure with cotton wool,
b. blood transferred to correct tubes
c. needle and equipment put in sharps box
d. Other materials eg tissues put in clinical waste e)ensure no equipment left on/in bed
e. tubes put in correct bags
f. clinical details put on forms

g. blood tubes / forms put in collecting box.

However, this would have increased the complexity of the metric further.

The team has encouraged the hospital to upgrade hardware so that bedside label printers would be available always. The metric should include a step to check the expiry date on equipment which can effect sample integrity [122] and remind the healthcare professional to use the safety system on the butterfly device and vacuette.

Conclusion

The results demonstrate that the metrics in phlebotomy can be scored reliably as indicated by the high IRR level. The metrics demonstrate construct validity and distinguished between the objectively scored performance of experienced and novice performance of phlebotomy. Based on the modified Delphi panel, the validation results, and consultation with an expert panel, the proficiency benchmark was established at a minimum observation of 69 steps, with no critical errors and no more than 13 errors in total. The created metric which has been internally validated for phlebotomy, could serve (with modifications as necessary) as the basis for further external validation at other sites/practices.

Main Messages

- A validated metric for the performance of phlebotomy has been developed with a particular emphasis on avoiding mislabelling errors, including WBIT.
- The metric can be used to provide a PBT training programme in phlebotomy.
- A proficiency benchmark is set to ensure healthcare practitioners have reached a standard in phlebotomy equivalent to the average score of experts in the field.

Chapter 3: PROFICIENCY-BASED PROGRESSION (PBP) INTERN TRAINING MITIGATES CRITICAL BLOOD SAMPLING ERRORS, INCLUDING 'WRONG BLOOD IN TUBE'

Abstract

Background: Blood sampling errors occur frequently, are costly and Wrong Blood in Tube (WBIT) may have adverse effects on clinical outcomes. WBIT errors occur when the blood sample in the tube is not that of the patient identified on the label. Reported WBIT rates range from 0.17 to 0.76 per 1,000 blood transfusion samples and about 30 per 1,000 blood transfusion samples are mislabelled [40]. Samples with minor mislabelling have a higher rate of WBIT [65]. Standard education interventions have not been shown to reduce incidence.
Objective: To determine the effect of proficiency-based progression (PBP) training in phlebotomy on the rate of blood sampling and labelling errors (including WBIT).
Design: Non-randomised controlled trial to compare the blood sampling error rates of historical controls who had not undergone PBP training in 2016 to PBP trained interventional groups in 2017 (pilot study) and 2018 (follow-on study).
Setting: A large university teaching hospital.
Participants: Intern doctors commencing work.
Intervention: A PBP training programme in phlebotomy was developed with three stages comprising an eLearning module, supervised phlebotomy in a simulated environment, and mentorship while performing phlebotomy in the clinical environment.
Outcome Measures: The primary outcome was frequency of WBIT and secondary outcome, any error in sampling and labelling.
Results: In the haematology laboratory, 43 interns in 2016 control group had an error rate of 2.4% compared to 44 interns in the 2017 pilot study, who had an error rate of 1.2% (OR=0.50, 95% CI 0.36-0.70 p-value<0.01) 46 interns in the 2018 follow-on group had an error rate 1.9% (OR=0.89, 95% CI 0.65-1.21 p-value=0.46). There were three WBITs in 2016 and 2017 and five WBITs in 2018.
In the transfusion laboratory, there was a reduction in overall error rates with the introduction PBP training, but the reduction was not statistically significant. There was no blood transfusion WBIT in 2016, there was one blood transfusion WBIT in 2017, and no blood transfusion WBIT in 2018.
Conclusions: The study demonstrates that PBP training in phlebotomy can help reduce blood sampling errors, but the PBP training must be delivered to a high standard.
Trial Registration Number: NCT03577561

Introduction

Errors during sampling, labelling and transport to the laboratory (pre-analytical errors) are a common problem in the laboratory and account for up to 70% of all laboratory mistakes [13]. Frequent errors occurring in the pre-analytical phase of testing include: i) identification errors, ii) errors in request procedures, iii) over- or under-filling of the specimen bottle, iv) empty or missing tubes, v) contradictory demographic information on the tube and the

request, (vi) 'Wrong Blood in Tube' (WBIT) [14]. Guidelines exist on the correct practice of phlebotomy [36-38]. An observational study in 12 European countries demonstrated the level of compliance with phlebotomy procedures was low, and confirmed patient identification and tube labelling as the most critical steps requiring immediate action [16]. Variation exists in how blood collections are actually performed in the real world and a recent review highlighted the need for standardisation [123].
The recent Testing the Utility of Collecting Blood Electronically (TUBE) study in the USA [65] shows a lower incidence of WBIT in electronically labelled samples than manually labelled samples (1:3046 compared to 1:14,606 respectively). Furthermore, the sample rejection rate for samples deviating from labelling policy was 1:67 samples. When these mislabelled samples were analysed, it was found that 1:26 of them could be WBIT samples, therefore justifying sample rejection policies which do not use mislabelled samples for analysis or cross match.

At our university hospital, CUH, the laboratory has been monitoring and recording details of the occurrence of WBIT and other sampling errors that result in rejection of blood samples for over 10 years. Previous efforts to reduce mislabelling errors have included educational sessions with the haemovigilence officer, a zero-tolerance policy for transfusion samples, and educational campaigns to inform staff. These time-consuming efforts mitigate a peak in mislabelling experienced every July, but fail to reduce the 'baseline rate' of sampling errors. Since the introduction of an online request clinical management system (iCM) in the hospital, identification errors have increased despite standard education and training. This is a major concern.

The healthcare practitioner is a key stakeholder in the prevention of controllable pre-analytical errors. Video recordings of doctors performing phlebotomy identified practices with the potential to lead to incorrect labelling of blood specimens. In the pre-analytical phase of testing it is necessary to ensure quality methods of patient identification and preparation, safety, specimen collection, and specimen transportation to avoid wasteful errors [124]. The most serious error, WBIT errors, occur when the blood is taken from the wrong patient but labelled with the intended patient's details (mis-collected) or blood is taken from the intended patient and labelled with the wrong patient's details (mislabelled samples) [40] . WBIT has serious consequences, including misinterpretation of a patient's - diagnosis or clinical status, incorrect referral or treatment, or incorrect cross-matching for blood of the wrong blood group (see Consequences of pre-analytical errors and WBIT).
Training and medical education can reduce the occurrence of pre-analytical errors including WBIT [28 40 62 125] but is not sufficient to eradicate WBIT. Despite a focus on remediation of WBIT in our hospital and internationally, the incidence of WBIT has not changed [126]. A new approach is needed. This study proposes proficiency-based progression (PBP) simulation training as a solution to reduce pre-analytical errors including WBIT. PBP is an approach demonstrated to be more effective than traditional training models in procedural skills [73 91 105]. The study aims to compare the blood sampling error rates of interns commencing work in CUH in July 2016 who did not receive PBP training in phlebotomy (historical controls) to PBP trained interventional groups commencing work in July 2017 (pilot study) and July 2018 (follow-on study) over a three-month period.

Methods

Study Design

In conjunction with the team at ASSERT, UCC, led by A.G.G., I designed an intervention suitable for use in a clinical trial. Trial design was a non-randomised controlled trial. The pre-trial phase involved developing the PBP training programme and the trial phase implemented this programme with monitoring for evidence of efficacy to determine the outcome of the PBP programme on reducing blood sampling errors and WBIT.

Phase 1: Proficiency-Based Training Programme Development
(previously described in Chapter 2)

To design a new training programme, the procedure metrics were characterised [63]. We identified and defined 11 phases of the phlebotomy procedure. These 11 phases had 77 steps (metrics) for safe phlebotomy performance. The procedure characterisation focused on the correct procedure performance, patient safety and on identifying critical steps to avoid errors, including pre-analytical phase blood specimen errors and WBIT. These phases and metrics were then presented to a multidisciplinary Delphi panel of procedure experts, who unanimously concurred that they represented a comprehensive depiction of the procedure. Following the Delphi panel, the performance of phlebotomy by novice and expert groups was video recorded and objectively assessed by two reviewers, blinded to group status using these metrics. The metrics demonstrated construct validity (mean inter-rater reliability 0.91) and distinguished between the objectively scored performance of experienced and novice clinicians. An expert panel established the proficiency benchmark at a minimum observation of 69 steps, with no critical errors and no more than 13 errors in total. A list of the 11 phases and the defined critical errors are illustrated in the Table 1 (chapter 2).

Phase 2: Controlled Trial

The second phase of the study aimed to determine if this bespoke PBP training programme could reduce the incidence of blood sampling and labelling errors, including WBIT. The effectiveness was examined during a pilot study in July 2017 and a follow-on study in July 2018 to determine if improvements were sustained. The PBP training programme was delivered to the incoming interns in July 2017 (as a pilot project) and in 2018 (as a follow-on study). Blood sampling error rates were monitored over a three-month period and compared to interns commencing work in July 2016 (historical controls).
Qualitative analysis took place during mentorship of the interns while performing clinical duties to investigate which factors were contributing to blood sampling errors and to inform the training programme for the next phase of the study in July 2018.

Setting and participants

The study took place in Cork University Hospital, a teaching hospital of University College Cork. Participants were interns who commenced work in Cork University Hospital in July of each year for a three-month rotation. Novices who had performed videos to develop the metric were not invited to training as they had now completed their intern year.

Control group

The control group was comprised of 45 interns who were commencing work for the first-time following graduation in July 2016 and had traditional training in phlebotomy. This group had received phlebotomy training as medical students in their third medical year on two occasions and once in the final year of medical school, comprising a phlebotomy guide, training videos, and a practical training session in the clinical skills laboratory. Students' performance of phlebotomy is assessed in the third year in an Observed Structure Clinical Examination. This group of interns did not provide information on their personal characteristics, but their blood sample requests and rejects were traceable on the laboratory information system as described. Tracking and trending errors is a routine part of the quality system analysis performed by the laboratory. The data on the 2016 interns was collected retrospectively.

2017 pilot study group and 2018 follow-on study group

The intervention group consisted of 45 interns who were commencing work for the first-time following graduation in July 2017 (pilot study) and 47 interns commencing work in July 2018. The new interns participated in the intervention (in the form of a PBP training programme) in the days before the commencement of their employment in the hospital. The group gave informed consent for enrolment into the controlled trial. The data was collected prospectively.

The intervention in July 2017 pilot study: proficiency-based progression training programme in phlebotomy

The interns commencing work in July 2017 first completed an online training module to familiarise them with the correct process of performing bloods in the hospital.

The online training module was entitled 'Bloody Excellence'. It consisted of a video of an expert performing phlebotomy on the wards. Each step of the metric was described and the participant watched the expert doctor perform the task correctly (see figure 3.2) and a video by a lead IT system analyst instructing the doctors on how to use the ICM software system to order and print blood sample labels correctly (Figure 3.3). This provided information such as how to log in to the ICM system, how to search for a patient on the system correctly, how to order a blood test and how to print a label after a blood test had been taken. A MCQ was provided at the end of the module which students were expected to pass before being provided with a certified to confirm they had completing the eLearning module.

In the second component of the training , the interns attended face-to-face training. This consisted of a short motivational introductory talk from a consultant haematologist and a laboratory scientist to outline the importance of following the correct procedure and the consequences of errors. The training took place on a simulated ward in CUH. Computers

were provided on the ward which had a dummy ICM system which could order blood tests without any order going through to the laboratory. Interns were able to print off blood labels using this system. A room on the ward was stocked with the equipment the interns would require to perform phlebotomy so that the interns had to gather each of the items of equipment required as part of the process. Each ward had 6 beds which had model IV arms so that the interns could take the bloods. The interns worked in groups of three, with one person acting as a patient (with a model IV arm adjacent to them on the bed), a second person marking according to the metric, and a third person taking bloods. A tutor was assigned to each team. Each person had to perform phlebotomy on model IV Arms (see figure 3.6) on the simulated ward to the proficiency standard of performing at least 69 steps with no more than 13 errors occurring and no critical errors allowed to graduate from the course. The interns were provided with the opportunity to meet stakeholders in the process of phlebotomy such as laboratory scientists, phlebotomists, IV nurses and senior doctors who were able to answer any questions they might have related to their speciality in a safe space before commencing work.

The third phase of training occurred once the interns had commenced work. The doctors were observed performing phlebotomy on patients on the wards to ensure they continued to achieve the proficiency benchmark in real time. The interns were asked to provide their contact details at the simulation training. During the first three weeks of on call in the hospital the researcher (NOH) contacted the doctors when they were on call and provided them with her mobile number so that if they were performing phlebotomy on the wards NOH would meet with them to observe their practice. After three weeks a session was scheduled in the mornings between 7am and 9am to perform scheduled bloods for patients. The interns met with NOH on the ward where the bloods were to be taken and NOH observed them from the instruction to take the bloods on the ward to the dispatch of the sample to the laboratory. If the intern was not performing the process according to the metric they were provided with non-judgemental guidance and reminded of the metric steps and any critical errors which require avoidance. The interns were provided with the opportunity to discuss any issues that had the potential to lead to errors or that were interfering with their ability to perform bloods according to the metric.

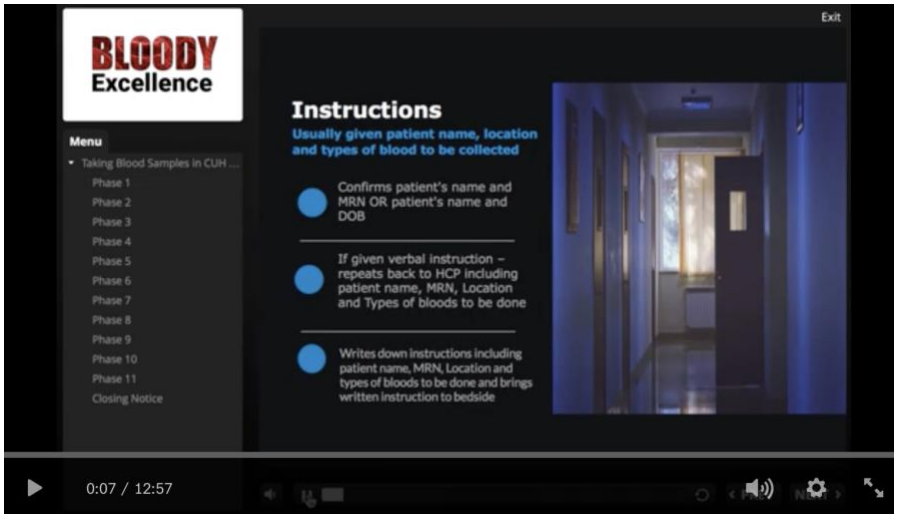


Figure 3.1 Bloody Excellence eLearning Programme, instruction to take blood

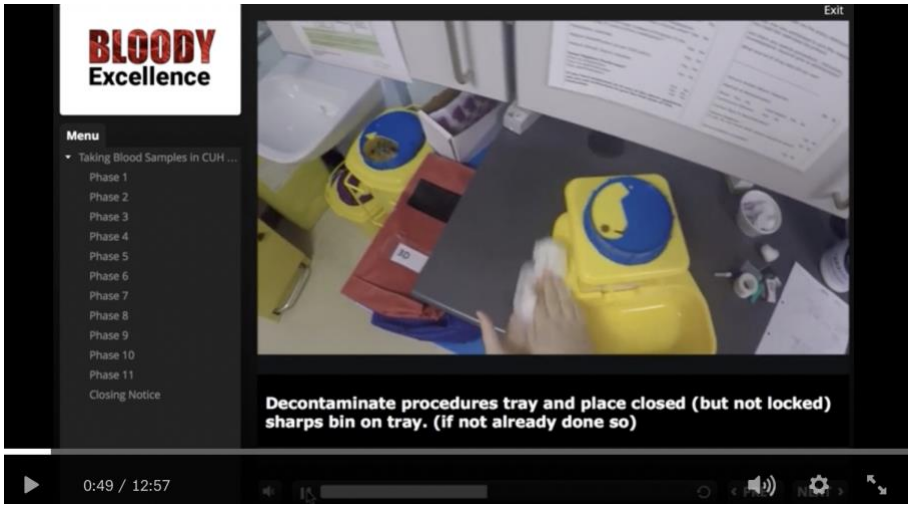


Figure 3.2 Bloods Excellence eLearning Programme, decontaminate the procedure tray

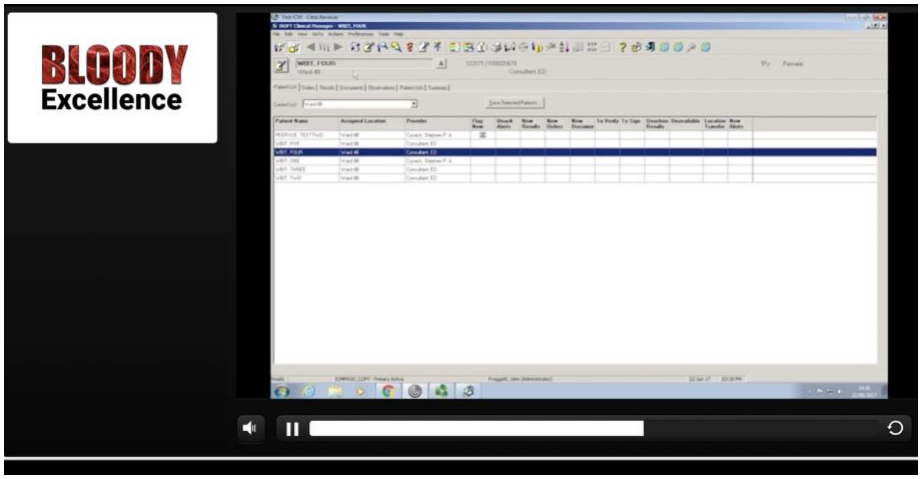


Figure 3.3. Bloody Excellence eLearning Programme, how to use the iCM software system

The intervention July 2018: proficiency-based progression training programme in phlebotomy

Following feedback in 2017, a decision was made to train all 124 interns due to work in the hospital during the 2018/2019 rotation. This training was done in July 2018, before the interns first commenced employment as doctors. Of these, 47 interns were due to commence work in CUH in July 2018 and the other 77 interns were due to commence their work in other local hospitals in July 2018 but would work in CUH later that year as an intern. The interns completed an online training module, which was updated using learning points from the pilot study. The introductory talk by the consultant haematologist and medical scientist was provided online. Again the interns had to complete a MCQ at the end of the eLearning module to certify competence was reached. Interns were asked to attend the face-to-face training, where each intern performed phlebotomy on model IV Arms. The ward was set up in a similar way to 2017 with model IV arms, 6 beds per ward, an adjacent room where materials required could be collected and computers with label printers available away from the patient. After achieving proficiency in the simulated ward, the interns were observed performing phlebotomy on patients in the normal clinical environment. In 2018 the interns were observed performing scheduled bloods between 7am and 9am each day and this took 4 weeks to achieve. This method was chosen as it had proven more efficient in 2017. To maintain improvements, each intern was provided with feedback on any error that occurred in the transfusion or haematology laboratory at the end of each month. This consisted of the researcher (NOH) sending an email to the each student individually at the end of the month to advise them on the number of blood tests that they had performed, the number of errors that they had performed, detail of the type of error, steps advised to avoid such errors and a reminder of the correct process (see Appendix D). An infographic was developed to summarise the metric and this was attached to the email.

The 2018 group had fewer tutors available and the intern-to-tutor ratio was much higher than in the pilot study. The ratio changed from three students per tutor in 2017 to 6-12 students per tutor for some sessions in 2018.



Figure 3.4 The phlebotomy simulation ward



Figure 3.5 Computers and label printers on the phlebotomy simulation ward



Figure 3.6 Interns training on the phlebotomy simulation ward



Figure 3.7 Model IV Arms used in the simulation ward to practice phlebotomy

Methods- accessing the data

Haematology laboratory

Cognos was used to interrogate the laboratory information system, APEX, for pre-analytical phase blood specimen errors and WBIT.(Cognos is an IBM software which provides a toolset

for reporting, analytics, score carding, and monitoring of events and metrics. It allows extraction of data in the laboratory). The analysis focused on blood tests ordered on the electronic ordering software ICM system. Using the requesters unique electronic ID, the system records the person requesting the test as well as the practitioner who prints the label placed on the bottle after taking the test. A search on the ICM system provided a list of each blood test performed in the three-month period, including the healthcare practitioner who performed the test and the patient identifier number, to link to the rejected samples in APEX. By matching the searches, this provided a list of the persons who performed the rejected samples and a list of how many blood tests were taken by the interns in the three-month period. Descriptive statistics were performed on the type and rate of errors. WBIT was the primary outcome. Secondary outcomes, expected to be much more common than WBIT, were other sampling errors. These included over- or under-filling of the bottle, clotted samples, haemolysed samples, incorrect bottle type received, no specimen received, and miscellaneous errors. Logistic regression analysis was used to compare the total number of rejects in the 2016 control group to the intervention group in 2017 and the intervention group in 2018 using Statistical Programme for Social Sciences (SPSS V26, IBM Corporation, 2016). To adjust for potential confounding, the month of the test and whether the test was taken on call or during normal working hours were included in the analysis.

Transfusion laboratory

Similar to data collection in haematology, data on blood sampling errors in the blood transfusion department were collected by generating a report from the laboratory information system using Cognos, which provided a list of all the blood samples performed and rejected in the laboratory during the months July, August, and September in the years 2016, 2017, and 2018 in CUH only. The laboratory also performed bloods for Cork University Maternity Hospital and general practitioners in the Cork and Kerry Region. However, in contrast to haematology, transfusion request forms are manual. Therefore, each of the blood forms was searched manually to determine if the blood test was performed by an intern or not. This was clear from the signature on the form, the bleep number provided, or the medical council registration number if the signature was not legible. A list of samples taken by interns was compiled in Excel and a list of rejected samples which were taken by interns was also compiled. The blood sample rejection rate by interns was compared for each of the three years. Logistic regression analysis was used to compare the total number of rejects in 2017 and 2018 compared to 2016 using Statistical Programme for Social Sciences (SPSS).

Results

Background rates of the primary outcome WBIT in the hospital before and during the study

Figure 3.8 describes the background rate of WBIT identified in the hospital's haematology department from October 2016 to December 2018. It illustrates how the rate of WBIT in the hospital overall appeared to be increasing per month as the study progressed. The majority of these WBITs occurred in blood samples taken by healthcare professionals who had not been trained.

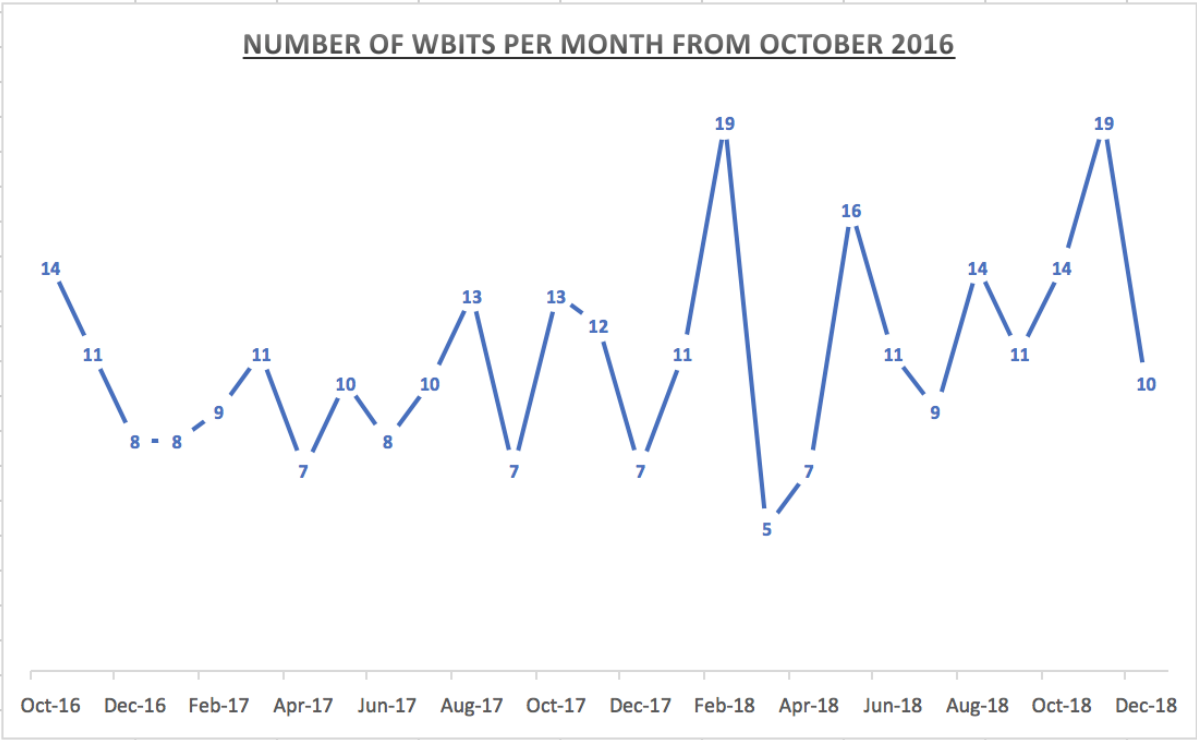


Figure 3.8 Background rate of haematology WBIT in the hospital (trained and non-trained healthcare practitioners) in the haematology laboratory from October 2016 to December 2018.

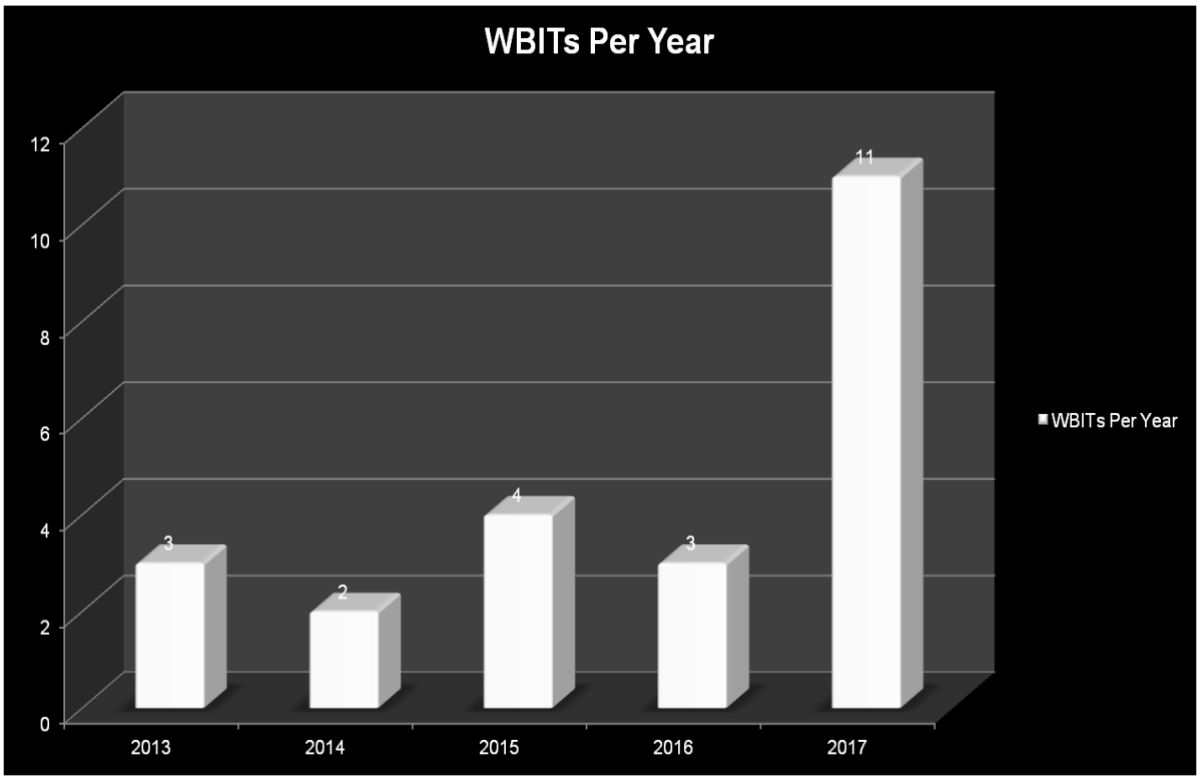


Figure 3.9 description of the background rate of WBIT in transfusion department in the hospital from 2013 to 2017.

Results: haematology department

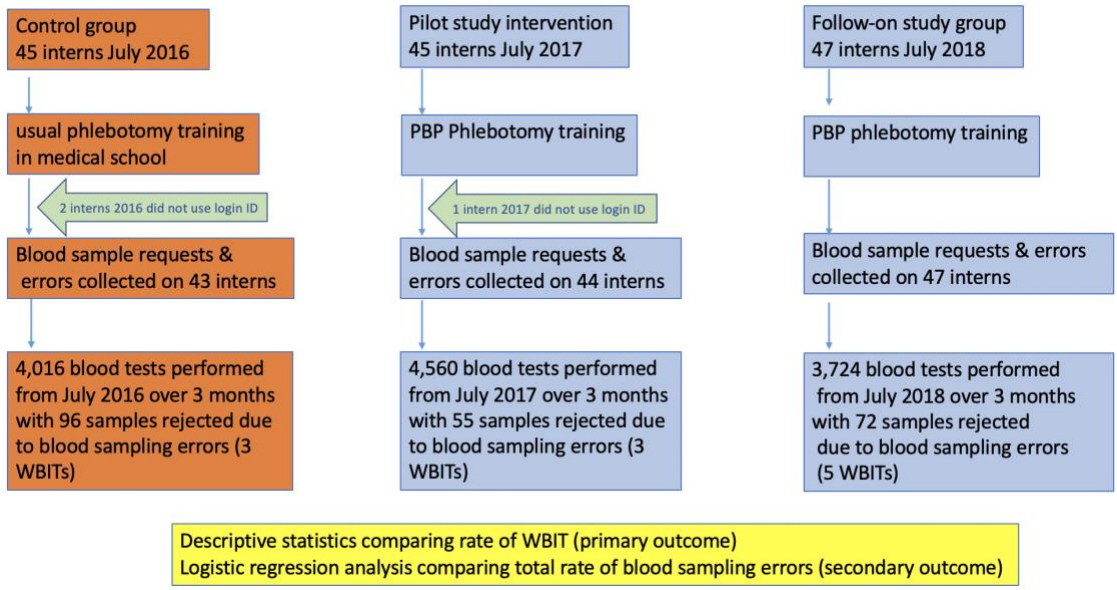


Figure 3.10 Flow diagram of interns and blood samples analysed in 2016 control group, 2017 pilot study group, and 2018 follow-on study group.

Table 3.1 Baseline characteristics 2017 pilot study and 2018 follow-on study groups.

Characteristics	2018 follow-on study group	Of 47 interns questioned answer provided by:	2017 pilot study group	Of 45 interns questioned in 2017 answers provided by:
Median age (Interquartile Range)	25 years (23,28)	39	24 (23,27)	44
Male	21 (45%)	47	18 (40%)	45
Right handed	14 (36%)	39	7 (16%)	44
Vision corrected	15 (37%)	41	16 (38%)	42
First language English	47 (100%)	47	45 (100%)	45

**Data was not collected on historical controls but 20 of the 43 who collected bloods were male.*

Table 3.2 Mean number of blood tests collected by interns

Year	Average Number of blood test collected (min-max)	Standard Deviation
2016	91 (10-228)	50
2017	101 (2-262)	52
2018	95 (26-224)	44

The baseline characteristics of the 2017 pilot study and 2018 follow-on study groups are provided in table 3.1. Descriptive statistics are not available for the 2016 control group as they were not working in the hospital at the time the study started. However, it is expected that median age, language, handedness and visual correction would not differ between the groups.

The mean number of errors performed by each intern in each year is described in Table 3.2. There appeared to be an increase in the primary outcome, WBIT, (although the number detected are very small) from 0.7 per 1,000 in 2016 (three WBITs), 0.66 per 1,000 in 2017 (three WBITs), and increased to 1.4 per 1,000 in 2018 (five WBITs). The absolute numbers make interpretation of trends difficult. Each of the WBITs was identified by the laboratory, but one of the WBITs in 2018 was identified when the doctor rang the laboratory to self-report that they had mislabelled the bottle. It is possible that this type of event would have been undetected in 2016 unless there was a discrepancy with previous results available in the laboratory.

There were 4,016 blood tests performed by interns in the control group who did not receive PBP phlebotomy training from July 11th, 2016, to September 10th, 2016, and 96 (2.4%) of the blood samples were rejected. For the same period in 2017, 4,560 tests were taken by PBP trained interns and 55 (1.2%) of the blood samples were rejected. In 2018, 3,724 tests were taken by PBP-trained interns and 72 (1.9%) were rejected. Table 3.3. describes the breakdown of errors that occurred.

Table 3.3. Errors by interns in the haematology department in a three-month period from commencement of employment

	2016 number of errors (number of errors per 1,000 samples) n=4,016	**2017 number of errors (number of errors per 1,000 samples) n=4,560**	**2018 number of errors (number of errors per 1,000 samples) n=3,724**
Clotted Samples	16 (4)	8 (1.8)	12 (3.2)
Haemolysed	6 (1.5)	6 (1.3)	12 (3.2)
Incorrect Bottle	9 (2.2)	4 (0.8)	11 (3)
No Specimen Received	4 (1)	5 (1.1)	2 (0.5)
Over-/under-fill samples	50 (12.5)	27 (5.9)	28 (7.5)
Other	8 (2)	2 (0.4)	2 (0.5)
WBIT	3 (0.7)	3 (0.7)	5 (1.3)
Total	96 (24)	55 (12.1)	72 (19.3)

Logistic regression analysis (Table 3.4) of these results showed that there was a 50% reduction in the odds of tests rejected in 2017 pilot study when interns underwent PBP phlebotomy training in comparison to the 2016 control group and this difference was statistically significant (OR=0.50, 95% CI 0.36-0.70 p-value<0.001). The results for 2018 showed that interns who received PBP training in 2018 had fewer blood samples rejected in comparison to 2016 control group, but this was not statistically significant (OR=0.89, 95% CI 0.65-1.21 p-value=0.46).

Table 3.4 Logistic regression analysis of the probability of a blood test rejection in the haematology laboratory for July 2017 and July 2018 in comparison to July 2016

	Crude		**Adjusted**	
	OR (95% CI)	**p-value**	**OR (95% CI)**	**p-value**
Month				
July			1.00	
August			0.60 (0.42-0.83)	<0.01
September			0.57 (0.41-0.81)	<0.01
October			0.49 (0.27-0.88)	0.02
On Call			1.07 (0.81-1.40)	0.64
Year				
2016 control group	1		1	
2017 pilot study	0.50 (0.36-0.70)	0.00	0.50 (0.36-0.70)	<0.01
2018 follow-on study	0.84 (0.62-1.14)	0.26	0.89 (0.65-1.21)	0.46

Results: Blood transfusion department

Primary outcome

There were no WBITs by interns in 2016 and 2018, but there was one WBIT during 2017.

2016

A total of 718 blood samples were taken by interns in 2016 in the two-month period analysed from July 11th, 2016, to September 10th, 2016, inclusive. There was a total of 69 blood samples rejected by the interns in this period, with a blood sample rejection rate of 9.61%.

2017

A total of 741 samples were taken by interns in 2017 in the two-month period analysed from the July 10th, 2017 to September 9th, 2017, inclusive. There was a total of 56 blood samples rejected by the interns in this period, with a blood sample rejection rate of 7.56%.

2018

A total of 721 samples were taken by interns in 2018 in the two-month period analysed from the July 9th, 2018 to July 8th , 2018, inclusive. There was a total of 56 blood samples rejected by the interns in this period, with a blood sample rejection rate of 7.77%

Logistic regression analysis (table 3.5) was performed to determine the association of the PBP training in phlebotomy on the rate of samples rejected from the transfusion laboratory. Dummy variables were generated to allow samples taken in 2017 and 2018 to be compared to 2016. There was a 24% reduction in the odds of the number of tests rejected in 2017 pilot study when interns underwent PBP phlebotomy training in comparison to the 2016 control group and this difference was not statistically significant (OR=0.76, 95% CI 0.53-1.21 p-value=0.14). The results for 2018 showed a 19% reduction in the odds of the number of tests rejected in the PBP-trained group in comparison to 2016 control group, but this was not statistically significant (OR=0.81, 95% CI 0.56-1.12 p-value=0.26). A breakdown of the reasons for rejection of blood samples is described in table 3.7.

Table 3.5 Logistic regression analysis of the probability of a blood test rejection in the transfusion laboratory for year July 2017 and July 2018 in comparison to 2016

	Odds Ratio	**Confidence Interval**	**p-value**
2016	1		
2017	0.76	0.53-1.1	0.14
2018	0.81	0.56-1.2	0.26

Table 3.6 Comparison of blood transfusion error rates between the three years for a two-month period from commencement of work by interns in July 2016, 2017, and 2018

Year	Rate of Error	Absolute Errors	Number of Requests	WBITs
2016	9.61%	69	718	0
2017	7.56%	56	741	1
2018	7.77%	56	721	0

Table 3.7 Reason for rejection of blood sample in the blood transfusion laboratory for a two-month period from commencement of work by interns in July 2016, 2017, 2018

Reason for Rejected sample	2016	2017	2018
Date of birth incorrect	20	20	14
Date of birth omitted	9	8	13
Incorrect or omitted name	3	4	1
Label applied for address	0	1	0
Patient ID incorrect	15	5	6
Patient ID omitted	10	8	9
Date incorrect	1	1	0
Omitted address form	1	0	0
Form not filled	0	0	1
Form/sample not signed	4	2	4
Signature mismatch	1	0	0
Haemolysed	1	0	3
Under-filled	0	0	2
Not specified	0	0	1
Sample not labelled	4	8	2
WBIT	0	1	0
Total	69	56	56

*some samples contained more than one error.

Discussion

Key findings of the study

This study demonstrated that interns receiving PBP training had significantly fewer haematology samples rejected during the three month study period in the 2017 pilot study. There was a significant reduction in errors in the haematology laboratory in 2017 (9.6 errors per 100 to 5.5 errors per 100). However, the training was demonstrably not as effective in 2018. While a reduction in errors was recorded (compared to historical control), it amounted to a 11% reduction in odds and did not reach statistical significance (9.6 errors per 100 to 7.2 errors per 100)

There was a non-statistically significant reduction in transfusion errors with the introduction PBP phlebotomy training. WBIT errors were rare but there was one transfusion WBIT in the 2017 interventional group. From a clinical viewpoint, all reductions are a welcome addition to patient safety.

A statistical analysis was not performed to investigate the different types of errors due to the small numbers of rejected samples within each category. The greatest fall in blood sample errors in the haematology department with the training was in under/over filling of the tube which reduced by almost 50%. In the transfusion laboratory the greatest improvement was observed in the number of errors related to the writing of the correct patients ID number on the form or blood tube.

There were a number of differences noted in the 2018 PBP training. In 2018, recruiting tutors was difficult. Only one member of the medical schoolteachers was available and there were no doctors in training available to provide tuition; previously, there had been at least one doctor in training present and two representatives from the medical school. Six members of the phlebotomy staff rotated during the training and we noted a lack of standardisation of the teaching on the electronic ordering system. Due to difficulty recruiting tutors, the ratio of tutors to students increased, with one tutor attempting to teach 6-12 students for some sessions. The enthusiasm around PBP training in the hospital was not as heightened in 2018. Factors affecting this may have included familiarity and the perceived lack of reduction in WBITs in the previous year when the laboratory had hoped the PBP training would eliminate WBIT. We invited medical SHOs to PBP training and to provide training for the incoming interns in 2018; however, despite multiple invitations, only half the SHOs attended the sessions. This attitude could have influenced the interns' adherence to the correct process to take bloods.

The primary outcome of the study were WBITs. We recognise that these are rare events and therefore also sought to influence less serious mis-labelling – known to be a risk factor for WBIT [65]. WBIT rates were the same in 2016 and 2017 for haematology but increased in 2018, with two extra incidents in 2018. However, one of these WBITs was self-reported, a phenomenon which was not seen in previous years. Kaufman et al identified that transfusion samples with labelling errors have a 1 in 26 rate of WBIT, a rate which is much higher than the median adjusted WBIT rate in the study of 1 in 4,236 in manually labelled samples. This confirms the policy in most transfusion services to reject even minor labelling errors as the phlebotomy process which led to the mislabelling is error-prone and a high risk for a WBIT event [65]. These human errors are clearly un- intentional and often minor slips can result in cases where the healthcare practitioner has been under increased pressure. The most prevalent root causes resulted from shortcuts which increase the risk of error such as: i) pre-printing labels, ii) labelling specimens away from the patient, or iii) inadequate positive patient identification techniques.

The occurrence of a WBIT event in 2017 in the first week after commencement of employment was disappointing. This error had occurred when the intern had taken the blood from a patient who had no patient identification wrist band. After taking the blood from the patient, the intern proceeded to label the blood tube away from the bedside using the chart of a different patient with the same name. This case exemplifies the two main causes of WBIT in a single case.
There was an increase in the overall rate of rejected samples and in WBITs from 2017 to 2018, despite the addition of individual feedback to the interns provided at the end of each month. Interns were advised on the overall error rates and given specific advice on how to avoid the errors in which they had been involved. However, this did not appear to have significant effect on reducing the error rate.

Comparison with other studies

This study contrasts to previous research indicating the benefits of PBP training [73 91 105]. It is a novel technique using technology-enhanced learning and simulation. Previous educational strategies tend to follow didactic style teaching to improve phlebotomy technique and often rely on self-reported questionnaires to determine an effect [35]. Previous studies using PBP methods focus on surgical error rates as the primary outcome. If we had chosen the error rates in phlebotomy by intern doctors as the primary outcome, it is possible that the effect of the intervention on the performance of doctors might be more easily demonstrated and the rarity of WBIT would not have affected the power of the study to show an association with improvements. However, it may not have allowed the same level of focus on the critical outcome of WBIT and may not have allowed for the same level of investigation of the effect of the PBP training programme when implemented in the real working environment of the interns.
Educational strategies have been shown to reduce but not eliminate WBIT [62 28]. Bar code systems that scan the patient wristband demonstrate a reduction in labelling errors and improve positive patient identification practices [65 127 128]. In contrast to this, an audit by the National Haemovigilance Office in 2017 did not demonstrate an improvement in WBIT events in hospitals where BloodTrack was introduced compared to hospitals which hand-labelled transfusion blood samples, highlighting the need for education and training for health professionals using the system and for robust positive identification practices [8]. In addition, many hospital organisations do not have sufficient resources to deploy these devices and the device is aimed primarily at transfusion sampling. Multiple interventions and feedback are likely to be more effective than single interventions, but the sustainability of improvements is not certain from previous research [62]. WBIT rates in mislabelled samples are estimated at 1.4% [65], which is much higher than in correct samples. This indicates that rejection of the sample due to any mislabelling event is indicative of an error-prone phlebotomy process that could have led to WBIT errors and justifies the investigation of all blood sample errors to represent instances where there was a high risk of WBIT errors [65]. This study demonstrates that, despite the introduction of comprehensive PBP training in phlebotomy, if the environment and process is error-prone, with the potential for shortcuts that can increase the risk of error, it is not possible to eliminate the risk of WBIT and other blood sampling errors, even with optimal electronic systems.

Strengths of the study

PBP training has robust evidence demonstrating a 40%-60 % improvement in procedural performance [73 90 91 105]. This study examines the effectiveness of the intervention for a three-month period over two years and gives a clear insight into the sustainability of the project. The development and design of the project was multidisciplinary and involved all stakeholders to develop a training programme that was highly relevant.
The historical data used for the control group is based on many years of data backing up the 2016 historical control year. The laboratory has been tracking and trending WBITs and sampling/labelling errors systematically since 2010. This allowed us to confirm the expected yearly rise each July when the new doctors take up their posts. While, in many cases, the use of historical data is not ideal, the thorough, systematic nature of this data allows us to be confident that the 2016 historical control group is representative.

Weaknesses of the study

The study has several limitations, outlined below.

Sample size

The study did not have a sufficient sample size to examine the effect of the intervention on rare events such as WBITs, the primary outcome of interest. Considering an incidence of WBIT of 0.7% in the haematology department, we would need to examine more than 11,000 blood tests in each group to determine if there was a statistically significant reduction in WBIT.

Inconsistent use of login details by doctors using the ICM system

One doctor in the 2017 group did not attend for the final assessment and three of the doctors in the study were discovered not to be using their own ICM login, therefore could not be followed up in the study.

Influence of untrained medical staff

Interns may have been negatively influenced by mentors who had not undergone PBP training and this could have undermined and weakened the potential impact of PBP training. There was a concern that, although the interns were trained to proficiency, they did not always follow the process when unsupervised as it took longer to perform.

Environmental factors

The qualitative element of the study identified a number of environmental factors which could potentially increase the risk of WBITs, including patients not wearing ID bands, difficulty accessing essential equipment, insufficient hardware, poorly set up ward environment, and stress. These factors were thought to be persistent in all years; however, it was not possible to measure the level over the three years.

Detection bias

Given that the project was heavily promoted in the laboratory, it is possible that there was an increased awareness of WBITs and this could have led to an increased detection rate amongst laboratory and ward staff. This detection bias has been described in previous studies involving WBITs, where errors increased despite the introduction of quality improvement initiatives [50]. There was an increase in the rate of WBIT in the hospital overall (including trained and non-trained personnel) supporting the occurrence of detection bias (figure 3.8) during the study. Similarly, in the transfusion laboratory there had been a WBIT rate of between two and four recorded in the hospital overall between 2013 and 2016; however, there were 11 WBITs recorded in 2017 in the entire hospital. There appeared to be an increase in transfusion and haematology WBITs in the hospital in 2017(figure 3.9)

Conclusion

PBP training in phlebotomy can reduce blood sampling errors, but must take place in an environment that clearly acknowledges the importance of the training. Quality of the training must be properly resourced and standardised.
This study was unable to demonstrate if PBP training in phlebotomy was associated with a reduction in the incidence of WBIT due to an inadequate sample size and possible detection bias, but it can be inferred from its beneficial effect on other sampling and labelling errors that this would be the case.

Educational interventions alone are possibly insufficient to reduce WBIT and blood sampling errors if the environment does not allow for a safe and efficient phlebotomy process, including the availability of bedside label printers.

Chapter 4: Observation of Assessment of Clinical Performance to determine factors contributing to common blood sampling errors identified during real-time mentoring phase of Proficiency-based Progression Training in Cork University Hospital – Barriers to Implementation of Evidence-based Training

Introduction

We know that 60-70% of laboratory errors occur in the pre-analytical phase of testing [13], a costly nuisance that have the potential to result in patient harm.

During the development of the metric for the PBP training programme, doctors in training attending the sessions revealed that positive patient identification often did not take place on the wards. I learned that doctors frequently received insufficient instruction from other healthcare practitioners when asked to perform bloods. For example, a list of intern jobs might include the name and bed number for the patient, but no date of birth or hospital ID number to facilitate positive patient identification. This deficiency highlighted the poor level of attention to the importance of positive patient identification in the hospital, an important risk factor in the occurrence of WBIT events. Doctors revealed that pre-printing of blood labels was common practice (See appendix E). Doctors noted it was faster to print the blood labels before attending the patient. If the doctor was unsure what blood bottles were required to perform the test, the ICM system would instruct them which were required (as the labels include the blood bottle type). If interns were called to an emergency, it was possible that they would have ICM labels on their possession for one patient while taking blood from another patient and were at high risk of a WBIT event at these times.
In 2019 there were 161 WBITs in the haematology laboratory (4,222,418 total specimens analysed), 22 in the biochemistry laboratory (894,801 total specimens analysed), 16 in the microbiology laboratory (527,767 total specimens analysed). In the blood transfusion laboratory, there were 19,607 samples taken in the CUH (including samples from Cork University Maternity Hospital) and there were a total of 8 WBITs.
Interns received training at undergraduate level on the clinical skills required for phlebotomy and attended lectures on the potential for WBIT. However, formal training on the ICM system was not provided (the systems differ in different hospitals) and the process was often learned in an apprenticeship style from their peers. Since the introduction of the ICM software system in the hospital, labelling errors and WBIT events have increased.
The IT department provided group tutorials, but these were poorly attended, likely due to inadequate time and the necessity of prioritizing clinical duties on the wards. During frequent busy times, interns were encouraged to be efficient and were at risk of error when trying to improve their productivity. Hand-labelling bottles at the bedside did not occur.
From analysing videos of novices performing bloods during metric development, it was clear that doctors pre-printed their blood bottle labels, used the labels to positively identify the patient at the bedside, and then affixed the pre-printed label to the bottle after taking the blood at the patient bedside. Alternatively, the doctors performed the blood test, then left the patient bedside to print the label for the bottle. To reach the label printer, the doctor

often returned the sharps bin to its place, washed their hands and then went to the computer at the ward desk. If computers on the ward desk were occupied by other healthcare practitioners, the doctor might have to walk to another ward to find an available printer. Labels were then printed and applied to the non-labelled blood tubes away from the patient bedside and distant in time from the phlebotomy event. Doctors would often have minimal patient identifiers in their possession at this point, e.g. patient name alone or patient name and bed number, and therefore were at high risk for a WBIT event.
While meeting with stakeholders in the process of phlebotomy, the team became aware of many obstacles to safe and efficient practice within the hospital. Doctors complained of a lack of appropriate equipment on the ward and difficulty finding equipment on different wards; the laboratory complained that doctors sometimes hand-labelled bottles when printers did not work, which led to increased workload in the laboratory; and the IT department identified a lack of adequate numbers of computers and label printers and suggested the need for bedside label printers on each ward. As the 77-step metric emerged, there was concern that to perform the process correctly, the added steps – such as hand-labelling each bottle with two patient identifiers at the bedside – would not be attractive to doctors. There was a concern that there might be some resistance to implementation of the correct process in practice due to time pressures and a lack of emphasis on the importance of avoiding pre-analytical errors, which were seen as unavoidable 'human errors' to a degree.
To investigate this theory further, during the mentorship of the interns on the wards in their usual clinical environment, I studied the performance of the interns and observed environmental factors which acted as barriers and facilitators to implementation of the training. A short discussion took place with each doctor at the end of every session to gain an insight into their views. Our goal was to identify environmental, organisational, and job factors in addition to the human and individual characteristics which influence human behaviour and could negatively contribute to blood sampling errors.

Observation for assessment of clinical performance

Observation is a quality assessment tool to enable improvements in non-medical industries such as aviation [129]. Observation has been reported as a sensitive method of error detection used to evaluate individual and group performance where clinical care is provided, such as care provided by nursing and surgical staff [130 131]. It provides useful information to identify changes required to practice. Errors often occur due to human factors, but can also be as a result of defective systems that allow errors and the causes of error to be undetected [132]. Causes for error include organisational factors, situational factors, team factors, individual factors, task factors, and patient factors [133]. A systematic review on the use of observation for the assessment of clinical performance identified several studies demonstrating the value of observations for designing and assessing the success of quality improvement interventions in improving clinician performance and can identify specific deviations that may compromise patient safety [134]. In this qualitative part of the thesis , I have applied these methods.

Conceptual framework to analyse intern verbal feedback

The theoretical domain framework was used to analyse verbal feedback which has been described as a suitable framework for semi structured interviews, for use in observational fieldwork [135] and for implementation and behaviour change research [136]. The TDF consists of an integrative framework of theories of behaviour change, developed by 18 psychological theorists,16 healthcare researchers and 30 health psychologists.[137] Behaviour change requires a comprehensive approach at multiple levels, including the patient, the healthcare practitioner and the wider healthcare environment [138]. The medical council UK has recommended the use of one or more theories when developing complex interventions. The TDF allows the use of multiple theories. It's straightforward and broad approach allows use by a wide range of disciplines who may not have training in psychology. It selects 33 theories and 138 key theoretical constructs and combines these into one framework. It originally consisted of 12 theoretical domains and typical questions for each, to use in interviews or focus groups. These provide a comprehensive theoretical assessment of an implementation problem [137]. The framework has been refined during a validation process in 2012 and now consists of 14 domains with 84 component constructs.[136] The domains of the framework are listed in the table 4.1. It considers a range factors affecting the behaviour of the healthcare practitioner such as knowledge, beliefs about capabilities but also considers social influences on behaviour and environmental context and resources to facilitate a comprehensive approach to data analysis, allowing for a comprehensive analysis of the data provided by the interns.

Table 4.1 Theoretical domain framework [136]

Domain	Constructs
Knowledge	Knowledge
	Procedural knowledge
	Knowledge of task environment
Skills	Skills
	Skills development
	Competence
	Ability
	Interpersonal skills
	Practice
	Skill assessment
Social/Professional Role and Identity	Professional identity
	Professional role
	Social identity
	Identity
	Professional boundaries
	Professional confidence
	Group identity
	Leadership

	Organisational commitment
Beliefs about capabilities	Self-confidence
	Perceived confidence
	Self-efficacy
	Perceived behavioural control
	Beliefs
	Self-esteem
	Empowerment
	Professional confidence
Optimism	Optimism
	Pessimism
	Unrealistic optimism
	Identity
	Beliefs
Beliefs about consequences	Outcome expectancies
	Characteristics of outcome expectancies
	Anticipated regret
	Consequents
	Rewards
	Incentives
Reinforcement	Punishment
	Consequents
	Reinforcement
	Contingencies
	Sanctions
Intentions	Stability of intentions
	Stages of change model
	Transtheoretical model and stages of change model
Goals	Goals
	Goal priority
	Goal target setting
	Goals (autonomous/controlled)
	Action planned
	Implementation research
Memory Attention and Decision Processes	Memory
	Attention
	Attention control
	Decision making
	Cognitive overload/ tiredness
Environmental Context and Resources	Environmental stressors

	Resources/material resources
	Organisational culture/climate
	Salient events/ critical incidents
	Person x environment interaction
	Barriers and facilitators
Social influences	Social pressure
	Social norms
	Group conformity
	Social comparisons
	Group norms
	Social support
	Power
	Intergroup conflict
	Alienation
	Group identity
	Modelling
Emotion	Fear
	Anxiety
	Affect
	Stress
	Depression
	Positive/negative affect
	Burnout
Behavioural regulation	Self-monitoring
	Breaking habit
	Action planning

Method

Setting

This study took place at Cork University Hospital a 800-bed hospital. The prospective observational study was conducted amongst intern doctors who had commenced work for the first time at CUH. The interns were undergoing PBP training in phlebotomy. They had completed an eLearning module online, PBP training on a simulated ward, and were now being observed performing phlebotomy on the wards to ensure they were reaching the proficiency benchmark when performing phlebotomy in their usual clinical environment. Interns were asked to contact the researcher (a medically qualified doctor) when they were asked to perform phlebotomy during on-call hours. The researcher was available for a three week period. After three weeks the interns who had not yet been observed were offered an appointment to meet the researcher at 7am to perform bloods on patients who had been

scheduled by their teams for phlebotomy. Phlebotomy was observed on the medical and surgical wards.

Study Sample

All forty five interns who commenced work in the hospital were invited to attend the PBP training and mentorship on the wards. Interns were contacted by phone on the nights they were on call and invited to contact the medical researcher (NOH, who would act as a mentor if there were emergency bloods to take between the times of 7pm and 11 pm on weekdays and during daytime hours on Saturday and Sunday. However, as blood taking was not frequently required during these on-call time periods and occasionally the interns were too busy to contact the researcher before performing phlebotomy, after three weeks the interns were invited to take scheduled phlebotomy bloods at pre-arranged appointment times between 7am and 9am. Forty four interns attended for observation on the wards. One intern did not attend for mentorship on the wards despite multiple invitations.

Study design

A prospective design was applied, combining structured observation of the interns performing phlebotomy during mentorship on the wards and recording of responses to two open-ended questions to provide feedback on the training and their experience of performing phlebotomy according to the metric on the wards, at the end of the observation of the phlebotomy procedure.

The medical researcher (N.O'H.), who had helped develop and deliver the PBP phlebotomy training, acted as a mentor for the interns while performing phlebotomy on the wards. The interns were advised that they would be observed performing phlebotomy on the ward following the steps of the metric previously taught. While observing the interns the researcher completed a standard form. Information came from observation and talking informally to the interns. The researcher intervened in a discreet and non-judgmental manner if the intern did not follow the steps of the metric correctly. These deviations from the metric were recorded.

When the blood sample had been taken, labelled correctly, and dispatched to the laboratory, a short semi-structured interview took place where any deviations from the metric were discussed. The researcher used a stop watch on her phone to record the time taken to perform the phlebotomy procedure from the instruction to take blood to the dispatch to the laboratory. Specific tasks within the phlebotomy procedure were also recorded including a) time to perform the phlebotomy procedure, b) time taken to locate equipment c) time taken to print labels if there was a delay locating a functioning computer to print labels.
Table 4.2 gives an outline of the standard form and the topic guide for the semi-structured interview. The standard form was developed based on the PBP training metric in phlebotomy and focused on key tasks and critical errors. In the early stage of metric development meetings had taken place with stakeholders to identify issues on the wards

which were leading to difficulty in performing phlebotomy such as lack of label printers at the bedside, difficulty locating equipment on the wards. It was decided to include these issues as part of the standard form to allow further investigation of these factors and the effect on the process of performing phlebotomy after implementation of the PBP training programme.

Each intern had given informed consent for participation in the study when they attended the PBP training programme simulation training on the phlebotomy simulated training ward.

At the end of the training session on the ward the intern was given an opportunity to ask any questions. The intern was then asked two open-ended questions (Table 4.3). Responses were recorded in a notebook carried by the researcher to each observation.

Table 4.2 Standard form completed by the medical researcher following mentorship of interns on the wards

Is the intern on call?
How many blood specimens have been taken since start of employment on July 10th?
Time taken to perform metric (from instruction to dispatch to laboratory)
Method of taking blood (butterfly needle or needle and Vacuette)
Location in hospital by ward where the blood taking was performed
Was a blood sample taken for the transfusion laboratory?
Was the equipment easily found on ward? (free text comment if no)
Was the sharps bin closed when it was found on the ward?
How much time did it take to collect the equipment required for phlebotomy?
Was the patient located easily on the ward? (comment if no)
Was the patient in their bed when the intern arrived at the bedside to take the blood sample?
Was there sufficient space at the patient bedside to perform the procedure safely?
Was there space available to place the sharps tray at arm's reach while performing phlebotomy?
Was the computer available (free) to print labels on ward when required?
If the computer was not available, record the time delay
Was the computer in working order?
Was the label printer in working order?
Were the blood sample forms/transport bags easily located?
Record the time delay if forms/bags were not available
Was the dispatch of bloods system working? (free text comment if no)
Were there interruptions while performing the procedure?
If interruptions occurred: free text comment on type and effect on procedure
Was the intern assisted while performing phlebotomy?
Which phases of the metric were the interns assisted with? (use numbers from metric)
Which steps of the metric were the interns assisted with?(use numbers from metric)
If intern deviated from the metric, did they provide a reason why?
What was the intern's overall score from metric?
What errors occurred? (step numbers per metric)

Table 4.3 Topic guide for intern interviews on the wards

Topic guide for semi-structured interview at end of mentorship on the wards
1. What has been your experience of phlebotomy in Cork University Hospital so far? 2. Can you give feedback on the training and any obstacles or challenges since commencing work?

Ethical approval

Ethical approval was obtained from the Clinical Research Ethics Committee of the Cork Teaching Hospitals.

Data collection and analysis

The standard form was completed by the medical researcher during observation of the phlebotomy procedure on the wards. A stop watch was used to record timing of the procedure. Results were later transferred from the field notes diary to an Excel sheet. Descriptive statistics were calculated using Excel.
Open-ended questions were recorded in the field notes by the researcher while the semi-structured interview took place on the wards. The notes were transcribed in the excel sheet and analysed by two reviewers using a framework analysis and the concepts of the theoretical domain framework [135].
The data was coded by the researcher who recorded the data on the wards (NOH) and a second researcher who was also a medically qualified doctor currently performing bloods in CUH (BM). Firstly, a meeting took place to discuss the methodology. Coding took place independently following the meeting. Data familiarisation was performed by re-reading each of the responses to open ended questions. Open coding was performed and emerging themes were mapped on to the domains of the TDF. If themes were relevant to more than one domain they were initially coded in both domains. Coding and mapping by the independent researchers was compared. Any minor differences that arose were discussed with the supervisor (MC) and agreement was reached.

Results

Forty five interns were invited to participate in the phlebotomy PBP training mentorship on the wards. Forty four interns attended the mentorship phase of the training and, of these, observations were documented in 40 cases. Four cases were not documented due to time pressure (there was not sufficient time to complete the standard form between sessions). The baseline characteristics of the interns who were observed in the study are described in the table 4.4 below.

Table 4.4 Baseline characteristics of 40 interns observed on the wards

Baseline Characteristic	Result
Male	20 of 40
First language English	40 of 40
Medical intern	19 of 40
Surgical intern	21 of 40

Ten (25%) of the interns were observed performing phlebotomy while they were on call while the other 30 interns were observed performing bloods on patients who had been scheduled to have bloods performed by the phlebotomist. All but one of the interns reached the proficiency benchmark on their first attempt. The interns were prompted on the steps of the phlebotomy metric by the medical researcher during mentorship and were provided with assistance as required. The number of bloods the intern had performed since commencing work on July 10th before mentorship took place is described in table 4.5. As it took almost five weeks to observe the 45 interns performing phlebotomy, 24 of the interns (60%) had performed more than 16 blood tests before being observed by the mentor.

Table 4.5. Number of bloods performed since commencement of employment up until PBP mentorship in phlebotomy

Number of bloods performed since commencement of employment up until PBP mentorship in phlebotomy	Number of interns who had performed this number of bloods
0 to 5	11
6 to 10	2
11 to 15	3
>16	24

The median time taken to perform bloods was 20 minutes (min 10, max 45 minutes). The time recorded commenced at the instruction to take blood on the ward when the researcher was present and finished on the dispatch of the sample to the laboratory. If the instruction had been provided verbally over the phone previous to the arrival of the researcher the time commenced when the intern re-read the written instruction they had recorded earlier. Only one of the interns took a blood transfusion sample and this episode took 40 minutes to perform. Three of the samples were taken using a Vacuette system and 36 of the samples were taken using a butterfly system (one case undocumented). The mean amount of time it took to find equipment was 3.5 minutes, ranging from <1 minute to 14 minutes. In the case where it took 14 minutes, the doctor had to walk to another ward to locate the essential equipment and had been asked to perform another task while there. There were difficulties finding equipment to perform phlebotomy in 17 of the cases (43%) and Table 4.6 provides further detail. However, on one occasion, the ward nurse manager, recognising that the intern was not familiar with the ward, voluntarily offered help finding the equipment on the ward. This was noted to have a positive effect on the performance of the doctor in that they were less distracted when they went to perform the procedure. In 11

(28%) cases, the sharps bin on the ward was not closed, which was a safety risk. In one case, the sharps bin was full and should have been permanently locked by the previous user.

Table 4.6. Equipment difficult to find on the ward/missing from the ward which is essential to perform phlebotomy

Equipment difficult to find/missing	Number of incidents
Blood bottles	1
Butterfly needle	3
Tourniquet	10
Sharps bin not there or full	2
Vacuettes	1

There were delays locating the patient on three occasions, once because the bed list on the ward had not been updated and was incorrect and on two other occasions the patient was not in their bed.
There was sufficient space at the bedside to perform phlebotomy and adequate space to place the equipment at arm's reach on each occasion phlebotomy was observed. The computer was not available to use on six of 38 occasions recorded (16%), resulting in time delays of <1 minute to five minutes. On one occasion, the computer was difficult to get to as the computer desk was being used for a nursing handover meeting. On four occasions, the intern had to walk to another ward to find a computer that was available. The printer did not work in six times out of 38 (16%). This became obvious when the person tried to print the label using the ICM system but, after instructing the computer to print the label, the printer did not function.
There were no issues with the dispatch of the blood samples to the laboratory. Dispatch is via the electronic chute to send the bloods to the laboratory, or by placing the bloods in the 'out tray' on the ward, which was collected by the porter every hour during normal working hours or, if during on call hours, bleeping the porter and the laboratory to inform them that the blood had been taken. Nursing staff often assisted the interns with dispatching the bloods.

Interruptions were recorded during six of 40 occasions blood taking was observed (15%) as described in Table 4.7.

Table 4.7. Interruptions noted during phlebotomy on the wards

Interruption that occurred	Number of Interruptions
Bleep sounded	4
Ward round interrupted	1
SHO admitting patient interrupted	1
Asked to write up a prescription on another ward when went to get equipment	1

Interns were assisted by the medical researcher on nine of the 40 occasions (23%) and this assistance was provided for two stages only (taking the blood and the computer). The most common deviations from the metric are outlined in Table 4.8. When taking bloods the

interns sometimes required advice on finding an appropriate vein, angle of the needle when inserting it to take bloods or prompting on performing hand hygiene. At the computer the interns sometimes required assistance with locating the patient on the system, ordering the blood test or printing the label.

Table 4.8. Most common deviations from the metric on the wards by interns

Metric steps omitted	Incidence(%)
Hand hygiene entering patient space	18
Release tourniquet to allow skin to dry after palpating and cleaning vein	47
Hand hygiene before opening equipment	44
Hand hygiene before putting on gloves	26
Connects blood tubes in correct order	18
Invert blood tube after blood taken	39
Activate safety device on removing needle	18
Confirms patient is not allergic to adhesive material	44
Hand hygiene after performing procedure	37

Data Analysis

Analysis of the answers provided by the interns to the questions outlined in the topic guide using a theoretical domain framework revealed four themes:

Environmental context and resources

Written instructions given to the interns on the ward were noted to be poor, with only one patient identifier provided. One of the interns reported an incident where he was provided with '***instructions given from ward on a sheet***' which provided the patient '***Room, name and job***'. However neither the patient's identity number nor date of birth were provided on the form (***male surgical intern)***.

Time delays were commonly caused by label printers not working (seven cases) and unavailability of computers (eight cases). Essential equipment such as Azowipes, tourniquets or blood bottles, were frequently missing (twenty one cases).

'There had been issue with the label printer not working on ward 5A the previous day, so everyone had to walk to ward 4B for their labels. I tried to turn the printer on and off but this did not work' – female surgical intern

A technical error was noted with the label printer by one intern. He described how blood labels belonging to another patient had printed with his labels. If he had not been carefully checking the labels were correct when affixing them to the tube, a WBIT event could have easily occurred**.**

Interns reported occasional instances of phlebotomy in patients who were not wearing ID wristbands; this issue was encountered on one occasion during the training, but the patient knew his ID number from memory.

Emotion

Nursing staff support on the wards contributed to calm and safe phlebotomy performance, while frequent interruptions by bleeps and time constraints contributed to stress and multiple technical errors. Several doctors expressed nervousness while somebody was watching them perform phlebotomy.

'***I have put in five IV cannulas today but feel nervous with someone looking over my shoulder' – male surgical intern***

Knowledge

Interns had an average of 5.8 errors. They required prompting to ensure the steps of the metric were followed correctly. Interns valued the training but indicated that it would have been useful to provide the training at undergraduate level.
'Training should be provided in college to allow more time to learn' – male medical intern

Social influences

The interns appeared to be influenced by their senior colleagues, some of whom felt that labelling at the bedside and printing labels after taking bloods was time consuming.
One of the interns required prompting to hand-label the bottles before leaving the patient bedside. ***'It's ok not to label the bottle with the patient if you are only performing bloods on one patient' – male surgical intern.*** He also considered the practice of pre-printing labels and then affixing the labels to the patient's blood bottle at the bedside to be safe despite the fact the PBP training programme had made it clear that this was not a safe way to perform phlebotomy if the critical event of a WBIT was to be avoided. He reported that he had seen many of his senior colleagues perform the procedure in this order.

Discussion

Key findings of the study

Variable time taken

The median time taken to perform phlebotomy at CUH from the instruction to take blood to the dispatch of the sample to the laboratory is 20 minutes (minimum 10 minutes, maximum 45 minutes). The time taken to perform phlebotomy commenced from when the observer on the wards instructed the doctor to take the bloods or the doctor reviewed a note where they had previously written the instruction to take the bloods if the bloods had been ordered verbally from another healthcare practitioner e.g. nurse or senior doctor.

Equipment not curated/available

Delays were common; for example, in 17 cases (43%), there was difficulty finding equipment.

Butterfly vs Vacuette System

The majority of interns utilise the butterfly system when performing bloods as it is easier to judge when the vein is entered due to a flashback.

Patient not available

Delays also resulted when there was difficulty locating the patient (three cases),

Computers and printers in short supply/not working

Computers were unavailable, or printers were not functioning correctly frequently. Technical glitches in the ICM system were occurring so that incorrect labels were printing, not due to any fault on the part of the user of the system.

Task disturbance

Interruptions occurred in six cases (15%), such as bleeps, other doctors, or being asked to complete other tasks while locating equipment. These environmental factors all increased the complexity of the simple task. Healthcare staff are required to adapt and respond to the changing circumstances they are faced with, which may be more challenging for doctors commencing employment.

Poor requesting practice

The study uncovered barriers to positively identifying the patient, such as interns not being given at least two patient identifiers by the person requesting they take the bloods.

Patients lacking wristbands

Patients did not always have a wrist band, which is critical to avoiding labelling errors.

Environmental/social factors

Interns admitted nervousness while being observed and the medical researcher noted that doctors were calm and less prone to error when they were supported by their peers in simple ways, such as providing assistance locating equipment on unfamiliar wards. After working on the wards, interns had learned that hand-labelling at the bedside added time to the process of taking blood and one intern admitted that he did not see a need to hand-label the bottle at the bedside when performing bloods on just one patient. This highlighted that safety and avoiding labelling errors on blood tubes was not a priority within the hospital culture, often due to time pressures and a need for high productivity. This was occurring despite the fact it had been clearly outlined to the interns at the educational session that labelling blood tubes at the bedside was time consuming but a necessary step that must be performed if blood sample mislabelling was to be avoided.

Economic Considerations to address the documented barriers to performing phlebotomy according to the metric

An audit performed by Haematology Medical Scientist, Padraig O' Sullivan highlighted the cost of rejection of blood samples due to mislabelling errors. In 2010 there were 14,480 bloods samples received from CUH and Cork University Maternity Hospital with 6.8% incorrectly labelled and 13,375 received from General Practitioners with 1.9% incorrectly

labelled. A conservative estimate was made of the cost of repeating blood samples if the sample was not taken correctly on the first occasion. In 2010, 304 days of work were wasted due to this error, leading to a cost of €147,880 in wages and €5,984 for additional materials required to collect and test the bloods. The cost of repeating samples in 2010 compared to 2021 would likely be approximately 9.9% higher due to inflation (calculated here). Healthcare organisations must also consider the potential cost of litigation if a serious error occurs. For example in 2020 9.4 million euro was paid to one individual who had suffered a catastrophic non brain injury while in hospital. It is estimated that providing a trolley for interns on a ward would cost €1500. This trolley would be correctly stocked and would have a dedicated label printer that could be taken with the trolley to the bedside and reduce the complexity of the procedure currently for interns.

Comparison with other research

Guidelines exist on the correct procedure when performing phlebotomy, including the Clinical Laboratories Standards Institute GP41 guideline [37] and the World Health Organisation guideline on drawing blood [38]. However, hospital staff often do not adhere to best practice, as illustrated in an observational study in 12 European countries, where inadequate patient identification in the pre-analytical phase was identified in 16% of venous blood collections [16]. Patient identification and tube labelling were identified as the steps in phlebotomy with the highest risk of error. The study showed that labelling did not take place in the presence of the patient in one in three episodes of phlebotomy. Poor practices are often not related to a lack of knowledge. In Sweden, nursing staff admit to non-adherence with best practice while performing phlebotomy despite nursing education facilities following the guidelines when teaching phlebotomy practices. Despite previous efforts to train the nursing staff at undergraduate level, nursing students and newly qualified graduates deviate from guideline practices over time [139]. In fact, a positive association between guideline adherence and students in earlier semesters has been found [140]. Our study again highlights non-adherence to best practice guidelines as doctors commence clinical duties in the hospital, despite an intensive educational intervention delivered in a comprehensive manner.

Research on the preparedness of doctors to commence clinical duties following graduation from university demonstrates that doctors feel under-prepared for the administrative components of their role, including time management and prioritisation of tasks [141]. In this study, doctors complained the education provided should have been delivered at undergraduate level. Interns also displayed evidence of stress when under time pressure, especially during their early experience of on-call.

Doctors required prompting to ensure they complied with the correct process as outlined by the metric and some doctors admitted that they did not see the requirement to hand-label at the bedside if only performing bloods on one patient. This represents an important procedural violation, likely to be taken by the doctors to prioritise their time. Procedural violations have been examined in other areas of healthcare. Models proposed to better understand procedural violations depict violations as being, to a greater or lesser extent, intentional. Behaviour in relation to rules tends to be consistent with other principles that

guide decision-making. In an observational and interview study with 23 consultant anaesthetists, the presence of three such principles were outlined: 'doing the right thing'; 'doing what works in the circumstances'; and 'using one's skills and expertise'. Rule-related behaviour in this setting is understood as a form of situational action, rather than as the following or breaking of rules [142]. It is likely that when doctors are faced with time pressure, they are likely to skip critical steps in the metric, such as bedside labelling, and consider this as 'doing what works in the circumstances'. However, such practices are shown to increase the risk of WBIT. Therefore, the hospital working environment must be designed in such a way that avoids error, must facilitate the doctor in doing the right thing, and health organisations must be clear in communicating the correct way to perform a process to healthcare practitioners.

Behaviour by interns was influenced by their peers, therefore highlighting the need for a strong culture of safety within any healthcare system to allow for implementation of standard operating procedures. Safety culture is defined as the shared commitment to patient safety by all members of an organisation, through common values, attitudes, competencies, and patterns of behaviour [143]. To develop a positive safety culture, healthcare organisations require comprehensive patient safety training, performance evaluation of leadership on patient safety, management of workload and fatigue, attention to resource management, effective organisational learning, positive incident reporting norms, disclosure, and a proactive safety analysis system [144]. Poor practice environment characteristics, such as perceptions of workload, fatigue, time to complete tasks safely, resources, and unreported errors can act as a barrier to implementation of guidelines [144]. Facilitators to the introduction of a falls management programme in Canada included good teamwork, well-educated staff, safety perceived as a priority, openness for change, a non-punitive environment, adverse event reporting systems, existence of safety committees, and a designated manager/director of patient safety, quality and risk management. This study investigated the barriers and facilitators to implementation of an educational programme in phlebotomy and found similar results.
Distractions during the phlebotomy procedure lead to a perceived level of increased stress when the interns were performing phlebotomy. Distractions are troublesome as they lead to a shift in the individual's attention from the primary task and the likelihood of an error occurring upon return to the primary task is increased Previous research has examined the effect of distractions and the need to multitask on errors in doctors. For example, emergency physicians have describe an increased level of prescribing errors when they are exposed to distractions and although multi-tasking is thought to be an efficient way of coping multitasking may also have negative implications for the safe completion of tasks [145]. Healthcare organisations need to provide a supportive environment for healthcare practitioners to increase their self-awareness and become resilient to the effect of distractions which are often unavoidable but also create a culture where distractions are minimised during procedures to promote patient safety.

Limitations

The standard form was completed by the researcher after completing PBP training mentorship on the wards with the interns. The researcher aimed to complete the form immediately after the interview but, occasionally short notes were taken and the form was

completed at the end of the session (within 1 hour of after the training took place). Data collection would have been improved if audio recorded and transcribed at later point. Questions answered were based on memory rather than video recordings, which would have been more accurate. Responses to open-ended questions were recorded by taking notes during the interview. Responses were not audio-recorded, which was less intimidating for the interns but may have led to inaccuracies in recording compared to audio recordings. Although a non-judgmental approach was taken during interviews with the interns, the doctors may have been slow to provide honest feedback to the medical researcher, who they may viewed as assessing their proficiency. It is possible the medical researcher could have displayed bias in the recording of answers.

What improvements are required in CUH to address the findings in this study

The observation of interns performing phlebotomy according to the metric on the wards identified substantial environmental factors adding complexity to the process of performing phlebotomy. Phlebotomists in the hospital are provided with a phlebotomy trolley that is well stocked with each of the materials required to perform phlebotomy and has a computer and label printer which is designated only for printing of labels for blood samples (1500 euro each). Ideally doctors in the hospital should be provided with similar trolleys, accessible on each of the wards in the hospital which would improve the efficiency of the process and streamline the process to avoid errors. Sometimes, the wards are too small to allow the trolley to access the ward so it would be important to ensure that the label printers can reach the bedside. A designated champion on each ward should take responsibility for ensuring the phlebotomy trolley is checked on a daily basis to ensure it is stocked appropriately and that label printers are functioning.

Conclusion

This study describes the performance of interns performing phlebotomy while undergoing PBP training. Although a simple procedure, it is a time-consuming task which can be exacerbated by challenges such as poor or missing equipment, difficulty locating patients, and interruptions. Interns required a median of 20 minutes (minimum 10, maximum 45 minutes) to perform phlebotomy, adding significant workload and time pressure, especially during on-call working hours when interns have multiple other tasks to complete and often need to prioritise their work. In contrast a phlebotomist can complete a venepuncture in 5-10 minutes as all equipment is available on a trolley at the bedside. Although the key learning point of the educational intervention was the importance of labelling blood specimens in the presence of the patient, some interns appeared to be influenced by their senior peers and did not adhere to this process. A strong culture of safety is required within healthcare organisations to facilitate the implementation of any guidance and hospitals need to make it efficient and easy to perform procedures correctly, even if the process is adapted due to time pressures. To avoid labelling errors during phlebotomy, healthcare institutions need to consider bedside label printers to ensure performing the procedure safely or even return to hand written labels. This would cause major delays in the laboratory however where the bar coded sample speeds demographic entry. Hospital need to review procedures to ensure that the common process of phlebotomy, is performed with care and attention even under time pressure.

Chapter 5: OVERALL DISCUSSION

Introduction

This thesis has studied the design, implementation, and evaluation of a PBP training programme in phlebotomy to reduce blood sampling errors, with a particular focus on mislabelling errors and WBIT. This chapter summarises the main findings of each of the papers included in the thesis. The main strengths and limitations are discussed. Key health services research and policy implications are outlined and areas which require further research are proposed. Finally, a brief conclusion to the overall thesis is given.

Summary of main findings

The problem of pre-analytical errors and WBIT

Venous blood sampling is one of the most common procedures performed in healthcare. The pre-analytical phase of blood testing is the first phase in the total testing process of blood samples and comprises the process from deciding to perform the blood test to the arrival of the blood sample in the laboratory for analysis. Between 60% and 70% of laboratory errors occur in the pre-analytical phase of testing [13] and include under-filling or over-filling of the blood bottles, clotted samples, haemolysed samples, and labelling errors [146]. Patient identification and tube labelling have been identified as high-risk phases and are inadequate in 30% of cases of blood collections [16]. Phlebotomists are also more efficient than medical staff. Samples collected by trained phlebotomists show lower rejection rates in the laboratory [23 24] and post-verification error rates are lower at laboratories that monitor identification errors highlighting the benefits of monitoring and feedback. WBIT errors occur when the blood in the tube in not that of the person identified on the label [40]. WBITs have been estimated to occur at a rate of between one in 1,303 to one in 2,717. WBITs are detected in blood transfusion when the patient has a historical blood group performed by the laboratory that is different from the result from the new sample and, in the haematology and other laboratories, when the bloods are markedly different from previous results documented in the laboratory. Contributory factors to WBIT are often due to human errors. These are slips and lapses, taking short cuts, distractions, and omission of essential steps [52]. Labelling the sample away from the patient is responsible for up to 44 % of WBIT events [40]. Failure to positively identify the patient is a key factor in WBIT events. WBIT events are an important patient safety issue as errors can lead to ABO-incompatible blood transfusions, inappropriate treatment and investigations, and misdiagnosis leading to significant anxiety.

To reduce the incidence of WBIT, a zero-tolerance approach is recommended, most especially in blood transfusion laboratories. Various interventions have been demonstrated to lead to improvements in WBIT events, but have not eradicated its occurrence, including: education and training [62 40 61], audit and feedback [61], electronic barcode scanning [64], [65] and a group check sample policy for blood transfusion samples [66] . However, a systematic review found that data collection has been insufficient to demonstrate sustainability of any

improvement. Multiple interventions and feedback is likely the most effective approach to reduce mislabelling and other blood sampling errors [62].

Pre-analytical errors and WBIT at Cork University Hospital

Cork University Hospital has been tracking and trending the incidence of WBIT in the transfusion and haematology laboratories for over ten years. This tracking and trending forms part of the laboratory quality management system. Multiple interventions have been introduced including a zero tolerance to mislabelling errors in the transfusion laboratory, educational workshops with the haemovigilance officers, and follow-up of each WBIT event in the hospital with letters to the consultants of the patients involved. Despite these efforts, the number of WBIT events were steady. Serial data from 2010 to 2016 confirmed the sharp rise in error rates when new doctors in training commenced work in the hospital in July and, to a lesser extent, demonstrated a January peak at doctor changeover. Given the significant patient risk of any WBIT event, the need for a solution to this problem was clear. The effectiveness of PBP training in phlebotomy to reduce mislabelling errors and WBIT has been determined in this study.

Evidence for PBP training for transfer of knowledge in procedural skills

There is robust evidence for the effectiveness of PBP training in the transfer of technical procedural skills including labour epidural catheter placement [90], arthroscopic knot tying [92], laparoscopic skills [94] including for cholecystectomies [93] and superficial femoral artery (SFA) angioplasty in a simulated environment. This is resulting in a shift from the apprenticeship style learning of procedural skills by doctors in training to training in a simulated environment. PBP training allows for objective assessment of performance using a metric consisting of operational definitions of the procedure. Proximate feedback is provided to the trainee while performing the procedure to enable learning due to deliberate practice. A proficiency benchmark ensures that the trainee can perform the procedure to at least the average standard of experts in the field, before graduating from the training.

Development of the PBP training programme in phlebotomy for CUH

The PBP training programme in phlebotomy was designed according to the methodology of Gallagher et al [63]. In developing the intervention to manage WBIT and sample mislabelling, Proficiency-based progression training is attractive as a systematic, quantitative, practical method of teaching that is supported by robust evidence. It avoids apprenticeship style training in a random unsupported manner and the concept of practicing on patients. This thesis describes the development and validation of a PBP training programme for doctors in training at CUH. We have produced a clearly defined, validated metric which allows for reliable scoring of intern performance and facilitates the provision of proximate feedback to the interns during training sessions to promote appropriate, deliberate practice. The process began with procedure characterisation. Five meetings with key stakeholders in the process of phlebotomy at CUH, took place to develop the phlebotomy metric. At the initial meeting a plan describing the study process and appropriate timelines was decided. Following this, multi-disciplinary meetings took place with different stakeholders in the process of phlebotomy at CUH attending each meeting to get a varied view on how best the

process should occur. A behavioural scientist with expert knowledge on how to develop a metric for the purpose of a PBP training programme attended each of the meetings. The procedure was comprehensively characterised. Metric stress-testing and definition verification coupled with reliability took place with four of the main investigation team. This involved watching a video of one of the doctors in the hospital performing phlebotomy in real time. The metrics that had been produced in previous meetings were stress-tested and discussed among the group to decide on the correct order, the clearest wording to avoid ambiguity, and to ensure critical errors were identified.
Following this, a modified Delphi meeting was held to assess the face and content validity of the metric. Each step of the metric was voted on to ensure that each member of the Delphi agreed that the step was correct and clear in its wording. Modifications to the metric which occurred at the Delphi meeting included three steps deleted, 13 steps added, 38 changes in the wording of existing metrics, and six modifications in the order of the metric. The final metric instrument consisted of 11 procedure phases and 77 procedure steps, which start from the instruction to take bloods and are completed with the dispatch of the sample(s) to the laboratory.
To establish construct validity, a group of six experts (healthcare practitioners from phlebotomy, nursing, and medical specialities) were compared in their performance of phlebotomy to a group of five novices (intern doctors in the hospital who had commenced work within the past year). The participants were asked to perform phlebotomy wearing a GoPro camera to observe the process from the instruction to take blood to the dispatch of bloods to the laboratory. The videos were reviewed using the phlebotomy metric and scored independently by two reviewers. The mean interrater reliability was 0.91 (min 0.83, max 0.95). The expert group completed more steps of the procedure (72 vs 69), made 46% fewer errors (19 vs 13, $p = 0.014$), and had 300% fewer critical errors (1 vs 4, $p = 0.002$) than the novice group.
A proficiency benchmark was decided at a meeting between the experts. The experts had a mean of 13 errors during video recording and had completed at least 69 steps. It was decided that to reach proficiency, the training programme would require the interns to perform phlebotomy according to the metric, with at least 69 steps completed and no more than 13 errors. Given the importance of avoiding any critical errors, it was decided that none should be allowed for the interns to reach proficiency. A reliable and validated metric scoring system has been developed to train healthcare practitioners to perform phlebotomy to a proficient standard. The created metric which has been internally validated for phlebotomy, could serve (with modifications as necessary) as the basis for further external validation at other sites/practices.

Controlled trial to determine the effect of PBP training in phlebotomy on the rate of blood sampling and labelling errors (including WBIT) at CUH

To determine the effect of PBP training in phlebotomy on the rate of blood sampling and labelling errors, including WBIT, at CUH, a non-randomised controlled trial was undertaken. Blood sampling errors of intern doctors who commenced work at CUH in July 2016 (before the study began) and were not provided with PBP training in phlebotomy were compared to prospective evaluation of blood sampling errors among interns in a PBP-trained interventional group in 2017 (pilot study) and 2018 (follow-on study). The intervention

consisted of a PBP training programme in phlebotomy based on the metric which had been developed and validated. There were three stages to the training, commencing with an eLearning module completed at home, followed by supervised training in a simulated environment, and finishing with mentorship while performing phlebotomy in the normal clinical environment. The intern had to reach the proficiency standard before graduating from the training. In the blood haematology laboratory , WBITs were a rare event, with three in 2016, three in 2017, and five in 2018. There appeared to be an increase. There was an encouraging decrease in the blood sample error rate in 2017 and 2018 when compared to the historical controls, but the improvement in errors was only statistically significant when comparing 2016 and 2017 groups. In the transfusion laboratory, there was one WBIT in the 2017 group but no WBITS in 2016 or 2018. There was a decrease in the blood sample error rate in 2017 and 2018 compared with 2016 historical controls, but, again, the difference was not statistically significant. The intervention in 2018 did not appear to be as effective as in 2017. In the follow-on study, some of the training was compromised due to lack of resources, such as time and tutors This was thought to be due to an effort to deliver the training to too large a group within a short period and with limited resources available. The study demonstrates that PBP training in phlebotomy can help reduce blood sampling errors, but the PBP training must be delivered to a high standard. This educational intervention can be adapted to be delivered in all hospitals in Ireland and internationally. This will enable training for doctors commencing work to move away from apprenticeship-style learning and ensure doctors in training are proficient before performing phlebotomy on patients.

Observation of assessment of clinical performance to determine factors contributing to common blood sampling errors identified during real time mentoring phase of PBP training in CUH – barriers to implementation of evidence-based training

To investigate the barriers and facilitators to implementation of the PBP training programme in phlebotomy, observations took place during the mentorship of the interns on the wards in their usual clinical environment. These took place to document the performance of the interns and gain an insight into environmental factors affecting implementation of the training.

The researcher documented the steps completed and omitted by the intern during mentorship on the wards and included situational factors which affected performance. A short discussion took place with the doctors at the end of each session to gain a perspective of their views. Our goal was to identify environmental, organisational, and job factors in addition to the human and individual characteristics that influence human behaviour and could negatively contribute to blood sampling errors. A theoretical domain framework (TDF) was chosen to analyse the discussion with the intern doctors [136].

The median time taken to perform phlebotomy at CUH from the instruction to take blood to the dispatch of the sample to the laboratory is 20 minutes (minimum 10 minutes, maximum 45 minutes). Given phlebotomy is one of multiple tasks the intern performs it requires a significant amount of time to perform. The majority of interns utilize the butterfly system when performing bloods. A variety of delays were common; for example, in 17 cases (43%) there was difficulty finding equipment. Delays also resulted when there was difficulty

locating the patient (three cases), computers were unavailable (six cases), or printers were not functioning correctly (six cases). Delays added to the stress associated with the performance. Interruptions occurred in six cases (15%), such as their bleep sounding, other doctors interrupting, and being asked to complete other tasks while locating equipment. Interns are expected to multitask and prioritise their work in a way that does not affect the quality of safety of their performance. Technical glitches in the ICM system were occurring, so that incorrect labels were printing at no fault to the user of the system. These environmental factors all increased the complexity of the simple task. The study uncovered barriers to positively identifying the patient, such as interns being requested to perform bloods on patients without being provided with least two patient identifiers required to positively identify the patient. Patients did not always have a wristband, which is critical to avoiding labelling errors. Interns were unsure what to do if the patient did not have a wristband but continued to perform phlebotomy. Interns admitted nervousness while being observed and the medical researcher noted that doctors were calm and less prone to error when they were supported by their peers in simple ways, such as providing assistance in locating equipment on unfamiliar wards. After working on the wards, interns had learned that hand-labelling at the bedside added time to the process of taking blood and one intern admitted that he did not see a need to hand-label the bottle at the bedside when performing bloods on just one patient. This highlighted that safety and avoiding labelling errors on blood tubes was not a priority within the culture of the hospital, often due to time pressures, a need for high productivity, and peer influences.
In conclusion, a strong culture of safety is required within healthcare organisations to facilitate the implementation of any guidance. The importance of positive patient identification must be instilled in all healthcare practitioners at an undergraduate and postgraduate level so positive patient identification with two patient identifiers becomes common practice. Hospitals should introduce carefully designed standard operating procedures that remain safe even when adapted by a healthcare practitioner under time pressure. The hospital working environment must be suitable and provide adequate and functional tools such as computers and bedside label printers to improve the efficiency. Wards must be well stocked, even during on call to improve efficiency, remove distractions and avoid labelling errors during phlebotomy. Bedside label printers are a possible solution to ensure performing the procedure safely is consistent and widespread. An economic analysis performed in 2010 highlighted the large cost to the hospital (approximately 153,864 euro) due to samples not taken correctly in one year alone. A trolley with a label printer would cost only 1500 euro per ward and would possibly reduce the potential for WBIT in the hospital, a critical error for patient safety.

Strengths and limitations of thesis

Proficiency-based progression training is an evidence-based methodology and has been shown to be effective in improving healthcare practitioner skills during procedural training with a 40%-60% improvement in procedural performance demonstrated in previous studies. An expert in PBP training (A.G.G.) designed the study with N.O'H. and supervised its execution closely. The development and design of the project was multidisciplinary and involved all stakeholders to develop a training programme that was highly relevant to CUH. This study examines the effectiveness of the intervention for a three-month period over two years and gives a clear insight into the sustainability of the project.

The findings of the study are prone to confounding. Although the rate of blood sampling error and WBITs in the hospital had been shown to be stable for the ten years previous to the project, it is possible that there was a difference in the skill levels of the doctors in the three groups, who were not randomised. The qualitative element of the study identified multiple environmental factors which could have influenced the ability to perform phlebotomy correctly, including the availability of appropriate equipment, time pressures, and support from other staff. The hospital has been under increasing pressure with recruitment issues and a growing number of hospital admissions, which could have had an effect on the ability to perform the process correctly. This could have weakened the effect of the training between the years.

Other issues which could have weakened the training include peer pressure, given that senior doctors in training were not trained on how to perform phlebotomy according to the metric.

However, detection of blood sampling errors may have increased as the awareness of staff in the laboratory and on the wards improved due to promotion of the project within the haematology department. The intervention changed between 2017 and 2018. An effort was made to improve the delivery of the project by updating the eLearning module and adding audit and feedback.

An ambitious decision was made to teach all 124 doctors due to work in the hospital in the 2018-2019 rotation, but, given the short time-frame available to train the doctors and a lack of tutors for some of the sessions, the training was not delivered according to the PBP standard for some of the sessions. This highlights the fact that the metric itself is an excellent educational tool to clearly teach a procedural process. The practical element of the student learning the task in a simulated environment by completing the specific procedure to the proficient standard consecutively, is key to the effectiveness of the intervention.

Health services research and policy implications

Proficiency-based progression training is an effective technique for training novices on how to perform tasks requiring procedural skills. This study has applied the technique to a relatively simple task that has become complex because it is occurring in an error-prone environment. PBT cannot address the environmental issues clearly. Ideally, phlebotomy should be performed in a quiet environment without interruptions. The healthcare practitioner should be provided with clear instructions to take the blood, with at least two patient identifiers provided. The patient should be able to provide their identity details clearly and must be wearing a patient identification wristband. Once the bloods are taken without any difficulty, there should be a label printer available at the bedside so the healthcare practitioner can affix the label to the blood bottle and confirm the identity details are correct in an efficient manner in the patient's presence. However, at CUH, when interns commence work, they often have several other urgent tasks to perform and may be interrupted by their bleep during the process. They are often taking bloods on patients who have been in hospital for long stays, with very poor venous access available. Equipment may be missing, (examples-such as blood tubes at the weekends). The patient's identity wristbands sometimes fall off or have not been put on if the patients have been just admitted. Label printers are not available at the bedside and each bottle should be hand-labelled to avoid labelling errors, but this takes time and doctors often rush off without

confirming the patient's identity or labelling any bottle. If they are called to another patient urgently, there is a high risk of a labelling error or a WBIT event. PBP training aims to provide the awareness and knowledge of how best to perform the procedure in a safe manner, with multiple steps included to safety net the patient and practitioner from error. Healthcare practitioners will be prone to human error due to factors such as stress, distraction and fatigue. It is important that healthcare practitioners are not judged for such events. However, if these errors are increasing then we must examine our health system and act. This study illustrates the value of education and training in reducing human error, but also highlights that we must improve the environment to achieve better outcomes. This training tool can be easily modified to adapt its use to the performance of phlebotomy in other hospitals, and the process should continue to be multidisciplinary with a number of stakeholders, including procedural experts and laboratory and IT managers included in this process. This thesis highlights the importance of a qualitative component to elucidate institution specific environmental factors which may modulate the effectiveness of the training.

Future research recommendations

The effectiveness of the PBP training in phlebotomy could be better examined using a randomised controlled clinical trial at multiple centres.
This study has highlighted the importance of the environment the practitioner is working within. Further studies should examine whether providing an adequate numbers of reliable bedside label printers would reduce the number of blood sampling errors, including mislabelling errors.
The importance of blood sampling errors begs the question; should doctors in training be taking bloods, or would it be safer for patients if this procedure was only performed by experts such as phlebotomists or nursing staff full time.
Mislabelling errors commonly occur due to time pressures. Human error increases when the healthcare practitioner is under increased strain. Future research should examine the adverse effects of requesting increased productivity from healthcare practitioners due to staff shortages within the healthcare system and how this affects patient safety in diverse ways. Research must aim to identify mechanisms to prevent mistakes by recognising where systems errors occur, preventing these errors by providing the required equipment, and providing effective training in an attempt to minimize errors and improve patient safety.

Conclusion

The health service in hospitals worldwide face the issue of Wrong blood in tube. My work has focused on seeking a generalisable solution, using quantitative and qualitative methods to address the problem.
I have designed a bespoke PBP education package with online, face-to-face and mentorship components and made this available to the HSE, implementing it in a multidisciplinary fashion.

The implementation, in the form of two clinical trials with a historical control group showed that sample mis-labelling can be addressed using this method but WBIT reduction is harder to generate as these are rarer events. Blood samples rejected due to mislabelling errors have been identified as having a higher incidence of WBIT than samples that are not

rejected, as this event likely indicates that the sample was taken using a poor process. It is therefore reasonable to conclude that reduction in mislabelling is also likely associated with downward pressure on WBITs.

An essential qualitative study complimented the quantitative study and shed valuable insight on barrier to implementation and retention of training. Significant environmental distractors have been documented, in contrast to the controlled environments of previous published work [76] .

My work shows that the PBP training needs to be delivered to a consistent standard and that it is not sufficient to impart the knowledge delivered during the programme. The practical steps of the PBP are of paramount importance and are required to ensure the effectiveness of the educational intervention. To achieve the best reduction in errors, the environment the healthcare practitioner is working within must be optimised to ensure availability of requisite equipment, including bedside printers, and support from peers to promote the awareness of positive patient identification techniques.

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Appendix

Appendix A. Ethical Consent

UCC

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Coláiste na hOllscoile Corcaigh, Éire
University College Cork, Ireland

COISTE EITICE UM THAIGHDE CLINICIÚIL
Clinical Research Ethics Committee

Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

ECM 4 (cc) 07/03/18

28th February 2018

NB - plea Scan + Email to Noirin O'Herlihy Th

Professor Mary Cahill
Consultant Haematologist
Cork University Hospital
Wilton
Cork

Re: Technology enhanced learning and proficiency-based progression to investigate and mitigate blood-sampling errors including "wrong blood in tube" in our hospitals; can we improve patient safety and reduce resource wastage?

Dear Professor Cahill

Approval is granted to carry out the above study at:

- Cork University Hospital and Kerry General Hospital.

The following documents have been approved:

- Application form signed 5 February 2018
- Information leaflet and consent form version 16 January 2018
- Evidence of insurance
- Study protocol.

We note that the co-investigators involved in this project will be:

- Professor Anthony Gallagher, ASSERT Centre, Dr Noirin O'Herlihy, General Practitioner, Dr Pat Henn, Lecturer, Dr Robert Gaffney, Medical School, UCC and Dr Sarah Griffin, Senior Specialist Registrar.

The date of this letter is the date of authorization of the study.

Please keep a copy of this signed approval letter in your study master file for audit purposes.

You should note that ethical approval will lapse if you do not adhere to the following conditions:

1. Submission of an Annual Progress Report/Annual Renewal Survey (due annually from the date of this approval letter)
2. Report unexpected adverse events, serious adverse events or any event that may affect ethical acceptability of the study
3. Submit any change to study documentation (minor or major) to CREC for review and approval. Amendments must be submitted on an amendment application form and revised study documents must clearly highlight the changes and contain a new version number and date. Amendments cannot be implemented without written approval from CREC.
4. Notify CREC of discontinuation of the study
5. Submit an End of Trial Declaration Form and Final Study Report/Study Synopsis when the study has been completed.

UCC

Tel: + 353-21-490 1901
Fax: + 353-21-490 1919

Coláiste na hOllscoile Corcaigh, Éire
University College Cork, Ireland

COISTE EITICE UM THAIGHDE CLINICIÚIL
Clinical Research Ethics Committee

Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

Yours sincerely

Professor Michael G Molloy
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised by the Department of Health and Children to carry out the ethical review of clinical trials of investigational medicinal products. The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice.

UCC

Tel: + 353-21-490 1901
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Clinical Research Ethics Committee

Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

Our ref: ECM 4 (r) 04/04/17

13th March 2017

Professor Mary Cahill
Consultant Haematologist
Cork University Hospital
Wilton

Scale document down

Re: Proficiency-based training to investigate WBIT: Technology enhanced learning and proficiency-based progression to investigate and mitigate "wrong blood in tube" in our hospitals: can we improve patient safety and reduce resource wastage?

Dear Professor Cahill

Approval will be granted to carry out the above study at:

- Cork University Hospital

subject to receipt and approval of the following:

- **Revised patient information leaflet/consent form:** Add section regarding
- anonymity
- **Revised health practitioner information leaflet/consent form for video recording:** Add section regarding anonymity.

The following documents have been approved:

- Application form signed 13th February 2017
- Study protocol version 2 dated 8 February 2017
- Study advertisement version 1 dated 8 February 2017
- Insurance details
- CV for chief investigator.

We note that the co-investigators involved in this project will be:

- Prof Anthony Gallagher, Director of Research ASSERT Centre, Dr Noirin O'Herlihy, General Practitioner, Dr Pat Henn, Lecturer, Dr Robert Gaffney, Medical School, University College Cork and Dr Sarah Griffin, Senior Specialist Registrar.

Yours sincerely

Professor Michael G Molloy
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials Products for Human Use) Regulations 2004, and is authorised by the Department of Health and Children to carry out the ethical review of clinical trials of investigational medicinal products. The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice.

Appendix B: Senior Phlebotomist Post (Training and Development) developed as an output of the study.

Phlebotomist, Senior (Training and Development)
Job Specification, Terms and Conditions

Job Title and Grade	**Phlebotomist, Senior (Training and Development)** *(Grade Code: 3433)*
Campaign Reference	HBS08349
Closing Date	Monday, 10th February 2020 at 12 noon
Proposed Interview Date (s)	To be confirmed
Taking up Appointment	A start date will be indicated at job offer stage.
Location of Post	South/ South West Hospital Group There is currently a permanent part-time (0.8 WTE) vacancy available at Cork University Hospital. A panel may be created on foot of this campaign for **Cork University Hospital** from which current and future permanent and specified purpose vacancies of full time or part time duration may be filled.
Informal Enquiries	Sinead Creagh, Laboratory Manager, CUH **Email:** Sinead.creagh@hse.ie **Tel:** 021 4922532
Details of Service	The Phlebotomy Department provides a varied service within the hospital. It covers the paediatric wards, adult wards and the Emergency Department as well as an outpatient service to CUH OPD clinics and to the General Practitioners in the City and County. The staff complement for the service currently stands at 18 WTE, including weekend workers.
Reporting Relationship	Reporting to the Laboratory Manager, Cork University Hospital

Purpose of the Post	The Phlebotomist, Senior (Training and Development) will develop and oversee a training and competency programme based on a Proficiency Based Progression (PBP) Training model and support the training of all phlebotomy practitioners as required. This post will involve audit, investigation and follow-up of phlebotomy and pre-analytical errors in conjunction with the laboratory. The Phlebotomist, Senior (Training and Development) will deputise as required for the Senior Phlebotomist in their line manager, administrative, operational and organisational duties. The Phlebotomist, Senior (Training and Development) will be required to work individually in the wards or as part of a team in the out-patients department and take an active role in the phlebotomy service.
Principal Duties and Responsibilities	*The Phlebotomist, Senior (Training and Development) will:* **<u>Training and Development</u>** • Develop and oversee a training and competency programme based on a Proficiency Based Progression (PBP) model. • Train incoming Phlebotomy practitioners using the PBP Training programme. • To provide follow up and top-up training to any practitioners making serious or recurrent errors – phlebotomy, medical or nursing staff as required • Ensure required e-Learning Modules have been completed by staff prior to PBP training. • Ongoing audit of compliance in the CUH laboratories with regard to Phlebotomy and pre analytical errors • Aid the laboratory in investigation of significant errors including, but not limited to WBIT (Wrong blood in tube)

Administrative

- Ensure all required records are maintained and securely stored in respect of the phlebotomy service.
- Maintain records of all phlebotomy staff – temporary and permanent – and take responsibility for all line management functions for the phlebotomy staff.
- Respond in a timely manner to all queries, complaints and complements and assist the Laboratory Manager in responses to equivalent communications.

Operational

- Ensure all equipment for use in the service is maintained to a reasonable level of function and participate in the selection of replacement or additional equipment as needed.
- Ensure all materials required for the operation of the phlebotomy service are available and fit for purpose.
- Roster staff according to the clinical needs of the hospital, as communicated by Senior Management and the Laboratory Manager.
- Participate in service planning and development and communicate service deficits where appropriate.
- Ensure good communication between phlebotomy staff, ward staff and laboratory.

Clinical

- Obtain blood specimens by performing venepunctures in line with blood processing and handling procedures.
- Promote a person centred approach to care,
- Interact directly with patients to obtain and verify information for laboratory records.
- Explain procedures, allay fears, and elicit co-operation and consent.
- Ensure that patient confidentiality is respected and maintained at all times.
- Ensure patient dignity is protected at all times
- Participate and /or initiate audit activities that ensure quality and or quality improvement initiatives relevant to the service.

Organisational

- Work with the senior Phlebotomist(s) to manage the Phlebotomy team at CUH.
- Represent the team at relevant Heads of Department forums and act as the link for senior management in the context of phlebotomy.
- Perform phlebotomy procedures and techniques for patients as requested in CUH.
- Carry out all tasks within clinical and patient care regulations, policies, procedures and standards.
- Manage supplies, equipment and stock ordering and rotation.

- Contribute to the development of phlebotomy policy, procedures and standards as a member of the Phlebotomy Team.
- Ensure that documentation is concise, accurate and in accordance with the requirements of the CUH Phlebotomy Service and any other statutory legislation requirements.
- Ensure that the service is cost effective, efficient and makes the best use of available resources.
- Work closely with Laboratory Medicine in the context of ISO accreditation standards and service quality.

Education and Self Development

- Participate in mandatory training programmes.
- Manage, participate and play a role in the practice education of trainee phlebotomists as required.
- Continuously develop a knowledge base at an advanced level to improve the quality and standard of the phlebotomy service delivery.
- Take responsibility for, and keep up to date with phlebotomy practice by participating in continuing professional development.
- Monitor and keep up-to-date with developments in the practice of phlebotomy and all other relevant healthcare matters to ensure maintenance of knowledge and skill base in order to facilitate contemporary professional practice.
- Engage in personal development planning and performance review for self and others as required.

Health & Safety

- Develop and monitor implementation of agreed policies, procedures and safe professional practice by adhering to relevant legislation, regulations and standards.
- Ensure the safety of self and others, and the maintenance of safe environments and equipment used in the Phlebotomy Department in accordance with legislation.
- Assess and manage risk in their assigned area of responsibility, identifying and implementing appropriate controls to manage and minimise risk.
- Take appropriate timely action to manage any incidents or near misses within their assigned area.
- Report immediately any accidents or incidents involving patients, staff, or members of the public to the Head of Department.
- Have a working knowledge of the Health Information and Quality Authority (HIQA) Standards as they apply to the role for example, Standards for Healthcare, National Standards for the Prevention and Control of Healthcare Associated Infections, Hygiene Standards etc.
- Support, promote and actively participate in sustainable energy, water and waste initiatives to create a more sustainable, low carbon and efficient health service.

The above Job Specification is not intended to be a comprehensive list of all duties involved and consequently, the post holder may be required to perform other duties as appropriate to the post which may be assigned to him/her from time to time and to contribute to the development of the post while in office.

Appendix C: Other Research Poster Presentations relating to the Project

Title	Authors	Conference
Procedure characterization, metric development and Delphi Panel consensus on phlebotomy performance metrics as part of Proficiency-Based training program to Mitigate Wrong Blood in Tube	Griffin S., O'Herlihy N., Gaffney R., Cahill M.R, Gallagher A.G.	Haematology Association of Ireland, October 2017, Belfast.
6 Months of Data on Error in Transfusion Related Blood Sampling from the Blood Bank at Cork University Hospital	Liston K., O'Herlihy N., Cahill M.R,	Haematology Association of Ireland, October 2017, Belfast.
Phlebotomy Training Prior to Commencement on the Wards: The Interns' Perspective	Liston K., O'Herlihy N., Cahill M.R,	Haematology Association of Ireland, October 2018, Cork
Wrong Blood in Tube: A Potentially Fatal Error Compared Across Two Irish Hospitals	Liston K., Creedon G., Sheehy J., Ring M.F., O'Herlihy N., Cahill M.R,	World Haematology Conference, Rome 2019

Appendix D: Example Feedback letter to Interns

Phlebotomy Training

Noirin O'Herlihy (CUH Registrar Haematology)

To: [redacted]

Sent Items 28 August

Dear [redacted]

We have looked at the rejected samples in Haematology for July.

You have taken 39 samples for the Haematology laboratory in July and 1 sample was rejected due to underfilling.

If using a butterfly system please remember to discard the first bottle with a serum red top bottle and a sufficient time for the blood bottle to fill.

I understand, in difficult cases, this is not always possible.

Please remember the points in the metric to avoid errors especially:

- Positive patient identification with at least 2 identifiers
- Handwriting the patient's name and MRN on the bottle at the bedside
- Printing labels after taking blood and checking that the label matches the detail on the bottle.

Thank you again for the hard work,

Best Regards

Noirin

Phlebotomy Training

Noirin O'Herlihy (CUH Registrar Haematology) Actions

To: [redacted]

Sent Items 28 August 2018 23:18

Dear [redacted]

We have looked at the rejected samples in Haematology for July.

You have taken 16 samples for the Haematology laboratory in July and 3 samples were rejected. This was due to using the incorrect bottle type for an FBC request. THis requires one purple (EDTA) bottle.

If you are unsure of the bottle type required for a test please refer to the laboratory user handbook for CUH available online and this can be downloaded to your phone as a pdf.

Please remember the points in the metric to avoid errors especially:

- Positive patient identification with at least 2 identifiers
- Handwriting the patient's name and MRN on the bottle at the bedside
- Printing labels after taking blood and checking that the label matches the detail on the bottle.

Thank you again for the hard work,

Best Regards

Noirin

CUH Intern Phlebotomy Course

Noirin O'Herlihy (CUH Registrar Haematology) Actions

In response to the [redacted] *018*

To: [redacted]

Sent Items 12 September 2018 20:22

Dear [redacted]

I am writing to inform you that of the six transfusion requests you submitted to the transfusion laboratory one was rejected.
The reasons for rejection of the sample was:

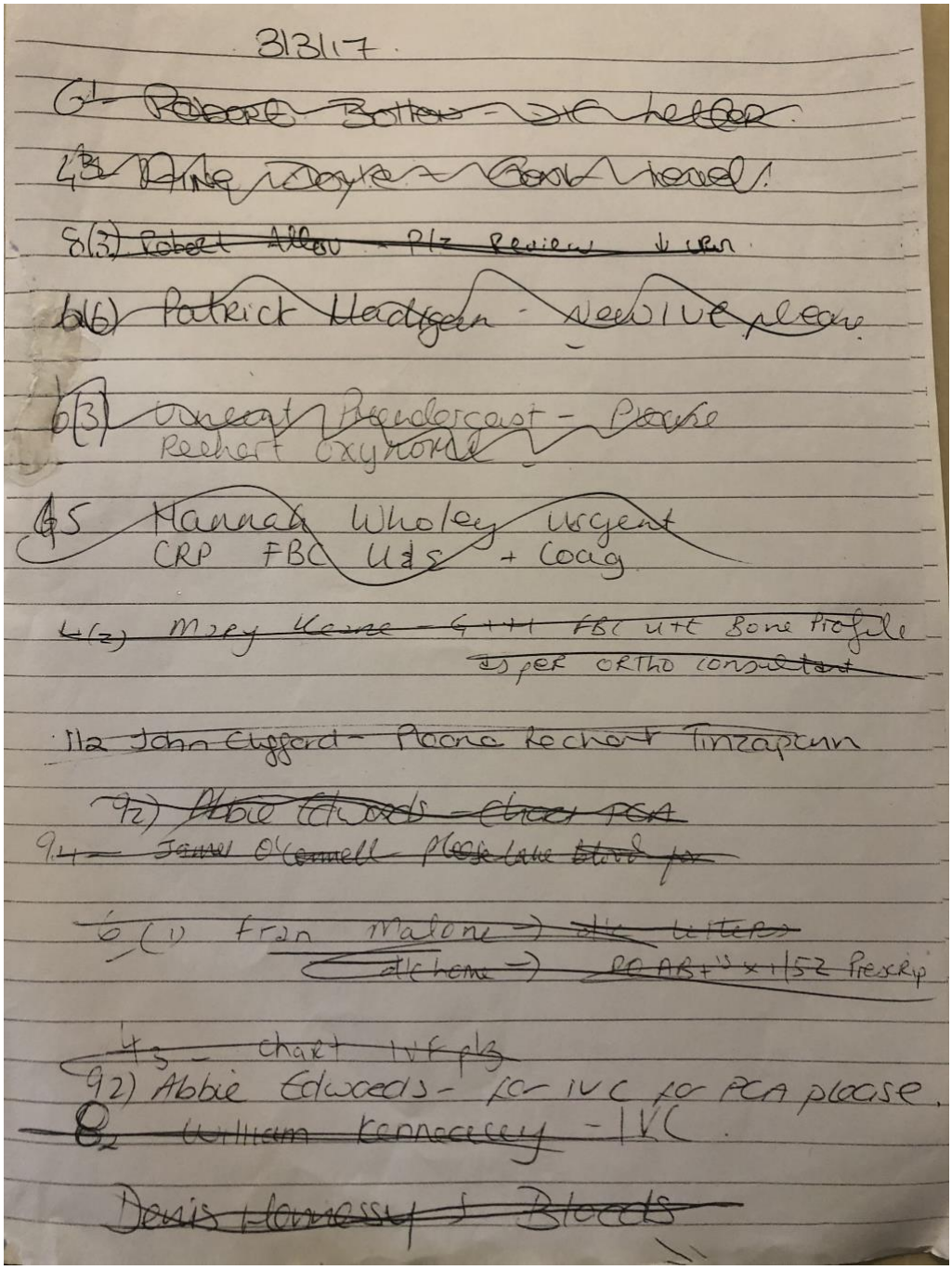
- No MRN

If you would like to discuss or meet for any further training please do not hesitate to contact me.

Best Regards

Noirin

Appendix E: Photograph of Intern Instructions for Jobs while On-Call



Review of Mislabelling Errors during Blood Sample Collection at Cork University Hospital-

A Report for Executive Management Board (EMB)

CUH

May 2020

Research carried out by Dr Noirin O' Herlihy, supported by HSE
Supervised by Prof Mary Cahill
External advisor Prof A.G. Gallagher

Executive summary

Scope of the report

This report details the findings of a comprehensive investigation into the problem of pre-analytical sample errors at Cork University Hospital. The pre-analytical stage of blood testing commences with the decision to take the blood test and ends with the arrival of the blood sample in the laboratory for testing. It encompasses everything in the patient space, describes the prevalent problems with sampling, the chronicity of the problems, the patient harm and potential patient harm occurring and a potential novel solution- proficiency-based progression training, together with the challenges implementing this and the possible reasons for those difficulties.

Background

What can go wrong with blood sampling?

The most critical pre-analytical errors in Wrong Blood In Tube (WBIT) which occurs when the blood in the bottle is not that of the person written on the bottle. In 2019, in CUH, this occurrence was detected in 200 samples. There are undoubtedly many undetected instances.

What are the worst consequences of blood sampling inaccuracies?

Pre-analytical errors are costly and can result in patient harm due to misdiagnosis and inappropriate or delayed correct treatment. WBIT can result in inappropriate blood transfusion and death.

Cork University has been vigorously addressing this problem through the laboratories for over a decade.

Cork University Hospital (CUH) has been tracking and trending pre-analytical errors including WBIT since 2007, for the purpose of accreditation. Despite educational interventions, awareness campaigns, and work by the hemovigilance teams, WBIT rates were persistent. A rise in WBIT was seen each July with the commencement of new doctors in training in the hospital.

The report

This report describes a novel potential solution to pre-analytical sampling errors

In conjunction with UCC, we developed a bespoke programme of proficiency-based progression (PBP) training to reduce the rates of pre-analytical errors (including WBIT) in CUH. This method has robust evidence for its effectiveness in surgical skill training and the details are addressed in the report. Training was provided in a simulated environment to new CUH interns who reached a proficient standard prior to commencing their posts.

The details of the solution are summarized and were implemented in a controlled clinical trial format in CUH so we could scientifically evaluate efficacy

A controlled ***clinical trial*** demonstrated that the PBP training programme in phlebotomy can reduce pre-analytical errors but did not find a reduction in WBIT events (which are comparatively rarer). The trial highlighted the need for the programme to be delivered to a high standard and for good hospital support for the programme if it is to be most effective.

A ***prospective observational study*** to investigate the performance of interns after commencement of employment was also conducted. Dr O'Herlihy provided post training mentorship on the wards as part of the PBP training.
This additional research highlighted a number of modifiable barriers and facilitators to implementation of the correct process of performing bloods (which can be addressed with institutional effort). These factors included lack of appropriate equipment, poor instructions, patients not wearing their ID wristbands, interruptions and poor access to functioning computers and label printers leading to increased complexity of the task. Positive patient identification and bedside labelling of blood samples was performed by all interns but not always by senior staff who were mentoring them once the programme concluded. This illustrates issues with a lack of safety culture among doctors around the subject of sample labelling.

Report recommendations

- Training of healthcare professionals through the use of the PBP training programme in phlebotomy developed in this study which can continue with multi-disciplinary CUH and UCC support.
- The programme can be adapted for use in other hospitals.
- Promotion of the importance of positive patient identification of patients with two patient identifiers before any patient interaction needs to continue post-programme and be promoted to more senior staff.
- The introduction of bedside label printers to ensure labelling of blood samples in the presence of the patient immediately after performing phlebotomy is highly desirable. If bedside label printers are not available bottles must be hand-labelled in the presence of the patient with at least two patient identifiers.
- A strong culture of safety needs to be promoted in CUH so that healthcare practitioners avoid adapting unsafe practices that can lead to error for the sake of time and patient safety is foremost at all times – even in the most routine of procedures.
- An appreciation of the consequences of WBIT should be promoted by senior management.
- The laboratory efforts to combat WBIT will not succeed without parallel effort on the wards and other clinical areas when the problem begins.

List of tables

		Page
Table 1	Errors by interns in the haematology department in a three-month period from commencement of employment in July 2016,2017 and 2018	17
Table 2	Logistic Regression analysis of the probability of a blood test rejection in the haematology laboratory for years 2017 – 2018 in comparison to 2016	17
Table 3	Comparison of blood transfusion error rates between the three years for a 2-month period from commencement of work by interns in July 2016, 2017, 2018	18
Table 4	Reason for rejection of blood sample in the blood transfusion laboratory for a 2-month period from commencement of work by interns in July 2016, 2017, 2018	18

List of figures

		Page
Figure 1.	Description of current practices of doctors performing blood collection at CUH in early 2017	13
Figure 2	Simulation ward where PBP training in phlebotomy took place	14
Figure 3	Model IV Arms used in the simulation ward to practice phlebotomy	14
Figure 4	Computers and label printers on the phlebotomy simulation ward	14
Figure 5	Flow chart illustrating the recruitment, data collection, data analysis and results of the control group in 2016, pilot study in 2017 and follow-on study group in 2018.	16

List of abbreviations

CI	Confidence interval
CUH	Cork University Hospital
OR	Odds ratio
PBP	Proficiency-based progression
TUBE	Testing the Utility of Collecting Blood Electronically
WBIT	Wrong Blood in Tube

Table of Contents

EXECUTIVE SUMMARY 151
FOREWORD 155
MEMBERS OF THE MULTIDISCIPLINARY TEAM 156
INTRODUCTION 158
PURPOSE OF THE STUDY 158
BACKGROUND 158
Pre-analytical errors 158
Phlebotomy Standards 159
Pre-analytical Errors and WBIT at CUH 160
PROFICIENCY-BASED PROGRESSION TRAINING (PBP)- A NOVEL SOLUTION? 160
Example of Reference events: Near Miss WBIT at CUH Emergency Department 161
Second Example of Reference event: 161
METHODOLOGY 162
Controlled trial to determine the effect of PBP training in phlebotomy on the rate of blood sampling and labelling errors (including WBIT) at CUH 162
*Observation of assessment of clinical performance to determine factors contributing to common blood sampling errors identified during real time mentoring phase of PBP Training in CUH – **barriers to implementation of evidence-based training** 164*
RESULTS 165
Controlled trial to determine the effect of PBP training in phlebotomy on the rate of blood sampling and labelling errors (including WBIT) at CUH 165
RESULTS IN HAEMATOLOGY & TRANSFUSION DEPARTMENTS 165
Observation of assessment of clinical performance to determine factors contributing to common blood sampling errors identified during real time mentoring phase of Proficiency-Based Progression Training in Cork University Hospital – Barriers to Implementation of Evidence Based Training 168
KEY RECOMMENDATIONS 170
APPENDIX A: DEVELOPMENT OF THE PBP TRAINING PROGRAMME IN PHLEBOTOMY 171
Procedure characterisation 172
Metric stress testing, definition verification and reliability 172
Modified Delphi meeting 172
Construct Validity 172
Proficiency benchmark 173
Conclusion 173
APPENDIX B: WBIT IN GENERAL PRACTICE 173
REFERENCES 174

Foreword

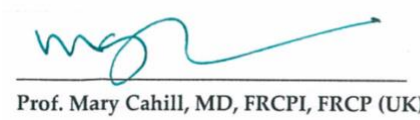
Venous blood sampling is one of the most common procedures performed in Cork University Hospital and indeed in healthcare. It has been suggested that approximately 60%–70% of all decisions made about diagnosis, treatment, or the evaluation of treatment are based on results from laboratory tests across all healthcare settings. The proportion would be higher in hospital medicine. Therefore, the accuracy of results which might affect a patient's treatment is paramount. In the laboratory setting, we do all that we can to quality control every aspect of our service and maintain accreditation as an important means of external quality control. However, we note that controlling sample quality, before the samples come to the laboratory, (pre-analytical variables) is more difficult than quality control of the processes within the laboratory itself. We seek to increase awareness of inaccurate samples in the clinical arena where they originate.

We recognise that the clinical arena, outside the laboratory is subject to pressures, stress and variable factors which mitigate against consistent quality control in a number of areas. Every patient is unique. In the laboratory, we notice and record the considerable variety of sample quality issues that arise on a cyclical basis biannually as new staff commence in CUH.

The most serious type of pre-analytical error occurs when the blood in the tube is not that of the person identified on the label. This error is so huge that colleagues need time to absorb the fact and the impact. We call this error Wrong Blood In Tube -WBIT. WBITs have been estimated to occur at a rate of between 1 in 1303 to 1 in 2717 blood samples in published international studies. This is a likely underestimate.
The idea that a blood tube might be perfectly labeled with a name and date of birth of say Mrs. Anne Murphy, but in fact contain blood from Mrs. Mary Murphy, who has a different set of clinical problems and therapeutic needs, is truly frightening. This occurred in CUH laboratories 200 times last year….at least 200 times that we detected.

The laboratories have been detecting and sharing their concern about this issue for over a decade. This project was conceived in part, to get our clinical colleagues fully engaged with prevention and mitigation.

This report is for CUH management who have fully supported this project from the outset and whom we thank for their encouragement of this multidisciplinary team effort to reduce laboratory sample errors – especially those of WBIT. We thank the CUH management for its support of Dr Noirin O'Herlihy who dedicated over two years to documenting, researching, designing PBP training and to reporting problems and solutions. We thank our many colleagues associated with ASSERT and the department of medical education in UCC for enabling this work to be done as a clinical trial.
We thank the HSE for financial support to carry out this work in a difficult but important area of patient safety.



Prof. Mary Cahill, MD, FRCPI, FRCP (UK), FRCPath (MCRN:11113)
Consultant Haematologist

Members of the Multidisciplinary Team

Department	Name
Biochemistry Department	Nicola Goulding
Business Manager	Ber Baker
Chief Executive Officer	Mr. Tony McNamara
Chief Medical Scientist	Mary F Ring
Chief Medical Scientist, Blood Transfusion Laboratory	John Sheehy
Clinical Director, UHK	Dr. Clare O'-Brien
CNM2 Paediatric Day Unit	Maria Watson
Consultant Geriatrician	Dr. Michael O''-Connor
Consultant Haematologist	Dr. Mary Ryan
Consultant Haematologist	Prof Mary Cahill
Consultant in Emergency Medicine	Dr. Iomhar O'-Sullivan
Consultant in Emergency Medicine	Dr. Martin Boyd
Director of Clinical Skills	Dr. Robert Gaffney
Doctor in Training	Dr. Alison Deane
Doctor in Training	Dr. Harry Mc Grath
Doctor in Training	Dr. Jenna O'-Sullivan
Doctor in Training	Dr. Orna Daly
Human Resources	Eileen Mc Carthy
Human Resources	Padraig Varian
Intern	Dr. Sean T O'Sullivan
IV Nurse Specialist	Aine Connolly
Laboratory Information System	Carmel Murphy
Laboratory Information System Leader	Brid O' Mahony
Laboratory Manager	Sinead Creagh
Lecturer Medical Education	Dr. Patrick Henn
Medical Manpower Manager	Mr. Michael Murphy
Medical Scientist, Blood Transfusion laboratory	Cora Mc Sweeney
Operations Manager	Mr. Brendan O'-Reilly
Phlebotomy	Ruth Mulcahy
Phlebotomy	Hilary Morton
Phlebotomy	Brid Fitzgibbon
Phlebotomy	Nelia Andrade
Phlebotomy	Ailish Normoyle

Professor in Medicine, Head of School, UCC	Prof Paula O Leary
Professor of Technology Enhanced Learning, UCC	Prof Anthony Gallagher
Senior ICT Analyst, IT Dept.	John Froggatt
Senior Instructional Designer	Patrick Kiely
Senior Medical Scientist, Haematology	Mairead O'-Reilly
South Intern Network Administrator	Geraldine Mc Nameee
Specialist Registrar in Haematology	Dr. Sarah Griffin

THANKS ALSO TO ALL THE MEMBERS OF THE DELPHI PANEL, THE NURSES OF THE PAEDIATRIC WARD OF CUH, LABORATORY STAFF IN TRANSFUSION, HAEMATOLOGY AND BIOCHEMISTRY WHO HAVE BEEN TRACKING WBIT FOR YEARS AND THE SECURITY DEPARTMENT AT CUH.

Introduction

This report presents findings of a research project carried out under the academic supervision of Professor Mary Cahill and Professor Anthony Gallagher by a multidisciplinary team, supported by the executive management of Cork University Hospital(CUH) to investigate pre-analytical errors especially Wrong Blood In Tube (WBIT) at CUH and to apply the novel methods of proficiency-based progression (PBP) training to reduce error rates by doctors in training. We thank the executive management board in CUH for their leadership and financial support.

Purpose of the study

The purpose of the study was to investigate the current process by doctors in training of performing bloods at CUH, to determine what improvements are required, to design a PBP educational intervention to improve the performance of doctors in training, implement the training and determine the effectiveness of the training using qualitative and quantitative research methods.

Background

Pre-analytical errors

Venous blood sampling is one of the most common procedures performed in healthcare. It has been suggested that approximately 60%–70% of all decisions made about diagnosis, treatment, or the evaluation of treatment are based on results from laboratory tests [147].

Types of pre-analytical errors

The pre-analytical phase of blood testing is the first phase in the total testing process of blood samples and comprises the process from deciding to perform the blood test to the arrival of the blood sample in the laboratory for analysis. It takes place in clinical areas. Up to 70% of laboratory errors originate during the pre-analytical phase of testing [13]. Sampling errors include the following:-

i) under filling or over filling of the blood bottles
ii) clotted samples
iii) haemolysed samples
iv) mislabelling errors
    a. minor mislabelling and
    b. WBIT [148] [146].

What is WBIT?

WBIT is the most serious type of pre-analytical error and occurs when the blood in the tube in not that of the person identified on the label [40]. WBITs have been estimated to occur at a rate of between 1 in 1303 to 1 in 2717 blood samples in published international studies [40]. WBITs are detected in blood transfusion when the patient has had a historical blood group performed by the laboratory and the record is checked noting that there is a different result from the new sample. In the haematology and other laboratories, WBIT is detected when the blood results are markedly different from previous results documented in the

laboratory. WBIT are an important patient safety issue as errors can lead to ABO incompatible blood transfusions, inappropriate treatment, investigations, and misdiagnosis leading to significant anxiety.

Factors which we know are associated with WBIT

Positive patient identification and labeling the sample in the presence of the patient are key areas requiring reinforcement with healthcare practitioners to improve the safety of their phlebotomy practice. Labelling the sample away from the patient is responsible for up to 44% of WBIT events [40]. Misidentification has been identified as a root cause of many errors by the Joint Commission in the United States of America, therefore, improving identification accuracy has been listed as a National Patient Safety Goals since 2003 [54]. Positive patient identification should be performed by asking the conscious patient to state his/her name and date of birth, rather than simply agreeing with a stated name provided by staff [40]. Despite patient identification and tube labelling being identified as high risk phases, these phases have been found to be inadequate in 30% of cases of blood collections [16].

How can we reduce the incidence of WBIT?

Various interventions have demonstrated improvements in WBIT events but have not eradicated its occurrence including: education and training [40 61 149], audit and feedback [61], electronic barcode scanning [64 65] and a group-check sample policy (i.e. all patients are blood grouped twice) for blood transfusion samples (66). A zero-tolerance approach is recommended, most especially in blood transfusion laboratories to reduce the incidence of WBIT [40]. Multiple interventions and feedback is likely the most effective approach to reduce mislabeling and other blood sampling errors [149].

Electronic solutions

The recent Testing the Utility of Collecting Blood Electronically (TUBE) study in the USA [65], shows a lower incidence of WBIT in electronically labelled samples than manually labelled samples (1:3046 compared to 1:14,606 respectively) illustrating that, electronic labelling is beneficial when provided in an effective and safe manner.

Phlebotomy Standards

Various guidelines exist to ensure standardisation of the phlebotomy procedure including the Clinical Laboratories Standards Institute GP41 guideline [37], the World Health Organisation guideline on drawing blood [38], the Guiding Framework for the Education, Training and Competence Validation in Venipuncture and Peripheral Intravenous Cannulation for Nurses and Midwives [36] and the British Committee for Standards in Haematology guidance provides recommendations specifically for blood transfusion sample collection.

Key Recommendations include

- Positive patient identification where the healthcare practitioner asks the patient their name and date of birth and if the patient is unconscious then a nurse or relative is required to give this detail. End of bed charts or other identification near the bedside are not adequate for identification purpose.

- All tubes must be labelled only once filled and whilst still in the presence of the patient so that taking the sample and labelling the bottle is one uninterrupted, continuous process that occurs in the presence of the patient, by just one healthcare practitioner.
- Bottles should be hand-labelled in the presence of the patient unless bedside label printers are available that can be used in the presence of the patient.
- Laboratories should have a policy on acceptance and rejection criteria of blood samples and request forms including acceptable labelling requirements and actions to be taken if the minimum criteria are not met.

The Guiding Framework for the Education, Training and Competence Validation in Venipuncture and Peripheral Intravenous Cannulation for Nurses and Midwives produced by the HSE in 2017 does not include positive patient identification or bedside labelling of blood samples as one of its key learning outcomes [36].

Pre-analytical Errors and WBIT at CUH

The occurrence of WBIT has been meticulously documented by the laboratories at CUH since 2007 when accreditation and the quality management system were becoming embedded in the daily life of the laboratories. The laboratories has been making strenuous efforts over the last 10 years to mitigate and reduce the incidence and effects of WBIT with limited success. In 2016, there were 124 WBITs in the haematology laboratory, 24 WBITs in biochemistry laboratory and 2 WBITs in the transfusion laboratory at CUH. In 2019, there were 200 in the hospital in total. This is partly due to increased awareness and detection but may also represent a real increase.
Training and medical education can reduce the incidence of WBIT. However, this problem remains at significant levels, may be rising and fresh thinking is required.
In 2010, a sharp rise in error rates when new doctors in training commenced work in the hospital in July was noted. Given the significant patient risk of any WBIT event the need for a solution to this problem is clear.

Proficiency-Based Progression Training (PBP)- a novel solution?

PBP training is a method of transferring procedural skills to trainees in an effective and quantifiable manner.
Metrics (operational definitions of the procedure) are first developed, based on analysis of the process in real time using video recordings of experts and novices. Using the metrics, trainees are provided with a specific checklist of how to perform the task in a simulated environment. The trainees can be objectively assessed and provided with proximate feedback while performing the procedure to enable learning due to deliberate practice. A proficiency benchmark ensures that the trainee can perform the procedure, to at least, the average standard of experts in the field, before graduating from the training.

There is robust evidence for the effectiveness of PBP training in the transfer of technical procedural skills including labour epidural catheter placement [90], arthroscopic knot tying [92],

laparoscopic skills [94] including for cholecystectomies [93] and superficial femoral artery (SFA) angioplasty in a simulated environment. This is resulting in a shift from the apprenticeship style learning of procedural skills by doctors in training, to training in a simulated environment.

In the laboratories, PBP is already utilised to train on call scientists for the techniques required to provide a safe on-call service. However, the concept had not been applied to doctors in training for venepuncture.

We developed a PBP programme, to train healthcare professionals on how to perform phlebotomy to a proficient standard specifically for use within the environment of CUH and applied it to incoming interns.

Example of Reference events: Near Miss WBIT at CUH Emergency Department

In July 2015 a 44 year old male patient (Mr Murphy) attended the emergency department at CUH and was diagnosed with a fractured neck of femur. A group and hold sample was taken by the specialist registrar in the emergency department. This returned with the following result: **Group B RhD positive**. There was no previous blood group result available for the patient. The patient's pre-operative haemoglobin was **13.1** g/dL but following surgery his post-operative haemoglobin dropped to **8.8** g/dL. The patient was not transfused but would have been transfused with **B Rh D Positive** blood components if required.
In April 2018 Mr Murphy was admitted to CUH and diagnosed with a second fractured neck of femur. A group & hold blood sample was taken in the emergency department. The blood result returned with **A Rh D Positive** – in contrast to the recorded group from July 2015. The 2018 result was ***confirmed by repeat specimen*** to be the correct blood group. A transfusion of B positive blood to this A positive patient in 2015 could have been fatal.

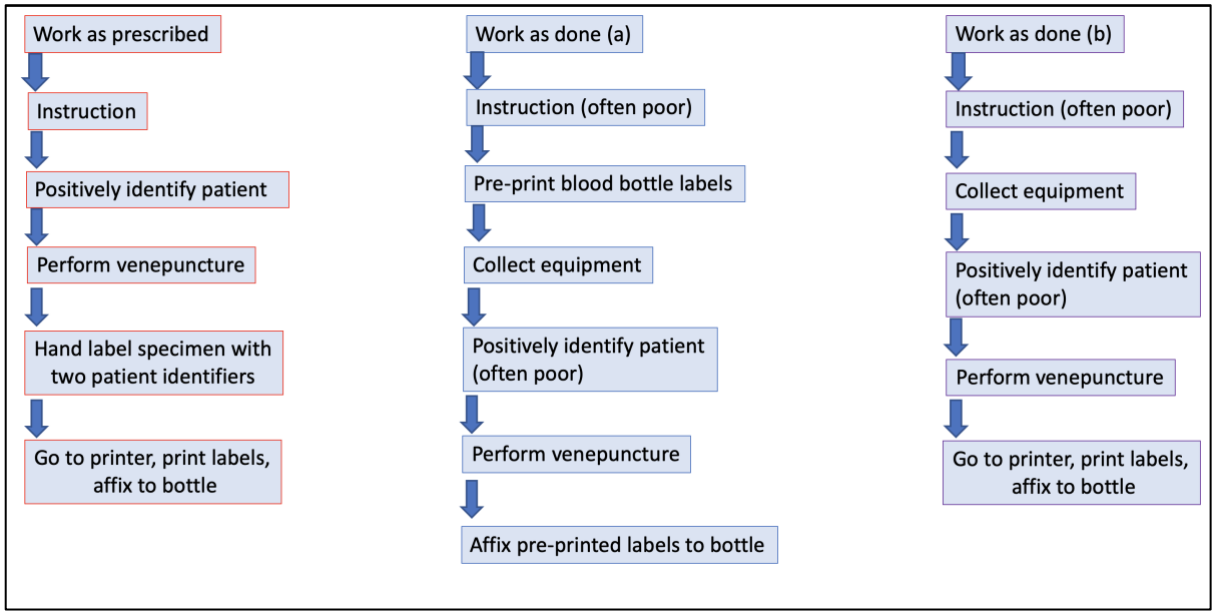
Second Example of Reference event

In 2017, an intern was asked to perform a group and hold on a patient during her first week of work at CUH. She went to the patient and took the blood sample. He was not wearing a patient identity wristband. The intern left the patient bedside without labelling the blood sample but instead went to find the patient's notes. The blood sample was labelled using the incorrect patient notes as there were two patients on the ward with the same name. The error was detected in the laboratory when there was a discrepancy in results (the patient tested **A Rh D Negative** and a previous blood group on the system for that patient was **B Rh D Negative**).

Methodology

The principles of PBP training development and implementation were used to facilitate this investigation and to design the PBP training programme.

Metric development comprised of multiple meetings with stakeholders (laboratory scientists, nursing, IT, phlebotomy, doctors in training, consultant haematologist) in phlebotomy at CUH. Video recordings of doctors performing phlebotomy on patients on the wards provided further insights. As per the model developed by Shorrock [107], the meetings imparted a clear picture of the "work as prescribed' by hospital management, as defined by the standard operating procedure in CUH and the "work as done" by the doctors in training in the clinical environment (figure 1). This information provided a multidisciplinary approach to the development of the correct process of performing bloods at CUH which is outlined in further detail in the appendix. The phlebotomy metric was developed, validated for content and construct validity and finally a proficiency benchmark was set so the metric could be used in training.



Work as prescribed = Standard operating procedure for phlebotomy at CUH
Work as done (a), Work as done (b)= following interviews with healthcare workers performing phlebotomy this is the process followed by most doctors in the hospital.

Figure 1. Description of doctors current practice of phlebotomy at CUH in early 2017.

Controlled trial to determine the effect of PBP training in phlebotomy on the rate of blood sampling and labelling errors (including WBIT) at CUH

"To determine the effect of PBP training in phlebotomy on the rate of blood sampling and labelling errors including WBIT at CUH, a non-randomised controlled trial was undertaken."

Participants consisted of a **2016 control group** of interns who had been working in CUH in July 2016 for a three-month rotation, one year before the study commenced. The control group were not provided with additional training in phlebotomy and provided a sample of the blood sampling error rates of interns in the hospital before the PBP training programme was introduced.
2017 and 2018 Interventional Groups were provided with PBP training in phlebotomy before commencement of employment in the hospital in July 2017 and July 2018 and blood sampling error rates were observed for a three-month rotation following this.

The **intervention** consisted of a PBP training programme in phlebotomy based on the metric which had been developed and validated. There were 3 stages to the training commencing with an eLearning module completed at home, followed by supervised training in a simulated environment where the interns performed bloods on IV arms (figure 2,3,4) and finishing with mentorship while performing phlebotomy in the normal clinical environment. The intern had to reach the proficiency standard before graduating from the training. Interns were expected to reach the proficiency standard before graduating from the PBP training programme in phlebotomy



Figure 2. Simulation ward where PBP training in phlebotomy took place



Figure 3. Model IV Arms used in the simulation ward to practice phlebotomy

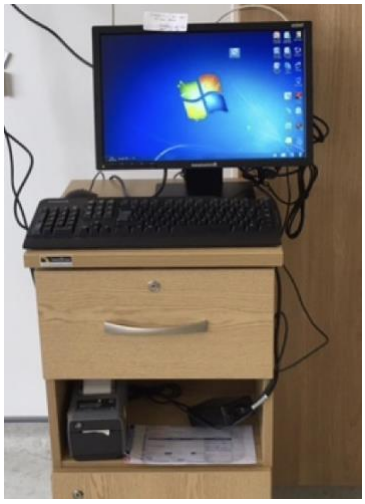


Figure 4. Computers and label printers on the phlebotomy simulation ward

Data collection comprised of evaluation of blood sampling errors among interns, accessed using the laboratory information system for the haematology department and by manual analysis of signatures on forms for blood transfusion samples over a three-month period from the commencement of employment in July.

The blood sampling errors in the historical controls who had not undergone PBP training in 2016 were compared to the PBP trained interventional group in 2017 (pilot study) and 2018 (follow-on study).

Observation of assessment of clinical performance to determine factors contributing to common blood sampling errors identified during real time mentoring phase of PBP Training in CUH – barriers to implementation of evidence-based training

To investigate the barriers and facilitators to implementation of the PBP training programme in phlebotomy, during the mentorship of the interns on the wards in their usual clinical environment, observations took place to document the performance of the interns and gain an insight into environmental factors affecting implementation of the training. The researcher documented the steps completed and omitted by the intern during mentorship on the wards and included situational factors which effected performance. A short discussion took place with the doctors at the end of each session to gain a perspective of their views. Our goal was to identify environmental, organisational and job factors in addition to the human and individual characteristics which influence human behavior and could negatively contribute to blood sampling errors. A theoretical domain framework was chosen to analyse the discussion with the intern doctors.

Controlled trial to determine the effect of PBP training in phlebotomy on the rate of blood sampling and labelling errors (including WBIT) at CUH

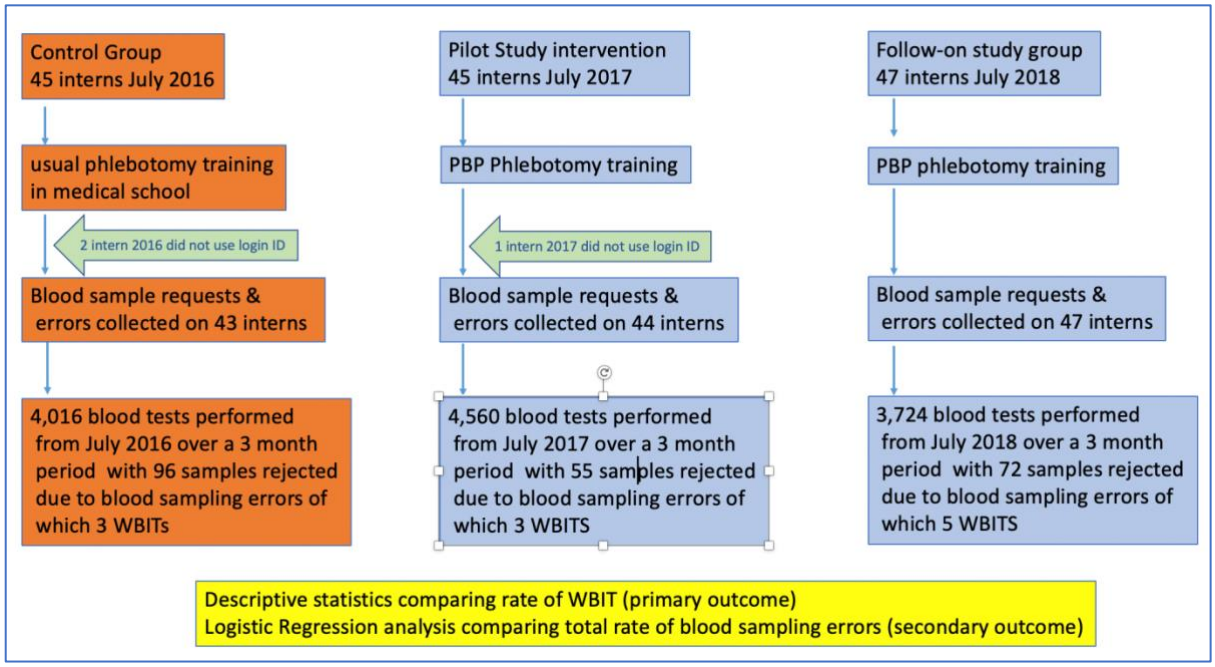


Figure 5. Flow chart illustrating the recruitment, data collection, data analysis and results of the control group in 2016, pilot study in 2017 and follow-on study group in 2018.

Results in Haematology & Transfusion Departments

In the haematology department WBITS were a rare event with three in 2016, three in 2017 and five in 2018. There appeared to be an increase but awareness of WBITs in the laboratory also increased which may have resulted in positive detection bias.

43 interns in 2016 control group had an error rate of 2.4% compared to 44 interns in 2017 pilot study who had error rate of 1.2% (OR=0.50, 95% CI 0.36-0.70 p-value<0.001) **demonstrating a statistically significant decrease in pre-analytical errors**.

47 interns in 2018 follow-on group had error rate 1.9% and this **demonstrated a modest reduction in errors** when compared to 2016 that was not statistically significant (OR=0.89, 95% CI 0.65-1.21 p-value=0.46).
The errors are described in Table 1 and 2.

Table 1. Errors by interns in the haematology department in a three-month period from commencement of employment in July 2016,2017 and 2018

	2016 number of errors (number of errors per 1,000 samples)	2017 number of errors (number of errors per 1,000 samples)	2018 number of errors (number of errors per 1,000 samples)
	n=4,016	n=4,560	n=3,724
Clotted Samples	16 (4)	8 (1.8)	12 (3.2)
Haemolysed	6 (1.5)	6 (1.3)	12 (3.2)
Incorrect Bottle	9 (2.2)	4 (0.8)	11 (3)
No Specimen Received	4 (1)	5 (1.1)	2 (0.5)
Over-/under-fill samples	50 (12.5)	27 (5.9)	28 (7.5)
Other	8 (2)	2 (0.4)	2 (0.5)
WBIT	3 (0.7)	3 (0.7)	5 (1.3)
Total errors	**96 (24)**	**55 (12.1)**	**72 (19.3)**

Table 2. Logistic Regression analysis of the probability of a blood test rejection in the haematology laboratory for years 2017 – 2018 in comparison to 2016

	Crude		Adjusted	
	OR (95% CI)	p-value	OR (95% CI)	p-value
Month				
July			1.00	
August			0.60 (0.42-0.83)	<0.01
September			0.57 (0.41-0.81)	<0.01
October			0.49 (0.27-0.88)	0.02
On Call			1.07 (0.81-1.40)	0.64
Year				
2016 control group	1		1	
2017 pilot study	0.50 (0.36-0.70)	0.00	0.50 (0.36-0.70)	<0.01
2018 follow-on study	0.84 (0.62-1.14)	0.26	0.89 (0.65-1.21)	0.46

In the transfusion laboratory, there was one WBIT in the 2017 group but no WBITS in 2016 or 2018. There was a decrease in the blood sample error rate in 2017 and 2018 compared

with 2016 historical controls but the difference was not statistically significant. The blood sampling errors in the transfusion laboratory are illustrated in Table 3 and 4.

Table 3.5 Comparison of blood transfusion error rates between the three years for a two-month period from commencement of work by interns in July 2016, 2017, and 2018

Year	Rate of Error	Absolute Errors	Number of Requests	WBITs
2016	9.61%	69	718	0
2017	7.56%	56	741	1
2018	7.77%	56	721	0

Table 4. Reason for rejection of blood sample in the blood transfusion laboratory for a 2-month period from commencement of work by interns in July 2016, 2017, 2018

Reason for Rejected sample	2016	2017	2018
Date of birth incorrect	20	20	14
Date of birth omitted	9	8	13
Incorrect or omitted name	3	4	1
Label applied for address	0	1	0
Patient ID incorrect	15	5	6
Patient ID omitted	10	8	9
Date incorrect	1	1	0
Omitted address form	1	0	0
Form not filled	0	0	1
Form/sample not signed	4	2	4
Signature mismatch	1	0	0
Haemolysed	1	0	3
Under-filled	0	0	2
Not specified	0	0	1
Sample not labelled	4	8	2
WBIT	0	1	0
Total	69	56	56

The intervention in 2018 did not appear to be as effective as the preceding year, especially in the haematology department. This was thought to be due to an effort to deliver the training to too large a group within a short period with limited resources (especially tutors) available. It is possible that there were unknown confounding factors influencing the groups such as environmental stress, peer influence and detection bias.

The study demonstrated that PBP training in phlebotomy can help reduce blood sampling errors but the PBP training must be delivered to a high standard.

This educational intervention can be adapted to deliver the programme in other Irish teaching hospitals and internationally to move away from apprenticeship style learning and ensure doctors in training are proficient before performing phlebotomy in patients.

Observation of assessment of clinical performance to determine factors contributing to common blood sampling errors identified during real time mentoring phase of Proficiency-Based Progression Training in Cork University Hospital – Barriers to Implementation of Evidence Based Training

Time
The median time taken to perform phlebotomy at CUH from the instruction to take blood to the dispatch of the sample to the laboratory is **20 minutes** (minimum 10 minutes, maximum 45 minutes). This is a slow process – especially on call.

Finding equipment
The majority of interns utilise the butterfly system when performing bloods as it is easier to know when the vein is entered due to a flashback. Delays were common, for example, in 17 cases (43%) there was difficulty finding equipment.

Finding the patient
Delays resulted when there was difficulty locating the patient (3 cases).

Computer and printer issues
Computers were unavailable (6 cases), printers were not functioning correctly (6 cases).

Interruptions
Interruptions occurred in 6 cases (15%) such as their bleep sounding, other doctors interrupting, being asked to complete other tasks while locating equipment. Technical glitches in the ICM system were occurring so that incorrect labels were printing at no fault to the user of the system. These environmental factors all increased the complexity of the simple task.

Hospital procedure on wristbands not always followed
The study uncovered barriers to positively identifying the patient such as interns being requested to perform bloods on patients without providing at least two patient identifiers required to positively identify the patient. Patients did not always have an identity wristband which is critical to avoiding labelling errors.

Intern factors
Interns admitted nervousness while being observed and the medical researcher noted that doctors were calm and less prone to error when they were supported by their peers in simple ways such as providing assistance locating equipment on unfamiliar wards.

Culture and lack of good senior example

After working on the wards, interns had learned that hand labelling at the bedside added time to the process of taking blood and one intern admitted that he did not see a need to hand label the bottle at the bedside when performing bloods on just one patient. This highlighted that safety and avoiding labelling errors on blood tubes was not a priority within the culture of the hospital, often due to time pressures, a need for high productivity and peer influences.

Additional observations by study team- specific examples

During dissemination of the key learning outcomes from the trial, the study team engaged with multiple departments within the hospital during grand rounds, quality meetings and tutorials in the emergency department etc., Feedback provided a further perspective on the phlebotomy practices in the hospital as follows:

- Phlebotomy trollies with label printers are too wide to fit inside certain wards and phlebotomists have been observed moving from the bedside with unlabelled tubes as a result.
- Nurses and doctors have reported long waits for computers to order and print off labels for blood bottles (up to 40 minutes reported in extreme cases).
- Printers are sometimes unavailable on the wards, so the healthcare practitioner has to walk to another ward to print a label (increasing risk in bottles which are unlabelled).
- Patients do not always have ID wristbands which makes positive identification difficult.
- There is a lack of routine use of two patient identifiers during positive patient identification on the wards.
- Pre-printed stickers have been noticed in notes and elsewhere on the wards.

Economic Considerations to address the documented barriers to performing phlebotomy according to the metric

An audit performed by Haematology Medical Scientist, Padraig O' Sullivan highlighted the cost of rejection of blood samples due to mislabelling errors. In 2010 there were 14,480 bloods samples received from CUH and Cork University Maternity Hospital with 6.8% incorrectly labelled and 13,375 received from General Practitioners with 1.9% incorrectly labelled. A conservative estimate was made of the cost of repeating blood samples if the sample was not taken correctly on the first occasion. In 2010, 304 days of work were wasted due to error, leading to a cost of €147,880 in wages and €5,984 for additional materials required to collect and test the bloods. The cost of repeating samples in 2010 compared to 2021 would likely be approximately 9.9% higher due to inflation (calculated here). It is estimated that providing a trolley for interns on a ward would cost €1500. This trolley would be correctly stocked and would have a dedicated label printer that could be taken with the trolley to the bedside and reduce the complexity of the procedure currently for interns.

Conclusion
A strong culture of safety is required within healthcare organisations to facilitate the implementation of procedures and guidance. Hospitals should strive to ensure that the environment is such that standard operating procedures can be followed easily. The procedures themselves should be designed so that when healthcare practitioners adapt the procedure to save time, the key steps of the procedure will be performed correctly. To avoid labelling errors during phlebotomy, bedside label printers are a possible solution to ensure performing the procedure safely is widespread, even under time pressure.

Key Recommendations

Report recommendations

- Training of healthcare professionals through the use of the PBP progression training programme in phlebotomy developed in this study which can continue with multi-disciplinary CUH and UCC support.
- The programme can be adapted for use in other hospitals.
- Promotion of the importance of positive patient identification of patients with two patient identifiers before any patient interaction needs to continue post-programme and be promoted to more senior staff.
- The introduction of bedside label printers to ensure labelling of blood samples in the presence of the patient immediately after performing phlebotomy is highly desirable. If bedside label printers are not available bottles must be hand-labelled in the presence of the patient with at least two patient identifiers.
- A strong culture of safety needs to be promoted in CUH so that healthcare practitioners avoid adapting unsafe practices that can lead to error for the sake of time and patient safety is foremost at all times – even in the most routine of procedures.
- An appreciation of the consequences of WBIT should be promoted by senior management.
- The laboratory efforts to combat WBIT will not succeed without parallel effort on the wards and other clinical areas when the problem begins.

Comment on key recommendations
Positive patient identification is a critical step in the avoidance of blood sample mislabeling. It requires two patient identifiers to complete. All healthcare professionals must be trained at undergraduate and postgraduate level on how to perform this task effectively before any interaction with a patient, even in cases where the patient is well known.

This report describes the development and implementation of a PBP training programme in phlebotomy which has demonstrated a significant reduction in pre-analytical blood sampling errors. PBP training in phlebotomy is recommended for all doctors in training at the commencement of employment in the hospital to improve their awareness of the importance of pre-analytical errors, most critically WBIT and to ensure the process

recommended by the metric is followed in the working environment. The metric which has been developed could be adapted to develop similar PBP training in other hospitals.

This report recommends the introduction of bedside label printers on all wards to improve the efficiency and safety of collecting blood samples. This would ensure the critical step of labeling the sample while in the presence of the patient. This measure could reduce WBITs and improve the efficiency and quality of phlebotomy.

If bedside label printers are not available, then the bottle must be hand labelled with at least 2 patient identifiers while in the presence of the patient. When the label is printed after taking the blood sample, health care practitioners must ensure the name on the sample matches the label that is affixed to the bottle.

A culture of safety must be promoted in our hospitals, so that senior colleagues encourage other healthcare practitioners to adapt safety measures into their practice. Healthcare practitioners must be discouraged from adapting unsafe practices to save time and improve productivity and realise that errors have serious consequences and lead to greater inefficiencies overall.

Appendix A: Development of the PBP training programme in phlebotomy

This study aimed to understand the clinical environment the healthcare practitioners are working within when collecting blood samples from patients at CUH and how best to equip newly qualified doctors with the knowledge and skills to adapt their work to the challenges posed by the system within they operate.
The PBP training programme in phlebotomy was designed according to the methodology of Gallagher et al [63]. This was comprised of procedure characterisation, metric stress testing, definition verification and reliability, a modified Delphi meeting, construct validity and

setting of the proficiency benchmark. Once the metric tool had been developed the PBP training could be developed based on the metric.

Procedure characterisation

Key stakeholders met with the research team to discuss the current process of phlebotomy at CUH including junior and senior doctors in training, consultants, nursing, phlebotomy, laboratory and IT staff. Current errors detected in the laboratory were discussed, barriers to efficiently performing bloods in the wards were revealed by doctors including poor positive patient identification techniques, pre-printing labels, poor access to functioning computers and label printers. The doctor's views on WBIT events was explored. Following the discussions, the group developed the metric to define each of the steps involved in collecting blood samples. As per the model developed by Shorrock [107] the meetings provided a clear picture of the "work as prescribed' by hospital management as defined by the standard operating procedure and the "work as done" by the doctors in training (Figure1).

Metric stress testing, definition verification and reliability

The metrics which were produced in previous meetings were stress tested and discussed among an expert group to decide on the correct order, the clearest wording to avoid ambiguity, and to ensure critical errors were identified. This involved watching a video of one of the doctors in the hospital performing phlebotomy in real time, recorded using a go-pro camera.

Modified Delphi meeting

This was held to assess the face and content validity of the metric. Each step of the metric was voted on to ensure that each member of the Delphi agreed that the step was correct and clear in its wording. Modifications to the metric which occurred at the Delphi meeting included 3 steps deleted, 13 steps added, 38 changes in the wording of existing metrics and 6 modifications in the order of the metric. The final metric instrument consisted of 11 procedure phases and 77 procedure steps which start from the instruction to take bloods and are completed with the dispatch of the sample(s) to the laboratory.

Construct Validity

To establish construct validity a group of 6 experts (healthcare practitioners from phlebotomy, nursing and medical specialities) were compared in their performance of phlebotomy to a group of 5 novices (intern doctors in the hospital who had commenced work within the past year). The participants were asked to perform the task of performing phlebotomy wearing a go-pro camera to observe the process from the instruction to take blood to the dispatch of bloods to the laboratory. The videos were reviewed using the

phlebotomy metric and scored independently by two reviewers. The mean inter-rater reliability was 0.91 (min 0.83, max 0.95). The expert group completed more steps of the procedure (72 Vs 69), made 46% fewer errors (19 vs 13, p = 0.014) and had 300% fewer critical errors (1 Vs 4, p = 0.002) than the novice group.

Proficiency benchmark

A proficiency benchmark was decided at a meeting between the experts. The experts had a mean of 13 errors during video recording and had completed 69 steps at least. It was decided that to reach proficiency the training programme would require the trainees to perform phlebotomy according to the metric with at least 69 steps completed and no more than 13 errors. Given the importance of avoiding any critical errors it was decided that no critical errors should be allowed for the trainees to reach proficiency.

Conclusion

A reliable and validated metric scoring system has been developed to train healthcare practitioners to perform phlebotomy to a proficient standard.

Appendix B: WBIT in General Practice

This report does not investigate the occurrence of WBIT events in primary care, however, in 2017 there were 33 WBITs recorded in the haematology laboratory and 2 WBITS recorded in the transfusion laboratory at CUH which had been taken in general practice in the Cork and Kerry region.

Example of a reference event in general practice October 2019
The laboratory phoned a GP practice to inform them of a patient's results, however when the patient details were confirmed to the secretary, it became apparent that the patient had not attended the surgery for a blood test. It was noted that the form and bottles had incorrect patient details. The surgery had two patients with the same name and details had been taken from the incorrect person and placed on the form and bottles. A WBIT event was identified.

The process of performing blood samples in general practice differs from the hospital. The patient's electronic record is usually available in front of the general practitioner or practice nurse while performing the blood test and a label printer prints the label. Ideally the label printer is available in the consultation room. Transfusion samples are hand labelled as per hospital policy.
Issues which increase the chances of a WBIT in General Practice include the following:

- If the secretary who enters the patient details in the electronic appointment system, enters the incorrect patient with the same name. When the patient arrives in the surgery the receptionist may not confirm the patient identity by checking the date of

birth or address. If the GP does not notice the incorrect details after calling the patient from the waiting room, then it is possible to print the incorrect label if positive patient identification does not take place with two identifiers.

- If the GP calls the patient from the waiting room but the incorrect patient enters, and the name is not clarified later in the consultation (this is more likely with patients whose first language is not English).
- If a family undergoes a joint consultation and the patient details are mistakenly mixed up.
- If the consultation is interrupted by a telephone consultation and the incorrect patient chart is left open on the computer.
- If the bottles are not labelled as a continuous process while the patient is present in the room and the samples are then confused with another patient.

Research focusing on WBIT events in general practice is lacking. Increased awareness of the risk of WBIT and how to avoid this patient safety issue is important among general practitioners to reduce the incidence of WBIT.

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