Preventing Retained Central Venous Catheter Guidewires

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Doctor of Medicine

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Declaration

This thesis is the result of my own work and includes nothing which is the outcome of work done in collaboration except as declared in the Preface and specified in the text. I further state that no substantial part of my thesis has already been submitted, or, is being concurrently submitted for any such degree, diploma or other qualification at the University of Cambridge or any other University or similar institution except as declared in the Preface and specified in the text. This dissertation does not exceed the prescribed word limit set by the Clinical Medicine and Clinical Veterinary Medicine Degree Committee of 60,000 words excluding references, figures, tables, front matter, and appendices.

Maryanne Mariyaselvam
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Abstract

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Title: Preventing Retained Central Venous Catheter Guidewires

Whole central venous catheter (CVC) guidewire retention is an iatrogenic error, with an incidence of 1:3,167, a morbidity of 4-53%, mortality of 4-6% and is a never event. Since 2011, health policy has mandated that all hospitals must implement national safety guidance to prevent this error, emphasising that the never event will be prevented if the guidance has been introduced. Despite this, the error continues to occur, and the reported frequency is rising. The aim of this thesis was to identify a novel approach to prevent this error occurring.

A literature search, an analysis of ten years of CVC guidewire retention events nationally, and interviews with ten clinicians who had made the error were conducted. Guidewire retention was found to be an omission error, occurring due to distraction or interruption at a ‘critical point’ in the CVC procedure. Current safety mechanisms were mostly ineffective, and none were 100% effective. Strategies were operator focused interventions and performed after the error had occurred when correction may be difficult. An intraprocedural systems solution that prevents over-insertion or forces early recognition was required. Several solutions were developed and trialled. Finally, the locked procedure pack was deemed the best solution, due to ease of use and implementation, and low cost.

A randomised controlled forced error simulation study was used to assess efficacy of the locked procedure pack and prevented CVC guidewire retention in 10/10 versus 2/10 with standard practice (p < 0.001). The locked procedure pack was developed into a clinical product and renamed ‘WireSafe’. When introduced into clinical practice, there were no demonstrable negatives compared to standard practice on procedure duration (10% non-inferior margin, p = 0.44), with a significant improvement in sharps safety (100% WireSafe versus 47% standard practice, p = 0.0008) and wide staff acceptability of the device in terms of preventing guidewire retention and improving sharps safety (20/20). Finally, a novel ‘suck out’ suction technique was developed to aid guidewire retrieval. No difference in retrieval techniques were found when the guidewire was retained above skin level, however the ‘suck out’ technique was significantly better when the guidewire was retained below skin level in 9/10 versus 0/10 in withdrawal and 1/10 in clamp and withdrawal (p < 0.001).
The WireSafe prevents CVC guidewire retention, protects clinicians from making this error and protects patients from the morbidity and mortality associated with this error. Further work is still required to evaluate the effectiveness of the solution through large scale clinical studies.
Acknowledgements

Firstly, I would like to thank Dr Arun Gupta and Professor David Menon for the opportunity to undertake this thesis. Without their support, guidance, and patience this work would not have been completed. I would like to thank my college tutor Dr Jane Greatorex for her kindness, mentorship, and support both academically and personally throughout my time at Cambridge.

I would like to thank Dr Peter Young for his mentorship and guidance throughout this thesis and all stages of the innovation process. Thank you also to Professor Kenneth Catchpole for his guidance in human factors and the practical application of this to medicine.

I would like to thank Robert and Jane Gaines-Cooper of Venner Medical Technologies for taking a chance on the WireSafe. With their support, the WireSafe is a regulatory approved medical device, being used in clinical practice and helping to achieve my goal of preventing this error. I would also like to thank Health Enterprise East for their support in developing the coloured wires and funding the curly wire’s development and initial commercialisation process.

I would like to thank Professor Sir Bruce Keogh for the NHS Innovation Accelerator Programme and Professor Tony Young for the Clinical Entrepreneur Programme. Being a fellow on both programmes has taught me the invaluable lessons required for developing and implementing an innovation into clinical practice. Their personal mentorship and kindness have given me great support in pursuing my work.

A heartfelt thank you to the interviewees who so kindly gave up their time to speak to me and helped me to understand the impact this error has on the clinician. Your personal experiences both good and bad have stayed with me and driven me to keep going. My thanks also to all that helped with the studies in this thesis for giving your time so generously.

I am grateful to the Eastern Academic Health Science Network who have made my time in research possible.

Finally, thank you to my family and dear friends for their love and support in helping me to complete this work.
Contributions

Chapter 1

The work in this chapter was performed by myself.

Chapter 2

Access to the NRLS database was formally requested by myself and my supervisors and provided by NHS England. The NRLS data was collated, anonymised, and analysed by myself and H. Young (medical student) independently and adjudicated by P. Young (anaesthetic and critical care consultant). The results were discussed with and reviewed by my supervisors. The results presented in this study are published in the paper “Central Venous Catheter Guidewire Retention: Lessons from England’s Never Event Database” which is available in the appendices. The interview questions were designed by myself with Professor K. Catchpole (human factors practitioner and cognitive scientist). The interviews, transcription and data analysis were conducted by myself, and the results were discussed with and reviewed by my supervisors. Unless stated, all other work was performed by myself.

Chapter 3

Four different types of solutions were invented, and the details of how these solutions were designed, from idea to prototyping to bench testing, are described below. The inventive step, that is, the idea alone of how to solve the problem, was by the following: Solution one: adding an attachment to the guidewire was invented by Dr A. Gupta, solution two: colouring the guidewire was invented jointly by myself and P. Young, solution four: the conformational change guidewire was invented by P. Young and solution four: the locked procedure pack was invented by P. Young. The development work which includes: the schematic drawings of these ideas, research, prototype creation and development, discussion with manufacturing companies and bench testing, were performed for each solution as follows. Solution one: the schematic drawings, research, prototype creation and development and bench testing were performed by myself. Solution two: the schematic
drawings, research, prototype creation and development and bench testing were performed by myself. Solution four: the schematic drawings and research were performed by myself, and the initial prototype creation and development were performed by myself and P. Young. For further prototype testing, two curly guidewire prototypes were manufactured by Shannon Microcoil and purchased for bench testing with the assistance of Health Enterprise East (an NHS advisory and innovation management service). Bench testing of the curly guidewires was performed by myself and P. Young. Solution four: the schematic drawings and research were performed by myself. The initial prototype creation, development and bench testing were performed by myself and P. Young. The CAD drawings and the 3D printing of prototypes were performed by Mr C. Rabicano, an engineering lecturer at the College of West Anglia, with input from myself and P. Young. Bench testing of the 3D printed prototypes was performed by myself and P. Young. The locked procedure pack was manufactured by Venner Medical International, with some guidance from myself and P. Young. Unless stated, all other work in this chapter was performed by myself.

Chapter 4

The forced error simulation study was designed by myself and P. Young. Six people were required to conduct the forced error simulation study, which was performed by myself and five others. In the simulation study, the roles were as follows: myself, observing the simulation to ensure it was conducted according to the script, A. Livensy (FY2) briefed the participant with the scenario and their objectives before entering the simulation and asked the participant the questions during the simulation, S. Sinha (Staff grade) recruited participants to the study and consented them, H. Young (Medical student) played the role of assistant, J. Patel (Medical student) recorded the data during the simulation study and P. Young, recruited participants to the study and consented them. The results were analysed by myself. The data in this study is published in the paper “Preventing Retained Central Venous Catheter Guidewires: A Randomized Controlled Simulation Study Using a Human Factors Approach” and is available in the appendices. The introduction to clinical practice study was designed by myself and P. Young. The investigator available to ‘troubleshoot’ any issues regarding the WireSafe was P. Young. The observations in the pilot study were performed by S. Samad, T. Swan and J. Gooch (Anaesthetic trainee doctors). The structured survey was conducted by D. Pearson and R. Heij (Anaesthetic and ICU Consultants). The results
were analysed by myself with P. Young. The non-inferiority statistical calculation, the probability calculation for a retained CVC guidewire never event occurring and the power analysis for future studies were performed by E. Young (Statistician, University of Cambridge). Data from this study is published in the paper “WireSafe™ – A pilot study of a novel safety engineered device designed to prevent guidewire retention and reduce sharps injuries during central venous catheter insertion” and is available in the appendices. Finally, the benchtop study was designed by myself and P. Young. The model was calibrated by P. Young, A. Sawyer (Anaesthetic Trainee) and J. Richardson (ICU Staff Grade). The study was conducted by myself with A. Sawyer and J. Richardson. The data in this study is published in the paper “A bedside rescue method for retrieving retained guidewires: The ‘Suck Out’ technique” and is available in the appendices. A critical appraisal of the statistics used in the studies presented in Chapter four was performed by E. Young, (Appendix B). Unless stated, all other work was performed by myself.

Chapter 5

The work in this chapter was performed by myself.
Conflicts of interest

I have both intellectual and financial conflicts of interest. I am a joint patent holder (an applicant) with Dr Young and Venner Medical International for the ‘Safety Apparatus’ (Locked Procedure Box, WireSafe) patent. As such I have a one third ownership of this patent and I may be entitled to receive royalties for the sale of the product. To date, I have received no payment from Venner Medical International, either from consultancy, royalties, or expenses.

I have received funding from the Eastern Academic Health Sciences Network to undertake this thesis and develop some of the innovations described in this thesis.

Health Enterprise East has funded the development of some of the innovations described in this thesis (coloured and curly wire). Kimal PLC donated the guidewire and CVC equipment used to develop and test the ideas developed in this thesis.

I am a fellow of the NHS Clinical Entrepreneur Programme, funded by NHS England and designed to support the development and commercialisation of novel innovations by clinicians working in the NHS.

I was a fellow of the NHS Innovation Accelerator Programme and now am an Alumni. This programme was funded by NHS England, The Academic Health Sciences Network and the Health Foundation and was designed to support innovators to implement novel innovations into clinical practice widely across the NHS. I have received funding through this programme to implement my innovations across the NHS.

I have also invented and own (jointly) four other novel innovations, which are not described in this thesis and are unrelated to preventing retained guidewires. Some of these are owned by the NHS under a profit share arrangement and some have been assigned to medical companies for development.
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XVIII
List of Abbreviations

ANP Advanced Nurse Practitioner
CVC Central venous catheter
ICU Intensive care unit
IR Interventional Radiology
NatSSIPs National Safety Standards for Invasive Procedures
NHS National Health Service
NHSE&I National Health Service England and improvement
NRLS National Reporting and Learning System
ODP Operating Department Practitioner
RCA Root cause analysis
StEIS Strategic Executive Information System
UK United Kingdom
US United States
VHA Veterans’ Health Administration
VMI Venner Medical International
WHO World Health Organisation
“We cannot change the human condition, but we can change the conditions under which humans work.”

James Reason
CHAPTER 1

INTRODUCTION

This chapter discusses the error of whole retained central venous catheter guidewires, why this error should be prevented, the current prevention strategies in healthcare policy and why a different strategy for preventing this error may now be required. The principles of error prevention from the high reliability industries and how these may be used to develop a novel prevention strategy for this error are then described. Finally, the chapter concludes with the aims of this thesis. This thesis concentrates solely on whole guidewire retention only. It does not include fractured retained guidewires as this error occurs via a different mechanism; therefore, it is not discussed in this work.

1.1 An overview of central venous catheter guidewire retention

1.1.1 What is a retained central venous catheter guidewire?

Central venous catheters (CVC) are used internationally for monitoring central venous pressures, administering medications which cannot be given via peripheral catheters and for haemodialysis or haemofiltration. More than five million CVCs are inserted annually in the United States (US).

The standard technique for CVC insertion utilises the Seldinger method, which involves: vein puncture with a needle, inserting a guidewire into the needle (so that the guidewire is partially inside the vein), removing the needle over the guidewire, passing a catheter over the guidewire and inserting it into the vein, removing the guidewire, securing the catheter in place and applying a dressing. Finally, a check radiograph is performed to confirm the correct positioning of the catheter.

A complication of this technique is whole guidewire retention, where the entire guidewire inappropriately remains inside the patient after the catheter insertion procedure is completed. This is a ‘retained foreign object post procedure’. When guidewire retention
occurs, it can migrate from the catheter lumen into the patient’s vasculature over time. Retained guidewires have been discovered in the superior vena cava, heart, inferior vena cava, femoral and iliac veins, and even protruding transcutaneously at the patient’s neck, thorax or foot.\textsuperscript{4–8} If guidewire retention occurs, it must be removed urgently,\textsuperscript{9,10} as migration of the guidewire from the catheter lumen into the patient’s vasculature and associated complications can occur at any time.\textsuperscript{7,11,12}

1.1.2 Incidence of CVC guidewire retention

The incidence of whole CVC guidewire retention is difficult to estimate as only six papers in the literature provide sufficient detail in their datasets to calculate the incidence in their institutions. This is summarised below in table 1.1.

Table 1.1: The reported weighted mean incidence of guidewire retention based on six papers.

<table>
<thead>
<tr>
<th>Study</th>
<th>No. of study sites</th>
<th>Study dates</th>
<th>Total CVC inserted over the study period</th>
<th>No. of guidewire retentions</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vannucci (2013)</td>
<td>1</td>
<td>Jan 2006 - Dec 2011 (6 years)</td>
<td>13163</td>
<td>4</td>
<td>1:3291</td>
</tr>
<tr>
<td>Omar (2013)</td>
<td>1</td>
<td>Jan 2011 - Feb 2013 (26 months)</td>
<td>15564</td>
<td>3</td>
<td>1:4295</td>
</tr>
<tr>
<td>Peh (2016)</td>
<td>1</td>
<td>Dec 2011 - Feb 2012 (3 months)</td>
<td>120</td>
<td>3</td>
<td>1:40</td>
</tr>
<tr>
<td>Odendaal (2017)</td>
<td>1</td>
<td>Jan 2010 - Dec 2013 (3 years)</td>
<td>1105</td>
<td>1</td>
<td>1:1015</td>
</tr>
<tr>
<td>Bell (2020)</td>
<td>2</td>
<td>Nov 2012 - Jul 2013 (9 months)</td>
<td>1179</td>
<td>1</td>
<td>1:1179</td>
</tr>
<tr>
<td><strong>Weighted mean incidence</strong></td>
<td></td>
<td></td>
<td><strong>44345</strong></td>
<td><strong>14</strong></td>
<td><strong>1:3167</strong></td>
</tr>
</tbody>
</table>

Between January 1992 to December 1999 (eight years), Bessoud et al. reported that 13,214 CVCs were inserted in their institution, and during this period, there were two cases of guidewire retention which required their interventional radiology (IR) expertise for removal, giving an incidence of 1:6,607.\textsuperscript{13} Importantly, this data is from the IR department and would not include any cases of guidewire retention that were resolved at the bedside. The study by Vannucci et al. reported an incidence of 1:3,291 in their institution, with 13,163 guidewire insertions over four years, between January 2006 to December 2011, and four
retained CVC guidewire incidents occurring during this period. Omar et al. reported that between January 2011 and February 2013 (two years and two months), 15,564 CVCs were inserted in their institution and stated that four whole retained guidewires occurred during this time. Therefore, the incidence is 1:3,221. However, they stated that one retention should be excluded because the error occurred at another institution and was recognised by their department after the patient was transferred to their hospital. With this case excluded, the incidence is 1:4,295. Conversely, the opposite may also be possible where guidewire retention had occurred in this institution, and the patient subsequently transferred to another hospital, and this would not be reported in their study; however, as the authors have excluded this case, it has also been excluded from this analysis. Peh et al. reported that between December 2011 and February 2012 (three months), 120 CVCs inserted were in their institution, and three cases of guidewire retention occurred during this period, giving an incidence of 1:40. Odendaal et al. reported that 1,105 CVCs were inserted in their institution over three years, between January 2010 and December 2013, and reported one guidewire retention occurred during this period, giving an incidence of 1:1,105. Finally Bell et al. stated that between November 2012 and July 2013 (nine months), 1179 CVCs were inserted in their institution and reported one whole retained guidewire occurred during this time, giving an incidence of 1:1179. One could argue that the data from Peh et al. should be excluded as there was a cluster of these errors in a short period and this may be due to chance or a lapse in training with a particular cohort of staff which may unfairly distort the results. However, all these studies have an element of selection bias; they report incidents or clusters of incidents over a non-standardised period. Therefore, all six studies were included in this analysis. Thus, the weighted mean reported incidence of guidewire retention is 1:3,167 (0.03%).

This equates to four whole guidewires retained a day in the US, based on annual insertion figures of five million per year from M‘Gee et al. (2003). M‘Gee et al. referenced this figure from Raad (1998). More than 20 years later, we must assume, given the increase in the number of intensive care beds, the volume of elective work, the number of people accessing healthcare and the advances in medicine, that annual insertion figures must be substantially higher. However, it has not been possible to find recent figures for annual CVC insertion in either the United Kingdom (UK) or the US in the literature. Given the few studies reporting their incidence of error and the difficulty in determining the denominator, the true
incidence of guidewire retention is difficult to ascertain. The incidence of 1:3,167 is the best one to elucidate from the available data.

### 1.1.3 Morbidity and mortality with CVC guidewire retention

Whole guidewire retention and embolisation can cause complications such as arrhythmia, thrombosis, cardiac perforation and tamponade. However, given the reported incidence, the morbidity and mortality are difficult to determine.

Only four studies report the morbidity of guidewire retention. A systematic analysis of 76 case reports determined that 14% developed life threatening complications, including massive pulmonary embolism, gall bladder perforation causing biliary peritonitis and vertebral artery thrombosis resulting in a stroke. A review of 42 incidents reported to the Illinois (US) patient safety reporting system determined that 31% required additional interventions (details not provided) and/or an increased length of hospital stay. Dushane et al. analysed 30 cases of guidewire retention reported to the Veterans Health Administration (VHA) National Centre for Patient Safety database and found that 16 resulted in harm to the patient (53%). Finally, the article by Vannucci et al. includes personal correspondence detailing Closed Claims data in 2011 of 25 cases of guidewire retention, of which one of these resulted in permanent disabling injury giving a morbidity of 4%. Thus, the morbidity for guidewire retention in the literature is between 4% and 53%.

Four studies report a mortality of up to 20% for CVC guidewire retention, and this figure is higher than expected. These papers reference historical papers, which also report the same mortality. However, analysing these references, it appears this figure is based on a single paper published in 1984 by Heberer et al. in Germany. On translation, Heberer et al. describe the complications of CVC in a case series of 149 insertions, where one was a case of embolism of a catheter fragment. In the discussion, the authors state that mortality associated with catheter embolisation is 20%, but this references another study by Richardson et al. (1974). Therefore, the 20% mortality figure is for catheter fragment and not guidewire embolisation and has been misquoted and then subsequently referenced by other authors. Only two papers in the literature discuss the mortality for retained CVC guidewires. Of the 30 cases of guidewire retention reported to the VHA patient safety database analysed by Dushane et al., there were two patient deaths attributed to guidewire retention, giving an incidence of 6%. The Closed Claims data in the article by Vannucci et al. describes one death in the 25 cases of guidewire retention, giving an incidence of 4%.
Hence, a mortality of between 4-6% for retained CVC guidewires is likely to be more accurate and the best that can be determined from the literature.

1.2 Why should this error be prevented?

Guidewire retention is an iatrogenic medical error and is an unintended or unexpected event that occurs during the provision of healthcare and has an associated risk of morbidity and mortality.

Guidewire retention is also considered a ‘never event’ in the US and the UK.\textsuperscript{25,26} Never events are high impact episodes of adverse patient care and can be comparable to catastrophic incidents in the transport or energy industry. Never Events are deemed as errors that should never happen in medicine. The National Health Service (NHS) England and Improvement describe these errors as:

“\textit{wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers.}”\textsuperscript{27}

If a never event occurs, it must be investigated under the serious incident framework and reported to the National Health Service (NHS) England and Improvement (NHSE&I).\textsuperscript{27} Given that CVC guidewire retention is a never event and that it should be ‘wholly preventable’, the consequences of this error are far reaching, impacting not just the patient but also the clinician, the hospital and the healthcare system - all become victims of this error.

The patient is the first victim of this iatrogenic error. The morbidity and mortality for guidewire retention are 4-53% and 4-6%, respectively. However, even if the patient does not experience harm directly related to the retained guidewire, they are still subjected to the risks of further procedures to correct the error to remove the guidewire and the morbidity of the initial underlying disease necessitating the CVC, which may not have been resolved or may have worsened due to the error occurring. Further procedures and longer inpatient episodes also increase the patient's risk of morbidity and mortality.\textsuperscript{28} There is also the potential for long terms effects post hospital discharge in terms of the ability to resume employment or living with a lifelong disease burden. Whether harm occurs or not, the negative experience of a medical error will have some psychological consequences for patients, their families and/or dependents.\textsuperscript{29}
The second victim of this error is the clinician that makes the mistake. When an error such as guidewire retention occurs, the focus is predominantly on the clinician who performed the procedure. Most healthcare workers enter the profession with a desire to care for patients; they do not choose to make mistakes. Wu states that whilst the “patient is the first and obvious victim of the mistake, doctors are wounded by the same error: they are the second victims”, and they also need help. Wu describes the clinician's experience after discovering a mistake as a “sickening realisation”, where the clinician themselves question their competence, dread the prospect of punishment, litigation or patient upset but also colleagues or senior supervisor’s disapproval, or worry about the future effects on their career. Wu also explains that without appropriate support mechanisms, clinicians may respond to their own mistakes with “anger, projection of blame on the patient or other colleagues… and in the long run, lose their nerve, burn out or seek solace in alcohol or drugs.” These reactions are likely perpetuated by the high impact of a never event error and potentially a ‘blame the individual’ culture in healthcare. Whilst we move from a blame culture, and NHSE&I promote a just culture, the clinicians who make mistakes still need support and failure to do so runs the risk of the system losing these individuals from the workforce.

The third and fourth victims of this error of these errors are the hospital and the healthcare system, respectively. The impact on both is similar. The costs to the hospital or healthcare system of preventable errors can be substantial. While there is no longer financial penalisation for the individual healthcare provider in the UK, the NHS must still pay for additional care and/or litigation costs. Additionally, there are costs regarding the reputation of the hospital and healthcare system, and whilst this is difficult to measure, its importance should not be under-valued. The recurrence of high profile preventable never event errors can damage the reputation of the hospital or healthcare system and the public’s faith in the quality and safety of healthcare services which they access and pay for through taxation.

In healthcare policy, guidewire retention is described as a preventable error. Given the high impact nature of these errors and the substantial impact that these errors can have on the patient, clinician, hospital, and healthcare system, the costs involved in rectifying the error and the potential litigation costs, one must understand why this error occurs and how it can be prevented.
1.3 Healthcare policy in NHS England

In 2011, the Department of Health published a never events framework and retained CVC guidewires were classified as a retained foreign object never event.\textsuperscript{34} As part of this framework, guidance for NHS hospitals was provided, with the requirement to implement the guidance to prevent these errors from occurring.\textsuperscript{34} The policy was updated in 2012 and this time included a guidance document, a signal document, specifically relating to retained CVC guidewires:\textsuperscript{26} Risk of harm from retained guidewires following central venous access (2011)\textsuperscript{35} which recommended that prevention of this error would be through:

a. A standardised process for guidewire management during CVC insertion:
   a. Two person process (operator and observer)
   b. Visual confirmation of guidewire removal by both persons
   c. Verbal confirmation of guidewire removal by both persons
   d. Documentary confirmation of guidewire removal by both persons

b. Training and education to emphasise appropriate control of guidewires

c. Involvement of manufacturers in developing future standard solutions to prevent guidewire retention.\textsuperscript{35}

These national recommendations were based on a single NHS hospital’s investigation and analysis of the error.\textsuperscript{35} The never events policy has been updated several times, with the latest guidance released in January 2018 (updated in February 2021).\textsuperscript{3,26,34,36–40} The current national safety requirements pertaining to guidewire retention are:\textsuperscript{3}

- National safety standards for invasive procedures (NatSSIPs) (2015)
- Patient Safety Alert – Supporting the introduction of NatSSIPs (2015)

These documents comprise checklists, standardisation, and improvements in safety culture.\textsuperscript{41,42} In these documents, it is emphasised that the never event will be prevented if the guidance and safety recommendations have been introduced, with the mandate that all healthcare providers must introduce them.\textsuperscript{3} Given available guidance and the mandate that all trusts must implement the national safety requirements, one could assume that guidewire retention is a never event error that no longer occurs. However, this is not the case. In England, all healthcare provider organisations must report serious adverse and never events to the Strategic Executive Information System (StEIS) and all patient safety incidents
(including never events) to the National Reporting and Learning System (NRLS). The incident, how the error occurred, and the preventative measures introduced based on the healthcare provider's root cause analysis (RCA) investigation must be reported.\textsuperscript{27,43} This information is published monthly anonymously by NHSE&I,\textsuperscript{44} and Figure 1.1 shows the reported frequency of guidewire retentions for CVC insertion between 2012 – 2022.\textsuperscript{45–54} NHSE&I state that “it is not possible to compare the number of never events reported” over subsequent years because of the revisions in the framework and the never events list over the years.\textsuperscript{44} However, the guidance specifically for guidewire retention has remained broadly the same. In 2015, the National Safety Standards for Invasive Procedures (NatSSIPs)\textsuperscript{42} was introduced to reduce the national incidents of surgical never events, which includes guidewire retention. Despite the availability of this guidance for nearly ten years and the mandate that hospitals must implement national safety guidance, Figure 1.1 shows that this has not led to a substantial decline in these errors.

![Figure 1.1: The reported frequency of CVC guidewire retention incidents reported to NHSE&I between 2012-2022 with the timeline of when national guidance was published to prevent this error. Data was collated from the never events published reports from NHSE&I over this period\textsuperscript{45–54} demonstrating that the reported frequency is increasing.](image-url)
Whilst there is variation from year to year in the number of incidents of CVC guidewire retentions, the trend appears to be rising. It could be argued, and it is highly likely, that the incidence of these errors has historically always been high. Therefore, the ‘rise’ is artificial, explained by an improved reporting culture and an increase in the volume of clinical work. However, if there is some beneficial impact of the mandated introduction and implementation of these ‘strong barriers,’ one would expect at least a plateau or decline in the trend line (Figure 1.1). This poses the question that if hospitals have implemented the strong barriers documented in national guidance to prevent these errors from occurring, why do they still occur, why is there not a substantial reduction in the numbers of these never event errors, and why are these same errors seen not only in England but internationally across many healthcare systems?

Moppett and Moppett (2016) analysed national surgical never event data between 2011 and 2013 (data from NHS England and surveys from Trusts) and demonstrated that nationally, never events are rare and random incidents. Rare in that the authors calculated the risk of a surgical never event as 1:16,423 procedures and a retained foreign object as 1:28,605 and determined that these are comparable to healthcare systems internationally. The authors also stated that the probability of a surgical never event occurring in a median sized trust (~24,000 operations or 17 theatres) over three years is 98%, which indicates an inevitability of these events occurring in the healthcare system. Whilst one knows these errors are inevitable, one cannot predict when or in which hospitals they will occur. Thus, they can occur at any time, in any organisation, and importantly, the lack of a never event occurring in a hospital is no assurance that the error will not occur at some point in the future.

A robust safety initiative must be implemented and adhered to across the entire healthcare system to prevent a never event error. However, the ‘strong barriers’ suggested by NHSE&I have not prevented this error (Figure 1.1). This may be because these checks depend on the operator preventing the error. Therefore, alternative strategies, such as those seen in the high reliability industries, may be required to develop a robust safety initiative to prevent this error.
1.4 Lessons from other industries

The energy and transport industries are commonly referred to as high reliability industries, and this is because of their safety reputation despite high risk working environments.\textsuperscript{56} Compared with healthcare, they have high productivity and efficiency with a low error rate.\textsuperscript{56} For example, in terms of the airline industry, despite rapid growth in the numbers of airlines, passengers and competition for cheaper fares, flying is a safe form of travel, as seen by the decline in fatal accidents and continuous safety improvements.\textsuperscript{57} Currently, the risk of a fatal flying accident is one in 29 million (in the US or Europe).\textsuperscript{57} In the high reliability industries, the advances are in part due to technological and scientific advancements in design and engineering but also predominantly due to the integration of the well established discipline of human factors in everyday working practice.

The study of human factors is the understanding of how the human operator performs and interacts, both in terms of their abilities and their limitations, with other staff, the technical equipment and the working environment\textsuperscript{58,59} and uses this knowledge to “design operating systems that are safe, effective and efficient”.\textsuperscript{60} This may be through equipment, training, policies or procedures. The discipline is based on the principle that whether the operator is a novice, in training, or an expert, mistakes and errors are inevitable and should be expected; this is human nature.\textsuperscript{60} With this fundamental understanding as the starting point, the “focus is shifted from operator blame”\textsuperscript{59} and reliance on the operator to prevent the error to engineers proactively anticipating risk, analysing where errors are likely to occur when the human interacts within the working environment (including other staff and technical equipment) and then optimises these interactions by building in safety mechanisms to prevent error, maximising safety and efficiency.\textsuperscript{59,60} This is done in many ways: firstly, there is an improvement in safety culture, training to work effectively during routine and emergency procedures, a learning culture and a just culture, where mistakes and errors are reported without fear. Secondly, regarding procedures, this is done through checklists, protocols, or standardisation and, thirdly, technology.

For specific procedures, checklists, protocols or standardisation are used to ensure tasks are completed safely, ensuring that the lapses or slips which cause errors to occur are minimised.\textsuperscript{61} These checks are designed to be easy to follow, rather than over complicated lists, supporting staff to do their job. For example, in an aeroplane, there are two checklists: the normal checklist for routine situations and the non-normal checklist for malfunctions or
emergencies. The normal checklist is a list of checks printed on a single side of the card, with each section between five and ten items long and is designed in a minimalist fashion for the pilots to ensure that all of the tasks have been completed. This standard checklist is initially created by the aeroplane manufacturer. It is then modified by the airlines according to their operating procedures or training and then given to aviation staff. Non-normal checklists are hundreds of complex checklists bound in a quick reference handbook, which guides the pilot through all possible error situations or malfunctions and is separated into easy access chapters and within immediate reach of the pilots in case of emergencies. This differs from checklists for CVC insertion in the literature. Where in one example, the authors suggested a 50-point checklist for CVC insertion, with one of these being removing the guidewire. Importantly, staff also undergo human factors training and understand the importance of correctly following the checklists or protocols. Pilots are disciplined to always use the checklist, even if they are entirely confident of their actions, to the extent that “in the airline environment, this discipline is taken for granted.”

When new equipment or operating systems are designed, they are evaluated through usability testing to determine their effectiveness and ease of use in supporting the operator to complete their task. The equipment is ergonomically designed to work for the user rather than the user needing to adapt their working practice to suit the equipment. It is designed to require minimal instructions or training for an operator to use them. For example, the levers used for the airline flaps, spoiler and landing gears are shaped to give visual and tactile cues of their function to reduce the incidences of using the wrong lever. Equipment is designed to reduce errors; for example, the inbuilt software in the aeroplane cockpit warns and alerts the pilots if it detects that specific statistics are outside of the accepted range or forcing functions, which will not allow the operator to continue a task without recognising an error has occurred and correcting said error. Systems are also designed with fail safes built into the background or failure tolerant systems, in order that a safe environment is maintained for passengers and crew if equipment failures occur. Additionally, when developing new equipment, the demands placed on the operator to perform the task are assessed: the cognitive load, the skills required and the physical demands of task performance. After evaluating the cognitive load, the operators can be given proper training to ensure they can perform tasks correctly, or appropriate staff rotas can be designed to prevent over stretched and tired working staff.
These principles have served the aviation industry well, and medicine has often looked to this industry to incorporate these values and principles. Using these concepts, it may be possible to design a sustainable solution to prevent retained CVC guidewire never events.

1.5 The aims of this thesis

CVC guidewire retention is a never event which has a substantial impact on the patient, operator, hospital, and healthcare system. Whole CVC guidewire retention occurs in 1:3,167 procedures and has a morbidity of 4-53% and mortality of 4-6%. NHSE&I has published guidance and mandated the implementation of these guidance as ‘strong barriers’ to prevent this error. Despite this, data from NHSE&I demonstrates that the reported incidents of CVC guidewire retention are rising. Thus, a new strategy must be developed and evaluated to prevent this error.

Therefore, the aims of this thesis are to:

1. **Further understand the aetiology of retained CVC guidewires to develop a preventative solution to this error.**
   This is discussed in Chapter two, where a literature review was undertaken, an analysis of the NRLS database of CVC guidewire retentions was performed, and interviews with clinicians who had experienced the error of CVC guidewire retention were undertaken to develop a better understanding of the mechanism of the error.

2. **Can a sustainable solution to prevent retained CVC guidewires be developed?**
   Chapter three discusses this question and describes the process of designing an engineered fail safe to prevent this error. Many solutions were developed in this process, and the methodology of the prototyping and testing of each is described, with a final solution chosen for further evaluation.

3. **Can the final solution be evaluated to demonstrate efficacy in preventing error?**
   This question is discussed in Chapter four, where a novel methodology to evaluate the preventative solution is described, and a study simulating the error of retained CVC guidewires is conducted to demonstrate efficacy.
4. If efficacy is demonstrated, can the solution be implemented into clinical practice?

In Chapter four, the real world benefits and limitations of the novel solution are discussed. This is by evaluating the clinical acceptability of the novel solution through a clinical trial of the device. Finally, in a scenario where the guidewire has already migrated down the catheter, a novel guidewire retrieval technique is developed and evaluated in a bench study, which clinicians may use whether or not the novel solution is available.

The thesis concludes with a chapter reviewing these findings and discussing the outcomes of the thesis. That is, whether the strategy used to develop a solution to prevent retained CVC guidewires could be used to prevent other never events and how the efficacy of these safety measures may be evaluated prior to introduction into clinical practice. Finally, the next steps in evaluating the novel solution are discussed.
CHAPTER 2

UNDERSTANDING THE AETIOLOGY OF CVC GUIDEWIRE RETENTION

This chapter comprises three studies performed to understand the aetiology of CVC guidewire retention: a literature review, an analysis of retained CVC guidewire incidents reported to NHS England’s NRLS and interviews with clinicians who have made this error. Publications by Mariyasevilam et al. were excluded from the literature search as the data in these papers are discussed in this thesis. In the interviews, staff discussed the aetiology of the error from their perspective and the personal consequences of making this error and that on their careers and relationships with other staff members. Only the interviewee’s recollection of the aetiology of the error and prevention strategies are reported in this thesis. Whilst the emotional impact on staff is important to understand, it did not directly contribute to developing a prevention strategy and therefore, not included in this thesis.

2.1 Introduction

National safety guidance pertaining to guidewire retention has been published by NHSE&I, with the mandate that all hospitals must implement this guidance to prevent the error. However, despite the availability of this guidance for nearly ten years, there is a rising trend in the reported incidents of retained CVC guidewires. Given these ‘strong barriers’ to prevent this error exists, why does it continue to occur and why is trend of the reported frequency of incidents rising? To understand this, the mechanism of this error must be understood.

To determine the aetiology of this error, three studies were conducted: a literature review, an analysis of retained CVC guidewire incidents reported to NHS England’s NRLS and interviews with clinicians who have made this error. This approach was to provide broad information on the causes and prevention strategies of this error in the literature and within a single healthcare system. Where these incidents would be comparable, given that they have occurred within the same healthcare system with clinicians operating within the same
boundaries. The interviews with clinicians were conducted to ascertain the granular detail of the aetiology of the error and prevention strategies implemented in the institution.

This chapter aimed to determine the mechanism of retained CVC guidewires and, where discussed, evaluate implemented preventative strategies. Once the mechanism of the error is understood and the point in the CVC procedure that the error occurs is determined, then one can understand the type of solution needed and point in the procedure where a potential solution might be most effective at preventing this error.

2.2 The literature review

2.2.1 Introduction

A literature review was conducted to determine the aetiology of whole CVC guidewire retention. The aim was firstly, to determine the causes of this error to inform the development of potential preventative mechanisms. Secondly, given that there are many preventative strategies, and the mechanism of these strategies are different and used at different points in the CVC procedure, the aim was to evaluate the preventative mechanisms discussed in the literature.

2.2.2 Methods

A literature search for whole retained CVC guidewires was conducted using PubMed, Scopus, and Google Scholar search engines (search terms available in Appendix 2.1). Given the infrequency of this error and potentially a low likelihood of authors choosing to publish their institution's errors in the medical literature, these search engines were selected to give a broad representation of the medical literature. Additionally, citations within articles were also reviewed to find other potentially relevant articles, and this was done iteratively until no further articles were found.

Eligibility criteria

In this review, inclusion criteria were:

- Any article describing whole retained CVC guidewires only
- CVC included: internal jugular, subclavian, femoral, and haemofiltration catheters (vascaths and renal)
• All types of articles
• Articles published up to December 2022

Exclusion criteria:
• Non-CVC related retained guidewires (i.e., radiology/cardiac)
• Fractured retained CVC guidewires
• Entrapment or kinking causing guidewire retention
• Non-English publications (both abstract and article unavailable in English)

Data extraction
Data were analysed to determine the causative factors and preventative mechanisms for CVC guidewire retention. The data were grouped into two themes: causative factors and preventative mechanisms, as described by authors in the articles. Data were further subgrouped by identifying recurring causative factors and preventative mechanisms, and these fields were updated and refined as papers were analysed. Data were extracted from articles that met the inclusion criteria and entered into an Apple Numbers spreadsheet (Numbers, Apple, Cupertino, California) using a standardised form. Results were analysed using Apple Numbers.

2.2.3 Results
The search strategy identified 2,758 articles, and a further 16 publications were identified through manual searching. Of these, 108 articles were selected for analysis, which included one literature review (with data up to 2015), one analysis of a state wide reporting system (Illinois, US) and two national reporting systems from the VHA, US and 104 case reports from individual institutions (Figure 2.1). Analysed articles spanned 30 years, between 1992 – 2022. An overview of the 108 articles included in this analysis is available in Appendix 2.2. These publications suggest 27 different causes for whole guidewire retention, where the most common causes reported were inexperience (27), inadequate supervision (25) and distractions (20). Other causes reported included operator inattention (12), human error (1), high workload (7), operator fatigue (8), the operator did not hold onto the guidewire (5), excessive guidewire introduced (1), no assistant (2), poor communication (2), conducting the procedure out of hours (5), emergencies (5), the presence of two CVCs
and hence two guidewires (3), lack of procedural standardisation (2), not adhering to the procedure (2), lack of a checklist (2), no safety count (1), no real time documentation (1), did not examine the catheter correctly (1), no reminders (1), nothing to confirm guidewire removal (1), no ultrasound (1), equipment fault (2), no post procedural check radiograph (1), only reviewed by anaesthetist or surgeon (1) or radiology team did not check the radiograph properly (2). Whilst not described as a cause of the error, seven authors described retention occurring when the guidewire ‘slipped’ into the vein\textsuperscript{21,65–70} and one of these described the guidewire ‘slipped and floated into the catheter.’\textsuperscript{21}

Most authors suggested or recommended mechanisms to prevent guidewire retention, and some reported that these had already been introduced in their institutions.\textsuperscript{14,16} In the 108 studies, there were 44 different recommendations to prevent guidewire retention (Table 2.1), which could be themed into operator based actions, instigation of new checks or reminders, the requirement for additional operators or assistants and system or equipment changes. On average, authors suggested three recommendations (range 0-14). The most common mechanism (44\%, 48/108) to prevent CVC guidewire retention described was ‘ensure the clinician grips the proximal end of the guidewire at all times’, with some publications further stating that “if this rule is followed, the guidewire cannot be lost.”\textsuperscript{71,72}
Other common prevention strategies described were to ensure clinicians follow the protocol (20), appropriate education and training of staff (24), ensure the clinician does not insert the guidewire beyond 18cm (23), ensure active senior supervision at all times with trainee doctors at all time (24), introduce a checklist (24) and the check radiograph should be checked (25).

Table 2.1: Mechanisms of preventing CVC guidewire retention suggested by authors in the literature.

<table>
<thead>
<tr>
<th>Preventative mechanisms suggested by authors</th>
<th>No. of studies suggesting changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operator based</td>
<td></td>
</tr>
<tr>
<td>Increase awareness of the error</td>
<td>18</td>
</tr>
<tr>
<td>Ensure clinicians are strongly vigilant and avoid the error</td>
<td>3</td>
</tr>
<tr>
<td>Ensure clinicians follow protocol</td>
<td>20</td>
</tr>
<tr>
<td>Ensure appropriate education and training of staff</td>
<td>24</td>
</tr>
<tr>
<td>Highlight or place emphasis on guidewire removal during education episodes</td>
<td>2</td>
</tr>
<tr>
<td>Ensure all physicians are aware of the signs of guidewire retention</td>
<td>3</td>
</tr>
<tr>
<td>Ensure the clinician grips the proximal end of the guidewire at all times</td>
<td>48</td>
</tr>
<tr>
<td>Ensure the clinician does not insert the guidewire beyond 18cm</td>
<td>23</td>
</tr>
<tr>
<td>Operator must state “guidewire out” loudly to the room when it is removed</td>
<td>7</td>
</tr>
<tr>
<td>Ensure active senior supervision at all times with trainee doctors at all times</td>
<td>24</td>
</tr>
<tr>
<td>CVC insertion only done by experienced insertors</td>
<td>3</td>
</tr>
<tr>
<td>Punitive measures which involved discussion with the physician involved and referral to medical leadership</td>
<td>1</td>
</tr>
<tr>
<td>Checks</td>
<td></td>
</tr>
<tr>
<td>New policy for CVC insertion or revise existing policies for guidewire removal during CVC insertion</td>
<td>4</td>
</tr>
<tr>
<td>Standardize CVC insertion</td>
<td>5</td>
</tr>
<tr>
<td>Operator should confirm the guidewire has been removed</td>
<td>3</td>
</tr>
<tr>
<td>Introduce a checklist</td>
<td>24</td>
</tr>
<tr>
<td>Include removal of guidewire on checklists</td>
<td>4</td>
</tr>
<tr>
<td>Document guidewire removal</td>
<td>9</td>
</tr>
<tr>
<td>Introduce reminders on electronic medical records for guidewire removal</td>
<td>2</td>
</tr>
<tr>
<td>Reminders to remove the guidewire in the CVC kit insertion kit</td>
<td>2</td>
</tr>
</tbody>
</table>
The literature review and analysis of state and national reporting systems provided further indication of the mechanism of CVC guidewire retention. In the literature review Pokharel et al. analysed 76 publications of whole retained guidewires. They determined that in 70% (53/76), guidewire retention was not detected on completion of the clinical procedure (CVC secured in place and sharps/equipment disposed of). A check radiograph was performed in 61/76 cases. Of these 61 cases, 42 were done as a routine investigation after CVC insertion; of these, guidewire retention remained undetected in 69% (29/42). Of the remaining 19/61, the check radiograph was performed to confirm guidewire retention, and
in all of these, guidewire retention was recognised instantly. In 82% (47/57) of publications, authors stated that the CVC procedure was performed by trainee doctors and in 25/43 (58%) publications, authors described that trainees were unsupervised during CVC insertion. Additionally, Pokharel et al. described unstable patient factors (13/76), interruptions/distractions (16/76), high workload (7/38), out of hours (13/76) and two CVCs and two guidewires (12/76) as other causes for guidewire retention. Based on their findings, the authors suggested nine mechanisms for error prevention: increase awareness, ensure the clinician grips the proximal end of the guidewire at all times, ensure the clinician does not insert the guidewire beyond 18cm, introduce an equipment count post procedure, check the trolley for the guidewire post procedure, think about guidewire retention when checking the radiograph post CVC insertion, avoid night time insertion, ensure adequate workforce and equipment changes to prevent the error. Pokharel et al. did not describe any variation between countries or continents regarding the mechanism of this error or prevention strategies.

Williams et al. reviewed 42 incidents entered into the University Health System Consortium Safety Intelligence Patient Safety Organization database in Chicago, Illinois, US over five years and found 31/42 were whole retained guidewires. The authors state that 1/3 of guidewire retentions were discovered during the clinical procedure, 1/3 were discovered incidentally on the routine check radiograph and the remaining 1/3 on reviewing the CVC port or due to lack of documentation that the guidewire had been removed. Williams et al. determined that causes for guidewire retention were operator inexperience (24%), interruptions/distractions (10%), operator inattention (7%), poor communication (5%) and inadequate supervision (5%). Based on these results, they suggested 15 mechanisms to prevent this error: increase awareness, appropriate education of staff, appropriate training of staff, ensure the clinician grips the proximal end of the guidewire at all times, ensure the clinician does not insert the guidewire beyond 18cm, CVC insertion done by experienced operators, a new policy for CVC insertion, standardise CVC insertion, introduce a checklist, examine the guidewire before and after insertion, think about retained guidewires when checking the check radiograph, equipment changes to the guidewire, a longer guidewire, a reminder in the CVC insertion kit, an engineered failsafe to prevent the error.

Cherara et al. reviewed 101 cases from the VHA patient safety reporting database between 2000-2016. Whole guidewire retention occurred in 91% (92/101) cases, and they
determined this error arises once every 58 days nationally across the VHA hospitals. In 38% (38/101) of these cases, guidewire retention was discovered during the clinical procedure, 31% on checking the first check radiograph and the remaining 31% after the first check radiograph. They found 36% (35/101) of guidewire retentions occurred when the operator was a trainee and 79% (80/101) during non-emergency insertions. Causes for guidewire retention given were: patient or procedural factors (28), interruptions/distractions (26), inexperience/inadequate training (46), inadequate supervision (12), lack of standardised procedure (36), lack of a checklist that specifically included guidewire removal (22) safety count not followed (15), no real time documentation (14), no supporting staff (14) and inadequate supervision (12). The authors suggested three techniques to prevent guidewire retention: introduce a checklist, use a two person approach and design an engineered failsafe.

Finally, Dushane and Paull also reviewed cases from the VHA patient safety reporting database and found 30 analysable cases over 13 years. In their analysis, they found poor communication was the commonest root cause of this error (70%, 21/30), inexperience/lack of training accounted for 43% (13/30), lack of policy/standardised procedure 30% (9/30), equipment fault 26% (8/30), operator fatigue (6/30) and other barriers 10% (3/30). They suggested four preventative techniques: standardise CVC insertion, document guidewire removal, a team based model for CVC insertion and design an engineered failsafe.

Of the 108 publications, that described prevention strategies, none reported whether these had been validated to determine their efficacy or effectiveness at preventing the error, even if these strategies had been introduced into their institution. Only two articles commented in detail on their preventative strategies or how their suggested preventative mechanisms could be or were achieved: Peh et al. stated that in the time following the implementation of their training programme and reminder drape to submission of their article for publication (three years and eight months), there were no guidewire retentions, in the 1,760 CVCs placed, and 97% of participants found their educational programme to be valuable and informative. Vannucci et al. stated that their institution had implemented an extensive training programme, a CVC checklist and paperwork documentation requiring operators to document and sign that the guidewire was removed. They subsequently went on to have two further instances of guidewire retention, where both operators had undergone
the training programme and signed the document stating that the guidewire had been removed.\textsuperscript{14}

2.2.4 Discussion

This review of 108 publications on whole CVC guidewire retention identified 27 reasons for guidewire retention and 44 different strategies to prevent this error. The number of reasons and prevention strategies described in these publications make determining a single cause and developing a simple prevention strategy very difficult. Regarding causative factors, inexperience, inadequate supervision, and interruption/distraction were most commonly reported. One would expect that this would reflect the preventative strategies; however, minimising distraction was only suggested in 8/108 articles without any mechanisms for how this should be achieved and ensuring adequate supervision was suggested in 24/108 articles without an explanation of how supervision should be improved. Where inexperience was a causative factor, suggested preventative strategies were improvement in education, training, following protocols and two specific rules regarding the guidewire: hold onto the guidewire at all times and do not insert beyond 18cm.

Almost half (48/108) of the publications stated that the guidewire could not be lost if the clinician holds onto the guidewire at all times. However, many articles also describe that this simple rule is impractical and unfeasible. To perform the steps for CVC insertion, the operator must let go of the guidewire, for example, to reach for other equipment.\textsuperscript{19,73} It is interesting that many articles state an unachievable rule to prevent this error. Therefore, other preventative techniques should be evaluated, and there must be an improvement in education for clinicians to understand that reliance on this technique alone to prevent retained CVC guidewires is unachievable. In 23 articles, not inserting the guidewire beyond 18cm was another common preventative strategy. This seems to be a very reasonable strategy; however, it requires all clinicians to know when they have inserted the guidewire to 18cm. Many companies manufacture guidewires; there are guidewires of different lengths,\textsuperscript{74} and the guidewire is presented in the CVC insertion kit coiled inside a circular CVC guidewire holder. Consequently, could a system that ensures clinicians know or are alerted when the guidewire is at 18cm prevent this error? Altering the guidewire to introduce colour changes or tactile changes was described in nine articles. If the demarcation was made at 18cm, then this may be a mechanism of preventing over insertion.
As inexperience was commonly described as a cause of the error, improvement in education and training, and following the protocol, should prevent this error. Three articles stated that only experienced operators should perform this procedure.\textsuperscript{19,75,76} If inexperience is the reason for this error, this implies that experienced clinicians should not make this mistake; however, the literature review and national reporting systems demonstrate that this is not the case: 18\% of publications from the literature review were guidewire retentions with experienced operators.\textsuperscript{4} Williams et al. found that 24\% of guidewire retentions were due to inexperienced operators,\textsuperscript{19} and does this mean that 76\% of retentions occurred with experienced operators? Similarly, Cherara et al. found that 36\% of guidewire retentions occurred with trainee doctors\textsuperscript{64} and Dushane and Paull found that 43\% of guidewire retentions were due to inexperience/lack of training.\textsuperscript{20} Therefore, this does imply that guidewire retentions in 64\% and 57\% of cases, respectively, occurred with experienced clinicians. Whilst inexperience may account for some cases of guidewire retention, with so many expert clinicians making this error, stating ‘inexperience’ or ‘doctor in training’ is far too simplistic as the main causative factor for this error. Regardless, re-education and re-training were commonly described as preventative strategies with ‘inexperienced’ clinicians. However, prevention cannot depend on improvements in education and training alone, as demonstrated by Vannucci et al., where their institution had two further guidewire retentions despite the clinicians having attended the training programme.\textsuperscript{14} The accompanying editorial states that “education and training is only as good as the length of time that clinicians remember to do it,”\textsuperscript{73} and implies that recurrent educational episodes are needed to prevent this rare error, which has the associated cost implications.

Many studies stated that trainee doctors were not supervised appropriately by their senior colleagues, and better supervision should prevent this error. However, in 25/108 articles, guidewire retention occurred despite supervision. This questions what ‘better supervision’ is and how this will prevent the error. None of the studies commented on how to improve supervision. However, one can assume this means the supervisor should be standing next to the operator monitoring their every move to ensure the procedure is performed correctly. However, in reality, this is not possible; senior clinicians often undertake other necessary and important clinical work. Hence, directly supervising all trainees to prevent this rare error in the context of an entire anaesthetic procedure is an unrealistic expectation. It also raises the question of other potential never event errors which could occur. Would this mean that every single procedure a trainee performs would become
a two person procedure? Whilst seven publications have suggested this as a preventative mechanism, the implications of this are far reaching, beyond CVC insertion alone. It would have substantial cost implications regarding the time taken to undertake clinical procedures, affecting the number of daily clinical activities (operations) that could be performed and the number of staff required to do this. Therefore, this is an unrealistic preventative strategy.

Many studies recommended reminders and checks to prevent this error, and 24 suggested a checklist for CVC insertion, with others describing the need to specifically include ‘remove guidewire’ on the checklist (4), to check the trolley and equipment (13) and check the radiograph post procedure (25). Cherara et al. stated that guidewire retention occurred in 22% (22/101) of cases because of a lack of a checklist that specifically included guidewire removal. The authors suggested that prevention was through introducing a checklist. However, does this imply that in 78% of cases, guidewire retention occurred despite the presence of a checklist which specifically included guidewire removal? This is similar to Vannucci et al. experience of guidewire retentions occurring despite reminders and documents requiring the operator's signature to confirm guidewire removal. There were 25 publications recommending that the ‘check radiograph should be checked’. If this check is used to prevent the error, the operator will only see the retained guidewire after completing the clinical procedure requiring a potentially invasive removal technique. However, the benefit of this as a check is also questionable, as the literature reviews and national reporting systems demonstrate that between 2/3 and 70% of guidewire retentions were missed on the first check radiograph. If a checklist and reminders are imperfect at preventing this error, why are they commonly suggested as preventative mechanisms? The preventative mechanisms in Table 2.1 have been described since 1992, and if they are effective, one would no longer expect to see publications documenting this error or incidents reported to NHSE&I. However, there are rising incidents of guidewire retention despite well established policies and prevention strategies in the literature.

The literature review and state and national reporting systems provide further insights. Pokharel et al. determined that in 70% of cases, guidewire retention was not recognised at the end of the clinical procedure. Both Williams et al. and Cherara et al. determined that 2/3 and 62% of guidewire retentions, respectively, were not discovered by the end of the clinical procedure. In most cases, guidewire retention is not recognised until after the completion of the clinical procedure. If the experience of the operator is not necessarily the cause of the error, and from education and training, clinicians know and
understand the step of guidewire removal must be done, why does this error occur? Why are clinicians missing the crucial step of removing the guidewire and not recognising it on the check radiograph? This suggests that guidewire retention may be due to the operator forgetting to remove the guidewire during the CVC insertion procedure, which is an omission error. Therefore, the numerous checks and reminders are mechanisms for ensuring the operator remembers this step. However, despite these strategies being available and implemented into clinical practice, they are fallible because the error continues to occur. Additionally, these checks often only allow detection after the problem has occurred,\textsuperscript{73} i.e., at the end of the clinical procedure. At this point the guidewire may have migrated into the vasculature. Hence, a novel approach to prevent the error is required.

Some authors suggest system changes, such as avoiding night time insertion, ensuring adequate workforce provision, minimising distractions, calling for ‘time out’ before the operator starts the procedure and creating a quiet and well lit environment. Whilst these initiatives are commendable, and institutions should ensure these system changes are in place, in the ‘real world’ healthcare system, this is not always possible with every CVC insertion or, in some cases, even prioritised by institutions. A more practical system change to prevent this error may be required to ensure guidewire retention does not occur in all situations. Some authors suggest changes to the CVC insertion kit or guidewire to prevent guidewire retention. However, before introduction, these solutions must be carefully thought through to prevent unintended consequences. For example, some authors used a longer 60cm guidewire in their department.\textsuperscript{11,70} However, a longer guidewire can be clinically dangerous for the patient. A longer guidewire entails a greater risk of arrhythmias and an increased risk of infection. Importantly, it does not stop the error, where six articles reported guidewire retention with the longer 60cm guidewire.\textsuperscript{7,11,70,74,77,78} Regarding national systems safety, this solution may be problematic for junior doctors who rotate between different departments or hospitals. Suppose one hospital uses a 60cm guidewire and the next uses a 45cm guidewire. If the clinician has moved from the hospital using a 60cm guidewire to a hospital using a 45cm guidewire it is highly unlikely that the clinician performing the CVC procedure will recognise that they are using a shorter guidewire. Thinking that there is extra guidewire length, further compounded by the guidewire being stored ready for use inside a circular holder, the clinician will be more likely to over insert the shorter guidewire and hence more likely that retention will occur.
Interestingly, none of the authors stated whether the preventative strategies suggested in their articles had been evaluated for efficacy or effectiveness before their introduction. Only two studies described the prevention strategies in detail. Despite using three strategies to prevent the error, Vannucci et al. described two further instances of these errors, demonstrating the failure of these strategies. Peh et al. had undertaken 1,760 CVC insertions after implementing their new strategy; however, for an error which occurs in 1:3,167, many more CVC insertions would need to have been performed to determine whether the prevention strategy could be deemed effective. Therefore, any novel solution that is developed must be tested for efficacy before clinical introduction; otherwise, there is the risk of the error recurring.

Limitations

There are many limitations to this literature review. Firstly, the results depend on clinicians and institutions prepared to publish an error they have experienced. Many clinicians or institutions would not be happy to publicise an error, given the need to maintain their reputations. Consequently, the number of publications may be limited due to underreporting. Secondly, given that this error has been described in the literature over 100 times and that many journals are not accepting case reports, the frequency of publications relating to these errors may decline. Thirdly, the information in the publication is determined by the word count. Descriptions of the error were variable in the articles, and some did not describe causes or provide detail about CVC insertion. This analysis is based on data available in the literature and may be limited by unknown factors. However, important information has been extracted from this analysis, which will be used to determine potential mechanisms of error prevention. Finally, the literature search and analysis were conducted by a single researcher and may have biases in interpreting the data. An attempt to mitigate this was through discussing the literature review and methodology with the thesis supervisors.

2.2.5 Conclusions

Retained CVC guidewires are a common never event. Numerous causes and prevention strategies were described; hence, it is difficult to determine the mechanism of the error. However, given that most guidewire retentions were not recognised until after the
CVC was completed, this hints that the error may be due to the clinician forgetting to remove the guidewire. In addition, many of the preventative strategies described in some articles failed to prevent the error in others. Further research is required to understand how this error occurs to develop a solution to prevent CVC guidewire retention.

2.3 Analysis of incidents of retained CVC guidewires reported to the National Reporting and Learning System

2.3.1 Introduction

In NHS England, all hospitals must report serious adverse and never events to the StEIS and the NRLS. Additionally they are required to provide data on the incident, how the error occurred and the preventative measures introduced based on the RCA investigation conducted by the provider.\textsuperscript{27,43} NHSE&I state that this data is published to improve transparency and enable learning.\textsuperscript{70} However, only the number of reported error incidents is published monthly (Figure 1.1). Whilst detailed information is collected, NHSE&I does not publish this data. Therefore, access to information on the incident, mechanism of error, the RCA investigation and preventative measures that have been introduced by the provider across a nation of hospitals that broadly perform the clinical procedure in the same format may provide further and specific details of the aetiology of this error which is unavailable in the literature. From this, it may also be possible to ascertain any inherent system errors that may cause this error. The effectiveness of preventative measures, based on the hospital’s RCA, may also be ascertained.

This study aimed to explore the mechanism of guidewire retention and identify potential preventative measures.

2.3.2 Methods

Upon discussion with staff at NHSE&I, it was recommended that the NRLS database would provide the information required to answer the aim of the study. Access to the NRLS database of reported retained guidewire never events between August 2004 and July 2015 was requested and granted by the Medical Director and Director of Patient Safety of NHS England. Anonymised data was provided, with approval to publish anonymised pooled data. Only confirmed retained guidewire data was provided, near miss data was unavailable for
analysis. Never events are underreported,\textsuperscript{80} therefore, this database may underrepresent guidewire retention nationally. Additionally, the denominator of total annual CVCs placed in NHS England is unknown; as such, an attempt to estimate incidence was not undertaken.

Hospital staff from NHS healthcare institutions in England submit information to the NRLS database through free text submission. The raw data were sifted and analysed by two independent investigators and adjudicated by a third investigator.

**Eligibility criteria**

**Data inclusion criteria:**
- Incidents describing whole retained CVC guidewires only
- CVC included: internal jugular, subclavian, femoral, and haemofiltration catheters (vascaths and renal)

**Exclusion criteria:**
- Non-CVC related retained guidewires (i.e., radiology/cardiac)
- Fractured retained CVC guidewires
- Entrapment or kinking causing CVC guidewire retention

**Data extraction**

Data were analysed to determine the annual reported number of incidents and, where available: the time and position of the guidewire when retention was recognised, the reported methods utilised for guidewire retrieval and success rates, the operator's experience, presence of supervision, causes of guidewire retention and prevention techniques instigated were collected. The data were grouped into the above themes and further sub grouped by identifying recurring causative factors and preventative mechanisms. These fields were updated and refined as incidents were analysed. Data that met the inclusion criteria were extracted and entered into a Microsoft Excel spreadsheet (Microsoft Excel for Mac, Microsoft, Redmond, Washington) using a standardised form. Results were analysed using Microsoft Excel.
2.3.3 Results

Between August 2004–July 2015, 236 incidents of whole CVC guidewire retention never events were reported. Data analysis highlights a rising trend in the frequency of reported retained guidewires per year (Figure 2.2), with an average frequency of two per month across the study period.

Figure 2.2: Annual national reported frequency of retained CVC guidewires. Data from the NRLS, NHS England, between August 2004 – July 2015.

Single catheter insertions accounted for 97.5% of reported guidewire retentions, and multiple insertions accounted for 2.5% of reported cases. Of these, 0.8% were due to a planned single insertion, but due to difficulties in the insertion, a second CVC pack was opened (more than one CVC pack and guidewire was used), and in 1.7% guidewire retentions occurred when planned multiple lines were inserted.

Of the 236 cases, 212 included sufficient information to analyse the time of error identification, where 22% (46/212) were identified before the first check radiograph. Of these, 52% (24/46) were identified during the procedure, 28% (13/46) were identified during equipment clear up, and 20% (9/46) after the procedure was completed and after the operator commenced other duties (Figure 2.3). Of the 212 cases that included details of when the retained guidewire was discovered, only 11% (24/212) were identified during the procedure,
with the remainder identified after catheter placement. Twenty-three per cent (49/212) of guidewire retentions were identified on the first check radiograph, and 55% (117/212) were missed on the first check radiograph and discovered later.

Of the 117 guidewire retentions missed on the first check radiograph, 54% (63/117) were recognised on a subsequent procedure (further imaging or catheter manipulation), where one case detailed that five imaging investigations were performed on the patient before guidewire retention was recognised on the 6th radiograph, even though retrospective review demonstrated that the guidewire was present on all the radiological images. Of the remaining, 31% (36/117) were discovered during routine catheter removal, and 15% (18/117) were recognised months or years after the procedure during further imaging for an unrelated procedure or when the guidewire had migrated transcutaneously (Figure 2.3).
The position of the guidewire when retention was identified was described in 179/236 cases. Most retained guidewires were discovered located within the catheter 64% (115/179), remaining in situ in the catheter on the first check radiograph, 19% (22/115), on subsequent procedures, 35% (40/115) and on catheter removal, 31% (36/115). The remaining 32% (57/179) had migrated into the vasculature, and 4% (7/179) had migrated transcutaneously (Figure 2.3).

Methods of guidewire retrieval and success rates were described in 76/236 cases (Figure 2.4). Most guidewires were successfully retrieved by invasive techniques, where 43% (33/76) reported the use of interventional radiology (IR) techniques, and 4% (3/76) reported surgical intervention was required.

![Figure 2.4: Reported retained guidewire retrieval methods (76 cases) and success rates. The first five methods were classified as bedside techniques, and the latter two as invasive techniques.](image)

The most common and successful bedside guidewire retrieval technique reported was catheter clamping and withdrawal 22% (17/76). Other bedside techniques were reported with varying levels of success: catheter withdrawal alone (simply pulling the catheter back) in 20% (15/76) and were successful in 1/3 of these cases. In 8% of cases, the guidewire was visible at the catheter port, discovered by a third party at a time distant from procedure completion and pulled out successfully. One case described successful guidewire retrieval
with catheter aspiration and withdrawal (1%, 1/76) and another catheter aspiration alone (1%, 1/76) which was unsuccessful.

Operator seniority was reported in 59 cases, where six were consultants, 52 were junior doctors, and one was an advanced nurse practitioner (ANP), described as very experienced. Of the 52 cases involving a junior doctor, 25% (13/25) had senior supervision during CVC insertion. Only one case reported that the operator had an assistant during the procedure.

Causes of guidewire retention were reported in 38/236 cases. The most common cause described was “operator fault” (32%, 12/38) for reasons described as not conducting the procedure currently, not adhering to the protocol or not checking. In 16% (6/38) of cases, the cause was described as an “operator mistake” or “human error”. Other causes described were workload pressure (3/38), emergency or out of hours procedure (3/38), personal pressures (2/38), inexperience (1/38), guidewire retention not preventable (1/38), distraction (6/38) and interruption (4/38) where in three of these cases, the operator was required to halt the CVC insertion midway, undertake another task and then start the procedure again. Examples from the NRLS data of interruption and distraction during CVC insertion are seen in Table 2.2.

Table 2.2: Summary of quotations from the NRLS data of cases describing interruption and distraction during CVC insertion. Quotations summarised to preserve anonymity.

<table>
<thead>
<tr>
<th>Interruption and distraction described by reporters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinician was inserting a vascath. Clinician informed that another patient self-extubated and needed re-intubation. Given that the CVC procedure had started, and the clinician was scrubbed, they suggested to contact another clinician to attend and perform re-intubation. However, within moments, the nurse informed the clinician that the patient’s saturation was 50% was they needed intubation immediately. The clinician abandoned the CVC procedure with the guidewire still in the patient and went to attend the other patient whose SpO2 was in fact 90%. The clinician stayed and re-intubated the patient and rescrubbed and continued the CVC insertion</td>
</tr>
<tr>
<td>A registrar on shift started the [CVC] procedure, gained IV access and inserted the guidewire and then asked another clinician to finish the procedure. The clinician took over the procedure and then dilated the vein and inserted the CVC. The guidewire could not be located during</td>
</tr>
</tbody>
</table>
post procedure checks despite a thorough search of the area and the bins. The registrar returned, searched the area for the guidewire and then performed an abdominal ultrasound on the patient. The clinician informed the consultant who advised an abdominal radiograph. The radiograph showed the guidewire was in situ within the central line lumen. The morning consultant removed the central line and the guidewire.

During CVC insertion the anaesthetic registrar was interrupted on four occasions by the surgical registrar once just prior to scrubbing and three times thereafter, to discuss second patient. On one of these interruptions, the anaesthetic registrar was required to descrub to speak with the surgical consultant on the phone to discuss the management plan of the second patient and then return to CVC procedure. The interruptions were described by the anaesthetic registrar and house officer as unnecessary and the manner in which they were conducted was perceived as rude and intrusive. Whilst the registrar was stitching the line in situ, they sustained a needlestick injury. Once the CVC was secure, the house officer placed the dressing on the CVC. The nurse helped by clearing away the equipment and the anaesthetic registrar administers first aid to needle stick injury.

During CVC placement the intensive care consultant came into the anaesthetic room and stated that a blood gas must be taken before the vein dilator is used. This was in response to an incident the day before when the carotid artery had been dilated on an intensive care patient. The guidewire was already in the patient, so the clinician was required to railroad a venous catheter over the guide wire and remove the guide wire to be able to take a sample for analysis. Obtaining and analysing the samples caused a considerable delay in placing the line. The clinician proceeded to reinsert the guidewire and dilate the vein. They railroaded the quad lumen line over the guide wire and failed to remove the guide wire. They aspirated and flushed all four lumens and sutured the line in place. The patient was transferred to ITU uneventfully. The guide wire was found to be in the SVC on check CXR.

Preventative actions undertaken by hospitals after guidewire retention events were described in 163/236 cases. In 36% (58/163) of cases, preventative actions involved the operator (Table 2.3). Of these, the most common preventative action, 62% (36/58) of cases, was that the junior doctor was “spoken to” and asked to “reflect on the error”.

33
Table 2.3: Actions instigated by the hospitals after a guidewire retention event to prevent a recurrence. Actions were either operator based, or department based (163 cases).

<table>
<thead>
<tr>
<th>Preventative actions taken by the hospital</th>
<th>No. of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operator</td>
<td></td>
</tr>
<tr>
<td>Spoken with the doctor and asked them to reflect on their actions</td>
<td>36</td>
</tr>
<tr>
<td>Junior doctor reported to educational and senior supervisors</td>
<td>6</td>
</tr>
<tr>
<td>Doctor re-trained to insert CVCs</td>
<td>13</td>
</tr>
<tr>
<td>Doctor not permitted to insert CVCs</td>
<td>3</td>
</tr>
<tr>
<td>Department</td>
<td></td>
</tr>
<tr>
<td>Root cause analysis investigation</td>
<td>24</td>
</tr>
<tr>
<td>Discussed at the department meeting</td>
<td>15</td>
</tr>
<tr>
<td>Additional teaching for junior doctors</td>
<td>6</td>
</tr>
<tr>
<td>Clinical supervision for junior doctors</td>
<td>4</td>
</tr>
<tr>
<td>Re-iterate the importance of guidewire removal to all staff</td>
<td>9</td>
</tr>
<tr>
<td>No action (unavoidable error)</td>
<td>1</td>
</tr>
<tr>
<td>Ensure clinicians are not distracted during procedures</td>
<td>2</td>
</tr>
<tr>
<td>Additional checks introduced</td>
<td>44</td>
</tr>
</tbody>
</table>

In 10% (6/58) of cases, the junior doctor was reported to their educational and senior supervisors, in 22% (13/58) of cases, doctors were required to undergo re-training to insert CVCs, and in 5% (3/58) of cases, doctors were not permitted to insert CVCs, and working rotas were changed during the formal investigation process. Examples from the NRLS data of actions undertaken against the individual are seen in Table 2.4.

Preventative actions undertaken by the department were reported in 105/163 cases. These included an RCA investigation (22%, 24/105), discussing the incident at department meetings (14%, 15/105), additional teaching for junior doctors (5%, 6/105), better supervision required for junior doctors (4%, 4/105), reminders sent to all staff members highlighting the importance of guidewire removal (8%, 9/105), ensure clinicians are not distracted during these procedures (2%, 2/105) and no action taken as it was felt to be an unavoidable error (1%, 1/105).
Table 2.4: Summary of quotations from the NRLS data of cases describing actions undertaken against the individual after they had made the error. Quotations summarised to preserve anonymity.

**Examples of actions undertaken against the individual described in the NRLS data**

The consultant anaesthetist inserted a vascath and inadvertently left the guidewire in situ. Consultant was reminded of the need for vigilance regarding CVC placement.

The doctor who performed the procedure was spoken to and asked not to perform any more CVC insertions until the investigation was completed.

The doctor was spoken to by their clinical supervisor. Retraining in central line insertion is being arranged and in the interim the doctor was not permitted to insert central lines.

The clinician who made the mistake stated that it was a ‘pilot error’ and that they took full responsibility for their actions. They went on to state that the lesson that they had learnt was: “*is never to have it happen again*”. The clinician also stated that they should not be distracted by the activity going on around them and to make sure that no one distracts or interferes with them whilst they are performing a procedure.

The doctor who made the error was interviewed, the background investigated, and the incident was documented in their clinical portfolio. The investigators found that this was a ‘one of’ and was ‘totally out of character’. Investigators concluded that they must ensure doctors’ competencies and understanding of the procedure irrespective of their grade.

From now on the junior doctor will be supervised during practical procedures by a consultant. This practice will continue until consultants are content that the junior doctor is safe to carry out these procedures unsupervised. A column could be added to the insertion care bundle which could be ticked to show that the guidewire has been safely removed.

The doctor’s practice is being reviewed by the consultant team. The doctor inserting CVCs need to be sure that they have removed the guidewire.

In addition, most hospitals introduced additional checks for CVC as a preventative measure (42%, 44/105), and 11 additional checks were instigated (Table 2.5). Of these checks, 16% (7/44) introduced a new CVC checklist, 18% (8/44) stated that guidewires
should be removed, checked, and removal documented by the operator, 2% (1/44) required a second person to observe the entire procedure, 9% (4/44) required a second person to ensure guidewire removal had occurred, 14% (6/44) required the operator to document and sign that guidewire removal had occurred, 2% (1/44) required the equipment to be checked against the procedure pack contents during disposal, 5% (2/44) required staff to count the equipment in and out during the procedure, 14% (6/44) required all patients to have a check radiograph after CVC insertion, 7% (3/44) required documentation that the radiograph had been checked, 11% (5/44) instigated a new CVC care bundle and 2% (1/44) stated that all patients returning from theatres should be checked for the presence of a guidewire.

Table 2.5: The different types of additional checks instigated by the hospitals after a guidewire retention event to prevent a recurrence (44 cases).

<table>
<thead>
<tr>
<th>Types of additional checks introduced</th>
<th>No. of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>New CVC insertion checklist</td>
<td>7</td>
</tr>
<tr>
<td>Guidewires must be removed by operators, checked, and noted that guidewire removed</td>
<td>8</td>
</tr>
<tr>
<td>Second person to observe the entire procedure</td>
<td>1</td>
</tr>
<tr>
<td>Second person to check has been guidewire removed</td>
<td>4</td>
</tr>
<tr>
<td>Operator must document and sign guidewire has been removed</td>
<td>6</td>
</tr>
<tr>
<td>Check equipment against procedure pack contents during disposal</td>
<td>1</td>
</tr>
<tr>
<td>Count equipment in and out during the procedure</td>
<td>2</td>
</tr>
<tr>
<td>Ensure check radiograph is performed after the CVC procedure</td>
<td>6</td>
</tr>
<tr>
<td>Document that the check radiograph has been reviewed</td>
<td>3</td>
</tr>
<tr>
<td>New protocol or care bundle</td>
<td>5</td>
</tr>
<tr>
<td>Check patients for guidewires on return from theatres</td>
<td>1</td>
</tr>
</tbody>
</table>

2.3.4 Discussion

Analysis of the NRLS data demonstrates that CVC guidewire retention is a common error, occurring on average twice per month nationally and has a rising frequency (Figure 2.2). This is comparable to the published national data seen in Figure 1.1. Whilst there are many factors that have contributed to the increase in the number of CVC insertions and an increase in the reported frequency of guidewire retentions such as: the increasing awareness
To the error, improved reporting culture, the increase in the numbers of CVC insertions due to the expansion of anaesthetic and intensive care services over the years are contributing factors to the rising frequency of retained guidewire incidents, the frequency of this error has not plateaued or decreased despite the publication of safety measures and strategies to prevent retained CVC guidewires. This highlights the need for better preventative strategies.

It may be assumed that guidewire retention is more likely to occur during multiple catheter insertions, i.e., if there are multiple catheters and guidewires on the same sterile field, then there is a greater chance for retention to occur. Four studies in the literature state that the presence of multiple catheters and guidewires was the primary reason for guidewire retention. However, the NRLS data demonstrates this is not the case; almost all guidewire retentions, 97.5%, occurred during single catheter insertions. Therefore, the search for a preventative mechanism can focus initially on single catheter insertions, rather than the complexities of multiple catheter insertion procedures, and this will prevent 97.5% of these errors.

In only 11% (24/212) of cases, guidewire retention was identified during the procedure. This was commonly due to the operator recognising that the guidewire had been pushed too far into the vein during CVC insertion. This questions the view, as some authors in the literature describe, that guidewires are primarily retained because of ‘slippage’ or being ‘sucked into the vasculature’ at the point of insertion, which, if true, would be immediately evident in these and almost all cases of guidewire retention. This would be due to physiological blood flow exhibiting a force on the guidewire which overcomes the frictional force between the guidewire and the CVC lumen, and is the basis for widely adopted guidance that operators should hold onto the guidewire at all times during CVC insertion. However, this may be an oversimplification of retention events as the vast majority of guidewires remain within the catheter should the operator inadvertently take their hand off them during the procedure; 64% (115/179) of retained guidewires remained within the catheter at the first radiograph, on subsequent procedures and even on catheter removal despite the administration of fluids. Indeed, the forces exerted by blood flow and pressure differentials are much greater during arterial procedures. However, in the opposite direction, and if these were sufficient to overcome friction, guidewires would be ejected from catheters whenever the operator takes their hand off the guidewire, which does not occur. If this mechanism of the guidewire ‘slipped or sucked’ into the catheter were true,
this should result in a far higher number of guidewire retentions identified during the procedure. However, the vast majority, 89% (188/212), were discovered by clinicians after the procedure was completed. Where guidewire retention was recognised either during equipment clear up, when first using and looking at the catheter, i.e., when attaching fluids and noting the guidewire within the catheter lumen, on the first check radiograph, after the first radiograph on subsequent clinical procedures, during routine catheter removal or after catheter removal. This data is similar to that in the literature, where 2/3 – 70% of guidewire retentions were not recognised after CVC insertion.\textsuperscript{4,19,64} The data demonstrates that the error occurs during the catheter insertion. As most guidewire retentions are not recognised until after the procedure is completed, importantly, this indicates that most operators do not recognise their mistake or that the error has occurred during the procedure and proceed to secure the catheter. The guidewire is retained after the procedure is completed, and the error becomes a never event. Therefore, does this indicate that guidewire retention is an operator omission error, where the operator has missed the step of removing the guidewire and completes the CVC insertion without recognising this error – which then becomes a never event.

Most guidewires (64%, 115/179) were located within the catheter when retention was identified and seen either on visual inspection of the catheter, on the first check radiograph, on a subsequent procedure, i.e., attaching fluids to the catheter or further radiological imaging or during routine catheter removal, which is five to seven days post insertion. The time from completion of CVC insertion to the first radiograph can be variable and up to several hours. In theatres, CVCs inserted in the anaesthetic room are immediately used to administer medication and fluids, and the radiograph is performed when the operating procedure is completed. That 64% (115/179) of guidewires remained within the catheter at the first radiograph and subsequently afterwards, demonstrates that guidewires generally remain within the catheter for some time before migrating into the vasculature. This data is comparable to the literature, with reports of the guidewire remaining within the catheter lumen immediately after catheter insertion,\textsuperscript{9} on the first check radiograph,\textsuperscript{9} several hours post procedure, despite continuous flush solution running through the catheter\textsuperscript{86} and in some cases, days post catheter insertion.\textsuperscript{14} One article even commented that the guidewire remained within the catheter and did not embolise into the vasculature despite an infusion of 12-15ml/h of fluids for more than 11 hours and that the infusion pump did not emit a high pressure alarm.\textsuperscript{86} That most guidewires remain within the catheter despite delayed
identification, demonstrates that the time course for guidewire migration and embolisation is variable and can take several hours or days. Therefore, if retention is detected early, ideally during the CVC insertion procedure, then migration of the guidewire into the vasculature may be prevented through quick retrieval. This data also supports the inaccuracy of describing guidewire retentions as due to ‘slipping’ or being ‘sucked into the vasculature’, where if this were true, all retained guidewires would be discovered in the vasculature.

In 55% (117/212) of cases, guidewire retention was not identified on the first radiograph, and this data is similar to that in the literature.\textsuperscript{4,19,64} In some cases, the guidewire remained unidentified despite repeated radiological investigations which were reviewed by intensive care (ICU) physicians, anaesthetists and/or radiologists. Again, this phenomenon is also described in the literature.\textsuperscript{87–89} Retained guidewires missed on check radiographs are likely due to the rarity of the retained guidewire error and the phenomenon of inattentional blindness - the psychological phenomena where obvious stimuli can be missed due to alternative mental focus, such as focusing on the position of the tip of the catheter or looking for common complications.\textsuperscript{90,91} If one is not looking for a retained guidewire, it is unlikely that one would find it. These findings are also seen in the study by Pokharel; guidewire retention remained undetected on the first check radiograph in 69% of articles. However, when radiological imaging was performed to confirm guidewire retention after recognition during the clinical procedure, 100% of clinicians instantly recognised guidewire retention on the radiograph. In some cases, failings were also attributed to a lack of communication. For example, the presence of a guidewire was reported on the radiograph, however, radiologists did not inform the clinical team.

After guidewire retention occurs, guidewire removal should be undertaken urgently to prevent further migration and complications.\textsuperscript{4,9} In this study, 8% (8/212) of guidewires were discovered after the catheter was removed on a subsequent radiograph for an unrelated procedure or through lesions and protrusion of the guidewire through the patient’s knee, calf, groin or neck following distal migration. Similar events were also seen in the literature where guidewire retentions were discovered several months or years later protruding from the neck,\textsuperscript{6} toe,\textsuperscript{5} through the chest wall,\textsuperscript{8,92} thigh\textsuperscript{93} or knee.\textsuperscript{94,95} If guidewire retentions are detected early, these potentially dangerous migrations could be prevented through quick retrieval. Interventional radiology (IR) techniques were the most commonly described guidewire retrieval method. Many bedside techniques were also described, clinicians reported attempting these techniques first, and if unsuccessful, IR methods were utilised.
Bedside techniques described had varying degrees of success (Figure 2.4), where catheter clamping, and withdrawal appeared to be the most successful technique. This may be due to the guidewire remaining within the catheter lumen when the distal guidewire portion remained above the skin level. As catheter clamping and withdrawal was the most successful technique, this also demonstrates that guidewires remain within the catheter lumen for some time before migrating into the vasculature. If guidewires ‘slipped’ or were ‘sucked’ into the vasculature, bedside techniques to remove the guidewire would not be successful. Guidewire retrieval via invasive techniques (IR or surgery) was required in 47% (36/76) of retained guidewires, demonstrating the morbidity of this error.

Only 59 cases described the experience of the operator who made the mistake, most of whom were junior doctors (88%) with varying degrees of experience. This finding is unsurprising; in terms of workload, the junior doctor group is more likely to make the error because they perform the greatest number of procedures. This group of clinicians is also learning their profession, and even though inexperience may be a contributing factor, it cannot be stated as the sole reason for this error. Whilst 27/108 reports in the literature review stated that inexperience was the primary cause of the error, in this data, only 1/38 reported inexperience as the causative factor and described six consultants and one experienced ANP who made the error despite many years of experience. Interestingly, as noted in the introduction, the state and national reporting systems (US) reported that most guidewire retentions, 76%19 and 64%64, respectively, were with non-training, experienced staff. Consequently, it is difficult to attribute operator experience as a causative factor in this error.

In this data, the most common reason for the error was described as the “clinician’s fault”, whereas some described this as a “mistake”. In cases where it was emphasised that the clinicians were at “fault” for guidewire retention, the preventative actions taken were against the individuals, which included clinicians being “spoken to” or “asked to reflect on their actions”. Other “at fault” clinicians were reported to senior supervisors, required retraining, or were not permitted to insert CVCs until investigations were complete. Despite efforts to move towards a “no blame culture,” it is interesting that the majority of reporters described the error as ‘operator fault’ (32%, 12/38), allowing blame to be placed on the individual, rather than ‘operator mistake’ (16%, 6/38), which implies a healthcare system that learns from errors. Even the subsequent preventative actions in Table 2.4, 36% (58/136) were punitive and re-iterate a blame culture. Asking clinicians to ‘reflect on their actions’
suggests that the clinician wilfully made the error, so they must think about their actions. Additionally, preventing clinicians from performing CVC insertions is a curious form of error prevention because this action does not consider the many, sometimes hundreds, of CVC insertions that these individuals have performed without error. Moreover, is the requirement for re-training clinicians perhaps an admission of failure to teach the individuals the procedure correctly in the first place? While blaming one person for an error is easy, isolating one individual will not prevent recurrence.

Other causes for guidewire retentions were reported as workload pressures, emergency procedures, distraction or interruption and are similar to those seen in the literature.\cite{4,19,64} Whilst there was insufficient information in this data on emergency procedures being the cause of guidewire retention, data from the state and national reporting systems in the US reported that 79\% and 90\% of guidewire retentions occurred during non-emergency CVC insertions.\cite{19,64} Therefore, it appears unlikely that emergency procedures are a cause of this error.

Operator interruption or distraction was described in several cases in this data, resulting in the clinician stopping midway through the CVC insertion procedure and restarting again (Table 2.2). Cases where distraction was quoted as the main reason were due to operator distraction by other clinicians, nurses, the patient, through being contacted via bleep or telephone or due to clinical referrals. These cases demonstrate that operators’ cognitive focus is taken away from the CVC procedure during interruptions or distractions, and therefore, they are more likely to make a mistake. Some preventative actions suggested that clinicians must not be distracted or interrupted when undertaking these procedures; however, this is unrealistic in the ‘real world’ healthcare environment. Table 2.2 demonstrates that often, interruptions are clinically important and may be necessary for the benefit of other patients. Additionally, these quotes (Table 2.2) demonstrate that CVC insertion is a small percentage of the operator’s workload and that a plethora of clinical activity surrounds them. Clinicians can and will be put into difficult or extraordinary circumstances and are expected to conduct these procedures without error. Thus, any preventative solution must be effective despite clinical distractions, interruptions, or workload pressures.

Several preventative strategies were introduced at a department level: an RCA, education and training for the department, additional supervision of staff and most commonly, new checks or checklists in 27\% (44/163) of cases. Checks described were either
a checklist, documentation, checking the equipment, the radiograph or a second person. Many required the clinician to sign that the guidewire had been removed, again implying a blame culture if the paperwork was not completed, or worse if the paperwork was signed by the clinician thinking that the guidewire had been removed. Whilst these measures are laudable, they are fallible, as retained guidewires have continued to occur despite the introduction of checks and checklists. Several checklists for preventing guidewire retention exist; one study highlighted that nine articles describing a checklist for CVC insertion were published within a one year period and one of these had a 50-point check for CVC insertion, of which one section was “remove the guidewire.” As previously discussed, Cherara et al. implied that 78% of these errors occurred despite the presence of a checklist. Hence, guidewire retentions continue to occur despite the introduction of checks and checklists. This may be because these reminders, checklists, and documentation for guidewire removal during CVC insertion are often signed and completed by the clinician after the CVC insertion has finished and the clinician has descrubbed. Therefore, the check reminds the clinician after they have made the mistake and when it is less likely to be easily corrected. Whilst checklists, reminders, re-education, and re-training may have an initial peak in benefit for patient safety, the long term impact is not guaranteed, and this is also seen in the literature.

Another preventative strategy described in this data was to use a two person approach through supervision, observation of the procedure, or a witness to guidewire removal. As discussed in the introduction, requiring two individuals to perform a procedure is both time and cost ineffective. In ‘real world medicine’, not always possible without frequent delays to every CVC insertion. Furthermore, in terms of rare events, after thousands of procedures with no errors, this leads to creeping complacency by both individuals, with each individual relying on the other to conduct the check correctly and leading to unclear accountability when the error occurs.

Analysis of this data provides some insights to the mechanism of the error: firstly, the majority of guidewire retentions are recognised after the procedure is completed suggesting that clinicians are usually unaware that they have made the error. Based on this, one could conclude that this is an omission error, i.e., that they had forgotten to remove the guidewire and not recognising this continued to complete the procedure. Secondly, most retained guidewires are found within the catheter on discovery; therefore, retrieval can be easily performed if the operator is alerted to the error quickly. Thirdly, bedside techniques
are easily performed and mostly successful, demonstrating the need to recognise this error quickly. Fourthly, the causes of guidewire retention and prevention strategies described in this data are the same as those in the literature. The prevention strategies are flawed in preventing the error because it continues to occur. These strategies are mainly operator focused; they depend on the operator to perform the procedure and check correctly. However, in the high reliability industries, rather than relying on the operator, safety mechanisms are designed to prevent error. This situation will likely keep occurring, unless the system changes or solutions that prevent guidewire retention are developed. To prevent this error, a non-operator focused approach may be required.

Limitations

There are limitations to this study. There was incomplete reporting, and in some cases, the ambiguity of free text user reported data in the NRLS system, especially where blame and accountability of reporters exist. This was overcome with intra-observer agreement on the likely accuracy of the data between three independent data extractors. There will be underreporting of the error, which may skew the presented data. However, the results are very similar to that seen in the literature; hence, this is unlikely to be the case. Near miss data was unavailable, which may have given greater insight into the cause of the error and would help to understand whether any preventative mechanisms used averted the error. However, there is no national mandate in the UK to report this data, it is difficult to access. The detail of the mechanism of the error was also not available in the data, perhaps due to free text user reporting or reporting within defined categories as specified by NHSE&I. Further studies are required to understand the fine detail of the aetiology of the error. This could be discovered through speaking with clinicians who made this error and analysing their first hand accounts of how it occurred. Finally, as the data provided was anonymised, it is not possible to determine whether the preventative strategy introduced by the hospital after the error occurred had any effect, that is, whether or not the institution went on to have another retained CVC guidewire error. Therefore, the effectiveness of these strategies are again challenging to evaluate.
2.3.5 Conclusions

This data demonstrates that guidewire retention is an error that is increasing in reported frequency which burden patients, clinicians, and hospitals. Whilst significant time and resources have been invested on operator focused interventions, the data demonstrates that this has been mostly unsuccessful, given the rising trend in the error. Further studies are required to determine the mechanism of the error, and a shift in focus into systems thinking may be required to develop strategies to eradicate this error from the clinical environment.

2.4 Interviews with clinicians who have experienced a retained guidewire error

2.4.1 Introduction

The NRLS data and the literature search indicated that CVC guidewire retention is potentially an omission error. However, the granular detail of the mechanism of the error is unavailable in the literature or the NRLS data. If this is an omission error, why do clinicians forget to remove the guidewire? This information may be obtained by speaking with clinicians who have made this error and analysing their first hand accounts. Understanding the error from the perspective of staff who have made this mistake by discussing both their and other clinicians’ actions during the event, understanding the working environment, and any other factors which may have influenced the error to occur may help to develop a better understanding of the mechanism of the error and from this better prevention strategies may arise. Whilst near miss data would be helpful to analyse, this data was not sought, as these incidents are not reported in the same manner as never event data. Consequently, it would be very difficult to find and interview these clinicians.

2.4.2 Methods

Approval to conduct the research was granted by the University of Cambridge Ethics Committee. Semi-structured interviews were conducted with clinical staff who had made a CVC guidewire retention error. A semi-structured interview guide (Appendix 2.3) was developed based on the findings from the literature search, the data from the NRCLS database, and an interview guide in the literature developed to speak with second victims after adverse events.99
All interviews were voluntary. Given the rarity of this error and the difficulty that clinicians may have in discussing an error that they have made, it was uncertain how many clinicians would voluntarily come forward to be interviewed; thus, there was no set minimum number of participants for the study. The maximum number was set after theoretical saturation was reached, and the remaining clinicians who had already agreed and volunteered their time were interviewed.

**Recruitment**

Given the rarity of the error and the difficulty in finding clinicians, the recruitment strategy was performed in three ways.

Firstly, all never are initially reported internally to the hospital reporting systems and subsequently nationally. Participants were found through a search of three hospital reporting systems by the patient safety lead of each hospital. These hospitals were selected because the author worked there during the study and could directly contact the patient safety leads. The patient safety leads searched the internal database and, if potential interviewees were available, invited clinical staff to participate in the interview. Participants from these centres self selected to be interviewed by contacting the interviewer directly.

Secondly, information about this study was shared with anaesthetic and intensive care clinicians working at the same hospitals as the author. These clinicians contacted colleagues (from anywhere in the country) whom they knew had made this error and clinical staff that were happy to be interviewed self selected by directly contacting the interviewer.

Thirdly at five anaesthetic and intensive care conferences, at the end of a lecture presentation, the author described the study and provided contact details (email) for any clinical staff who wished to participate. Participants self selected to be interviewed by directly contacting the interviewer.

With all the recruitment strategies, only the interviewer knew that the interviewee had participated in the study. The patient safety leads, the anaesthetic and intensive care colleagues or conference parties were unaware if any of their contacts had participated unless this was disclosed to them by the participants. Participants were provided with information on the purpose of the study, the interviewer’s background, and the motivation for the study.
Eligibility criteria

Inclusion criteria:
• Any trained clinical staff capable of inserting CVC independently who had made this error
• Clinical staff working in either NHS or private hospitals
• Clinical staff who had left their profession since the incident
• Clinical staff currently working or retired
• The guidewire retention error was a whole retained CVC guidewire/s only
• CVC included: internal jugular, subclavian, femoral, and haemofiltration catheters (vascaths and renal)
• The error occurred at any point in the clinician’s career (no minimum timeframe).

Exclusion criteria:
• Non-CVC related retained guidewires (i.e., radiology/cardiac)
• Fractured retained CVC guidewires
• Entrapment or kinking causing CVC guidewire retention.

A single interviewer conducted all the interviews to maintain the anonymity of the interviewees. Signed, written, and informed consent was obtained from each participant prior to the interview. Participants were informed that their identity would only be known to the interviewer to preserve anonymity and allow a frank conversation about the event should they wish to disclose personal information. No personal demographics of interviewees, other than their grade at the time of the error, was collected.

Face to face interviews were conducted in settings that were convenient to the interviewee and of their choosing. These were either in a private office or in a coffee shop. If agreeable to the participant, interviews were tape recorded, and the recordings were destroyed after transcription. Interviewees were asked to recount the day of the error event, the error itself and any subsequent changes they or the department had introduced to prevent future errors (Appendix 2.3). Participants were allowed to discuss the event and aftermath without time restrictions, and all interviews lasted 1-2 hours.

Transcription of tape recordings and analysis were conducted by the author and anonymised before discussing with supervisors. Analysis of the interviews was conducted
Conducting a qualitative study through interviews to identify the aetiology of a clinical error is a novel approach. Therefore, inductive thematic analysis, with the themes arising from the results of the literature search and the NRLS data, was used to identify the emerging themes from the data. Complete coding was performed during iterative readings of the transcripts. Codes were applied to sections of the transcribed data. The codes and emerging themes were analysed by hand and tabulated in Microsoft Word (Microsoft Word for Mac, Microsoft, Redmond, Washington). Theoretical saturation was reached before the final interview was conducted.

There was no further contact or follow up with interviewees after the interview, as this was felt too onerous for the individual.

2.4.3 Results

The interviews were conducted over five years, between 2016 – 2021. All clinicians, who self volunteered for the study by contacting the interviewer, had made the mistake of CVC guidewire retention and were eligible to participate; and no further screening took place. Clinicians self selected via all three recruitment strategies. In total, 24 clinicians self volunteered, and whilst all were given the opportunity to participate, 14 (nine junior doctors and five consultants) later declined to be interviewed. Reasons for declining were not requested. The remaining ten were interviewed, and this data was used for analysis.

At the time of the interview, all participants worked in NHS hospitals. Participants comprised of eight junior doctors (CT1 – pre-consultant grade), one consultant and one advanced nurse practitioner (ANP). At the time of the error event, all participants were capable of independent CVC insertion. Interviewees were able to recall their error event in detail despite, in some cases, the number of years that had passed since the event. Participants described the CVC procedure, equipment clear up, any safety checks performed, the timeline of discovery of the retained guidewire, the method of guidewire retrieval, safety checks introduced into the department after the error event and other CVC guidewire retention never event incidents. Participants clearly and quickly responded if they were unable to answer questions or did not recall specific details.

On analysis of the participant’s description of the event, the following themes emerged for the potential causes of the error. These were: patient, operator, environment, technical issues and whether safety checks were performed and the success or failure of
these checks. A summary of the contributing factors of all the interviews can be seen in a fishbone analysis (Figure 2.5).

**Patient factors**

All patients had a clinical need for CVC insertion, performed in either theatre or ICU settings. CVC insertions were routinely planned (4) or urgent/emergency insertions (6). Two elective cases had complex medical histories. Two operators described unexpected difficulties with patients during anaesthetic induction or the operation. However, all interviewees described their patients as “usual” in terms of medical complexity and felt comfortable managing these patients with the support available at the time. None of the interviewees felt that patient factors contributed to this error.

![Figure 2.5: A fishbone analysis summarising the factors contributing to the guidewire retention error described in the ten interviews.](image-url)
All participants stated that they were unaware of any personal factors that could have affected their clinical practice or performance on the day. Interviewees were all well in themselves and their mental health, and the day of the error was described as a typical working day. All operators were capable of independent CVC insertion, where five were very experienced operators, and of these, 3/5 had placed several hundred CVCs during their careers and were senior clinical staff. Four described themselves as reasonably experienced, having performed between 10-20 CVC insertions independently, and one stated that the error occurred on their first independent CVC insertion. At the time of the error, 8/10 stated that they were experienced enough to train their juniors to perform CVC insertions and had already done so. Six interviewees described feeling required to rush to perform clinical tasks quickly due to clinical emergencies (2) or pressure from other staff members (4). These six interviewees found this added to stress levels but not enough to affect the CVC procedure. One described feeling frustrated because additional tasks over and above their clinical workload were requested. One described feeling uncomfortable due to “being pushed into starting a list without a consultant present”:

“The co-ordinator suddenly said, ‘there is a bed, so we’ve got to do it now,’ ‘but it’s 1:15pm, I haven’t got a consultant.’ It was an aortic aneurism, known difficult airway, previous radiotherapy... So, I went to theatres and the ODP, you could see immediately was het up and wasn’t prepared for the case and didn’t know anything about it. So, she said ‘we can’t send until the consultant arrives,’ and I said, ‘no no, we’re definitely not sending until he comes.’ But the floor coordinator said, ‘you’ve just got to do it, we’re going to be late, send, send, send’ and then all of the sudden the patient arrived. But we weren’t ready.”

One interviewee described feeling flustered because of difficulties with other clinical procedures. These six participants described the pressures as typical of everyday clinical practice and stated that these factors did not directly affect the CVC insertion. The remaining four stated they felt relaxed and comfortable whilst performing the CVC insertion. All participants felt the clinical caseload during their error event was normal; the expected patient management was within their frame of competency, and they described instances of managing similar cases competently without error.
Environment

Descriptions of the environment varied from being calm and relaxed (4) to hectic, noisy, and busy (6), where clinicians, operating department practitioners (ODPs) or nursing staff were ‘running around’ busily performing tasks. Three interviewees described a rapidly changing clinical environment, from calm to suddenly busy, due to either patient deterioration or scheduling operations with little notice (2). Of these two cases, interviewees described feeling required to perform clinical procedures quickly to get the operations started, with little or no help from the ODPs, who were also rushing to run errands such as restocking the anaesthetic room or gathering equipment:

“Then literally at the last min, they changed the theatre, the ODP had to go and prepare another theatre, she was on the back foot, so she was trying to run around and set up a theatre that had been used all day.”

In these three cases, there was a sense of urgency to perform the CVC insertion quickly, and staff felt pressure to complete tasks quickly.

None of the operators had a formal assistant by their side throughout the CVC insertion. Interviewees described the ODPs or nurses were attending to other tasks, monitoring patients, assisting other clinicians and providing some assistance to the interviewees whilst also undertaking their own clinical tasks. One interviewee described being mostly left alone in a side room during the CVC insertion because the nurse was attending to another patient in a different side room. One interviewee stated that there were two ODPs available to assist with the CVC insertion; however, both were busy performing other tasks, which led to confusion as to which was assisting the CVC insertion and performing the ‘second person check’.

Other environmental factors described were the lack of physical space to perform CVC insertion comfortably and the temperaments of other medical staff. For example, one interviewee described the surgeon shouting at the surgical registrar throughout the duration of the CVC insertion.

Seven interviewees described repeated interruptions and distractions during CVC insertion. Where one described interruption by a senior ODP entering the anaesthetic room to speak to the ODP assigned to the list to ensure they went for their break:

“The ODP was trying helping all three of us, so then another ODP came in and said to the ODP ‘why aren’t you on your break, you need to go on your break’ and she
said, ‘no I’m busy, I’ll do it in ten mins’. So, ten mins later she came back, and we still weren’t finished. So, this kept happening every ten mins.”

One described the surgical team asking for the anaesthetic plan to be changed at the last minute, one described the surgical registrar moving the patient’s bed during the CVC insertion, one described the porters ‘hanging around’ waiting for the interviewee to finish, one described the consultant interrupting asking whether the CVC insertion was complete, one described having to pause multiple times during CVC insertion due to the lack of permanent assistant and one described the consultant wanting to view the guidewire position on the USS and then asking for the USS machine and probe to be handed to them.

However, all staff described these environmental factors as ‘not unusual’ for their everyday working practice and did not feel they directly contributed to the error.

**Technical factors**

Most guidewire retentions (7/10) occurred with single catheter insertions. Two operators described technical issues with the CVC equipment or difficulty accessing the patient’s vein. Whilst 5/10 described the technical process of CVC insertion as easy, 2/5 described feeling rushed to complete the procedure, 2/5 described feeling stressed due to technical difficulties with the other clinical procedures, and 1/5 described numerous interruptions.

Seven interviewees described distractions or interruptions during CVC insertion, and five of these specifically described problems, such as distractions or interruptions during CVC insertion at the moment the catheter was placed over the guidewire and felt that this may have contributed to the guidewire retention:

“At the point that I had threaded the central line over the guidewire was when he asked me for the USS probe, it was somewhere around that time and as soon as he asked for the probe, I took and handed it over to him, (whilst holding on the central line) but maintained sterility.”

“And then paused, and I think I hadn’t take the guidewire out at that point. There was a pause, I came back to the procedure and assumed I had taken the guidewire out. It was a time I was distracted because I was on my own in the room and had to call out or calling out at that point [for the assistant].”
“I was doing the central line, and the surgical reg said, ‘right I’m going to do the catheter now, because we’re going to over run,’……I didn’t think at the time, I should have said no……during the process [CVC] the surgeon tilted the bed, and I said, ‘oh hang on don’t do that while I’m doing the line.’”

All interviewees stated that interruptions or distractions were commonplace and so were unsure whether they directly related to the guidewire retention.

Safety checks

Interviewees described nine different types of safety checks to ensure guidewire removal, and the success of these can be seen in Table 2.6. Safety measures were either personal checks performed by the interviewee or department safety checks. According to the ten interviewees, 48 different checks were performed, which in theory should have ensured recognition of guidewire retention; however, these safety measures failed 92% (44/48) of the time (Table 2.6). Two interviewees recognised guidewire retention during sharps clear up; however, in 80% (8/10), the same check failed, and 2 interviewees stated that guidewire retention was recognised on the first check radiograph by a different clinician.

All participants stated that a permanent assistant was unavailable during the CVC insertion. While ODPs and nurses were present, they were engaged in other clinical activities and were not always available to assist.

There were five personal safety checks described by the interviewees, which were the operator states ‘guidewire out’, the operator checks the trolley for guidewire during equipment clear up, the operator signs the paperwork to confirm CVC performed, the checklist to confirm guidewire removal and check the radiograph (Table 2.6) however, most of these checks failed. One interviewee described that they were required to state ‘guidewire out’ once it had been removed; however, this check failed because there were two guidewires, and the operator had forgotten the presence of the first guidewire. One interviewee stated that they would normally organise the CVC equipment in the order it would be used, replacing them in the same order and counting out the sharps to prevent errors. However, this interviewee described the environment as stressful and hectic with an urgent need for the CVC, and they felt there was no time to undertake their usual checks:

“Felt pressured to hurry up and get it all done. Normally I line everything up and put things in the order that I use it, and I’ve always done that. But the environment
“was just so stressed, it was chaotic. So, I just started doing the line, instead of ordering and organising my trolley.”

Table 2.6: The different types of checks or safety measures used in the hospital to prevent guidewire retention as described by each interviewee. Where ticks (✓) and crosses (X) indicate the success and failure of each check, respectively, and the total no. of missed opportunities to recognise guidewire retention in each interview. In interview three, guidewire retention was discovered by the surgeon, in interview five, recognition was due to difficulty aspirating the line and in interviews six, seven, eight and nine recognised latterly incidentally by a clinician reviewing the radiographs.

<table>
<thead>
<tr>
<th>Safety checks performed / safety measures</th>
<th>Interview no.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>No permanent assistant during CVC insertion</td>
<td>X</td>
</tr>
<tr>
<td>Operator announces guidewire out during CVC insertion</td>
<td>X</td>
</tr>
<tr>
<td>Second person check to ensure guidewire removed</td>
<td>X</td>
</tr>
<tr>
<td>Check trolley for guidewire during equipment clear up</td>
<td>X</td>
</tr>
<tr>
<td>Paperwork signed to confirm CVC performed</td>
<td>X</td>
</tr>
<tr>
<td>Checklist specifically confirming guidewire removed by operator and ODP</td>
<td>X</td>
</tr>
<tr>
<td>First check radiograph</td>
<td>✓</td>
</tr>
<tr>
<td>Radiograph not checked by clinical team</td>
<td></td>
</tr>
<tr>
<td>Radiologist checked radiograph</td>
<td>X</td>
</tr>
<tr>
<td>Recognised guidewire retention, but did not inform clinician team</td>
<td>X</td>
</tr>
<tr>
<td>Did not recognise guidewire retention</td>
<td>X</td>
</tr>
<tr>
<td>Subsequent radiographs</td>
<td>X</td>
</tr>
<tr>
<td>2nd check radiograph</td>
<td></td>
</tr>
<tr>
<td>3rd check radiograph</td>
<td>X</td>
</tr>
<tr>
<td>4th check radiograph</td>
<td>X</td>
</tr>
<tr>
<td>5th check radiograph</td>
<td>X</td>
</tr>
<tr>
<td>6th check radiograph</td>
<td>X</td>
</tr>
<tr>
<td>7th check radiograph</td>
<td>X</td>
</tr>
<tr>
<td>CT scan</td>
<td>X</td>
</tr>
<tr>
<td>Total no. of missed opportunities to recognise guidewire retention</td>
<td>4</td>
</tr>
</tbody>
</table>
In this same case, the interviewee was told after the RCA investigation was completed that the error would have been prevented had they stuck to their normal routine:

“I was told ‘well if you’d just done it that way it would have been fine, ironically if you don’t do that inevitably everything goes wrong but because you didn’t follow your routine, that’s why you made the mistake’”

Four interviewees stated that they recognised the guidewire was missing during equipment clear up. Of these, 2/4 interviewees stated this check led to the recognition of guidewire retention and in one of these, the interviewee was congratulated by senior colleagues for diligently performing this check. However, in the remaining two, one interviewee stated they queried the missing guidewire and assumed an ODP had disposed of it, and one recollected that the ODP had cleared away the equipment and when the interviewee asked where the guidewire was, was told by the ODP that it had been disposed of in the sharps bin. The interviewee even confirmed this by checking inside the sharps bin:

“So, I count my sharps away and as I was cleaning, and finishing, a lot of my sharps had gone and I said, ‘oh had someone tidied my sharps away’ and the wire wasn’t there. ODP said ‘the wire is in the bin,’ and I looked in the bin and saw it there and went ‘oh ok.’”

None of the remaining interviewees (6) recognised the missing guidewire during equipment clear up.

Eight interviewees stated that they had signed paperwork confirming the CVC had been completed. Of these, one interviewee ticked the checklist to confirm guidewire removal and, having thought the ODP had also witnessed this, ticked the checklist on behalf of the ODP, intending to confirm with them later. This interviewee was criticised for these actions and investigated for falsifying documentation but was finally informed that there would be no disciplinary action because it was deemed an honest mistake. The remaining two recognised guidewire retention before starting the paperwork.

“and the part where it asked whether the guidewire was removed, I clicked that I had done it, I thought that I had done it, because at that point, I had no idea that I’d left it in, so subconsciously I just ticked it away, I was just in automatic, I thought I had, because I have done this procedure over 200 times, and that I had no idea I hadn’t taken it out, I hadn’t removed it. I wasn’t even aware that I was in. And it was tick, tick, tick, tick, I can’t remember my thought processes, but when it came to guidewire, it didn’t flag, because I was in automatic mode, I thought I had done it.”
In these interviews, the paperwork or a checklist did not help 8/10 operators recognise guidewire retention.

Three interviewees stated that a formal second person check was in place in the department; however, this check failed to help operators recognise guidewire retention in all three cases.

“This OPD, they are always busy doing things, there was definitive lack of attention during critical moments….but afterwards, there was some discussion afterwards by the ODP that I hadn’t even asked her to check that the guidewire was out. She was busy doing something with the arterial line, so looked at me....... and I went guidewire out, and she went ‘ah ha’. And afterwards she said, ‘yes, but I hadn’t seen it’. And it was because she wasn’t really looking.”

Of these three interviews, one stated that the operator and the ODP had forgotten that two CVC packs and two guidewires were used. When the operator held up a guidewire and said, ‘guidewire out,’ both assumed they had performed the safety check correctly. Another interviewee stated that they had assumed the ODP had seen the guidewire and ticked the checklist to say they had, but latterly failed to confirm this. This situation was then confused by the presence of two ODPs, so they were unsure which ODP was assisting and performing the safety check.

Two interviewees stated that the guidewire was recognised on the first check radiograph, and this was by a different clinician in both instances. Four stated that guidewire retention was missed on the first check radiograph. Of these four, the check radiograph was either not reviewed for several days by clinical staff or the guidewire was missed despite multiple anaesthetic, intensive care unit (ICU) and radiology staff reviewing the imaging. In these four instances, a retained guidewire was missed on a total of ten radiological images, all of which were reviewed by clinicians.

Four interviewees stated that their consultants supervised them while performing the CVC insertion. Interviewees described that their consultants were simultaneously performing other clinical tasks, and there was no direct supervision of the interviewee performing the procedure.

“One of the comments that someone had made was that there wasn’t a consultant supervising [me] in the original case, but I was like well I’m ST5, I don’t need, and he shouldn’t feel as though he needs to be supervising me like that, he wasn’t actively standing over my shoulder watching me.”
The remaining six interviewees were too senior to require a supervisor and were experienced enough to undertake the procedure alone.

None of the interviewees recognised guidewire retention during the procedure, and all secured the catheter to the skin and applied the dressing, finishing the CVC insertion. At the end of the procedure, all interviewees assumed that they had removed the guidewire and had no reason to doubt that they had missed this step. None of the interviewees could remember why they missed the step of removing the guidewire during the procedure and were perplexed at why they made this error (Table 2.7). All interviewees stated that they knew the guidewire should be removed during CVC insertion and had always performed this action on previous procedures. Given that this was their normal practice, all interviewees stated that this step of removing the guidewire would not be an event that would be specifically remembered:

“So, there were lots of raised eyebrows when I said I did it on autopilot. I don’t remember categorically, because whenever I’ve done them, I don’t categorically remember taking the guidewire out, I just did it”

Therefore, all assumed they had performed this action as per their routine practice.

Table 2.7: Quotations of the interviewee’s recollection of the moments of guidewire retention.

<table>
<thead>
<tr>
<th>No.</th>
<th>Interviewee’s recollection of the moment of guidewire retention</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>“If you had asked me then, had I taken the wire out, I would have said categorically yes. Didn’t even think about it….as far as I was concerned I had done it right, and it was only after, it transpired the wire had been left in and even when I thought about it, and thought about it and thought about it and thought about it a million times, at the time if you’d said to me have you taken the guidewire out, I would have said categorically yes.”</td>
</tr>
<tr>
<td>2</td>
<td>“It hadn’t occurred to me that I had no longer had the wire end, because obviously you would have a small amount of wire out of the proximal end. I don’t remember looking back and seeing that, but at the same time, I don’t remember thinking oh where’s the wire. I just advanced the rest of the catheter in.”</td>
</tr>
<tr>
<td>3</td>
<td>“I was thinking about it all day, I was totally unhappy. I realised that I hadn’t got to the bottom of what was causing such a total blockage….and it was obvious it was the central line, but it didn’t occur to me until the surgeon said, what’s this in the cava?” “I had a complete blank, because I couldn’t even remember, I had a complete absence, through the sheer familiarity of doing something almost second nature, everything went to a sub-thalamic level and before I knew where I was, I’d completely missed that critical stage…..It wasn’t a knowledge problem, I seemed to just pass over that step and miss it out, I had a lapse.”</td>
</tr>
</tbody>
</table>
“Couldn’t remember what I had done wrong. The next step was to take the guidewire out, which I obviously didn’t do, and I don’t know why. I didn’t realise it, I pushed the catheter into the correct depth, and then I sutured in the catheter onto the skin....in my mind I was doing what I always do, I wasn’t trying any shortcuts, I was in automatic mode.....I have done this procedure over 200 times, and that I had no idea I hadn’t taken it out, I hadn’t removed it.”

“I have no recollection of taking the guidewire out, but then I have no recollection of taking the guidewire out most of the time when I do a line, you just do it.”

Whenever I reflect back on it, even now honestly speaking I don’t remember leaving that guidewire in. I obviously did because it was there and the x ray showed it and they took it out.....I think at the moment that I would have taken it out, there must have been something, that’s the only rational explanation that I have, because I don’t understand otherwise why I wouldn’t, because that what you always do isn’t it, you always put the guidewire in and once you have it in you railroad the central line on top of it, and you pass it over and take the guidewire out and that’s the way you do it. And then you aspirate and make sure it’s in and that’s it. And I couldn’t for the life of me figure it out...I would have normally then pulled it out. And I could have sworn that I had.”

“I didn’t think that it could be a retained guidewire, didn’t cross my mind at all. I had never made a mistake like that before, and usually tie it in a knot as a reminder to myself that the guidewire is out, so I thought that must have been what happened and I just didn’t remember doing it.....I started clearing away and that’s when realised that guidewire wasn’t on the trolley. But I was so busy focusing on what I was doing, I just thought that someone who was trying to be helpful had cleared it away...but I didn’t vocalise it, and say did anyone throw away the guidewire at that point, but neither did I think it was a retained guidewire at that point either.....The fact that I even thought at the time, where did my guidewire go? But I never thought it could be in the patient. It didn’t feature in my mind at all.”

“I think I must have left the cap on; I can’t see how else I would have left the wire I mean in. Because you’d see it coming out of the port otherwise.”

“I was thinking about the heparin and then paused, and I think I hadn’t taken the guidewire out at that point. There was a pause, I came back to the procedure and assumed I had taken the guidewire out. Assumed I aspirated and flushed the line, nothing else sticks.”

“Both of us were doing it [the procedure], but I can’t remember which one of us specifically put the catheter over the guidewire and we must have taken it out. I don’t know why either of us wouldn’t.....It was only when I started clearing up the trolley that I noticed the guidewire was missing and started to look for it, but I didn’t think it would be in the patient. I assumed I had dropped it on the floor or it was in the bin. It was only when we’d searched for ages and neither of us could find it that we thought could it be in the patient?”

Two interviewees described that guidewire retention was recognised during equipment clear up and, in these cases, staff spent time searching the drapes on the patient, the procedure trolley, the floor and the bins before finally querying whether it was inside the patient:
“I rummaged through all of the paper packaging and realised that it wasn’t in there… looked around on the surrounding floor, where I had pushed the trolley to thinking that it may be on the floor in the distance between me and the patient and slowly traced my steps back, realising it wasn’t there….. I was looking on the floor and then this ODP was going around the floor with the magnet, firstly under the table and then basically all around the patient, and around the anaesthetic machine and not being able to find it. At this point [consultant] re-iterated, ‘do you know where it is, do you know that it is out of the patient?’ and I said, ‘I thought it was, but now in view of the fact that we can’t find it, I just don’t know.’”

In two interviews, participants stated that guidewire retention was recognised whilst the CVC was in clinical use during the operation, where one was discovered when the catheter was difficult to aspirate. The other, the surgeon discovered the guidewire in the vena cava intraoperatively. Of the remaining six, two were discovered on the first check radiograph and four on subsequent imaging or review of the first check radiograph by other clinicians (Table 2.8).

Table 2.8: The time of guidewire retention identification as described by each interviewee.

<table>
<thead>
<tr>
<th>No.</th>
<th>Time of error identification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Discovered on the first check radiograph</td>
</tr>
<tr>
<td>2</td>
<td>Discovered during CVC equipment clear up</td>
</tr>
<tr>
<td>3</td>
<td>After the procedure and paperwork were completed, the surgeon discovered guidewire mid operation (before first radiograph)</td>
</tr>
<tr>
<td>4</td>
<td>Discovered on the first check radiograph</td>
</tr>
<tr>
<td>5</td>
<td>After the procedure and paperwork were completed, found the CVC catheter was difficult to aspirate and queried a retained guidewire. Got a chest radiograph to confirm.</td>
</tr>
<tr>
<td>6</td>
<td>After the first check radiograph. The patient was discharged home and readmitted for an outpatient appointment and the guidewire discovered on radiological investigation</td>
</tr>
<tr>
<td>7</td>
<td>After the first check radiograph. The patient was transferred to a private hospital for an angiogram and discovered on this investigation</td>
</tr>
<tr>
<td>8</td>
<td>After the first check radiograph. The guidewire was discovered on chest radiograph by consultant on the Monday morning ward round.</td>
</tr>
<tr>
<td>9</td>
<td>After the first check radiograph. The guidewire was discovered as an incidental finding on day 8 of patient’s admission</td>
</tr>
<tr>
<td>10</td>
<td>Discovered during CVC equipment clear up</td>
</tr>
</tbody>
</table>
On reflection, 5/10 interviewees felt they could pinpoint the moment of the error occurring (Table 2.9). These five described technical factors, interruptions or distractions, at the point at which the catheter was threaded over the guidewire and inserted into the vein. Of the remaining, 4/10 described interruptions or distractions occurring throughout the CVC insertion but could not identify any single factor which may have caused the error, and one interviewee stated that there were no contributory factors at any point of the CVC insertion. As far as they were concerned, it was a routine and easy procedure.

<table>
<thead>
<tr>
<th>No.</th>
<th>Specific contributory factors described by the interviewee which may have influenced the error</th>
<th>Point of CVC insertion when the error occurred</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Difficulty manipulating catheter over a kinked guidewire</td>
<td>When the catheter was threaded over the guidewire and pushed into the vein</td>
</tr>
<tr>
<td>2</td>
<td>Distracted by a consultant asking if CVC insertion was finished</td>
<td>When the catheter was threaded over the guidewire and pushed into the vein</td>
</tr>
<tr>
<td>3</td>
<td>None described</td>
<td>Not described</td>
</tr>
<tr>
<td>4</td>
<td>Last min change of plan to insert CVC, not rushing but wanted to complete insertion quickly so surgeons could start</td>
<td>Distraction was throughout the procedure</td>
</tr>
<tr>
<td>5</td>
<td>Interrupted by the surgical registrar titling the bed to insert a urinary catheter</td>
<td>When the catheter was threaded over the guidewire and pushed into the vein</td>
</tr>
<tr>
<td>6</td>
<td>Chatting with the consultant during CVC insertion about difficulties with the intubation</td>
<td>Distraction was throughout the procedure</td>
</tr>
<tr>
<td>7</td>
<td>Consultant asked to see guidewire in the vein on the USS to confirm the position and use it immediately. Once happy, asked operator to pass him the USS probe to help with arterial line insertion</td>
<td>When the catheter was threaded over the guidewire and pushed into the vein</td>
</tr>
<tr>
<td>8</td>
<td>Porters arrived to transport the patient, and was “speeding through” the procedure to finish</td>
<td>Distraction was throughout the procedure</td>
</tr>
<tr>
<td>9</td>
<td>Had to call out and wait for an assistant to come back into the room to ask for another piece of equipment and deliver this before being able to continue CVC insertion</td>
<td>When the catheter was threaded over the guidewire and pushed into the vein</td>
</tr>
<tr>
<td>10</td>
<td>CVC insertion difficult, two operators actively attempting to insert CVC</td>
<td>Distraction was throughout the procedure</td>
</tr>
</tbody>
</table>
Eight participants described that the CVC was in clinical use whilst the guidewire was retained, and of these, two patients developed ectopics. In the remaining 2/10, the catheter was not in use whilst awaiting a check radiograph. All ten patients underwent further clinical procedures to have the guidewire removed. Guidewire removal was either by clamp and withdrawal (3), removal via interventional radiology (6) or removal by surgeon intraoperatively (1).

Seven interviewees described new safety checks that were subsequently introduced in their department. Of these, four described that operators were required to hold the guidewire up announcing ‘guidewire out’ to the room, and operators were required to document they had done this and write the name of the witness of the safety check or both the operator and the witness needed to sign the notes to confirm guidewire removal. One described that they had helped to develop a special sticker and a form, and operators were required to confirm in writing that the guidewire was removed, one described the introduction of a checklist and one described the introduction of a ‘two person approach’ to CVC insertion. In two departments modifications were made to existing safety checks, where the radiology department were required to formally report all chest radiographs and flagged issues communicated verbally with relevant departments. Finally, to reduce distractions and support the junior doctors, one department contacted all anaesthetic trainees stating:

“Juniors be aware that if people are trying to distract you, no matter who they are, you are completely within your rights to tell them to go away and we will support you.”

Interviewees indicated that guidewire retention was a frequent occurrence. Nine interviewees described other incidents of guidewire retention. Of these, 5/9 reported that a retained CVC guidewire error had occurred again in their hospital whilst they were working there and 4/9 reported it had occurred twice. Four interviewees stated that other clinicians had told them they had also made the same mistake and one stated that three guidewire retentions had occurred in a neighbouring hospital. One interviewee described a conversation with the vascular surgeon who assisted in the guidewire removal:

“They said, this is how we do it, we’ve done it so many times before, this is how you remove it.”

Three interviewees stated that the error was reported as a near miss rather than a never event. Despite the catheter being in clinical use, interviewees stated that this was
because the guidewire retentions were recognised during equipment clear up (1) or during the surgical procedure (2). All three of these retained guidewires were removed at the end of the operation, before the patient woken up, using an additional procedure by a surgeon or interventional radiologist.

2.4.4 Discussion

This study sought to understand the mechanism of CVC guidewire retention through the first hand accounts of clinicians who have made this error. A total of 24 clinicians volunteered to be interviewed and of the ten interviewees, nine related other retained guidewire incidents in their own hospitals. Whilst these numbers are anecdotal, it indicates the frequency of this error.

None of the participants recognised guidewire retention at the end of CVC insertion, when the catheter was sutured into place and the dressing applied.\textsuperscript{101} However, three interviewees stated that the error was not formally reported as a never event but as a ‘near miss’ because it was discovered on equipment clear up or before the end of the surgical operation before the patient was woken up. Here one could say that this is downgrading the severity of the error due to a technicality or flexible interpretation of the description of the never event by hospitals. As with clinicians unwilling to discuss their errors, hospitals and departments are also fearful of the consequences of the error, particularly where there is the potential for scrutiny by regulatory bodies. Hence, one could understand why hospitals may choose to downgrade the error event, and as described in the literature,\textsuperscript{102} the practice of these three hospitals demonstrates that underreporting does occur.

In this study, all participants were capable of independent CVC insertion, having performed the procedure previously without error and 8/10 were involved in teaching juniors the CVC insertion procedure. Whilst eight were junior doctors, it is still difficult to attribute clinician inexperience to this error, particularly when 90% of interviewees were experienced and made the error, similar to that seen in the literature and the NRLS data.\textsuperscript{19,20,64}

Various patient, environmental and technical factors were described in the ten interviews. Across the ten interviews, these descriptions were often opposing, i.e., procedures were emergency or routine, patients were straightforward or complex, the environment was quiet or noisy, calm or busy and changeable, and the CVC insertion was easy or complicated. These descriptions demonstrate that this same error occurs despite the
widely opposing situations described by interviewees. Whilst the NRLS data and the literature have described workload pressure, the patient, the equipment, emergency or out of hours as causes of these errors, the opposing situations described in these interviews demonstrate that these factors cannot solely be causative factors. The complex environments described in these interviews and the NRLS data demonstrates that a prevention strategy must be effective despite all patient, operator, environmental and technical factors.

Seven interviewees described repeated interruptions and distractions. These were throughout the procedure and were from one or multiple clinical staff members (anaesthetic consultants, surgeons, ODPs or porters). In the literature, some authors have suggested that this error is preventable by minimising distractions or interruptions. In this study, one interviewee stated that their department informed all junior anaesthetic staff that they should ‘tell staff to go away’ if they were being distracted during the anaesthetic procedures and would be supported in this strategy. However, these interviews and the NRLS data demonstrate the wide ranging activity occurring alongside the CVC insertion. Interviewees described interruptions and distractions as routine occurrences, demonstrating the simplistic nature of using “do not interrupt or distract” as a prevention strategy. Therefore, these interruptions and distractions are inevitable and mostly likely unpreventable and, as discussed previously, may be clinically necessary for patient and staff safety in some cases.

Interviewees described numerous personal and departmental safety checks to prevent the error. A total of 48 checks were described in these interviews, all of which should have prevented this error; however, 92% of these checks failed. These checks are the same as those described in the literature and the NRLS data (checklists, two person checks etc), and in this study, they were demonstrated to be ineffective 92% of the time. Whilst some checks prevented the error, in most cases, the same check failed in others (Table 2.6). Only two types of checks were effective, but both had a low success rate: checking the trolley for guidewire during equipment clear up (20%, 2/10) and checking the first check radiograph (33%, 2/6). The interviewees that recognised guidewire retention on equipment clear up were praised for diligently making this check and recognising the error. Incident investigators criticised one interviewee for failing to perform this check correctly, stating the error would have been prevented had they simply stuck to their routine. However, both responses are simplistic analyses of the cause and prevention of the error. When clinicians are rushed or there is clinical urgency, there is no time to perform the procedure calmly; and
it becomes difficult to ensure clinicians perform this check every time. The equipment check is also difficult to enforce, as one interviewee described that a helpful ODP had cleared away their equipment to allow them to move on to the next task rapidly. One could insist that only the operator should clear up the equipment and perform the count out check themselves; however, clinicians depend on their colleagues in times of clinical urgency and must trust each other to ensure the patient has timely and safe care.

Six out of ten interviewees stated that the first check radiograph was reviewed, and in 2/6, guidewire retention was recognised. However, in 4/6 instances, this same check failed, and two of these described that guidewire retention was missed despite multiple radiological investigations and reviews by multiple staff members. This is similar to that seen in the literature\(^4\) and the NRLS data. As discussed above, clinicians are susceptible to inattentional blindness and can miss errors obvious in hindsight. However, despite its limited success, checking the radiograph is commonly stated as a prevention strategy.\(^7,76,107\) If the clinician is forced to concentrate on the possibility of the retained guidewire, a rare error, it draws the focus away from more common errors, which could be more dangerous for the patient.

Eighty per cent of interviewees described the paperwork confirming CVC insertion and checklists specifically relating to guidewire retention failed to ensure recognition of the error. Whilst a checklist is commonly suggested as a mechanism of error prevention, as seen in the NRLS data and the literature search, which found 24 studies that suggested a checklist for CVC insertion (Table 2.1). The quotations demonstrate, as with alert fatigue, clinicians can get ‘checklist fatigue’,\(^108\) where the check, instead of being a useful tool to prevent error, becomes a tick box exercise, particularly when designed and implemented poorly.\(^108\) This becomes particularly relevant for rare errors. If the error only occurs once in several thousand procedures, i.e., only once or twice in a clinician's working lifetime, as with inattentional blindness, if one does not expect to see the error, it is easily missed. Additionally, these paperwork checks are performed after the procedure is completed and have limited benefit in preventing or recognising an error, which was seen in this study and in the literature.\(^64\) We could conclude that the times when these checks have been ‘successful’ have been when the clinician has not made the error in the first place, potentially making checklists a false success story in preventing this error. Therefore, we must question the benefit of the check. Whilst it may not help prevent the error, it is helpful for audit purposes and, as demonstrated in this study, finding an individual to be blamed. Having not
recognised that they had made the error, one interviewee was accused of falsifying documentation because they had ticked the box confirming guidewire removal. Falsifying documentation is potentially a criminal charge, which may have affected their ability to practice medicine. However, this same action was seen by seven other interviewees, who confirmed that the guidewire had been removed on the paperwork after failing to recognise guidewire retention, and in the published literature.\textsuperscript{14} One could suggest a checklist or paperwork that is executed during CVC insertion where the operator or assistant, if available, ticks off each aspect of the procedure as it is performed; however, not only is this impractical, it increases clinical workload and cognitive load and has the potential to introduce more errors.

Four interviewees stated that a formal second person check was in place, and in all cases, this check failed. In all these, interviewees described the lack of a permanent assistant during the CVC insertion. Quotations demonstrate that ODPs and nurses are busy performing other clinical tasks, which are also critical for safe and timely patient care. Consequently, assistants can also be distracted when performing the second person check; one interviewee stated that whilst the ODP had said “yes” to confirm that the guidewire was out, they later admitted that they had not really \textit{seen} the guidewire; they had just said they had. Similarly, as with alert and checklist fatigue, there is creeping complacency. If the error is not commonly seen, one does not expect to see it, and the clinician becomes complacent with the check and misses the error when it occurs. Unless the assistant is by the operator's side diligently watching the CVC insertion from start to end, this check is flawed, and as demonstrated in these interviews, prone to failure.

Almost all departments introduced new safety measures after the error incident. Interestingly, many of the ‘new’ safety measures introduced by hospitals after the error occurred were the same checks described by other interviewees that had failed. Indeed, 9/10 interviewees stated that another retained guidewire incident occurred in the same Trust after introducing the ‘new’ safety measure. That 92\% of checks to prevent guidewire retention failed in this study demonstrates that other preventative mechanisms are required to prevent this error.

Improving the supervision of junior colleagues was suggested in 24 articles in the literature search. In this study, four interviewees described that whilst they were supervised, it was not active supervision, similar to that seen in the NRLS data. One interviewee said they should not need active supervision for every procedure they perform, which may be
correct. In terms of practicality and time management, it is impossible to actively supervise every junior doctor for every procedure until they become a consultant, just in case of a mistake. We must train and, at some point, trust that junior doctors can perform clinical tasks correctly. In fact, before the incident, all the interviewees were capable and had performed CVC insertions without error and some, many hundreds of these procedures without error. Therefore, the suggestion of active supervision or the requirement to retrain instead of being a practical and effective preventative strategy may simply be a management tick box exercise.

All participants believed that they had removed the guidewire during the procedure, and all stated that they knew this action must be performed and that it was their normal practice to do this. This demonstrates that there is no intent or malice and that the error was a mistake and it is sad that one interviewee described the potential for penalisation with substantial consequences for their career. The two interviewees who recognised guidewire retention during equipment clear up described that they and other staff spent time searching the drapes on the patient, the procedure trolley, the floor, and the bins and one described an ODP crawling around the floor with a magnet, before finally querying whether the guidewire was inside the patient. This exact scenario was also seen in the NRLS data. Therefore, even when the guidewire is missed on the trolley, the possibility of the guidewire being retained is so low in the operator’s mind that every other eventuality is deemed more probable. Which demonstrates the difficulty that clinicians have in recognising the mistake after it has occurred.

The quotations in Table 2.7 demonstrate that none of the interviewees could fathom why they missed this step and confirms that guidewire retention must be an omission error, i.e., that they forgot to perform this action and, without a mechanism to recognise this, completed the procedure. Interestingly, five interviewees stated these interruptions came precisely at the moment in the CVC procedure when they had placed the catheter over the guidewire and should have taken it out. As seen in the NRLS data, these distractions or interruptions at this critical moment in the CVC procedure may be the cause of why clinicians had forgotten this step. This supports the theory that guidewire retention is an omission error. During CVC insertion, clinicians may forget that the guidewire has not been removed if they are distracted or interrupted at the critical moment in the procedure (catheter over guidewire and guidewire out). Without confirmation of guidewire removal, the operator
completes the procedure, and the never event occurs. Therefore, to prevent this error, an intra procedure safety mechanism at this ‘critical point’ is required to prevent this error.

Limitations

There are several limitations to this study. Participants self selected to be interviewed, and due to the nature of this never event error, descriptions may not represent the majority of circumstances or clinicians’ views. An attempt to overcome this was to speak with as many clinicians that volunteered as possible to get the broadest representation of the error. The interviewer had no prior experience conducting these interviews. An attempt to mitigate this was through reading the literature and discussing the study with supervisors experienced in this field. Additionally, as a clinician, it was felt that the interviewer would have procedural understanding when discussing the specifics of the error and environment with interviewees. Only ten interviews were conducted, despite 24 clinicians volunteering, 14 later chose not to be interviewed. Whilst ten interviews may be a low number of participants, theoretical saturation was reached prior to the tenth interview and there were no other volunteers for the study, therefore the number of participants was the best achievable in the time frame. The interviews were semi-structured; discussions were based on what the interviewer or interviewee felt was important, potentially leading to bias. All discussions were solely based on the operator’s memory of the incident at the time of the interview. As the interviewee must have been repeatedly processed memories of the specific event, this may have led to re-interpretations of events or bias in the descriptions. However, the descriptions by all interviewees were broadly similar and comparable to the NRLS data and the literature; therefore, whilst memories may have faded or adjusted, this possibility of bias was broadly discounted. The interviewer transcribed and analysed all the interviews, and whilst this was to preserve anonymity for the interviewees, this could also have led to bias in the description and the analysis. In this study, translations were verbatim, so the intonations and expressions of interviewees were unavailable. However, this analysis was solely to understand the mechanism of the error, and these were appropriate to be excluded. Interviews were conducted at a location comfortable for the interviewee. Hence, there may have been some difficulty in hearing the recordings and the accuracy of transcription where interviews were conducted in noisy public settings. An attempt to confirm the accuracy of the recordings was by reading the transcript whilst listening to the recordings several times. The interviewer did not contact individuals to confirm or clarify details, so there may have
been bias in the interpretations and analysis. Inductive thematic analysis, based on themes seen in the NRLS data and literature, was used to analyse the results, which may also have led to bias in the interpretation. An attempt to overcome this was through discussing the analysis with supervisors. Whilst a criticism of thematic analysis is that the analysis simply consists of descriptions, in this study, the specific descriptions by interviewees were the data required to understand the mechanism of the error. Finally, the analysis was not performed using electronic coding software, and this was due to a lack of funds. The analysis was performed by hand and tabulated in Microsoft Word, and this may have unknowingly biased the results. An attempt to mitigate this was through discussing the analysis with supervisors.

2.4.5 Conclusions

In these interviews, guidewire retention occurred with skilled operators, who knew the guidewire should be removed during CVC insertion but failed to do so. They then failed to recognise their error and continued securing the catheter. This data demonstrates that guidewire retention must be an omission error and is a mistake rather than malice or ignorance. The current mechanisms of error prevention were mostly ineffective and, in most hospitals, the error recurred even after new safety mechanisms were introduced. Distractions and interruptions were common and specifically occurred at a ‘critical point’ in the CVC procedure; when the catheter was placed over the guidewire and the guidewire should have been removed. Therefore, a novel solution must be designed around the ‘critical point’ in the CVC procedure. If this solution can be effective despite interruptions and distractions, then CVC guidewire retentions may be prevented.

2.5 Chapter conclusions

The main findings of the literature search, NRLS data and interviews and the conclusions drawn from the data are summarised in Table 2.10.
Table 2.10: A summary of the main findings of the literature search, the NRLS data and the interviews and the resulting conclusions.

<table>
<thead>
<tr>
<th>Findings</th>
<th>Conclusions</th>
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</thead>
<tbody>
<tr>
<td>1  The reported frequency of CVC guidewire retention is rising despite current prevention strategies</td>
<td>A novel prevention strategy must be developed</td>
</tr>
<tr>
<td>2  97.5% of guidewire retentions are single catheter insertion</td>
<td>Focus the prevention strategy on single line insertions rather than the complexities of multiple catheter insertion procedures</td>
</tr>
<tr>
<td>3  The vast majority of guidewire retentions are not recognised at the end of the clinical procedure</td>
<td>Clinicians have made the error mid procedure and not recognised their mistake</td>
</tr>
<tr>
<td>4  Most guidewire retentions are not even recognised on the first check radiograph</td>
<td>Most clinicians are unaware that they have made this mistake and given the rarity of the error, do not recognise the error and, it may be unrecognised for hours, days, months or even years</td>
</tr>
<tr>
<td>5  Most safety checks were found to be ineffective and none were 100% effective</td>
<td>Current strategies do not ensure recognition of guidewire retention</td>
</tr>
<tr>
<td></td>
<td>A different prevention strategy must be developed</td>
</tr>
<tr>
<td>6  In the interviews, in 90% of hospitals the error recurred even after new safety measures were introduced.</td>
<td>A different prevention strategy must be developed</td>
</tr>
<tr>
<td>7  All interviewees knew that they should remove the guidewire during CVC insertion</td>
<td>Training and clinicians’ knowledge is appropriate</td>
</tr>
<tr>
<td></td>
<td>Retraining and re-education unlikely to be effective</td>
</tr>
<tr>
<td>8</td>
<td>All interviewees <em>believed</em> that they had removed the guidewire</td>
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<td></td>
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<tr>
<td>9</td>
<td>Most interviewees described interruptions or distractions during CVC</td>
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<td></td>
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<tr>
<td>10</td>
<td>50% of interviewees felt that they were interrupted or distracted at the point the catheter was placed over the guidewire and the guidewire should have been removed, and thought this was why they had not removed the guidewire</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Catheter over guidewire and guidewire removal is the ‘critical point’ in the CVC when the error occurs</td>
</tr>
<tr>
<td>12</td>
<td>Most retained guidewires are located within the catheter on recognition, even several days post insertion</td>
</tr>
</tbody>
</table>
Bedside guidewire retrieval techniques were easily performed and mostly if guidewire retention is recognised early, then bedside rather than invasive and costly interventional radiology or surgical techniques could be used.

These are, that all clinicians knew they should remove the guidewire, and all believed they had done so. Therefore, they must forget to remove the guidewire during CVC insertion and, failing to recognise this error, secure the catheter. The data in these studies have confirmed that guidewire retention is highly likely to be an omission error at a ‘critical point’ in the CVC procedure. In addition, most guidewire retentions were unrecognised at the end of CVC insertion, safety checks were mostly ineffective, and none were 100% effective. This may be because they were operator focused interventions or were checks performed after the error had occurred, when it may be too late to correct easily. Thus, a systems solution, a strategy not dependent on the operator, may be the best mechanism for preventing this error. Given that distractions or interruptions at the critical moment in the CVC procedure may clinicians to forget to remove the guidewire, an intraprocedural safety mechanism must be developed to prevent this error, either by physically preventing over insertion of the guidewire or by enforcing early recognition of guidewire retention. To prevent this error, first lessons on error prevention from the high reliability industries must be evaluated and adapted to medicine. Then further work is required to understand the CVC insertion procedure and the equipment used to perform the procedure, to determine how a systems solution to prevent this error may be designed.
CHAPTER 3

DEVELOPING A SOLUTION TO PREVENT CVC GUIDEWIRE RETENTION

This chapter describes the process of developing a novel solution to prevent CVC guidewire retention. Given that the current safety mechanisms for preventing this error are mostly ineffective, lessons from the high reliability industries are initially discussed to determine how a novel systems solution could be developed. The CVC procedure was analysed to determine how and where a systems solution could be incorporated into the procedure to prevent the error. The detailed process of developing a novel solution is then discussed, including why the final solution was chosen and how it was developed with a manufacturing company. The chapter concludes with the lessons learnt from the development process.

3.1 Lessons from the high reliability industries

3.1.1 Adapting the lessons from the high reliability industries to medicine

Cafazzo and St-Cyr’s work on the risk management theory discusses the effectiveness of interventions that are used in the workplace. They suggested that, in terms of intervention effectiveness, there are two groups of interventions or prevention strategies: people focused, and system focused. This is presented in their hierarchy of intervention effectiveness (Figure 3.1). This theory suggests that strategies such as education and training, rules and policies, reminders, checklists and double checks are people focused and dependent on the operator to prevent errors. Strategies such as simplification and standardisation, automation, and computerisation, and forcing functions are system focused changes. When introduced, system focused changes support or force the operator to perform the procedure by the safest mechanism or the action that will prevent harm. The system focused strategies are not reliant on the operator. They usually are devices or interfaces which force the operator, when required or necessary, to behave in the safest way to prevent
the occurrence of an error. In terms of the effectiveness of interventions, Cafazzo and St-Cyr suggest that forcing functions are the most effective type of intervention (Figure 3.1).\textsuperscript{109} Notably, Cafazzo and St-Cyr do not mention elimination in their theory, where if the procedure is not performed or substituted with a different procedure, then guidewire retention would not occur. However, in terms of CVC insertion, elimination is not always possible. Therefore, in terms of preventing retained CVC guidewires, a forcing function would be the most effective solution.

**Figure 3.1:** The hierarchy of intervention effectiveness, by Cafazzo and St-Cyr\textsuperscript{109} demonstrating the system focused and people focused strategies. The flow model demonstrates the effectiveness of interventions used in the workplace, where forcing functions are the most effective and education and training are the least effective. Image adapted to include ‘elimination’ at the top of the hierarchy and the ‘foundation’ of medical education and speciality training, illustrating that 99.97% of retained CVC guidewire never events are prevented because medical education and speciality training is effective. To prevent the remaining 0.03% of these errors other strategies are required.

In designing safety systems, human factors engineers analyse the procedure and anticipate where errors may occur when the operator performs the procedure.\textsuperscript{59} The prevention of these errors is addressed by incorporating a safety mechanism into the design of the product or process, i.e. a forcing function. The forcing function safety mechanism works in two ways and either prevent unintended or undesirable actions by the operator or only allows a process or procedure to be completed after a specific safety action has been
Forced functions are commonly seen in our everyday environment to ensure that the technology we use is practical and safe. For example, a microwave oven can only be activated when the door is closed and will automatically deactivate if the user opens the door. This safety feature has been designed because it is anticipated that the operator may want to prematurely stop the cooking process by simply opening the door rather than first pressing the stop button and then opening the door. By understanding this behaviour and the shortcuts humans inevitably take, the manufacturers have introduced an automatic shutdown of the electricity and electromagnetic radiation as soon as the door is opened to keep the user safe. Another example is when the user attempts to shut down a computer programme without saving the document. The user does this because, in their mind, they have finished their task and are moving on to the next, so the process of saving the document is not always at the forefront of their mind when the programme is shut down. To prevent this, software engineers have designed a forcing function. If the operator attempts to close the programme before pressing the save button, the software temporarily halts this process to deliver a safety message to the user asking whether or not they want to save the document. Importantly, if the user has remembered to save the document before closing the programme, the safety message does not appear. Therefore, the safety function is only activated when required, forcing the user to perform the safety action. These processes are integrated into the everyday environment, and most users are unaware of their existence. Now they are increasingly being used in healthcare. For example, the VanishPoint® retractable syringe is an engineered forcing function which automatically retracts the needle into the syringe barrel immediately after use to prevent the reuse of the needle and syringe, a significant source of blood-borne infections in the developing world. In terms of never events, where the user mainly performs the correct action, but once in every few thousand procedures, a mechanism is needed to ensure the clinician performs the safety procedure correctly. In these cases, a forcing function is likely to be the most effective preventative safety strategy. Unlike checklists, warnings, alerts or reminders, a forcing function does not rely on the clinician remembering to perform the safety action every time the clinical procedure is undertaken. Hence, a forcing function should be a sustainable prevention strategy without the need for repeated reminders or training interventions. A well-designed forcing function should ideally be integrated into healthcare practice with little user training. The lessons from human factors design engineers in the high reliability industries suggest that:
a) if the clinical procedure could be analysed, i.e., CVC insertion,
b) the potential error points in the procedure anticipated, i.e., the critical step, and
c) the equipment or process could be modified to introduce safety solution i.e., a forcing function,

then this should ensure the user performs the correct or safe action every time. As with the computer programme, the forcing function must not impact the CVC insertion during the thousands of times the clinician performs the procedure correctly but would come into effect if the error was about to occur.

In terms of never events, one aspect that Cafazzo and St-Cyr do not touch on in their theory is the foundation below the interventions: education and training. In terms of medicine, this is a medical education and speciality training (Figure 3.1). In terms of retained CVC guidewires and every other never event, the error is rare because most clinicians do not make the mistake. This is because these procedures are performed after medical education and during or after speciality training. Because this ‘foundation’ is strong, the error only occurs once every 0.03% of procedures. Hence, the interventions described by Cafazzo and St-Cyr are to prevent the error occurring in 0.03% of these procedures and may demonstrate why people focused interventions for never events may not be as effective as forcing functions.

3.1.2 Designing a forcing function in healthcare

Despite the comparisons made with the high reliability industries, healthcare is more complex. In the high reliability industries, one human interacts with one or multiple machines. For example, there are two pilots inside an aeroplane cockpit, and they interact with a mechanical operating system to fly the aeroplane safely. In industry, it is arguably easier to design machines ergonomically, with forcing function safety features to ensure tasks are performed in the safest fashion because the engineers only have to map the interaction between the human and the operating system. In medicine, this has been achieved with the anaesthetist and the anaesthetic machine to some extent. However, in its simplest form, healthcare is the interaction of one human, the clinician, with another human, the patient, using equipment to support the diagnostic or treatment process. In designing forcing functions to prevent never events, human factors design engineering has to account for the human–human interaction which occurs in an emotionally stressful and complex
environment. The designer must understand how the equipment is used in this interaction. Therefore, there must be an understanding of the clinical procedure that needs to be undertaken, the clinical working environment, understanding the system flaws\textsuperscript{111} which the clinician has to work in, the expected behaviour of the clinician undertaking the clinical procedure and the circumstances in which the error occurs.

The prevailing theory of error causation is described by James Reason, where the causes of errors are either person based or systems based.\textsuperscript{111} The person approach focuses on the individual’s actions, which can lead to blame.\textsuperscript{111} The systems approach focuses on the organisational processes and the environment in which the individual works.\textsuperscript{111} This can be seen visually in Reason’s Swiss Cheese Model,\textsuperscript{111} where the system has several defence layers (layers of cheese). These are the organisational processes, the environment, and the individual. All the layers work together to prevent the error from occurring 99.97\% of the time, in the case of retained CVC guidewires. However, each layer has holes (i.e., Swiss cheese), allowing a small slip to occur. If a slip occurs in one layer, the remaining layers may still prevent the error. However, the error will occur if all of the holes in each layer are aligned. Reason also states that the holes in the Swiss Cheese are not static; they move and can open and close\textsuperscript{111}, and the factors that cause this are variable depending on the organisational processes, the clinical environment, the clinician or the patient. This was seen in the different scenarios in which guidewire retention has occurred in the literature search, the NRLS data and the interviews. Reason also states that in terms of accurate error prediction, the number of mechanisms by which a particular error occurs is limited,\textsuperscript{111} and they fall into recurrent patterns which relate to the “nature of the task, the environmental circumstances and the mechanisms which govern the performance of the individual”.\textsuperscript{111} Regardless of the clinician involved in the error, the nature of CVC insertion and the environmental circumstances cause this mistake to occur repeatedly.\textsuperscript{111,112}

Taking this into consideration and knowing that latent failures are difficult to solve or remove, one must focus on the active failures\textsuperscript{111} to prevent CVC guidewire retention. The literature search, the NRLS data and the interviews demonstrated the many patterns by which the CVC guidewire retention occurred. A Swiss cheese model could be drawn for every one of these incidents, and all the models would have slight differences. However, if these were all mapped together (Figure 3.2), one can see that the final hole in the cheese is the same for every retained CVC guidewire retention: the clinician forgets to remove the guidewire from the patient and, failing to recognise the error, completes the procedure. This
active failure at the final hole in the cheese is likely to be the ‘critical point’ in the CVC procedure and, therefore, is the point where the preventative solution or forcing function is required. If a forcing function is developed at this ‘critical point’, guidewire retention would be prevented in every CVC insertion.

Figure 3.2: Swiss cheese model by James Reason\textsuperscript{111} is adapted to demonstrate that CVC guidewire retention occurs in several different fashions through variable holes in the cheese, as seen in the literature, NRLS data and the interviews. However, the final error point, where the clinician forgets to remove the guidewire, is the same hole in all the cheese models of CVC insertion. Therefore, the final hole is the ‘critical point’, the ‘active failure’ in the procedure, and is where the prevention strategy is required.

3.2 The CVC procedure

3.2.1 CVC insertion: the procedural steps

To develop a solution which prevents over insertion of the guidewire or enforces early recognition of guidewire retention, we must understand the procedural steps of CVC insertion to determine at which point a preventative strategy might be most effective.
Figure 3.3: A flow diagram detailing the procedural steps involved in CVC insertion.

CVC insertion is an invasive procedure performed by a highly skilled clinician using specifically designed equipment. The procedural steps involved are lengthy, requiring preparation of the patient, equipment and the requirement for maximum sterile barriers.\textsuperscript{101} Post procedure, paperwork must be signed, and a check radiograph performed to confirm the position of the tip of the catheter.\textsuperscript{101} The procedural steps involved in CVC insertion are detailed in the literature\textsuperscript{101,113} and a flow diagram of these steps can be seen in Figure 3.3.
3.2.2 The critical error point during CVC insertion

Most interviewees stated that distractions and interruptions occurred throughout CVC insertion, and 50% felt they were interrupted or distracted at the point the catheter was placed over the guidewire, and the guidewire should have been removed. Interviewees thought this was why they had not removed the guidewire. This appears to be a critical moment in the CVC insertion, where if clinicians have failed to recognise guidewire retention, they proceed to complete the procedure (Figure 3.4).

![Figure 3.4: A flow diagram detailing the ‘critical point’ in the CVC insertion procedure where guidewire retention is most likely to occur, that is, after the catheter is passed over the guidewire but before it is sutured into place and the points at which guidewire retention was discovered in the NRLS data and the interviews.](image)

This theory is supported when reviewing the time of discovery of guidewire retention in the NRLS and interview data.

All guidewire retentions were discovered after the ‘critical point’; therefore, guidewire retention must have occurred at or immediately after the ‘critical point’ (Figure
3.4. Any novel solution which prevents over insertion or early recognition must be effective at the ‘critical point’, otherwise retention will occur.

However, when designing a novel solution, it is essential to understand why the prevention strategies suggested by authors in the literature, reports from the NRLS data, and the interviewees may or may not be effective.

3.2.3 Why are the current mechanisms of error prevention mostly ineffective?

Figure 3.5 demonstrates the point of the CVC procedure where the prevention strategies described in the literature, NRLS data and the interviews would be effective.

Figure 3.5: A flow diagram detailing the steps in the CVC insertion and the points at which the prevention strategies detailed in the literature, NRLS data and the interviews would be used. Where strategies in blue would be effective prior to the procedure starting, those in red would be effective during the procedure and those in purple, effective after the ‘critical point’ in the procedure, when the error may have already occurred.
As discussed in Chapters one and two, these strategies are ineffective so far because the error continues to occur. The mechanism of action of the current preventative strategies would be effective either prior to the procedure starting and relies on the operator preventing the error, such as improvement in education and training and standardisation (Figure 3.6 and 3.7, blue).

Figure 3.6: A flow diagram detailing the steps in the CVC insertion and the reasons why the prevention strategies detailed in the literature, the NRLS data and the interviews may not be effective (bold boxes). Where the strategies in blue would be effective prior to the procedure starting, those in red would be effective during the procedure and those in purple would be effective after the ‘critical point’ when the error may have already occurred.

Or effective during the procedure, where these strategies may be difficult to enforce to reliably prevent guidewire retention, such as do not distract operators, ensure vigilance, or follow protocol (Figure 3.6 and 3.7, red). Or effective after the ‘critical point’ in the procedure when the error has already occurred, and may not be easily correctable, such as checklists, equipment check or check the radiograph (Figure 3.6 and 3.7, purple). However, changing the guidewire may be an effective strategy and is commonly described in the literature. As discussed previously, whilst longer guidewires can be impractical, an infection control risk and have not prevented the error, physically altering the...
guidewire to prevent the operator from over inserting beyond 18cm or a method of ensuring
the operator recognises over insertion may be a mechanism of preventing this error.

3.2.4 Anatomy of the guidewire

To understand how the guidewire may be altered to prevent this error, we must first
understand the anatomy of the guidewire. Whilst many variations and varieties of guidewires
are available from different manufacturers, most guidewires for CVC insertion are flexible
with a soft j-tip at the proximal end (closest to the patient) and a soft straight portion at the
distal end (furthest away from the patient) to prevent damage to the epithelium when the
 guidewire is inserted into the vein (Figure 3.7).

![Figure 3.7: Image of a standard guidewire (Kimal PLC, Uxbridge, UK) used for CVC insertion, showing
the j-tip (proximal end), which is inserted into the patient’s vein, distance markings at 10cm, 20cm and
30cm and the soft straight portion of the guidewire (distal end).]

CVC guidewires are usually 45cm long but can be up to 60cm long. They are commonly
made with a nitinol core, and this material is used to provide the flexibility required.\textsuperscript{115} Nitinol has the additional benefit of memory recoil, allowing the wire to spring back into
shape after use.\textsuperscript{115} The core is wrapped, through welding and bonding, with a stainless steel
wire coil. The density and tightness of the coiling determine the flexibility of the guidewire,
where a balance of flexibility and stiffness is needed for inserting the guidewire into a vessel
and to reduce kinks.\textsuperscript{115} Finally, the guidewire is finely coated with a polymer such as
polytetrafluoroethylene (PTFE) or silicone to reduce friction and allow ease of movement.\textsuperscript{115} Most guidewires have black demarcations at intervals along the body to indicate the distance
from the j-tip, with demarcations at 10cm, 20cm and 30cm (Figure 3.7). These demarcations
are created during manufacturing through laser markings etching the metal. They are a guide
for clinicians to ensure they know how much of the guidewire has been inserted into the
patient. The guidewire is presented to the clinician loaded (curled up) inside a circular holder
(Figure 3.8). This circular holder is ergonomically designed: it has a wheel or protrudings at
the leading edge (Figure 3.8) to thread the guidewire out of the holder and through a 2mm
pointed aperture at the exit point. This allows the operator to feed the guidewire out of the circular holder and into the CVC needle with one hand. Due to the intricacies of the manufacturing process and the cost of all the components, the guidewire is an expensive part of the CVC equipment.

Figure 3.8: Images of standard CVC guidewires loaded inside the circular holders ready for insertion into the needle during the CVC procedure. Where: A) Kimal CVC circular holder (Kimal PLC, Uxbridge, UK), B) Vygon CVC circular holder (Vygon (UK) Ltd, Swindon, UK), C) Arrow CVC circular holder (Teleflex, Athione, Ireland).

3.2.5 How the guidewire is used in CVC insertion

```
Steps during CVC insertion

Operator prepares CVC equipment, patient & scrubs
USS to find vein
Insert needle into vein
Insert guidewire into needle
Remove needle
Make skin incision
Place dilator over guidewire
Remove dilator
Pass catheter over the guidewire
Pass catheter into the vein and remove guidewire
Aspirate and flush catheter
Place catheter caps on lumens
Catheter secured to skin
Apply dressing
Clear away equipment
Start to use CVC
Sign paper work

Points in the CVC procedure when the guidewire is used

Figure 3.9: A flow diagram detailing the steps in the CVC insertion and the points at which the guidewire is used in the procedure.
```
In the CVC procedure, the guidewire is first used when it is fed out of the circular holder through the pointed aperture, which is slotted into the distal hub of the introducing needle. The guidewire is then used six times during the CVC procedure (Figure 3.9): when the guidewire is inserted into the needle, when the needle is removed and passed over the guidewire, when the dilator is passed over the guidewire and subsequently removed, when the catheter is passed over the guidewire and finally when the guidewire is removed by being threaded through the catheter lumen. When the guidewire is used, it must freely pass through the lumen and the proximal and/or distal ends of the circular holder, needle, dilator, and catheter. Therefore, this equipment must be considered when a novel prevention strategy altering the guidewire is developed.

3.3 Prevention strategies involving the guidewire

3.3.1 Adding an attachment to the guidewire

Some authors have suggested attaching artery forceps to the straight end of the guidewire to prevent over insertion of the guidewire.\textsuperscript{104,107,114,116–118} This may be an effective solution as the operator cannot over insert the guidewire as the artery forceps will physically prevent this action. However, artery forceps are not routinely available in the CVC insertion kit. The operator has to remember to ask an assistant to procure the equipment mid-CVC procedure and remember to clamp the guidewire with the forceps after the catheter is threaded over the guidewire and the guidewire is visible at the distal catheter port. At which point guidewire retention would be unlikely to occur.

An idea was developed, consisting of a guidewire with a blinking light or a sound emitting device, which is attached to the end of the guidewire. The aim of this guidewire would alert the operator to the presence of the guidewire and would physically prevent over insertion, in a similar fashion to the artery forceps. However, relying on the operator to remember to place the attachment on the artery forceps after the catheter is placed over the guidewire would be impractical. Hence, this idea was further developed so that the device was already attached to the straight portion guidewire. A schematic of this idea was sketched to understand what this guidewire would look like (Figure 3.10).
Idea: A guidewire with a blinking light or sound device attached to the straight portion (Figure 3.10 schematic).

Figure 3.10: Schematic of a guidewire with a device (a blinking light or sound emitting) attached to the straight portion of the guidewire.

Mechanism of action
1. Alert the user to the presence of the guidewire
2. Prevent over insertion of the guidewire

Prototype development

A prototype was developed to test the theory and determine whether this solution would be practical. A makeshift ‘device’ was applied onto the straight portion of the guidewire to act as the attachment. Half a gram of yellow Play-Doh modelling clay (Play-Doh, Hasbro, Rhode Island, US) was attached to the straight portion of a guidewire (Kimal PLC, Uxbridge, UK) as a makeshift ‘device’ to test the theory of this idea (Figure 3.11). If this was practical, work to develop and manufacture a light or sound emitting device could be started, and a study performed to determine which would be most effective.

Figure 3.11: A prototype of a guidewire with a ‘device’ (a blinking light or sound emitting) on the straight portion of the guidewire. Guidewire (Kimal PLC, Uxbridge, UK) with yellow Play-Doh modelling clay (Play-Doh, Hasbro, Rhode Island, US) as the makeshift ‘device’.

Feasibility and functionality testing

On a benchtop, the prototype in Figure 3.11 was inserted into a CVC catheter to determine whether this guidewire would be a practical solution to prevent this error. However, after manipulating the guidewire into the catheter, it was quickly apparent that this solution would be highly impractical for CVC insertion (Figure 3.12).
Figure 3.12: Bench test of the prototype guidewire with a ‘device’ (a blinking light or sound emitting) on the straight portion of the guidewire. The guidewire can only be passed through the catheter in 1 direction. It cannot pass through the entire catheter lumen or out of the proximal and distal ends, which is necessary for CVC insertion. Guidewire (Kimal PLC, Uxbridge, UK) and CVC catheter (Kimal PLC, Uxbridge, UK) with yellow Play-Doh modelling clay (Play-Doh, Hasbro, Rhode Island, US) as the makeshift ‘device’.

Evaluation

The guidewire could only be passed through the catheter in one direction. It was not possible to pass the catheter through the entire catheter lumen or out of the proximal and distal ends of the catheter. Consequently, this guidewire could also not be passed through the circular holder, CVC needle or CVC dilator, all necessary for CVC insertion. The catheter lumen is 1mm in diameter, and the ‘device’ requiring electronics for a light or a sound would be too large to pass freely down the lumen and the proximal and/or distal ends of the circular holder, needle, dilator, and catheter. It was too challenging to develop a device with electronics that would be thin enough to surround the guidewire and fit into the circular holder, needle, dilator, and catheter. Even if such a device were developed, over insertion would still be possible. Therefore, this idea was dismissed as unfeasible.

Pros:

• Prevents over insertion

Cons:

• Unable to use the circular holder to insert guidewire into the needle
• Unable to thread the needle over the guidewire
• Unable to thread the dilator over the guidewire
• Unable to thread the catheter over the guidewire
• Unable to develop a device thin enough to allow the guidewire to still pass freely through the lumen of the circular holder, needle, dilator, and catheter

**Conclusion:** Unfeasible solution.

### 3.3.2 Colouring the guidewire

Some authors in the literature have suggested a brightly coloured guidewire\textsuperscript{119} to alert operators of the presence of the guidewire or colouring the last 2cm-3cm of the straight portion of the guidewire\textsuperscript{120} to alert the user when they are nearing the end of the guidewire during CVC insertion, thereby preventing over insertion. However, a colour change in the last 2cm-3cm of the straight portion of the guidewire implies that the operator may insert up to 42cm-43cm of the guidewire before they are alerted to the possibility of over insertion. This may be too late, as retention may be more likely because most of the guidewire is inside the patient.

An idea was developed to design a fully coloured guidewire to demonstrate the safe depth of guidewire insertion to the operator, rather than the black makings currently seen at 10cm, 20cm and 30cm (Figure 3.7), which may be challenging to visualise or interpret. Many authors have suggested that guidewire retention could be prevented if the operator does not insert the guidewire beyond 18cm,\textsuperscript{70,75,121} and some suggest this can be up to 20cm.\textsuperscript{14,19,119} Hence, the aim with these fully coloured guidewires was to clearly and visually alert the user when they have inserted the guidewire up to 18cm, thereby preventing over insertion. Two fully coloured guidewires were designed: a traffic light guidewire coloured green, yellow, and red with a colour change transition of green to yellow at 18cm and yellow to red at 20cm on the guidewire. The colour demarcations are as follows: green is safe, yellow is acceptable but starting to be unsafe and red alerts the user that too much guidewire has been inserted into the patient. The second idea was a green and red coloured guidewire, with a colour change transition of green to red at 18cm on the guidewire, where green is safe and red is unsafe. Schematics of these ideas were sketched to understand what these guidewires would look like (Figure 3.13 and 3.14).
Ideas

1. A traffic light guidewire coloured red, yellow, and green, demarcating safe inserting distances at 18cm and 20cm (Figure 3.13).

![Diagram of fully coloured traffic light guidewire](image)

**Figure 3.13:** Schematic of the fully coloured traffic light guidewire. The guidewire is coloured green from the soft j-tip of the guidewire up to 18cm, yellow between 18cm and 20cm and red from 20cm up to the end of the straight portion of the guidewire.

2. A red and green guidewire, demarcating safe inserting distances at 18cm (Figure 3.14).

![Diagram of fully coloured red and green guidewire](image)

**Figure 3.14:** Schematic of the fully coloured red and green guidewire. The guidewire is coloured green from the soft j-tip of the guidewire up to 18cm and red from 18cm up to the end of the straight portion of the guidewire.

Mechanism of action

1. Alert the user to the presence of the guidewire
2. Prevent over insertion of the guidewire by visually informing the operator when they have reached the safe insertion distance.

Prototype development

To test the theory and determine whether this solution would be practical, a prototype of this guidewire was developed by applying a single thin coat of coloured acrylic paint (Crayola, Pennsylvania, US) to a guidewire (Kimal PLC, Uxbridge, UK). Acrylic paint was used to brightly colour the guidewire to determine whether the visual colour change warnings would be effective. Whilst other types of paints were initially trialled, the acrylic paint was bright, ensuring the colours were clearly visible to the naked eye and this was achievable with a single thin coat of paint. This was important as multiple layers of paint would increase the diameter of the guidewire and may have prevented the movement of the guidewire through the CVC needle, dilator, and catheter.
Two different guidewire prototypes were created, a traffic light guidewire and a red and green coloured guidewire, as seen in Figures 3.15 and 3.16, respectively. On visual inspection of the guidewire, the colour demarcations appeared obvious to the naked eye.

![Figure 3.15: A prototype of a fully coloured traffic light guidewire. The guidewire (Kimal PLC, Uxbridge, UK) has been coloured green from the soft j-tip of the guidewire up to 18cm, yellow between 18cm and 20cm and red from 20cm up to the end of the straight portion of the guidewire.](image)

![Figure 3.16: A prototype of a fully coloured red and green guidewire. The guidewire (Kimal PLC, Uxbridge, UK) has been coloured green from the soft j-tip of the guidewire up to 18cm and red from 18cm up to the end of the straight portion of the guidewire.](image)

**Feasibility and functionality testing**

A downside of using acrylic paint was that, after drying, it cracked and peeled slightly when the guidewire was manipulated. However, the theory behind these guidewires was the colour change; therefore, despite slight peeling and cracking of the paint, these guidewires were still tested on the benchtop model, with the knowledge that the appropriate mechanism for colouring would be investigated later if these were deemed suitable.

Both guidewire prototypes were tested on a benchtop for functionality and to determine how easily the colour change could be seen when used with the CVC equipment. The coloured guidewires were inserted into the guidewire holder (Kimal PLC, Uxbridge, UK), Figures 3.17 and 3.18.
Loading both of the coloured guidewires into the circular holder was straightforward. However, both the loading and threading of the guidewire over the wheel in the circular holder (as if to insert the guidewire into the needle) was not smooth due to the increase in diameter of the guidewire when coated in paint.

The guidewires were tested on a benchtop with a mannequin model (Laerdal, Gatesville, US) adapted for CVC insertion and the CVC needle (Kimal PLC, Uxbridge, UK) normally used to puncture the vein for CVC insertion. The needle was used to ‘puncture the
The coloured guidewires were inserted and threaded into the needle (Figure 3.19) until the coloured demarcations were visible. Despite the change in the diameter of the guidewire due to the paint, inserting the guidewire into the needle and down into the mannequin ‘vein’ was straightforward for both the traffic light guidewire and the green and red guidewire. Furthermore, on inspection of the guidewire during testing, the colour change at the appropriate distance markings were clearly visible. Consequently, it would be easy for users to know how much of the guidewire had been inserted into the vein, preventing over insertion (Figures 3.19).

![Figure 3.19: The prototype of A) the fully coloured traffic light guidewire and B) the fully coloured green and red guidewire is inserted into a CVC needle (Kimal PLC, Uxbridge, UK) used for vein puncture in a mannequin (Laerdal, Gatesville, US) adapted for CVC insertion. Image A) demonstrates the colour demarcation on the guidewire at 18 cm and 20 cm to indicate to the operator the length of the guidewire inserted into the vein to prevent over insertion. Image B) demonstrates the colour demarcation on the guidewire at 18 cm to indicate to the operator the length of the guidewire inserted into the vein to prevent over insertion.](image)

The next steps of the CVC insertion procedure were then tested with both guidewires in the mannequin model. The needle was removed by threading it over the guidewire, and a CVC catheter (Kimal PLC, Uxbridge, UK) was threaded over the guidewire. Again, despite the widening of the diameter of the guidewire, due to the paint, threading the needle over the guidewire was straightforward. However, threading the catheter over the guidewire and into the ‘vein’ was harder and required further force than would usually be needed to be applied (Figure 3.20). Despite this, on inspection of the guidewire during testing, the colour
demarcations were easily visible when threading the needle and the catheter over the guidewire.

Figure 3.20: The prototype of A) the fully coloured traffic light guidewire and B) the fully coloured green and red guidewire is located in the ‘vein’, and the CVC catheter (Kimal PLC, Uxbridge, UK) is threaded over the guidewire and pushed into the ‘vein’ in a mannequin ((Laerdal, Gatesville, US) adapted for CVC insertion. Image A) demonstrates the colour demarcation on the guidewire at 18cm and 20cm to indicate to the operator the length of the guidewire inserted into the vein to prevent over insertion. Image B) demonstrates the colour demarcation on the guidewire at 18cm to indicate to the operator the length of the guidewire inserted into the vein to prevent over insertion.

Evaluation

Testing the novel guidewires with the CVC equipment on the bench model determined that the colour change demarcations on both the traffic light guidewire and green and red fully coloured guidewires were easily visible on inspection. Therefore, these guidewires would be capable of alerting operators when they had reached the appropriate insertion depth (18cm-20cm) and would be compatible with existing CVC insertion equipment. However, to maintain the current diameter of the guidewire and reduce friction
when threading the needle, dilator and catheter over the guidewire, the stainless steel coil of the guidewire or the polymer coating would need to be coloured.

Currently, green guidewires are available for clinical use in cardiac Seldinger procedures. A US patent entitled “Colour coded guidewire and methods of making same” was published in 2012 and described the methods of colour coding guidewires. Whilst this patent was filed to prevent a different problem, the process would be applicable for preventing CVC guidewire retention. The authors described that colouring of the guidewire could be performed by electrochemically altering the colour of the guidewire to produce any colour in the spectrum that may be required. The guidewire is then immersed in a heated acid bath, and an electrical current is applied to thicken the transparent chromium oxide film, and this is to provide colour and protect the stainless steel from corrosion. Or the PTFE or silicone coating could be used to colour the guidewire to produce potentially any colour in the spectrum that may be required, where after the guidewire has been assembled, the PTFE coating could be sprayed with colour or a continuous reel coating applied.

However, colouring the guidewire whilst possible, on enquiring with guidewire manufacturers, was costly even for a prototype. This was because, whilst in theory, any colour could be used, colours other than green had not been trialled in the guidewire moulds or manufacturing processes. As different colours have different constituent chemical compositions, trials would need to be performed to understand whether different colours could be applied or sprayed within the current manufacturing process before a prototype could be used. Again, whilst in theory, multiple colours could be used, trials would need to be performed to determine the process of accurately colouring each portion of the guidewire within the current moulds and manufacturing process and ensuring the coloured distances were standardised for every prototype produced. The cost was also increased when more colours were used. Additionally, it was unknown the whether the weight of colouring the entire guidewire, given that the constituent chemical compositions are different for each colour, would affect the flexibility of the guidewire. Therefore, producing prototypes for this study was deemed too expensive to continue, particularly considering these guidewires could potentially still be over inserted.

In the benchtop trials of the coloured guidewires with the CVC equipment, the colour change was clearly visible on inspection. However, it is possible that the colour change was obvious to the investigators during testing because the focus of the testing throughout these
benchtop trials was the colour change and whether this colour change would be visible or obvious to the user is unknown. The solution also requires the operator to look at the guidewire during all the steps of CVC insertion to ensure that they recognise the colour change. However, most operators are not focused on the guidewire during CVC insertion; they also look at the monitoring equipment, the patient, or the ultrasound machine etc. Whilst one can assume that the operator will glance at the guidewire, there is no guarantee that the operator will see the colour change. Additionally, as discussed, the phenomenon of inattentional blindness, where very obvious stimuli are missed because of focus on other tasks, could also be applied in this situation. Operators may not ‘see’ or miss the colour change if they focus on other tasks. Consequently, over insertion, and guidewire retention is still possible. Therefore, this idea was also dismissed.

**Pros:**
- Attempts to prevent over insertion through visual colour alerts
- The colour change is visible on inspection of the guidewire throughout the process of CVC insertion

**Cons:**
- Reliant on the operator looking at the guidewire to prevent over insertion
- Potential for inattentional blindness with the colour change
- It still allows over insertion and possible loss of the guidewire, with no mechanism to ensure recognition
- Expensive to manufacture

**Conclusions:** Expensive and may not prevent the error.

### 3.3.3 Conformational change in the guidewire

Whilst changing the colour of the guidewire and adding attachments were proven impractical and expensive, altering the guidewire itself was still thought to be the most effective and potentially practical mechanism for preventing guidewire retention. The hierarchy of intervention effectiveness demonstrates that changing the colour of the guidewire is a person based preventative mechanism. As such, a system based solution was required to physically prevent the operator from over inserting the guidewire.
An idea was developed to design a guidewire with a conformational change, such as a curl or kink at 18cm, to indicate to the operator through tactile sensation that the correct insertion depth had been reached. This change in conformation would physically prevent the operator from over inserting the guidewire but still allow the catheter to be easily threaded over the guidewire. Three ideas for conformational changes were developed: a guidewire with a kink at 18cm, a guidewire with a single curl formation at 18cm, and a guidewire with a double curl formation at 18cm (Figures 3.21, 3.22 and 3.23, respectively). Schematics of these ideas were sketched to understand what they might look like.

**Ideas**

1. A guidewire with a kink at 18cm to demarcate safe insertion distances (Figure 3.21)

![Figure 3.21: A schematic of the guidewire with a kink at 18cm.](image)

2. A guidewire with a curl at 18cm to demarcate safe insertion distances (Figure 3.22)

![Figure 3.22: A schematic of the guidewire with a single curl at 18cm.](image)
3. A guidewire with a double curl at 18cm to demarcate safe insertion distances (Figure 3.23)

Figure 3.23: A schematic of the guidewire with a double curl at 18cm.

**Mechanism of action**

1. Prevent over insertion of the guidewire through tactile sensation at 18cm that the correct depth of insertion had been reached
2. The change in conformation would physically prevent the operator from over inserting the guidewire

**Prototype development**

To test the theory and determine whether this solution would be practical, prototypes of these guidewires were developed, and a new guidewire was used at each attempt to create each prototype.

Initially, an attempt to create a kink in the guidewire was made by applying force with plyers. However, this resulted in fracturing the metal core of the guidewire. Realising that the force required to kink the guidewire without fracturing the core was substantially less than initially thought, the kinked guidewire was created by bending the guidewire at 18cm and applying fingertip pressure to create the kink (Figure 3.24). This conformational change was straightforward to achieve. Anecdotally, some clinicians have been known to bend or kink the guidewire before CVC insertions. Thus, this conformational change would not be unusual for the operator and potentially common practice for some individuals.
Creating a prototype for the curved guidewire was more difficult because the metal in the guidewire had memory recoil; making a permanent curl required several attempts. Initially, the guidewire was wrapped around the body of a whiteboard pen (whiteboard marker pen, Staples, Sheffield, UK) which was 1.5cm in diameter and held in place for one minute to determine whether the shape could be altered. However, this only produced a bend in the entire guidewire.

Next, to try and produce a permanent and more visible curl at 18cm, the guidewire was curled three times and twisted around itself to keep the curl in place (Figure 3.25).
The guidewire was then baked in the oven at 180°C for 10mins and uncoiled when cooled, however, this only produced a bend in the guidewire. The coiling and twisting process was repeated with another guidewire (Figure 3.25), but this time baked in the oven at 220°C for 30mins and uncoiled when cooled. This produced a guidewire with a permanent single curl (Figure 3.26).

Several attempts were made to make a double curl by curling the guidewire around a greater number of times and baking at the same temperature for various lengths of time up to an hour. However, all these attempts only produced single permanent curl. Consequently, initial prototype testing was only performed on a guidewire with a single curl.

**Feasibility and functionality testing of the kinked guidewire**

On a benchtop, the kinked guidewire was tested for functionality. First, the guidewire was tested by inserting it into a needle, dilator, and threading the catheter over it. Whilst these actions were straightforward, slight friction was felt when the needle, catheter and guidewire were threaded over the kink. This increase in friction was thought to force the clinician to recognise that they had reached 18cm and, through this tactile sensation, alert the operator when the correct insertion depth had been reached.
Evaluation of the kinked guidewire

This may have been a successful strategy, however, whilst it would remind the operator that they had reached 18cm, it would not prevent over insertion, and this guidewire could still be retained. During difficult CVC insertions, guidewires can kink, bend and even fracture. In these situations, the user would not easily know which kink in the guidewire was the ‘correct’ one to recognise over insertion, as it would be too subtle compared to the kinks, bends or fractures seen during difficult CVC insertion. Therefore, this idea was dismissed.

Pros:
- Attempts to prevent over insertion through tactile alerts

Cons:
- Reliant on the operator recognising the tactile sensation
- It may not be effective during difficult CVC insertions
- It still allows over insertion and possible loss of the guidewire, with no mechanism to ensure recognition

Conclusions: This conformational change is too subtle for the user; therefore, it is an impractical solution.

Feasibility and functionality testing of the curly guidewires

The aim of this guidewire was to physically prevent the operator from over inserting the guidewire. The mechanism of preventing over insertion was subtly different to the previous guidewires. The curved guidewire has a permanent curl at 18cm (Figure 3.27).

Figure 3.27: A prototype of the curly guidewire, demonstrating that a permanent curl is retained in the guidewire at 18cm. The prototype was made with a Kimal guidewire (Kimal PLC, Uxbridge, UK).
When the guidewire was stretched, by holding the straight end and the j-tip end of the guidewire and stretching the guidewire (Figure 3.28), the guidewire straightened and the curl would disappear (Figure 3.28). However, when released, the guidewire would regain its curly shape again.

By using the curly guidewire, the operator would be prevented from over inserting the guidewire because, when they had inserted the guidewire to the depth of the curl (18cm), it would become difficult to insert more of the guidewire into the needle or patient. This would force the operator to recognise when they had reached the correct insertion depth. Next, the curl must be straightened to thread the needle, dilator, or catheter over the guidewire. To do this, the operator must hold onto the guidewire whilst pushing the needle, dilator, or catheter over the curl. This action straightens out the curl to allow free movement of the needle, dilator, or catheter over the guidewire. Thus, the operator is forced to hold onto the guidewire at the critical moment in the procedure when guidewire retention is most likely to occur. Therefore, the operator never lets go of the guidewire, preventing retention.

This theory was tested on the benchtop with the CVC needle, dilator, and catheter. First, the curly guidewire was inserted into a CVC needle, and could be inserted easily up to the curl (Figure 3.29). Over insertion of the guidewire was then attempted, but this was met with resistance. Whilst this resistance could be overcome, and the guidewire could be pushed further into the needle, it was clear that this would not be an easy action to perform and would ensure the user would recognise the depth of the guidewire that had been inserted and is likely that over insertion would be prevented. Next, the needle was threaded over the guidewire (i.e., removed from the vein and threaded over the guidewire), and it was found that the operator was required to maintain their grip on the proximal (j-tip) portion of the guidewire to do so.
Figure 3.29: The prototype of the curly guidewire is inserted easily into the CVC needle (Kimal PLC, Uxbridge, UK) up to the curl in the guidewire at 18cm, after which threading the guidewire into the needle becomes more difficult. The prototype was made with Kimal guidewire (Kimal PLC, Uxbridge, UK).

When the operator held the guidewire, the curl easily straightened out as the needle was threaded over the guidewire (Figure 3.30). This would ensure that the operator always maintained their grip on the guidewire.

Figure 3.30: The CVC needle (Kimal PLC, Uxbridge, UK) is threaded over the prototype of the curly guidewire. Demonstrating that the operator is forced to maintain their grip on the guidewire to thread the needle over the curl in the guidewire, ensuring the operator always holds onto the guidewire. The prototype was made with a Kimal guidewire (Kimal PLC, Uxbridge, UK).

This was repeated with the dilator. The dilator was threaded over the guidewire, which was straightforward up to the point of the curl in the guidewire (Figure 3.31). However, when the curl in the guidewire was reached, resistance was felt.
Figure 3.31: The CVC dilator (Kimal PLC, Uxbridge, UK) is easily threaded over the curly guidewire prototype up to the curl point at 18cm. The prototype was made with a Kimal guidewire (Kimal PLC, Uxbridge, UK).

The dilator was then pushed over the curl in the guidewire. To do this, the straight end of the guidewire was held to provide the traction to overcome the uncoiling and straightening of the curl to allow the dilator to be threaded over the guidewire (Figure 3.32). This ensured that the operator was always forced to hold onto the guidewire during this step, thereby preventing guidewire retention.

Figure 3.32: The CVC dilator (Kimal PLC, Uxbridge, UK) is threaded over the prototype of the curly guidewire. The image demonstrates that the operator is forced to maintain their grip on the guidewire to thread the dilator over the guidewire. Thereby ensuring the operator always holds onto the guidewire. The prototype was made with a Kimal guidewire (Kimal PLC, Uxbridge, UK).

The test was repeated with the catheter (Figure 3.33). Again, threading the catheter up to the point of the curl in the guidewire was straightforward, and resistance was met when the catheter met the curl.
Figure 3.33: The CVC catheter (Kimal PLC, Uxbridge, UK) is easily threaded over the prototype of the curly guidewire up to the point of the curl at 18cm. The prototype was made with a Kimal guidewire (Kimal PLC, Uxbridge, UK).

As with the dilator, when the catheter was threaded over the curl in the guidewire, the operator was forced to hold the straight end of the guidewire to push the catheter over the curl (Figure 3.34). Again, ensuring the operator is always forced to hold onto the guidewire during this step, thereby preventing guidewire retention.

Figure 3.34: The CVC catheter (Kimal PLC, Uxbridge, UK) is threaded over the prototype of the curly guidewire. The image demonstrates that the operator is forced to maintain their grip on the guidewire in order to straighten the curl and thread the catheter over the guidewire. Thereby ensuring the operator always holds onto the guidewire. The prototype was made with a Kimal guidewire (Kimal PLC, Uxbridge, UK).
Evaluation of the curly guidewires

The success of this step was crucial. As seen in Figure 3.4, this is the critical moment when guidewire retention is most likely to occur. If the operator is forced to hold onto the guidewire during the critical step, guidewire retention should not occur. The curly guidewire was deemed a potentially successful solution to prevent over insertion and guidewire retention.

However, a negative to the curly guidewire became apparent during benchtop model testing. When the curly guidewire was tested with the CVC equipment, due to the curl, the guidewire would spin and twist from side to side as the needle, dilator and catheter were threaded over the guidewire. This became even more apparent when the equipment was threaded over the curl specifically. Whilst this could make guidewire insertion more difficult for the user, there was uncertainty as to whether the spinning and twisting of the guidewire would still be as pronounced if it was partially inside the vein. Whilst the curly guidewire could successfully prevent guidewire retention, further testing would be required to determine how user friendly this guidewire would be.

Several guidewire manufacturers were approached, and one company, Shannon MicroCoil (Limerick, Ireland), agreed to manufacture prototypes of the curly guidewire at the most reasonable price. Two curly guidewires were produced for £600 per guidewire, with a single curl at 18cm (Figure 3.35) and a double curl at 18cm (Figure 3.36). There was an assumption that a curved guidewire would prevent over insertion and ensure the operator always held onto the guidewire. However, there was uncertainty whether a single curl would be a sufficient trigger for the operator to recognise that they had reached the correct insertion depth. Therefore, the double curved guidewire was also commissioned. Shannon MicroCoil is a guidewire manufacturer and produces guidewires for CVC kits and other Seldinger procedures. Shannon MicroCoil utilised their guidewires to manufacture the curly guidewires. The curly guidewires were produced by wrapping the guidewire around a steel rod at 18cm and heated uniformly to produce the coil. The manufacturer performed several trials and tests to produce uniform coils at the correct position in the guidewire, contributing to the cost of the prototypes. Due to the cost, only two curly guidewires were commissioned for testing.
Feasibility and functionality testing of commercial prototypes

The single curved and double curved guidewires were tested on a benchtop with the CVC equipment. These guidewires were initially placed inside the CVC guidewire holder. Both guidewires were easily inserted into the guidewire holder up to the point of the curve, however when the curve was reached, there was difficulty in inserting the guidewire past the curl. However, this was overcome with force and fingertip manipulation (Figures 3.37 and 3.38).
Figure 3.37: The prototype of the curly guidewire (Shannon MicroCoil, Limerick, Ireland) with the single curl inserted into the CVC guidewire holder (Kimal PLC, Uxbridge, UK). The image demonstrates that with effort, the guidewire could be inserted into the holder for ease of CVC insertion for the user.

Figure 3.38: The prototype of the curly guidewire (Shannon MicroCoil, Limerick, Ireland) with the double curl inserted into the CVC guidewire holder (Kimal PLC, Uxbridge, UK). The image demonstrates that with effort, the guidewire could be inserted into the holder for ease of CVC insertion for the user.

However, when the guidewires were threaded out of the circular holder using the threading wheel, as soon as the curved section of the guidewire was approached, the guidewire twisted and sprang out spinning in different directions to reform the curl, rather than forwards and in a straight line as normally seen with current guidewires (Figures 3.39 and 3.40). Whilst
this may not be a problem, it could make the procedure slightly more difficult for the operator.

Figure 3.39: The prototype of the curly guidewire (Shannon MicroCoil, Limerick, Ireland) with the single curl partially threaded out of the CVC guidewire holder (Kimal PLC, Uxbridge, UK). Demonstrating that as the curl at 18cm is reached, the guidewire springs out of the CVC holder and twists upon itself to reform the curl.

Figure 3.40: The prototype of the curly guidewire (Shannon MicroCoil, Limerick, Ireland) with the double curl partially threaded out of the CVC guidewire holder (Kimal PLC, Uxbridge, UK). Demonstrating that as the curl at 18cm is reached, the guidewire springs out of the CVC holder and twists upon itself to reform the curl.

Next, benchtop testing was continued with these guidewires and the CVC needle, catheter, and mannequin model. On the mannequin model, the CVC needle was ‘inserted’ into the vein, and the guidewire was inserted into the needle. With both guidewires, insertion up to the point of curl was easy. However, once the curl in the guidewire was reached, insertion
was noticeably more difficult to proceed with (Figure 3.41). It could be assumed that the user would quickly know or understand that they had reached the safe insertion distance, thereby preventing over insertion.

![Figure 3.41: The curly guidewire (Shannon MicroCoil, Limerick, Ireland) with the A) single curl and B) double curl. The curly guidewire is inserted into the CVC needle (Kimal PLC, Uxbridge, UK) used for vein puncture in a mannequin (Laerdal, Gatesville, US) adapted for CVC insertion. Demonstrating that insertion up to the point of the curl at 18cm is easy and indicates to the operator that they have reached the correct depth of insertion of the guidewire.]

Next, the needle was removed over the guidewire, and this was mostly straightforward. To thread the needle over the curl, the operator must hold onto the guidewire close to the skin (near the j-tip end). As the needle was threaded over the curl, the 27cm of guidewire (from the curl to the straight portion of the guidewire) twisted and rotated on itself. This meant that 27cm of guidewire was twisting and spinning between the patient,
the table, and the operator, making it difficult to control whilst manipulating the needle. This was more pronounced with the double curved guidewire.

Next, the catheter was threaded over the guidewire (Figure 3.42). Threading the catheter over the guidewire up to the point of the curl was straightforward; however, the twisting and rotational movement of the guidewire, become apparent again as the catheter approached the curve of the guidewire.

![A] Figure 3.42: The CVC catheter (Kimal PLC, Uxbridge, UK) is easily threaded over the guidewire (Shannon MicroCoil, Limerick, Ireland) with the A) single curl and B) double curl up to the point of the curl at 18cm. The image demonstrates that the operator is forced to recognise when they have reached the correct depth of insertion of the guidewire.

The catheter was then threaded over the guidewire curl, the ‘critical point’ in the CVC insertion when guidewire retention was most likely to occur. Threading the catheter over the guidewire curl was difficult with both the single and double curled guidewires. As the catheter was threaded over the guidewire curl (Figure 3.43), it was apparent that the operator would be forced to hold onto the straight end of the guidewire whilst the catheter was inserted into the vein. As the operator was forced to hold onto the guidewire during this step,
this should prevent guidewire retention. However, when this action was performed, neither of the curly guidewires fully straightened out to be like a standard straight guidewire (Figure 3.43), and both guidewires became difficult to control as they twisted and rotated on itself even when the catheter was being threaded past the curl and into the vein.

![Figure 3.43: The CVC catheter (Kimal PLC, Uxbridge, UK) is threaded over the curl of the curly guidewire (Shannon MicroCoil, Limerick, Ireland) with the A) single curl and B) double curl. The image demonstrates that the operator is forced to maintain their grip on the guidewire to straighten the curl and thread the catheter over the guidewire. Thereby ensuring the operator always holds onto the guidewire.](image)

**Evaluation testing of commercial prototypes**

On the benchtop model, testing the single and double curved guidewires with the CVC kit determined that both would prevent guidewire retention by ensuring the operator would know when they had reached the correct depth of insertion and ensuring the operator always held onto the guidewire at the ‘critical point’ in the procedure. Both guidewires would be compatible with existing CVC insertion equipment. However, substantial changes to the guidewire production line would be needed to manufacture a guidewire with a curl at
18cm and insert it into the circular holder. This would have substantial initial cost implications. The cost of the prototypes alone were £600 each, and whilst the cost of manufacturing this guidewire would reduce with mass production, it became apparent that this type of solution would become too expensive to pursue. A company producing CVC equipment would be required to take on this innovation and manufacture the guidewires. Some of these companies do not make their guidewires but source them separately and then package them inside their own CVC insertion kit. Whilst this innovation was disclosed and discussed with manufacturers, none were interested in pursuing this further due to the cost.

Additionally, from benchtop testing, it became apparent that both guidewires were cumbersome, which made the procedure more complex and may have increased the incidence of errors. Whilst it may have been possible to train individuals to learn to use the curly guidewire, this would also have a substantial cost and time implication to re-train every clinician to change their practice of CVC insertion, which may be acceptable if there was the impetus at both a clinician and managerial level. However, the potentially cumbersome CVC insertion with curly guidewires poses another problem: if the curly guidewire was an acceptable solution to prevent never events, training may overcome the cumbersome nature of the guidewires in straightforward CVC insertions. However, many CVC insertions are not straightforward; some require manipulation, removal, and rethreading of the guidewires, and this would be far more complicated if the guidewire had a conformational change. For an error that occurs in 0.03% of procedures, a solution that affects or changes the normal clinical CVC insertion process would over complicate the procedure and increase the incidence of this or other errors. Therefore, this idea was also abandoned.

**Pros:**
- Attempts to prevent over insertion by preventing over insertion of the guidewire
- Ensures the clinician always holds onto the guidewire during the ‘critical point’ in the procedure

**Cons:**
- Cumbersome and potentially challenging to use, possibly increasing the risk of this and other CVC errors
- Would have to re-train every clinician to perform CVC insertion with the new guidewire
• High cost and time implication of re-training all clinicians with a new CVC insertion technique
• It may only be suitable for straightforward CVC insertions
• Expensive to manufacture
• No interest from CVC manufacturers

**Conclusions:** too expensive, potentially difficult for clinicians and may increase the risk of errors. Therefore, not a viable option.

### 3.4 Changing the CVC equipment

#### 3.4.1 Lessons learnt so far

Whilst all the guidewires designed so far may have prevented guidewire retention, they could not be guaranteed to do so and/or had cost and undesirable clinician training implications. Despite these failures and the many discussions with CVC equipment manufacturers, several lessons were learnt in this process:

• Changing the guidewire was not a practical or cost effective solution
• Changing the current CVC insertion equipment was not practical or cost effective
• Any new solution must be able to be introduced easily into the manufacturing process or production line
• Any new solution must be cost effective for CVC manufacturers to either produce themselves or purchase and put into their CVC insertion kit
• The cost increase for the new equipment must be acceptable to the manufacturer and subsequently the hospital user/purchaser
• The solution must be easy for the clinician to use
• The solution must not adversely affect the CVC insertion procedure
• There must not be an inadvertent increase in the risk of this error or other errors

Given the work by Cafazzo and St-Cyr, a forcing function was still deemed the best mechanism of developing a sustainable preventative strategy for solving this problem. From the lessons learned, changing the CVC equipment was still deemed the best way to achieve this.
3.4.2 Reviewing the CVC procedure

The steps involved in the CVC procedure and the equipment used at each step were reviewed again (Figure 3.44).101,113

Figure 3.44: The steps in the CVC procedure and the equipment used at each step. Where the * demarcates the points in the CVC procedure when the guidewire is used, and the step where the catheter is passed over the guidewire and the guidewire removed is the ‘critical point’ in the procedure.

The guidewire is necessary for several stages of the procedure and used at the following points indicated by the * in Figure 3.44: guidewire is inserted into the needle, the needle is removed, the dilator is threaded over the guidewire, the dilator is removed, the catheter is threaded over the guidewire, and the guidewire is removed. In the literature, NRLS data and the interviews, there were no instances of guidewire retention before the ‘critical point’ in the CVC procedure (Figure 3.4). If guidewire retention had occurred before the ‘critical point’, it would be evident to the user as they could not move on to the next procedural step. Whilst possible, a never event occurring at this stage in the clinical procedure would be so unusual that it would have been published or reported. However, no incidents of guidewire retention prior to the ‘critical point’ in the procedure have been reported or are known. The guidewire is not used after the ‘critical point’ in the procedure. Therefore, it can be determined that guidewire retention must occur at the ‘critical point’. From the literature
search, NRLS data, and interviews, we have established that guidewire retention must be an omission error. The clinician must forget to remove the guidewire at the ‘critical point’. If the clinician can be forced to recognise this error at the ‘critical point’ or is prevented from moving to the next step in the procedure until the guidewire is removed, then guidewire retention may be prevented by ensuring it is removed every time.

3.4.3 The locked procedure pack

Reviewing the equipment required for CVC insertion (Figure 3.44), the syringe, saline flush, catheter caps, catheter skin fixations, suture material, needle holder and biocclusive dressing are not required before the ‘critical point’ in the procedure but are necessary after the ‘critical point’ to complete the procedure. Thus, a solution to prevent access to this equipment until after the guidewire was removed may be effective.

An idea was developed whereby the equipment used after CVC insertion could be locked away from the user. The mechanism of accessing this equipment would be by using the guidewire to open the lock to access the contents. If the guidewire was required to complete the next step in the procedure, then retention may be prevented as the user would be forced to remember to remove the guidewire in order to complete the procedure.

Idea: A locked procedure pack that can only be opened by using a guidewire. A schematic of this idea was sketched to understand what a locked procedure pack might look like (Figure 3.45).

In this idea, the equipment required to complete the procedure after the guidewire would usually be removed from the patient and placed inside the box. The box has a lid with a hinge at the top end and a channel inside the lid (Figure 3.45). When the operator needs access to the contents inside the box, the guidewire would be required to open the box. First, they must insert the guidewire into the channel in the lid and push it all the way around (Figure 3.45). Both the ends of the guidewire stick out of the holes of the channel, and these are used as a handle to lift the lid with counter traction on the base of the box by pulling it down. Thereby the procedure cannot be completed unless the guidewire is removed from the patient and used to open the locked procedure pack.
Figure 3.45: A schematic of the locked procedure pack, demonstrating how this device may work to prevent guidewire retention. Where the locked procedure pack contains the equipment required after the ‘critical point’ in the procedure after the guidewire is normally removed. The guidewire is placed into the lightbulb shaped channel, and the handles of the guidewire are used to open the lid of the box. The lid is secured with magnets, and the force is overcome by using the handle of the guidewire to lift it up. Counter traction is applied by pulling down the base of the box.

**Mechanism of action**

1. Prevent guidewire retention by impeding the user from moving to the next step in the procedure without removing the guidewire from the patient, forcing recognition of guidewire retention.

**Prototype development**

A working prototype was created in plastic and wood to test the theory and determine whether this solution would be practical. The bottom of the box was made using half of a black DVD case, reinforced with wooden supports at the side (Figure 3.46).
Figure 3.46: The base of the prototype of the locked procedure pack. Half of a black DVD case was used to make the base of the locked procedure pack and reinforced on the side with wood.

The lid was made of a flat piece of wood the same size as the DVD box. The guidewire channel was made using a wire stiffener from a percutaneous tracheostomy dilatational kit (Venner Medical International, Jersey, UK), was fashioned into a lightbulb shape and glued (Gorilla Glue, Cincinnati, Ohio) onto the wooden lid. The lid was then covered with black tape (Gorilla Tape, Cincinnati, Ohio) (Figure 3.47) and was also used to fashion a hinge connecting the DVD base and the wooden lid (Figure 3.48). Magnets were glued to the underside of the lid to secure the lid to the base. Labels with instructions were Sellotaped (Gorilla Tape, Cincinnati, Ohio) to the lid for the user to understand how to use the box (Figure 3.47).
Figure 3.47: The lid of the prototype of the locked procedure pack, where A) was the outside of the box and B) was the inside surface of the lid. A flat piece of wood, the same shape as the DVD base, was used for the lid. The guidewire channel was made using a wire stiffener from a percutaneous tracheostomy dilatational kit (Venner Medical International, Jersey, UK) fashioned into a lightbulb shape and glued (Gorilla Glue, Cincinnati, Ohio) onto the wooden lid. Black tape (Gorilla Tape, Cincinnati, Ohio) was used to cover the lid and the channel and fashion the hinge. Two magnets were used to secure the lid to the base of the box.

Figure 3.48: Side view of the locked procedure pack demonstrating how the black tape (Gorilla Tape, Cincinnati, Ohio) was used to fashion the hinge of the locked procedure pack.

The base of the box and the lid were flush so that the only mechanism of opening the box was by using the guidewire. The mechanism of opening the box was tested using a
guidewire. However, the box was difficult to open, requiring the user to hold the box in their hands and firmly hold onto the base and lift the lid with the guidewire (Figure 3.49).

![Figure 3.49: Opening the locked procedure pack. The guidewire (Kimal PLC, Uxbridge, UK) has been inserted into the channel and lifted to open the lid. To achieve the counter traction force required to lift the lid, the user must pick up the locked procedure pack from the trolley and hold onto the base to open the box.](image)

This was deemed to be too cumbersome for the user. Therefore, a makeshift shelf was placed at the bottom of the box (Figure 3.50).

![Figure 3.50: The locked procedure pack with a shelf at the base. A makeshift shelf was attached to the bottom of the box. A) Birdseye view, B) underside of the box view. The shelf, made of a T-shaped piece of wood, was covered with black tape and attached to the base of the locked procedure pack. This allowed the user to provide counter traction by positioning their fingers on the shelf whilst the lid was lifted by using the ends of the guidewire as a handle. This was so the user was not required to pick up the locked procedure pack to open the box.](image)

The shelf was made of a T-shaped piece of wood and was covered with black tape and attached to the base of the box with gorilla tape so that part of it jutted forwards from the
bottom of the box. This was to allow the user to place their fingers on the shelf to provide
counter traction whilst the ends of the guidewire were used as a handle to lift the lid to
overcome the force of the magnets. When this shelf was attached to the box, the user was
not required to pick up the locked procedure pack to open it, and opening the lid became
very easy (Figure 3.51).

Figure 3.51: The locked procedure pack with a shelf at the base. With fingers placed on the shelf to
provide counter traction, lifting the lid of the box using the ends of the guidewire (Kimal PLC, Uxbridge,
UK) became a straightforward task.

**Feasibility and functionality testing and evaluation**

Initial bench testing determined that the locked procedure pack was easy to open
using the guidewire and would require a simple training session to show users how to use it.
While inserting a guidewire into a channel may be deemed complicated, it is the same action
used when the guidewire is threaded into the needle or catheter. Therefore, it was determined
that all clinicians that insert CVC would also be capable of inserting the guidewire into the
channel of the procedure pack. Additionally, there would be no requirement to change the
CVC insertion procedure, and there would be no change for the operator or, most
importantly, the patient. The contents would be the equipment required for securing the
catheter after the guidewire would normally be removed, and it may be convenient for the
user to have this equipment easily accessible inside a single box. CVC manufacturers already
provide this equipment, and this idea would only require the addition of the locked procedure
pack to the CVC equipment. Unlike changing the CVC guidewires above, this idea would
not require changes to the manufacturing process and would be an inexpensive addition to
the CVC insertion equipment. In terms of manufacturing, it would require a change to how
the insertion equipment is packed; however, as each hospital chooses the contents of these packs, hospitals could easily request that the equipment needed after the guidewire is removed from the patient is placed inside the locked procedure pack before the final wrapping in sterile drapes. Whilst this would incur an additional cost, this would be minimal compared to changing the guidewire.

One negative is that, as the guidewire is not changed, over insertion and retention may still be possible. However, this procedure pack would immediately alert the operator to this error. As discussed previously, guidewires migrate down the catheter into the vasculature over time, some do not migrate at all despite being used for medication administration, and some are still present in the catheter 5-7 days after routine removal. If the user is alerted quickly to guidewire retention, which would occur with the locked procedure pack, the operator could take corrective action immediately, preventing guidewire retention. This solution was deemed suitable for further development.

**Pros:**

- Inhibits the operator from performing the next step in the procedure until after the guidewire has been removed, thereby preventing guidewire retention
- Ensures the clinician always recognises guidewire retention
- Always ensures the clinician removes the guidewire
- No change to the CVC procedure for the operator or patient
- Maybe more convenient for the operator
- Convenient for the CVC equipment manufacturer

**Cons:**

- It may be possible to open without the guidewire
- No change to the guidewire, consequently, still allows over insertion and potential guidewire retention

**Conclusions:** a convenient and potentially cheap solution which may prevent the error. Therefore, further testing is required.
Informal user testing

Whilst the locked procedure pack appeared to be a good solution to preventing this error without hindering or adversely impacting the clinical CVC insertion procedure, any unknown factors, and its reception by clinicians in the real world could not be accounted for. Before proceeding with the development of the locked procedure pack, informal testing was undertaken.

Testing aimed to determine whether the locked procedure pack would be a suitable safety solution for preventing guidewire retention without hindering or adversely impacting the clinical CVC insertion procedure and to determine clinicians’ opinions of the innovation.

Methods: Written approval from the research and development department at the Queen Elizabeth Hospital, Kings Lynn, was sought and obtained. The problem and the mechanism of action of the locked procedure pack were demonstrated and discussed informally with five anaesthetists experienced in CVC insertion. The five anaesthetists were given a guidewire and the locked procedure pack and asked to open the device. Anaesthetists were observed to determine the ease of opening the locked procedure pack and whether this could be performed in less than 10 secs to determine whether the locked procedure pack would adversely impact the length of the procedure. The time when the locked procedure pack and the guidewire were handed to the anaesthetists and when the box was opened was recorded. The time taken to open the box was recorded as less than 10 secs or greater than 10 secs. Timings were noted using the room clock. Anaesthetists were asked what they thought of the concept of the innovation, whether the solution would prevent the error, if there would be any clinical impact on the CVC procedure when using the locked procedure pack and any other general comments (Appendix 3.1).

Results: A convenience sample of five anaesthetists who self-identified as experts in CVC catheter insertion (inserting at least ten CVCs per year) volunteered for the informal testing. Once the technique was demonstrated, all five clinicians could easily open the locked procedure pack in less than 10 secs on their first attempt. When asked about the idea, all five clinicians thought that the concept was sound. When asked about the impact of the locked procedure pack to prevent the never event, 3/5 thought that it would prevent the never event, 1/5 thought that users would try to work around it, and 1/5 thought that a solution was unnecessary. When asked if there may be an impact on the clinical procedure by using the locked procedure pack, 4/5 said that they did not think it would impact the procedure but would need to see this working during a CVC insertion, and 1/5 stated that it might take
longer to perform CVC insertions which may be a problem during emergency procedures. Some anaesthetists provided additional comments which are available in Table 3.1.

Table 3.1: Feedback from informal testing with five anaesthetists

<table>
<thead>
<tr>
<th>Feedback from informal testing</th>
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</thead>
<tbody>
<tr>
<td><strong>Concept:</strong></td>
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<tr>
<td>“Clever solution.”</td>
</tr>
<tr>
<td>“Simple solution which logically seems like it should work.”</td>
</tr>
<tr>
<td>“Like the simplicity of the design.”</td>
</tr>
<tr>
<td><strong>Impact to prevent never event:</strong></td>
</tr>
<tr>
<td>“Cannot see how the clinician could make the mistake with this.”</td>
</tr>
<tr>
<td>“Ensures the clinician cannot go to the next step. I think this will work.”</td>
</tr>
<tr>
<td>“People will try and work around it. I could break it open.”</td>
</tr>
<tr>
<td>“Do we need it? Can we just tell the clinicians not to make the mistake”?</td>
</tr>
<tr>
<td><strong>Clinical impact</strong></td>
</tr>
<tr>
<td>“Do not think it will impact the CVC insertion but will need to see it work during CVC insertion.”</td>
</tr>
<tr>
<td>“It may take longer to do CVC insertions – what about emergencies? Will it take longer to finish the procedure?”</td>
</tr>
</tbody>
</table>

Conclusions: During informal testing, the locked procedure pack was easily opened by anaesthetists in less than 10secs on their first attempt. A single demonstration was sufficient to teach the opening mechanism of the locked procedure pack and showed its ease of use. With repeated interactions, the time to open the box will decrease. The feedback from anaesthetists on the locked procedure pack was mostly positive. However, further testing would be required to ensure that there would not be any negative impact on the clinical procedure when using the locked procedure pack.

Limitations: There are many limitations to this informal testing. The testing done with only five clinicians; therefore, a broad range of opinions about the locked procedure pack may be unknown. However, testing was purposefully undertaken with a few clinicians to maintain confidentially of the intellectual property prior to patenting. Additionally, testing was done with colleagues. As such opinions may be biased either favourably or
unfavourably. However, positive and negative feedback was provided, and given confidentially requirements for patenting, this was the best achievable. The time taken to open the locked procedure pack was timed as less than or more than 10secs, and whilst this provided the required data to progress to the next stage of development, further formal testing is required.

Next stage of prototype development

The feedback from anaesthetists in the informal testing was mostly positive. In addition, the ease of opening and the time taken to open the locked procedure pack by the five anaesthetists in the usability testing demonstrated the ease of use. Based on this, the potential for preventing guidewire retention without adversely affecting the clinical procedure and that manufacturers could easily package the locked procedure pack in with the CVC insertion equipment, it was decided to pursue testing with this device as a potential solution to preventing CVC guidewire retention.

Contents

The contents inside the device would affect many aspects of the locked procedure pack. Therefore, the contents that would be placed in the box were decided prior to further prototype development. The following equipment is required after the guidewire is usually removed: the syringe, saline flush, catheter caps, catheter skin fixations, suture material, needle holder and bio-occlusive dressing (Figure 3.44). The catheter caps and skin fixations are supplied with the CVC catheter and provided to the clinician in a sealed blister pack containing the guidewire holder, guidewire, needle, dilator, scalpel, and guiding syringe (CVC catheter/guidewire pack). This CVC catheter/guidewire pack is opened with another CVC insertion pack, which has all the equipment required for CVC insertion other than those provided in the CVC catheter/guidewire pack, that is: the sterile ultrasound probe cover, sterile ultrasound gel, small gauge needle, syringe, suture material, bio-occlusive dressing. Saline flush is not commonly provided inside the sterile CVC catheter/guidewire pack or CVC insertion pack. This is due to difficulties with sterilising the saline when it is packaged with all the CVC equipment inside the CVC insertion pack. Whilst syringes are often provided inside the CVC insertion pack, it was decided, not to include a syringe in the locked procedure pack for now because some clinicians pre-flush the catheter before starting the CVC insertion. Depriving the operator of a syringe and preventing them from performing
this action may have an unknown and inadvertent effect on the clinical procedure. For initial further prototype development, it was decided that the contents placed inside the locked procedure pack would be the: suture, needle holder and bio-occlusive dressing alone.

An additional benefit of the locked procedure pack was that it could be used as a sharps receptacle at the end of the clinical procedure. If required, the magnet ensures the lid can be closed shut, and the contents sealed again. If the guidewire is left inside the channel of the locked procedure pack, the pack can easily be opened and closed. Thus, during equipment clear up, the locked procedure pack could be used as a point of care sharps receptacle to store the sharps used during CVC insertion. The guidewire could be left inside the channel to facilitate safe disposal. Should the clinician choose to do so, the locked procedure pack could be used as a convenient and safe container for collecting and transporting the sharps to the sharps bin. The clinician can dispose of their sharps as per their usual practice or dispose of the locked procedure pack and contents into the sharps bin.

**Designing the locked procedure pack**

A lecturer skilled in computer aided design (CAD) drawings and 3D printing, created and designed CAD drawings of the locked procedure pack. The initial drawings were redesigned five times before the exact shape of the locked procedure pack, including the channel, shelf, and hinge, was created (Figure 3.52).

![Figure 3.52: The first CAD drawings of the locked procedure pack required to 3D print a prototype.](image)

These drawings were then used to 3D print the locked procedure pack for bench testing with a guidewire (Figure 3.53). The first 3D print replicated the first prototype in Figure 3.51.
with slight modifications. There was no hinge, and the lid was held in position with three magnets.

Benchtop testing demonstrated that the opening mechanism was practical and easily performed. The guidewire was easily threaded into the channel (Figure 3.54), and the handles of the guidewire were lifted to open the locked procedure pack. The lid came off the box completely, as seen in Figure 3.53. However, removing the lid entirely was not desirable, and it was felt that the box and lid should remain together in one piece after it was opened.

Figure 3.53: The first 3D print of the locked procedure pack. A) Closed bird's eye view of the locked procedure pack. The opened box showing the B) base of the box and C) the underside of the lid. In this prototype, the lid was secured with three magnets and, when opened, lifted away from the base completely.

Figure 3.54: Bench testing with the first 3D print of the locked procedure pack. The guidewire (Kimal PLC, Uxbridge, UK) is easily inserted into the channel, and the lid is removed.
 Modifications were made to the CAD design (Figure 3.55), and the design changed, whereby the shelf was raised to be flush with the box, and the hinge was created.

Figure 3.55: A CAD drawing of the locked procedure pack. Demonstrating that the shelf has been raised to be flush with the box lid. The hinge was created, and drawings show the view of the locked procedure pack at each angle.

This design was 3D printed (Figure 3.56) and tested on the benchtop with guidewires (3.57).

Figure 3.56: A 3D print of the redesigned locked procedure pack based on the CAD drawings in Figure 3.55.
Benchtop testing determined that inserting a guidewire into the channel was easy. The raised shelf improved the previous design and provided better counter traction when the guidewire was lifted, and the box opened. The lid opened easily when the guidewire was used. However, it could only be lifted to 90°. It was felt that the lid should open completely, and the hinge should allow rotation of the lid to 180° so that the user would not be required to keep the lid open themselves or keep having to open the box every time a new piece of equipment was required.

Figure 3.57: Benchtop testing with the 3D printed redesigned locked procedure pack based on the CAD drawings in Figure 3.55. A) shows the guidewire (Kimal PLC, Uxbridge, UK) in the channel with the two ends of the guidewire sticking out to make the handle, B) the locked procedure pack is opened using the guidewire as a handle to lift the lid and counter traction with fingers on the shelf. Demonstrates that the guidewire feeds easily into the channel, and whilst the lid is easily lifted, it only opens to 90°, which may be cumbersome for the user.

Many ideas were posed for the writing on the shelf: insert guidewire here, an indentation which looked like fingertips to demonstrate where the fingers should be placed for counter traction or an arrow pointing to the channel with the word ‘wire’. The last of these ideas was thought to be the most appropriate option for paucity of words and ease of understanding for the operator. It was also necessary to improve the design or position of the magnets, and it was decided that the best mechanism for achieving this was to have a shelf on the inside of the box with two magnets on either side of the shelf (Figure 3.58). This would allow the lid to rest on the internal shelf and the magnets on the lid to be attracted to the magnets on the internal shelf.
Three additional CAD drawings and 3D prototypes were made, incorporating the above ideas, and refining the design to make the final prototype. The final versions can be seen in Figure 3.58.

![Figure 3.58: Final CAD drawings of the locked procedure pack. A) the closed locked procedure pack, B) the opened locked procedure pack and C) the clear plastic version of the locked procedure pack, showing the internal shelf upon which, the lid rests and the magnets sit to keep the locked procedure pack closed.](image)

Bench testing was undertaken with this final design and a guidewire (Figure 3.59). The results indicated that the guidewire was easily inserted into the channel, and the lid opened using both ends of the guidewire as a handle, with minimal effort. The lid rotated 180° and once opened out fully, the lid remained in the open position. The internal shelf held the magnets in the correct position. The magnets attracted well to those in the lid to prevent the locked procedure pack from being opened with anything other than the guidewire. Finally, the lid was flush with the rest of the box so that fingertips could not be used to open the box.
Figure 3.59: 3D printed locked procedure pack based on the final CAD drawing seen in Figure 3.58. A) the closed locked procedure pack with clear instructions demonstrating where to feed the guidewire, B) the closed locked procedure pack with the guidewire (Kimal PLC, Uxbridge, UK) in the channel and the two ends of the guidewire sticking out to make the handle, C) the opened locked procedure pack, which shows the lid now opened by 180°, the guidewire remains in the channel and an internal shelf for the magnets and for the lid to rest on.

It was decided that a clear box would be the ideal design, allowing the operator to see the contents inside the box and understand what the locked procedure pack would be for. Given that bench testing of the 3D printed prototypes was successful, and a product which fulfilled the criteria to prevent this error was developed, it was decided to proceed to the next step in the development process with this innovation. That is, engaging a manufacturer and creating a clinically usable version of the locked procedure pack.

**Manufacturing**

Several manufacturing companies were approached and asked to develop the locked procedure pack. Finally, Venner Medical International (VMI) agreed to develop this innovation, and the patent was assigned to them. Once the patent had been assigned, VMI
had the rights to design and manufacture the locked procedure pack. In the concept and prototype creation phase, the locked procedure pack could be designed to have the best user experience; however, once a manufacturer is involved, many other factors must be considered during product development. These are the production and creation of moulds to manufacture the device, the type of plastic used: in terms of sourcing, moulding and environmental aspects, the ease of use for packers to be able to pack the contents inside the locked procedure pack, the storage, the shipping, the ability to sterilise the product, contents, and wrapping, the regulatory approvals and the cost.

**Improvements:**

- A neatly designed biohazard label was placed inside the box to demonstrate that sharps could be placed inside the box after the procedure had been completed (Figure 3.60)
- Clear instructions were placed on the back of the device for users to understand how to use the locked pack had they not been previously trained (Figure 3.61):
- The movement of the hinge improved to make opening the lid easier (Figure 3.60)
- Counter traction forceps, a pair of scissors, a pen, a syringe, and a drawing up needle were added to the contents in addition to the suture, suture holder and bio-occlusive dressing. The suture was changed to a curved suture. These were to improve the user experience through safety and convenience (Figure 3.60):
  - A curved suture, suture holder and counter traction forceps were provided for the operator to enable safe suturing
  - The scissors were provided so that the clinician could use these to cut the suture material rather than the bloody blade previously used to make the skin incision
  - An additional 20ml syringe was provided in case a solution to the problem of sterilising normal saline could be found
  - A sterile pen was provided so that the operator could write the date of CVC insertion on the bio-occlusive dressing, a task often forgotten because of the lack of a sterile pen at the time of insertion.
Figure 3.60: A prototype of the clear locked procedure pack (Venner Medical International, Jersey, UK). A) the closed locked procedure pack with the contents required to complete the CVC procedure after the guidewire is normally removed, where the contents are visible through the clear plastic, B) the closed locked procedure pack with the guidewire (Kimal PLC, Uxbridge, UK) in the channel and the two ends of the guidewire sticking out to make the handle, C) the opened locked procedure pack demonstrating that the lid opens fully and the guidewire remains in the channel, D) the empty locked procedure pack with the sharps label inside showing that the user can place the sharps used in the CVC procedure inside the box if required. Next to the locked procedure pack are the contents: a curved suture, suture holder, counter traction forceps, scissors, a pen, a syringe, and a drawing up needle.
Figure 3.61: The instructions on the back of the locked procedure pack, created by Venner Medical International, to demonstrate to users how to use the WireSafe if required.
Compromises:

- A single magnet in the middle of the lid and shelf was used rather than two magnets at either side of the box. This was to reduce costs. However, an unfortunate downside to this was that when the clinician tried to insert the guidewire into the channel, it was attracted to the magnet and made the insertion into the lid channel cumbersome and irritating to the user. However, despite requests, this could not be changed back to the previous iteration (Figure 3.62).

- The arrow and the wording ‘wire’ was removed from the shelf because the instructions were on the back of the locked procedure pack, and it was deemed unnecessary by the company designers (Figure 3.62).

Figure 3.62: A prototype of the locked procedure pack by Venner Medical International, demonstrating two compromises which were made during the manufacturing process. A single magnet in the middle of the shelf, rather than the two at either side, attracts the guidewire and can push it off course during insertion (demonstrated with Kimal guidewire, Kimal PLC, Uxbridge, UK). The instructions on the shelf of the box were removed as deemed unnecessary.
Some of these were improvements and compromises; however, these were required to produce a clinically usable product at a low cost to the user and in a cost effective manner for the manufacturer.

**The final product**

The final size of the locked procedure pack was decided so that the box could easily contain the suture, suture holder, counter traction forceps, antimicrobial dressing, scissors, a pen, a drawing up needle, a 20ml syringe and flush solution if this could later be possible (Figure 3.63). The lid was flush with the shelf and the base of the box so that fingertips could not be used as a workaround to open the box. A single magnet was used to ensure the lid was held shut and was strong enough to keep the locked procedure pack closed and the contents inside, even if turned upside down and shaken. The opening mechanism was a light bulb shaped channel within the lid and accepted guidewire up to 10G in size. The two ends of the guidewire formed a convenient handle, allowing the user to lift the lid through the force of lifting and counter traction by placing fingertips on the shelf. It was felt that the contents of the locked procedure pack, described above, would provide the best user experience. However, if clinicians requested different or fewer contents, then this could be accommodated and the boxes bespokely packed. VMI designed the instructions for use and this was available on the underside of the box.

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Figure 3.63: The final design of the locked procedure pack produced by Venner Medical International (Jersey, UK), with the contents for CVC insertion. A) bird's eye view, B) side view and C) side view showing the hinge.
When the locked procedure pack is used the steps of the CVC insertion would be modified slightly and the changes can be seen below in Figure 3.64.

Figure 3.64: The steps performed when using the locked procedure pack during CVC insertion: (A) venepuncture, (B) guidewire insertion, (C) catheter placed over guidewire and guidewire removed, (D and E) guidewire inserted into the light bulb shaped channel in the lid of the locked procedure pack, (F) the locked procedure pack is opened by grasping the protruding ends of the guidewire and using them as a handle to open the lid of the locked procedure pack, (G) contents of locked procedure pack are used for catheter insertion, (H) the sharps used for catheter placement are put inside the locked procedure pack and (I) the lid of the locked procedure pack is closed and sharps are sealed inside for transfer to the sharps bin. Sharps and guidewire can be emptied into the sharps bin or the locked procedure pack can be disposed of in the sharps bin.

The locked procedure pack was renamed by VMI and called the Venner WireSafe™. The patents were renewed and maintained internationally in the territories VMI had decided appropriate, and the name was trademarked. Once the final design was settled upon, the company performed all the formal heuristics, usability and sterilisation testing that were required for regulatory purposes for approval by the Medicines and Healthcare Products Regulatory Agency in the UK, the European Medicines Agency in Europe and the US Food and Drug Administration in the US, and sale in these territories. After regulatory approval, mass manufacturing was commenced, and international distributors were found that could pack the WireSafe, sterilise it and distribute it to hospitals internationally.
3.5 Discussion

The data from Chapter two determined that guidewire retention could be prevented by physically preventing over insertion or enforcing early recognition of guidewire retention. Using this information, the CVC procedure was analysed and point in the CVC procedure at which a novel solution would be most effective was determined. That is when the catheter is placed over the guidewire and the guidewire removed. Given that this was the ‘critical point’ in the procedure where the error occurred, this was where the prevention strategy was required.

The initial approach to prevent CVC guidewire retention was to change the guidewire, which has been discussed many times in the literature.4,16,19,73,83,103,114,119,120 However, all the solutions developed that involved changes to the guidewire were either impractical, ineffective or too cumbersome to use. Additionally, it was recognised that changing the guidewire may have unintended consequences on the clinical procedure. Changing how the operator performs the CVC insertion may have unknown and wide ranging implications and inadvertently increase the risk of this or other CVC errors. An increase in error rate would not be acceptable, even if the solution could be proven to prevent CVC guidewire retention. Changing the guidewire also had substantial cost implications for the manufacturer, and none wanted to develop an innovation that changed the guidewire. Hence, all solutions involving a change to the guidewire were abandoned.

Upon rethinking the strategy of preventing this error from both the user's and the manufacturer’s perspective, the locked procedure pack (WireSafe) was developed. The WireSafe prevented the error, did not affect the clinical procedure, and worked by adding a forcing function step in the CVC insertion process to ensure the operator performed the correct safety action, removing the guidewire. This innovation mainly had positive feedback and as demonstrated in the informal usability testing, only required a single teaching episode to demonstrate the opening mechanism. Compared with re-education, retraining, alerts and checklists, no further training would be required with the locked procedure pack. The locked procedure pack is a forcing function and would effectively prevent the error despite interruptions, distractions, inattention, inexperience, inadequate supervision, operator fatigue, high workload, out of hours, or emergency CVC insertions. This ensures that the error can be prevented regardless of the situation, environment, or operator and as such, is a solution that may sustainably prevent the error. At the end of the procedure, the presence of
the guidewire in the channel of the locked procedure pack potentially removes the need for a second person to witness guidewire removal, an equipment check specifically looking for the guidewire at the end of the procedure or documentation and checklists focusing on guidewire removal. The locked procedure pack is easily slotted into the clinical procedure and the manufacturing processes. It is essentially a plastic box with magnets; thus, it was deemed an easy and inexpensive solution for both manufacturers and hospitals.

A problem with the locked procedure pack is that the guidewire could still be over inserted and retained because the clinical procedure has not been changed. However, the locked procedure pack would immediately alert the operator to the error, allowing for correction during the clinical procedure. Of course, if a solution that prevents over insertion, does not affect the clinical procedure, is easy to manufacture and introduce into clinical practice is developed, then this would supersede the locked procedure pack. However, there are potential problems with changing the clinical procedure and then re-teaching every clinician to change their practice of CVC insertion. Therefore, for the time being, it was decided that alerting the operator to the error almost immediately after it has occurred (whilst the guidewire is still in the catheter and therefore easily retrievable) was the best available strategy for preventing this error. Importantly, in 99.97% of all CVC procedures where this error does not occur, the locked procedure pack would not impede the operator or affect the clinical process. Instead, it attempts to improve procedural safety and provide a good user experience with the box contents.

Another problem is with the locked procedure pack is that it does not prevent guidewire retention when two or more CVC packs (and two or more guidewires) are used. This is a rarer error, where most guidewire retentions, 97.5%, in the NRLS data occur with single catheter insertions. Multiple CVC packs are used in two scenarios: firstly, there is a planned insertion of multiple CVC within the same procedure requiring multiple CVC kits, accounting for 1.7% of guidewire retentions in the NRLS data. Secondly, there is a difficulty in catheter insertion with the first kit, and then a second kit is opened, accounting for 0.8% of guidewire retentions in the NRLS data. Whilst one could use an equivalent number of locked procedure packs on the sterile field, this solution is inelegant, and a more appropriate preventative strategy is required, which is not within the scope of this thesis. However, guidewire retentions when multiple CVC are used represent a small minority of reported retained CVC guidewire incidents, 2.5% of CVC guidewire retentions in the NRLS data. Whilst the locked procedure pack cannot prevent every retained CVC guidewire, it mitigates
the risk in the substantial majority of cases (97.5%). Therefore, the focus of the work in this thesis was directed at preventing single catheter insertions; hence, the solutions in this chapter were developed. A further problem, also described in the informal user testing, is that operators could try to work around the safety feature, i.e., they could try to open the locked procedure pack without the guidewire or could break it open. This cannot be prevented, and if clinicians wished to work around the safety feature, they could do so with some difficulty. However, the same could be said of any safety feature, be it a checklist, paperwork, alert, or device. The locked procedure pack was designed so that the safest option was the easiest option for the user, with as many built in benefits as possible to make using the locked procedure pack a positive user experience. Whilst one cannot account for the behaviour of every individual, the hope is that users will recognise the safety and user benefits. Whilst the locked procedure pack was deemed the best solution for preventing CVC guidewire retention, further testing would be required to determine the efficacy and effectiveness of the innovation.

Despite the failed ideas for preventing guidewire retention, many concepts in designing a solution to prevent a never event error and the manufacturing process to create these solutions were learnt and discussed in this chapter. When designing a solution to prevent a rare error, one must first understand why the error occurs and why the current error prevention mechanisms are ineffective. If available, near miss data would be useful to understand how the error was avoided. Secondly, the clinical procedure must be analysed in detail to determine the moment when the error occurs and locate at which point the prevention strategy is required. Thirdly, there must be an understanding of the procedure and equipment from the perspective of the operator and the interaction between the operator and the equipment. Fourthly, regarding rare errors, any solution designed must not adversely affect the clinical procedure; otherwise more errors are likely to occur. Fifthly, designers must be aware of the potential for unintended consequences of the solutions. Hence, testing must be performed to determine efficacy and usability before clinical introduction. This should apply to any intervention, i.e., alerts, checklists or forcing functions. Sixthly, one must understand the perspective of the manufacturer and the impetus required to spend vast amounts of money on developing an innovation. To reduce costs to the end user as much as possible, the solution should ideally not affect the manufacturer’s production line to allow ease of manufacturing and production with the current equipment. Finally, as well as preventing the error, the user must have a good experience when using the new solution. As
many clinicians will not see the rare error in the lifetime of their working practice, any new solution must not impede their current practice; otherwise, the risk of error could increase. These lessons helped to develop the locked procedure pack and could be applied to developing preventive solutions to other rare errors.

**Limitations**

There are limitations to this development process. The benchtop testing of the prototypes was performed with the CVC equipment and a mannequin adapted for CVC insertion. Whilst this appeared to be informal testing, the first stage of developing the innovation was to test the feasibility and functionality of each idea. Testing with other users, both informal and formal, could only be performed after device feasibility and functionality testing was performed. There were no standardised methods of testing a novel innovation to prevent retained CVC guidewires available in the literature. Whilst generic human factors methods of developing products are available in terms of usability heuristics and ergonomics,⁵⁹,¹²⁴–¹²⁶ these are mainly focused on the user interaction with the device and not specific to determining the feasibility or functionality of the innovation, preventing the retained CVC guidewire error. A study using usability heuristics to evaluate the CVC procedure found that it did not “reflect realistic issues experienced in operation conditions or effective countermeasures.”¹²⁴ These evaluations may be more relevant when a final solution is developed, and a manufacturer wants to provide a product that gives the operator a good user experience. Thus, to determine the feasibility and functionality of each solution developed, it was decided that the prototypes should be tested in the order they would normally be used in the CVC insertion procedure. This ensured that each prototype was tested in the same methodical fashion so that the results were comparable. In addition, all guidewire prototypes were made with 45cm Kimal CVC guidewires. The same CVC equipment (Kimal CVC needle, dilator, and catheter, Kimal PLC, Uxbridge, UK) and mannequin model (Laedal, Gatesville, US) were used for benchtop testing. This was the best method of testing that could be performed with the funds available.

The benchtop testing of the prototypes was either performed by clinicians skilled in CVC insertion. This skill is required for initial feasibility and functionality testing of the innovation to understand the practical implications of each novel solution from the operator’s perspective when tested with the CVC equipment. Given that testing was performed by two inventors, whilst one could argue that this may lead to bias in the testing,
many of the innovations invented were rejected, and the reasons for each were discussed above. Hence, whilst the potential for bias existed, this was mitigated by adhering to the methodical testing process described above.

Formal testing was performed for further product development and regulatory approvals by VMI. This was done independently by the manufacturer and out with consultation with the inventor and author, therefore this has not been included in this thesis.

3.6 Chapter conclusions

In this chapter, many lessons were learnt through the developing, testing and manufacturing process of solutions designed to prevent CVC insertion. It is important to understand the error, the operator's actions, the equipment the operator interacts with and the clinical procedure. It is also important to understand the perspective of the manufacturer and the incentives for them to develop a novel device into a clinically usable product. These lessons could be used to develop solutions to other never events. Whilst many solutions were developed and tested, the locked procedure pack (WireSafe) was deemed the best mechanism for preventing CVC guidewire retention. It prevents the error, is easy to use by the operator and is easy and cheap to manufacture. However, further testing is required to determine the efficacy and effectiveness of the innovation.
CHAPTER 4

EVALUATING THE LOCKED PROCEDURE PACK AND GUIDEWIRE RETRIEVAL TECHNIQUES

This chapter comprises of five main themes. The first discusses of forced error simulation, a novel methodology to test the efficacy of preventative strategies to never events. The second describes a study performed to evaluate the locked procedure pack: a forced error simulation study. The third discusses the clinical introduction of the locked procedure pack (WireSafe) by Venner Medical International. The fourth describes a pilot study performed during the introduction of the WireSafe into clinical practice in a single hospital is described. Finally, a novel guidewire retrieval method, which could be used with or without the WireSafe, and a benchtop study evaluating guidewire retrieval techniques is described.

4.1 Introduction

The locked procedure pack is a novel innovation designed to prevent CVC guidewire retention. It is a clear plastic box with a lightbulb shaped channel in the lid and contains the equipment required to complete the procedure after the guidewire is usually removed. The locked procedure pack is a forcing function. It ensures the user cannot secure the catheter and complete the procedure without removing the guidewire. Theoretically, the locked procedure pack should prevent guidewire retention; however, it must be evaluated to determine efficacy and effectiveness.

When evaluating a novel solution to prevent an error that occurs once in several thousand procedures, replicating routine practice with a randomised controlled study, as is usually performed in medicine, would be difficult to achieve due to numbers of participants involved. Therefore, a novel method for evaluating the locked procedure pack was required, a forced error simulation study. This approach was to determine the efficacy of the prevention strategy. Usually, the next step is to determine the effectiveness of a solution. However, the effectiveness of an innovation like the locked procedure pack cannot be
evaluated until it is widely implemented. Thus, to ascertain whether there would be any impact of the locked procedure pack on the CVC procedure in clinical practice and assess the acceptability to staff regarding safety and convenience, the device was evaluated during its introduction in a single centre. Finally, the locked procedure pack does not change the clinical CVC procedure up to the ‘critical point’. Whilst it forces recognition of guidewire retention, guidewire retention is still possible at any point in the CVC procedure before the ‘critical point’. If this occurs, a bedside retrieval method may be required to aid in the quick recovery of the guidewire. However, guidewire retrieval methods currently described in the literature are not always successful. A novel strategy for guidewire retrieval was developed and compared with two others in a benchtop study, to develop an effective strategy for recovery of the guidewire. This strategy could also be used by clinicians even if they were not using the locked procedure pack and recognised guidewire retention via another mechanism, i.e., checklist, documentation, or equipment check.

This chapter aimed to determine the efficacy of the locked procedure pack, clinician acceptability to using the new safety device and guidewire retrieval strategies to aid recovery if retention occurs with or without the locked procedure pack.

4.2 Forced error simulation

Currently, in healthcare, the solutions to prevent never events are educational reminders, checklists, warnings, and alerts, double or triple check systems, reminders, or memory/communication aids. These are, usually, designed locally and implemented by the RCA investigators, who often have had little training in system safety practices. The efficacy of these strategies are rarely tested before their introduction. More commonly, after introducing the above strategies into clinical practice, an audit is performed to determine the effectiveness of the prevention strategy. However, when performing the audit, the investigator only has the documentation to determine whether the safety check has been performed, and this evaluation is performed retrospectively. Additionally, these checks depend on the operator signing the documentation confirming that they have performed the check. Consequently, an assumption must be made by the audit investigator that the operator has performed the check correctly and they have documented that process. One could argue, then, that the audit only determines whether the clinicians have signed the document confirming the check has been performed rather than the effectiveness of the check.
Therefore, an audit cannot determine the effectiveness of checks or reminders in preventing a never event; it can only check staff compliance with documenting that they have performed the check. With the assumption that if they have documented that they have complied with the check, then the check must be effective. However, this is not the case, as seen in the interviews study and the article by Vannucci et al., where the documentation to confirm guidewire removal was signed by the operators, despite guidewire retention occurring. Additionally, the audit must be frequently repeated to ensure clinicians adhere to the checking system, which utilises cost and time resources, and is unsustainable to prevent every never event which may or may not occur. Consequently, an audit is not a helpful method of assessing the effectiveness of safety interventions to prevent never events.

Usually, in medicine, a novel product is evaluated by replicating routine practice in a randomised controlled trial to determine whether the new practice is better than the current practice. However, this is almost impossible for an error that occurs once in several thousand procedures. Evaluating a prevention strategy for a never event, replicating routine clinical practice is impractical due to the number of participants required and the size of the study. For example, for an error occurring in 1:3,167 procedures, a power calculation shows that around 12,000 participants would be required for the study if one were to test the device replicating routine clinical practice in a randomised controlled trial. To contextualise this, there are 12,443 working Anaesthetists in the UK. Thus, conducting these studies for never event would be highly impractical and expensive. In addition, there is the ethical dilemma of withholding potentially safer practices from a large cohort of patients. A novel solution to a never event should not be introduced into clinical practice without determining efficacy. However, these impracticalities demand a different method of evaluating prevention strategies to never events.

The high reliability industries use simulation to replicate and re-enact situations to determine the potential causes of critical errors and also test solutions or train crew to react to rare errors by using ‘forced error’ or ‘disaster scenario’ simulation test methodology. A forced error simulation is a created environment manipulated to make a rare error, or a never event, highly likely to occur. In these simulations, the participant is distracted by multiple elements of routine practice and is presented with hidden, latent errors. The scenario is configured to push or force the error and determine how the participant or participants react to the situation. For example, in the airline industry, pilots are trained to recognise and manage rare events in a simulator, such as runway incursions or
sudden instrument failure. Instead of undertaking hundreds of hours of “vigilance” or watching and waiting simulations, where a rare error may or may not occur, which is an expensive and inefficient use of training time with limited learning opportunities, simulations are performed with scenarios that have predetermined failures, forcing the rare error to test the pilot’s reactions and capability of altering their actions to fly the aeroplane safely. These types of simulations can be conducted in an inexpensive and replicable manner. During these training events, pilots are given bogus reasons for training and are unaware of the actual study to prevent cheating the system.\textsuperscript{133}

An example of testing safety interventions can be found in the car industry. To determine the efficacy of new airbag safety technology and understand whether it will deploy correctly during a car crash, an unfeasible and non-sensible randomised controlled trial would be the manufacturer installing the new technology in half of the car manufacturing lines and asking drivers to report whether the airbag deployed correctly during a car crash. This would not only be highly unethical; it would also require many thousands of drivers randomised to each group driving for most of their lifetimes to achieve the required power for the study. Instead, with forced error simulation, the manufacturer tests the equipment by crashing the car repeatedly in many different accident scenarios, assessing the efficacy of the technology through a reduction in damage to the crash test dummies.\textsuperscript{134} This determines the efficacy of the technology and provides the data to determine whether the improvement in practice is sufficient to implement the safety solution across the manufacturing line.

If this methodology is used to test prevention strategies for never events, the simulation study can determine whether participants first recognise the error as it is about to occur and, secondly, if the error is recognised, whether they can prevent it or correct the mistake. Importantly, this methodology is validated, inexpensive to replicate\textsuperscript{133} and can be easily powered for randomised controlled trials making this an ideal methodology for testing preventative solutions to rare errors in healthcare. Simulation is commonly used for medical education and training,\textsuperscript{135,136} and disaster scenario or forced error simulation are used to train clinicians to prepare for major incidents.\textsuperscript{132} Therefore, using forced error simulation to test novel preventative strategies to never events is an adaption of these simulation techniques.

For this forced error simulation study, the scenario must be designed around the never event. To do so, instead of considering an individual error pathway in isolation, the entire clinical pathway should be understood. This is done by understanding the potential
system errors, the patterns of the operator’s normal behaviour and that when the error occurs, and analysing all the potential ways that the error could occur. With this knowledge, designing a simulation that reliably replicates the error is possible. The simulation must be designed so that the latent failures in the system and common human error pathways are aligned to ensure the pre-determined error is all but inevitable. However, the error can be prevented if the participant recognises the clinical mistake within the scenario. The study participant must be given a false pretext for the experiment, which distracts their focus, to reduce the likelihood of intentionally or unintentionally altering their normal safety behaviour. Under these conditions, the participant should reliably fall into the error traps. Participants can also be randomised into two groups, and the simulation can be conducted using current practice or standard equipment and the safety intervention. In this way, the control group highlights the ease of making these rare errors in unfavourable circumstances when the system and human failures are aligned, similar to Reason’s Swiss cheese model.\textsuperscript{111} In comparison, the intervention group demonstrates the efficacy of the novel strategy in preventing the error. There is also an added advantage of understanding the usability of the intervention in this setting. In this way, the efficacy of these interventions to prevent never events could be evaluated before their introduction into clinical practice. This may support the introduction of efficacious and in terms of systems solutions, a sustainable mechanism of preventing these errors.

4.3 A randomised controlled forced error simulation study

4.3.1 Introduction

The transport and energy industries use safety engineering to modify their equipment and design errors out of the system.\textsuperscript{103} In this thesis, these principles were used to modify the CVC equipment to design a locked procedure pack to ensure the operator completes the procedure by the safest method, that is, removing the guidewire.

The locked procedure pack is designed to prevent CVC guidewire retention. If the step by step process of the CVC procedure is reviewed, in theory, this innovation should prevent the error. However, before the clinical introduction of the locked procedure pack, the device be evaluated to determine efficacy at preventing the error.
This study was designed to evaluate the locked procedure pack in a forced error simulation study to determine whether it would prevent CVC guidewire retention with operators naive to the solution. The simulation study design was based on real never event cases reported to the NRLS.\textsuperscript{137} Whilst forced error simulation techniques are used in the transport and energy industries to test safety solutions to rare errors, this has not been previously done in healthcare. In this study, the simulated environment is designed to make a rare incident occur, allowing the preventative solution to be tested. The participant is ‘forced’ into making the error to determine whether the intervention makes the participant recognise and correct the error. Forced error simulation is a validated, safe, repeatable, and inexpensive test methodology.\textsuperscript{133,134} Therefore, it is ideal for testing solutions to prevent rare errors.

This study aimed to determine whether the locked procedure pack would prevent guidewire retention at the completion of CVC insertion.

4.3.2 Methods

The University of Cambridge granted ethical approval to conduct the research. The institutional research and development review board approved the simulation study conducted at the Queen Elizabeth Hospital, Kings Lynn.

Study design

A randomised controlled forced error simulation study was conducted on a single day to ensure the confidentiality of the study between participants.

Recruitment and participants

A convenience sample of 20 participants were selected for the study. Volunteers were requested, and clinicians of any grade self selected on a single day from the operating room, ICU, general medical or surgical wards. Signed, informed consent was taken from all participants.

Eligibility criteria

Inclusion criteria:

- Clinicians capable of independent CVC placement
• Clinicians from any speciality background
• Clinicians of any grade or experience
• Medical or nursing staff

Exclusion criteria:
• Clinicians who required supervision for CVC insertion
• Clinicians with prior knowledge of the locked procedure pack
• Clinicians with prior knowledge of the study aims

Randomisation
Participants were randomised to standard practice or locked procedure pack by sealed envelope randomisation. Twenty identical envelopes were sealed with control (n = 10) or intervention (n = 10) indicated on the paper within and shuffled into a random order (Figure 4.1). Immediately before the participant entered the scenario room, the data collection team, blinded to the participant’s identity, opened an envelope and set up the procedure trolley appropriately.

Scenario
Participants were informed that the study was observing the technical capabilities of clinicians of various grades during CVC insertion. However, they were not informed of the real purpose of the study, that is, whether they would recognise guidewire retention or whether the locked procedure pack would force recognition of the error. A scenario was described to the participants using a standardised script before entering the room (Appendix 4.1). The scenario outlined was that a colleague had been urgently called away partway through a routine CVC insertion on a clinically stable patient.

Participants were asked to assess the situation, complete the procedure safely, and perform any additional safety checks before approving the CVC for use. Participants were informed that an assistant was available to assist and answer questions. The assistant played the role of operating department practitioner (ODP) or ICU nurse.

The simulation utilised a mannequin model (Laerdal, USA) adapted for CVC insertion and covered with standard blue surgical drapes (Vygon, UK) with a clear window for CVC insertion.
20 participants, medical doctors, capable of CVC insertion
Envelope randomisation into two groups

Standard group
n = 10

Locked procedure pack (LPP)
n = 10

Equipment arranged for the Standard group

Equipment arranged for the LPP group

Scenario described to participants

Using standard equipment, participants required to secure CVC in place, apply dressings and complete procedure to their satisfaction and instigate appropriate safety checks

Using the locked procedure pack, participants required to secure CVC in place, apply dressings and complete procedure to their satisfaction and instigate appropriate safety checks

Participants given a structured questionnaire asking their opinion of the locked procedure pack in terms of safety convenient, sharps and guidewire disposal

Figure 4.1: A flow diagram detailing the methodology of the simulation study.
A CVC (Arrow International, Inc., UK) was placed in the right internal jugular vein, with the guidewire visible in the transparent portion of the catheter lumen (Figure 4.2, A). The guidewire tip was also visible, just protruding from the brown hub but not within the clear hub (Figure 4.2, B). If recognised, the guidewire was easily retrievable with fingertips or artery forceps, provided upon request. The mannequin was connected to an electrocardiogram monitor, which displayed ectopic beats. This was to give the clinicians an idea that there could be an error in the scenario. An ultrasound machine was available in the room for use if requested. A trolley with the equipment required to perform CVC insertion (Rocialle, UK, Figure 4.1) was positioned on the patient's right side. The equipment was arranged depending on participant randomisation to standard practice or the locked procedure pack group.

Figure 4.2: Image of the position of the CVC in the mannequin displaying the guidewire within the catheter lumen. Where A) shows the guidewire within the catheter lumen, and B) shows the tip of the guidewire just protruding from the brown hub but not visible within the clear hub.

The assistant was available to answer questions and help the participant if required (Appendix 4.1). If participants asked about the patient's stability, the assistant responded, “Obs are stable, sats 95% on air, normotensive,” if asked about the ectopic beats, the
assistant stated these had commenced during the CVC insertion. If participants specifically asked about the location of the guidewire, the assistant stated that they had not seen it. If the participant used the ultrasound machine and asked what they could see on the screen, the assistant informed them that “it looks like the catheter is in the right internal jugular vein”. If asked about the location of the stitch or dressing, they were told to direct the participant to the ‘sterile field’ or ‘box’ depending on randomisation. If asked about the locked procedure pack, the assistant responded, “It is a new safety initiative, but I do not know what it is for or how to use it”. To distract the participant during the simulation, elements of routine practice were introduced by questioning them regarding their usual practice when inserting CVCs, including the position of the catheter on the mannequin, catheter fixation practice and the dressings they would use on the catheter (Appendix 4.2).

Control

In the control group, participants entered the room, assessed the situation, and proceeded to secure the CVC in place and apply the dressings. Upon completing the procedure to their satisfaction and safely disposing of the equipment, participants were asked whether they would perform any additional safety checks before using the CVC. At the end of the study, participants were asked not to discuss the simulation study with any other staff members.

Intervention

Participants randomised to the locked procedure pack group entered the room and assessed the situation. When participants attempted to secure the CVC in place, the assistant did not explain how to use the locked procedure pack. Instructions on the locked procedure pack indicated that the guidewire should be inserted into the channel and the lid lifted to open. The time taken to open the locked procedure pack by the participants was recorded. This was the time from inserting the guidewire into the channel of the locked procedure pack to the lid fully open and the participant able to access the contents. One investigator timed this surreptitiously on the room clock. At the end of the procedure, participants randomised to the locked procedure pack group were also asked their opinion of the safety initiative regarding the safety of the procedure, convenience, sharps disposal, and guidewire disposal. These were categorised as better, same, or worse (Appendix 4.2).
At the end of the study, participants were asked not to discuss the simulation study with any other staff members.

**Outcomes**

The primary outcome of this study was the number of incidents of guidewire retention at the completion of the CVC insertion procedure.

**Statistical analysis**

A power of 0.87 for a statistical significance of 0.05 and for $n = 10$ to detect a 50% absolute difference in proportions was calculated. A two-tailed Fisher exact test was used to analyse the data (GraphPad Software, Inc., USA).

**4.3.3 Results**

On a single day, 20 clinicians, all capable of independent CVC insertion, volunteered for the study. Participants were qualified medical doctors at various degrees of seniority (foundation trainee to consultant level) from various speciality backgrounds: anaesthetic, ICU, general medical and surgical specialities.

The standard group consisted of four women (aged between 23 and 60), and six men (aged between 24 and 60), of which four were consultants and six were junior doctors. The locked procedure pack group consisted of three women (aged between 25 and 40), and seven men (aged between 25 and 60), of which three were consultants and seven were junior doctors.

The locked procedure pack prevented guidewire retention at the completion of CVC insertion. Guidewire retention was prevented in 2/10 (20%) in the standard group versus 10/10 (100%) locked procedure pack group, $n = 20$, $p < 0.001$.

Participants were asked if they were happy with the depth of insertion (the position) of the catheter and all looked at the catheter. However, only 2/10 in both the standard and locked procedure pack group recognised the guidewire inside the catheter lumen. In the standard group, 80% (8/10) of participants failed to recognise the guidewire in the catheter lumen. They secured the CVC, applied the dressings, and were satisfied that they had completed the procedure correctly. In the locked procedure pack group, two participants recognised the guidewire in the lumen, and those who did not (8/10) attempted to complete
the procedure. However, the inability to access the equipment inside the locked procedure pack triggered a search for the guidewire by the participant. Participants searched the trolley, floor, and sharps bin before looking at the CVC, where all found the guidewire within the catheter lumen. These eight participants confirmed that the locked procedure pack reminded them to look for the guidewire. In the locked procedure pack group, all were able to remove the guidewire from the catheter, insert the guidewire into the channel of the locked procedure pack, lift the lid to open the box and access the contents to finish the procedure. All participants managed to open the locked procedure pack in less than 10 secs. In the locked procedure pack group, all participants reported that the safety intervention was better regarding the safety and convenience of CVC insertion, sharps disposal and guidewire disposal (10/10).

4.3.4 Discussion

This study sought to determine whether the locked procedure pack would prevent guidewire retention at the completion of CVC insertion. In this study, the locked procedure pack prevented guidewire retention compared to standard practice. In addition, using the locked procedure pack forced participants to recognise guidewire retention when they were unable to complete the procedure without the guidewire. This ensured that the guidewire was removed every time.

All participants were asked to look at the catheter to confirm whether they were happy with the depth of insertion, which would, in theory, provide ample opportunity to see the guidewire inside the catheter lumen and recognise guidewire retention. In the study, whilst all participants stood in the usual position for a right internal jugular CVC insertion, only two participants in each group saw the guidewire in the catheter lumen. This can be explained by the psychological phenomenon of inattentional blindness, where the participant’s mental focus is on other tasks, and something obvious in hindsight is missed. The participants were not looking for a retained guidewire, hence, it was easily missed. Therefore, recognition of the error must be forced into the operator’s mind; otherwise, guidewire retention will occur. This was seen with the locked procedure pack group, where 8/10 participants attempted to complete the CVC procedure and were prevented from doing so by the locked procedure pack. As with the standard group, it is most likely that without the locked procedure pack, participants in the intervention group
would not have recognised guidewire retention, and would have secured the catheter, and returned the patient to the ward with the guidewire in situ. The locked procedure pack forced recognition of the error and, importantly, allowed correction of the error by the operator. The NRLS data shows that the guidewire often remains within the catheter lumen and migrates into the vasculature over time. If guidewire retention is immediately recognised, at this stage, retrieval is almost always possible by clamping artery forceps at the skin level to the catheter and enclosed guidewire and removing en-block. Which reverses the potential for further migration and embolisation. This study demonstrates that the locked procedure pack was a successful forcing function and safety initiative that prevents guidewire retention.

In the locked procedure pack group, all participants, despite being inexperienced with the device, were able to understand how to use the device. All participants took less than 10secs to utilise the guidewire to unlock the mechanism and access the contents to complete the procedure without demonstration or assistance. Therefore, in the most basic sense, the locked procedure pack was intuitive to use, with naive users, even on their first interaction with the device. This demonstrates that the locked procedure pack prevents the error and has a user friendly and intuitive interface. Whilst there was also overall approval for the locked procedure pack, formal heuristic evaluation and usability studies would need to be conducted to confirm the intuitive nature of the device and ease of use.

The scenario in the study was designed to force the error to occur reliably and repeatedly to test the intervention. Whilst one could suggest that the simulation scenario appeared unrealistic, which is somewhat valid. This type of artificial scenario was constructed to force the occurrence of the error. However, it was based on real never, event cases reported to the NRLS database, seen in Chapter two, where a clinician was asked to take over the CVC insertion mid way through the procedure. Many extraordinary situations were described in the NRLS data with interruptions and distractions, and clinicians were still expected to perform the CVC insertion without error. The scenario in this study, whilst unusual, it is still realistic. Consequently, one could think of the simulation study as a worst case example of a scenario where this error could occur. Interestingly, this shows that the locked procedure pack can prevent guidewire retention, even in extreme circumstances, and demonstrates why forcing functions are the most effective form of error prevention.

An interesting observation in the locked procedure pack group was the participant's behaviour when searching for the guidewire after it was discovered missing. All eight
participants initially searched the trolley, floor, and sharps bin, and finally, realising it might be in the patient, looked at the CVC lumen. The responses of these eight participants are almost identical to that seen in the NRLS data and in one of the interviews. This highlights that the error of a retained guidewire is a low possibility in the clinician’s mind. As seen in this study, the least likely place a missing guidewire could be is inside the patient, which may be why most guidewire retentions are not recognised during CVC insertion. Therefore, to aid quick retrieval, clinicians must be made aware of this possibility as quickly as possible. In this study, the locked procedure pack ensured recognition of guidewire retention almost immediately after the ‘critical point’ in the procedure.

Usually, when guidewire retention occurs, common solutions are reiterating and emphasising the importance of guidewire removal. However, forcing awareness of a rare error into the operator's mind increases cognitive load. This potentially can detract awareness from other CVC complications, such as pneumothorax, arterial puncture, dysrhythmias, or air embolism. Whilst the locked procedure pack aided the participant in recognising the error, importantly, it did not adversely interfere with the procedure. As seen with two participants in the intervention group that did recognise guidewire retention, it forced recognition of guidewire retention only when necessary and did not affect the participant’s cognitive load in the simulations when guidewire retention was recognised.

This simulation study used a novel methodology for evaluating a preventative strategy for a never event, forced error simulation. The study was performed to ‘force’ the error to occur to determine whether the participants would recognise the error and whether the intervention would prevent the error. One may argue that the locked procedure pack should be tested by replicating routine clinical practice. However, a literature search determined that a randomised controlled trial replicating routine clinical practice to test a prevention strategy for a never event has not been previously performed. This is likely because the incidence of the never event error is so small that conducting a study replicating routine practice would require thousands of participants and cost hundreds of thousands of pounds to conduct. Replicating routine clinical practice is an impractical method of testing a safety solution for a rare error in a safe, repeatable, and inexpensive fashion. Hence, a novel methodology is required. Forced error simulation is commonly used in the high reliability industries. The simulation scenario in this study was designed from the principles developed in these industries where rare errors are replicated to analyse operator behaviour and improve or test new safety measures. As described previously, in the car industry,
the manufacturer does not perform a randomised controlled trial with a new safety intervention by driving the car for thousands of hours and waiting for a crash to occur before determining the safety of the equipment. This is unethical, unsafe, expensive, and time inefficient. Instead, the intervention is tested by repeatedly replicating the driver crashing the car, forcing the error to occur.\textsuperscript{134} In medicine, it is far more ethical and cost effective to systematically design methods to test safety interventions, where the scenarios are designed to align the latent causes of failure to make a rare event more common. This is effectively an extrapolation of Reason’s Swiss Cheese Model.\textsuperscript{111} Forced error simulation has been used in medicine in simulation training for major incidents,\textsuperscript{131} and has also been used to test clinician recognition of other never event errors.\textsuperscript{141–143}

In this study, the locked procedure pack prevented guidewire retention compared to standard practice by forcing participants to recognise guidewire retention and allowing them to take corrective action to prevent this error. This ensured CVC guidewire retention did not occur. However, whilst the locked procedure pack will improve safety, one cannot solely rely on this single intervention. Introducing a safety initiative does not remove the need to cognitively engage during the procedure but aims to minimise error and aid operators in performing their job safely. If introduced clinically, the locked pack may improve patient safety and protect clinicians from making this error. The next step in evaluating the locked procedure pack is developing a clinically usable product and determining its effectiveness.

Limitations

There are several limitations to this study. Firstly, this simulation tested the locked procedure pack using a novel methodology in medicine. When designing these scenarios, a balance must be met to ensure the error is not too obvious to the participant and equally not too challenging to discover. Whilst forcing the error to occur, it must also attempt to replicate clinical practice for the study to be realistic. This was through the careful design of the study scenario. Additionally, the scenario was rehearsed with the investigators so that all knew their roles to allow a seamless flow of the simulation whilst the clinician was participating in the study and to prevent bias by unknowingly helping the participant to, i.e., recognise the guidewire in the catheter or explain how to open the locked procedure pack. This scenario is specific and does not cover all guidewire retention scenarios because the guidewire inside the catheter lumen is not always visible during guidewire retention.
However, the study aimed to determine whether the device prevents guidewire retention and not test the error or mechanism of error occurrence.

Secondly, the simulation was not performed in a clinical environment. The unusual situation could introduce bias in the results, as clinicians may not perform the procedure replicating their usual clinical practice. An attempt to mitigate this was to ensure that the simulation was as realistic as possible and that both groups were treated similarly. Additionally, clinicians usually revert to ‘best practice’ when their clinical practice is assessed, which may have biased the results in this study. However, in this simulation study, if ‘best practice’ was demonstrated, it should have been more likely that the participant found the guidewire. One could also state that the mannequin model was unrealistic as it was adapted for CVC insertion rather than a model designed for CVC insertion with blood being pumped around the vein. In the simulation study, there was no blood in the catheter. However, this study did not require vein puncture or assess the candidate’s ability to insert a catheter; therefore, this model was deemed acceptable. Additionally, blood is not always visible in the catheter during CVC insertion; so theoretically, the guidewire in the lumen should have been easier to identify.

Thirdly, the ‘experience’ of the participant is debatable. The literature search, NRLS data and the interviews determined that inexperience is not always a causative factor in guidewire retention. For example, clinicians requiring active supervision during CVC insertion may not readily recognise guidewire retention. If these inexperienced clinicians were included in the study, this might have biased the results. However, in this study, all participants self-selected and confirmed that they were capable of independent CVC insertion during consent.

Fourthly, participants were taken as a convenience sample of clinicians of various speciality backgrounds from a single hospital. This population may not represent clinicians nationally or internationally. Since participants were not all anaesthetic or ICU clinicians, this may also have biased the results. Anaesthetic or ICU clinicians, arguably, may be more likely to recognise the error if they more commonly perform these procedures. However, all participants stated that they were capable of independent CVC insertion and whether or not these procedures are performed frequently, it is an error that clinicians be aware of.

Fifthly, at the end of the simulation, participants were asked not to discuss the simulation study with any other members of staff who could be potential participants. This was to prevent the leakage of information regarding the scenario and study outcomes. Whilst
this cannot be controlled, there was some confidence that this had not happened; as later in the day, more participants would have known to look for the error in the simulation and quickly ‘recognised’ guidewire retention, changing the results of the study, but this did not occur.

Finally, there were intellectual and financial conflicts of interest, where it is in the interest of the inventor and the author for the innovation to be successful, which might have introduced bias into the study. This was mitigated by assigning the roles of briefing the participant, asking questions during the simulation, and assistant and data collector to other investigators.

4.3.5 Conclusions

The aim was to determine whether the locked procedure pack would prevent guidewire retention at the completion of CVC insertion. The locked procedure pack was tested with forced error simulation testing, a novel clinical application of the methodology that is validated in the high reliability industries. The locked procedure pack prevented guidewire retention in all cases, whereas in the standard group, most failed to recognise guidewire retention. The adoption of this technique could not only improve patient safety but also protect clinicians from making this error. However, whilst efficacy has been tested, real world testing is required to determine effectiveness.

4.4 The WireSafe: the clinical product

Formal evaluation and testing for regulatory approvals were performed by VMI, and the device was approved for clinical use. The locked procedure pack was manufactured and distributed as a clinically usable product. The device was called the WireSafe and was made available to hospitals for clinical use during CVC insertion via two different mechanisms.

Firstly, the WireSafe containing the suture, suture holder, counter traction forceps, antimicrobial dressing, scissors, pen, drawing up needle and a 20ml syringe was provided as a standalone pack inside a sterile drape. When this sterile drape was opened (Figure 4.3, path flow A), the operator could separately open and add the rest of the equipment required for CVC insertion onto this sterile field (Figure 4.3, C). The operator could then open the CVC catheter/ guidewire pack onto the sterile field and the trolley would be ready for CVC insertion (Figure 4.3, D). Secondly, all the equipment needed for CVC insertion, including
the WireSafe, was packaged inside a single sterile pack, a CVC insertion pack (Figure 4.3, path flow B) and opened to reveal the contents (Figure 4.3, C). The CVC catheter/guidewire pack is opened onto the sterile field, and the trolley would then be ready for CVC insertion (Figure 4.3, D). In the first method, the operator must collect the individual pieces of equipment separately and arrange the trolley for CVC insertion. In the second method, all the equipment, including the gown, is contained in one convenient pack for the operator so that they only need to collect two packs of equipment: the CVC insertion pack and the CVC catheter/guidewire pack.

![WireSafe packaging diagram](image)

**Figure 4.3:** There are two methods of packaging the WireSafe, made as per the request of clinicians and hospital procurement staff. The WireSafe standalone pack is the WireSafe alone with contents packaged in a sterile drape. Where A1) is the WireSafe standalone pack that the operator collects, A2) the outer package is opened to reveal the sterile drape and A3) the sterile drape is opened to reveal the WireSafe inside the clean, sterile field. Then in C), the rest of the equipment for CVC insertion is added to the sterile field. D) the CVC catheter/guidewire pack is added onto the sterile drape, and the trolley is ready for CVC insertion. Or the WireSafe is provided inside a complete CVC insertion pack. Where B1) is the CVC insertion pack that the operator collects. B2) the outer packaging is opened to reveal the sterile gown and CVC insertion packs. B3) the gown pack is opened. The operator puts on the sterile gown and then B4) opens the sterile CVC insertion pack to reveal C) which contains all the equipment required for CVC insertion, and D) the CVC catheter/guidewire pack is added onto the sterile drape. The trolley is ready for CVC insertion.

Whilst two methods of providing the same product may seem unnecessary, both pathways benefit the user in different ways, i.e., in the first method, the user has a greater choice in selecting the different types of equipment they would prefer to use during CVC insertion. Whereas with the second method, they must use what has been made available. In
addition, both methods have different purchasing options, and both have different packaging options. To provide a good user experience for the clinician, making these choices available to the hospital before the clinical introduction was important.

After a clinically usable device was produced for use during CVC insertion, the WireSafe (locked procedure pack) was introduced into clinical practice in a single hospital, and the impact of the new safety initiative on clinicians and the clinical workflow was evaluated.

4.5 The WireSafe: a pilot study introducing the locked procedure pack into clinical practice

4.5.1 Introduction

The simulation study demonstrated that the locked procedure pack prevented guidewire retention at the completion of CVC insertion. It was also demonstrated to be intuitive, as all participants naive to the device could use the guidewire to unlock the box and access the contents. The simulation study demonstrated efficacy; however, the WireSafe must be evaluated in real world settings to determine effectiveness. With an error that occurs in 1:3,167, effectiveness can only be assessed after several thousand trials of the device in clinical practice. Whilst a large clinical trial was not possible during this thesis, the WireSafe could be evaluated by introducing the device in a single centre and assessing the impact on clinical workflow and the acceptability to staff.

In addition to guidewire retention, CVC insertion is associated with the risk of sharps injury during catheter securement and sharps disposal. A systematic review of reported sharps injury rates in the UK calculated an incidence of 12.74 per 100 beds per year. An estimated 40,000 needlestick injuries occur annually in the NHS, but this figure is likely to be higher due to under reporting. One study from the US reported that 16% (21/131) of all needlestick injuries in residents and fellows, over four years, occurred whilst they were suturing a catheter to the skin with a suture needle. Another study from the US demonstrated that during suturing, the rate of needlestick injuries when using straight suture needles (14.4 per 1000) was nearly eight times higher than when using curved sutures (1.9 per 1000). Needlestick injuries have a health burden and an estimated to cost an average
of £500,000 per year for every NHS trust.\textsuperscript{148} Health and safety legislation requires hospitals to take action to prevent sharps injuries.\textsuperscript{145}

The WireSafe is a safety engineered locked procedure pack designed to prevent CVC guidewire retention. Additionally, to improve the user experience through safety and convenience, during the design process with VMI it was decided to provide a curved suture, suture holder and counter traction forceps inside the device to enable safe suturing practice and reduce the risk of sharps injuries. Scissors were provided so the clinician could use these to cut the suture material rather than the bloody blade previously used to make the skin incision. Whilst operators can choose their preferred method of suturing, having the correct equipment ‘to hand’ is likely to encourage the use of non-touch safer suturing practices as recommended by the Royal College of Surgeons of England.\textsuperscript{149} If clinicians are provided with the safest equipment, they will perform the procedure in the safest manner. Additionally, a biohazard label was placed inside the base of the box. This was to demonstrate that during equipment clear up, the sharps used during the CVC insertion could be placed inside the box, and when the lid is closed, the magnet seals the sharps inside the box. The sharps and guidewire can be safely transported to the sharps bin in a closed container. The guidewire can be removed, the contents dropped into the sharps bin, or the whole device can be dropped into the sharps bin.

During CVC insertion, when the WireSafe is used, the initial steps in the procedure are unchanged (Figure 4.4). However, an additional step is introduced into the CVC procedure after the catheter is placed over the guidewire, and the guidewire is usually removed. Here, the clinician removes the guidewire from the patient and inserts it into the channel of the WireSafe. The contents of the WireSafe are then used to complete CVC insertion: to suture, flush and dress the CVC and act as a container for safe sharps disposal.

The forced error simulation study using the WireSafe demonstrated its efficacy in preventing guidewire retention.\textsuperscript{97} Next, the clinician acceptability of the WireSafe and any impact of the WireSafe on the CVC procedure in a real world clinical setting would need to be evaluated. In this pilot study, the WireSafe was introduced into a single hospital, in the ICU and operating theatre environments.
Figure 4.4: A flow diagram detailing the steps of the CVC procedure, either during standard practice or when using the WireSafe. When the WireSafe is used, an additional step is introduced to the procedure where the guidewire is inserted into the WireSafe, and the lid is opened to access the equipment. During standard practice, the sharps are transferred and disposed of in the sharps bin. In the WireSafe group, sharps are placed inside the WireSafe, and the lid is closed. The guidewire and sharps are sealed inside the WireSafe for transfer to the sharps bin. Sharps and guidewire can be emptied into the sharps bin, or the WireSafe can be disposed of in the sharps bin.

The primary aim of this study was to assess the impact of the WireSafe on CVC insertion in terms of procedure duration and sharps safety. A literature review determined that no information was available regarding the time to insert a CVC in the clinical setting, therefore a power calculation to determine sample size could not be performed. Hence, this pilot study was performed to determine both the duration of CVC insertion using standard practice and the impact of the WireSafe.
The secondary aim was to evaluate the acceptability and perceived safety benefits of the WireSafe to clinicians in terms of sharps safety and guidewire retention with a structured survey one year following implementation.

4.5.2 Methods

The institutional research and development review board and clinical governance committee approved the pilot study conducted at the Queen Elizabeth Hospital, King’s Lynn.

Introduction to clinical practice

The study centre procured the WireSafe for introduction into clinical practice. The ICU and anaesthetic personnel were consulted in departmental meetings and via email that the WireSafe would be introduced into clinical practice, and any questions or concerns were discussed. Key clinicians: the anaesthetists, supporting staff, practice development nurses, and ODP educational practitioners were trained to use the WireSafe. Training with staff to demonstrate how to open the WireSafe took approximately one minute each, and the educational practitioners were instructed to cascade this training to their team members. This ensured the nurses and ODPs could support clinicians using the WireSafe during CVC insertion if required. The WireSafe contained instructions printed on the underside to pictorially demonstrate how to use the device. During the initial implementation period, an investigator was available by telephone to ‘troubleshoot’ any issues regarding the equipment or technique. All staff were made aware that this support was available.

Study design

A single centre clinical observational pilot time and motion study comparing CVC insertion using the WireSafe and standard practice.

Recruitment and participants

Participants were clinicians inserting CVCs during their routine clinical practice and were chosen as a convenience sample. Observations were taken over two months. The group selection was not randomised and depended upon participating clinicians’ and observers’
availability and the availability of either the standard or WireSafe packs. All participants in
the clinical observational study provided written and signed consent to participate.

For the structured interviews, a convenience sample of 20 anaesthetists and ICU
consultants experienced in using the WireSafe volunteered to be interviewed.

**Eligibility criteria**

**Observation study**

**Inclusion criteria**

- Clinicians capable of independent CVC insertion
- CVC insertions performed in operating theatres, ICU, or emergency
department environments
- Single line insertions only

**Exclusion criteria**

- Clinicians being actively trained to perform CVC insertion by supervisors
- Clinicians with knowledge of the study aims
- Clinicians who became aware of which aspect of the CVC insertions were
  being observed and/or timed during the observations

**Structured interview**

**Inclusion criteria**

- Anaesthetic and ICU clinicians who have used the WireSafe in their
  clinical practice

**Exclusion criteria**

- Anaesthetic and ICU clinicians who have not used the WireSafe in their
  clinical practice

**Participant information**

Participants were informed that their CVC insertion technique was being observed.
However, to prevent a change in their behaviour and bias of the results, they were unaware
of which specific observations of the CVC insertion were being taken. They were unaware that they were being timed or that their practice of sharps disposal was being observed.

**Control and intervention groups**

In both groups, the initial steps of CVC insertion up to guidewire removal were the same (Figure 4.4). In the standard group, clinicians would have the equipment required to complete the procedure (suture pack, suture, and dressings) immediately available separately on the trolley. In the WireSafe group, this equipment was located inside the locked device and could only be accessed by using the removed guidewire to unlock the box.

**Observations**

Standardised observations were performed by three designated investigators who observed CVC insertions using both standard and WireSafe techniques. Timings were performed surreptitiously using the investigator's watch, phones, or the anaesthetic room clock. Data points recorded (Appendix 4.3) for both groups were in stages and defined as (i) the total procedure time. This was needle to skin to sharps disposal, that is: (1) the needle to skin to guidewire removal, (2) guidewire removal to catheter secured, (3) catheter secured to label dated, (4) label dated to sharps disposal. (ii) In the standard and WireSafe groups, the time from guidewire removal to sharps disposal which included stitching the CVC to the skin, dressing application and sharps disposal, was calculated. (iii) The method of sharps disposal used was recorded. The information gathered by the observers was transferred to a Microsoft Excel file (Microsoft Excel for Mac, Microsoft, Redmond, Washington).

Safe sharps behaviour was defined as either the sharps bin brought to the procedure and utilised at the bedside or sharps transferred to the bin after the procedure in an open tray, container or wheeled on the procedure trolley. In the WireSafe group, the transfer of sharps to the bin inside the closed WireSafe container was also defined as a safe option. Unsafe behaviour was defined as the transfer of sharps to the bin in the clinician’s hands, sharps thrown any distance into the sharps bin, or sharps left to be cleared away by an assistant, which is counter to institutional policy.
Structured Interview

One year after the introduction of the WireSafe, a structured survey (Appendix 4.4) of 20 clinicians who had used the WireSafe technique was undertaken by two investigators. Clinicians were asked standardised questions on (1) the approximate number of WireSafe CVC procedures they had completed, (2) the type of clinical scenarios in which they had utilised the WireSafe, (3) any problems they encountered using the WireSafe, (4) whether the WireSafe was easier, the same or harder to use compared to standard equipment, (5) whether or not they thought the WireSafe reduced the risk of a guidewire retention, (6) whether the WireSafe was more convenient, the same or less convenient for sharps and guidewire disposal compared to using standard equipment, (7) whether or not they approved of the WireSafe device for central line insertion and (8) whether or not they would support the ongoing use of the WireSafe for its safety and convenience benefits. Participants were also given white space areas to comment on any general likes or dislikes of the new technique and equipment. Free text comments were analysed using inductive thematic analysis. Coding was performed through the iterative reading of the free text comments, and codes were analysed by hand and tabulated in Microsoft Word (Microsoft Word for Mac, Microsoft, Redmond, Washington).

Outcomes

The primary outcome of this study was to assess the impact of using the WireSafe on the CVC insertion procedure in terms of the duration of the procedure and sharps safety. The secondary outcome was the evaluation of the acceptability of the WireSafe in terms of perceived safety benefits of sharps safety and guidewire retention.

Statistical analysis

Given that the literature review determined that no information was available regarding the time to insert a CVC in the clinical setting, the number of observations required to adequately power this study and perform the statistical analysis was unknown. After observations were conducted, the following calculations were performed:
Total procedure time

a. an analysis to determine non-inferiority, to demonstrate that using the WireSafe has no demonstrable negative impact on the total procedure time

b. an analysis to determine the superiority of the WireSafe for the total procedure time where continuous variables (time) were expressed as mean plus standard deviation and compared using an unpaired t-test

Time that the WireSafe impacts the clinical procedure ‘guidewire out to sharps disposal’

c. an analysis to determine superiority for the time that the WireSafe impacts on the procedure, continuous variables (time) were expressed as mean plus standard deviation and compared using an unpaired t-test

Sharps safety

For the method of sharps disposal, the categorical variables were expressed in exact numbers and proportions in a two × two contingency table and compared using a Fisher’s exact test (graphpad.com). An alpha value of < 0.05 was taken as significant.

4.5.3 Results

Fifteen procedures were observed using standard practice, and 16 using the WireSafe technique.

Total procedure time

a. A non-inferiority statistical analysis was performed to demonstrate whether using the WireSafe had any demonstrable impact on the clinical procedure. The range of the data for the total procedure time in the standard group was between 5mins-33mins and the mean 16mins. A non-inferiority margin of 10% (1.6min) was assumed, whereby if the total procedure time when using the WireSafe was within this margin, it can be concluded that there was no demonstrable difference between the WireSafe and standard practice. This analysis was independently calculated by a statistician and found that the total procedural time for the WireSafe is non-inferior to standard practice at the 10% margin, p = 0.044 (Appendix 4.5).

b. In the WireSafe group, the mean ± standard deviation (SD) total procedure duration was 14.2min ± 2min. In the standard group, the mean ± SD duration of the procedure was
16min ± 7min (Figure 4.5). There was no statistically significant difference in
the duration between the groups (p = 0.17).

**Time that the WireSafe impacts the clinical procedure ‘guidewire out to sharps disposal’**

c. When the WireSafe was used the time that the WireSafe impacts the procedure, from
guidewire removal to sharps disposal, was significantly shorter in the WireSafe group
compared to the standard group (8.7min ± 1.4min vs 11.4min ± 5.6min respectively, p
= 0.035, Figure 4.5).

![Figure 4.5: Box and Whisker graphs. A) Illustrating the total time to complete CVC insertion comparing standard practice against the WireSafe. Using the WireSafe reduced the overall procedure time (16min ± 7min standard group vs 14min ± 2min WireSafe, p = 0.17, unpaired t-test). B) Illustrating the time taken from guidewire removal to sharps disposal, the part of the procedure that the WireSafe impacts, comparing standard practice against the WireSafe. Using the WireSafe reduced the time taken from guidewire removal to sharps disposal (11.4min ± 5.6min standard group vs 8.7min ± 1.4min WireSafe, p = 0.035, unpaired t-test).](image)

**Sharps safety**

In the WireSafe cohort, all 16 (100%) clinicians demonstrated an appropriate and
safe sharps disposal technique. In the standard group, seven (47%) clinicians demonstrated
an appropriate and safe sharps disposal technique, while eight (53%) did not. A statistically
significant difference was found between sharps disposal when using the WireSafe
compared with standard groups, p = 0.0008. In the standard group, out of the eight
procedures where sharps disposal was not deemed safe, four participants transferred sharps
to the sharps bin across the room using their hands. The remaining four left sharps behind them after completion of the procedure for an assistant to clear up.

Structured interviews

One year following the introduction of the WireSafe, over 600 devices were used for CVC insertion at the study site, and there were no incidents of guidewire retention. The structured interview surveys were conducted with ten anaesthetists and ten ICU doctors of varying seniority from junior doctor to consultant. All interview participants stated that they had used the WireSafe in their clinical practice. Between them, a total of approximately 225 WireSafe packs had been used during CVC insertion. The WireSafe had been used during CVC insertion in various clinical situations, including unconscious patients, awake patients, and awake agitated patients. None of the clinicians reported any equipment related problems whilst using the device. Half (10/20) of the clinicians surveyed felt that the WireSafe had made the CVC insertion easier, and the other half reported no difference compared to standard practice. None felt that the WireSafe made the process harder, and all felt that the risk of guidewire retention was reduced by using the WireSafe. Most participants (16/20) stated that using the WireSafe was more convenient for sharps disposal at the end of the procedure, and the remaining four clinicians found no difference compared to standard practice. All 20 participants said they approved of the WireSafe for CVC insertion and would continue supporting its use for safety and convenience benefits.

Interview participants’ free comments were analysed using inductive thematic analysis. Emerging themes were categorised as staff perceptions of safety when using the WireSafe, ease of use, opinions and perceptions of sharps safety when using the device, and criticisms or negative aspects of using the WireSafe (Table 4.1).

Most comments were positive and rated the safety aspect of the WireSafe both in terms of preventing guidewire retention and improved sharps safety. Many comments described that the WireSafe was easy to use and user friendly, once they were familiar with the device. This was described as similar to their experience with other changes of practice. The ready availability of the equipment inside the device was perceived as a benefit over the standard practice. Some commented that they would not use the device if the speed of CVC insertion was critical, as it may slow down the procedure. Some commented that the increased use of plastic was problematic, and in the contradictory view, others thought the look of the plastic was cheap.
Of note, a perceived benefit of the WireSafe that was repeatedly described in the interviews (12/20) was that staff liked that the device could be moved from the procedure trolley and placed next to the surgical site, i.e., next to the patient on the drapes. This meant that clinicians were not required to repeatedly twist their torso between the patient and the trolley to access equipment and temporarily store sharps. This process was also observed by the three investigators when study participants were using the WireSafe. Observers also reported no equipment related problems whilst using the WireSafe during CVC insertion.

Table 4.1: Clinicians’ free text comments on their opinions of using the WireSafe coded by themes arising from the qualitative analysis.

<table>
<thead>
<tr>
<th>Clinician’s comments on their opinion of using the WireSafe</th>
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<tbody>
<tr>
<td><strong>Safety</strong></td>
</tr>
<tr>
<td>“Having used the WireSafe, I would now be concerned about it not being available for the trainee doctors on our unit.”</td>
</tr>
<tr>
<td>“Gives me confidence in stressful situations, emergencies and out of hours that I will not be able to make this mistake.”</td>
</tr>
<tr>
<td>“It’s safer - ensures you have taken the guidewire out.”</td>
</tr>
<tr>
<td>“Improves the procedure - reassurance that the guidewire has been removed, an improvement on the WHO check.”</td>
</tr>
<tr>
<td>“Using the WireSafe is good practice - and good for sharps/ guidewire disposal.”</td>
</tr>
<tr>
<td>“There is no additional risk when using the WireSafe.”</td>
</tr>
<tr>
<td>“I have left a guidewire in as a trainee, so I like it.”</td>
</tr>
<tr>
<td>“Pretty good to stop the guidewire being left in.”</td>
</tr>
<tr>
<td>“The WireSafe makes sure you remove the guidewire from the patient; this is important in the heat of the moment when people can forget or if there is a distraction, and we know that other solutions don’t always work.”</td>
</tr>
<tr>
<td>“I like that it stops you from leaving the guidewire.”</td>
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<tr>
<td><strong>Equipment</strong></td>
</tr>
<tr>
<td>“Like the WireSafe packs it is good in that everything is in one place.”</td>
</tr>
<tr>
<td>“Like that everything is in one place.”</td>
</tr>
<tr>
<td>“I like the readiness of the availability of the equipment.”</td>
</tr>
<tr>
<td>“Like the pen - very useful being sterile.”</td>
</tr>
</tbody>
</table>
Ease of use

“I like that everything is in the right place and so it's all to hand, especially if you are getting it all [the equipment] yourself, you are more likely to forget something.”

“Using the WireSafe is safer than not having it.”

“I place the WireSafe on the drapes near the patient and then all of my equipment is conveniently located for me to work – I really like it.”

“100% easier to use the WireSafe than not use it.”

"There was a lack of familiarity when first starting to use the WireSafe, because I have been trained to insert central lines without it. Same as with using USS for the first time, there was a lack of familiarity with it, but after learning how to use it was fine.”

“It is user friendly once familiar.”

“The WireSafe takes split seconds to open it.”

“Once I learnt that if you put a finger over the magnet when putting the wire in, then it's really easy.”

“With every new piece of equipment, it was a learning curve and it's just a matter of getting used to it, didn't know how to use it and initially struggled but after doing one or two it wasn't a problem and technically it is not difficult considering the CVC procedure.”

“It takes getting used to when first using.”

“A new piece of kit always takes some getting used to, change is always difficult and much of the time with equipment, it is about the way it feels in your hands. I've seen other people struggle with the threading the guidewire at first, and it's about getting used to it, but this is not insurmountable as you have to have a lot of dexterity to place a central line, so this is nothing.”

Sharps

“Easier and safer to use, I have had two needlestick injuries during suturing, during a central line and arterial line procedure, before the WireSafe was introduced.”

“Like the forceps and counter traction.”

“I rate the principle of safety, easy to clear up sharps, useful to have needle holders for suturing as don't normally get this, pen is helpful.”

“Using the WireSafe is good practice - and good for sharps / guidewire disposal.”
"Like - the organization of everything in one place and easy to get rid of sharps."
"I like the bedside sharps clear up."
"I like the needle holder for suturing."

**Criticisms / negative aspects**

"I dislike the magnet in the middle."
"It can be a bit wasteful to have so much disposable equipment."
"The quality of the plastic box looks a bit cheap."
"It’s not entirely foolproof and can slow down process."
"If I am in a hurry, I would not use it."
"More plastic waste."
"I don't like that the 20ml syringe is inside the box but is necessary. Better if the dressing was bigger."

### 4.5.4 Discussion

The WireSafe was designed to prevent guidewire retention and improve the user experience of CVC insertion through safety and convenience by providing the correct equipment for safer suturing practices and a receptacle for safe sharps and guidewire disposal. Introducing the WireSafe adds a step to the CVC procedure (Figure 4.4). After the guidewire is removed, it must be placed inside the channel of the WireSafe, and the lid of the device lifted to access the contents and complete the procedure. During the first user interaction and structured survey with a prototype of the WireSafe (Chapter three), some commented that the device might make the CVC procedure longer, which may be problematic during emergency or difficult procedures.

This pilot study was designed first to assess whether the introduction of the WireSafe had any demonstrable impact on the CVC insertion in terms of procedure duration and sharps safety. Secondly, to ascertain the acceptability and perceived safety benefits of the WireSafe, staff members were surveyed via a structured questionnaire one year after the device's introduction.

This data demonstrated no statistically significant difference in the total time of the CVC procedure between the standard practice group and the WireSafe group. Thus, the additional step in the CVC procedure with the WireSafe does not negatively impact the duration of the procedure. In fact, when the non-inferiority analysis was conducted, no
demonstrable difference between the WireSafe and standard practice (p = 0.044, 10% margin) was seen. In terms of rare errors, one does not want a change to adversely affect the procedure otherwise there is a risk of increasing the rate of this or other errors, showing no demonstrable difference is an argument for wider implementation. Whilst superiority in terms of total procedure time may be helpful for implementation, in terms of the safety of introducing a novel device into clinical practice, non-inferiority is more important to evaluate. By demonstrating non-inferiority, it was clear that the WireSafe has no statistically significant impact on the clinical procedure time.

Interestingly, the part of the procedure directly impacted by the introduction of the device, that is, guidewire removal to sharps disposal, was significantly faster in the WireSafe group (8.7 min ± 1.4 min vs 11.4 min ± 5.6 min, p = 0.035). This result was unexpected, but important to note, and may warrant further investigation. A possible reason for this was that participants placed the WireSafe next to the patient on the sterile drapes rather than on the procedure trolley during catheter securement. This provided ready access to the equipment rather than the need to repeatedly twist their torso to access equipment and temporarily store sharps. This improvement in the ergonomic movement for the clinician is interesting and perhaps should be investigated further. Ergonomic workflow improvements are known to increase productivity and reduce the costs associated with musculoskeletal disorders and guidance from the medicines and healthcare products regulatory agency details that medical devices should be developed with ergonomic principles in mind. Moving the WireSafe from the trolley to the surgical field may be helpful to inform new users during training. This study was undertaken during the first clinical introduction of the WireSafe and no demonstrable impact was seen on the total procedure time. The time taken to perform the part of the procedure impacted by the WireSafe was significantly shorter. It is possible, with time and clinician familiarity with the device, that the time to perform the total CVC insertion could also be shorter.

NHS Employers reported that of the needlestick injuries which occurred during clinical procedures, 35% occurred after the procedure during the clearing up and disposal of sharps. Nationally, in both the US and the UK, there are substantial cost implications of needlestick injuries which could be avoided by adopting safer sharps practice. In this study, there was a significant improvement in safe sharps disposal practices among participants when using the WireSafe. The WireSafe provides a specific receptacle on the trolley for sharps disposal. In all procedures observed with the WireSafe, clinicians placed
their used sharps inside the WireSafe, closed the lid to seal the contents, and transferred the sharps to the bin in the closed container during equipment clear up. As sharps were transferred inside the sealed container, this was deemed safe practice in the study. Whilst transferring sharps to the bin in an open tray/container or on the procedure trolley in the standard practice group was defined as safe practice, transferring sharps in a closed container with the WireSafe represented an improvement in safe practice. This pilot study demonstrates that CVC insertion using the WireSafe may improve sharps safety

In the structured survey one year post introduction, the views expressed were positive or neutral. All interviewees felt that the device reduced the risk of guidewire retention, and 80% felt that the device was more convenient for safe sharps disposal at the end of the procedure. Qualitative analysis of free text comments was encouraging and determined that the WireSafe has wide acceptance amongst staff. Many rated the safety aspect of the device, preventing retained guidewires, the ease of use and convenience when using the WireSafe for CVC insertion. However, it was helpful to understand that clinicians required more practice with the device before they felt familiar and comfortable using it. This is true of all new devices or changes of practice. If this device were to be introduced into another hospital, repeated training sessions providing clinicians with the opportunity to practice with the WireSafe before using it in clinical practice may be the best method of supporting clinicians during their first interactions with the device. The criticisms of the device were helpful feedback to pass onto VMI to be considered during further development of the WireSafe. The comment regarding the magnet in the centre of the box, discussed in Chapter three, was at the time was felt to be one of the compromises made during device manufacture. Interestingly, clinicians had also independently developed a workaround for this problem: to place a finger over the magnet to prevent the guidewire from being pushed off course during insertion into the channel. Again, this ‘tip’ is also helpful to inform new users of the device and during training and introduction into other hospitals.

In this study, one year following the introduction of the WireSafe, over 600 devices were used for CVC insertion with no incidents of guidewire retention. With an incidence of 1:3,167, a randomised controlled trial to determine whether guidewire retention could be prevented when using the WireSafe in the real world setting would be very difficult to perform. However, using this incidence, one could statistically work out how many trials of the WireSafe would be required to say with high confidence that the intervention would prevent the error. A statistician independently calculated this probability calculation
(Appendix 4.5) and determined that 9,486 trials of the WireSafe with no incidents of guidewire retention would be required to say with statistical significance ($p = 0.05$) that using the WireSafe prevents guidewire retention. From the time this calculation was performed (2019) up to the point of writing this thesis, 4,000 devices have been used at this study site with no incidents of guidewire retention. Therefore, a further 5,486 more trials or five and a half years of WireSafe use (if uptake is at the current rate) in this study site alone would be required to obtain a statistically significant result.

In this study, none of the clinicians reported any equipment related problems whilst using the device in the structured survey, and none were seen during the observations. This is important as one does not want to affect the procedure clinical procedure adversely and inadvertently introduce more or different errors by using the WireSafe. In addition, there were no instances of staff refusing to use the WireSafe once it was introduced into their clinical area, or vice versa, of staff insisting on using the device. In this clinical introduction of the device, the WireSafe was acceptable to clinicians regarding safety and convenience. No demonstrable impact on clinical CVC procedure was found, however, larger and broader introduction studies are still required to determine the effectiveness of the intervention and any unknown impacts of using the device.

**Limitations**

There are several limitations to this study. Firstly, it is a single centre study from a small hospital. Observations were of single line insertions in the operating theatres or in the ICU; consequently, the data may not be generalisable to, for example, other hospitals, cardiac centres, lines inserted in A+E, or double line insertions.

The number of observations were small; however, this was dependent on the willingness of clinicians to participate in the study and the availability of the three observers, who were anaesthetic trainees working at the study site during the study period and the availability of either standard or WireSafe equipment.

Secondly, a literature review determined that no information was available regarding the time to insert a CVC in the clinical setting. Hence, this pilot study was performed to determine both the duration of CVC insertion using standard practice and the impact of the WireSafe. Non-inferiority of the WireSafe compared to standard practice in terms of total procedure time was demonstrated, the small sample size resulted in a study that was underpowered to assess superiority of the device in terms of total procedure duration,
compared with standard practice. However, the data generated from this pilot study could be utilised to perform a power calculation to determine the sample size required for future studies: a statistician independently calculated this power calculation (Appendix 4.5) and determined that at least 43 observations in each group would be required to conduct an appropriately powered study to determine whether there would be a statistically superior difference in procedural time. Whilst the time from guidewire removal to sharps disposal was significantly less when using the WireSafe, this finding was fortunate. Ideally, the total duration of CVC insertion from needle to skin to sharps disposal would be of most clinical interest but would require a larger sample size.

Thirdly, the study was conducted whilst the WireSafe was being introduced across our hospital, where clinicians had ready access to both the WireSafe and standard equipment. It was felt that given the introduction period, when clinicians were familiarising themselves with a new device during their clinical practice, randomisation was not appropriate or in the best interests of the staff or patients.

Fourthly, the study was not blinded. Participants were aware that they were being observed for research purposes, which could lead to bias in participant performance. To limit this, they were not informed which aspect of the procedure was being observed or that they were being timed. Observational timings were by hand utilising a phone, watch or clock. In this case, timings will not be as accurate as seen in studies when purpose designed data collection devices are used.153,154 Whilst these devices would have been helpful to utilise in this study, they were unavailable due to lack of funds. However, it was felt that split second timings were not required for this pilot study. Further studies exploring CVC insertion duration should utilise these data collection devices for more accurate results. Before commencing this pilot study, interobserver reliability was also not assessed, and this would need to be performed if a more extensive study were to be conducted.

Fifthly, the study was performed in the same centre where the WireSafe was developed. Therefore, this may have biased the results in several ways: participants may have had prior knowledge of the device or have been participants in the simulation study. Whilst it was acknowledged that this would be the case, for the introduction of the WireSafe, clinician familiarity with the device during the introduction period was necessary to perform clinical CVC insertions safely. Additionally, given that the device was developed at the study site, there may be more willingness to try a new practice or think positively about a
change, which may have influenced the survey results. However, this was the only study site available to perform the pilot study, so this potential bias could not be avoided.

Finally, given that the inventor and author were involved in the study, the potential for bias exists. To mitigate for this, the data collection for the observations and structured survey were performed independently of inventor and author.

4.5.5 Conclusions

This pilot study was designed first to assess whether the introduction of the WireSafe affected the duration of the CVC insertion and investigate its impact on sharps safety and, secondly, to ascertain staff acceptability and perceived safety benefits of the WireSafe. This pilot study demonstrates that CVC insertion using the WireSafe device may improve sharps safety and had no demonstrable negatives compared to the current standard of practice regarding procedure duration and staff acceptance. However, further evaluation in terms of the duration of CVC insertion with the WireSafe, usability and staff acceptability should be performed.

4.6 A bedside rescue method for retrieving retained guidewires: the ‘Suck Out’ technique

4.6.1 Introduction

The forced error simulation study using the WireSafe demonstrated efficacy in preventing guidewire retention. The clinical introduction study, evaluating the use of the WireSafe during CVC insertion, demonstrated an improvement in sharps safety, with no negative impact compared with standard practice on procedure duration and staff acceptance. Additionally, 100% of staff interviewed felt that the device reduced the risk of guidewire retention.

However, a problem with the WireSafe is that the clinical procedure up to the ‘critical point’ has not been changed. Therefore, it is still technically possible for the guidewire to be over inserted and retained at any point in the procedure when it is used up to the ‘critical point’. Whilst the WireSafe would alert the operator to the error immediately, the possibility of the error remains. However, as the operator is forced into early recognition
of the error when using the WireSafe, correction could be quickly undertaken during the clinical procedure at the bedside.

The NRLS data demonstrated that most retained guidewires (64%, 115/179) were located within the catheter on recognition of guidewire retention, even at the time of the first check radiograph, on subsequent procedures involving manipulating the catheter and on catheter removal.\textsuperscript{137} Cases in the literature demonstrate that the guidewire can remain within the catheter lumen, and migrates into the vein over a period of time, which can take hours or days to occur or even remain within the catheter lumen throughout the lifetime of the CVC and discovered on removal.\textsuperscript{4,14,86} If guidewire retention has occurred, the WireSafe forces early recognition of the error immediately after the ‘critical point’ in the procedure at a point when it is highly likely that migration of the guidewire would not have occurred and would remain in the catheter. At this point, the guidewire should be easily retrievable.

Currently, when guidewire retention occurs, the position of the guidewire inside the catheter lumen is not always apparent, particularly if it has passed below the skin level. With the delay and patient manipulation required to obtain a radiograph, further migration of the guidewire into the vasculature may occur, preventing the use of bedside techniques. Whilst successful and unsuccessful methods are reported in the literature, once guidewire retention is recognised or discovered on the radiograph, there is no guidance on the best technique to rescue the guidewire promptly.

Methods of guidewire retrieval and success rates were described in the NRLS data, and most were successfully retrieved by invasive techniques either through interventional radiology or surgery.\textsuperscript{137} Common bedside guidewire retrieval techniques reported in the NRLS data and the literature were catheter clamping and withdrawal or simply pulling the catheter back.\textsuperscript{4,137} These bedside techniques are only suitable if the guidewire has not migrated through the catheter beyond the skin level. Invasive techniques are required if beside techniques fail or the guidewire has migrated beyond the catheter. Whilst interventional radiology may be convenient in tertiary centres, this may be difficult in smaller hospitals or out of hours without immediate availability of specialist clinicians or interventional radiology suites, requiring patient transfer to an appropriate tertiary centre with all the costs this may incur and potential harm to the patient. Therefore, simpler, and immediate bedside solutions for quick guidewire retrieval are needed.

Two cases in the NRLS database described a suction technique attempting to aspirate the guidewire distally towards the catheter hub, where one was successful and one was
This technique for retrieving retained CVC guidewires has not been previously described in the literature. It was thought that suction applied to the distal end of the catheter and withdrawal might be a novel mechanism of removing a retained guidewire if it remains within the catheter lumen and even if the distal end (straight end) has passed beyond the level of the skin. This retrieval technique may be helpful when using the WireSafe, and retention is immediately recognised. Additionally, a novel bedside technique for guidewire retrieval when it has migrated beyond the skin level may be helpful for clinicians even if they are not using the WireSafe and retention is recognised.

This study investigated a range of bedside techniques for guidewire retrieval using simulated models. First, a benchtop study was performed to test the feasibility of applying suction to facilitate guidewire retraction. Then a pigskin model was used to compare a novel suction, ‘suck out’, method of guidewire retrieval against traditional removal techniques.

This study aimed to determine the best technique for bedside guidewire retrieval when the straight portion of the guidewire was retained within the catheter lumen either above or below the skin level.

4.6.2 Methods

The Institutional Research and Development Committee approved the simulation study conducted at the Queen Elizabeth Hospital, King’s Lynn, United Kingdom.

Study design

Simulation study one: A randomised benchtop simulation feasibility study assessing intraluminal guidewire retraction with CVCs of varying designs.

Simulation study two: A simulation study comparing a novel suction technique to standard practice.

Eligibility criteria

Simulation one:

Inclusion criteria:

- CVCs available for clinical use at the Queen Elizabeth Hospital Kings Lynn
- CVCs included: CVCs, vascaths and percutaneous sheath introducers
Exclusion criteria:

- Non-CVCs

Simulation study two:

Inclusion criteria:

- Bedside guidewire retrieval techniques: simple withdrawal, clamping and withdrawal and the suction ‘suck out’ technique

Exclusion criteria:

- None

**Randomisation**

Simulation study one: Using closed envelope randomisation, the CVCs were tested ten times in a benchtop model in a randomised order.

Simulation study two: Non-randomised sequential testing of three guidewire retrieval techniques.

**Simulation study one: Intra-luminal guidewire retraction using suction**

In this feasibility study, seven CVCs with varying designs were each tested ten times in a benchtop model (Figure 4.6) in a randomised order. CVCs tested were: Vygon multicath4expert CVC, 32cm (Vygon, Aachen, Germany), Kimal ALTIUSTM PRO HP CVC, 26cm (Kimal Plc, Middlesex, England), Arrow® CVC, 30cm (Teleflex Medical, Athione, Ireland), Vygon DUALYSE Expert Vascat, 32cm (Vygon, Aachen, Germany), Gambro GamCath Vascat, 26cm (Gambro®, Hechingen, Germany), Arrow® Percutaneous Sheath Introducer, 14cm (Teleflex Medical, Athione, Ireland) and Edwards Intro-Flex Percutaneous Sheath Introducer, 14cm (Edwards Lifesciences, Irvine, USA). Each CVC had its corresponding guidewire placed within the catheter lumen, where the distal portion (straight end) of the guidewire was positioned at 2cm above the catheter tip, simulating a nearly fully migrated guidewire. The pre-flushed catheter was submerged in a long tray of gelofusine (B. Braun, Melsungen, Germany), ensuring a free lying wire and the catheter was positioned in a quarter circle curved conformation to replicate the anatomical position as feasibly possible. A 50mL syringe (Terumo®, Luven, Belgium) was attached to the distal lumen catheter hub, and suction was applied by rapidly pulling back the plunger.
continuously for five seconds. The distance of guidewire retraction was determined by measuring the residual guidewire remaining in the gelofusine tray.

![Diagram](image)

**Figure 4.6:** A schematic diagram illustrating the benchtop model utilised for simulation one. Each CVC was submerged in gelofusin (B. Braun, Melsungen, Germany). The distal portion (straight end) of the guidewire was placed 2cm above the catheter tip, simulating a nearly fully migrated guidewire. A 50mL syringe (Terumo®, Luven, Belgium) was attached to the distal lumen catheter hub, and suction was applied by rapidly pulling back the plunger continuously for five seconds.

**Simulation study two: A new suction technique for guidewire removal**

A distal lumen syringe suction technique was tested in a pigskin model to indicate efficacy. A 10cm x 5cm x 2cm (depth) piece of pigskin and subcutaneous tissue was cannulated at 45 degrees using the Seldinger technique, and the CVC (Arrow CVC, Teleflex Medical, Athione, Ireland) was placed at a depth of 15cm in the skin. The corresponding J-tipped CVC guidewire (Arrow CVC guidewire, Teleflex Medical, Athione, Ireland) was intentionally retained within the catheter. The straight end (distal portion) was either 5cm above or below the skin level. The pigskin, catheter and guidewire were placed in a water trough with a 100g weighted sponge (Vygon, Ecouen, France) applied to the guidewire to simulate resistance to longitudinal movement in the vasculature (Figure 4.7).
Figure 4.7: A schematic diagram illustrating the pigskin model utilised for simulation two. A pigskin and the subcutaneous tissue were cannulated at 45 degrees, and the CVC (Arrow CVC Teleflex Medical, Athione, Ireland) was placed at a depth of 15cm in the skin. The corresponding J-tipped CVC guidewire (Arrow CVC guidewire, Teleflex Medical, Athione, Ireland) was intentionally retained within the catheter. The straight end (distal portion) was either 5cm above or below the skin level. The pigskin, catheter and guidewire were placed in a water trough with a 100g weighted sponge (Vygon, Ecouen, France) applied to the guidewire to simulate resistance to longitudinal movement in the vasculature. Suction was applied with a 50ml syringe (Terumo®, Leuven, Belgium).

This model was calibrated by three clinicians familiar with CVC insertion, who manipulated the model to ensure a realistic feel of the resistance usually experienced clinically. Three techniques were assessed to test guidewire retrieval: simple catheter removal by pulling back the catheter, clamping the catheter at skin level, and withdrawing the catheter and the ‘suck out’ technique. All three techniques were tested ten times with the guidewire retained at 5cm above the skin level and ten times with the guidewire retained at 5cm below the skin level. This resulted in 60 trials performed under identical conditions.

The ‘suck out’ method of guidewire retrieval

The ‘suck out’ technique involved attaching a 50mL syringe (Terumo®, Leuven, Belgium) to the distal lumen of the catheter and strong suction was continuously applied by retracting the plunger fully whilst simultaneously withdrawing the catheter. After informal testing with a 10mL and 20mL syringe, a 50-mL syringe was identified as the most optimal solution.

Primary Outcome

Simulation study one: The primary outcome was guidewire retraction distance.

Simulation study two: The primary outcome was the successful retrieval of the guidewire.
Statistical Analysis

For simulation study two, with a power of 0.9 for a statistical significance of 0.05 and to detect a 60% absolute difference in proportions, ten determinations were required in each group. A two-tailed Fisher’s Exact test was used to analyse the data comparing the suction technique with the standard clamping technique. Analysis was performed using Microsoft Excel (Microsoft Excel for Mac, Microsoft, Redmond, Washington).

4.6.3 Results

Simulation study one: Intra-luminal guidewire retraction with suction

Upon applying maximal suction with a syringe to the catheter, all guidewires retracted and moved distally towards the catheter hub.

![Figure 4.8: Average guidewire retraction distance (cm) using the suction technique with different types of CVCs (mean, 2SD). Where guidewires tested from left to right were, Vygon multicath4expert CVC (Vygon, Aachen, Germany), Kimal ALTIUSTM PRO HP CVC (Kimal Plc, Middlesex, England), Arrow CVC (Teleflex Medical, Athione, Ireland), Vygon DUALYSE Expert Vascath (Vygon, Aachen, Germany), Gambro GamCath Vascath (Gambro, Hechingen, Germany), Arrow percutaneous sheath introducer (Arrow, Teleflex Medical, Athione, Ireland) and Edwards Intro-Flex Percutaneous Sheath introducer (Edwards Lifesciences, Irvine, USA).]
Using this technique, the distance the guidewires retracted was an average of 13cm, range of averages 6.2cm-19.5cm (Figure 4.8). The average percentage movement (retraction) of the guidewire back into the catheter lumen compared with its corresponding catheter was 52% (range 27% -82%, Figure 4.9).

![Diagram showing average percentage movement (retraction) of the guidewire back into the catheter lumen compared with corresponding catheter length, when using the suction technique with different types of CVCs (mean, 2SD). Where guidewires tested from left to right were, Vygon multicath4expert CVC (Vygon, Aachen, Germany), Kimal ALTIUST™ PRO HP CVC (Kimal Plc, Middlesex, England), Arrow CVC (Teleflex Medical, Athione, Ireland), Vygon DUALYSE Expert VasCath (Vygon, Aachen, Germany), Gambro GamCath VasCath (Gambro, Hechingen, Germany), Arrow percutaneous sheath introducer (Arrow, Teleflex Medical, Athione, Ireland) and Edwards Intro-Flex Percutaneous Sheath introducer (Edwards Lifesciences, Irvine, USA).]

**Simulation study two: A new suction technique for guidewire removal**

When guidewires were retained intraluminally at 5cm above the skin level, all techniques, simple catheter withdrawal, clamping and withdrawal and the ‘suck out’ techniques enabled guidewire retrieval in all trials (10/10, 100% successful). When guidewires were retained intraluminally at 5cm below the skin level, guidewire retrieval
using simple catheter withdrawal was ineffective in all trials (0/10), clamping and withdrawal was successful in 10% (1/10) of trials, and the “suck out” technique was successful in 90% (9/10) trials, (n = 60, p < 0.001) (Table 4.2).

Table 4.2: Success rates of techniques used to retrieve the guidewire when the straight portion of the guidewire is located either 5cm above or below the skin level.

<table>
<thead>
<tr>
<th>Techniques used for guidewire retrieval</th>
<th>Position of straight portion (distal end) of the guidewire</th>
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<tbody>
<tr>
<td></td>
<td>5cm above skin level</td>
</tr>
<tr>
<td>Simple withdrawal</td>
<td>100%</td>
</tr>
<tr>
<td>Clamping and withdrawal</td>
<td>100%</td>
</tr>
<tr>
<td>Suction ‘suck out’ technique</td>
<td>100%</td>
</tr>
</tbody>
</table>

4.6.4 Discussion

When guidewire retention occurs, and the error is recognised, retrieval should be attempted immediately to prevent further migration and complications. When retention occurs, most guidewires initially remain within the catheter and migrate into the vasculature over time. Data from the NRLS study and reports in the literature have shown that the guidewire may remain within the catheter lumen for hours, even days post procedure, despite ‘flushing’ and infusions running through the catheter and after patient repositioning for a check radiograph. Therefore, early recognition of guidewire retention is essential, as the earlier the guidewire is recognised, the more likely that it, in part, will remain within the catheter lumen and retrieval could be easily performed at the bedside.

There are currently no recommended techniques in the literature to retrieve retained guidewires. In the literature and the NRLS data, interventional radiological techniques were the most commonly used retrieval techniques, likely due to increased availability. In the NRLS data, guidewire retrieval via interventional radiology techniques was successful in all incidents when this method was reported to be used. However, using interventional radiology to correct this error is an additional invasive procedure for the patient to correct an iatrogenic error. It is expensive and is not always immediately available, particularly in non-tertiary centres. If these techniques fail, surgical intervention may required which also
carries high morbidity and cost. Consequently, bedside techniques for quick guidewire retrieval are best for both the patient and the operator.

This study aimed to evaluate a novel technique for guidewire retrieval, which could be used if guidewire retention occurs. The first simulation study shows that if the guidewire remains within the catheter lumen, it can be retracted back into the catheter using the suction technique. If retraction brings the guidewire to above skin level, this will enable guidewire and catheter clamping and retrieval. Notably, guidewire retraction occurred with all seven types of CVCs tested when suction was used. In this study, when guidewires were nearly fully migrated into the vasculature and retained at 2cm above the catheter tip, guidewires retracted an average distance of 13cm (Figure 4.8), which was an average of 52% of their catheter length (Figure 4.9). In most cases, assuming a typical depth of CVC insertion of 15cm, retracting the guidewire by 13cm (or 52% of the catheter length) would be sufficient to bring the guidewire to a position above the skin margin, at which point it can be removed. The wider bore catheters, such as vascat catheters, demonstrated the greatest retraction length, and this is possibly due to lower frictional resistance, but conversely may also allow for faster migration if retained. The two percutaneous sheath introducers retracted the shortest distance; however, these catheters are shorter in length, and upon suctioning, almost full retraction was seen to near skin level. This is likely due to minimal catheter extension above skin level during normal placement.

In the second simulation study, the ‘suck out’ method was compared with the two methods commonly described in the literature and NRLS data for CVC guidewire retrieval. All three bedside retrieval techniques were equally effective when the guidewire was retained intra-luminally at 5cm above the skin surface. However, when retained 5cm below the skin, the ‘suck out’ technique was most effective compared with simple catheter withdrawal or catheter clamping and withdrawal (p < 0.001) for guidewire retraction. This technique was 90% effective and would not be effective if the guidewire had migrated fully beyond the tip of the catheter into the blood vessel. However, in this situation, none of the bedside techniques could be used, and interventional radiology or surgical techniques for retrieval would be required. Interestingly clamping and withdrawal was successful in 10% of attempts when the guidewire was 5cm below the skin level. This may be due to frictional forces between the catheter and the guidewire and negative pressure created within the lumen as the catheter pulled back on the guidewire against resistance. Given that this occurred in only 10% of attempts, this method could not be relied upon if the
guidewire was below the level of the skin. Additionally, the arrow CVC was chosen for the second simulation study as the catheter lumens above the converging hub at the skin level are clear. Thus, a guidewire could be visible inside the lumen if present after retraction. Other catheter lumens, such as the Kimal CVC catheter, are opaque. In a real world situation, catheters with opaque distal lumens would make guidewire retention much more challenging to recognise, as it would be unknown whether the guidewire would be above or below the skin level. The ‘suck out’ method would be more applicable in these situations.

The first simulation study demonstrated that guidewires retract on average 13cm, or 52% of the catheter length, back into the catheter even when all but 2cm of the guidewire was inside the vasculature. When guidewire retention is recognised, suction should be considered to convert a distally retained guidewire into one proximal to the skin level to enable removal. If suction alone fails to retract the guidewire to above the skin level, suction can be combined with simultaneous removal of the catheter to facilitate retrieval.

Guidewire retention can occur at any point the guidewire is used during CVC insertion, up to the ‘critical point’ in the CVC procedure. Even if the WireSafe is used during CVC insertion, over insertion and guidewire retention is still possible. However, the WireSafe forces early recognition of the error when the guidewire most likely remains inside the catheter, at which point corrective action can be taken. At this point, the ‘suck out’ technique was found to be the best method of guidewire retrieval, whether the distal portion of the guidewire was above or below the skin level. When used together, the WireSafe and the ‘suck out’ bedside guidewire retrieval technique prevent guidewire retention. Therefore, when introducing the WireSafe into clinical practice, clinicians could also be informed of bedside techniques to prevent guidewire retention, of which the ‘suck out’ technique was the most effective.

Knowledge of the ‘suck out’ method is important as it is effective whether or not the WireSafe is used for CVC insertion. The time scale for widespread implementation of a safety intervention in the healthcare system is long. Most clinicians will not have access to a device that prevents guidewire retention or forces early recognition. One could argue that it is more important, for the time being, that clinicians know about the ‘suck out’ method than the WireSafe, as they will then have the best chance of guidewire retrieval at the bedside despite the length of time it takes for recognition of the error to occur. However, the ‘suck out’ method alone is not enough in the long term. As with all bedside and invasive techniques, guidewire retrieval is only possible after recognition. The NRLS data and the
interviews demonstrated that most guidewire retentions (89% and 100%, respectively) were recognised after the CVC procedure was completed. At that point, the guidewire may have migrated into the vasculature and bedside techniques may not be possible. Therefore, the WireSafe and ‘suck out’ method are both needed to ensure prompt recognition of the error and guidewire retrieval.

Limitations

There are limitations to this study. Firstly, the model selected will not accurately demonstrate a guidewire lying distally in the circulation in all circumstances. The model of vascular frictional resistance may not accurately represent the vascular tree in vivo. There are no studies assessing CVC guidewire retrieval methods in the literature; hence, there was no basis for a model to replicate in this study. Whilst mannequin models for CVC insertion exist, they also have limitations and the fluid inside these model veins may not represent the free flowing blood inside the patient's vein which may assist the guidewire in migrating into the patient. The model developed required free flowing fluid in the catheter. Whilst cheaper, it still demonstrates the physical characteristics of the guidewire dynamics inside the lumen of a range of catheters, confirmed by three clinicians familiar with CVC insertion. Attempts were made to make this model as accurate as possible by using a pre-flushed catheter submerged in gelofusine or water with a free lying wire. The catheter was positioned in a quarter circle curved conformation. Unfortunately, research in this area is not readily available to study within conventional clinical trials due to the rarity of the error and inherent clinical concerns in practice. Thus, simulation was the only practical and ethical way to understand the mechanism of guidewire retrieval and improve the management of these events. This was the best achievable with the available funds.

Secondly, the retained guidewires in the first simulation study demonstrated a worst case scenario, where only 2cm of the distal portion of the guidewire was retained inside the catheter. All guidewires retracted back into their catheters an average distance of 13cm, showing the effectiveness of suctioning the catheter to remove the guidewire. Perhaps in the second simulation, the bedside techniques should also have been tested with only 2cm of guidewire retained inside the catheter. Whilst this could be done as a further study, in real life when guidewire retention is recognised and it is below the skin level, the exact position of the guidewire is unknown. There is no information in the literature regarding standard guidewire retention depth; thus, 5cm above and below the skin level was chosen.
Thirdly, one could argue that this study should not have included percutaneous sheath catheters. These catheters are seldom used in the ICU anymore and because of their shorter length compared with CVCs and vascaths the retraction distances may not be comparable. Additionally, comparing the retraction distances for the different CVCs was not attempted in the scope of this study. It may be helpful to know if one manufacturer's guidewire may retract more than another and some indication of this is seen in Figure 4.9. However, the differences are likely to be affected by a complex interaction of the variations found in the manufacture of the catheter and the guidewire, and clinical features such as the shape of the longitudinal lie of the catheter, the luminal contents (dry or flushed), and minor kinks within the wire caused during placement. It was felt that these factors were too nuanced and complicated to unravel to compare one CVC with one another, and therefore, it was not done.

4.6.5 Conclusions

When the WireSafe is used for CVC insertion, guidewire retention is almost immediately recognised, and this point is highly likely to remain within the catheter. Whilst there are currently no recommended techniques for guidewire retention, this study indicates that the ‘suck out’ technique is likely to be the most successful method of guidewire retrieval, even if the distal portion of the guidewire has migrated beyond the level of the skin. Suction should be considered to convert a distally retained guidewire into one proximal to the skin level to enable removal. If suction alone fails, this can be combined with the simultaneous removal of the catheter to facilitate retrieval. Importantly, this technique can be used whether or not the WireSafe is used for CVC insertion. Adopting this rescue ‘suck out’ technique may prevent a never event and patient harm.

4.7 Chapter conclusions

This chapter aimed to determine the efficacy of the locked procedure pack, clinician acceptability to using the new safety device and guidewire retrieval strategies to aid recovery if retention occurs with or without the locked procedure pack. This forced error simulation study is a novel clinical application of the methodology seen in high reliability industries. When used to evaluate the locked procedure pack, guidewire retention was prevented in 100% of cases compared with standard practice.
When introduced into clinical practice, it was determined that, using the WireSafe had no demonstrable impact on procedure duration compared to the standard practice and none of the clinicians reported any WireSafe related equipment problems. To determine whether the WireSafe is superior to standard practice, an appropriately powered study would need to be conducted. The observations demonstrated that there may be an improvement in sharps safety and the practical tactics employed by clinicians when using the WireSafe either to make practice easier by moving the WireSafe from the trolley to the surgical site or to overcome the compromises which were made during the development process, which will be helpful to teach to new users. In addition, there was general staff acceptability of the device in preventing guidewire retention and improving sharps safety.

Finally, during the development of the WireSafe, it was recognised that guidewire retention could, in theory, still occur because the clinical procedure before the ‘critical point’ was not changed. Whilst the WireSafe would ensure quick recognition of the error, a bedside technique to retrieve a retained guidewire was still required. Given the mixed success of reported bedside guidewire retrieval techniques, a novel suction solution, the ‘suck out’ technique proved to be significantly better at retrieving retained guidewires when they had been retained both above and below the skin level. Additionally, this technique could be used whether or not the WireSafe is used.

The adoption of the WireSafe could not only improve patient safety but also protect clinicians from making this error. However, further evaluation to determine the effectiveness of the solution and the usability of the device should be performed.
CHAPTER 5

CONCLUSIONS AND FUTURE WORK

CVC guidewire retention is an iatrogenic error, where the guidewire inappropriately remains inside the patient at the end of the clinical procedure. This error is described as a retained foreign object post procedure and is classified as a never event in the UK and US.\textsuperscript{25,26} The incidence in the literature is 1:3,167\textsuperscript{13–18} and complications can be severe, including cardiac dysrhythmias, blood vessel or cardiac muscle perforation.\textsuperscript{4} The error has a morbidity of 4-53\%\textsuperscript{4,14,19,20} and correction requires additional and often invasive procedures,\textsuperscript{4,137} which also have associated morbidity. In addition, fatalities have been reported as a consequence of guidewire retention, with a mortality of 4-6\%.\textsuperscript{14,20} A retained CVC guidewire not only causes direct patient harm but can also affect the clinician that has made the mistake, potentially leading to a “second victim” phenomenon,\textsuperscript{30} and can cause reputational harm to healthcare organisations.

Guidewire retention was classed as a never event in the UK in 2011, and since then, guidance to prevent this error has been published by NHSE&I\textsuperscript{3,26,34,36–40} with the mandate that hospitals must implement this guidance. The latest guidance to prevent this error was published in 2021\textsuperscript{3} and required hospitals to implement the WHO surgical safety checklist and NatSSIPs.\textsuperscript{41,42} NHSE&I emphasises that the never event will be prevented if the guidance and safety recommendations have been introduced.\textsuperscript{3} These recommendations include checklists, standardisation, and improvements in safety culture.\textsuperscript{41,42} Other preventative strategies described in the literature include re-education and retraining of staff, reminders, audits, extra documentation or two person checking techniques.\textsuperscript{3,4,14,19,41,42} Despite this, CVC guidewire retention not only continues to occur but worryingly, the reported frequency is increasing,\textsuperscript{45–54} and analysis of retained CVC guidewire never events from the NRLS database also confirms this is the case. With over ten years of guidance from NHSE&I, descriptions of this error and preventative strategies in the literature, one would expect that there should be at least a plateau, if not a decline, in the reported frequency. However, this is not the case and demonstrates that a novel approach to prevent this error is required.
The aforementioned prevention mechanisms are effective for common errors; however, relying on these strategies to prevent rare errors is problematic because these solutions are operator dependent.\textsuperscript{109} Currently, we depend on the operator to prevent CVC guidewire retention, which is reliable in 99.97\% of CVC procedures. However, these prevention strategies also rely on the operator to prevent the error in the remaining 0.03\% of procedures. Therefore, the error is prevented by relying on the operator not to make a mistake in the first instance, and then they are provided with the check that they must perform to confirm that they have not made the error. However, from the interview study and the actions of the participants in the locked procedure pack group in the simulation study, one can see that the possibility of this error occurring is very low in the operator’s mind. In fact, in the interviews, most thought that they had performed the procedure correctly and did not realise that they had made the error. These checks, rather than ensuring the operator recognised that they had made the error, simply confirmed the operator’s original thought that they had indeed removed the guidewire. These strategies then became tick box exercises rather than effective error prevention mechanisms. Additionally, for solutions such as checklists and reminders to be effective, they require a robust safety culture at all times, with all individuals and in all circumstances. Unfortunately, in a disparate healthcare system, this is not currently possible.

Employing the current preventative mechanisms, it is known with some certainty that never events will occur relatively predictably across a healthcare system. However, one cannot predict where or when these errors will occur.\textsuperscript{55} Thus, a systems solution was required to reliably prevent this error across a healthcare system.\textsuperscript{109} This has been recognised in the literature, with some authors suggesting changes to the equipment\textsuperscript{4,16,19,73,83,103,114,119} or designing a safety solution\textsuperscript{15,20,64,94,95,103,160,161} to prevent the error. Some authors have developed and implemented their solutions into clinical practice. Peh et al. developed a modified surgical drape with stickers stating ‘Remember to remove guidewire’, which was reported as successful and helpful in their institution.\textsuperscript{16} Ang developed a tag attached to the distal port of the four-lumen catheter, which stated ‘removed guidewire’, which they described as helpful but unreliable.\textsuperscript{160} Horberry et al. performed two studies: a human factors and safe design investigation into this error and employing usability heuristics to understand CVC guidewire retention.\textsuperscript{120,124} The authors developed 14 potential solutions to prevent this error. After discussion with clinicians, three solutions were highly rated: improve awareness with a strong emphasis on guidewire removal during training, check for the presence of the
guidewire on the trolley at the end of the procedure and standardise equipment.\textsuperscript{120} The authors concluded that these solutions might minimise the error, but further work is required to develop a solution to eliminate or engineer out the error.\textsuperscript{120} Horberry et al. also described the need for balance between a practical and effective solution, which prevents the error and does not negatively impact the procedure.\textsuperscript{120}

Whilst performing the work in this thesis, the need for this balance of developing a solution that prevents the error and does not negatively impact the procedure was apparent. Whilst this was of the utmost importance, other additional factors also needed careful consideration. These included: all aspects of the manufacturing process, which were material sourcing, development, sterilising, regulatory approval, heuristics, shipping, storage, costs etc., the ability to package the solution with current equipment without significant impact on the manufacturing production line, the cost to the hospital and ease of use for the clinician were all important factors that needed to be considered. If these were not considered, viable solutions may not be developed or introduced into clinical practice, even if they prevent the error. This was seen with all the solutions in this thesis which involved altering the guidewire, and hence why they were abandoned. The final solution chosen, the WireSafe, does have its limitations. However, it is a solution that prevents the error and does not negatively impact the procedure, but it also accounts for the other factors required for product development and introduction into clinical practice. Therefore, it was the WireSafe that garnered interest from a manufacturer rather than the other solutions described in this thesis.

5.1 Developing a solution to prevent a never event

In this thesis, to develop a solution to prevent CVC guidewire retention, the first step was to understand why this error occurs and how it occurs. Using the data from the literature search, the NRLS database and the interviews, it was determined that the error occurs via two mechanisms: over insertion of the guidewire and failure to recognise guidewire retention when it had occurred, leading to late recognition when it may be too late to correct easily. After creating a flow map of the steps of the CVC insertion procedure, it was understood at which point in the clinical procedure these errors occurred and, at which point a solution was required. Using this flow map, and the data from the literature search, NRLS and interviews, it was also determined why the current solutions to prevent this error were
ineffective and why a new method was required. The data demonstrated that there were two potential mechanisms of error prevention: prevent over insertion of the guidewire or force recognition of the error at a point when it is easily correctable so that retention does not occur. Solutions developed were initially based on preventing over insertion, which involved changing the guidewire. Whilst these may have been effective, they were challenging to manufacture and, specifically for the curly guidewire, required a change in the clinical procedure, which may have introduced more errors. Consequently, the focus shifted to a solution that forces recognition of the error at a point in the procedure when the error is easily correctable, preventing the error from occurring. A forcing function was required to prevent this error, and thus the WireSafe was developed and later manufactured into a clinical product.

This process has been adapted to prevent other never event errors. Firstly, it has been used to prevent the never event of retained Seldinger chest drain guidewires. An analysis of the literature and NRLS data on retained Seldinger chest drain guidewires determined that the error occurs via the same mechanism as retained CVC guidewires. Therefore, the contents of the WireSafe could be adapted for chest drain insertions and introduced similarly to prevent these errors. Indeed, the natural progression is the adaptation of the WireSafe to other Seldinger guidewire procedures if guidewire retention occurs via the same mechanism. Secondly, the concept of the forcing function has been further adapted to prevent the serious adverse event of inappropriately prolonged ureteric stent retention (provisional patent: GB2102419.5 automated closure to force data recording). Indwelling ureteric stents are temporary stents that should be removed within months, depending on the urological condition it was inserted for. Whilst patients should routinely be booked in for stent removal, this does not always occur due to human error and haphazard tracking systems, leading to inappropriate retention and complications. Through understanding the mechanism of the error, a solution was developed which prevents the operator from accessing the sent until the patient’s details have been entered onto a stent register, which in turn automatically reminds the operator to organise for the patient to have their stent removed at the appropriate time. These two examples are adaptations of the locked procedure pack and the forcing function concept, where the equipment or a system prevents the operator from performing the next step in the procedure until the crucial safety step has been completed.
Given that this process has been used to prevent other retained guidewire never events and has been adapted to prevent a urological serious adverse event, this process could be used to develop solutions to prevent other never event errors. The process described in this thesis of developing a solution to prevent CVC guidewire retention was mapped onto a flow diagram (Figure 5.1).

**Figure 5.1: A flow map of a method of developing a solution to a never/serious adverse event error.**

This flow map details how an investigator may understand why a clinical error occurs and why the current strategies may or may not be effective at preventing said error. It is important to understand why the current prevention strategies are ineffective. This is so that the investigator can understand which type of solution may be effective. Following the pathway, the investigator can use this information to start designing a solution to prevent the error, which may require trial and error until a suitable innovation is developed. As discussed in this thesis, there are caveats to the solution developed. It must fit the requirements of the user, the manufacturer and the hospital whilst preventing the error and not adversely impacting the procedure. It is likely that this pathway may only apply to single procedures and may be ineffective for more complicated processes like medication errors. Additionally,
the pathway may only apply to serious adverse or never events errors. Due to their rarity, these errors are unique and require a systems solution across a healthcare system rather than a novel solution in each hospital; therefore, any solution must fit the caveats described above. This pathway could be used for more common errors; however, further work would be needed to understand whether further adaptions would be required.

5.2 Forced error simulation

After a novel solution is developed, it must be tested to determine efficacy before introduction into clinical practice. In the literature search, NRLS data and interviews, there are no studies or descriptions stating that any of the solutions (checklists, reminders, training) proposed or introduced into the clinical environment had been tested to determine efficacy before introduction. Some authors even described the recurrence of the error after introducing their preventative strategies. Despite this, in the literature, the NRLS data and the interviews clinicians ardently continued to use these untested strategies, even if they had failed in their institutions. It is easy to understand why these solutions have not been evaluated in a conventional study; they would require an impossible number of participants to undertake such a study. Thus, a novel mechanism for evaluating a solution to prevent a never event was required. This thesis evaluated the locked procedure pack through forced error simulation, a method adapted from the high reliability industries. During simulation, the error is forced to occur to determine whether participants recognise the error and respond appropriately or whether a novel solution prevents the occurrence of the error. This type of simulation, called disaster scenario training, has been used in medicine for major incidents. Where the disaster, such as a terrorist attack, major explosion or train collision, for example, is made to occur in a simulation setting and is performed to train clinicians for real life versions of these incidents. However, this type of simulation has not previously been used as a methodology to test novel solutions for rare errors by replicating the clinical procedure in a simulation setting and forcing the error to occur to either determine whether the clinician recognises the error and/or whether a novel solution tested prevents the error from occurring. This methodology was used successfully in this thesis to determine the efficacy of the WireSafe, which was found to prevent guidewire retention compared with standard practice. It has also been used in four further studies evaluating serious adverse and never event errors: to determine whether the locked procedure pack
prevents retained Seldinger chest drain guidewires,\textsuperscript{162} to determine staff awareness of the glucose error during arterial sampling,\textsuperscript{142} to determine staff recognition of the inadvertent, simultaneous use of a heat and moisture exchanger and a heated humidifier\textsuperscript{143} and to determine the ease of accidental injection into the arterial line.\textsuperscript{141} Therefore, this novel methodology could be used to test recognition or a solution to prevent never event errors.

\section*{5.3 Safety systems}

Whilst there is greater assurance of guidewire and sharps safety during CVC insertion if the WireSafe is introduced into clinical practice, a single intervention is not a fool proof solution. For example, operators can choose not to use the device or find workarounds to open the device without the guidewire. However, these safety solutions are not designed to remove the need to cognitively engage with the procedure but to minimise risk and aid operators in performing their job safely. Introducing the WireSafe may improve patient safety and protect clinicians from making this error; however, there must still be robust medical and speciality training programmes to ensure that the majority of these errors do not occur. Other safety aspects, such as adequate workforce and safety culture, also need to be improved; however, these are much harder to change financially and politically.

Whilst it is easy to look to the high reliability industries, it is important to remember that the shift to a safety culture in the airline industry has taken decades to achieve.\textsuperscript{57} Healthcare has limited financial resources and an inability to redesign the whole system from scratch and train all staff in human factors to deliver an improvement in patient safety quickly: in industries, for example, a factory can be shut down a factory to investigate the cause of an error, whereas, in healthcare, care must be provided whether or not the equipment works to the best standard or there are adequate staffing levels. Furthermore, in the current healthcare system, any new safety measure has to be effective despite the existing latent failures.\textsuperscript{111} Whilst awaiting the funding and political will for all healthcare staff to be trained and disciplined in human factors and improved safety culture, action should be taken now to prevent errors. As such, there is currently a need for safety solutions like the WireSafe.

Importantly, now that the WireSafe has been developed to prevent CVC guidewire retention, it does not mean that we should stop innovating or improving. Nor does it mean that the WireSafe will be the only solution for preventing this error. Should another, better
solution be developed that is either cheaper to manufacture or purchase, more effective at preventing the error or prevents guidewire retention for single and multiple line insertions, this should take precedence. However, until such an innovation is developed, the WireSafe could be used.

5.4 Critique and conflicts of interest

There are limitations to the studies presented in this thesis which have been discussed in the previous chapters. The types of studies performed depended on the availability of the data in the interviews and NRLS study, the willingness of interviewees to candidly discuss their mistakes, the willingness of participants to participate in the simulation and introduction to clinician practice study, and the limitations of funding.

The studies in Chapter two, the literature search, NRLS data and interviews were all required to understand the aetiology of this error. Before commencing this work, many operator based solutions were proposed in the literature. However, to understand the scale of the error and the granular detail of why and how the error occurs, analysis of a large dataset of these never event errors and interviews with clinicians who had made these errors was necessary. The conclusions drawn from this chapter were understanding how and why guidewire retention occurred and at which point in the procedure a solution would be required, but not what this solution could be.

Several solutions to prevent this error were proposed in Chapter three, and to prevent bias, all were tested in the same manner to determine the functionality and feasibility of the innovation. The final solution, the locked procedure pack, was selected not only because it prevented the error and did not adversely affect the clinical procedure but, more importantly, because a manufacturer independently chose to fund and develop the innovation. Suppose none of the medical device manufacturers chose to develop the locked procedure pack. In that case, this innovation would likely have been rejected in favour of the ‘next’ idea, like the curly guidewire. Because of this dependence on the manufacturer, author bias was mitigated, as the manufacturer chose which innovation to develop.

Three studies were presented in Chapter four to evaluate the locked procedure pack. One could argue that with knowledge of the CVC procedure and by simply looking at the mechanism of the locked procedure pack, it would be evident that this solution would prevent the error. Similar to the arguments presented in the parachute study, why conduct
a randomised controlled forced error simulation trial to show the obvious? It may be evident to an anaesthetist or intensivist that the locked procedure pack will prevent the error. However, it may not be evident to those outside these specialities or those without knowledge of the locked procedure pack. Randomised controlled trials are a gold standard for evidence based medicine. As such, it was felt this approach was required to demonstrate that this innovation prevents the error and shows that this type of simulation study can be used to evaluate strategies to prevent rare errors. There was the potential for conflict of interest, both intellectually and financially, with the forced error simulation study and the introduction into clinical practice study; and this was limited as described in Chapter four. One could argue that these studies should have been performed independently. Unfortunately, it was not possible due to a lack of interest and funding from independent parties. Funding is usually available to correct an error because it is obvious when it happens. However, by the very definition of prevention, most will never see the error, particularly never event errors which use engineered solutions to remove the error from the system. Hence, funding to develop a preventative solution and studies to evaluate them is difficult to obtain. Therefore, the author performed these studies, mitigating for bias as much as possible with the understanding that if funding could be obtained, subsequent studies with larger cohorts could be performed independently.

5.5 Concluding remarks

This thesis aimed to determine whether it would be possible to prevent CVC guidewire retention, a never event. The outcome of this work is a fully developed clinical product, WireSafe, which is currently being used in clinical practice in the UK and the US. Additionally, in this thesis, the aetiology and the mechanism by which CVC guidewire retention occurs have been clearly defined. It is understood why the current error prevention mechanisms are ineffective and why a novel mechanism for preventing this error was required. A novel pathway for developing a solution to prevent a never event was created, which may apply to other never event errors. A novel method of evaluating the efficacy of solutions to prevent never events was developed, which may also be used to test other solutions designed to prevent rare errors. Finally, a novel method of guidewire retrieval which can be used with or without the WireSafe may help clinicians to rescue the potentially lost guidewire and prevent a never event situation.
Further work has been started with WireSafe. Firstly, as described above, the WireSafe was adapted to prevent retained Seldinger chest drain guidewire errors. Secondly, the device has been licensed to other manufacturers, and the cost is incorporated into the price of the CVC insertion pack to make the device more affordable to hospitals. Thirdly, the WireSafe is now used in the UK and the US. Finally, further work to evaluate the WireSafe is required, and this is currently underway, independently, by the Yorkshire and Humber Safety Translational Research Centre, commissioned by NHS Improvement.
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<td>26</td>
<td>Department of Health. The never events policy framework. An update to the never events policy. 2012. Available from:</td>
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Appendix A, Chapter 2

2.1 The search terms used for each search engine

**Pubmed:**
("Central venous catheter"[Mesh] OR "Catheterization, central venous"[Mesh]) AND
("Guidewire*"[All Fields] OR "Guide wire*"[All Fields]) AND ("loss"[All Fields] or
"lost"[All Fields] or "migrate*"[All Fields] or "embol*"[All Fields] or "miss*"[All Fields]
or "retain*" or "forgot*"[All Fields] or "discover*"[All Fields] or "retrieve*"[All Fields] or
"complicat*"[All Fields] OR "Adverse effect"[All Fields] or "Foreign Objects"[All Fields] or
"Foreign Object"[All Fields] or "Object, Foreign"[All Fields] or "Objects, Foreign"[All Fields])
372 results

**Scopus:**
"Central venous catheter" AND ("Guidewire" OR "Guide wire") AND ("retain" OR "loss"
OR "miss" OR "migrate" OR "forgot" OR "discover")
1447 results

**Google:**
"Central venous catheter" AND ("Guidewire" OR "Guide wire") AND ("retain" OR "loss"
OR "miss" OR "migrate" OR "forgot" OR "discover") -fracture -infection
939 results
## Appendix A, Chapter 2

### 2.2 Studies included in the literature search

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Appendix A, Chapter 2

2.3 Semi-structured interview questions

Will re-designing the central line guidewire or catheter prevent the never event of retained central line guidewires?

Section 1: Interview Questionnaire

Participant number:
Trust:
Date:
Time:

Note – Participants should try to answer questions in their own words. Only prompt with examples if they are struggling to answer the question.

1. Can you tell me in your own words what happened when you were putting the central line in.

2. Further detail of questions if not given in 1:
   a. Where were you doing with the procedure - theatres, ITU, ward?
   b. What time of day was this?
   c. How many hours into your shift were you at the time?
   d. Why did the patient need the procedure, were they conscious?
   e. How did you do the procedure, did you get the equipment, was someone helping you, did you have a nurse or another doctor with you? Was there a junior/med student with you that you were teaching?
   f. What was happening to the patient at the time - were other procedures being conducted at the same time, was the patient stable? What were the observations like?
   g. Were you happy with how the procedure was going? Tell me how you inserted the central line at that time? Beginning to end, go through the steps
   h. Was there anything at all that you weren’hui happy with or thinking about at the time? e.g.
i. The way the patient was positioned

ii. The equipment trolley was too far away

iii. You hadn’t had your break/meal yet

iv. You still had your other patients to see, needed to get to theatres or clinic

v. You had an issue at home or with your family that you were thinking about

vi. You were thinking about revising for an exam?

vii. Thinking about getting home early or getting through the list?

viii. Was someone else or the patient talking to you about something non-work related

i. What was going on around you at the time in the rest of the environment? Was there anything unusual happening or was everything normal?

3. When did you realise that the error had been made?
   a. What alerted you to the fact?
   b. What did you do then?
   c. What happened to the patient?

4. Why do you think you made the error? e.g. the equipment, training?

5. How many times had you put a central line before?

6. How were you trained?

7. At the time were you aware that retained central line guidewires were a potential problem? Had you seen it before, or seen a near miss before?

8. What grade were you at the time the incident happened?

9. What happened to you after the incident? Did you have to have further training?

10. What happened in the department – were any changes made to the equipment, was the department informed?

11. Do you think you approach putting in central lines differently now? How do you think your behaviour has changed?

12. Has your behaviour changed when you now do other procedures? Not just those with guidewires in e.g. chest drain insertion but any invasive procedure?

13. Do you train juniors? What do you tell them? How do you train them?

14. What if the equipment was altered to ensure that doctors don’t make this mistake again? Do you think this would be useful?
Appendix A, Chapter 3

3.1 Informal user testing questionnaire

Participant number:

Section 1

1. Demonstrate to the participant how the locked procedure pack is opened.

2. The locked procedure pack and guidewire are given to the anaesthetist.

3. Note and record the time when the locked procedure pack and the guidewire were handed to the anaesthetists.

4. Note and record the time when the locked procedure pack was opened.

   Result: □ less than 10 seconds, □ more than 10 seconds

Section 2

Questions:

1. What do you think of the concept of the locked procedure pack?

2. Do you think the solution would prevent the error?

3. Do you think that there may be any clinical impact on the CVC procedure if the locked procedure pack was used?

Comments:
Appendix A, Chapter 4

4.1 Forced error simulation study scenario and instructions

Instructions to candidate

Candidate information:

The aim of this study is to look into the technical capabilities of doctors of various grades in central line insertion.

Your role in the study is to be the anaesthetist/trainee anaesthetist who is inserting a central venous catheter.

Scenario:

A colleague of yours was inserting a central venous catheter on a clinically stable patient, but in the middle of inserting the CVC they were called away for an emergency. They asked if you can take over the procedure and complete it safely.

When you enter the room, you will need to assess the situation, complete the CVC procedure, perform any additional checks prior to approving the CVC for use and answer the questions. You will have an assistant in the role of an ODP or ICU nurse to help you with this task. This insertion of the line will be undertaken on a model.

Assistant Instructions

You are playing the role of an assistant (nurse) to the insertion of a central venous catheter.

You should assist the candidate in the way normally expected.

If asked about the stability of the patient you should answer:
‘Obs stable, Sats 95% on air, normotensive’

If asked about the ectopic beats you should answer:
‘I think those started during the CVC insertion’

If asked about the location of the guidewire, you should answer:
“I don’t know, I haven’t seen it.”

If asked further, you can confirm that you can’t find it:
“Err don’t know, isn’t it there on the field”
If participants ask to use the ultrasound machine, you should give them the ultrasound probe.

If the participant asks what can they see on the screen? you should respond: “It looks like the catheter is in the right internal jugular vein”

If asked about the location of the stitch or dressing you can direct them to their location: “it’s on the field”
OR “I think it’s in that box”

If asked about the locked procedure pack, you should answer: “It is a new safety initiative, but I do not know what it is for or how to use it”
Appendix A, Chapter 4

4.2 Forced error simulation study data collection form

Name:

Speciality:

Grade:  Junior  Middle grade  Consultant

1. Are you happy with the position of the catheter?  Yes  No

2. How many cm do you normally put the catheter up to?  ___cm

3. How would you normally fix the catheter?
   a. Steristrips  
   b. Venigard  
   c. Suture:  
      i. curved suture  
      ii. straight suture  
         1. 2 point fixation  
         2. 4 point fixation  
      iii. Do you use a needle holder?  Yes  No

4. How would you normally dress the insertion site?
   a. Bio-occlusive dressing  
   b. Tegaderm dressing  
   c. Tegaderm with antiseptic  
   d. Do you know what this material is (indicate chlorhexidine dressing)? What is it?

5. Is there anything else you would normally do to complete your line insertion?

6. Have they noticed the guidewire?  Yes  No
a. If yes, action taken:

If using the locked procedure pack

7. Was the locked procedure pack the only reason that they noticed the guidewire was still in the patient?
   Yes ☐ No ☐

8. How long did it take to open the locked procedure pack? From starting to insert the guidewire into the channel of the lid to lid fully open and participant able to access contents.
   <10 seconds ☐ >10 seconds ☐

9. How many CVC have you inserted in your career?
   >10 ☐ 10-50 ☐ 50-100 ☐ >100 ☐

10. What do you normally do with the guidewire?

11. What do you normally do with the sharps?

If using the locked procedure pack.

12. Did using the box remind you to look for the guidewire (and then realise it was inside the patient)?
   Yes ☐ No ☐

13. Is using the locked procedure pack safer than standard practice?
   Better ☐ Same ☐ Worse ☐

14. Is the locked procedure pack more convenient than standard practice?
   Better ☐ Same ☐ Worse ☐

15. Is the locked procedure pack a convenient method of disposing of the guidewire
   Better ☐ Same ☐ Worse ☐

16. Is the locked procedure pack a convenient method of disposing of the sharps?
   Better ☐ Same ☐ Worse ☐
# Appendix A, Chapter 4

## 4.3 WireSafe introduction into clinical practice study data collection form

<table>
<thead>
<tr>
<th>Study Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location:</td>
</tr>
<tr>
<td>CVC insertion: Standard / WireSafe</td>
</tr>
</tbody>
</table>

### CVC insertion observation:

<table>
<thead>
<tr>
<th>Point in the procedure</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needle to skin</td>
<td></td>
</tr>
<tr>
<td>Guidewire out</td>
<td></td>
</tr>
<tr>
<td>Catheter dressed</td>
<td></td>
</tr>
<tr>
<td>Label dated</td>
<td></td>
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<tr>
<td>Sharps disposal</td>
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</tr>
</tbody>
</table>

### Sharps disposal:

<table>
<thead>
<tr>
<th>Safe sharps disposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sharps bin brought to the procedure and used at the bedside</td>
</tr>
<tr>
<td>Sharps transferred to the bin in a container</td>
</tr>
<tr>
<td>Sharps transferred to the bin in the WireSafe</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Unsafe sharps disposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sharps transferred to the bin in the clinician’s hand</td>
</tr>
<tr>
<td>Sharps being thrown any distance into the sharps bin</td>
</tr>
<tr>
<td>Sharps being left to be cleared away by an assistant</td>
</tr>
</tbody>
</table>
Appendix A, Chapter 4

4.4 WireSafe introduction into clinical practice study structured survey

Participant number:
Participant speciality:
Participant grade:

1. How many CVCs have you inserted in your career? Estimate a number

2. Have you used the WireSafe? Yes / No
   a. If yes – how many times? Estimate number
   b. Have these been in patients who have been:
      i. Asleep – Yes / No
      ii. Awake – Yes / No
      iii. Agitated – Yes / No
   c. Have there been any problems when using the WireSafe during CVC insertion? Yes / No
      i. If yes please explain:

3. There has been a comment that “you would have to take your hands off the patient when you use the WireSafe which may make the clinical procedure unsafe” Compared with clinical practice prior to using the WireSafe, do you agree or disagree with the statement

4. There has been the comment that “blocking access to the suture equipment may make the clinical procedure unsafe” Do you agree or disagree with the statement?

5. Is using the WireSafe for CVC insertion: easier / no difference / harder than using standard equipment?

6. Is the risk of guidewire retention with the WireSafe reduced / no difference / worse compared with standard practice?

7. Is there anything you like about the WireSafe?

8. Is there anything you dislike about the WireSafe?
9. Do you think the sharps / guidewire clear up with the WireSafe is: more convenient / no difference / less convenient compared with standard equipment?

10. Overall, would you approve of the WireSafe? Yes / No

11. Would you continue to support the introduction of the WireSafe for safety and convenience? Yes / No

12. Are there any further comments that you wish to add about the WireSafe?
Appendix A, Chapter 4

4.5 WireSafe introduction into clinical practice statistical calculations by E. Young, Statistician, University of Cambridge

Non-inferiority statistical calculations

For the first $t$-test performed in this study (testing for a reduction in the total procedure time) we see that for the sample size of the study used (an underpowered test) we cannot reject the null ($p = 0.17$).

Alternatively, one could carry out a non-inferiority hypothesis test. Consider testing the null hypothesis that the total procedural time of the WireSafe is no more than 10\% slower than standard practice (non-inferiority margin of 10\%). Carrying out this test results in the total procedural time for the WireSafe is non-inferior to standard practice at the 10\% margin (1.6 minutes) ($p = 0.044$).
Probability Calculation – Sample Size requirements for Hypothesis Testing for Retained Guidewires

Let $X$ be the number of never events occurring in $n$ trials, with the probability of a never event on a single trial being $p$. Then $X$ follows a binomial distribution; $X \sim \text{Binomial}(n, p)$. We consider the hypothesis test of the null hypothesis $H_0: p = \beta$ (the WireSafe has no effect at reducing the number of never events over a baseline never event occurrence $\beta$) against the alternative hypothesis $H_1: p < \beta$ (the WireSafe prevents never events over the baseline). Suppose that in $n$ observation zero never events occur with the WireSafe. Then, under the null hypothesis ($p = \beta$) we have that

$$P(\text{no never events occur in all } n \text{ events, under the null}) = (1 - \beta)^n.$$  

If one carries out this hypothesis test at the $\alpha$ level (rejecting the null if the p-value is less than $\alpha$), the null would be rejected provided $(1 - \beta)^n \leq \alpha$. Therefore, the sample size $n$ for the test should be chosen of

$$n \geq \frac{\log \alpha}{\log(1 - \beta)}.$$  

Therefore, were one to take $\beta = \frac{1}{3167}$ and $\alpha = 0.05$ then we require $n \geq 9486$. 


Power Calculation to determine the sample size required to show a difference in the total procedure time comparing WireSafe and standard practice

With an approximate estimate from this pilot study of the effect size, we can approximate the sample size required for a future well powered hypothesis test. For example:

Comparing Overall Time for Procedure: With the estimates of the means (standard group = 16, WireSafe = 14) and standard deviations (standard group = 7, WireSafe = 2) the value of effect size (Cohen’s d) can be calculated as

\[
\text{Effect Size} = \frac{16 - 14}{\sqrt{7^2 + 2^2}} = 0.39.
\]

This is often related to a ‘moderate effect size’, and as a result a \( t \)-test with \( n \) observations per group (with the effect size as estimated from the pilot study) at the 5% level would have a power of at least 0.8 for sample sizes (for each group) of \( n \geq 43 \).
## Appendix A, Chapter 4

4.6 A bedside method for retrieving retained guidewires study

### Data collection form

#### Simulation 1: how much the guidewire is retracted back into the catheter in \_\_cm

<table>
<thead>
<tr>
<th>CVC</th>
<th>No.</th>
<th>VYGON</th>
<th>KIMAL</th>
<th>ARROW</th>
<th>VYGON</th>
<th>GAMCATH</th>
<th>ARROW</th>
<th>EDWARDS</th>
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#### Simulation 2:

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<thead>
<tr>
<th>Method</th>
<th>Guidewire retrievable: Y / N</th>
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<tbody>
<tr>
<td>Simple withdrawal</td>
<td>5cm above the skin level</td>
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<td>5cm below the skin level</td>
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<tr>
<td>Clamping and withdrawal</td>
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Suction ‘suck out’ technique

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Appendix B: Review of statistics in the thesis Preventing retained central venous catheter guidewires, by E. Young, Statistician
University of Cambridge

Chapter 4, 4.2: Forced Error Simulation – Power Calculation
The power calculation gives a reasonable and appropriate estimate for the sample size required to test an intervention against standard practice for a never event with an incidence of 1:3167 (at a low effect size).

Chapter 4, 4.3: A Randomized Controlled Simulation Study
For this simulation study, a Fisher exact test would be appropriate to perform (and in fact requires no additional assumptions to be imposed). The sample size of the test (determined via an appropriate power calculation) results in a sample size large enough for a well powered test (relating to a power of 0.87, above the industry practice level of 0.8).

Chapter 4, 4.5: The WireSafe – A pilot study introducing the locked procedure pack into clinical practice
This pilot study constitutes an exploratory analysis to measure the impact of the WireSafe on clinical procedural time compared with standard practice. This is done via two statistical analyses: comparing the total procedure time; and the time the WireSafe impacts on the procedure. These hypothesis tests are carried out via t-tests (unpaired, unequal variances). This is appropriate in this setting for small sample sizes (such as that used in this pilot study) provided the times taken are assumed to be normally distributed. Given the data observed, there is no strong evidence to suggest this is not the case, and so it doesn’t seem unreasonable to assume this could approximately hold. If one wanted to avoid this assumption, an alternative methodology would be to perform a non-parametric test such as a Mann-Whitney U test.

For the two t-tests performed, note that under the assumption that the time for needle to skin to guidewire removal is the same for both standard procedure and WireSafe groups (which seems reasonable in this context), the hypotheses for the two tests are identical.
However, as the total procedure time is equal to the guidewire removal to sharps disposal time plus the additional random variable of the needle to skin to guidewire removal (which has the same mean for both groups), the difference in means for that studied in the first test (total procedure time) is equal to the difference in means of that studies in the second test (guidewire removal to sharps disposal time). This would result in the first test necessarily having a larger \( p \)-value than the second test. If the primary goal would be to show a significant time impact of the WireSafe over standard practice, the second hypothesis test would be preferable as it would allow a smaller \( p \)-value for the same sample size. Both hypothesis tests however still provide useful interpretation for the two times considered.

Note that as the effect size was not known (even approximately, and even the direction of the effect) prior to this study being performed. As a result, the pilot study may not necessarily be powered, and in fact we can retrospectively see this is indeed the case. The rationale of this pilot study is thus to estimate the effect size so that one can then calculate the sample size required for a future and subsequent well powered test.

The statistical analysis of sharps disposal safety is performed with a Fisher’s exact test, which is appropriate.

**Chapter 4, 4.6: A bedside rescue method for retrieving retained guidewires: The ‘Suck Out’ technique**

The Fisher’s exact test used to compare the techniques for guidewire retrieval is appropriate (and, as it is exact, uses no additional assumptions). The power calculation allows the construction of a sample size for the hypothesis test with power 0.9 (greater than the industry practice level of 0.8).
Appendix C: Approvals and Ethics

Ethics to conduct this thesis was applied for and approved by the University of Cambridge Psychology Research and Ethics Committee. Research and Development approvals where required were sought from the study site institution. Details of approvals for each study are as follows:

Chapter 2

The literature review

- No ethics required

The analysis of incidents of retained CVC guidewires reported to the NRRLS

- Access to the NRRLS database of reported retained guidewire never events between August 2004 and July 2015 was granted by Mike Durkin, the Director of Patient Safety of NHS England, and Bruce Keogh the Medical Director of NHS England through a formal data sharing agreement on the 16/10/2015, with approval to publish anonymised pooled data as per the NRLS public agreement. Additionally, I have also received comments and nominal corrections from the NRLS analytical team with approval for publication in my thesis.

- Following the IRAS pathway, it was determined that this study did not require ethical approval. https://www.hra-decisiontools.org.uk/ethics/index.html

- The Cambridge Psychology Research and Ethics committee stated that large, anonymised datasets do not require ethical approval. https://www.bio.cam.ac.uk/psyres/approval

Interviews with clinicians who have made this error

- Ethical approval to conduct the study was granted by the University of Cambridge Psychology Research and Ethics committee.
Chapter 3

Informal user testing
- The research and development review board approved the study conducted at the Queen Elizabeth Hospital, King’s Lynn.

Chapter 4

A randomised controlled forced error simulation study
- The University of Cambridge granted ethical approval to conduct the research.
- The research and development review board approved the study conducted at the Queen Elizabeth Hospital, King’s Lynn.

The WireSafe: a pilot study introducing the locked procedure pack into clinical practice
- The research and development review board and clinical governance committee approved the study conducted at the Queen Elizabeth Hospital, King’s Lynn.

A bedside rescue method for retrieving retained guidewires: the ‘Suck Out’ technique
- The research and development review board approved the study conducted at the Queen Elizabeth Hospital, King’s Lynn.
Appendix D: Publications arising from this thesis


