Health Technology Assessment 2003; Vol. 7: No. 36

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Health Technology Assessment
NHS R&D HTA Programme

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Declared competing interests of authors: none

Published November 2003

This report should be referenced as follows:

Boland A, Haycox A, Bagust A, Fitzsimmons L. A randomised controlled trial to evaluate the clinical and cost-effectiveness of Hickman line insertions in adult cancer patients by nurses. *Health Technol Assess* 2003;**7**(36).

Health Technology Assessment is indexed in *Index Medicus*/MEDLINE and *Excerpta Medica*/EMBASE.

NHS R&D HTA Programme

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The research reported in this monograph was funded as project number 95/16/06.

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The editors and publisher have tried to ensure the accuracy of this report but do not accept liability for damages or losses arising from material published in this report. They would like to thank the referees for their constructive comments on the draft document.

ISSN 1366-5278

Published by Gray Publishing, Tunbridge Wells, Kent, on behalf of NCCHTA.
Printed on acid-free paper in the UK by St Edmundsbury Press Ltd, Bury St Edmunds, Suffolk.

Abstract

A randomised controlled trial to evaluate the clinical and cost-effectiveness of Hickman line insertions in adult cancer patients by nurses

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Objectives: To examine the clinical and cost-effectiveness of image-guided Hickman line insertions versus blind Hickman line insertions undertaken by nurses in adult cancer patients.
Design: A cost-effectiveness analysis was carried out alongside a randomised controlled trial.
Setting: A large acute cancer centre in Manchester, UK.
Participants: Cancer patients due to have a Hickman line insertion who were over 18 years of age and were clinically and physically compliant with specified protocols.
Interventions: In order to obtain central venous access for the patient, two interventions were investigated: (i) blind insertion of a Hickman line and (ii) image-guided insertion of a Hickman line. Both interventions involved blind venipuncture of the subclavian vein. In the blind arm, the Hickman line was routinely inserted without the use of image guidance at any point in the procedure. Transfer to the interventional X-ray suite and use of image guidance were options immediately available to the operator during the procedure if required. In the image-guided arm, the position of the guidewire was checked before the Hickman line was introduced and later the Hickman line was positioned with the use of X-ray fluoroscopy.
Main outcome measures: The primary clinical outcome measure was catheter-tip misplacement and this was expected to be higher in the blind arm. When comparing the skill level of the trainer and the trainees, pneumothorax was the primary clinical outcome measure. Other outcomes measures included arterial puncture, haematoma, infection, failed insertion and assistance from other healthcare professionals.
Results: No statistically significant difference was found between the mean cost per patient in the two arms of the trial. The only statistically significant difference in clinical outcomes was the frequency of catheter-tip misplacement, which was higher in the blind arm of the trial. At very low costs, the image-guided approach dominates the blind approach as fewer costs and greater benefits are incurred. It is evident that nurses previously inexperienced in the procedure can be trained to insert Hickman lines successfully both at the bedside and under image guidance within a 3-month period.
Conclusions: This report indicates that nurse insertion of Hickman lines in the majority of adult cancer patients is both safe and effective. However, there are a select group of patients for whom image-guided insertion may be preferred. The results reveal that skills and expertise can be transferred from trainer to trainee through a relatively short, but intensive, training course. It is also evident that patients support nurse insertion. Further research is suggested to compare the safety and efficacy of nurse versus doctor insertions in particular subgroups of patients and also to assess the quantity and quality of current service provision in order to inform NHS decision-making in this area.

Contents

List of abbreviations

AIDS	acquired immunodeficiency syndrome
ALD	Adult Leukaemia Database
BCSH	British Committee in Standards in Haematology
CBA	cost–benefit analysis
CEA	cost-effectiveness analysis
CHNT	Christie Hospital NHS Trust
CLIP	central line insertion project
CL	confidence limits
CMA	cost-minimisation analysis
CNS	clinical nurse specialist
CTSU	Clinical Trial Support Unit
CUA	cost–utility analysis
CVC	central venous catheter
df	degrees of freedom
HIV	human immunodeficiency virus
ICER	incremental cost-effectiveness ratio
ICVAD	implantable central venous access device
KP	Karnofsky performance
PHLS	Public Health Laboratory Service
PICC	peripherally inserted central catheter
QALY	quality-adjusted life year
RCT	randomised controlled trial
SD	standard deviation
TPN	total parenteral nutrition
VAD	venous access device

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.

Executive summary

Objectives

To examine the clinical and cost-effectiveness of image-guided Hickman line insertions versus blind Hickman line insertions undertaken by nurses in adult cancer patients at Christie Hospital NHS Trust. To explore whether or not experienced nurses can transfer skills to trainee operators via a short but intensive training programme.

Design

A cost-effectiveness analysis was carried out alongside a randomised controlled trial.

Setting

Christie Hospital NHS Trust (CHNT), a large acute cancer centre in Manchester, UK

Subjects

A total of 470 adult cancer patients were randomised to receive either blind or image-guided Hickman line insertions. Patients were eligible for the study if they were due to have a Hickman line insertion at Christie Hospital NHS Trust, were over 18 years of age and were clinically and physically compliant with specified protocols.

Interventions

The aim of both interventions was to obtain central venous access for the patient. The two interventions under investigation were (i) blind insertion of a Hickman line and (ii) image-guided insertion of a Hickman line. In the trial, blind insertion of a Hickman line took place at the patient's bedside whereas the image-guided insertion of a Hickman line took place in the interventional X-ray suite. Both interventions involved blind venipuncture of the subclavian vein. In the blind arm, the Hickman line was routinely inserted without the use of image guidance at any point in the procedure. Transfer to the interventional X-ray suite and use of image guidance were options immediately available to the operator during the procedure if required. In the image-guided arm, the position of the guidewire was checked before the Hickman line was introduced and later the Hickman line was positioned with the use of X-ray fluoroscopy.

Main outcomes measures

When comparing image-guided versus blind Hickman line insertions, the primary clinical outcome measure was catheter tip misplacement and this was expected to be higher in the blind arm. When comparing the skill level of the trainer and the trainees, pneumothorax was the primary clinical outcome measure. Other outcomes measures included arterial puncture, haematoma, infection, failed insertion and assistance from other healthcare professionals.

Results

When comparing image-guided with blind Hickman line insertions, no statistically significant difference was found between the mean cost per patient (£464.57 versus £440.40, respectively) in the two arms of the trial. The only statistically significant difference in clinical outcomes was the frequency of catheter tip misplacement; this was higher in the blind arm of the trial. In the blind arm, 14% of patients had misplaced catheter tips whereas in the image-guided arm only 1% of patients had misplaced catheter tips. Consequently, incremental cost-effectiveness analysis was undertaken and the incremental cost per misplaced catheter tip avoided was £183.22. Sensitivity analysis demonstrated that the cost of the interventional X-ray suite charge might have an impact on the preferred method of insertion. At very low costs, the image-guided approach dominates the blind approach as fewer costs and greater benefits are incurred. Based on the clinical evidence from the trial, it is evident that nurses previously inexperienced in the procedure can be trained to insert Hickman lines successfully both at the bedside and under image guidance within a 3-month period. The only statistically significant

difference identified when comparing the skill level of the three nurses was that the trainer was less likely to call for assistance from another healthcare professional during the procedure than the trainees.

Conclusions

This report indicates that nurse insertion of Hickman lines in the majority of adult cancer patients at CHNT is both safe and effective. However, there are a select group of patients for whom image-guided insertion may be preferred. The results reveal that skills and expertise can be transferred from trainer to trainee through a relatively short but intensive training course. From the patient satisfaction evidence available, it is evident that patients support nurse insertion. Nurse insertions can free up clinical resources in a safe and effective manner.

Recommendations for future research

Reliable estimates of the clinical and cost-effectiveness of Hickman line insertions in adult cancer patients can only be calculated if further research to compare the safety and efficacy of nurse versus doctor insertions in particular subgroups of patients is carried out. It is also recommended that future studies be conducted to assess the quantity and quality of current service provision in order to inform NHS decision-making in this area.

Chapter 1
Introduction

Background to the study

In the NHS, approximately 200,000 central venous catheters (CVCs) are inserted in adult patients per year.[1] As the average cost of insertion is estimated to be approximately £450,[2] the annual direct cost to the NHS of CVC insertions can be conservatively estimated at around £80 million. For many seriously ill patients, the availability of venous access devices (VADs) not only improves quality of life but also saves lives. Consequently, the appropriate use of VADs (or CVCs) is recognised as an integral part of total patient management across a wide spectrum of specialties.[3] Central venous access is required for a variety of reasons, the most common being for the administration of chemotherapy and the delivery of total parenteral nutrition (TPN). A wide range of CVCs are available for hospital and domiciliary use in the UK. This research focuses on the Hickman line, a tunnelled and cuffed CVC which is the most frequently used CVC in the NHS.

General surgeons and anaesthetists were the first clinicians to insert Hickman lines surgically in the operating theatre. More recently, interventional radiologists have developed innovative methods for the insertion of Hickman lines under image guidance. Extensive clinical evidence exists to support the hypothesis that the image-guided approach to insertion is superior to the surgical approach in terms of both improved health outcomes and patient satisfaction.[4] Empirical study in this area is currently focused on comparing image-guided and blind methods of insertion. Recent study results suggest that, for the majority of patients, the blind insertion of a Hickman line is no less safe or effective than image-guided insertion.[5] Also, clinicians are no longer the sole group of operators; nurse-led central venous access services are being established and CVC insertion training for nurses is being delivered both with and without the routine use of image guidance. This research addresses a range of issues but concentrates on the two issues at the forefront of research in this area: first, what are the costs and benefits of image-guided versus blind approaches to Hickman line insertions in adult cancer patients undertaken by nurses?; second, how effectively and over what time frame can the necessary insertion skills be transferred from experienced nurses to trainee nurses? The issue of skill transference is crucial to generalising the results of this research throughout the NHS.

This first chapter serves to introduce the reader to the topic of CVC insertion. Fundamental areas of interest are discussed. Where appropriate, published references have been used to support key statements. A comprehensive review of the published medical literature was undertaken in order to identify relevant clinical papers. The main databases searched (1980–2000) included MEDLINE, EMBASE and CANCERLIT. Only references published in English were retrieved.

Clinical applications of CVCs

In the past, CVCs have been primarily used for long-term parenteral nutrition.[6] However, over the years, indications for their use have continued to expand. Nowadays, common applications for long-term central venous access are prolonged chemotherapy, TPN and haemodialysis. Less common applications include plasmapheresis, antibiotic therapy, iron supplements, vitamins, repeated administration of blood products, fluid replacement and needle phobia.[6–8] Other indications for catheter insertion include poor peripheral venous access, when intravenous therapy involves drugs known to be venous sclerosants, resuscitative intravenous therapy and when ambulatory chemotherapy is to be given as an outpatient procedure.[9]

As more and more patients are being treated for leukaemia, solid tumours, infection and AIDS, the demand for CVCs has risen. Consequently, several different types of central venous access device are available. When deciding which access device is appropriate for the patient, a range of factors must be considered. Hagle and colleagues[10] suggest that both the doctor and the patient have choices to make. The doctor must assess the costs, benefits and clinical risks of the device for the patient. At the same time, the patient must consider the daily maintenance requirements of the device, any cosmetic implications and whether

or not the device will interfere with his or her activities of daily living. The choice of access site is very important. Evidence suggests that patients prefer the non-dominant side for subclavian or upper extremity access. However, for patients who have had previous surgery or radiation therapy to one side, it may be necessary to use contralateral access. Hamilton[8] believes that the choice of venous access device should meet the individual patient's requirement and be based primarily on patient preference.

Types of CVCs

For simplicity, the different types of central venous access device can be broadly categorised as follows: (1) non-tunnelled, (2) tunnelled and (3) implanted infusion ports.[10,11] First, non-tunnelled catheters are designed for short-term use of days to weeks. Typical non-tunnelled catheters include the standard triple lumen (tapered) and Hohn (non-tapered) catheters, midline catheters and peripherally inserted central catheters (PICCs). PICCs are a relatively new venous access device and have lower procedure risk compared with centrally placed tunnelled devices.[7] PICCs are either single- or double-lumen catheters and are often inserted if patients fail to meet the criteria for subclavian line insertion.[9] PICCs are inserted into the basilic or cephalic networks near the antecubital fossae.[12]

Second, tunnelled single- and multi-lumen devices are intended for long-term use of months to years and are inserted either via the subclavian vein, under the clavicle or in the jugular vein in the neck (*Figure 1*).[8] Tunnelled catheter insertions are designed to separate the point of vein entry from the skin exit site. Subcutaneous tunnelling provides greater mechanical stability of the catheter and helps protect against endovascular infection from the skin.[7] The exit site must be chosen carefully as the patient often has to self-care.[13] The optimal tip location of the catheter is in the lower part of the superior vena cava. Most tunnelled catheters have a radiopaque strip that allows the catheter to be visualised on radiography/fluoroscopy.[10] These catheters have a small-circumference cuff made from Dacron. The cuff is positioned within the skin tunnel and engrafts within 3 weeks.

Third, implantable subcutaneous ports are available in single or multiple designs and may be placed via central or peripheral venous access.[7,11] All portions are surgically implanted beneath the skin.[12] Dacron cuffs are found on ports designed for intraperitoneal and epidural placement and long-term plasmapheresis catheters.[11] British Committee in Standards in Haematology (BCSH) guidelines[14] recommend that fully implantable catheters (ports) are more suitable for children and for less frequent but long-term use, whereas non-fully implantable lines are better for short-term use and intensive access.

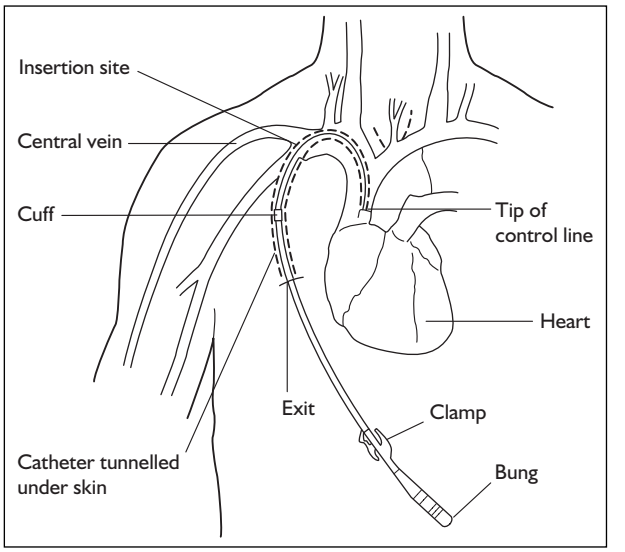

FIGURE 1 *Tunnelled central venous catheter placement. Source: Care of your central venous catheter (Christie Hospital NHS Trust).*

Within each of the above categories, catheter sizes can vary as do the number of lumens. Multi-lumen CVCs facilitate the concurrent administration of different medications and fluids. However, operators (the individual inserting the VAD) often prefer single-lumen catheters because they have been shown to lead to fewer problems for the patient.[15] It has been suggested that double-lumen catheters are linked to a higher infection risk and may become infected earlier in the course of treatment than single-lumen catheters. There are two main explanations for this. First, with two lumens, the catheter is manipulated more frequently, thus increasing the risk of infection. Second, infection may start at the hub and progress intraluminally, which means that double-lumen catheters could present twice the risk of infection regardless of frequency of catheter access.[16] There do exist specific indications that require multiple-lumen catheters. For example, dual-lumen catheters are advantageous in patients undergoing bone marrow or stem cell transplantation or high-dose chemotherapy where a number of agents and blood products require to

be infused simultaneously.[9] Also, recent guidelines recommend that if TPN is being administered alongside other medications or fluids, then one lumen should be used exclusively for this purpose.[16]

Methods of Hickman line insertion

Although there are many different types of central venous access device available, this report concentrates on the insertion of tunnelled Hickman catheters in adult cancer patients via the subclavian vein. There are three main approaches to the insertion of Hickman catheters and these can be broadly categorised as cutdown/surgical approach, radiological percutaneous placement and blind percutaneous placement.

Cutdown/surgical approach

The cutdown/surgical approach is the traditional approach to central venous access. When catheters were first used to provide long-term venous access, the procedure was routinely performed in the operating theatre by surgeons and anaesthetists whilst the patient was under general anaesthesia. The venous cutdown approach frequently uses the cephalic vein to obtain venous access. However, the external jugular vein and the internal jugular vein have been used as insertion sites.[6] Subclavian and femoral veins are also sometimes used. The cutdown technique requires a surgical incision and manipulation of the skin and subcutaneous tissue. The catheter is inserted into the subclavian vein and advanced along the superior vena cava.[4] The ability to see and thus control possible bleeding has been used as an argument in favour of the surgical cutdown technique for catheter insertion. In the mid-1980s, lack of complications associated with the cutdown technique made it attractive to operators.[17] The surgical approach had initially been proved to be safe and effective. However, when compared with the percutaneous technique, the cutdown technique was soon considered to be problematic.[18] Other reported disadvantages associated with this method include lengthy average operating times, a relatively low success rate (approximately 75%), veins being compromised for future use as vessels are not ligated and relatively large entry wounds (5–10 cm). The cutdown approach is also relatively expensive given high operating theatre overheads and surgeons' salaries. Finally, it can be argued that the success of the surgical service very much depends on ample operating room availability in order to ensure that demand can be met.[13]

Radiological percutaneous placement

Interventional radiologists place lines using percutaneous techniques in an interventional X-ray or angiographic suite. The insertion is usually carried out under local anaesthesia and light sedation. Imaging guidance can be used to identify the entry site and/or patient anatomy at various stages during the insertion procedure.[19,20] Image guidance may or may not be used for venous puncture. Depending on the insertion site, ultrasonic vein-locating devices may or may not be of use. Results of a large randomised controlled trial (RCT) concluded that there were no advantages associated with the use of ultrasonic guidance in locating the subclavian vein for catheter insertion.[19] However, the availability of venography, fluoroscopic and ultrasound guidance in the radiology suite can facilitate central venous access for both the patient and the operator.

The main advantages of a radiological service over a surgical service can be described as convenience and excellent patient tolerance.[21] In addition, the use of general anaesthesia as part of the cutdown approach, possible multiple cutdown attempts and postoperative check radiographs only serve to prolong the operative time within the surgical group as compared with radiological placements. Very few lines are misplaced if the procedure is carried out in an interventional X-ray suite as imaging is used to confirm the position of the catheter tip before the procedure ends. Finally, it has been suggested that, compared with operating rooms, interventional radiology suites do not usually carry as expensive overheads and can usually accommodate requests for catheter placement within 24 hours.[13] The main disadvantage associated with this insertion method is that patients are dependent on the availability of skilled interventional radiologists and access to radiological facilities. Adam[4] argues that the demand for interventional radiologists is usually greater than their supply. Mauro and Jacques[13] suggest that most interventional X-ray suites can accommodate most patients. However, evidence supporting this statement is required, especially if hospitals have a high throughput of patients who require central venous access. If waiting times for X-ray suites do exist, then the optimal management of patients can be delayed. Akin to the other insertion techniques available, radiological insertions are associated with morbidity including non-infectious and infectious complications.

Blind percutaneous placement

Blind insertion of Hickman catheters is routinely carried out in a variety of locations and these can

include the operating theatre, at the bedside in a hospital ward or in an outpatient clinic. Image guidance is not used for venous puncture. Instead, the catheter is advanced blindly by the operator to the lower part of the superior vena cava. Accurate placement of the Hickman catheter relies on correct identification of anatomical landmarks. After the catheter has been inserted, a chest X-ray is performed in order to check both the position of the catheter and to identify any pneumothorax, hydrothorax or haemothorax.[22]

The greatest benefit of the blind approach is that, if a suitably qualified healthcare professional is available, then there is no need to wait for gaps in operating theatre or X-ray suite lists. As long as there is emergency access to image-guidance facilities, the procedure itself can be performed in most clean environments. Other purported advantages of the blind percutaneous method over the surgical cutdown approach are similar to the advantages associated with radiological placement: decreased operative time, less morbidity, better primary placement, higher success rates and more accurate positioning of the catheter.[21] Blind percutaneous placement of the catheter also appears to provoke less anxiety in patients as they are often more familiar with their hospital ward surroundings and do not have to fear the operating theatre or the X-ray suite. The main disadvantage associated with blind placement of a central catheter is the risk of catheter-tip misplacement. Although chest X-rays immediately after the procedure identify any tip misplacements, it can take time for the line to be repositioned as the patient will have to wait for an available slot in the X-ray list and this may cause discomfort and inconvenience to the patient.[4] Also, if the insertion procedure is non-routine and the patient has to be moved from the ward to the X-ray suite during the procedure, this might cause some patients to become anxious. Blind placement is also associated with significant morbidity including non-infectious and infectious complications.

Choice of access site for the Hickman catheter

Sansivero[22] states that choosing an access site requires simultaneous consideration of patient, therapy and device characteristics. Options for the access site of VADs include the following: ancillary/subclavian vein, superficial and deep veins of the arm, internal jugular vein, inferior vena cava, cephalic vein and the hepatic veins.[4,11] Parker[3] advises that VADs inserted via the subclavian vein are associated with fewer mechanical complications and have a lower risk of infection than those devices placed in the femoral or jugular veins.

Choice of operator to perform the insertion procedure

There exists a range of possible operators for the insertion of Hickman catheters in adult cancer patients and these include surgeons, anaesthetists, interventional radiologists, medical oncologists and nurses trained in the procedure. As expected, the skills required by the operator have changed in line with advances in the insertion technique. For example, when the cutdown approach was in favour, surgeons and anaesthetists routinely placed Hickman catheters. Now that there exists research to support the insertion of catheters at the bedside, trained nurses are leading some central venous insertion services.[9,23]

The transition from operating theatre to bedside placement of catheters is still taking place. Along the way, interventional radiologists have begun to insert Hickman lines in interventional X-ray suites.[4,24,25] In the past, radiologists were only involved in the manipulation of malpositioned catheters or retrieval of intravascular catheter fragments.[7] However, this role has expanded and radiologists are becoming primary operators in the placement and management of CVCs. The case for interventional radiologists to take on the role of operator is directly related to the research evidence supporting the superiority of the radiological techniques over surgical techniques. In addition, Adam[4] argues that the technique is easy to learn and that most interventional radiologists are already proficient in the use of the equipment required, for example, fluoroscopic or ultrasound guidance.

Nurses are currently being trained to insert Hickman lines and there are three main hospitals across the UK which offer insertion training [Christie Hospital NHS Trust (CHNT), John Radcliffe Hospital and Manchester Royal Infirmary]. Although nursing staff do not routinely place Hickman catheters, there are some cancer centres in the UK whose central venous access service is nurse led. Various studies have been published supporting the extension of the nurse's role in this area.[8,9,23] It can be argued that nurse insertions of CVCs of all types can lead to improved care for patients as a more holistic

approach can be adopted as effort is made to deliver unfragmented patient care. Nurse placements of CVCs at the patient's bedside mean that insertions can take place at the optimal time in a patient's management as waiting lists for consultants, theatres or X-ray suites are no longer barriers to insertion. Nurses are being trained to use fluoroscopic guidance to verify the position of the catheter and the location of the catheter tip during the insertion procedure. Nurses are also using these skills to reposition Hickman lines if blind insertions lead to misplaced catheter tips. It is often more convenient for the patient if a nurse is available to accompany the patient to the interventional X-ray suite and perform the procedure; otherwise the patient would be dependent on the availability of the suite and on a suitably trained doctor.

Regardless of who inserts Hickman catheters, it is generally accepted that operator experience is positively correlated with successful patient outcomes. Indeed, BCSH guidelines[14] state that insertion should be performed by experienced operators, regardless of specialty. McBride and colleagues[21] demonstrated that there exists a steep operator learning curve and that complication rates improve notably after the operator has carried out more than 30 procedures. Indeed, most centres that provide CVC insertion training for nurses demand that at least 30 supervised insertions are performed before the trainee is permitted to work unsupervised. Whether or not there is a need for a dedicated team to provide a comprehensive insertion service is debated in the literature. Wisborg and colleagues[26] compared 140 catheters inserted by three operators and 60 catheters inserted by seven trained operators and found no statistically significant differences between the operators. The authors concluded that even a large pool of operators could achieve acceptable complication rates as long as they are experienced in central venous catheterisation. Fitzsimmons and colleagues[9] demonstrated how an experienced member of staff performing and overseeing Hickman catheter insertions by others can also lead to improved outcomes for the patient and increased success rates for the operator.

Morton and colleagues[27] emphasised the tendency for some senior medical staff to consider the insertion of CVCs to be tedious, leading them to delegate such insertions to more junior members of staff. Such delegation may lead to an increased number of failed insertions.[9] In contrast, others argue that some junior doctors feel that their role and status may be threatened by nurses who are trained to insert Hickman lines, leading certain doctors to insist on performing Hickman line insertions to ensure that they do not lose this valuable skill. Historically, education and training in CVC insertion have been very different for clinicians and nurses. Anecdotal evidence suggests that junior doctors are permitted to 'watch one, do one' whereas nurses have to undertake a formal period of training requiring them to participate in at least 30 supervised insertions.

Complications associated with the insertion of Hickman catheters

Central venous access devices have undoubtedly revolutionised patient cancer care by both extending and improving patient quality of life. However, it must be remembered that the use of CVCs is associated with significant morbidity and is therefore not without limitation. Hickman-related complication and infection rates have been shown to vary depending on the choice of access device, insertion method and site. There exists a variety of procedural complications that can manifest both during and soon after the insertion of CVCs, including catheter-tip misplacement, pneumothorax, arterial puncture, haematoma and failed insertion. Post-procedural complications include line and tunnel infections and thrombosis.

Catheter-tip misplacement

Catheter-tip misplacement is primarily associated with blind puncture of the subclavian vein. Interventional radiologists and, more recently, trained nurses routinely reposition misplaced catheter tips under image guidance. The misplaced catheter tip can usually be repositioned without any additional risk to the patient, that is, the device can be manipulated *in situ*. However, any repositioning may potentially cause the patient some discomfort and inconvenience. Misplaced catheter tips are usually found to be in the neck (jugular vein) or across the midline. Lines across the midline are often easy to flush down into position with saline. However, misplaced lines in the jugular vein are more difficult to reposition as they can require hooking from the femoral vein or reinsertion of a guidewire into the existing line.

Pneumothorax

Most insertion-related pneumothoraces are usually small and manifest shortly after the catheter is inserted. A pneumothorax may resolve

spontaneously, especially if a 21-gauge needle is used.[13] If not, it can be easily treated by a small-bore catheter that is positioned over the apex of the lung; it is then introduced through the second anterior interspace, and is attached to an underwater device (intercostal tube/chest drain). The risk of pneumothorax is particularly associated with blind puncture of the subclavian vein because the operator is solely reliant on anatomical landmarks for the venipuncture.

Arterial puncture

Inadvertent or unrecognised arterial cannulation, although rare, may have serious consequences for the patient. It is therefore important to make sure that the patient is kept under observation by nursing and/or clinical staff for at least 24 hours if accidental arterial puncture occurs.[28]

Haematoma

Haematomas can occur if the needle inadvertently enters the subclavian or axillary artery[13] or if there is bleeding within the subcutaneous tunnel or pocket.[7] If a 21-gauge needle is used there is usually no clinical sequelae to a haematoma.

Infection

Every year, approximately 6000 patients in the UK are diagnosed with catheter-related bloodstream infections.[29] Catheter-related infections following insertion of a CVC vary in severity. Localised infections can occur at the exit site, insertion site or in the skin tunnel. When CVC insertion-related infection is suspected, it is important to locate the origin of the infection.[30] Catheter-related bacteraemia is established if positive blood cultures are obtained from both the catheter and peripheral blood for the same organism, with no other source identified. Most infections can be treated with appropriate antibiotic coverage. However, catheter removal is inevitable for some patients.[31] Evidence suggests that infection rates are no higher when the procedure is performed in the radiology suite than when performed in the operating room.[32,33]

Failed insertion

Failed insertions can occur in both blind and image-guided placements. Rates of failure are usually low. Failure rates associated with blind catheter insertions range from 5 to 9% whereas image-guided failures are usually <2%.[13,20]

Thrombus

Thrombus, like infection, is one of the more serious complications after insertion of a CVC. Removal of the catheter is usually advocated at the same time as anticoagulation treatment.

Reasons for catheter removal

There are a variety of reasons for catheter removal, the most common being that the patient's therapy has been completed and the catheter is no longer required. Other reasons include the following: the patient requests that the catheter is removed, clinical complications necessitate catheter removal (including infection), thrombus or the catheter has become accidentally misplaced or removed.

Analysis of empirical evidence (1980–2000)

A review of 21 empirical studies identified by the comprehensive literature search and published between 1980 and 2000 reveals that in the past there have been three principal foci of research in this evolving field. The first research theme to emerge is the retrospective presentation of case-study results of clinical experience of Hickman line insertions (n = 10). A second theme is the comparison of Hickman line catheters with other types of CVC (n = 7) for the same clinical purpose. The final theme to surface is the head-to-head comparison of a range of different techniques for the insertion of Hickman lines (n = 4). These three foci represent the natural progression of empirical work describing any new healthcare technology. First, there is the need to make sure that the technology works, second, to assess whether it is superior to the other technologies available, and finally, to investigate how the healthcare technology is to be used and by whom.

Case studies of Hickman line experiences

Surgical insertion

In 1990, Claessen and colleagues[34] performed a retrospective analysis of 120 Hickman catheters in The Netherlands. They analysed incidence of complications, risk factors for complications and patient satisfaction; 102 lines were inserted by means of a minor operation by direct vision and 11 by percutaneous puncture; no details were supplied for the remainder. Two patients whose lines were inserted in a minor operation suffered pneumothoraces that required tube drainage. Twenty-eight infections were identified across both groups. Males were found to be associated with a higher rate of infection than females. Patient satisfaction was obtained by questionnaire and was found to be high.

Newman and colleagues[35] retrospectively reviewed 690 Hickman insertions by surgeons. The authors identified 160 exit site infections, 46 tunnel infections and 397 bacteraemias. The authors concluded that the key to improved Hickman catheter management was the establishment of a dedicated team who were responsible for insertion, routine care and management of catheter-associated complications.

Radiological insertion

Several options exist for the insertion of Hickman catheters in an interventional X-ray suite or radiology department. Catheters can be placed percutaneously with radiological guidance on entry and/or on placement of the guidewire. In the late 1980s and 1990s, many studies were carried out in order to demonstrate the superiority of radiological procedures over surgical placements. In all of these papers, some form of real-time imaging, including fluoroscopy, ultrasound, venography or a mix of these techniques, was used.

In 1985, Pessa and Howard[36] analysed data on 157 Hickman–Broviac catheters in 136 patients. Their results demonstrated that although the percutaneous approach with intraoperative fluoroscopy to guide catheter placement was often quicker and simpler to perform, due consideration must be given to complication rates. The authors experienced a 17% intraoperative complication rate with the percutaneous method and this included a 7% chance of arterial puncture and a 2% risk of pneumothorax. Although the authors described two different insertion methods, percutaneous method and cutdown technique, the majority of the results did not differentiate between the two.

Robertson and colleagues[25] reported findings on 60 Hickman catheters placed in a radiology department in the USA. Fluoroscopy was used to determine entry site, confirm intravenous location and check the position of the guidewire. One patient out of 51 was found to have a pneumothorax that required a chest tube drain and an air embolus to the pulmonary artery. One case of arterial puncture was identified which contributed to the patient's death at a later date. Catheter sepsis was confirmed in four patients (2%) and there were four (5%) suspected cases of local infection or inflammation. The authors believed their results to be favourable compared with those of other studies and they support the view that radiological Hickman catheter placement offers substantial benefits over traditional surgical placement.

Page and colleagues[37] demonstrated the usefulness of prior digital subtraction angiography (interventional radiology suite) and video-imaging of the vein (catheterisation laboratory) when performing a Hickman line insertion. Analysis of 31 Hickman catheters placed in 21 patients suggested that radiological placement was an excellent alternative to blind surgical placement. There was only one documented line infection, there were six cases of suspected infection and nine patients had episodes of septicaemia. Only one patient suffered a puncture of the subclavian artery.

In 1991, Wisborg and colleagues[26] prospectively analysed 200 percutaneous placements of CVCs; 181 Hickman catheters and 19 subcutaneous infusion ports were inserted in 172 patients. Eighteen procedures were performed in 15 patients below the age of 4 years. Sixteen patients suffered complications. There were 12 arterial punctures, two failed attempts, one pleural puncture, one person developed transient hoarseness and one line migrated into the right atrium after 24 hours. Three operators performed 70% of the placements; the rest were inserted by seven other experienced anaesthesiologists. There was no difference in complication rates between the two groups of operators, or between children and adults.

Ray and colleagues[38] conducted a review of 560 Hickman catheter insertions in 475 patients. Catheters were inserted by a percutaneous technique using fluoroscopic screening. An anaesthetist of Registrar grade or above inserted Hickman lines. There were nine pneumothoraces (2%), one of which required a chest tube drain, and there were 21 (4%) arterial punctures with no significant consequences. There were 17 (3%) initial failed venous punctures. The results showed that 30% of catheters required removal owing to incidence of complications including sepsis, migration, thrombosis and blockage. The authors support Pessa and Howard[36] as they argue that despite huge improvements in catheter manufacture and care in recent years, it is important to remember that catheters are still associated with significant morbidity.

Teh and Leong[18] described their experiences with 20 Hickman line insertions in adult patients. In the study, the central position of the guidewire was confirmed by fluoroscopy. The authors found that the advantages of using Hickman catheters outweighed any attendant complications.

In 1997, Nightingale and colleagues[39] reported findings from a prospective analysis of 949 long-

term central venous access catheters for ambulatory chemotherapy in patients with gastrointestinal malignancy. Study results revealed that more experienced operators had fewer complications associated with insertion than lesser experienced operators. They also found that catheter insertions in the superior vena cava were more at risk of removal than those placed in the right atrium.

Bedside insertion

In 1994, Morales and Dorta[5] reported their experience with 84 single-lumen tunnelled Hickman catheters which were inserted percutaneously at the bedside in a general oncology ward; 74% of catheters were placed through the right subclavian vein. One case of pneumothorax (1%) and six (7%) arterial punctures were identified. The authors concluded that the placement of Hickman catheters at the bedside was a safe procedure that could be performed by skilled physicians. The authors stated that the advantages of this approach include reduced costs, independence from surgeons and the fact that catheters can be inserted at the optimal time in the patient's management.

Comparison of Hickman lines with other types of CVC

Raaf [40] compared seven types of CVCs. In total, 826 access devices in 681 patients were analysed; 135 catheters were Hickman catheters. When comparing four types of silastic right atrial catheters for vascular access in cancer patients, the authors found that there were no statistical differences in terms of complications. However, the authors concluded that Hickman catheters performed well with an overall complication rate of 17% ($n = 23$) and a relatively small number of catheters were lost because of complications ($n = 7$).

Stanislav and colleagues[41] explored the reliability of Hickman catheters and implantable central venous access devices (ICVADs) in patients with cancer. Forty-four Hickman catheters were placed in 34 patients and were compared with 71 ICVADs in 68 patients. Analysis showed that although there were insertion complications (two arterial punctures and a pneumothorax), none required treatment. The study results demonstrated that complications necessitated removal of 39% of Hickman catheters and 18% of ICVADs. Complication rates were calculated as one in 501 days for the Hickman group and one in 1450 days for the ICVAD group. The authors concluded that the ICVAD should be the preferred type of CVC for patients with cancer.

In 1991, Gray[33] evaluated data on 252 indwelling CVCs that had been placed within a radiology department; 139 catheters were placed for haemodialysis of renal failure patients and 123 Hickman–Broviac catheters were inserted in 99 patients for a variety of reasons including TPN, chemotherapy, intravenous antibiotics and plasmapheresis. Hickman–Broviac patients suffered seven (5%) pneumothoraces, four of which required chest tube drains, whereas there were no cases of pneumothorax in the haemodialysis group. There was more bleeding (7/1), failed catheters (28/0) and suspected infections (10/6) in the haemodialysis group than in the Hickman–Broviac group. The authors concluded that their figures can be used to support the placement of CVCs by interventional radiologists in a radiology department.

A study comparing Groshong with Hickman catheters was published in 1992 by Pasquale and colleagues;[42] 55 Groshong catheters and 53 Hickman catheters were inserted during the study period. There was an overall complication rate of 71% for Groshong catheters compared with 42% for Hickman catheters. Catheter infections were recorded for 13% of the Groshong group and for 11% of the Hickman group. On the basis of their results, the authors concluded that the Hickman catheter was superior to the Groshong catheter.

In 1992, Meuller and colleagues[43] carried out a prospective RCT to compare infectious and non-infectious complications of Hickman catheters versus Port-a-Caths. Data were available on 46 patients randomised to receive a Hickman catheter and on 46 patients randomised to receive a Port-a-Cath. Nineteen patients in each group did not experience any complications. Of the Hickman catheter complications, 42% were infection-related, compared with 21% in the Port-a-Cath group. Eleven complications in each group led to the removal of the device line. The authors concluded that there was no difference between the two study groups in terms of documented infections or mechanical or thrombolitic complications.

Sharpe and Morris[44] compared three different types of central venous catheters in terms of septic and non-septic complication rates. Forty-three patients were included in the study: 17 in group A (Hickman line), 20 in group B (Port-a-Cath) and 11 in group C (Pasport). *Table 1* provides a summary of the study results.

TABLE 1 *Comparing outcomes from three different types of CVC*

	Group A	Group B	Group C
Cumulative total days	2757	6857	3120
Complication free	10 (59%)	15 (75%)	8 (73%)
Sepsis complication	5 (30%)	3 (15%)	1 (9%)
Non-sepsis complication	2 (12%)	2 (10%)	2 (18%)

TABLE 2 *Sonographic versus blind insertion outcomes*

	With sonographic guidance on entry (n = 40)	Without sonographic guidance on entry (n = 40)
Unsuccessful catheterisation	0	2 (5%)
Pneumothorax	0	3 (7.5%)
Haematoma	0	1 (2.5%)
Bleeding at entry site	2 (5%)	2 (5%)
Local infection	1 (2.5%)	0
Thrombosis	1 (2.5%)	0
Catheter sepsis	10 (25%)	14 (35%)
Occlusion	0	2 (5%)
Migration	2 (5%)	2 (5%)

The authors concluded that although the three types of catheter under investigation improve quality of life, septic complications remain a significant problem.

Kincaid and colleagues[45] published a report of 589 blind placements of long-term central venous access devices; 278 tunnelled and 280 non-tunnelled catheters were placed percutaneously in an outpatient setting without the use of real-time imaging. Several different catheter types were used, including the Hickman catheter. Catheter misplacement occurred in 16 patients (3%) and the incidence of pneumothorax was 2%. Data analysis showed that late complications, including infection and thrombosis, occurred in 9% of patients. The authors also estimated the costs of placing a single-lumen Port-a-Cath at the bedside, in the operating room and in a radiology department. They concluded that routine placement of central venous access devices in an outpatient setting yields favourable results and should be subjected to further investigation.

Comparing different settings, operators and techniques for Hickman insertions

Lameris and colleagues[20] compared 40 sonographically guided and fluoroscopy-controlled Hickman procedures with 40 blind percutaneous punctures and fluoroscopy-controlled catheterisations. Key results from the study are presented in *Table 2*.

The authors concluded that sonographically guided insertion was the preferred method of insertion as it appeared to lead to improved outcomes including increased success rates and reduced puncture-related complications.

In 1994, Mansfield[19] addressed a similar question to that of Lameris and colleagues.[20] They conducted an RCT trial to compare ultrasound-guided location of the subclavian vein (n = 411) compared with standard insertion procedures (n = 410). They found that the use of ultrasound techniques did not influence the rate of complications or failures of subclavian vein catheterisations. The authors reported a 12% (n = 51) failure rate in the ultrasound group and 12% (n = 49) in the control group. As the use of ultrasound guidance was demonstrated to have no effect, all patients were considered together in the evaluation of other risk factors for adverse outcomes. In total, 10% of patients (n = 80) had complications and these included misplacement (n = 49), arterial puncture (n = 30), pneumothorax (n = 12) and mediastinal haematoma (n = 5). Sixteen patients were identified as having more than one complication. The strongest predictor of a complication was a failed insertion attempt. The trial was designed to recruit 1100 patients;

TABLE 3 *Comparing radiological insertion with surgical insertion*

	Radiology (%)	Surgery (%)
Two attempts	0	10 (7.5%)
Three attempts	0	5 (3.7%)
Five attempts	0	2 (1.5%)
Primary failure	0	6 (4.6%)
Pneumothorax	4 (3.3%)	1 (<1%)
Local bleed/haematoma	2 (1.7%)	3 (2.3%)
Primary misplacement	0	5 (3.7%)
Cerebrovascular accident/ death	0	1 (<1%)
Catheter infection	20 (17%)	33 (24.8%)
Tunnel infection	7 (5.8%)	17 (12.8%)
Removed early	50 (41.6%)	76 (57.1%)

TABLE 4 *Comparing cutdown and percutaneous outcomes*

Complication	Cutdown technique (n = 65)	Percutaneous technique (n = 112)
Excessive bleeding	40 (61%)	9 (8%)
Haematoma formation	27 (41%)	0
Malposition	3 (4%)	6 (5%)
Pneumothorax	0	6 (5%)
Catheter thrombosis	6 (9%)	8 (7%)
Exit site infection	17 (26%)	8 (7%)
Tunnel infection	12 (18%)	0

however, the trial was stopped after the interim analysis (n = 824) showed that ultrasound guidance had no effect on complications.

A comparative analysis of radiological and surgical placement of CVCs was conducted by McBride and colleagues.[21] Retrospective analysis of Hickman catheters was carried out in order to explore differences in practice and outcomes of radiologically and surgically placed catheters; 120 catheters were placed radiologically in 102 patients and 133 were placed surgically in 107 patients. *Table 3* provides a summary of important outcome measures.

The authors concluded that radiological placement was consistently more reliable than surgically placed catheters. The authors demonstrated that radiologically inserted catheters were associated with fewer placement complications, except for pneumothorax and haematoma, and fewer catheter infections overall.

Ahmed and Mohyuddin[46] retrospectively investigated complications associated with different insertion techniques for Hickman catheters. They compared 65 tunnelled Hickman insertions via the cutdown method with 112 non-tunnelled percutaneous insertions. Key clinical outcomes are summarised in *Table 4*.

The authors stated that their results were indicative of the fact that minimal dissection and therefore percutaneous insertion without tunnelling should be the technique of choice for catheter placement.

Review of health economics literature

To date, few published articles describing CVC insertions in adult cancer patients have given any consideration to economic or costing issues. A comprehensive search of electronic databases, including MEDLINE and NHSEED, identified only eight papers and one letter, published in English, that had included any quantitative reference to costs in the last 15 years. The majority of the studies summarised below provide inadequate methodological detail on costing issues. Consequently, the reader is unable to judge the quality of the economic analyses presented. Only one study is described as a cost-effectiveness analysis[47] and it is this article that provides the most useful economic data. It is noted that there have been no economic evaluations or published RCTs comparing operators or locations for the insertion of Hickman lines in adult cancer patients.

Neuman and Murphy[47] set out to compare bedside intravenous nurse insertions of PICC lines with interventional radiologist insertions of PICC lines under fluoroscopy and/or venographic guidance. The authors state that the cost-effectiveness of PICC insertions depends on (i) the ability of the intravenous team to access a vein at the patient's bedside, (ii) the cost of fluoroscopy or interventional radiology suite and (iii) the intended use of the PICC. The authors conclude that cost-effectiveness analysis should be tailored to the characteristics of individual institutions in order to determine the optimal strategy. No definitive cost-effectiveness ratios were presented. Ratios were presented as a function of the cost of the interventional radiology suite for varying levels of useable access.

Kyle and Myers[48] compared the average placement costs of PICCs (US$265), implanted ports (US$1020) and tunnelled catheters (US$1155).

Hamilton[2] suggested that nurse-led Hickman line insertions were cost-effective compared with Hickman line insertions by medical staff. It was estimated that inserting a Hickman line in the operating theatre by a surgeon would cost £450 whereas a line inserted by a nurse on the ward would cost £150. However, it is not clear whether or not the cost of treating complications was included in these figures.

Raad and colleagues[49] compared tunnelled CVCs with non-tunnelled silastic CVCs. The authors found that, given the low infection rate and long durability of non-tunnelled silicone CVCs, these catheters could offer a cost-effective and safe alternative to surgically implantable tunnelled catheters. When compared with the tunnelled Hickman catheter, there was an estimated insertion cost saving of US$2322 per CVC. Scarpinato[50] suggested that Raad and colleagues[49] had underestimated these figures as they had not included the cost of catheter removal. Scarpinato[50] proposed that the true cost saving per CVC would be US$4600.

Thomson[51] published a financial feasibility study to compare peripheral catheters with midline catheters. A retrospective audit was performed to address the question 'does the midline catheter really provide significant cost savings overall?'. Thomson concluded that use of the midline catheter could lead to substantial cost savings (US$11,844 in 23 patients) when compared with the cost of multiple peripheral venipunctures.

Foley[52] advocated the placement of lines and ports by interventional radiologists instead of surgeons. He argued that more accurate catheter placement, improved patient safety, acceptable complication rates and reduced costs constitute support for the placement of lines by radiologists.

Kincaid and colleagues[45] stated that the average procedure-related fee for insertion of a single-lumen central venous Port-a-Cath in an outpatient setting was US$1691 versus US$4559 in the operating theatre and US$3890 in the radiology department. These prices do not include any subsequent interventions that were related to the procedure but which took place post insertion.

Finally, in a comparison of hospital with home CVC survival, Melville and colleagues[53] suggested that if home sepsis rates could be achieved in the hospital setting, there would be considerable cost savings to the NHS.

Summary of published literature

Much of the published literature in this important area is descriptive in nature. This review of the literature reveals that relatively few comparative studies have been conducted. Not only is there a paucity of published economic evaluation results, but also there are few published RCTs which address the following key issues: (i) choice of insertion method, (ii) location of insertion procedure and (iii) choice of operator. These three issues are central to the current debate about the most clinical and cost-effective method of Hickman line insertion in adult cancer patients. Reporting standards for central venous access have recently been published.[54] These guidelines have been designed to facilitate consistent reporting of clinical trial results so that true comparisons among studies can be made. It is clear from the review of the literature undertaken in this report that these guidelines are both timely and appropriate. There is currently much debate in the NHS about who should be responsible for the insertion of CVCs, yet this issue is not reflected in the literature. To date there are no comparative published studies involving nurses, yet it is nurses who are the most recent group of healthcare professionals to be trained to insert CVCs. Although the trial in this report does not compare the performances of different types of operator, it does compare two different methods of Hickman line insertion by nurses and should therefore be a useful addition to the evidence base.

Rationale for the study

As the range of indications for the use of CVCs expands, the number of eligible patients requiring CVCs will rise. Consequently, there will be a parallel increase in the demand for healthcare resources to fund central venous access services, be they hospital- or community-based schemes. Evaluation of both the costs and benefits of such services is essential if resources are to be targeted in a manner that generates maximum clinical benefits to patients. A key component of any central line service is the efficient organisation and delivery of the CVC insertion service. Every effort must be made to ensure that Hickman line insertions are carried out at the optimal time in the patients' management in order to minimise the risk of adverse health outcomes for the patient. If scarce healthcare resources are to be invested in the timely delivery of cost-effective insertion services, then the following organisational issues must be addressed:

1. Which is the safest and most cost-effective method/setting for the insertion of Hickman lines in adult cancer patients?
2. Which operators provide the safest and most reliable source of expertise in the insertion of Hickman lines in adult cancer patients?

Clearly, the answers to such questions are important from both economic and clinical perspectives. First, from an economic perspective it is clear that as the range of indications for Hickman lines widens, the demand for Hickman lines will grow. For example, recent evidence has shown that new treatments for cancer and HIV/AIDS have already led to a dramatic increase in the demand for Hickman line insertions. It is vital, therefore, to determine which of a range of options for Hickman line insertion is the most cost-effective.

Second, it is imperative that NHS hospitals provide adequate training for their staff in this procedure. Inadequate training may mean that Hickman-related complication and infection rates are higher than necessary and this translates into a poor quality service for the patient. In addition, the costs of treating complications and infections are considerable. Although very few patients die as a direct result of a Hickman line insertion, the clinical complications for the patient can be very serious, especially in the field of cancer, where it might mean the delay of chemotherapy treatment. Also, as new nursing posts are being created (e.g. clinical nurse specialists and nurse consultants), the number of nurses with CVC insertion skills is rising. Performance monitoring and evaluation of both medical and nursing operators are then required if clinical governance issues are to be addressed. The development of a training programme which includes core competencies and expected standards of practice to improve the quality of Hickman line insertions could yield important benefits to both patients and healthcare professionals in the NHS. This report therefore evaluates the potential contribution of nursing staff to the improvement of patient care in the NHS as their role expands to include the insertion of Hickman lines at the bedside and under image guidance.

Study setting: CHNT

The CHNT in Manchester provides an ideal setting from which to address both the clinical and economic questions outlined above. At CHNT, the preferred method of Hickman line insertion is bedside placement for routine procedures with access to image-guidance facilities if required. Pre-1995, junior doctors were primarily responsible for the insertion of Hickman lines in the Haematological Oncology Department at CHNT. However, as a result of inadequate training and sporadic supervision by more senior staff, the organisation and delivery of the service were poor and waiting times for the procedure were long.[9] Consequently, patients suffered as maximum health benefits were not being realised.

In an effort to address clinical concerns, a clinical nurse specialist (CNS) was employed and trained to insert Hickman lines. Once experienced in the procedure, the CNS was responsible for the training and supervision of junior medical staff. The CNS was also responsible for the coordination of the central venous access service across the Departments of Haematology Oncology and Medical Oncology.

Since 1996, the profile of the CNS has grown significantly and in 1998 she was responsible for carrying out approximately 90% of all Hickman line insertions, approximately 670 per year, at CHNT. However, as the service continued to expand, the demand for Hickman line insertions was greater than supply. Supply was constrained by the lack of trained staff at CHNT available to carry out the procedure on a regular basis. Before the trial, all Hickman lines inserted by the CNS were performed at the patient's bedside. If an image-guided insertion was required, then the patient was referred to an appropriately trained consultant. At the same time, awareness of evidence-based medicine and clinical governance issues meant that staff at CHNT were keen to explore the costs and benefits of image-guided versus blind insertion Hickman line insertions.

Key nursing and medical staff at CHNT, in collaboration with health economists at the University of Liverpool, decided to apply for HTA funding. A proposal was submitted with twin aims: (i) to carry out an economic evaluation alongside an RCT to compare image-guided and blind Hickman line insertions and (ii) to evaluate a nurse training programme for the insertion of Hickman lines both at the bedside and under image guidance. The HTA application was successful and the primary research carried out as a result forms the basis of this final report.

Hypotheses and clinical objectives of primary clinical research

As outlined in the grant application submitted, the aim of the RCT was to examine the clinical and cost-effectiveness of image-guided Hickman line insertions versus bedside Hickman line insertions performed by nurses in adult cancer patients. The primary hypothesis was that, other than catheter-

tip misplacement, there were no real differences between the two insertion approaches. The secondary hypothesis was that, once trained, trainees could insert Hickman lines with the same level of competency as the trainer. The clinical objectives of the trial were to identify success rates and also frequency and severity of clinical complications in each of the trial arms. Comprehensive data analysis on image-guided versus blind insertions was planned together with subgroup analysis focused on comparisons between the three nurses (two trainees and trainer).

Aims and objectives of the study

The three stated principal objectives of the study were as follows:

1. to compare the performance of the CNS and junior doctors in the insertion of Hickman lines
2. to compare the marginal costs and benefits arising from image-guided versus blind insertion of Hickman lines
3. to identify the training requirements that will enable the benefits (if any) of the nurse training programme to be reproduced throughout the NHS.

Within these three broad objectives, a range of specific research objectives were also identified:

1. to evaluate the net incremental resource implications of routine use of image guidance for Hickman line insertion in comparison with blind insertion
2. to evaluate the safety and efficacy of the two treatments under investigation
3. to evaluate variations in other treatment outcomes, for example, patient satisfaction
4. to document the frequency and implications of complications and other significant clinical factors related to Hickman line insertions by nurses
5. to assess the incremental cost-effectiveness ratio underlying Hickman line insertion in specific subgroups of patients in both treatment arms
6. to assess the generalisability of patient benefits and resource savings arising from nurse-inserted Hickman lines throughout the NHS.

The null hypotheses of the study were that there would be no difference in:

1. outcomes (except for frequency of catheter-tip misplacement) between the two arms of the trial
2. the costs associated with the interventions in the two groups.

The majority of the research aims and objectives were achieved. However, a comparison of the insertion skills of the CNS and junior doctors was not undertaken. This was primarily because a direct evaluation of CNS and junior doctor insertion performances had previously been carried out at the CHNT and a summary of the research report has been published.[9] In brief, this paper demonstrated that rates of failed insertions, complications, infections and waiting times at CHNT were lower for the CNS than for the junior doctors. Patient satisfaction was also shown to be higher for the CNS than the junior doctors. As the result of these findings, the CNS has been responsible for the training and supervision of all junior doctors who are interested in CVC insertions. Consequently, the performance of junior doctors has improved substantially with both complications and failure rates falling. Based on this information, the research team believed the continued funding of the CNS post to be evidence enough to support the superior skills of the CNS as compared with JDs at the CHNT.

Chapter 2
Methods

This chapter is divided into two main parts. The first part describes the methodologies employed to collect primary data and is divided into four separate sections: overview of nurse training programme, evaluation of the RCT, collection of NHS resource use data and survey of patients' views. The statistical approach planned is also outlined. The second part describes the economic evaluation method used to analyse the primary data collected. An outline of the statistical methods employed is also presented. Finally, a simple arithmetic exercise is described in order to estimate the effect of increasing the number of nurse insertions on the total annual costs of Hickman line insertions in cancer centres and units in England and Wales.

Overview of nurse training programme

Recruitment of trainees

Two qualified nurses were recruited as trainees to the CHNT. Two nurses were recruited in order to ensure the viability of the RCT if one trainee were to pull out of the training programme unexpectedly. There were 12 applicants for the posts, six of whom were short-listed and called for interview. Contracts were initiated on 1 January 1999. The trainee nurses were contracted to complete the 3-month training programme and also to participate in the RCT. The trainee nurses were also expected to provide hands-on support to the CNS in related clinical areas. Neither of the nurses had previous working experience of CVC insertion.

Hospital organisational requirements

Hickman line insertions are not routinely carried out by nursing staff, but are usually carried out by medical personnel. This expansion of the traditional role of the nurse means that there exist certain documented requirements to which employer and employee must adhere. The contract signed by the trainees explicitly stated that they were permitted to insert Hickman lines in adult cancer patients as required by the CHNT.

Supervisors to the trainees

Throughout the training period, a range of key personnel were identified to give advice and guidance to the trainees if support was required (Nurse Executive Director, Senior Nurse Manager, Consultant Medical Oncologist, Director of Radiology, Consultant Radiologist and Clinical Nurse Specialist). However, it was the CNS, mentor and teacher, who had day-to-day contact with the trainees and was responsible for designing, coordinating and delivering the training programme.

Timetable

The timetable of the training programme was very flexible. From the onset it was agreed that the initial estimate of a 3-month training programme need not be rigid – that more or less time could be spent on the nurse training programme as required. The CNS felt that the number of observed, supervised and unsupervised central line insertions was the most important factor in the education of the trainees, and not the number of weeks spent in training. However, as it turned out, the trainees were trained for the estimated 12-week period. The trainees spent the initial stages of the training programme observing the CNS insert lines, they then progressed to insert lines under the direct supervision of the CNS and then finally they inserted lines without supervision.

Training programme for blind insertion of Hickman lines

The nurse training programme was designed by the CNS in conjunction with key medical and clinical oncology personnel at the CHNT. The training programme was based on the training programme that the CNS had herself undertaken a few years previously. The training programme was divided into four key phases. The aims and objectives for each phase are outlined in Appendix 1. In summary, the trainee nurses spent the first 2 weeks familiarising themselves with their new work environment and studying relevant central line insertion literature. The CNS gave the trainees seminars on central line insertion-related topics. From week three onwards, both trainees

became actively involved in insertion procedures as they observed, participated in and completed Hickman line insertions. Although more than 100 lines were inserted at the CHNT during this 12-week period, it was inappropriate for the trainees to be involved in all of the insertion-related procedures. This was due to a variety of reasons, for example, CNS and patient preference, patient health status and trainee nurse workload.

Training for image-guided insertion of Hickman lines

Both trainer and trainees undertook external training before they were permitted to insert Hickman lines in patients with the use of image guidance in the X-ray department. All three nurses attended a training day in order to complete the 1-day course 'Training in Radiation Protection related to Diagnostic Radiology'. This course is approved by the Royal College of Radiologists and covers 'core of knowledge' as detailed in the regulations. During the 3-month training period, staff in the Department of Diagnostic Radiology at the CHNT briefed nurses on procedures in the X-ray department. Guidelines regarding image-guided Hickman line insertions in the form of a working protocol were drawn up by diagnostic radiology staff in order to ensure patient and professional health and safety at all times. Nurses were also given a copy of Diagnostic Radiology Local Rules.

Type of CVCs inserted

Nurses were trained by the CNS to insert a variety of central venous lines, including single-, double- and triple-lumen Hickman lines and also PICCs. It was appropriate for nurses to be trained to insert PICCs because if a patient is not eligible for a Hickman line, a PICC is often inserted in order to gain temporary venous access. Or, if the operator attempts to insert the Hickman line but fails, then a PICC is often inserted if venous access is required immediately. The CNS also trained the nurses to remove Hickman lines and PICCs.

Complications

Every Hickman line insertion procedure carries the risk of complication(s) occurring. It was anticipated that some complications would arise during the course of the training period. Most frequently occurring complications are catheter-tip misplacement, pneumothorax, arterial puncture, haematoma, infection and failed insertion. As the CNS was present during most of the procedures and especially in the early stages of the training programme, all appropriate action was taken to ensure patient safety.

In-house assessment

In-house assessment of the competency of the two trainee nurses was carried out at the end of the 3-month period. A consultant oncologist experienced in Hickman line insertion assessed each nurse as she inserted a Hickman line blind at the bedside. A consultant interventional radiologist assessed each nurse as he or she inserted a Hickman line under image guidance in the interventional X-ray suite. Each consultant asked each nurse pertinent questions before, during and after insertions. The CNS was not present for any of the procedures that were assessed. Following the successful completion of the assessment, both internal assessors signed statements that the two trainees were competent to perform blind and image-guided insertions of Hickman lines.

External assessment

A consultant oncologist from St James' Hospital in Leeds, who is experienced in blind Hickman line insertions, conducted the external assessment. The external assessor was present at the blind insertions and undertook rigorous evaluation of the practical abilities and theoretical knowledge of both nurses. Following successful completion of the assessment, the external assessor signed a statement that the two trainees were competent to perform blind insertions of Hickman lines. There was no need for the external assessor to assess the image-guided insertions as they were performed in exactly the same manner as the blind insertions.

Evaluation of nurse training programme

A diary was kept of all (blind and image-guided) trainee Hickman line insertions during the 3-month training period. This information was documented in order to ensure that an accurate description of all trainee Hickman line insertions (number and type) was available. Any clinical complications that occurred and their outcomes were also recorded and analysed. The information was collected as part of a quality assurance exercise to ensure that the training programme was able to equip the nurses with the necessary insertion skills and that patients did not suffer any major adverse effects during the training period.

Cost analysis

A cost analysis was undertaken to estimate the resources incurred during the 3-month training period. The cost analysis was carried out from the perspective of the NHS. Costs of the nurse training programme were categorised as follows:

salaries, training courses, use of X-ray suite, clinical complications and travel expenses.

Salaries

Three months' salary costs of the two trainee nurses were included in the cost of the training programme. In addition, 1 month's salary of the CNS was also included as an estimate of the replacement cost of time used. If the CNS had not participated in the nurse training programme, she would have spent one-third of her time performing bone marrow procedures and acting as a resource for training and supervising junior doctors. In her absence, another member of staff carried out bone marrow procedures. This replacement cost is therefore an estimate of the opportunity cost of the CNS's time.

As part of the training programme, two consultant oncologists and a consultant radiologist formally assessed the skills of the trainee nurses. Salary costs for half a day for each of the assessors was therefore included in the total costs of the training programme. During the training programme, staff in the Department of Diagnostic Radiology at CHNT briefed nurses on procedures to be carried out in the X-ray suite. Therefore, half a day's consultant radiologist salary was also included in the total costs of the nurse training programme.

Training courses

All three nurses (trainer and trainees) attended a training day in order to complete the 1-day course 'Training in Radiation Protection Related to Diagnostic Radiology', the fees for which were included in the cost analysis.

Use of X-ray suite

As the nurses would have to insert Hickman lines under image guidance in the interventional X-ray suite as part of the RCT, they observed and participated in 15 image-guided Hickman line insertions during the period of the training programme. In normal circumstances, these 15 lines would have been inserted at the bedside. Therefore, the X-ray suite charges for these lines were included in the total costs of the nurse training programme.

Clinical complications

As some clinical complications were expected during the training programme, the cost of treating these complications was considered. However, as a proportion of these complications would have occurred under normal circumstances, a cost estimate based on the CNS's actual performance within the RCT was calculated. It was estimated that the cost of treating two misplacements and three pneumothoraces would be over and above what was expected in the trial and these were therefore included as part of the costing exercise.

Expenses

The expenses of the external assessor were also paid, as were travel and subsistence costs to the three nurses on their radiation protection training course day.

RCT

The study was a prospective RCT that aimed to measure any difference in effectiveness between the image-guided approach and bedside approach to Hickman line insertions by nurses in adult cancer patients.

Ethical approval and support for the project

Ethical approval was sought and obtained from South Manchester Medical Research Ethics Committee. An advisory committee to the project was also set up before the trial commenced. Key stakeholders from the CHNT and the University of Liverpool made up this small group and included nursing and medical staff, health economists and statisticians.

Trial population

All of the patients who were recruited for the study during the period April 1999 to May 2000 were cancer patients attending the CHNT. At the CHNT, patients can be admitted for Hickman line insertions as either inpatients or day-case patients depending on a variety of factors such as patient preference, patient health state, patient residence and consultant recommendation. The recruited patients were a mix of both inpatients and day-case patients. However, the procedure itself is classified as a day-case procedure. Patients were both male and female and were diagnosed with either haematological or solid tumour cancers. Patient inclusion and exclusion criteria to the RCT are listed in *Box 1*. All patients who were not eligible for the trial were labelled as off-study patients. The same information was collected for off-study patients as was collected for those patients who were recruited to the trial.

Interventions

The aim of both interventions was to obtain central venous access for the patient. The two interventions under investigation were (i) blind

BOX 1 *Patient inclusion and exclusion criteria*

Inclusion criteria

>18 years of age
Referred for Hickman line insertion
Patient able to lie flat and be compliant
Platelets ideally $>100 \times 10^9$/l, not less than $<75 \times 10^9$/l

Exclusion criteria

Patient too ill – nurse assessment
Patient refused consent
X-ray facilities were unavailable on request
Patient had a failed previous insertion attempt within 24 hours
Patient had poor haematological profile
Other

insertion of a Hickman line and (ii) image-guided insertion of a Hickman line. In the trial, blind insertion of a Hickman line took place at the patient's bedside whereas the image-guided insertion of a Hickman line took place in the interventional X-ray suite. Both interventions involved blind venipuncture of the subclavian vein. In the blind arm, the Hickman line was routinely inserted without the use of image guidance at any point in the procedure. However, transfer to the interventional X-ray suite and use of image guidance were options immediately available to the operator during the procedure if required. In the image-guided arm, the position of the guidewire was checked before the Hickman line was introduced and the Hickman line was positioned with the use of X-ray fluoroscopy (i.e. the location of the Hickman line was checked using image guidance during the procedure and any misplacement of the tip was then rectified before the procedure was completed). Patients in both arms of the trial had chest X-rays after the procedure in order to identify any possible pneumothoraces. All activities in the X-ray suite were recorded in a log book after the procedure was performed. The information recorded included the amount of time spent using the fluoroscopic facilities. In the interests of safety, a pre-set alarm was activated if the screening time was over 5 min.

Informed consent

Patients were given an information leaflet describing the Hickman line insertion procedure and a description of what was required from patients participating in the trial. The nurse read through the information leaflet with the patients and gave the patients an opportunity to ask questions or raise concerns. Patients were then left alone to consider whether or not they wanted to participate in the trial. Patients were made aware that they could withdraw from the trial at any time without having to give a reason. In order to check that the information given to patients was complete and that consent was fully informed, the issue of informed consent was addressed within the patient satisfaction questionnaire (Appendix 2). As patient consent was obtained before randomisation, the nurse taking consent may or may not have been the nurse to whom the procedure was randomised.

Randomisation

Patients who were eligible for the study were randomly assigned to either Hickman line insertion at the bedside or Hickman line insertion under image guidance and to one of the three nurses. Patients were recruited to the study by the nurses involved in the RCT. Randomisation was to both procedure mode (blind or image-guided insertion) and to nurse (nurse1, nurse2 or nurse3).

To clarify further, if all three nurses were available then the randomisation was to a substudy labelled central line insertion project 3 CLIP3 – this study had six trial arms:

Nurse	*Procedure mode*
1	Blind
2	Blind
3	Blind
1	Image-guided
2	Image-guided
3	Image guided

If, however, only two nurses were available then the randomisation was to a substudy labelled CLIP2 – once the available nurses were re-labelled A and B, this study had four trial arms:

Nurse	*Procedure mode*
A	Blind
B	Blind
A	Image-guided
B	Image-guided

Finally, if only a single nurse was available, the randomisation was to a substudy labelled CLIP1, which only had two arms:

Procedure mode
Blind
Image-guided

In the instances where entry was to either CLIP1 or CLIP2, the names of the unavailable nurse(s) and also the reason for their absence were

recorded at the time of randomisation. The procedure was a valid one provided that:

1. Nurse unavailability was not manipulated.
2. Selection bias was guarded against, that is, all eligible cases continued to be entered into the trial when only one or two nurses were available.

The reasons for nurse unavailability were recorded and were consistent with the practicalities of working lives. The second aspect is difficult to ensure. However, comparison between the case series in CLIP1 and CLIP2 did not reveal any marked differences in the case mix of the two substudies.

After the nurse taking consent had checked that the patient was eligible for the trial, that the X-ray suite was available and that the patient had given informed consent, one of the nurses involved in the RCT telephoned the Clinical Trial Support Unit (CTSU) to find out how the procedure was to be performed and by whom. Computerised randomisation was carried out centrally by the CTSU at the CHNT. There was complete separation of the people involved in the generation and implementation of allocations. A minimisation algorithm with an additional random element was employed to ensure that the numbers of participants in each of the trial arms was closely balanced within each of the following strata: diagnosis, single- or double-lumen line and pre-booked or emergency patients.

Information communicated over the telephone to the randomisation centre by the nurse included: patient characteristics (name, date of birth, hospital number); patient's consultant; planned number of lumens; emergency or planned insertion and which of the three nurses were available. The patient was then randomised to either blind or image guidance and to a specific nurse. If there was only one nurse available for randomisation, then this group of patients was labelled as CLIP1; if there were two nurses available for randomisation, CLIP2; and if there were three nurses available for randomisation, CLIP3. There was no significant time delay between allocation and randomisation; the procedure was started within 10 minutes of allocation. The nursing staff kept a diary and recorded which patients were allocated to which arm of the trial on which date. Post-randomisation, this diary was cross-checked with the randomisation database allocations.

Protocol violations

Before the RCT commenced, a list of possible protocol violations was compiled and included the following: patient being randomised twice, insertion procedure being interrupted and completed by a different nurse, X-ray suite in use, image-guided facilities out of order, only one nurse being available for randomisation. All protocol violations that occurred during the RCT were recorded.

Blinding

It was impossible to conceal the outcome of randomisation from the patient or the operator as both parties had to be in the same room at the time of the insertion procedure. The analyst was not blinded to the outcome of randomisation at the time of analysis.

Sample size and power

Two separate sample size calculations were performed in order to ensure that the trial had a sufficient number of subjects to address the two principal research questions of interest using the conventional levels of statistical significance (95%) and power (80%).

1. To assess the procedure mode, that is, blind versus image-guided insertion, the primary outcome measure was chosen to be the misplacement rate. With 200 cases in each arm, a one-tailed test at the 5% level of significance would have approximately 80% power if the true malposition rate were 0.5% under image guidance and 5% under blind insertion.
2. To assess nurse skill, the primary outcome measure was chosen to be the pneumothorax rate. The main comparisons would be performed separately for each trainee against the nurse specialist. With 150 cases for each nurse, a one-tailed test at the 5% level of significance would have approximately 80% power if the true pneumothorax rate were 2.5% for the nurse specialist and 10% for a trainee (the power rising to 95% if the true trainee rate was as high as 13.5%). Additionally, with 150 insertions, if the rate were approximately 10% then the precision of the estimator would be approximately $\pm 5\%$ to facilitate comparison with national rates.

To accommodate both of these requirements, it was planned to allocate 75 patients to each nurse/procedure mode combination (i.e. 450 cases in total).

Analysis of data

The analysis of the data was conducted on both an intention-to-treat and a per protocol basis. The results of the intention-to-treat analysis are

presented in the main body of this report. Two different intention-to-treat analyses are undertaken in order to answer two different questions. All of the randomisations were included in the comparison of blind and image-guided insertions. Only the randomisations in CLIP2 and CLIP3 were included in the comparison of nurse skill as CLIP1 patients were not truly randomised to a nurse as there was only one nurse available at the time of randomisation.

Subgroup analysis

The study has the two main modes of comparison:

1. procedure mode (blind versus image-guided insertion) – primary analysis
2. nurse skill (trainer versus trainees) – *a priori* subgroup analysis.

The assessment of procedure mode can be validly made using all of the randomisations. However, the assessment of nurse skill can strictly only be made using data from CLIP3. Owing to a 3-month period of sickness of the CNS during the period of the trial, the number of patients recruited to CLIP3 was not as high as was previously anticipated. After statistical advice was sought, it was believed that no bias would result from also including the CLIP2 randomisations in the analysis of nurse skill.

Exploratory analysis

Although not stated beforehand, further exploratory analysis was undertaken after the data were collected. *Ex ante* exploratory analysis was carried out to compare outcomes among different groups of patients and included the following: type of Hickman line inserted (single versus double) and booking (emergency versus pre-booked). Multiple analyses of the same data are likely to create a considerable risk of false-positive findings[55] and so the patient and study characteristics used for subgroup analysis were carefully chosen. The subgroup analyses conducted were carried out because it was thought that these characteristics might influence outcomes and because they were used in the stratification process.

General data collection – patient case report forms

The information recorded by the nursing staff on the patient case report forms provided the majority of the patient data used in the study. The nursing staff completed the specially designed patient case report forms because of the clinical nature of the information solicited and also for convenience as the nursing staff were in contact with the patients throughout the duration of their stay at CHNT. The researcher later completed, where possible, information that was missing from the forms. Every completed patient case report form was checked against the data entered onto the computerised database at regular intervals. The few errors that were identified were noted and rectified by the researcher. A copy of the patient case report form is presented in Appendix 3.

Key outcome measures

Clinical outcomes of interest included the following: catheter-tip misplacement, pneumothorax, arterial puncture, haematoma, line and tunnel infection. When comparing blind versus image guidance, the primary clinical outcome measure was catheter-tip misplacement. When comparing the performance of the three nurses, the primary clinical outcome measure was pneumothorax. Process outcomes included the following: number of successful procedures, failed insertions, assistance by nurse, assistance by radiologist, assistance by oncologist and patient transfer from bedside to interventional X-ray suite. Time taken to perform procedure, length of time spent in interventional X-ray suite to reposition misplaced catheter tip and waiting time between basic insertion and repositioning of Hickman line were also explored.

Catheter-tip misplacement

All catheter-tip misplacements in the RCT were identified from post-procedural chest X-rays and were recorded by the nursing staff on the individual patient case report forms. Initially, the nurses recorded only whether or not catheter-tip misplacement had occurred. However, it soon became clear that differences between patients in terms of the clinical and psychological consequences suffered could not be identified. Clearly, a patient whose Hickman line only requires a saline flush to manipulate the tip into a better position does not suffer the same consequences as a patient whose Hickman line has to be removed by a nurse and then reinserted. Where tip misplacement occurred, patient medical records were always reviewed in order to obtain more detailed clinical information including tip position and how and when the line was repositioned. All repositionings were successfully conducted under image guidance in the interventional X-ray suite.

Pneumothorax

In the RCT, all pneumothoraces were identified from post-procedural chest X-rays and were

TABLE 5 *Sources of clinical evidence*

Clinical outcome	Source of evidence of clinical outcome				
	Case record forms	Medical records	Chest X-ray/ radiology report	ALD	PHLS
Misplacement	✓	✓	✓		
Pneumothorax	✓	✓	✓		
Arterial puncture		✓			
Infection rates	✓	✓		✓	✓
Successful/failed insertion	✓	✓			

recorded by the nursing staff on individual patient case report forms. Patient medical records were then reviewed in order to obtain more detailed clinical data including size of pneumothorax, whether or not a chest drain was required and patient length of stay.

Arterial punctures and haematomas

In the RCT, all arterial punctures and haematomas were recorded by the nursing staff on the patient case record forms and were written up in the medical record notes.

Infection

The nurses recorded all episodes of infection within 14 days of the procedure on the patient case report forms. It was assumed that all infections that manifested during this period were linked to the insertion procedure. Confirmed line infections were those infections identified by positive blood cultures. Confirmed tunnel infections were identified by positive wound specimens. If the culture results and specimens were negative, before assuming that the infection was suspected, the researcher reviewed the patient's medical records in order to determine whether or not the tests were carried out because infection was truly suspected or for some other valid reason. If there was a valid reason for taking the cultures and specimens which was unrelated to infection, then a suspected infection episode was not recorded. Although patient case report forms were designed to capture all incidences of infection, the delay (up to 14 days) before infections were recorded meant that patient medical records were not always easily available to nursing staff who were completing these forms. Patient databases the CHNT [Adult Leukaemia Database (ALD)] and Withington Hospital [Public Health Laboratory Service (PHLS)] were then accessed by the researcher in order to complete the patient information required. In this report, all line and tunnel infections reported are a combination of suspected and confirmed infections.

Summary of clinical outcomes evidence

Evidence from a variety of sources was used to confirm and cross-check that all clinical and process outcomes had occurred and these are presented in *Table 5*.

Successful insertion

Successful insertions were defined as those which did not require any assistance by another healthcare professional and did not result in any clinical complications or infection.

Failed insertions

In the RCT, a failed insertion was recorded if the insertion procedure was performed as planned but, given unforeseen circumstances, the operator was unable to insert a Hickman line. The procedure was defined as a failed insertion only if the operator had been unable to insert a Hickman line in the patient; in all other circumstances, for example, if the Hickman tip was misplaced, a failed insertion was not recorded as the outcome. Failed insertions usually resulted in one of the following three scenarios:

1. The operator inserted a PICC instead of a Hickman line.
2. The operator referred the patient to an oncologist or radiologist for a femoral or a jugular vein insertion.
3. The operator rebooked the patient for a Hickman line insertion by one of the nurses at a later date.

The nursing staff recorded all failed insertions on the patient case record forms. Medical records were reviewed in order to determine how or if venous access was achieved at a later date. In time, central venous access was obtained for all patients in the trial.

Assistance from other healthcare professionals

All insertions that required assistance from any of

the nurses or a radiologist or an oncologist, for whatever reason, were recorded on the patient case report forms.

Patient transfer

The nurses identified all of the patients who were transferred from the bedside to the interventional X-ray suite on the patient case report forms.

Time taken to perform procedures

In all cases, key times taken to perform different procedures were recorded. Start and finish times were noted on the patient case report forms.

Generalisability

As there were no significant differences between the trial protocol and real-world clinical practice and owing to the 100% patient compliance rate, the generalisability of the clinical trial effectiveness data was anticipated to be fairly high.

The focus of the research was not only to assess the optimal form of Hickman line insertion for the CHNT; it was also to identify generalisable lessons for the NHS as a whole. Current provision of Hickman line insertions by a small number of nurses in England is widely recognised. This research attempted to identify the extent to which expertise in Hickman line insertion by experienced nurses can be transferred to others via a short-term training programme. One aim was to assess whether or not nurses previously unskilled in the procedure could rapidly assimilate the necessary skills to perform unsupervised Hickman line insertions.

NHS resource use

Perspective

All resources consumed as part of the RCT were identified and measured throughout the duration of the trial from the perspective of the NHS. The resources associated with infection episodes within 14 days of the insertion procedure were also recorded. Resource-use data were collected in order to estimate the impact of the two trial interventions on NHS budgets. A decision was taken not to adopt a societal perspective based on evidence that the difficulties of estimating patient borne direct and indirect resource consumption are well documented.[56] Given that very ill adult cancer patients made up the study population and would not have been able to complete detailed resource consumption forms or take part in interviews, an NHS perspective seemed appropriate.

BOX 2 *Identifying resource groups*

Resource groups

(A) Basic insertion procedure
(B) Failed insertions
(C) Clinical complications subdivided into: misplacement, pneumothorax, arterial puncture and haematoma
(D) Infections subdivided into: suspected or confirmed line and suspected and confirmed tunnel infection
(E) Assistance subdivided into: nurse, oncologist or radiologist assistance
(F) Patient transfer from bedside to interventional X-ray suite
(G) Additional line inserted

Resource groups

For ease of exposition, resources were crudely divided into resource groups as detailed in *Box 2*. Within each resource group a range of NHS resources were consumed. Wherever possible, physical quantities of resources consumed in natural units have been reported. Descriptions of actual resource consumption in each of the resource groups are presented in Appendix 4.

Group A: basic insertion procedure

If the basic insertion procedure was performed at the bedside, then the use of the following resources was considered: Hickman line insertion pack, wide range of consumables, nursing time, time spent on the ward, routine tests and chest X-ray. Even if a Hickman line was not inserted and a failed procedure was recorded, a chest X-ray was always performed in order to identify any pneumothorax present. If the basic insertion procedure was performed in the interventional X-ray suite, then use of the following resources was considered: Hickman line insertion pack, wide range of consumables, nursing time, time spent on the ward and in the interventional X-ray suite, routine tests and chest X-ray. Even if a Hickman line was not inserted and a failed procedure was recorded, a chest X-ray was always performed in order to identify any pneumothorax present. A trolley equipped with the required items was prepared for each patient before the procedure began. The same trolley was prepared for blind and image-guided insertions.

Given the confidential nature of the service provided by the nurses, it was impossible for the researcher to observe how long each nurse spent with each patient during the trial over and above time spent during the insertion procedure. It was also very difficult for the nurses to record how long they spent with each patient on a daily basis because they tended to treat more than one

BOX 3 *Consequence of rectifying catheter-tip misplacement*

Manipulation technique	Clinical consequences for patient
Flushing the line into position by nurse	Extra 15 minutes in X-ray suite, no additional risk of pneumothorax, arterial puncture or haematoma
Line *in situ* is repositioned via line by nurse	Extra 30 minutes in X-ray suite, no additional risk of pneumothorax, arterial puncture or haematoma
Line is repositioned with pigtail catheter through the femoral vein by radiologist	Extra 80 minutes in X-ray suite, no additional risk of pneumothorax, arterial puncture or haematoma
Line is rewired using guidewire and new line by nurse	Extra 30 minutes in X-ray suite, no additional risk of pneumothorax, arterial puncture or haematoma
Line is removed and reinserted by nurse	Extra 80 minutes in X-ray suite, additional risk of pneumothorax, arterial puncture or haematoma

patient at a time. Based on their experience during the trial, the nurses were asked to estimate how much time, in general, they spent with each patient. It was estimated that one nurse would spend 3 hours with a patient if the procedure had been straightforward. If the patient had a misplaced catheter tip or a pneumothorax or if a PICC was inserted during the procedure, the nursing time spent with each patient was estimated to be 4 hours. This extra hour of nursing resource was itemised under catheter-tip misplacement, pneumothorax and failed insertion as appropriate.

The nurses recorded actual times spent during blind and image-guided insertion procedures on the patient case report forms. These times differed across patients and were usually less than 1 hour. However, it was agreed that the approximation of 1 hour be used to calculate the use of X-ray suite charges as it was impossible for the nurses to know in advance how long the procedure would take and as a consequence the X-ray suite was typically booked for 1 hour.

Group B: failed insertions

The resources consumed within the failed insertion resource group varied considerably between patients. The additional resources consumed by each patient who had a PICC inserted, or were referred to an oncologist or radiologist, or who were rebooked for insertion, were identified and measured. The resource consequences of failed insertions were estimated from reviews of individual patient medical records. The resources consumed were mainly made up of consumables used to insert PICC lines, nursing time, salaries and consumables associated with Hickman line insertion at a later date.

Group C: clinical complications

Clinical complications were subdivided into the following groups: catheter-tip misplacement, pneumothorax, arterial puncture, haematoma and infection. The resource consumption associated with misplaced catheter tips was measured by reviewing individual patient medical records. This was performed to determine how the tips were repositioned and to identify whether or not an overnight stay was required. Resources consumed during repositioning included consumables and healthcare professional time and occupancy of X-ray suite (based on actual times). Two nurses were usually involved in the repositioning of the line. As explained before, 1 hour of extra nursing time was also included in the estimate of resource consumption associated with misplaced lines. This extra hour was over and above the time taken to reposition the catheter tip. *Box 3* summarises the most common manipulation techniques used by nursing and medical staff at the CHNT to rectify catheter-tip misplacement.

The medical records of all patients who suffered a pneumothorax during the trial period were reviewed. Individual patient resource use data were collected for these patients. Resource estimates of additional days in hospital, number of chest X-rays performed and whether or not a chest drain was required were noted. Other resources included in the treatment of a pneumothorax were 1 hour of extra nursing time from the nurses and, where appropriate, the consumables and specialist registrar and nursing time involved in inserting and removing chest drains.

The length of stay of all patients who suffered an arterial puncture was checked on the CHNT database in order to determine whether or not an overnight stay was required. No other resources were assumed for these patients. No additional resources were assumed for those patients who suffered a haematoma.

BOX 4 *CHNT infection policy*

Group 1:	Patient is pyrexial with a normal white cell count and there is no other obvious reason for a high temperature other than line infection.
Regime 1:	Patients are given 400 mg of intravenous teicoplanin, followed by 200 mg (intravenous) per day for 5 days. Patients are also given 500 mg per day of oral levofloxacin for a 6-day period. Teicoplanin can be administered as an outpatient treatment if the patient lives within travelling distance of the CHNT and is able to attend every day for 6 days.
Group 2:	Patient has a high temperature and a low white cell count and does not have a chest infection.
Regime 2:	Patients are given 420 mg of intravenous netilmicin per day for 6 days (estimate is made on the assumption of a 70 kg patient and 4.5 mg of intravenous tazocin three times per day for 6 days).

Group D: infection episodes

In order to determine how each patient's infection episode was treated, the researcher reviewed, where appropriate, each patient's medical records. Cancer patients are often prescribed antibiotics for a variety of reasons and it was impossible for the researcher to be confident that accurate links between indication and prescription were being made. As an alternative, one of the trial nurses also reviewed patient medical records for this purpose. However, after much time was spent employed in the task, it was agreed that only verification of the actual status (suspected or confirmed) of the infection could be made and that actual resource use could not be measured in this way. After much discussion between medical and nursing staff, it was agreed that patients with symptoms of infections at the CHNT were typically divided into two groups as described in *Box 4*.

As far as resource use is concerned, whether or not a patient had a suspected or a confirmed infection was of no consequence, as patients were treated in exactly the same way until the results of the cultures and swabs were returned from the laboratories. Given the problems associated with indication and prescription of antibiotics, for the purposes of this report it was assumed that no changes to the antibiotic regimens were initiated after the laboratory results were known.

Group E: assistance from nurse or radiologist or oncologist

The only resource consumed when assistance was required was nursing or medical staff time. It was estimated that if assistance was required it was for approximately 15 minutes. This figure is based on discussions with nursing and medical staff.

Group F: patient transfer from bedside to interventional X-ray suite

Resources consumed in this group were mainly X-ray suite charges. It was estimated that if a patient was transferred from the bedside to the interventional X-ray suite then the extra time spent in the X-ray suite was approximately 30 minutes and this was charged appropriately. This figure is based on discussions with nursing and medical staff. No additional nursing time was required.

Group G: additional Hickman line

An additional Hickman line was only required if it was decided, during the procedure, to insert a single-lumen line instead of a double-lumen line. Resource use in this group was therefore made up of single Hickman lines. This group did not include the insertion of PICCs, as these have already been included in the failed insertion resource group.

Patient satisfaction questionnaire

After the patient's Hickman line had been inserted and the patient was able to leave the hospital, the patient was given a patient satisfaction questionnaire to complete. The aim of the patient satisfaction questionnaire was to elicit patient attitudes towards their Hickman line insertion experience. The self-administered questionnaire was designed by nursing staff and epidemiologists working at the CHNT. The questionnaire was short (two pages) and consisted of mainly closed questions. A space for general comments was provided. The key topics covered by the questionnaire included waiting time, information provided and patient experience of procedure. The questionnaire was both anonymous and confidential in nature. A copy of the questionnaire is provided in Appendix 2.

In order to obtain a greater number of responses, questionnaires were distributed to both on- and off-study patients. Patients were asked to complete the questionnaire and hand it in to the ward clerk on leaving the hospital or post it to the Quality

Assurance Programme in the pre-paid envelope provided. Patients were asked not to return the questionnaires to the nursing staff who had inserted their line. It was made clear to the patients that their views and opinions were valuable and they were encouraged to record their true perceptions and experiences of their insertion procedure. As the questionnaires were not to be returned to the nursing staff, it was anticipated that an accurate reflection of patient experience could be obtained.

Statistical and data analysis of primary data

All analyses of the data were carried out on an intention-to-treat basis. Data analysis was carried out using microsoft Excel 97 and SPSS version 10.0. Categorical variables were analysed primarily by the chi-squared test or, where appropriate, by Fisher's exact test. Levene's test to compare equality of variances was used before comparing means using the *t*-test for equality of means. For dichotomous variables, actual numbers, percentages and, where appropriate, confidence intervals were reported. In the analysis of the patient questionnaires, the Mann–Whitney *U*-test was used to identify differences between groups where variables were non-continuous.

Economic evaluation

Background and aims

The aim of the economic evaluation was to determine the cost-effectiveness of image-guided Hickman line insertions versus blind Hickman line insertions from the perspective of the NHS. In order to do this, costs and benefits associated with the two arms of the trial were compared. A review of the literature revealed that no economic evaluations of Hickman line insertions by nurses had ever been undertaken. Therefore, conducting the economic evaluation alongside the RCT provided the ideal opportunity to assess whether or not the added benefits of image-guided Hickman line insertions, if any, outweighed the cost of achieving them. Economic evaluation was therefore fully integrated into the RCT in order to inform and support decision making by senior hospital management in an NHS environment.

There are four main methods of economic evaluation and these are summarised in *Table 6*. All four forms of economic evaluation seek to identify, measure and value both the costs and outcomes of healthcare interventions. In this study, the costs and benefits of image-guided and blind Hickman line insertions were compared.

TABLE 6 *Summary of economic evaluation methods and outcomes*

Type of economic evaluation	Outcomes
Cost-minimisation analysis (CMA)	Identical outcomes
Cost-effectiveness analysis (CEA)	Natural units of effect
Cost–utility analysis (CUA)	Quality-adjusted life-years
Cost–benefit analysis (CBA)	Monetary valuation of outcomes

Each of the four main methods of economic evaluation addresses costing issues using similar techniques. The main difference between the methods lies in the identification, measurement and valuation of health benefits.

In cost-minimisation analysis (CMA), there must be no evidence to reject the hypothesis of equivalence of health outcomes of the healthcare interventions under investigation. If this is the case, then outcomes can be ignored and the focus of the analysis is therefore on the costs of the healthcare interventions. In cost-effectiveness analysis (CEA), outcomes are measured in natural units (e.g. life-years saved) and so consideration of both costs and benefits is required. Similarly, in cost–utility analysis (CUA), outcomes are typically measured in quality-adjusted life-years (QALYs) and issues of both cost and benefit are addressed. In cost–benefit analysis (CBA), both costs and outcomes are measured in monetary values and their derivations are of equal importance.

Before the start of the RCT, it was very difficult to state unambiguously which method of economic evaluation would be used to compare image-guided with blind Hickman line insertions. If it were known with certainty that the outcomes would be exactly the same in both arms of the trial, then it would have been appropriate to focus solely on the cost issues. However, this was clearly not the case. It was anticipated that CEA would be used to compare the two healthcare interventions as it was expected that there would be differences in outcomes between the two arms. Indeed, one of the objectives of the trial was to assess the magnitude of the difference in clinical outcomes. A decision was made at the start of the trial not to address quality of life issues. This was taken, in

large part, because of the nature of the healthcare intervention being evaluated. Insertion of a Hickman line is a procedure that, in isolation, does not lead to improved health outcomes for patients. Only through its use, with chemotherapy drugs or blood products, does it directly affect patient quality of life. It was therefore impossible to use CUA, as no estimates of quality of life were collected. CBA was not undertaken because of the difficulty of attaching monetary values to the intangible costs associated with Hickman line insertions.

Incremental cost-effectiveness ratios are presented in terms of the incremental cost per natural unit of effect. In this trial, given the stated objectives, the most important ratio to be calculated was the incremental cost per misplaced catheter tip avoided. Although other clinical outcomes were of interest, it was this outcome which was expected to differ between the blind and image-guided arms of the trial. The actual insertion puncture in the two arms of the trial was identical. Consequently, rates of failure, pneumothorax, arterial puncture and haematoma were expected to be similar in the blind arm and in the image-guided arm. The incremental cost of a successful procedure was also calculated as this outcome was also expected to differ between the two arms. Finally, for completeness, the likelihood of having a clinical outcome excluding a misplaced catheter tip was explored within incremental CEA.

Identification of costs

The choice of perspective influences the range of costs to be identified, measured and valued in any economic evaluation. Given the NHS perspective adopted in this study, only direct healthcare costs were identified and estimated and included consumables, salaries, tests and investigations, pharmacy supplies and hospital resources. Indirect costs and intangible costs were not estimated in this economic evaluation. All CHNT salaries included 'on costs' (National Insurance and superannuation) and overhead costs (indirect and direct). Hourly rates for nursing costs were based on a 37.5-hour week and hourly rates for medical staff were based on a 35-hour week. A mix of patient-specific and non-patient-specific resource use data sources was used to collect important clinical and cost information. Average costs, not marginal costs, were used in the economic evaluation for two reasons. First, the use of marginal costs requires access to large and complex cost datasets that are both expensive and difficult to acquire; given the time and budget constraints of the project, marginal costs would have been impossible to obtain. Second, as the results of the economic evaluation were intended to be of use to a mix of NHS hospital decision-makers and the marginal costs of each hospital are different, average costs were used to improve the generalisability of the results. None of the costs incurred in the RCT were associated with the trial *per se* rather than the costs of providing healthcare. No protocol-driven costs were incurred during the RCT.

BOX 5 *Resource groups*

(A) Basic insertion procedure
(B) Failed insertions
(C) Clinical complications subdivided into misplacement, pneumothorax and arterial puncture
(D) Infections subdivided into line and suspected and tunnel infection
(E) Assistance subdivided into nurse, oncologist or radiologist assistance
(F) Patient transfer from bedside to interventional X-ray suite
(G) Additional Hickman line

Measurement of costs

The costs associated with insertion of the Hickman line were based on the resource group categories as described previously and as presented in *Box 5*.

The costs reported in this study were obtained from a variety of sources and are summarised in *Table 7* below. All costs were based on the most up-to-date market prices available. Whenever possible, local sources of cost data were used. All costs used in the economic evaluation are listed in Appendix 4.

Basis for cost calculations

The methods used for calculating costs in the economic evaluation were very simple. A bottom-up approach was adopted in an attempt to present as much detailed costing information as was available. As far as possible, all relevant cost information was included in the economic analysis. Patient cost distributions were summarised by their mean, 95% confidence intervals and standard deviation, and any cost variations identified were explored. Evidence suggests that it is the arithmetic mean cost that is most useful to NHS decision-makers.[57] The discounting of costs was not appropriate in the comparison of image-guided and blind Hickman line insertions given the time horizon of the clinical and economic analysis.

TABLE 7 *Cost data*

Cost categories	Source	Year
Consumables	Logistics Catalogue	2000
	British National Formulary	2000
	Bard	2000
Pharmacy items	Pharmacy Department, CHNT	2000
	British National Formulary	2000
Radiology charges	Radiology Department, CHNT	1999/2000
Salaries	Finance Department, CHNT	1999/2000
Tests	Department of Haematology, CHNT	200
	Finance Department, CHNT	

Allowing for uncertainty in the economic evaluation: sensitivity analysis

Sensitivity analysis was undertaken in order to test the robustness of the economic evaluation results, that is, in order to determine whether or not changes in key assumptions or costs would have an impact on the results of the economic evaluation. For each of the assumptions that were varied the following information was presented: type of sensitivity analysis conducted, reason for varying the assumption, plausible range of values for the variation and the source of the range of values. Given that the CHNT is a specialist cancer centre with a relatively unique cost structure, sensitivity analysis was conducted around unit X-ray costs in an effort to improve external validity to ensure that the economic results of the study can be used in different settings. The main limitation of the economic evaluation was that CHNT X-ray suite charges were used to estimate the cost of occupancy of the X-ray suite for image-guided Hickman line insertions. However, by varying the radiology charges in the sensitivity analysis to explore whether or not the economic evaluation results were affected, it was anticipated that this limitation would be somewhat overcome.

Summary of assumptions used in the economic evaluation

1. All patients (inpatients and outpatients) were treated as day-case patients for the purposes of the costing study.
2. The cost of an overnight stay resulting from a clinical complication for patients who were booked in as inpatients was not included in the economic evaluation as these patients would have been hospitalised anyway. Therefore, the cost of an overnight stay was only included, where appropriate, for those who were booked in as outpatients or day-case patients.
3. On average, each nurse spent 3 hours with every patient who participated in the trial whether a day-case patient or an inpatient.
4. If a patient suffered a catheter-tip misplacement, pneumothorax or had a PICC inserted during the procedure, then the nurse was deemed to have spent an extra hour with the patient during the course of their stay.
5. All X-ray suite charges were as calculated by the Radiology Department at the CHNT.
6. When assistance was required, the nurse, radiologist and/or oncologist were each reckoned to have assisted for 15 minutes.
7. Each patient was considered to have spent 30 minutes in the X-ray suite after being transferred from the bedside to the interventional X-ray suite.
8. Before antibiotics are prescribed, a patient suspected of having a Hickman line infection received either (i) three blood cultures and one swab (single-lumen line) or (ii) six blood cultures and one swab (double-lumen line).
9. A patient with an infection either received antibiotic regime 1 or 2 as previously described.
10. Most of the lines placed during the trial were single- or double-lumen lines. However, two patients had a triple-lumen line inserted. Where appropriate, for the purposes of the economic evaluation, these triple-lumen lines were considered as double-lumen lines.

Chapter 3
Results

Evaluation of pre-trial nurse training programme

Both nurses completed the training programme and each nurse was assessed favourably by the CNS and both the in-house and external assessors. Both nurses went on to participate fully in the RCT.

Table 8 presents summary data on the frequency and type of CVCs inserted by the trainee nurses during the training programme. These lines do not include the number of Hickman line insertions that were observed. The majority of lines inserted during the training programme were single- and double-lumen Hickman lines.

Table 9 provides a brief description of the clinical complications experienced by patients during the training period whilst a trainee was participating in the procedure. Seventeen (18%) complication episodes were recorded, none of which had serious clinical consequences for patients. Catheter-tip misplacement was the most frequent complication associated with Hickman line insertion during the training period.

Table 10 shows the resources that were identified to estimate the total costs of the training programme.

The total cost of the nurse training programme was estimated to be £19,127.27, as shown in *Table 11*.

Of the total cost of training the two trainees, 83% was made up of salary costs. Radiology charges for use of the X-ray suite and the costs of treating patients with pneumothorax, which included an overnight stay, were relatively small in comparison with salary costs.

A variety of insertion training programme options could be designed. *Table 12* shows the effect on total costs of reducing the training programme from 12 to 8 weeks assuming that the same number of patients are treated. This would be

TABLE 8 *Frequency and type of CVC inserted during training programme*

Type of line insertion participated in, or completed by, trainee nurse	Nurse1	Nurse2	Pearson χ^2
Single	28	23	
Double	14	18	
Triple	0	1	
Single PICC	6	4	$\chi^2 = 1.606$
Total	48	46	$p = 0.448$, df = 2

df, degrees of freedom.

TABLE 9 *Clinical complications during training period*

Complications during insertions by nurse trainees	No. of events	Other information
Tip misplacement – positioned across midline	5	3 tips were repositioned in X-ray at a later time; 2 tips were correctly placed using flushing and vigorous respiration
Tip misplacement – positioned in jugular vein	4	2 tips were repositioned during the procedure in X-ray; 1 tip was repositioned in X-ray at a later time; 1 tip was referred to a radiologist for repositioning
Arterial puncture	5	No bleeding
Pneumothorax	3	No chest drain required

TABLE 10 *Sources of costs*

Description of cost items	Unit cost (£)	Source	Year
G grade salary – annual cost	24983	Finance Department	1999/2000
I grade salary – annual cost	30671	Finance Department	1999/2000
Consultant salary – annual cost	86326	Finance Department	1999/2000
X-ray training day – course fee	50.00	Invoice	1999
Radiology charges – hourly rate	124.33	Radiology Department	1999/2000
External assessor expenses – travel and subsistence	50.00	CHNT invoice	1999
X-ray training day expenses	10.00	CHNT invoice	1999
Average cost of misplaced line	109.14	See Appendix 4	1999/2000
Average cost of pneumothorax	355.53	See Appendix 4	1999/2000

TABLE 11 *Resources and costs*

Training programme resources	Quantities of resources	Cost (£)
Salaries	2 × G grade nurse salary for 3 months	12491.50
	1 × I grade nurse salary for 1 month	2555.92
	4 × Consultant hourly rate for 4 hours	804.96
Courses	3 × Training day course fees	150.00
Radiology charges	15 × Hourly radiology charge	1864.95
Travel expenses	1 × External assessor expenses	50.00
	3 × Travel expenses to training day course	30.00
Complications – misplacement	2 × Mean misplacement cost	231.88
Complications – pneumothorax	3 × Mean pneumothorax cost	948.06
Total		19127.27
Mean cost per nurse trained		9563.63
Mean cost per patient		203.48

TABLE 12 *Costs of alternative training programmes*

Training programme	Cost (£)	Cost per nurse trained (£)	Cost per patient (£)
8 weeks	14111.46	7055.73	150.12
1 trainee	12821.52	12821.52	136.40

possible if the trainees were able to participate in more insertions during a shorter training period. *Table 12* also shows the effect on costs of training one trainee instead of two trainees over a 12-week period assuming that the same number of patients are treated. This would be the case if more intensive training were provided. Further analysis can be carried out to identify the costs of training more than two trainees at a time and/or over a different time period. At the CHNT it was decided that each of the trainees should participate in at least 50 Hickman line insertions. If this number were higher or lower then this would affect the duration of the training programme and would also lead to an increase or decrease in costs.

This type of training course is clearly a one-off cost for any institution and one which is time limited by technological advance. The costs and benefits of expanding this training programme throughout the NHS are explored in the section 'Resource implications of Hickman line insertions by nurses across the NHS' (p. 51).

In-house feedback from training programme

Feedback was sought from the CNS and the trainee central lines nurses throughout the period of the training programme. All parties concerned agreed that the training programme was a success. At the end of the training programme, trainee

BOX 6 *Patient exclusion*

Reason for patient exclusion	No. of patients excluded
Patient was too ill	9
Patient had a failed previous attempt	2
Patient had poor haematology	15
Patient was under 18 years of age	9
Doctor was performing insertion as part of his or her training	5
Other[a]	8

[a] Other reasons for exclusion included the following: patient did not speak English and did not want to be parted from her husband if she was randomised to X-ray suite; patient was taking regular aspirin; patient wanted a general anaesthetic in theatre; patient had a clot in the neck; patient was neutropenic and could not leave the ward; patient had an anatomical abnormality, reason not stated.

nurses felt confident in their ability to insert lines and the CNS was more than satisfied with the trainees' performance. With hindsight, the nurses and the CNS agreed that a few changes to the training programme could be made. It was thought that a more intensive training programme could be undertaken. This could be achieved if the CNS trained only one trainee at a time. One trainer to one trainee means that the length of the programme can be reduced as the target number of insertions can be achieved in a shorter time period. Or, if one trainee were working under the supervision of more than one trainer, this would also mean that the target number of insertions could be achieved in a shorter time period.

Results of the RCT

Recruitment

During the 13-month period of the RCT, 667 central venous lines were inserted in cancer patients at the CHNT. Of the 667 lines requested for patients, 619 were for patients who were deemed suitable for entry into the clinical trial by the nursing staff. *Box 6* lists the reasons why 48 patients were excluded from the RCT.

Of the 619 patients who were eligible to participate in the RCT, 17 refused to give written and oral consent to the nursing staff and were therefore not included in the trial; 132 patients were also excluded from the trial because the X-ray suite was unavailable on request before randomisation took place. The remaining 470 were randomised to either blind or image-guided insertion.

A total of 470 patients were randomised as part of the RCT; 235 patients were allocated to blind insertion and 235 to image-guided insertion (*Figure 2*). Each of the patients was also randomised to nurse1, nurse2 or nurse3.

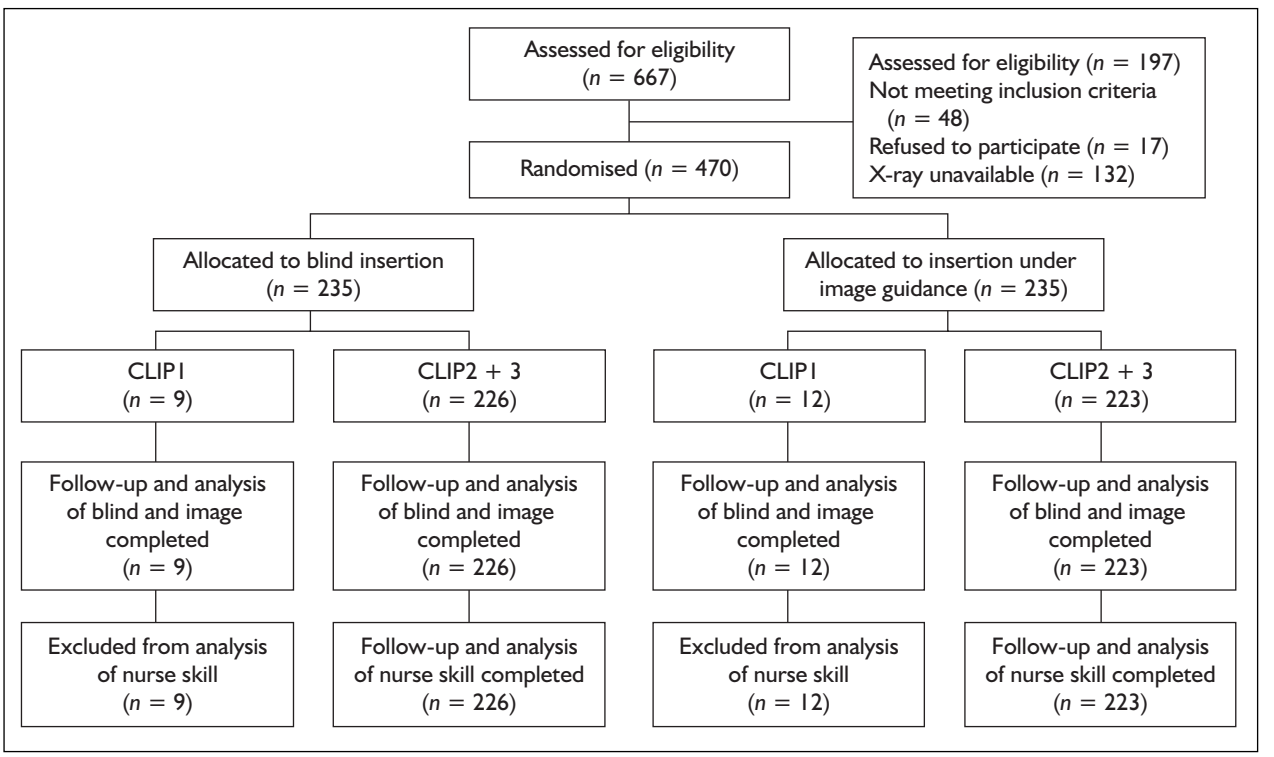

FIGURE 2 *Progress of patients through RCT*

In the blind arm, 88 patients were randomised to nurse1, 77 to nurse2 and 70 to nurse3. Nine patients were randomised to CLIP1, 85 to CLIP2 and 141 to CLIP3.

In the image arm, 90 patients were randomised to nurse1, 71 to nurse2 and 74 to nurse3. Twelve patients were randomised to CLIP1, 81 to CLIP2 and 142 to CLIP3.

Protocol violations

There were two protocol violations in the blind arm. In one instance, the nurse who was allocated to one patient was called away during the procedure and so another nurse took over the procedure. On another occasion during the insertion procedure, it was clear that the patient had a hidden anatomical abnormality and was not suitable for a Hickman line; a PICC line was then inserted instead. There were four protocol violations in the image-guided arm. Three patients were taken to the X-ray suite for their procedure only to be told that the suite was occupied and so their Hickman lines were inserted at the bedside. On one occasion, a patient was taken to the X-ray suite only to be told that the fluoroscopy machine was out of order. Again, the patient was taken back to the ward and a Hickman line was inserted at the bedside. All of the insertions that violated the protocol were included in the intention-to-treat analysis.

Patient characteristics

Patient randomisation ensured that there were no real differences between the groups of patients in the blind and image-guided arms of the trial. There were slightly more men than women in the trial (*Table 13*) and the majority of both sexes were over 40 years of age (*Table 14*). Just over half of the patients weighed between 60 and 79 kg (*Table 15*). About 80% of patients were of normal physical state, that is, they were neither over- nor under-weight (*Table 16*). *Table 17* shows that three-quarters of patients had a Karnofsky performance (KP) score between 80 and 100% (a KP score of 80% means that the patient is able to carry out normal activities with effort and a score of 100% means that the patient is normal). Some 54% of patients had been diagnosed with gastrointestinal cancer. Patients were more likely to be suffering from a solid tumour cancer than a haematological cancer (*Table 18*). There were 76% of patients who were treated on the day ward, with the remainder spread across the Adult Leukaemia Unit, Nathan House (private ward) and CHNT general oncology wards (*Table 19*). Some 66% of patients were treated as inpatients (*Table 20*) and 91% of Hickman line insertions were pre-booked (*Table 21*). There were 8% of patients who required a blood and/or platelet transfusion before their Hickman line insertion (*Table 22*). *Table 23* shows how many lines were inserted blind and under image guidance by each of the three nurses.

TABLE 13 *Gender*

Gender	Blind (n = 235)	Image-guided (n = 235)	Total (n = 470)	Fisher's exact test
Men	133 (57%)	125 (53%)	258 (55%)	$\chi^2 = 0.550$
Women	102 (44%)	110 (47%)	212 (45%)	$p = 0.516$

TABLE 14 *Age*

Age (years)	Blind (n = 235)	Image-guided (n = 235)	Total (n = 470)	Pearson χ^2
<25	13 (5%)	12 (5%)	25 (5%)	
25–29	5 (2%)	9 (4%)	14 (3%)	
30–34	12 (5%)	10 (4%)	22 (5%)	
35–39	6 (2%)	15 (6%)	21 (5%)	
40–44	22 (9%)	9 (4%)	31 (6%)	
45–49	20 (8%)	32 (14%)	52 (11%)	
50–54	29 (12%)	31 (13%)	60 (13%)	
55–59	44 (19%)	42 (18%)	86 (18%)	
60–64	31 (13%)	25 (11%)	56 (12%)	
64–69	31 (13%)	32 (14%)	63 (13%)	
70–74	16 (7%)	11 (5%)	27 (6%)	$\chi^2 = 15.217$
≥ 75	6 (2%)	7 (3%)	13 (3%)	$p = 0.173$, df = 11

TABLE 15 *Weight*

Weight (kg)	Blind (n = 235)	Image-guided (n = 235)	Total (n = 470)	Pearson χ^2
<50	13 (6%)	7 (3%)	20 (4%)	
50–59	30 (13%)	36 (16%)	66 (14%)	
60–69	54 (25%)	56 (25%)	110 (23%)	
70–79	56 (26%)	64 (29%)	120 (26%)	
80–89	36 (16%)	27 (12%)	63 (13%)	
90–99	23 (11%)	24 (11%)	47 (10%)	
≥ 100	7 (3%)	11 (5%)	18 (4%)	$\chi^2 = 5.031$
Missing	16 (7%)	10 (4%)	26 (6%)	$p = 0.540$, df = 6

TABLE 16 *Physical state of patients*

Physical state	Blind (n = 235)	Image-guided (n = 235)	Total (n = 470)	Pearson χ^2
Cachexic	29 (12%)	27 (11%)	56 (12%)	
Normal	189 (80%)	187 (80%)	376 (80%)	$\chi^2 = 0.503$
Obese	17 (7%)	21 (9%)	38 (8%)	$p = 0.778$, df = 2

TABLE 17 *KP score of patients*

KP score	Blind (n = 235)	Image-guided (n = 235)	Total (n = 470)	Pearson χ^2
≤ 60	22 (10%)	21 (9%)	43 (9%)	
70	33 (14%)	35 (15%)	68 (15%)	
80	85 (36%)	74 (32%)	159 (34%)	
≥ 90	93 (40%)	104 (44%)	197 (42%)	$\chi^2 = 1.455$
Missing	2 (1%)	1 (1%)	3 (1%)	$p = 0.693$, df = 3

TABLE 18 *Primary diagnosis of patients*

Primary diagnosis	Blind (n = 235)	Image-guided (n = 235)	Total (n = 470)	Pearson χ^2
Leukaemia + other haematological	19 + 0 (8%)	18 + 1 (8%)	38 (8%)	
Lymphoma	24 (10%)	21 (9%)	45 (10%)	
Myeloma	20 (8%)	25 (11%)	45 (10%)	
Gastrointestinal	127 (54%)	124 (54%)	251 (53%)	
Breast	19 (8%)	17 (7%)	36 (8%)	$\chi^2 = 1.066$
Other solid tumour	26 (11%)	29 (12%)	55 (12%)	$p = 0.957$, df = 5

TABLE 19 *Location of patients*

Location	Blind (n = 235)	Image-guided (n = 235)	Total (n = 470)	Pearson χ^2
Day ward	181 (77%)	176 (75%)	357 (76%)	
Adult Leukaemia Unit	10 (4%)	13 (6%)	23 (5%)	
General wards	38 (16%)	39 (17%)	77 (16%)	
Nathan House	6 (3%)	6 (3%)	12 (3%)	$\chi^2 = 0.472$
Missing	0	1 (1%)	1 (1%)	$p = 0.925$, df = 3

TABLE 20 *Inpatient or outpatient*

	Blind (n = 235)	Image-guided (n = 235)	Total (n = 470)	Fisher's exact test
Inpatient	155 (66%)	156 (66%)	311 (66%)	$\chi^2 = 0.100$
Outpatient	80 (34%)	79 (34%)	159 (34%)	$p = 0.500$

TABLE 21 *Pre-booked or emergency patients*

	Blind (n = 235)	Image-guided (n = 235)	Total (n = 470)	Fisher's exact test
Pre-booked	214 (91%)	212 (90%)	426 (91%)	$\chi^2 = 0.100$
Emergency	21 (9%)	23 (10%)	44 (9%)	$p = 0.874$

TABLE 22 *Platelet or blood transfusion*

	Blind (n = 235)	Image-guided (n = 235)	Total (n = 470)	Fisher's exact test
Blood transfusion	14 (6%)	6 (3%)	20 (4%)	$\chi^2 = 3.342$ $p = 0.108$
Platelet transfusion	16 (7%)	12 (5%)	28 (6%)	$\chi^2 = 0.608$ $p = 0.560$

TABLE 23 *Insertions by nurse*

Trial nurse	Blind (n = 235)	Image-guided (n = 235)	Total (n = 470)	Pearson χ^2
Nurse1	88 (37%)	90 (38%)	178 (38%)	
Nurse2	77 (33%)	71 (30%)	148 (30%)	$\chi^2 = 0.377$
Nurse3	70 (30%)	74 (31%)	144 (31%)	$p = 0.828$, df = 2

TABLE 24 *Planned Hickman line insertions*

Planned	Blind (n = 235)	Image-guided (n = 235)	Total (n = 470)	Fisher's exact test
Single	177 (75%)	177 (75%)	354 (75%)	
Double	57 (24%)	57 (24%)	114 (24%)	$\chi^2 = 0.000$
Triple	1 (1%)	1 (1%)	2 (1%)	$p = 1.000$

TABLE 25 *Actual Hickman lines inserted during the trial*

Inserted	Blind (n = 235)	Image-guided (n = 235)	Total (n = 470)	Pearson χ^2
Single	170 (72%)	178 (76%)	348 (74%)	
Double and triple	57 +1 (25%)	54 + 1 (23%)	113 (24%)	
PICC	4 (1%)	1 (1%)	5 (1%)	$\chi^2 = 3.064$
None	3 (1%)	1 (1%)	4 (1%)	$p = 0.382$, df = 3

Characteristics of RCTs

At the CHNT, the patient's health status and corresponding need for treatment determine whether or not a single-, double- or triple-lumen Hickman line is planned for each patient. In the RCT, the majority (97%) of Hickman lines planned for the patients was subsequently inserted (*Table 24*). The most frequently inserted line was the single-lumen Hickman line. Only 3% (n = 13) of Hickman lines were not inserted as planned. In nine instances, Hickman lines were not inserted in patients at all; in five of these patients PICCs were inserted and no lines were inserted in the remaining four patients (*Table 25*). Two planned single-lumen Hickman lines were inserted as double-lumen lines and two planned double-lumen lines were inserted as single-lumen lines. Of patients who participated in the RCT, 81% were having their first Hickman line inserted (*Table 26*). Of Hickman lines inserted, 83% were on the patients' right side (*Tables 27* and *28*).

Clinical outcomes from RCTs

The rate of misplaced catheter tips was statistically different between the blind and the image-guided arms ($p < 0.001$). Of Hickman lines inserted at

TABLE 26 *Insertion number*

Insertion no	Blind (*n* = 235)	Image-guided (*n* = 235)	Total (*n* = 470)	Pearson χ^2
1	192 (81%)	190 (82%)	382 (81%)	
2	32 (14%)	34 (14%)	66 (14%)	
3	7 (3%)	10 (4%)	17 (4%)	
>4	4 (2%)	0	4 (2%)	$\chi^2 = 4.598$
Missing	0	1 (1%)	1 (1%)	$p = 0.204$, df = 3

TABLE 27 *Left- and right-sided insertions*

Insertion side	Blind (*n* = 235)	Image-guided (*n* = 235)	Total (*n* = 470)	Fisher's exact test
Left	40 (17%)	36 (15%)	76 (17%)	$\chi^2 = 0.251$
Right	195 (83%)	199 (85%)	394 (83%)	$p = 0.707$

TABLE 28 *Reason for choice of insertion side*

Reason for choice of side	Blind (*n* = 235)	Image-guided (*n* = 235)	Total (*n* = 470)	Pearson χ^2
Operator preference	174 (74%)	184 (79%)	358 (76%)	
Venous compromise	6 (2%)	5 (2%)	11 (2%)	
Breast disease	22 (9%)	17 (7%)	39 (8%)	
Other anatomical	20 (9%)	21 (9%)	41 (9%)	
Compromised lung function	8 (3%)	5 (2%)	13 (3%)	$\chi^2 = 2.228$
Other	5 (2%)	3 (1%)	8 (2%)	$p = 0.817$, df = 5

TABLE 29 *Clinical complications*

Complication	Blind (*n* = 235)	Image-guided (*n* = 235)	Estimated difference (lower 95% CL to upper 95% CL)	Total (*n* = 470)	Fisher's exact test
Misplacement	32 (14%)	1 (1%)	–31 (–13%) (–8 to 18%)	32 (7%)	$\chi^2 = 33.199$ $p = <0.001$
Pneumothorax	7 (3%)	2 (1%)	–5 (–2%) (–4 to 0.3%)	9 (2%)	$\chi^2 = 2.832$ $p = 0.175$
Arterial puncture	15 (6%)	13 (5%)	–2 (–1%) (–5 to 3%)	28 (6%)	$\chi^2 = 0.152$ $p = 0.846$
Haematoma	2 (1%)	4 (2%)	2 (5%) (2 to 8%)	6 (1%)	$\chi^2 = 0.675$ $p = 0.685$
Line infection	10 (4%)	14 (6%)	4 (2%) (–2 to 5%)	24 (5%)	$\chi^2 = 0.598$ $p = 0.531$
Tunnel infection	11 (5%)	4 (2%)	–3 (–3%) (–6 to 2%)	15 (3%)	$\chi^2 = 3.569$ $p = 0.069$

CL, confidence limit.

the bedside, 14% had misplaced catheter tips. Only one catheter tip was misplaced under image guidance (*Table 29*). The majority (78%) of the lines with misplaced tips were either flushed or manipulated into position by the nurses on the same day (*Table 30*). There were no statistically significant differences in frequency of arterial puncture, pneumothorax or haematoma between the two arms. Infections related to the insertion were defined as all infections taking place within

TABLE 30 *Catheter-tip misplacement remedial technique*

Technique	Blind (n = 32)	Image-guided (n = 1)	Total (n = 33)
Flush	9 (28%)	0	9 (27%)
Reposition (nurse)	16 (50%)	0	16 (48%)
Rewire	4 (12%)	0	4 (12%)
Reposition (interventional radiologist)	1 (3%)	1 (100%)	2 (6%)
Removal and reinsertion	2 (6%)	0	2 (6%)

TABLE 31 *Process outcomes*[a]

Outcome	Blind (n = 235)	Image-guided (n = 235)	Estimated difference (lower 95% CL to upper 95% CL)	Total (n = 470)	Fisher's exact test
Successful insertion	157 (67%)	191 (81%)	34 (14%) (7 to 22%)	348 (74%)	χ^2 = 12.797 p = <0.001
Failed insertion	7 (3%)	2 (1%)	–5 (–2%) (–5 to 0.3%)	9 (2%)	χ^2 = 2.832 p = 0.175
Nurse assistance	28 (12%)	18 (8%)	–10 (–4%) (–9 to 1%)	46 (10%)	χ^2 = 2.410 p = 0.162
Radiologist assistance	3 (1%)	4 (2%)	1 (0.4%) (–2 to 3%)	7 (1%)	χ^2 = 0.145 p = 1.000
Oncologist assistance	3 (1%)	0	–3 (–1%) (–3 to 0.2%)	3 (1%)	χ^2 = 3.019 p = 0.248

[a] Note that this table is explanatory only and is not meant to include all patients.

14 days of the insertion procedure. There were seven suspected infection episodes and 14 confirmed infection episodes in the blind arm. There were six suspected infection episodes and 12 confirmed infections in the image-guided arm. In total, there were 24 line infection episodes and 15 tunnel infection episodes recorded during the trial period (*Table 29*).

Process outcomes

In the blind arm, 67% of Hickman lines were successfully inserted without any clinical complications or assistance from other staff. There were seven (0.02%) failed insertions in the blind arm. In the image-guided arm, 81% of Hickman lines were successfully inserted without any complications or assistance from other staff. There were two (0.008%) failed insertions in the image-guided arm (*Table 31*).

Of all insertions performed in the clinical trial, 11% (n = 51) required assistance from a nurse, oncologist and/or radiologist (*Table 31*). Nurses were called upon for assistance much more frequently than radiologists or oncologists. The CNS was the most frequently called upon member of staff in both the blind and image-guided arms.

Only three patients were transferred from the bedside to the interventional X-ray suite during the course of the insertion procedure.

Time

The average time taken to complete the procedure in the blind and image-guided arms of the trial was 38 minutes (95% CL: 36 to 39) and 40 minutes (95% CL: 38 to 42), respectively. Minimum and maximum times taken to complete the procedure in the blind arm were 15 and 90 minutes, respectively. Minimum and maximum times taken to complete the procedure in the image arm were 20 and 150 minutes, respectively. In the economic analysis it is assumed that the interventional X-ray suite is occupied for a 60-minute period. Clearly, the average actual time spent by each of the nurses performing image-guided procedures is sometimes more and sometimes less than 60 minutes.

If a patient has a misplaced catheter tip, then the patient is taken to the interventional X-ray suite in

TABLE 32 *Average time taken to reposition misplaced catheter tips*

Technique used to reposition misplaced catheter tip	Average time (minutes) (95% CLs)	SD	Assumption used in economic analysis (minutes)
Flushing	17 (24 to 29)	10	15
Reposition by nurses	27 (19 to 34)	14	30
Reposition by radiologist	80		80
Rewiring	30 (10 to 50)	12	30
Removal and reinsertion by nurse	Unavailable[a]		80

SD, standard deviation.
[a] Time taken was assumed to be the same as for the reposition by the interventional radiologist for the purposes of economic evaluation.

TABLE 33 *Exploratory analysis using blind versus image-guided dataset*

Outcome	Single vs double lumen			Pre-booked vs emergency		
	Single (n = 354)	Double[a] (n = 116)	Fisher's exact test, p-value	Pre-booked (n = 426)	Emergency (n = 44)	Fisher's exact Test, p-value
Pneumothorax	8 (2%)	1 (1%)	0.463	9 (2%)	0	0.410
Misplacement	17 (5%)	16 (4%)	0.003	25 (6%)	8 (18%)	0.007
Arterial puncture	22 (6%)	6 (5%)	0.823	25 (6%)	3 (7%)	0.738
Haematoma	4 (1%)	2 (2%)	0.640	4 (1%)	2 (5%)	0.101
Successful insertion	279 (79%)	69 (59%)	0.000	325 (76%)	23 (52%)	0.003
Failed insertion	6 (2%)	3 (3%)	0.013	7 (2%)	2 (5%)	0.638
Line infection	9 (3%)	15 (3%)	0.000	17 (4%)	7 (16%)	0.001
Tunnel infection	7 (2%)	8 (7%)	0.696	13 (3%)	2 (5%)	0.202
Nurse assistance	32 (9%)	14 (12%)	0.369	39 (9%)	7 (16%)	0.177
Oncologist assistance	3 (1%)	0	1.000	3 (1%)	0	1.000
Radiologist assistance	3 (1%)	4 (3%)	0.066	7 (2%)	0	1.000

[a] Includes two triple-lumen lines.

order to have the tip repositioned. *Table 32* describes the average time taken for nurses to reposition misplaced catheter tips during the trial period.

The average waiting time between the initial procedure and the patient's visit to the interventional X-ray suite for repositioning of the line was 105 minutes (95% CL: 72 to 138 minutes). The minimum waiting time was 15 minutes and the maximum waiting time was 330 minutes. The waiting time between procedures depends on the demand for the interventional radiology suite.

Exploratory analysis

Single- versus double-lumen lines

Single- versus double-lumen Hickman lines were also compared for the clinical and process outcomes of interest (catheter-tip misplacement, pneumothorax, arterial puncture, haematoma, line infection, tunnel infection, successful insertion, failed insertion, nurse assistance, oncologist assistance and radiologist assistance). A range of statistically significant differences were found between these two groups. Double-lumen lines were associated with significantly more assistance from the radiologist, more frequent catheter-tip misplacement and more episodes of line and tunnel infections. Consequently, single-lumen lines were significantly more likely to be successful than double-lumen lines.

Pre-booked versus emergency

When comparing pre-booked lines and emergency lines, three statistically significant differences were found (*Table 33*). Pre-booked patients were significantly more likely to have successful outcomes than emergency patients. Patients with emergency lines were significantly more likely to have Hickman lines with catheter-tips misplaced and suffer from line infections.

TABLE 34 *Clinical outcomes*

Clinical outcome	Nurse1		Nurse2		Nurse3	
	Blind (*n* = 86)	Image-guided (*n* = 87)	Blind (*n* = 72)	Image-guided (*n* = 67)	Blind (*n* = 68)	Image-guided (*n* = 69)
Pneumothorax	3 (3%)	0	4 (6%)	2 (3%)	0	0
Misplacement	14 (16%)	0	7 (10%)	1 (2%)	10 (15%)	0
Arterial puncture	7 (8%)	3 (3%)	6 (8%)	7 (11%)	2 (3%)	3 (4%)
Haematoma	1 (1%)	2 (2%)	0	2 (3%)	1 (1%)	0
Line infection	1 (1%)	6 (7%)	7 (10%)	1 (2%)	2 (3%)	7 (10%)
Tunnel infection	0	1 (1%)	6 (8%)	2 (3%)	5 (7%)	1 (1%)

TABLE 35 *Process outcomes*

Clinical outcome	Nurse1		Nurse2		Nurse3	
	Blind (*n* = 86)	Image-guided (*n* = 87)	Blind (*n* = 72)	Image-guided (*n* = 67)	Blind (*n* = 68)	Image-guided (*n* = 69)
Failed insertion	4 (5%)	1 (1%)	2 (3%)	0	0	1 (1%)
Nurse assistance	12 (14%)	8 (9%)	12(17%)	9 (13%)	4 (6%)	1 (1%)
Oncologist assistance	0	0	1 (1%)	0	0	0
Radiologist assistance	0	2 (2%)	1[a] (1%)	1 (1%)	2[b] (3%)	1 (1%)

[a] Patient was transferred from bedside to X-ray suite during procedure.
[b] Patient was transferred from bedside to X-ray suite during procedure.

TABLE 36 *Assistance required from other nurse*

Assistance			Nurse1 (called)		Nurse2 (called)		Nurse3 (called)	
Nurse	Blind	Image-guided	Blind	Image-guided	Blind	Image-guided	Blind	Image-guided
Nurse1	*n* = 86	*n* = 87	n/a	n/a	4 (5%)	1 (1%)	8 (9%)	7 (8%)
Nurse2	*n* = 72	*n* = 67	4 (5%)	4 (6%)	n/a	n/a	8 (11%)	5 (7%)
Nurse3	*n* = 68	*n* = 69	4 (6%)	1 (1%)	0	0	n/a	n/a

Comparing nurse skill

All of the outcome data that were collected during the period of the RCT can be linked to the nurse who carried out the insertion procedure.

Three-way comparison of nurse skill

Tables 34–36 show the clinical and process outcomes associated with each individual nurse in both arms of the RCT. The total number of procedures performed by all three nurses was 449. Nurse1 inserted 173 Hickman lines and nurse2 and nurse3 carried out 139 and 137 procedures, respectively.

Comparing nurse trainees (nurse1 and nurse2) with trainer

To explore whether or not the trainees and the trainer were operating at a similar skill level during the trial, the outcomes of the trainees were combined and then compared with those of the trainer (*Table 37*). Rate of pneumothorax was the primary clinical outcome of interest. When comparing the two nurse trainees together versus the trainer for a range of clinical and process outcomes (pneumothorax, catheter-tip misplacement, arterial puncture, haematoma, line infection, tunnel infection, successful insertion, failed insertion, nurse assistance, oncologist

TABLE 37 *Comparing nurse trainees with trainer*

Outcome	Trainees (n = 312)	Trainer (n = 137)	p-Value	Test
Pneumothorax	9 (3%)	0	0.063	Fisher's exact
Misplacement	22 (7%)	10 (7%)	1.000	Fisher's exact
Arterial puncture	23 (7%)	5 (4%)	0.202	Fisher's exact
Haematoma	5 (2%)	1 (1%)	0.672	Fisher's exact
Line infection	15 (5%)	9 (6%)	0.499	Fisher's exact
Tunnel infection	9 (3%)	6 (4%)	0.411	Fisher's exact
Successful insertion	223 (71%)	105 (77%)	0.299	Fisher's exact
Failed insertion	8 (2%)	1 (1%)	0.287	Fisher's exact
Nurse assistance	41 (13%)	5 (4%)	**0.002**	**Fisher's exact**
Oncologist assistance	3 (1%)	0	0.556	Fisher's exact
Radiologist assistance	4 (1%)	3 (2%)	0.441	Fisher's exact

TABLE 38 *Comparing nurse1 with trainer*

Outcome	Nurse1 (n = 173)	Trainer (n = 137)	p-Value	Test
Pneumothorax	3 (2%)	0	0.258	Fisher's exact
Misplacement	14 (8%)	10 (7%)	0.834	Fisher's exact
Arterial puncture	10 (6%)	5 (3%)	0.436	Fisher's exact
Haematoma	3 (2%)	1 (1%)	0.633	Fisher's exact
Line infection	7 (4%)	9 (6%)	0.440	Fisher's exact
Tunnel infection	1 (1%)	6 (4%)	0.048	Fisher's exact
Successful insertion	131(76%)	105 (77%)	0.894	Fisher's exact
Failed insertion	5 (3%)	1 (1%)	0.233	Fisher's exact
Nurse assistance	20 (12%)	5 (3%)	**0.012**	**Fisher's exact**
Oncologist assistance	1 (1%)	0	1.000	Fisher's exact
Radiologist assistance	2 (1%)	3 (2%)	0.658	Fisher's exact

assistance and radiologist assistance), there was only one statistically significant difference. Procedures carried out by the trainees were significantly more likely to require the assistance of another nurse than procedures carried out by the trainer (p = 0.002).

Comparing nurse1 with trainer

In order to ensure that one trainee was not compensating for the other trainee in terms of skill level, each of the trainees was compared with the trainer. *Table 38* shows that no statistically significant differences were identified between nurse1 and the trainer for a range of clinical and process outcomes (pneumothorax, catheter-tip misplacement, arterial puncture, haematoma, line infection, tunnel infection, successful insertion, failed insertion, oncologist assistance and radiologist assistance). The only statistically significant difference was found between nurse1 and the trainer in terms of the number of times assistance from another nurse was required. Nurse1 was more likely to ask for assistance from another nurse than the trainer (p = 0.012).

Comparing nurse2 with trainer

Table 39 shows that no statistically significant differences were identified between nurse2 and the trainer for a range of clinical and process outcomes (catheter-tip misplacement, arterial puncture, haematoma, line infection, tunnel infection, successful insertion, failed insertion, oncologist assistance and radiologist assistance). Two statistically significant differences were found between nurse2 and the trainer. Nurse2 was more likely to ask for assistance from another nurse than the trainer (p = 0.002) and was also more likely to cause a pneumothorax (p = 0.03) during the procedure.

Comparing nurse1 with nurse2

In order to check that there were no real differences between the skill levels between the trainees, the outcomes of nurse1 and nurse2 were compared. *Table 40* shows that no statistically significant differences were identified between nurse1and nurse2 for a range of clinical and process outcomes (pneumothorax, catheter-tip misplacement, arterial puncture, haematoma, line

TABLE 39 *Comparing nurse2 with trainer*

Outcome	Nurse2 (*n* = 139)	Trainer (*n* = 137)	*p*-Value	Test
Pneumothorax	6 (4%)	0	**0.030**	**Fisher's exact**
Misplacement	8 (6%)	10 (7%)	0.808	Fisher's exact
Arterial puncture	13 (9%)	5 (4%)	0.086	Fisher's exact
Haematoma	2 (1%)	1 (1%)	1.000	Fisher's exact
Successful insertion	92 (66%)	105 (77%)	0.063	Fisher's exact
Failed insertion	3 (2%)	1 (1%)	0.622	Fisher's exact
Line infection	8 (6%)	9 (6%)	1.000	Fisher's exact
Tunnel infection	8 (6%)	6 (4%)	0.785	Fisher's exact
Nurse assistance	21 (15%)	5 (4%)	**0.002**	**Fisher's exact**
Oncologist assistance	2 (1%)	0	0.498	Fisher's exact
Radiologist assistance	2 (1%)	3 (2%)	0.683	Fisher's exact

TABLE 40 *Comparing nurse1 with nurse2*

Outcome	Nurse1 (*n* = 173)	Nurse2 (*n* = 139)	*p*-Value	Test
Pneumothorax	3 (2%)	6 (4%)	0.194	Fisher's exact
Misplacement	14 (8%)	8 (6%)	0.508	Fisher's exact
Arterial puncture	10 (6%)	13 (9%)	0.278	Fisher's exact
Haematoma	3 (2%)	2 (1%)	1.000	Fisher's exact
Successful insertion	131 (76%)	92 (66%)	0.100	Fisher's exact
Failed insertion	5 (3%)	3 (2%)	0.736	Fisher's exact
Line infection	7 (4%)	8 (6%)	0.597	Fisher's exact
Tunnel infection	1 (1%)	8 (6%)	**0.012**	**Fisher's exact**
Nurse assistance	20 (12%)	21 (15%)	0.401	Fisher's exact
Oncologist assistance	1 (1%)	2 (1%)	0.587	Fisher's exact
Radiologist assistance	2 (1%)	2 (1%)	1.000	Fisher's exact

TABLE 41 *Comparing all three nurses*

Outcome	Nurse1 (*n* = 173)	Nurse2 (*n* = 139)	Trainer (*n* = 137)	Fisher's exact test, *p*-value
Pneumothorax	3 (2%)	6 (4%)	0	0.036
Misplacement	14 (8%)	8 (6%)	10 (7%)	0.724
Arterial puncture	10 (6%)	13 (9%)	5 (4%)	0.140
Haematoma	3 (2%)	2 (1%)	1 (1%)	0.741
Successful insertion	131 (76%)	92 (66%)	105 (77%)	0.088
Failed insertion	5 (3%)	3 (2%)	1 (1%)	0.398
Line infection	7 (4%)	8 (6%)	9 (6%)	0.623
Tunnel infection	1 (1%)	8 (6%)	6 (4%)	0.03
Nurse assistance	20 (12%)	21 (15%)	5 (4%)	0.006
Oncologist assistance	1 (1%)	2 (1%)	0	0.335
Radiologist assistance	2 (1%)	2 (1%)	3 (2%)	0.759

infection, successful insertion, failed insertion, nurse assistance, oncologist assistance and radiologist assistance). The only statistically significant difference was found between nurse1 and nurse2 in terms of the number of tunnel infections. Nurse2 was more likely to insert a Hickman line in those patients who go on to have a confirmed tunnel infection than nurse1 ($p = 0.012$).

Comparing all three nurses

As a final check, the skill levels of the three nurses were compared simultaneously. The results in *Table 41* show that there were no real differences and that the skill levels of the three nurses are in fact comparable.

Exploratory analysis

Analysis was also carried out in order to explore

TABLE 42 *Nurse assistance and outcomes*

Outcome	Total no. of events	Nurse assistance required during event	Fisher's exact test, *p*-value
Pneumothorax	9	4 (44%)	**0.008**
Misplacement	32	8 (25%)	**0.010**
Arterial puncture	28	14 (50%)	**0.000**
Haematoma	6	2 (33%)	0.118
Line infection	24	1 (0.04%)	0.711
Tunnel infection	15	0	0.382
Successful insertion	328	0	**0.000**
Failed insertion	9	7 (78%)	**0.000**
Oncologist assistance	3	2 (67%)	**0.029**
Radiologist assistance	7	3 (43%)	**0.026**

TABLE 43 *Mean insertion times for the three nurses*

	Nurse1 (*n* = 173)	Nurse2 (*n* = 139)	Nurse3 (*n* = 137)
Blind, mean (minutes) (SD)	38 (15)	41 (11)	34 (12)
Image-guided, mean (minutes) (SD)	39 (18)	46 (14)	38 (15)
Single-lumen, mean (minutes) (SD)	37 (14)	43 (11)	34 (13)
Double-lumen, mean (minutes) (SD)	44 (22)	45 (11)	40 (17)
Triple-lumen, mean (minutes)		90	50

TABLE 44 *Time taken for failed insertions*

Nurse	Arm	Type of line inserted	Duration of failed insertion (minutes)
Nurse1	Blind	Single PICC	75
Nurse1	Blind	Single PICC	75
Nurse2	Blind	0	70
Nurse2	Blind	0	90
Nurse1	Blind	Single PICC	90
Nurse1	Blind	0	75
Nurse2	Blind	Single PICC	60
Nurse3	Image-guided	0	60
Nurse1	Image-guided	Single PICC	120

whether or not those insertions that had required assistance from another nurse were more likely to result in poorer clinical and process outcomes than those insertions which did not require assistance. Haematoma and line and tunnel infections were the only outcomes that did not differ significantly depending on whether nurse assistance was required (*Table 42*).

Time

Table 43 presents a range of mean insertion times for each of the nurses. Nurse3 is the most experienced of the three and this is evident by the fact that, in general, she inserted Hickman lines more quickly than the trainees did. For all of the nurses, image-guided insertions took slightly longer than blind insertions and double- and triple-lumen lines took slightly longer than single-lumen lines.

Levene's test for equality of variances was used to identify whether or not equal variances could be assumed. The *t*-test for equality of means was then used to generate *p*-values to compare the mean times of the three nurses. When comparing the trainees, statistically significant differences were found in mean times for the insertion of single-lumen lines and those lines inserted under image guidance. Mean times for nurse1 were not significantly different from the trainer's times for single- or double-lumen lines or for lines inserted under image guidance. Mean times for nurse2 were significantly different from the trainer's times for single-lumen lines and lines inserted blind and

under image guidance. Simple analysis of mean insertion times appears to show that nurse1 and the trainer have similar insertion times whereas insertions performed by nurse2 take slightly longer. There were no differences in the length of time taken to insert double-lumen lines among the three nurses.

Table 44 presents the length of time that each failed insertion procedure took to complete. All of the failed insertion times were at least one hour long. Minimum time taken for a failed insertion was 60 minutes and the maximum time taken was two hours. Mean time for a failed insertion was 79 minutes (95% CLs: 65 to 93; SD = 18).

Patient satisfaction questionnaire

Information generated from the patient satisfaction questionnaire (Appendix 2) provides valuable information about the impact of extending the nurse's traditional role to include the insertion of Hickman lines.

Questionnaires were given to patients who took part in the CLIP trial (n = 470) and also to those patients who did not participate in the CLIP trial but who had a Hickman line inserted during the same study period (n = 197). A total of 150 (22%) questionnaires were completed and returned by patients.

Patient location and waiting times

Fifty-nine patients (41%) who completed the questionnaire were inpatients and 86 (59%) were day-case patients; 49% (n = 73) of patients had their line inserted on the ward and 51% (n = 75) had their line inserted in the X-ray department.

Patients whose lines were inserted on the ward were asked how long they had to wait for a bed. Of the 49 patients who responded, 10% were inpatients so they did not wait at all; 59% waited less than half an hour, 22% waited between half an hour and 1 hour and 8% waited longer than 1 hour.

Patients whose lines were inserted in the X-ray department were asked how long they had to wait for a bed. Of the 60 patients who responded, 58% waited less than half an hour, 17% waited between half an hour and 1 hour, 10% waited longer than 1 hour and 15% did not know how long they had waited. These same patients were also asked how long they waited for a vacant slot in the X-ray department. Of the 57 patients who responded, 63% waited less than half an hour, 21% waited between half an hour and 1 hour, 12% waited longer than 1 hour and 4% did not know how long they had waited.

Patients were asked how they felt about their experience of waiting times on the day of their Hickman line insertion. Of the 116 patients who gave a qualitative response, 91% were positive about the waiting time experienced. Only 10 patients (9%) were negative and felt that their waiting time was too long or their waiting time added to the anxiety felt before the procedure. Approximately 54% of patients stated that their waiting time was 'not a problem' or that it was 'fine' or 'no bother'. About 15% said that their waiting time was 'satisfactory' or 'as expected'. About 24% of patients recorded that they were pleased with their waiting time or that the waiting time was better than expected and 20% of patients said that they felt that they 'didn't have to wait' or that the waiting times were 'very good' or that they were 'very pleased' with the waiting times.

Patient appraisal of information provided

Patients were asked about the amount of written information provided to them regarding their central line insertion. The patient information leaflet used during the trial period is presented in Appendix 5. Almost 97% (n = 143) of patients stated that they had been given the right amount of written information and 3% (n = 5) felt that they had been given more information than they wanted. Patients were also asked about the amount of verbal information provided to them regarding their central line insertion. Again, 97% (n = 145) felt that they had been given the right amount of verbal information and only 3% (n = 4) felt that they had been given more information than they wanted.

Patient experience of anxiety

Patients were asked about their level of apprehension prior to the insertion of their central line: 22% (n = 33) of patients said they were not at all apprehensive, 49% (n = 73) said they were a little apprehensive and 29% (n = 44) said they were very apprehensive. Patients were asked to state what caused them to feel anxious before having their central line inserted. They were given a range of options to choose from: fear of pain, a complication occurring, unsuccessful procedure, other reason or not applicable as the patient did not feel anxious. Patients were invited to choose as many reasons as was appropriate. About 34% of all patients (n = 141) stated they

were anxious due to fear of pain, 46% stated they were anxious because of the possibility of a complication occurring, 21% were anxious about an unsuccessful procedure and 19% gave another response as the source of their anxiety. Other responses included lack of information given at satellite hospital, general anxiety about having cancer treatment and fear of the unknown. About 20% of patients claimed not to be anxious about the procedure.

Of the 80% (n = 113) of patients who stated a reason(s) for their apprehension, 21 said that their apprehension was due to fear alone, 33 said that their apprehension was totally due to the possibility of a complication occurring, eight solely feared an unsuccessful procedure and 11 listed a single other reason for their apprehension. Forty patients therefore listed more than one reason for their apprehension before the procedure.

Sedation

Some 98% (n = 147) of patients stated that they were offered sedation to make them feel drowsy and relaxed during the procedure. One patient responded that they did not know if it had been offered and one patient said that sedation had not been offered. About 83% (n = 124) stated that they accepted the sedation and 17% of patients refused sedation.

Patient experience of the procedure

Patients were asked if they found the procedure uncomfortable: 117 patients (78%) stated that the procedure was not uncomfortable at all, 31 (21%) said the procedure was a little uncomfortable and two (1%) felt that it was very uncomfortable. Patients were also asked if they found the procedure painful: 120 patients (80%) did not find the procedure painful at all whereas 30 (20%) found the procedure a little painful.

When asked if the level of pain or discomfort experienced was what was expected, 63% (n = 86) reported that it was not as bad as expected, 11% (n = 15) said that it was the same as expected, 1% (n = 1) said it was worse than expected and 25% (n = 34) said that they had not known what to expect.

Further comments from patients

About 58% (n = 63) of respondents had further comments to make about the insertion of their Hickman line. Only 1% could be interpreted as negative comment. Almost all patient comments were favourable and there was great support for the nursing staff (n = 35). In general, patients praised the nursing staff for their reassurance (n = 19), helpfulness (n = 11) and professionalism (n = 8). Although the survey responses suggest that 5% (4/73) of patients had misplaced lines and one patient suffered a pneumothorax, these patients were generally positive about their experience. To illustrate this, one respondent made the comment, 'had to go to X-ray to readjust line from neck to correct position, would have been good if this had not happened, but the procedure went well'.

Statistical analysis

In order to identify any statistically significant differences between the patients who had their line inserted on the ward and the patients who had their line inserted in the X-ray department, a chi-squared analysis or Fisher's exact test was performed where appropriate. There was only one identified statistically significant difference between these two groups. Some 13% (8/60) of patients who had their line inserted on the ward stated that the possibility of an unsuccessful procedure caused them to feel anxious; 42% (21/50) of patients who had their line inserted in the X-ray department reported that the possibility of an unsuccessful procedure caused them to feel anxious. This difference was statistically significant at the 95% level as p = 0.012.

The Mann–Whitney U-test was performed in order to identify any differences between patients whose lines were inserted on the ward and in the interventional X-ray suite in terms of apprehension, pain and discomfort levels. No statistically significant results were found

The Mann–Whitney U-test was also performed to identify any differences in discomfort and pain between patients who were given a sedative and patients who were not given a sedative. No statistically significant results were identified.

Economic evaluation

In order to conduct the economic evaluation, total costs and total benefits were calculated for each arm of the trial. *Table 45* presents the total cost figures for the blind and the image-guided arms of the RCT. It also shows mean per patient costs in each of the trial arms.

Minimum and maximum costs per patient in the blind arm were £309.07 and £2102.97, respectively. The mean cost per patient was £440.40 (95% CL: 397.00 to 483.81; SD = 337). Minimum and maximum costs in the image arm

TABLE 45 *Total and per patient costs in each of the trial arms*

Cost	Blind (£)	Image-guided (£)	Per patient in blind arm (£)	Per patient in image-guided arm (£)
Basic insertion	73463.39	89704.94	312.49	381.72
Unplanned events	30059.33	19469.43	128.37	83.22
Care of misplacement	3710.36	281.35	1.10	1.67
Care of pneumothorax	2488.62	355.62	10.55	1.52
Care of arterial puncture	260.00	390.00	15.72	1.20
Care of infection	19538.52	17372.24	82.79	74.24
Failed insertion	3707.04	806.30	15.71	3.45
Nurse assistance	92.80	57.60	0.39	0.25
Oncologist assistance	37.74	0.00	0.16	0.00
Radiologist assistance	37.74	50.32	0.16	0.22
Transfer from blind to image	186.51	0.00	0.79	0.00
Extra line	0.00	156.00	1.00	0.67
Total	103495.62	109174.40	440.40	464.57

Note: figures are all rounded to two decimal places.

TABLE 46 *Basic insertion costs*

	Unit cost (£)		Events		Cost (£)	
Hickman lines	Blind	Image-guided	Blind	Image-guided	Blind	Image-guided
Single-lumen	309.07	378.40	175	177	54087.25	66976.8
Double-lumen	321.07	390.40	59	57	18943.13	22252.8
Triple-lumen	406.01	475.34	1	1	406.01	475.34
Total			235	235	73436.39	89704.94

were £378.40 and £1530.54, respectively. The mean cost per patient was £464.57 (95% CL: 428.58 to 500.56; SD = 280). Levene's test for equality of variances showed that the mean costs had unequal variances. The *t*-test for equality of means revealed that there were no real differences in costs between the two arms of the trial ($p = 0.399$).

Basic insertion costs

In the blind arm, 175 single- and 59 double-lumen lines were inserted during the trial period (not the planned 177 and 57 as in *Table 24*). This is due to two planned single-lumen lines being inserted as double-lumen lines. As the decisions to change the types of line inserted were made before the start of the procedures and were related to the patient's health status, only one line was required during each of the insertions. All other insertion procedures which included lines which were planned but not actually inserted ($n = 11$) during the trial incurred the additional cost of the planned line, where appropriate, because they would have been used during the basic procedure.

The costs of the basic insertion procedure (*Table 46*) made up the majority of the total costs in the blind and image-guided arms of the trial (71 and 81%, respectively). Inserting Hickman lines in the X-ray suite under image guidance was more costly than insertion at the bedside. The main reason for this cost difference between the two approaches was the cost of using the X-ray suite, for which additional charges were incurred. The X-ray suite charges included the cost of the chest X-ray.

Catheter-tip misplacement costs

In the blind arm, 32 catheter tips were misplaced. The resources consumed in order to reposition a line included radiology charges, nursing time, radiologist time, consumables and Hickman line insertion pack. The actual resources consumed depended on the position of the misplaced catheter tip. Different patients required different manipulation techniques to be performed by the nurses and, in two cases, by a radiologist. Only one patient required an overnight stay in order to have their line repositioned the next morning. However, this patient had been admitted as an inpatient and therefore the costs of the overnight stay were not included in the analysis. *Table 47* shows the costs associated with each of the

TABLE 47 *Costs of rectifying catheter-tip misplacement*

Misplacement technique	Unit cost (£)	Blind	Image-guided	Blind arm cost (£)[a]	Image-guided arm cost (£)
Flush single	50.98	8	0	407.84	0
Flush double	55.23	1	0	55.23	0
Reposition single (n)	98.98	7	0	692.86	0
Reposition double (n)	99.53	9	0	895.77	0
Reposition single (r)	280.80	1	0	280.80	0
Reposition double (r)	281.35	0	1	0	281.35
Rewire double	188.43	4	0	753.72	0
Single removed and reinserted by nurse	306.07	1	0	306.07	0
Double removed and reinserted by nurse	318.07	1	0	318.07	0
Total				3710.36	281.35

[a] Mean cost of catheter tip misplacement in blind arm is £115.94 (95% CL: £89.47 to 142.41; SD = 73).
n, Nurse; r, interventional radiologist.

TABLE 48 *Costs of treating pneumothorax*

Costs of pneumothorax	Unit cost (£)	Event	Blind (£)	Events	Image-guided (£)	Total (£)
Consumables	25.09	1	25.09	0	0	25.09
Overnight stay	130.00	11	1430.00	0	0	1430.00
Chest X-ray	55.00	17	935.00	6	330.00	1265.00
Nurse	1.28	1	1.28	0	0	1.28
Specialist registrar	7.58	1	7.58	0	0	7.58
Extra nursing time	12.81	7	89.67	2	25.62	115.29
Total			2488.62		355.62	2844.24

techniques used. The costs of repositioning a misplaced catheter tip ranged from £50.98 to £318.07.

Pneumothorax costs

The clinical and resource consequences of patients with pneumothoraces were different and therefore the resource implications were analysed at an individual patient level. For example, only one patient had a large pneumothorax and had a chest drain inserted by a specialist registrar and removed by a nurse. Patients with pneumothoraces consumed the following resources: overnight stay, consumables, nursing time, specialist registrar time and chest X-rays. *Table 48* summarises the costs associated with seven pneumothoraces in the blind arm and two pneumothoraces in the image-guided arm of the trial. The mean cost of a pneumothorax in the blind arm was £316.02 (95% CL: £23.80 to 608.25; SD = 380).

Arterial puncture costs

In the blind arm, 15 patients had arterial punctures during the insertion procedure. Eleven out of these 15 patients were admitted as inpatients. Therefore, only four patients in the blind arm had overnight stays that were unplanned. Two of the four patients with arterial punctures also suffered pneumothoraces. To avoid double counting for these patients, only one overnight stay per patient was accounted for and this was included under the pneumothorax resource group heading. Two of the four had failed procedures without a pneumothorax and therefore the costs of two unplanned overnight stays were included in the analysis at a total cost of £260.00. In the image-guided arm, 13 patients had arterial punctures. Ten out of 13 patients were booked in as inpatients. Therefore, only the cost of three unplanned overnight stays were included in the analysis at a total cost of £390.00.

Infection costs

The unit costs of treating infection (*Table 49*) were the same for patients who had their Hickman lines inserted in either arm of the trial. Resources associated with the treatment of both line and tunnel infections included inpatient stay, drugs, nursing time, medical staff time, blood cultures, swabs and consumables. Patients with infected double-lumen lines were more expensive to treat than patients with infected single-lumen lines as swabs and blood cultures had to be taken from more than one lumen. The cost of treating patients ($n = 5$) with a line and a tunnel infection at the same time was assumed to be the same as a patient with a line infection.

TABLE 49 *Costs of infection*

Infection (excluding doubles)	Unit cost (£)		Cost of events (£)[a]			
	Single	Double	Blind		Image-guided	
			Single	Double	Single	Double
Line infection	1062.14	1104.14	4248.56	6624.84	5310.7	9937.26
Tunnel infection	1062.14	1104.14	4248.56	4416.56	2124.28	0

[a] Total costs in blind arm = £19,538.52. Total cost in image-guided arm = £17,372.24.

TABLE 50 *Failed insertion costs*

Failed insertion type	Blind arm (£)[a]	Image-guided arm (£)[a]
PICC insertion during procedure	66.33	
PICC insertion during procedure	66.33	
PICC insertion during procedure/insertion in jugular by radiologist at a later date	368.95	
PICC insertion during procedure/insertion in femoral by oncologist at a later date/ infection/PICC insertion	1778.69	
Referred for femoral insertion by oncologist at a later date	402.28	
Referred for femoral insertion by oncologist at a later date		415.90
PICC inserted during procedure/Hickman inserted at a later date	444.73	
PICC insertion 2 days later/Hickman inserted at a later date	579.73	
Rebooked for Hickman line insertion by nurse		390.40
Total cost	3707.04	806.30

[a] Mean cost of failed insertion in blind arm = £529.60 (95% CL: £–9.82 to 1069.04; SD = 583). Mean cost of failed insertion in image arm = £403.15 (95% CL: £241.17 to 565.15; SD = 18).

TABLE 51 *Costs of assistance by healthcare professionals*

	Unit cost (£)	Events		Cost (£)	
		Blind	Image-guided	Blind	Image-guided
Nurse assistance	3.20	30[a]	17	92.80	57.60
Oncologist assistance	12.58	3	0	37.74	0
Radiologist assistance	12.58	3	4	37.74	50.32
Total				168.28	107.92

[a] During one procedure, assistance was provided by two nurses, hence this figure is one higher than reported previously (*Tables 35* and *37*).

Failed insertion costs

Each of the procedures which were defined as failed insertions (n = 9) had different clinical and resource consequences. It was necessary to calculate the costs of the procedure for each individual patient in the RCT (*Table 50*). If a PICC line was inserted during the procedure, then the cost of the PICC line was included in this category with the cost of the planned line included in the basic insertion cost category as insertion of the Hickman line would have been attempted. In the blind arm, costs ranged from £66.33 to £1778.69. In this group, resources consumed included PICC insertion pack, referral to radiologist or oncologist for Hickman line insertion and treatment of infection.

Assistance from other healthcare professionals

The costs of assistance from other healthcare professionals during the RCT were relatively small compared with the other cost generating events that took place (*Table 51*). The costs of assistance from a nurse were less expensive than the costs of

TABLE 52 *Mean cost of single-, double- and triple-lumen lines*

Type of line	No. of lines	Average cost of insertion (£)	SD	95% CI
Single, blind	177	395.27	263	355.89 to 433.69
Double, blind	57	581.14	321	453.84 to 708.81
Triple, blind	1	406.01		
Single, image-guided	177	414.48	180	387.80 to 441.16
Double, image-guided	57	619.86	439	503.13 to 736.59
Triple, image-guided	1	478.54		

assistance from an oncologist or a radiologist as the cost of healthcare professional assistance was measured in minutes and estimated using CHNT salary scales. It was assumed that the duration of assistance by any of the healthcare professionals was 15 minutes. The total cost of nurse assistance was greater than oncologist or radiologist assistance in both arms because the assistance of another nurse was called for more frequently than assistance from a doctor.

Transfer costs

Only three patients were transferred from the bedside to the interventional X-ray suite during the procedure. Radiology charges were used to calculate the total transfer costs based on a 30-minute stay in the interventional X-ray suite. The total cost of transfer was £186.51.

Additional line costs

Only two Hickman lines were included in the additional line costs category and these lines were double-lumen lines that were changed to single-lumen lines during the basic insertion procedure. Both of these procedures took place in image guidance. The total additional line cost was £156.00 for the image arm of the trial.

Planned single- versus planned double-lumen Hickman lines

Table 52 presents cost data on single- and double-lumen Hickman lines. It shows that the mean insertion cost of a double-lumen Hickman line in the trial was more expensive than the mean insertion cost of a single-lumen Hickman line. The mean cost of a double-lumen line was the most expensive of all three lines because double-lumen lines were associated with more expensive complications than the others.

Table 53 shows the mean cost of inserting single-, double- and triple-lumen Hickman lines during which complications occurred. *Figure 3* shows the cost of uncomplicated insertions versus complicated insertions.

TABLE 53 *Mean cost of single-, double- and triple-lumen lines with complications*

Type of line	Mean (£)	SD
Single, blind, complicated	625.51	431
Double, blind, complicated	957.81	556
Triple, complicated	478.54	
Single, image-guided, complicated	733.22	463
Double, image-guided, complicated	1044.37	527

Incremental cost-effectiveness analysis

In the economic analysis of blind and image-guided Hickman line insertions by nurses, the primary clinical outcome of interest was the rate of catheter-tip misplacement. However, in any economic evaluation, the choice of effectiveness measure can impact on the incremental cost-effectiveness ratio (ICER) calculated. In order to explore the potential effect of different effectiveness measures in this economic analysis, a range of outcome measures were used. The three effectiveness measures used in the economic evaluation were as follows:

1. catheter-tip misplacement avoided
2. successful insertion
3. all other clinical complications avoided.

Catheter-tip misplacement avoided

Figure 4 shows both the costs and proportion of misplaced catheter tips avoided associated with each of the trial arms. Proportion of misplaced catheter tips can also be expressed as proportion of correctly placed tips during the basic insertion procedure. The 95% CIs around the point estimates are also shown.

For meaningful comparison, it is important to look at the additional costs and benefits that the image-guided approach would impose over the blind approach. In order to do this, incremental cost-effectiveness per misplaced catheter tip avoided was calculated.

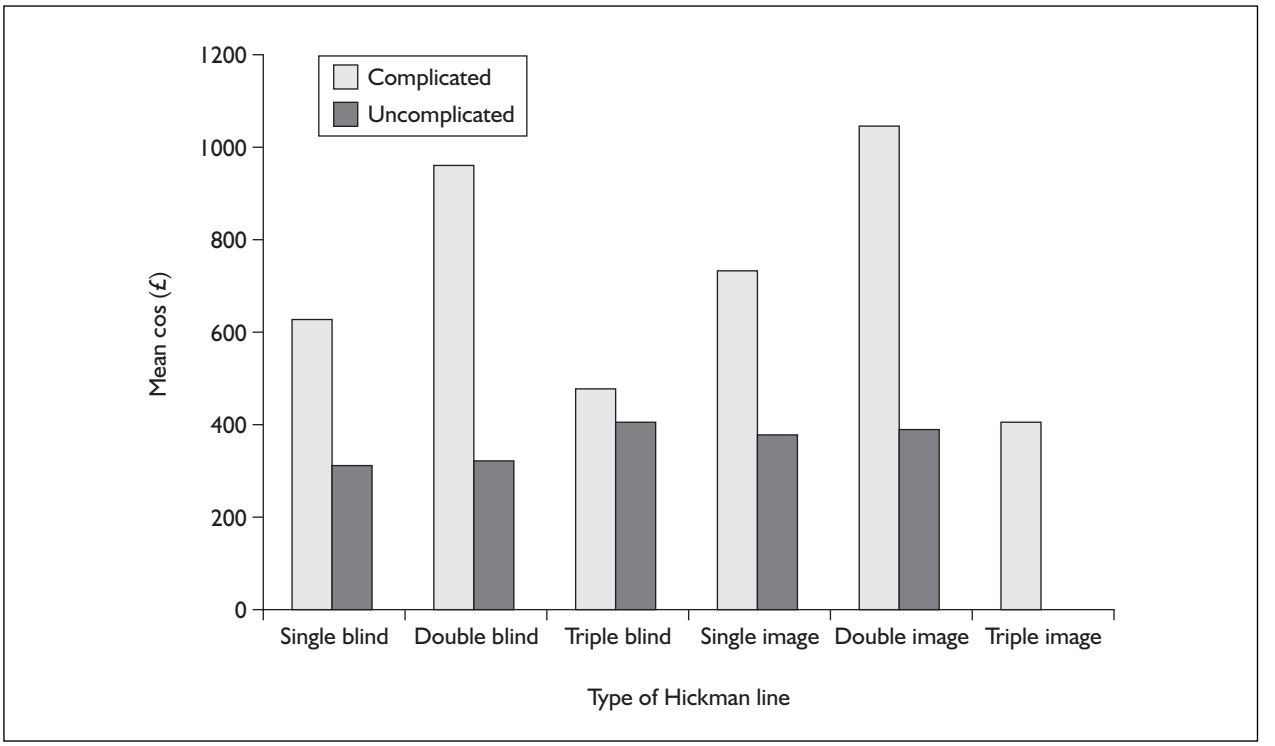

FIGURE 3 *Costs of complicated and uncomplicated Hickman line insertions*

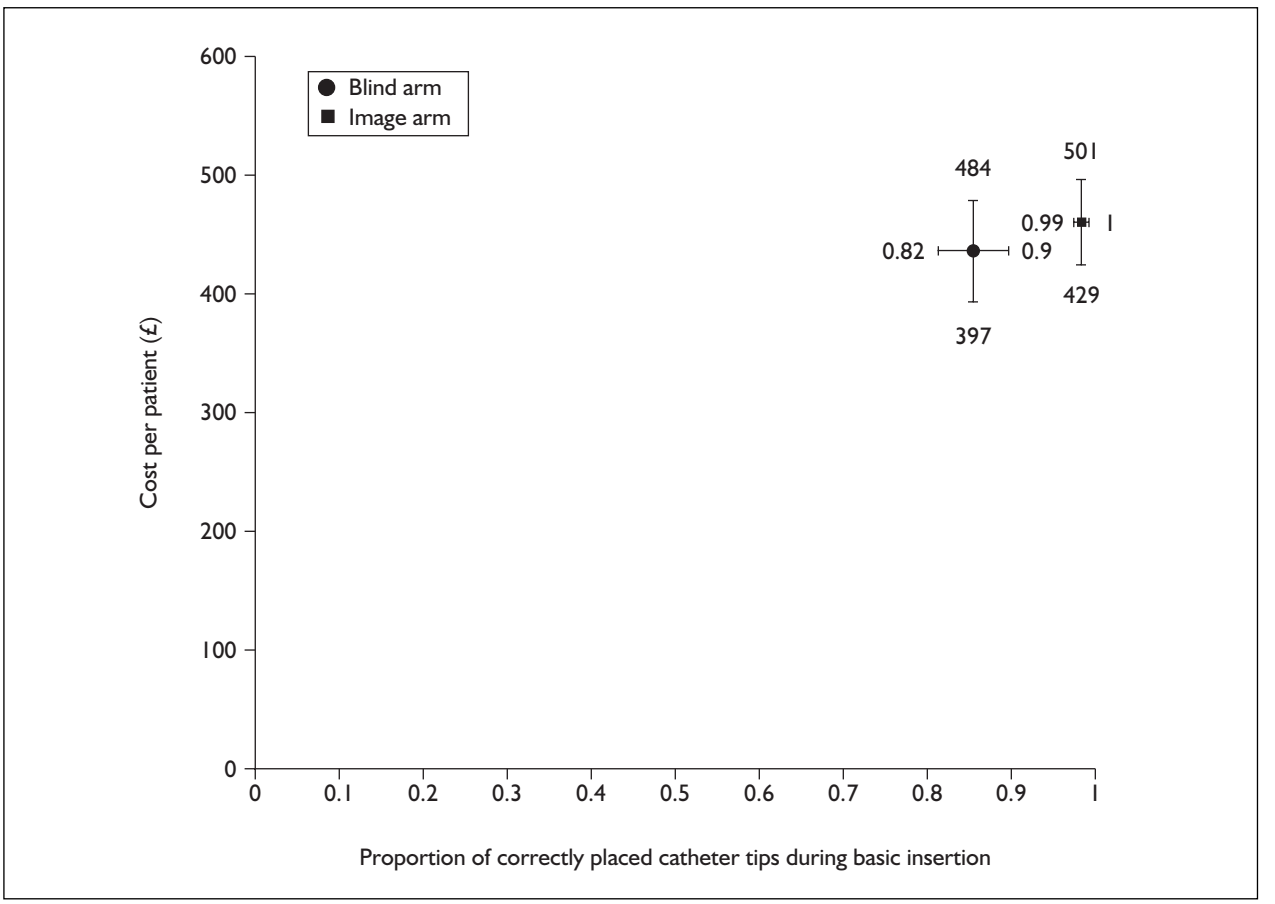

FIGURE 4 *Cost-effectiveness plane for correct placement of catheter tips during basic insertion*

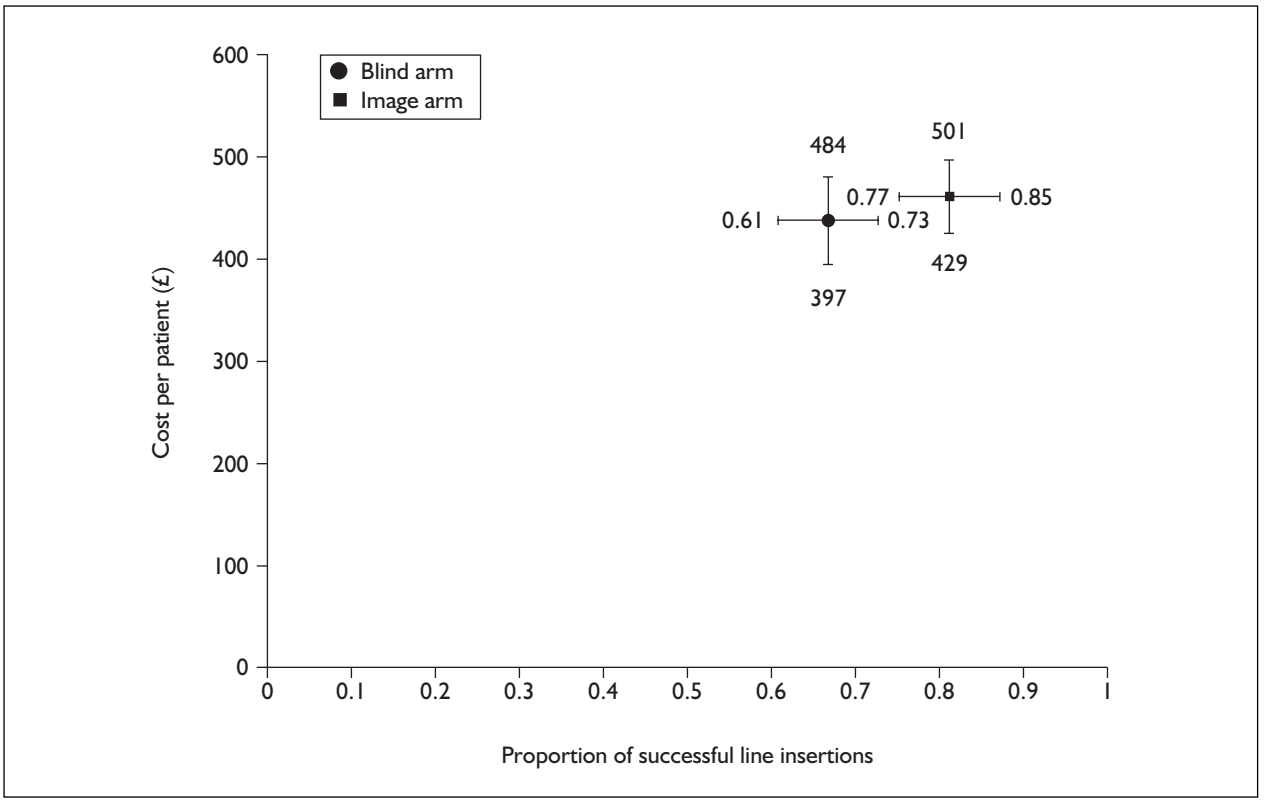

FIGURE 5 *Cost-effectiveness plane for successful line insertion*

Incremental cost per misplaced catheter tip avoided

= (Mean cost per patient in the image-guided arm – mean cost per patient in the blind arm)/(rate of misplacement in the blind arm – rate of misplacement in the image-guided arm)
= (£464.57 – 440.40)/(0.13617 – 0.00425)
= £24.17/0.13192
= £183.22

This means that if there is a switch from blind insertion to image-guided insertion, then a cost of £183.22 is incurred for every additional misplaced catheter tip that is avoided.

Successful line insertion

A successful insertion was defined as an insertion that did not require any assistance by another healthcare professional, nor did it result in any clinical complications or infection. Clearly, the number of successful lines associated with blind and image-guided insertion is affected by the rate of misplaced catheter tips. This measure of effectiveness also incorporates the process outcomes described in this report as the number of successful lines is also affected by the rate of assistance required during the procedure. *Figure 5* shows both the costs and proportion of successful line insertions associated with each of the trial arms. Again, 95% CIs around the point estimates are also shown.

Incremental cost per successful line insertion

= (Mean cost per patient in the image-guided arm – mean cost per patient in the blind arm)/(rate of successful insertions in the image-guided arm – rate of successful insertion in the blind arm)
= (£464.57 – 440.4)/(0.812766 – 0.668085)
= £24.17/0.144681
= £167.05

This means that that if there is a switch from blind insertion to image-guided insertion, then a cost of £167.05 is incurred for every additional successful Hickman line inserted.

All other clinical complications avoided

The term 'all other clinical complications avoided' refers to the risk of any other clinical complication occurring excluding catheter-tip misplacement (i.e. risk of pneumothorax, arterial puncture, haematoma or infection). During the trial, all catheter-tip misplacements were routinely repositioned on the same day as the basic insertion procedure. In the blind arm there were 39/235 (17%) other complications excluding misplacement. In the image-guided arm there

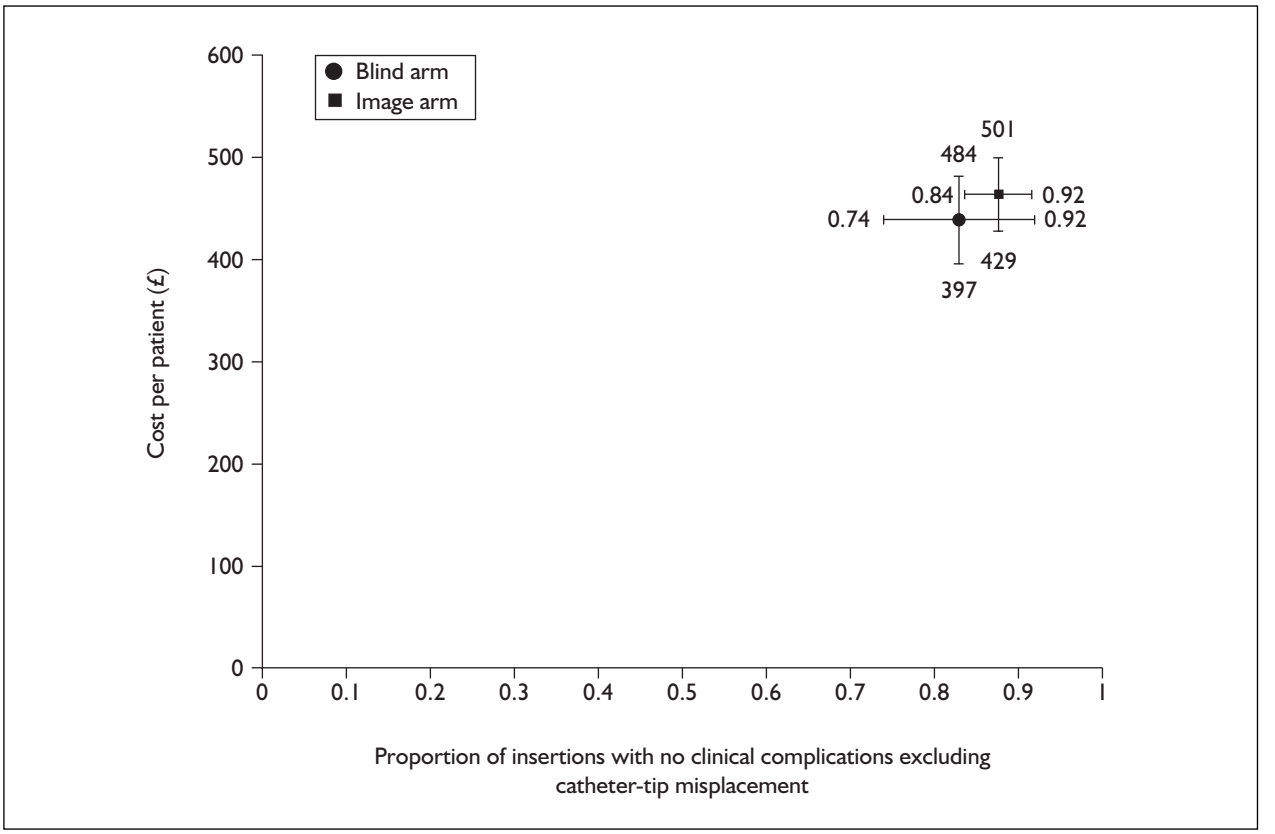

FIGURE 6 *Cost-effectiveness plane for all other clinical complications avoided*

were 28/235 (11%) other complications excluding misplacement. *Figure 6* shows both the costs and proportion of all other clinical complications avoided with each of the trial arms. Again, 95% CIs around the point estimates are also shown.

Incremental cost per clinical complication avoided (excluding misplaced catheter tip)

= (Mean cost per patient in the image-guided arm – mean cost per patient in the blind arm)/(rate of misplacement in the blind arm – rate of misplacement in the image-guided arm)
= (£464.57 – 440.40)/(0.165 – 0.119)
= £24.17/0.046
= £525.43

This means that if there is a switch from blind insertion to image-guided insertion, then a cost of £525.43 is incurred for every additional clinical complication avoided excluding catheter-tip misplacement.

Sensitivity analysis

Interventional X-ray suite charges

One-way sensitivity analysis was undertaken on the data in order to estimate the effect of changing the costs of using the interventional X-ray suite on total costs and on the ICERs. The primary reason for varying the radiology charges was that the radiology charges were the main difference in costs between routine blind and image-guided Hickman line insertions. Also, X-ray costs were a cost component of catheter-tip misplacement and failed insertions. In addition, the radiology costs are tariff-based unit costs and therefore may not reflect the true cost of using the X-ray suite for this particular group of oncology patients. After discussions with staff in the Finance Department at the CHNT, the plausible range of values for the variation was estimated to be 10% above and 10% below the unit costs already used in the analysis. However, to illustrate the importance of the effect of changing these costs, the range for the sensitivity analysis is –50 to +50%.

Figure 7 shows the relationship between the interventional X-ray suite charges and the mean cost per patient in each of the trial arms. As is anticipated, the mean cost per patient in the image-guided arm is positively correlated with the rise in X-ray suite charges.

If there had been large differences in the skill levels among the nurses, then the effectiveness outcomes would have been varied to see whether or not there would have been any effect on costs.

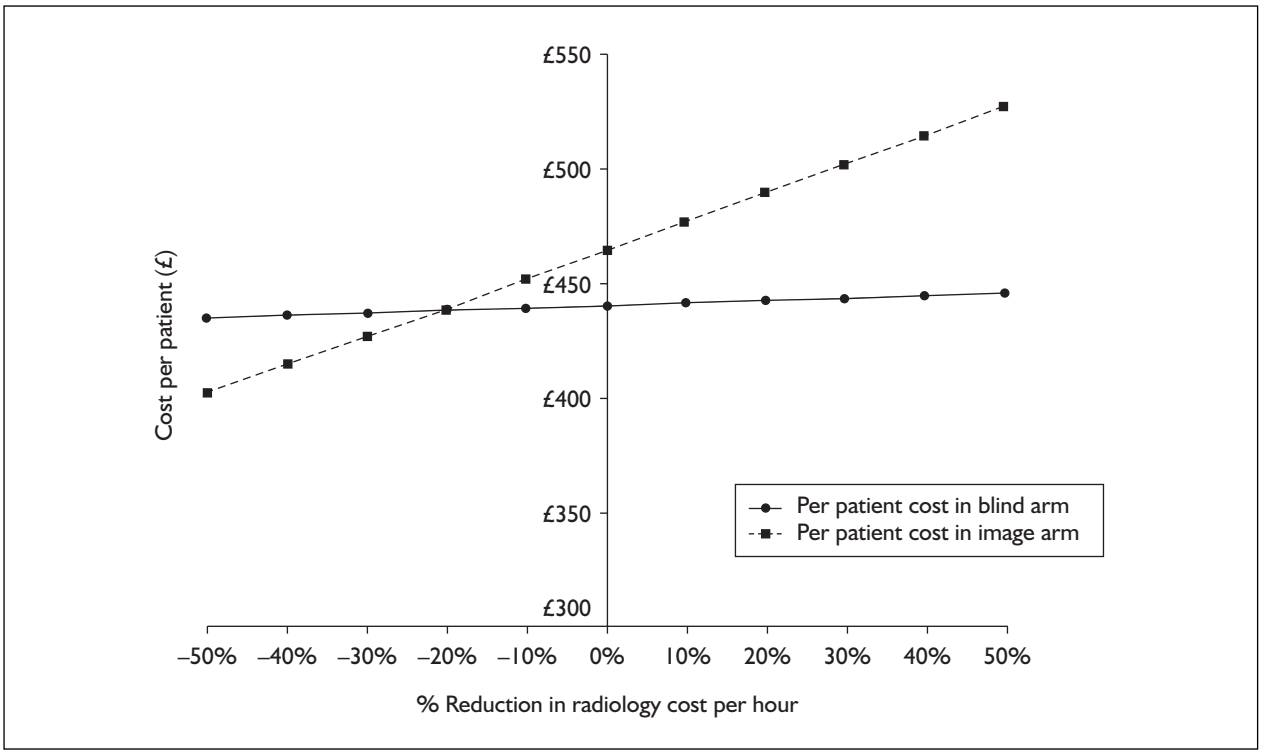

FIGURE 7 *Effect of varying radiology charges on per patient costs*

However, there were no real differences in the performance of the three nurses and so this exercise was not performed.

No sensitivity analysis was carried out on the acquisition costs of the Hickman lines as both arms in the trial used approximately the same number of lines. Even though the CHNT purchases the lines at a discounted price, varying this figure in the analysis would have no effect on the preferred mode of insertion, only on total costs.

Figure 8 shows how changing the interventional X-ray suite charges affects the ICERs. It is clear that two of the ICERs are very similar. This is to be expected because they both include an estimate of catheter-tip misplacement. If X-ray suite costs were 30% less than the costs stated in the trial (i.e. £87.03), then the ICERs become negative, that is, savings can be made by adopting the dominant strategy, which in this example would be the image-guided approach.

Resource implications of Hickman line insertions by nurses across the NHS

The three main aims of this section are as follows:

1. to estimate the costs of expanding the nurse training programme for the insertion of Hickman lines to meet the needs of cancer centres and units across the NHS
2. to estimate the total annual costs and benefits of Hickman line insertions by nurses and doctors in cancer centres and units in England and Wales
3. to describe the cost of moving towards 100% image-guided Hickman line insertions and 100% bedside insertions in cancer centres and units in England and Wales.

As there are no readily available published data to achieve the above aims, much use is made of unpublished results from a national survey carried out by a member of the current research team. As the conduct of this survey was not included in the original grant application, it has not been included in the main body of this report. Inclusion of the survey results in this section is for illustrative purposes only. Full details of the survey can be found in Appendix 6.

Expanding the nurse training programme to meet the needs of the NHS

Any estimate of the cost of a national nurse training programme for the insertion of Hickman lines depends on an accurate estimate of demand

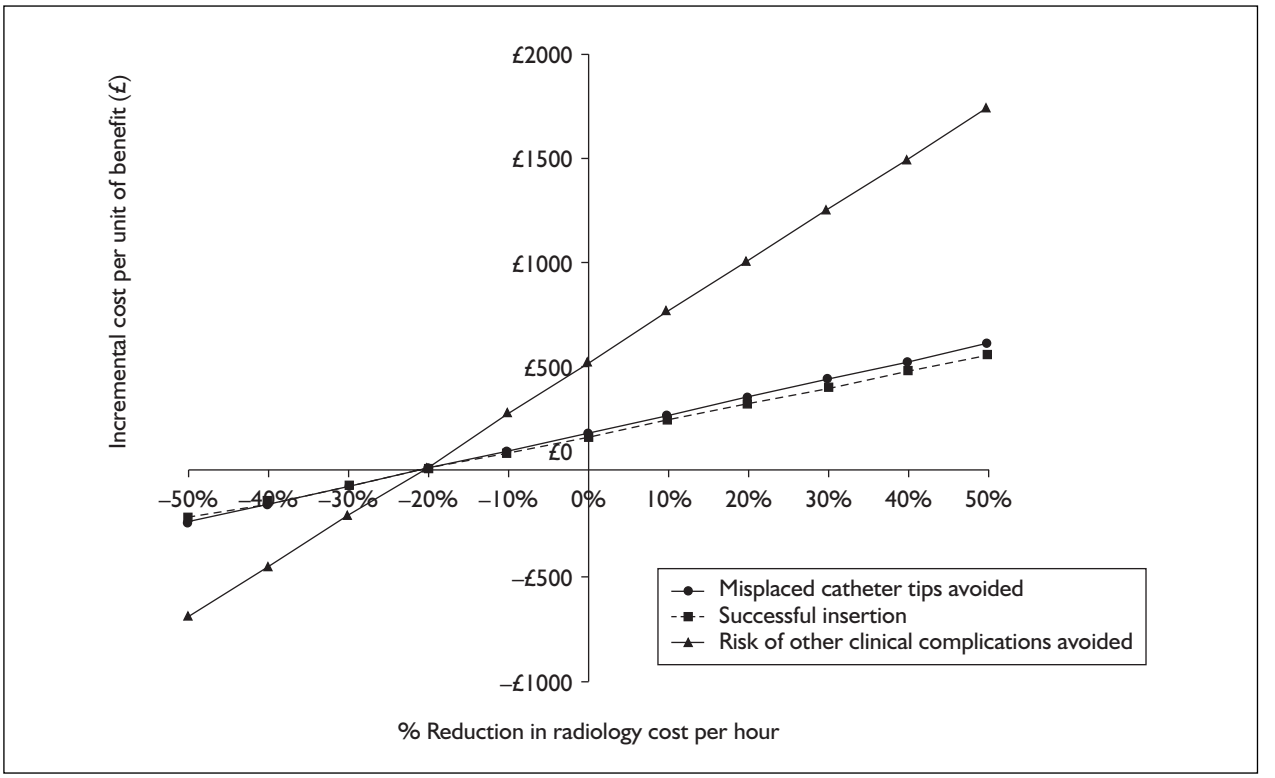

FIGURE 8 *Incremental cost-effectiveness ratios*

for this service. Not every cancer centre or cancer unit in the UK will require that staff be trained in the insertion of Hickman lines. Some cancer centres and cancer units may not want to change the delivery of their current insertion services or the organisation may have insufficient demand for Hickman line insertions to merit the training of new staff. As shown in *Table 54*, estimates from a national survey, as described in Appendix 6, revealed that approximately 70% of cancer centres and units perform between one and five Hickman line insertions per week. One member of staff could be expected to manage this level of service provision. About 21% of respondents stated that they insert less than one Hickman line per week; additional information from this latter group of respondents suggested that a more accurate estimate would be two Hickman line insertions per month for these centres and units. Only 5% of the cancer centres or units who responded to the survey insert more than five Hickman lines per week.

When asked, survey respondents revealed that, in principle, they were eager for nursing staff to be trained to insert Hickman lines. Approximately 40% of organisations that responded stated that they would like at least one nurse to be trained to insert Hickman lines. Not all organisations that were surveyed responded to the questionnaire.

TABLE 54 *Number of Hickman line insertions*

Hickman lines inserted per week	*n* = 107	%	Minimum implied total annual volume	Estimated implied total volume	Maximum implied total annual volume
0	23	21	0		0
1–5	76	71	3952	11856	19760
6–15	3	3	936	1638	2340
16–30	2	2	1664	2392	3120
31–45	0	0	0	0	0
>45	0	0	0	0	0
Don't know	3	3	189 (est.)	455	728 (est.)
Total	107	100	6741	16341	25948

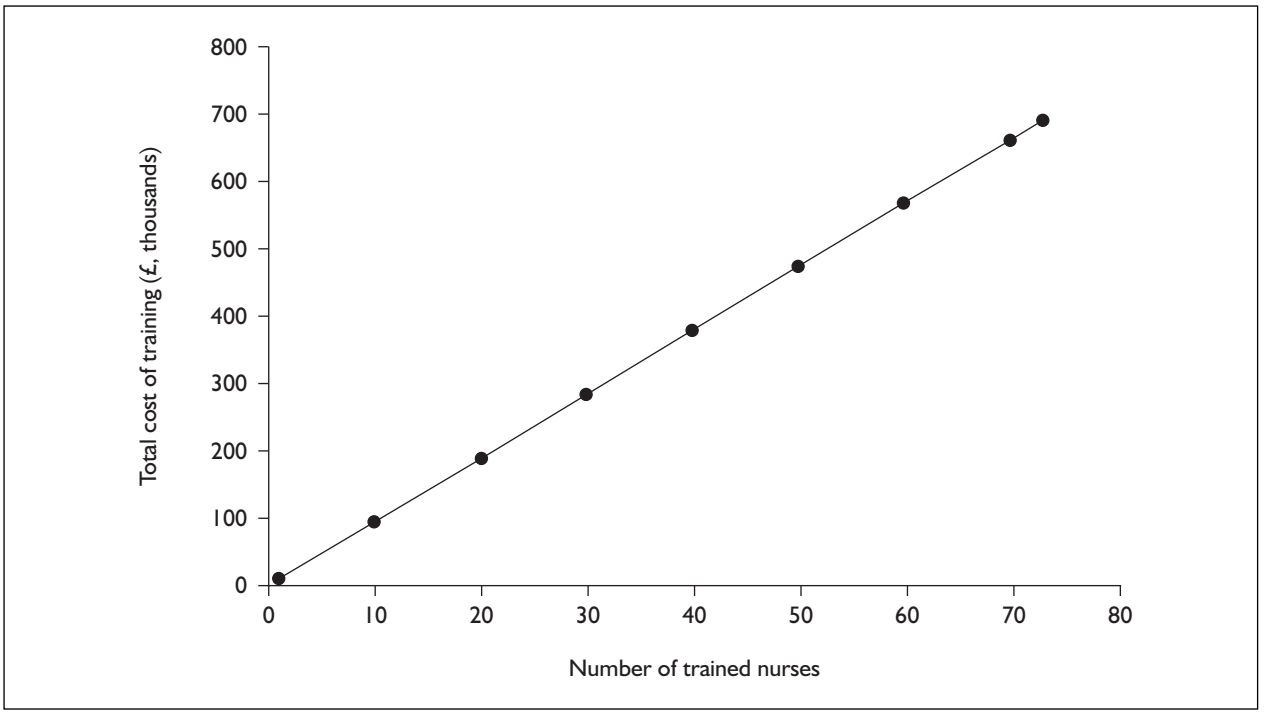

FIGURE 9 *Total nurse training costs*

Had they responded in a similar way to those who did reply, it is estimated that 73 cancer centres and cancer units across England and Wales would demand at least one nurse to be trained to insert Hickman lines (42% of 172). As shown in *Figure 9*, at an average cost of £9564 per nurse trained, the estimated total resource cost would be approximately £700,000.

If training were demanded for 73 nurses, then clearly the design of the nurse training programme as described in this report would have to be revisited. Given the hands-on clinical training involved, no single organisation could take responsibility for training this number of nursing staff. A network of regional training centres would have to be set up to coordinate the provision and organisation of this level of training. However, if a national programme were developed, then economies of scale could be achieved and the training cost per nurse would be reduced. The estimated nurse training cost of £9564, as calculated in this report, is based on only two nurses being trained simultaneously. It is acknowledged that the training cost per nurse calculated is therefore likely to be an upper estimate of the true cost of training.

Annual costs of Hickman line insertions in cancer centres and units

Before the annual total costs of inserting Hickman lines in cancer centres and units in England and Wales can be estimated, the following information is required:

1. How many Hickman lines are currently inserted in cancer centres and units?
2. Who inserts Hickman lines?
3. Where are Hickman line insertions performed?
4. How are Hickman lines inserted?

Answers to the above questions are not available. There are no published estimates of the annual number of Hickman lines inserted in adult cancer patients in the NHS in England and Wales. There are no reports of how many lines are inserted by doctors and nurses. Although it is well known that the majority of Hickman line insertions are performed in operating theatres, interventional X-ray suites and at the patient's bedside, there are no reliable sources of evidence detailing who does what, where and how often.

Based on national survey responses and expert opinion in the field, we estimate that about 16,000 Hickman line insertions (minimum = 6500 and maximum = 25,000) are currently performed each year in cancer centres and units across the UK NHS (see *Table 54*). We also assume that of all the Hickman lines inserted by doctors, 30% are inserted in X-ray suites, 55% in operating theatres and 15% at the patients' bedside. If we further assume that nurses perform approximately 10% of all Hickman line insertions in cancer centres and

BOX 7 *Assumptions*

Estimated total number of Hickman line insertions per year = 16,000
Mean cost of tip misplacement by nurse at the bedside = £505.49
Mean cost of insertion with tip OK by nurse at the bedside = £430.148
Mean cost of tip misplacement by nurse in X-ray =£684.33
Mean cost of insertion with tip OK by nurse in X-ray = £468.633
Mean cost of tip misplacement by doctor at the bedside = £542.99
Mean cost of insertion with tip OK by doctor at the bedside = £467.65
Mean cost of tip misplacement by doctor in operating theatre = £721.83
Mean cost of insertion with tip OK by doctor in operating theatre = 501.13
Mean cost of tip misplacement by doctor in X-ray =£721.83
Mean cost of insertion with tip OK by doctor in X-ray = £501.13
Costs of using X-ray suite = costs of using operating theatre
Benefits of using operating theatre = benefits of blind insertion
30% of Hickman lines inserted under image guidance by doctors
55% of Hickman lines inserted blind in the operating theatre by doctors
15% of Hickman lines inserted blind at the bedside by doctors
60% of Hickman lines inserted under image guidance by nurses
40% of Hickman lines inserted blind at the bedside by nurses
Catheter-tip misplacement avoided rate if inserted blind = 0.863
Catheter-tip misplacement rate avoided if inserted under image guidance = 0.995

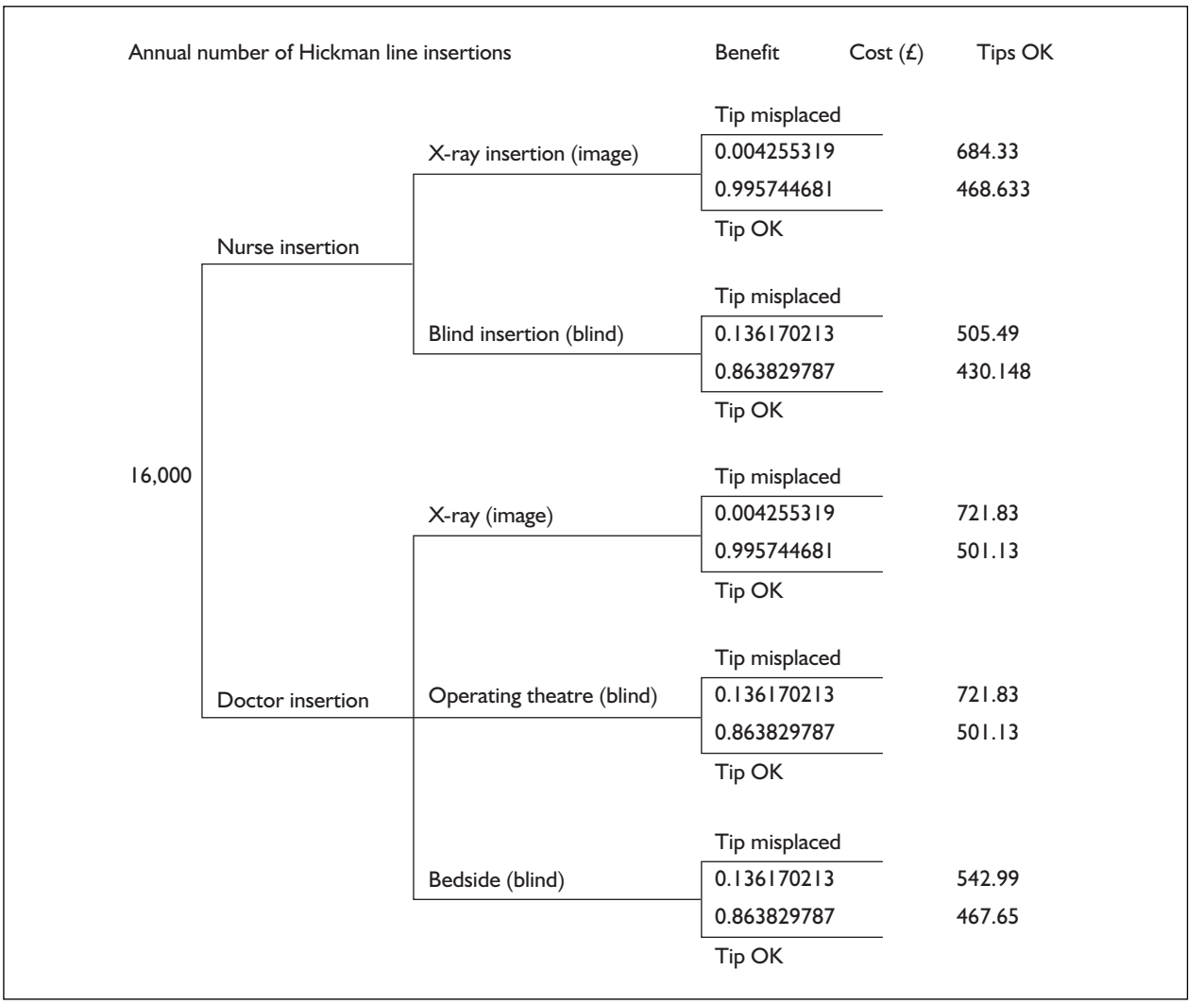

FIGURE 10 *Total annual costs of Hickman line insertions in cancer patients*

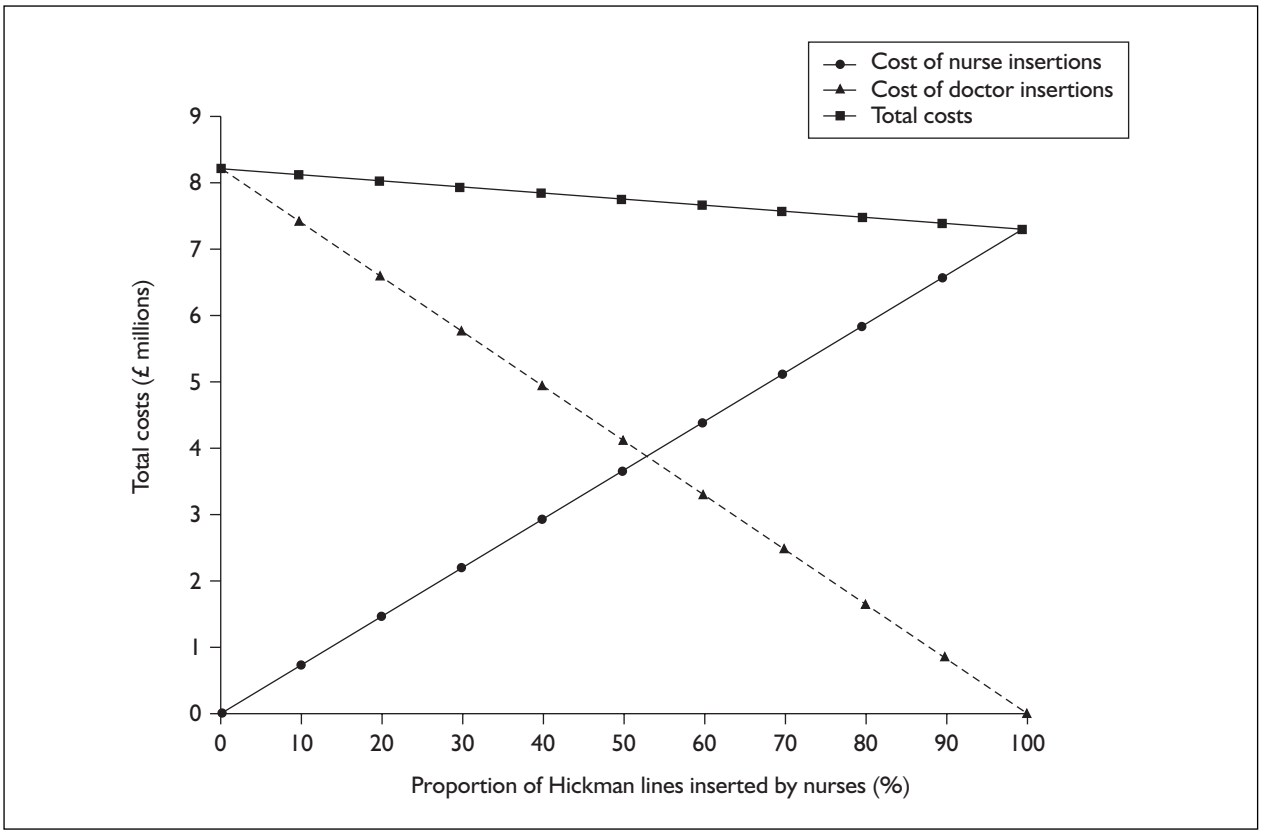

FIGURE 11 *Total annual cost of Hickman line insertions in adult cancer patients*

units, then it can be deduced that the breakdown for nurses is 60% inserted in X-ray suites with at least 40% inserted blind at the bedside. This calculation is based on the fact that nurses at the CHNT insert 650 Hickman lines per year at the bedside (650/1586 = 40%). Using the assumptions listed in *Box 7*, the annual costs and associated outcomes of Hickman line insertions across cancer centres and cancer units in England and Wales can be estimated. Costs of insertions with and without tip misplacement by nurses are based on the cost estimates calculated in this report. Costs of similar insertions by doctors are also based on the cost estimates calculated in this report, with 1 hour of doctor time substituted for 1 hour of nursing time. Benefit estimates are measured in terms of the number of correctly placed catheter tips during the basic insertion as this is the primary clinical outcome measure used in the report. Therefore, blind and image-guided benefit data are based on the estimates calculated in this report. The aim of the analysis is to explore the effect of increasing the proportion of Hickman line insertions by nurses on total annual costs. Given that the analysis of total costs is based primarily on estimated figures, sensitivity analysis is carried out around the proportions of nurses performing Hickman line insertions (0–1.0).

The decision tree in *Figure 10* illustrates how the total annual cost of Hickman line insertions using the assumptions in *Box 7* can be calculated.

By varying the proportion of doctor and nursing insertions from zero to one, and holding the X-ray suite, operating theatre and bedside proportions constant, the graphs of total annual costs and benefits shown in *Figures 11* and *12* can be drawn.

Estimates of the total annual cost and benefits of Hickman line insertions in adult cancer patients are presented in *Table 55* for different proportions of nurse- and doctor-performed insertions. Clearly, the training costs of nurses have not been included in the cost of nurse insertions as the design of the training programme is uncertain.

There are many combinations of doctor and nurse insertions, X-ray suite, operating theatre and bedside insertions. *Tables 56* and *57* present a few combinations based on an estimated 16,000 Hickman line insertions per year for the purposes of illustration only.

Limitations to estimating total annual costs of Hickman line insertions

There are three main limitations to this analysis as

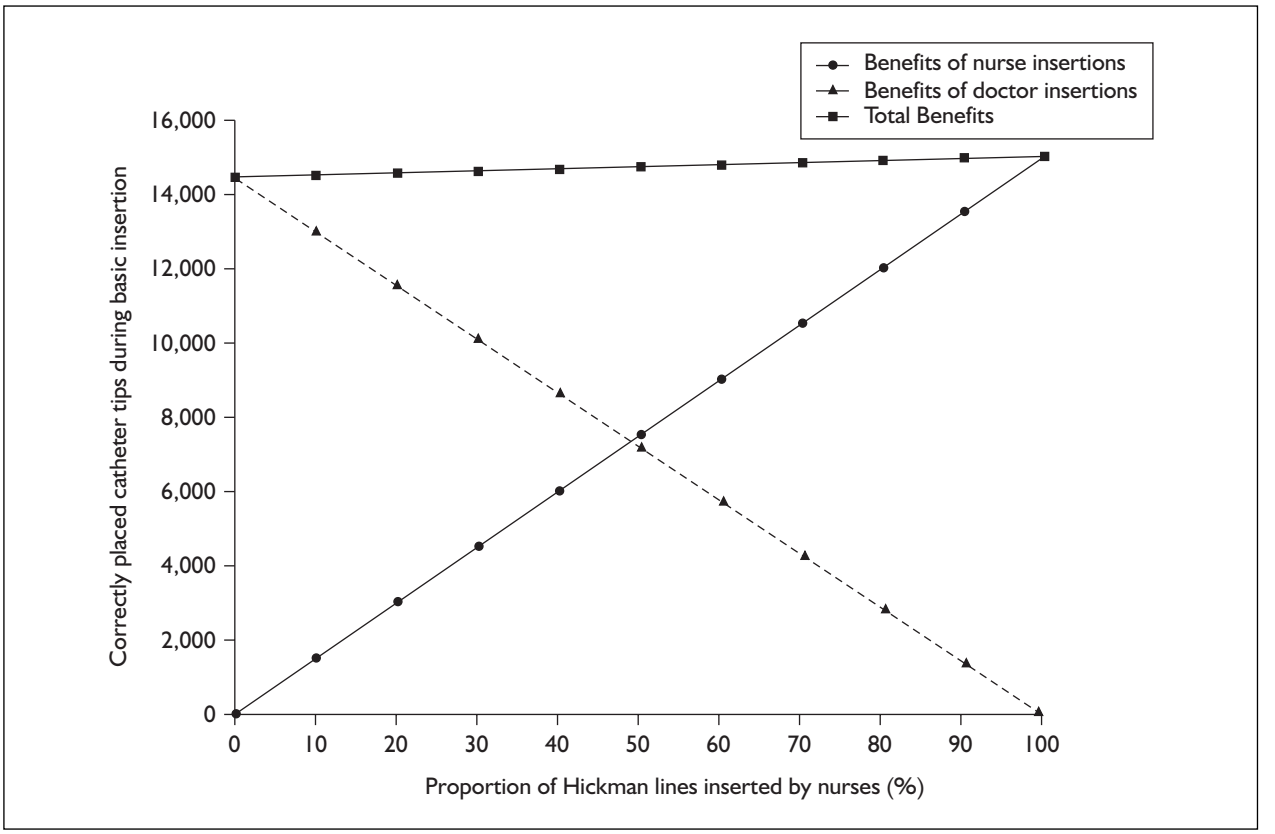

FIGURE 12 *Total annual benefits of Hickman line insertions in adult cancer patients*

TABLE 55 *Increasing the proportion of nurse Hickman line insertions*

Proportion of nurse insertions	Cost of nurse insertions (£)	Benefits of nurse insertions	Cost of doctor insertions (£)	Benefits of doctor insertions	Total costs (£)	Total benefits
0.0	0	0	8,231,322	14454	8,231,322	14,454
0.1	732,630	1509	7,408,190	13009	8,140,819	14,518
0.2	1465,259	3018	6,585,058	11564	8,050,317	14,581
0.3	2197,889	4526	5,761,925	10118	7,959,814	14,644
0.4	2930,518	6035	4,938,793	8673	7,869,311	14,708
0.5	3663,148	7544	4,115,661	7227	7,778,809	14,771
0.6	4395,777	9053	3,292,529	5782	7,688,306	14,834
0.7	5128,407	10561	2,469,397	4336	7,597,803	14,898
0.8	5861,036	12070	1646,264	2891	7,507,301	14,961
0.9	6593,666	13579	823,132	1445	7,416,798	15,024
1.0	7326,295	15088	0	0	7,326,295	15,088

TABLE 56 *100% blind insertions at the bedside*

Proportion of nurse insertions	Cost of nurse insertions (£)	Cost of doctor insertions (£)	Total costs (£)
0	0	7,646,545	7,646,545
0.5	3,523,258	3,823,272	7,346,531
1	7,046,517	0	7,046,517

TABLE 57 *100% image-guided insertions*

Proportion of nurse insertions	Cost of nurse insertions (£)	Cost of doctor insertions (£)	Total costs (£)
0	0	8,033,106	8,033,106
0.5	3,756,406	4,016,553	7,772,960
1	7,512,813	0	7,512,813

a direct result of the paucity of data available. The first is that estimates of total numbers of annual Hickman line insertions are based on the national survey responses only. As only responses from 71% of cancer centres and units were available, the figures used in the calculations may be an underestimate of the total number of annual insertions. However, given that the reason for the lack of responses is unknown (cancer centre or unit may or may not insert Hickman lines, cancer centre or unit may insert only very few Hickman lines), these figures were not grossed up to 100%. Second, catheter-tip misplacement rates may or may not be the same for doctors and nurses. As there are no published head-to-head comparisons of nurse versus doctor Hickman line insertions, the results obtained from the clinical trial as described in this report were used. Finally, given that there is a range of medical salary scales, only consultant salary scales were used in the analysis. This means that the analysis is focused on the maximum costs of doctor insertions.

Chapter 4
Discussion

Evaluation of nurse training programme

Both the trainee nurses and the trainer felt that the nurse training programme as carried out at the CHNT had been a success. All concerned felt that the right balance between theory and practice had been achieved in the early weeks and this enabled the trainees to participate fully in the latter weeks of the training programme. The trainees experienced very few problems during the 12 weeks and no complaints were taken to the appointed supervisors. The value added by the training programme is emphasised by the fact that both nurses are now permanent full-time members of staff at the CHNT. At the end of the RCT, the referring consultants showed how much they valued the Hickman line service provided by the nursing staff by supporting a request to secure funding to ensure their continued employment.

Irrespective of the structure of the service, high-quality training is the key to a successful insertion service. There appears to be a general acknowledgement that both nursing and medical staff in the NHS could benefit from improved training in this area. As the national survey results emphasise (Appendix 6), cancer centres and units perceive training for both doctors and nurses to be important. This perhaps represents an implicit awareness by service providers that the current training of doctors in this area could be improved.

As the largest single-site cancer hospital in Europe, the CHNT is ideally suited to the evaluation of a nurse training programme in Hickman line insertion. Staff at the CHNT currently perform approximately 670 Hickman line insertions per year, of which a significant proportion are inserted by a trained nurse. This means that an adequate number of Hickman lines can be observed and participated in for training purposes during a relatively short time period. Other hospitals, where the demand for Hickman line insertions is relatively small, might find that the length of their training programme would have to be extended and the staff to be trained might have to be involved on a part-time basis. Alternatively, selected large-scale regional training centres could be established for this purpose.

It is important to remember that cancer patients are not the only patients who require Hickman line insertions. Central venous access is indicated for a variety of reasons and it might also be possible to conduct training in large non-cancer NHS hospitals where the demand for Hickman insertions is high.

Costs of the nurse training programme

The cost of implementing and running the nurse training programme at the CHNT was approximately £9500 for each nurse. This training programme is based on the trainee experiencing almost 50 insertion procedures within a 3-month period. The nurse training programme covers both blind and image-guided insertions, so that should a catheter tip be misplaced, the nurse is equipped with the skills to undertake repositioning in the interventional X-ray suite. Previously at the CHNT, repositioning had been carried out exclusively by interventional radiologists. Hence it is envisaged that the initial cost of the training programme is likely to be recouped as a consequence of reduced input from medical staff.

The most significant cost driver appears to be the length of the training programme. The duration of the training programme is largely determined by the time required to observe and undertake sufficient numbers of supervised and non-supervised Hickman line insertions in order to ensure nurse competency in the procedure.

In organisations where trainee nurses could undertake approximately 50 insertions in less than the 12-week period, then training costs would be reduced. If the training period were to be reduced to 8 weeks, then training costs would be about £7000 per nurse. This figure represents an extra £150.12 per patient during the 12-week period of the training programme.

The scale of the training programme undertaken is also an important cost driver and care must be taken to ensure that increasing the number of trainees does not adversely affect the quality of the training programme that can be provided.

There is a variety of insertion training programme options available, such as part-time, full-time, small-group training, large-group training, cancer patient-specific insertion, non-cancer patient-specific insertion, local programme, national programme. Each of the options has advantages, disadvantages and a different impact on costs. Given the lack of published annual reports on numbers of Hickman line insertions for what purpose, using what method and by whom, it is very difficult to estimate accurately the demand for insertion training across the NHS in England and Wales. However, the costs of setting up and coordinating a national programme are likely to be substantial. Nevertheless, there are potential resource savings associated with this type of training programme and in the future the savings arising from the training programme could perhaps outweigh the initial investment costs of training, especially in NHS organisations where insertions are currently predominantly carried out by senior medical staff.

The section 'Resource implications of Hickman line insertions by nurses across the NHS' (p. 51) provides estimates based on survey responses and expert opinion to demonstrate the impact on costs of increasing the number of nurse insertions and reducing the number of doctor insertions. The results of a simple arithmetic exercise reveal that substantial cost savings could be made available to the NHS. However, the actual benefits to the NHS are more likely to be in a reduced workload for doctors, senior and junior, rather than in financial terms. In particular, given the difficulties in implementing the new deal for junior doctors in the NHS, substituting nurse insertions for doctor insertions might be one way of reducing time pressures on more junior medical staff.

Clearly, there any many financial, organisation and professional issues that need to be addressed if the viability of a widespread NHS training programme is to be seriously considered to support CVC insertion by nurses. Many challenges would have to be faced, including a lack of critical mass of CNSs to support trainees and the development of national standards and protocols. The setting up of a CVC insertion training programme for nurses at the CHNT has been successful in recent years and it is hoped that this success can be replicated in other institutions throughout the NHS.

RCT

Patient characteristics

Patients in both arms of the trial were not significantly different in terms of gender, age, weight, primary diagnosis and KP score. Although the insertion of a Hickman line can be performed as an outpatient procedure, most patients were admitted as inpatients. For most patients, Hickman lines were inserted for the administration of chemotherapy. In such circumstances, patients at the CHNT are usually admitted overnight for a Hickman line insertion if their chemotherapy is due to start early the next day. Very few patients had their lines inserted as an emergency procedure. The availability of a core team of insertion nurses means that insertions can be pre-booked wherever possible so that insertions can take place at the optimal time in the patient's management. Three-quarters of all patients in the trial were initially seen in the day ward where the insertion team is based and where there are 15 beds. The location of the insertion staff in the day ward means that they are in close contact with patients at all times.

Study characteristics

All procedures were carried out by the nurse and in the setting to which it was randomised. Nurse1 carried out more insertions in both arms than the other nurses. Despite being off sick for 3 months, nurse3 carried at almost the same number of insertions as nurse2. Nurse2 performed more insertions off-study than the other two nurses did. A small number of Hickman lines were not inserted as planned. This reflects the fact that some of the operators faced unexpected problems during the procedure itself. Most Hickman lines were, however, inserted as planned and this demonstrates the accuracy of nurse assessment of the patient and procedure before insertion takes place. The majority of the insertions were performed on the patient's right side. This is because all three nurses are right-handed and it is easier to perform the insertion on the patient's right. However, it is not always possible to choose the right side as the patient's anatomy and health status can dictate otherwise.

Catheter-tip misplacement

The evidence suggests that Hickman insertions carried out at the bedside were significantly more likely to result in misplaced catheter tips than insertions carried out in the interventional X-ray suite.

A difference in the number of misplaced catheter tips across the two arms was expected prior to the trial. Operator previous experience, review of the medical literature and awareness of benefits of fluoroscopy all indicate that use of fluoroscopy techniques is likely to lead to a reduced incidence

of tip misplacement. One of the aims of the trial was to determine the magnitude of this difference and to investigate whether or not this difference was acceptable to both staff and patients.

Blind insertion of Hickman lines in the RCT was associated with a 14% catheter-tip misplacement rate. This figure is slightly higher than those reported in other studies.[4] However, it is misleading to present absolute numbers of misplaced tips without a corresponding description of the clinical implications for patients. There exists a range of manipulation techniques available to the operator who is responsible for repositioning the Hickman line. Choice of technique depends on the actual position of the line on the post-insertion chest X-ray. Each of the techniques has different clinical implications for the patient.

The majority of misplaced catheter tips in the trial were manipulated by either flushing or repositioning. Neither of these techniques imposed any major clinical implications upon the patient as no additional venipuncture was required. The technique of flushing combined with heavy breathing would appear to be unique to the CHNT and takes approximately 15 minutes to perform. Repositioning of the line takes approximately 30 minutes and again is a routine procedure with limited clinical implications for the patient. Use of flushing and repositioning techniques means that patients do not have to undergo a further invasive procedure with the associated possibility of additional clinical complications. Rewiring or removal and reinsertion may have substantial clinical implications for the patients, as does a reposition by a radiologist. Rewiring, although there is no additional risk of puncture-related complications, may be uncomfortable for the patient. With removal and reinsertion or reposition by a radiologist, the risk of pneumothorax, haematoma or arterial puncture is again present. However, only one-fifth of patients in the trial with misplaced tips had to undergo either a rewire or a removal and reinsertion, which means that 78% of repositioning procedures were simple and routine.

The framework for evaluating clinical outcomes is therefore not straightforward. If patients who received either a flush or whose lines were repositioned by a nurse were removed from the analysis ($n = 25$), there would be no statistically significant results between the two arms ($p = 0.136$).

A more detailed analysis of catheter-tip misplacement identified that double-lumen lines were also significantly more likely to be misplaced than single-lumen lines. Equally, emergency lines were more likely to be misplaced than pre-booked lines. Double-lumen lines are more rigid than single-lumen lines. This means that where a single-lumen line might manoeuvre itself into an ideal position as the patient moves, this does not readily happen with double-lumen lines and so there are more misplaced double-lumen lines than single-lumen lines. Emergency patients usually have acute leukaemia with mediastinal disease lymphadanopathy. This means that anatomical landmarks are more difficult to view both at the bedside and under image guidance and therefore there is a higher risk of a catheter-tip misplacement occurring.

Clearly, this analysis of catheter-tip misplacement would benefit from detailed commentary of patient experience within the trial. However, this information was not collected during the trial period. Professional clinical observation of patients who return to the X-ray suite to have their line repositioned is consistent with the view that unless an additional venipuncture is required, then catheter-tip misplacement is rarely more than inconvenient for the patient. However, it is recognised that different patients may have different concerns and anxieties regarding catheter-tip misplacement and that minimisation of patient clinical risk is a priority for medical staff at the CHNT.

Pneumothorax, arterial puncture and haematoma

The results of the RCT demonstrate that there are no statistically significant differences in numbers of pneumothorax, arterial puncture or haematoma between blind or image-guided insertions of Hickman lines. No real differences were expected for these clinical outcomes because they are only associated with the actual physical puncture of the subclavian vein and the same puncture technique was used in the blind and image-guided arms of the trial. The most serious of these clinical outcomes is pneumothorax. Very few pneumothoraces were caused during the trial with only one chest drain being inserted in a patient. Pneumothorax rates of 3% in the blind arm and 1% in the image-guided arm are indicative of the high quality of the insertions performed by all of the nurses in both arms of the trial.

Infection

There were no real differences between the groups in terms of line or tunnel infections between blind and image-guided insertions. This result is

reassuring given possible anxiety that lines not carried out in an operating theatre under the strictest of conditions might be associated with a significant number of infection episodes. This was clearly not the case during the trial at the CHNT. However, when comparing double-lumen and single-lumen lines, both line and tunnel infections were significantly more likely to occur with double lumens than single lumens. Published evidence suggests that this is because lines with dual lumens are manipulated more than single lumens.[16]

Assistance by healthcare professionals

As expected, the nurses were more likely to request assistance when faced with non-routine insertions. Oncologists and radiologists were rarely called to assist the nurses with their procedures. This demonstrates the nurses' confidence in their own abilities and those of their nursing colleagues to deal with non-routine cases. It also suggests that the X-ray training undertaken by the nurses was sufficient to enable them to work effectively in the X-ray suite. One in nine Hickman line insertions required the assistance of a nurse colleague. Unfortunately, the reason for assistance was not recorded and so the exact nature of the assistance sought or provided is unknown. In any case, some might argue that this figure is too high and that this evidence supports the delivery of insertion services by a team of operators rather than by an individual. This finding has implications for the future organisation of nurse-led insertion services. Where sole nurses are employed to deliver the insertion service, consideration must be given to how immediate medical backup can be guaranteed if required.

Comparing nurse skill

The evaluation of the nurse training programme at the CHNT emphasises that through the use of a short but intensive training course, nurses with longstanding experience can effectively transfer key Hickman line insertion skills to fellow nurse trainees by following the training programme which is outlined in Appendix 1. A more detailed discussion of the clinical outcome data is presented in Chapter 3. Rate of pneumothorax was the primary clinical outcome of interest when comparing across the three nurses. No statistically significant differences in pneumothorax rates were identified between the trainer and the trainees. The sample size was based on an expected pneumothorax rate of 5% for the trainer and the power calculation stated that an acceptable rate for the trainees was not greater than 10%. As the overall pneumothorax rate was 2%, both the trainer and the trainees performed better than anticipated. The results appear to indicate that the training course achieved its objective of skill transference from trainer to trainee.

When comparing the performance of the three nurses, the only statistically significant difference identified was associated with the frequency with which the trainee nurses called for assistance. This is perhaps to be expected for two reasons. First, despite having successfully completed their training course, the trainees may have felt it prudent to call on the trainer when a non-routine situation arose. Second, the very fact that there was help available might have encouraged the nurses to err on the side of caution and call for assistance when perhaps it was not strictly essential. In fact, during the training programme, the trainer went to great lengths to ensure that the trainees' requests for assistance in appropriate circumstances were perceived as praiseworthy rather than blameworthy. Consequently, the nurses were equipped with the clinical skills which ensured that the number of unnecessary complications was minimal during the RCT.

Based on the available clinical evidence, it is evident that nurses previously inexperienced in the procedure can be trained to insert Hickman lines successfully both at the bedside and under image guidance within a 3-month period. Evidence from the RCT suggests that the majority of Hickman lines can be undertaken blind at the bedside without clinical complications by both trainees and trainer. It is acknowledged, however, that the skill level of the trainer was greater than that of the trainees, especially in outcomes relating to misplacement and also in identifying when assistance was required. Nevertheless, pre-trial assessment by internal and external examiners and outcome evidence from the trial both show that the skill level of the trainees is more than adequate.

There may be circumstances under which image-guided insertion would be preferable to blind insertion. Based on their experiences during the trial period, the nursing staff have since developed a working protocol which outlines those patients who might be more suited to image-guided insertion methods. Such patients include very young patients, very anxious patients, patients who have abnormal anatomy or patients who have had a previously failed or complicated procedure. Procedures being undertaken when there is known

mediastinal disease are also undertaken in the interventional X-ray suite. Finally, high-risk patients who require double-lumen lines could also be taken to the X-ray suite for the insertion of a Hickman line. These are all patients who, in the opinion of the trained nurses at the CHNT, would benefit from avoiding the potential complication of a misplaced catheter tip.

As outlined above, evidence from the RCT suggests that it is possible to train previously inexperienced nurses in CVC insertion techniques in a relatively short time. Neither of the trainees had any experience in CVC insertion before the trial. However, as only two nurses were trained in this way for the purposes of the trial, it is recognised that not all nurses may replicate their successful learning and that different nurses may require different approaches to CVC insertion training.

Patient satisfaction questionnaire

The response rate to the questionnaire was lower than anticipated (22%). However, despite this response rate, the views of 150 patients were obtained. After deliberation by the research team, it was agreed that it was appropriate to include the limited information collected using the survey in this report. Responses from 150 cancer patients provide the reader with useful insights into the organisation and delivery of the insertion service as perceived by the user. Given that the respondents were ill cancer patients, the return of 150 completed responses was not viewed as insignificant by the research team.

As the questionnaires were completed anonymously, reminder questionnaires could not be sent out in an attempt to improve them, nor could the patients be split into trial participants and non-trial participants. With hindsight, it is evident that the design of the survey could have been improved. In particular, it should have been possible to analyse the results by a range of different subgroups, for example, on-study patients, patients with misplaced lines.

The inpatient/day-case split and the ward insertion/X-ray department insertion split are very similar to splits of patients within the RCT. Therefore patient responses may be considered representative of the patient group as a whole.

Analysis of the patient satisfaction questionnaires revealed that patients were very supportive of both the organisation and delivery of the Hickman line insertion service at the CHNT. Patient waiting times for insertion on the ward or in the X-ray department were generally acceptable, with some patients experiencing no waiting time at all. Survey responses suggested that the organisation of Hickman line insertion procedures at the CHNT was currently being managed successfully by nurses.

Responses suggested that the amount of both written and verbal information provided to patients appeared to be about right. Even though some patients did not know what to expect, when asked to judge their experience of pain or discomfort almost 100% of patients felt that the right amount of information had been provided. If too much information is provided, patients may feel over-burdened and this can lead to increased levels of patient stress and anxiety; conversely, if too little information is provided, this can lead to patients feeling disorientated and fearful of the procedure to be performed. When balance is achieved and the right amount of patient information is provided, patients feel more relaxed and at ease and the procedure is therefore more likely to be successful. No changes will be made to the information package given to patients as it is appears that the majority of patients are satisfied with both the structure and the content of the information currently provided.

Given the invasive nature of the Hickman line insertion, a proportion of patients will inevitably experience some form of apprehension about the procedure. Questionnaire responses revealed, however, that almost three-quarters of patients having a Hickman line inserted either did not feel any apprehension at all or felt only a little apprehension. Just over one-quarter of patients felt very apprehensive. These figures suggest that, for the majority of patients, the delivery of the Hickman line insertion service was not associated with high levels of anxiety. The single reason most likely to cause apprehension in patients was the possibility of a complication occurring, which indicates that patients were aware of the nature of the procedure and the associated risk of complications.

Patients whose lines were inserted in the X-ray department were more likely to be anxious about the possibility of the procedure being unsuccessful than those patients whose lines were inserted on the ward. This might suggest that patients are more likely to think about the consequences of the procedure simply because it is being carried out in

the X-ray department and not on the ward. Further research is merited to identify whether or not insertions carried out in the X-ray department lead to higher levels of anxiety than for those patients whose lines are inserted on the ward. If so, this could have implications for the future organisation and delivery of the Hickman line insertion service.

One explanation for higher levels of anxiety in the group of patients having their line inserted in the X-ray department is that some of these patients might have been managed off-study and therefore they would have had their line inserted in the X-ray department for a valid medical reason. Unlike those patients who were randomised to X-ray as part of the RCT, these patients were probably more aware of the likelihood of an unsuccessful procedure as a result of their pre-insertion consultation with nursing staff.

The majority of patients accepted the offer of sedation to make them feel drowsy and relaxed during the procedure. Unsurprisingly, use of a sedative appears to have led to less patient discomfort. There was no real difference in pain between the groups who took sedation and those who did not take sedation. Very few patients experienced either discomfort or pain during the procedure, which suggests that the technique used to insert Hickman lines by the nursing staff is appropriate and that the trained nurses have acquired excellent insertion skills.

At the end of the questionnaire, patients were asked for additional comments. As more than half of the patients completed this section, it is clear that the patients surveyed were keen to show their appreciation of this service. Favourable responses included the following comments: nursing staff were excellent and really put me at ease; procedure made more pleasant and bearable by the professional way the staff carried out their duties and explained all details; sister who performed the insertion was excellent; I am very happy with the care I have received and reassurance given; nursing staff very professional, courteous, put me at ease – no complaints. Patients appear to be very satisfied with the standard of care received during their experience of this procedure; this may be in part due to the fact that their care was unfragmented and that the same nurses were present throughout the procedure. It is recognised that patient relief at leaving hospital after a successful procedure may explain, to some extent, such strong patient support for the service.

The limited survey evidence available suggests that the patients at the CHNT are at least satisfied with the organisation and delivery of the Hickman line insertion service by nursing staff. Clinical analysis and economic evaluation of this service have been carried out as part of the RCT. However, patient verification and support of nurse-led Hickman line insertion can only add weight to the argument that nurses can be trained to insert Hickman lines successfully. The main conclusion from this survey evidence must be that patients are very satisfied with the nurse-led Hickman line insertion service currently operating at the CHNT.

Economic evaluation

Economic results

The results of the economic evaluation appear to demonstrate that the difference in per patient costs between the two arms of the trial is not significant. By implication, this suggests that the preferred option would be the mode of insertion with the best clinical outcomes as the cost of achieving these outcomes is the same no matter which method is adopted. This study shows that the clinical outcomes in both arms of the trial were not significantly different, except for the occurrence of catheter-tip misplacement. Given that blind insertion of Hickman lines is associated with an increased number of catheter-tip misplacements and that frequency of catheter-tip misplacement is the primary outcome of interest in this trial, the evidence suggests that image-guided insertion of Hickman lines would be the preferred option. However, it must be recognised that this is only true if all catheter-tip misplacements are judged to be of equal severity by the patient, a topic that has not been adequately addressed by the clinical literature or this trial.

Common costs versus other costs

The total costs of the resources consumed in the RCT can be divided into two categories. First, there are those costs that are common to all basic insertions no matter what the outcome. Second there are those costs that are associated with certain types of outcomes, that is, complications, infections, failed insertions and assistance. Most of the costs that were incurred fall into the first category. Within this first category, the main difference in costs between the image-guided and the blind arms was the costs of occupying the interventional radiology suite and using the fluoroscopy equipment. Clearly, it is less expensive

to insert Hickman lines at the bedside without the aid of image guidance. However, without the aid of image guidance, the incidence of misplaced lines increases. A proportion of the savings gained by inserting lines at the bedside is offset by the costs of repositioning lines at a later time under image guidance. The debate regarding which insertion mode is the most cost-effective raises the question of whether or not it is more important to invest resources early in the patient's management, that is, at the time of insertion, or later in the patient's management, that is, after the insertion. Clearly, a balance must be struck between avoiding clinical complications and optimising the use of scarce healthcare resources.

Costs of catheter-tip misplacement

The costs of catheter-tip misplacement primarily relate to the blind arm of the trial. The costs of treating this complication were greater than the costs associated with treating pneumothorax, arterial puncture and haematoma. There are nine different costs described in this report associated with catheter-tip misplacement. This reflects the variety of different methods available for the repositioning of a misplaced catheter tip. About 80% of all repositionings undertaken in the trial cost between £50.98 and £99.53.

Costs of pneumothorax, arterial puncture and haematoma

The costs associated with pneumothorax were much larger than those associated with arterial puncture and haematoma. This is largely because a patient with pneumothorax undergoes a series of chest X-rays while hospitalised for observation. Although these costs are mainly associated with pneumothoraces conducted in the blind arm, there is no reason to suggest that they could not have been incurred in the image-guided arm of the trial as the initial venipuncture was the same in both arms of the trial.

Costs of infections

The costs associated with line and tunnel infections were high-cost events. When comparing the image-guided arm with the blind arm these figures were similar, as the number of events in each arm was simply multiplied by unit costs and there were no statistically significant differences. However, when comparing patients with single-lumen lines versus patients with double-lumen lines, there is a stark contrast, primarily because double-lumen lines were more likely to be associated with infections than single-lumen lines. The frequency of both line and tunnel infections is higher in double-lumen lines than single-lumen lines and this has expensive cost implications for the NHS. It is likely that the antibiotics costs associated with the treatment of Hickman line infection are underestimated in this report, given the fact that no patient-specific resource consumption was recorded. As the numbers of patients who had a Hickman line infection were similar in each arm of the trial, this underestimate is not likely to bias the results of the economic evaluation.

Cost of failed insertions

The cost differential associated with failed insertions between the two trial arms was found to be high. The cost of failed insertions was four times higher in the blind arm than in the image-guided arm. Would those failed insertions in the blind arm have been successfully carried out under image guidance? Only one patient was transferred from the bedside to the interventional X-ray suite during the procedure in order to attempt insertion under image guidance. This suggests that if the failed insertions in the blind arm had been carried out under image guidance then this would not have made any difference to the clinical outcome for the patient and the failed insertions would still have occurred. Image guidance helps to ensure the correct positioning of the line; however, it does not guarantee insertion of the Hickman line. The fact that this differential exists is largely due to chance or some other factor that the research team may not have considered. Differences in the numbers and costs of pneumothoraces and arterial punctures were also higher in the blind arm and again there is no reason for this; analysis shows that the results were not statistically significant and therefore may have occurred by chance.

Incremental cost-effectiveness ratio

As the mean cost per patient in the image-guided arm was greater than the mean cost per patient in the blind arm, and the benefits appear to be greater in the image-guided arm than in the blind arm, incremental cost-effectiveness analyses were undertaken. The results of the key economic evaluation demonstrated that the incremental cost per misplaced catheter tip avoided was £183.22. The decision rule here is whether NHS decision-makers believe that the benefit of avoiding one additional catheter-tip misplacement is greater or less than this monetary value. However, ICERs should only ever be used to guide decision-makers; they should not be used in isolation. Data, expertise and knowledge from a variety of sources must be taken into consideration as decisions about health policy and practice are being

discussed. In summary, the results of the economic evaluation do not offer clear guidance on which mode of Hickman line insertion is the most cost-effective. Evidence from other sources must be used alongside economic data if informed decisions are to be made regarding the preferred method of insertion.

Sensitivity analysis

Sensitivity analysis was conducted in order to explore the impact of varying the cost of the interventional X-ray suite charges. It is demonstrated that the results of the sensitivity analysis can have an impact on the preferred method of insertion. At very low costs, the image-guided approach dominates the blind approach as fewer costs and greater benefits are incurred.

Organisational considerations

If the economic evaluation had clearly demonstrated that the most cost-effective option was image-guided insertion of Hickman lines, reorganisation of the current use of X-ray space available in the CHNT would have to be undertaken as it is unlikely that sufficient spare capacity in the X-ray suite would be available to allow extra procedures to be performed. Given that 132 patients were excluded from the RCT because the X-ray suite was unavailable before randomisation, due consideration must be given as to whether or not the current X-ray space available could meet the extra demand for services. The results of the economic evaluation are only a guide to decision-making and must be viewed alongside other key considerations.

Limitations of the study

It could be argued that there might be some bias or imprecision in the costing approach adopted because unit costs were sometimes used instead of patient-specific costs. In addition, the cost of some sterile consumables was estimated in the study because real costs could not be identified. However, the costs of consumables and use of unit costs were equally accounted for in both arms of the trial and so no bias was present. Also, the fact that pre-calculated Radiology Department charges were used in the cost-effectiveness analysis might mean that total costs are under- or overestimated. The representativeness of the patient population in the trial might come under scrutiny. The proportion of emergency patients who participated in the trial was 10%. In the analysis of off-study patients during the same period, 23% of patients were emergency patients. This is not really surprising as the trial exclusion criteria were designed to exclude the most critically ill patients. However, the trial population did account for almost 80% of the patients who had a Hickman line inserted at the CHNT during the trial period.

Conclusions

Implications for healthcare

This report has indicated that blind and image-guided nurse insertions of Hickman lines in adult cancer patients at the CHNT are both safe and effective. The study results appear to demonstrate that the skills and expertise required by nurse operators are not confined to a few exceptional nurses but can be transferred to trainees through a relatively brief but intensive training course.

At the CHNT, for the majority of adult cancer patients, blind insertion of Hickman lines at the bedside represents a safe and effective procedure by nurses. When a blind insertion procedure is being performed, nursing staff have immediate access to radiological facilities if required. Indeed, the study recognises that immediate access to radiological facilities is vital to support the small minority of patients in whom complications occur during the insertion procedure.

There are no significant differences in mean cost per patient between blind and image-guided insertions. However, a significant difference in frequency of catheter-tip misplacement between the two arms was identified. A balance must be struck between avoiding clinical complications and optimising the use of scarce healthcare resources.

Implementing trained nurse insertion on a national basis could provide a number of significant benefits to the NHS. First, it could supply a stable and reliable source of expertise in this procedure. Currently, at the CHNT a significant proportion of insertions are undertaken by junior doctors on rotation who do not have adequate training or expertise in the procedure. Second, junior doctors and radiological facilities are amongst the most pressurised resources within the NHS. Expanding the role of the nurse to include Hickman line insertions could help to ease this pressure and free up scarce resources. Where CVCs are inserted by more senior medical staff, increased savings could occur.

Recommendations for research

Nurses are currently being trained to insert Hickman lines in a small minority of hospitals across the NHS and the expansion of their role is

supported by clinical evidence from this RCT. In cancer units and centres across the NHS, further research to compare the safety and efficacy of nurse versus doctor insertions in particular subgroups of patients is required to enhance the rigour of our principle conclusion. Given the paucity of published information describing how many insertions are performed per year, in what setting, by whom and with what outcome, it is recommended that research be carried out to assess the quantity and quality of current service provision. Only then can reliable estimates of the clinical and cost-effectiveness of Hickman line insertions in adult cancer patients be calculated and the extent of potential improvements in resource use and outcome be accurately estimated.

Acknowledgements

This study was supported by the NHS R&D Executive's Health Technology Assessment Programme, project number 95/16/06. We are indebted to the referees for reading the report and the quality of their comments.

Contributions of the authors

Angela Boland conducted the literature review, collected clinical data, analysed the clinical and economic evidence, carried out the economic evaluation and prepared the final report for publication.

Alan Haycox supervised the economic evaluation and helped to prepare the final report for publication. He had the original idea for the economic evaluation.

Adrian Bagust contributed to the economic evaluation and the modelling sections, advised on the appropriate use of statistical techniques and helped to prepare the final report for publication.

Lesley Fitzsimmons and her team carried out the clinical research and collected the clinical data. Lesley Fitzsimmons also helped to prepare the final report for publication by editing all of the draft reports. She also had the original idea for the clinical research.

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Appendix 1

Nurse training programme

Phase 1: week 1

Aims of the programme

1. to assess the personal need of the appointee related to the post
2. to begin study of theory related to central line insertion. Topics to include:
   (a) the Christie Hospital procedural policy, guidelines and criteria for line insertion
   (b) ethical/legal issues of informed patient consent, professional accountability and nature of 'extended role'
   (c) anatomy of the head, neck, thorax and cardiovascular system
   (d) pharmacology related to the administration of intravenous sedation (midazolam) and local anaesthesia (lignocaine 2%)
3. to observe insertion of central lines by CNS.

(Trainee) objectives

1. to outline personal needs of the appointee from the training period
2. to discuss any queries related to the training process from the trainee's perspective
3. to understand the requirements of central venous access and the need for tunnelled central lines
4. be familiar with Christie Hospital policy and criteria for central line insertion
5. understand theory related to central venous access and potential complications
6. know the anatomy and vascular structures of the head, neck and thorax
7. be familiar with the administration and potential side-effects of midazolam and lignocaine
8. observe the insertion of tunnelled subclavian central venous lines.

Phase 2: week 2

Aims of the programme

1. to practice and demonstrate, using a mannequin and models, practical skills required for subclavian vein cannulation and tunnelled line insertion.
2. to assist the mentor in the insertion of central venous catheters.

(Trainee) objectives

1. to practice on a mannequin and demonstrate skills of: subclavian vein cannulation; administration of sedation and local anaesthetic; tunnelling technique; skin incision; suturing
2. be able to assist the mentor in the insertion of a central line
3. be able to prepare the equipment for central line insertion
4. be able to prepare and position the patient for central line insertion
5. be able to identify the correct use and side-effects of local anaesthetic and sedatives relevant to the insertion of a central line, and assist the mentor in their administration
6. understand the potential complications of the procedure and be able to recognise their symptoms
7. be able to identify on X-ray the correct tip location of a central line.

Phase 3: weeks 3–9

Aims of the programme

1. to insert central lines using perfect technique, operating under direct supervision and with the assistance of the mentor.

(Trainee) objectives

1. be able to adapt the practice of phase 2 to real patients
2. be able to give a clear explanation of the procedure to patients and obtain written informed consent.

Phase 4: weeks 10–12

Aims of the programme

1. to insert central lines under image guidance, operating under direct supervision and with the assistance of the mentor and consultant radiologist.

(Trainee) objectives

1. to understand the theory of image-guided technique for line placement

2. to undertake the relevant training to enable the trainee to operate in the X-ray department
3. to consolidate and maintain the fundamentals of practice acquired in phases 2 and 3 of the training programme
4. be able to adapt the procedure to the local demands of the X-ray department environment.

Appendix 2

Patient satisfaction questionnaire

Christie Hospital NHS Trust

CENTRAL LINE INSERTION PROJECT TRIAL
Patient Satisfaction Questionnaire

Introduction

Thank you for agreeing to take part in the central line insertion project trial. The aim of the trial is to compare whether it is more advantageous to have the central line inserted in the x-ray department or on the ward.

We would be grateful if you could answer the following questions so we can include your experiences and preferences about the different methods of putting the central line in. The information you give will remain confidential and you do not have to give your name.

---

1. Were you …. ☐ an in-patient ☐ a day case?

2. Where did you have your central line inserted?

   a) ☐ on the ward (please specify which ward) _____
   b) ☐ x-ray department

3. ***If your line was inserted on the ward:*** How long did you wait for a bed?

   ☐ 0–30 minutes ☐ 31–60 minutes ☐ more than an hour
   ☐ not applicable – I was an in-patient and already in bed

   If your line was inserted in x-ray: How long did you wait for a bed?

   ☐ 0–30 minutes ☐ 31–60 minutes ☐ more than an hour
   ☐ not applicable – I was an in-patient and already in bed

   How long did you wait for a vacant slot in x-ray?

   ☐ 0–30 minutes ☐ 31–60 minutes ☐ more than an hour ☐ don't know

4. How did you feel about the waiting times?

   _____

5. How did you feel about the amount of written information you were given about central line insertion?

   ☐ not enough information ☐ the right amount of information
   ☐ more than I wanted to know

6. How did you feel about the verbal information/explanation you were given about central line insertion?

   ☐ not enough information ☐ the right amount of information
   ☐ more than I wanted to know

7. ***If you had too much information***, what would you have liked less of?

   _____

If you did not have enough information, what would you have liked more of?

_____

8. How apprehensive did you feel about having a central line inserted?

☐ not at all apprehensive
☐ yes, a little apprehensive
☐ yes, very apprehensive

9. What caused you to feel anxious before having the central line inserted?
(*tick as many boxes as you like*)

☐ fear of pain
☐ something going wrong (a complication occurring)
☐ not being able to have a central line inserted (procedure unsuccessful)
☐ another reason (please specify) _____
☐ not applicable – I did not feel anxious

10. Were you offered sedation to make you drowsy and relaxed during the procedure?

☐ Yes ☐ No ☐ Don't know

11. Did you have sedation?

☐ Yes ☐ No ☐ Don't know

12. Did you find the procedure uncomfortable?

☐ Not at all ☐ Yes, a little ☐ Yes, very

13. Did you find the procedure painful?

☐ Not at all ☐ Yes, a little ☐ Yes, very

14. Was the level of pain or discomfort what you expected?

☐ Not as bad as I expected ☐ Same as I expected
☐ Worse than I expected ☐ I didn't know what to expect

15. Do you have any further comments to make regarding the insertion of your central line?

_____

_____

_____

Appendix 3

Patient case report forms

CLIP STUDY

Patients Details

Trial or Off Study Number

Hospital Number

Surname

First name(s)

Date of Birth (ddmmyyyy)

Gender
1=Male
2=Female

Primary Diagnosis
(as trial factor)
1=Leukaemia
2=Lymphoma
3=Myeloma
4=Other Haematological Cancer
5=GI
6=Breast
7=Other Solid Tumour

Date of Procedure (ddmmyyyy)

Weight (Kg)

Physical State
1=Cachexic
2=Normal
3=Obese

KP Score
0(10)100

In/Out Patient
1=In Patient
2=Out Patient/Day Case

Where is the patient?
See Appendix 1
(e.g. W11, XRAY, DAYW)

Proposed Treatment
See Appendix 2
(e.g. VAD, 5FU, FEC)

CLIP STUDY NUMBER

Reason for Central Line **use 1=No, 2=Yes**

First Treatment	Adjuvant Treatment	Relapse	Antibiotics	Blood Products
☐	☐	☐	☐	☐

Poor Peripheral Access	Needle Phobia	TPN	Other
☐	☐	☐ _____	☐

Pre-Line Bloods

Hb g/dl	WBC x 10^9/l	Platelets x 10^9/l	PT	APTT
☐☐.☐	☐☐☐.☐	☐☐☐	☐☐	☐☐

Has the patient had a Hb transfusion? 1=No, 2=Yes ☐

Has the patient had a Platelet transfusion? 1=No, 2=Yes ☐

Trial/Off Study Central Line Details

Was this a pre-booked insertion? 1=No (emergency), 2=Yes(planned) ☐

Does the patient fit the criteria for the CLIP trial? 1=No, 2=Yes ☐

Which Study/Trial is this procedure in? 0=Off Study, 1=Single, 2=Two Nurses, 3=Three Nurses ☐

		First Nurse	Second Nurse
If in the Single or Two Nurse Trial give reasons for missing nurse(s)	1=Holiday 2=Sick 3=Busy 4=On a course 5=Other: _____ 8=Not applicable	☐	☐

Trial Arm Randomised to: 0=Not entered (off study), 1=Drew Blind insertion, 2=Drew Image Guided insertion ☐

Trial Nurse Randomised to: 0=Off Study, 1=Andrea, 2=Jude, 3=Lesley ☐

CLIP STUDY NUMBER

If not in the Trial, give the main reason

1=Patient too ill
2=Refused consent
3=Xray not available
4=Failed previous procedure (Study No._____)
5=Outside of the hours 9am-5pm
6=Other: _____
8=Not Applicable

If not in the Trial, what was done?

1=Line inserted off study
2=PICC inserted
3=Referred on to a Surgeon
4=Referred on to a Radiologist
5=Referred on to an Oncologist

Which Line Insertion is this? (Use 1,2,3,etc.)

If not First line insertion give reason for this line

1=Start of new treatment
2=Previous pulled/fell out
3=Previous removed for medical reason
4=Other: _____

On which side was the insertion/attempt?

1=Left
2=Right

Give main reason for Choice of side

1=Operator preference
2=Venous compromise
3=Breast Disease
4=Other anatomical abnormality
5=Compromised lung function
6=Other: _____

What kind of line was inserted?

0=None inserted
1=Single Lumen
2=Double Lumen
3=Triple Lumen
4=Single PICC
5=Double PICC

Operator

1=Andrea
2=Jude
3=Lesley
4=Doctor (for training)

If Doctor for training which nurse did the training?

1=Andrea
2=Jude
3=Lesley
8=Not applicable

CLIP STUDY NUMBER

Trial Outcome Information in the first 14 days

How did the procedure go? __

1=Routine
2=Non-routine
3=Failed, put in PICC
4=Failed, referred on to Surgeon
5=Failed, referred on to Radiologist
6=Failed, referred on to Oncologist
7=Failed, insertion

Was any assistance required?

use 1=No, 2=Yes

Doctor	Nurse Specialist	Who?	Radiological Intervention
__	__	__ 1=Andrea	__
		2=Jude	
		3=Lesley	

If there were problems what were they?

use 1=No, 2=Yes

Arterial Puncture	Pneumothorax Puncture	Haematoma	Line Misplaced	Other
__	__	__	__	__
			_____	

		h h	m m		h h	m m
How long did it take? (from scrubbing up to scrubbing down or abandonment)	Start	__ __ : __ __		Finish	__ __ : __ __	
If any Image Guidance was used record time in XRAY Theatre	Start	__ __ : __ __		Finish	__ __ : __ __	

Post Line Insertion Information (for first 14 days)

		Date of Event d d m m y y y y
Was there a line infection within 14 days?	__ 1=No 2=Suspected 3=Confirmed (by positive blood culture)	__ __ __ __ __ __ __ __
Was there a Tunnel infection?	__ 1=No 2=Suspected 3=Confirmed (by positive swab culture)	__ __ __ __ __ __ __ __
If an infection event occurred what was done with the line? (AB=antibiotics)	__ 1=Nothing done (no add AB) 2=Treated by AB 3=Line removed (no add AB) 4=Line removed and treated by AB	__ __ __ __ __ __ __ __
Was there a Post line Thrombus within 14 days?	__ 1=No 2=Suspected 3=Confirmed	__ __ __ __ __ __ __ __
Was anticoagulant therapy started within 14 days?	__ 1=No 2=Yes 8=Not Applicable	__ __ __ __ __ __ __ __
If Post line Thrombus, was the line removed ?	__ 1=No 2=Yes 8=Not Applicable	__ __ __ __ __ __ __ __

Appendix 4

Unit costs and cost estimates

Code	Description of cost items	Unit cost (£)	Source
A1	Incontinence sheet	0.11	LAC 2000
A2	Sterile green drapes	0.25	Estimated
A3	Sterile gown	0.50	Estimated
A4	Sterile i.v. cut down set	1.00	Estimated
A5	Sterile gloves	0.24	Estimated
A6	Sterile wood pulp receiver	0.20	Estimated
A7	Dressing pack with gallipot	0.46	LAC 2000
A8	Non-woven swabs	0.005	LAC 2000
A9	I.v. 3000 dressings	1.19	BNF 2000
A10	20 ml syringe	0.09	LAC 2000
A11	Orange needle	0.07	LAC 2000
A12	Green needle	0.02	LAC 2000
A13	Surgical scalpel 15 blade	0.05	LAC 2000
A14	Skin suture and 2.0 straight needle	0.25	LAC 2000
A15	10 ml syringe	0.05	LAC 2000
A16	Cotton-wool ball	0.01	LAC 2000
A17	Alchowipe	0.02	LAC 2000
A18	Green plastic forceps	0.07	LAC 2000
A19	Butterfly cannula	0.25	LAC 2000
A20	Labels	0.10	LAC 2000
A21	Chest drain bottle	8.66	LAC 2000
A22	Chest drain tubing set	4.97	LAC 2000
A23	Trochar introducer	7.04	LAC 2000
A24	50 ml syringe	0.31	LAC 2000
A25	Sterile obdurator	0.18	LAC 2000
A26	Sodium chloride/sterile waters (2 × 10 ml)	0.25	BNF 2000
A27	Midazolam (10 mg–2 ml)	0.81	BNF 2000
A28	Lignocaine (20 ml–2%)	0.71	BNF 2000
A29	Chlorhexadine in spirit (50 ml)	0.07	BNF 2000
A30	Hepsal ampoules (5 ml)	0.28	BNF 2000
A31	50 ml saline	0.24	Pharmacy
A32	Single-lumen Hickman line – discounted	51.00	Bard
A33	Double-lumen Hickman line – discounted	63.00	Bard
A34	Single-lumen Hickman line – undiscounted	59.95	Bard
A35	Double-lumen Hickman line – undiscounted	74.50	Bard
A36	Peel-apart percutaneous introducer kit	27.00	Bard
A37	Tunnelling device	5.00	Bard
A38	Single PICC–discounted	49.48	Bard
A39	Double PICC–discounted	71.82	Bard
A40	G grade nurse per hour	12.81	Finance
A41	Consultant radiologist per hour	50.31	Finance
A42	Consultant oncologist per hour	50.31	Finance
A43	Specialist registrar per hour	15.16	Finance
A44	Day ward cost	80.00	Finance
A45	Overnight/inpatient day	130.00	Finance
A46	Full blood count	10.50	Finance
A47	Chest X-ray	55.00	Finance/Radiology
A48	Coagulation screen	21.00	Finance

Code	Description of cost items	Unit cost (£)	Source
A49	Group and save	10.50	Finance
A50	Radiology group 1 hourly charge	52.61	Radiology Dept
A51	Radiology group 2 hourly charge	85.47	Radiology Dept
A52	Radiology group 3 hourly charge	124.33	Radiology Dept
A53	Radiology group 4 hourly charge	247.62	Radiology Dept
A54	Radiology group 5 hourly charge	290.59	Radiology Dept
A55	Blood culture from the Line	14.00	Finance
A56	Exit site swab	8.00	Finance
A57	I.v. teicoplanin (400 mg)	37.80	BNF 2000
A58	I.v. teicoplanin (200 mg)	18.90	BNF 2000
A59	I.v. levofloxacin (500 mg)	2.78	BNF 2000
A60	Netilmicin (150 mg)	11.76	BNF 2000
A61	Tazocin (4.5 mg)	39.48	BNF 2000
A62	Giving set	0.92	LAC 2000
A63	100 ml saline	0.48	Pharmacy
A64	Radiographer	23.31	Radiology Dept
A65	Oncall	1.14	Radiology Dept
A66	A&C staff	2.84	Radiology Dept
A67	X-ray films (weighted) R3	6.72	Radiology Dept
A68	X-ray equipment (weighted) R3	0.61	Radiology Dept
A69	X-ray maintenance R3	10.78	Radiology Dept
A70	X-ray chemistry R3	0.76	Radiology Dept
A71	Pharmacy R3	0.39	Radiology Dept
A72	Print and Stat	0.24	Radiology Dept
A73	Capital charges R3	16.50	Radiology Dept
A74	Other	14.60	Radiology Dept
A75	X-ray films (weighted) R4	8.96	Radiology Dept
A76	X-ray equipment (weighted) R4	0.82	Radiology Dept
A77	X-ray maintenance R4	14.38	Radiology Dept
A78	X-ray chemistry R4	1.01	Radiology Dept
A79	Pharmacy R4	0.53	Radiology Dept
A80	Capital charges R4	21.99	Radiology Dept
A81	Dressing (sleek)	1.58	LAC 2000
A82	5 ml syringe	0.04	LAC 2000
A83	Blood transfusion	80.00	Finance Dept
A84	Platelet transfusion	150.00	Finance Dept
A85	Single-blind insertion	309.07	Report
A86	Double-blind insertion	321.07	Report
A87	Single-image insertion	378.40	Report
A88	Double-image insertion	390.40	Radiology Dept
A89	Femoral ventricular pigtail catheter	17.00	Radiology Dept
A90	Needle	3.50	Radiology Dept
A91	Guidewire for pigtail catheter	3.50	Radiology Dept
A92	Triple lumen and kit (undiscounted)	179.94	Bard
A93	Additional single lumen line and introducer	78.00	Report

Cost estimates (£)

Basic insertion costs

Single-blind Hickman line insertion	**Cost**	**Ref.**
Hickman line insertion pack	83.00	A37 + A36 + A32
Consumables	10.64	A1 + (A2 × 4) + A3 + A7 + (A8 × 4) + (A9 × 2) + (A10 × 3) + A11 + (A12 × 3) + A5 × 2 + A13 + A14 + (A15 × 2) + (A16 × 2) + A17 + (A26 × 2) + A19 + (A20 × 2) + A27 + A28 + (A6 × 2) + A29 + (A30 × 3) + A18 + A4
Nursing time	38.43	3 × A40
Day ward costs	80.00	A44
Tests	42.00	A46 + A48 + A49
Chest X-ray	55.00	A47
Total	309.07	

Double-blind Hickman line insertion	**Cost**	**Ref.**
Hickman line insertion pack	95.00	A33 + A36 + A37
Consumables	10.64	A1 + (A2 × 4) + A3 + A7 + (A8 × 4) + (A9 × 2) + (A10 × 3) + A11 + (A12 × 3) + A5 × 2 + A13 + A14 + (A15 × 2) + (A16 × 2) + A17 + (A26 × 2) + A19 + (A20 × 2) + A27 + A28 + (A6 × 2) + A29 + (A30 × 3) + A18 + A4
Nursing time	38.43	3 × A40
Day ward costs	80.00	A44
Tests	42.00	A46 + A48 + A49
Chest X-ray	55.00	A47
Total	321.07	

Single-image Hickman line insertion	**Cost**	**Ref.**
Hickman line insertion pack	83.00	A37 + A36 + A32
Consumables	10.64	A1 + (A2 × 4) + A3 + A7 + (A8 × 4) + (A9 × 2) + (A10 × 3) + A11 + (A12 × 3) + A5 × 2 + A13 + A14 + (A15 × 2) + (A16 × 2) + A17 + (A26 × 2) + A19 + (A20 × 2) + A27 + A28 + (A6 × 2) + A29 + (A30 × 3) + A18 + A4
Nursing time	38.43	3 × A40
Day ward costs	80.00	A44
Tests	42.00	A46 + A48 + A49
Radiology charge	124.33	A52
Total	378.40	

Double-image Hickman line insertion	**Cost**	**Ref.**
Hickman line insertion pack	95.00	A33 + A36 + A37
Consumables	10.64	A1 + (A2 × 4) + A3 + A7 + (A8 × 4) + (A9 × 2) + (A10 × 3) + A11 + (A12 × 3) + A5 × 2 + A13 + A14 + (A15 × 2) + (A16 × 2) + A17 + (A26 × 2) + A19 + (A20 × 2) + A27 + A28 + (A6 × 2) + A29 + (A30 × 3) + A18 + A4
Nursing time	38.43	3 × A40
Day ward costs	80.00	A44
Tests	42.00	A46 + A48 + A49
Radiology charge	124.33	A52
Total	390.40	

Costs of misplaced lines: flush/single	**Cost**	**Ref.**
Consumables	3.88	A1 + A31 + A24 + A7 + A25 + A3 + A2 + (A5 × 2) + A29 + A9 + A11 + A12
Nurse in X-ray	3.20	A40 × 0.25
Radiology charge	31.08	A52 × 0.25
Extra nursing time	12.81	A40
Total	50.98	

Costs of misplaced lines: flush/double	**Cost**	**Ref.**
Consumables	4.93	A1 + (A24 × 2) + (A31 × 2) + A7 + A12 + A11 + (A3 × 2) + A2 + (A5 × 2) + A29 + A9 + A25
Nurses in X-ray	6.41	A40 × 0.25 × 2
Radiology charge	31.08	A52 × 0.25
Extra nursing time	12.81	A40
Total	55.23	

Costs of misplaced lines: reposition/single	**Cost**	**Ref.**
Consumables	11.19	A1 + (A2 × 3) + A3 + (A8 × 4) + (A9 × 2) + (A10 × 3) + A11 + (A12 × 3) + (A5 × 2) + A13 + A14 + (A15 × 2) + (A16 × 2) + A17 + (A26 × 2) + A19 + (A20 × 2) + A27 + A28 + (A6 × 2) + A29 + (A30 × 3) + A18 + A4 + A24 + A31
Nurses in X-ray	12.81	A40 × 0.5 × 2
Radiology charge	62.17	A52 × 0.5
Extra nursing time	12.81	A40
Total	98.98	

Costs of misplaced lines: reposition/double	**Cost**	**Ref.**
Consumables	11.74	A1 + (A2 × 3) + A3 + (A8 × 4) + (A9 × 2) + (A10 × 3) + A11 + (A12 × 3) + (A5 × 2) + A13 + A14 + (A15 × 2) + (A16 × 2) + A17 + (A26 × 2) + A19 + (A20 × 2) + A27 + A28 + (A6 × 2) + A29 + (A30 × 3) + A18 + A4 + (2 × A31) + (2 × A24)
Nurses in X-ray	12.81	A40 × 0.5 × 2
Radiology charge	62.17	A52 × 0.5
Extra nursing time	12.81	A40
Total	99.53	

Costs of misplaced lines: reposition/single/radiologist	**Cost**	**Ref.**
Consumables	11.19	A1 + (A2 × 3) + A3 + (A8 × 4) + (A9 × 2) + (A10 × 3) + A11 + (A12 × 3) + (A5 × 2) + A13 + A14 + (A15 × 2) + (A16 × 2) + A17 + (A26 × 2) + A19 + (A20 × 2) + A27 + A28 + (A6 × 2) + A29 + (A30 × 3) + A18 + A4 + A24 + A31
Radiology charge	165.73	A52 × 1.333
Extra nursing time	12.81	A40
Radiologist's time	67.06	A41 × 1.333
Reposition pack	24.00	A89 + A90 + A91
Total	280.80	

Costs of misplaced lines: reposition/double/radiologist	**Cost**	**Ref.**
Consumables	11.74	A1 + (A2 × 3) + A3 + (A8 × 4) + (A9 × 2) + (A10 × 3) + A11 + (A12 × 3) + A5 × 2) + A13 +

		A14 + (A15 × 2) + (A16 × 2) + A1 + (A26 × 2) + A19 + (A20 × 2) + A27 + A28 + (A6 × 2) + A29 + (A30 × 3) + A18 + A4 + (2 × A31) + (2 × A24)
Radiology charge	165.73	A52 × 1.333
Extra nursing time	12.81	A40
Radiologist's time	67.06	A41 × 1.333
Reposition pack	24.00	A89 + A90 + A91
Total	281.35	

Costs of misplaced lines: rewire/single	**Cost**	**Ref.**
Hickman line insertion pack	78.00	A32 + A36
Consumables	10.64	A1 + (A2 × 4) + A3 + A7 + (A8 × 4) + (A9 × 2) + (A10 × 3) + A11 + (A12 × 3) + A5 × 2 + A13 + A14 + (A15 × 2) + (A16 × 2) + A17 + (A26 × 2) + A19 + (A20 × 2) + A27 + A28 + (A6 × 2) + A29 + (A30 × 3) + A18 + A4
Nurses in X-ray	12.81	A40 × 0.5 × 2
Radiology charge	62.17	A52 × 0.5
Extra nursing time	12.81	A40
Total	176.43	

Costs of misplaced lines: rewire/double	**Cost**	**Ref.**
Hickman line insertion pack	90.00	A33 + A36
Consumables	10.64	A1 + (A2 × 4) + A3 + A7 + (A8 × 4) + (A9 × 2) + (A10 × 3) + A11 + (A12 × 3) + A5 × 2 + A13 + A14 + (A15 × 2) + (A16 × 2) + A17 + (A26 × 2) + A19 + (A20 × 2) + A27 + A28 + (A6 × 2) + A29 + (A30 × 3) + A18 + A4
Nurses in X-ray	12.81	A40 × 0.5 × 2
Radiology charge	62.17	A52 × 0.5
Extra nursing time	12.81	A40
Total	188.43	

Costs of misplaced lines: remove/reinsert/nurse/single	**Cost**	**Ref.**
Hickman line insertion pack	78.00	A36 + A32
Nurses in X-ray	34.15	A40 × 1.333
Consumables	15.38	A1 + (A2 × 3) + A3 + (A8 × 4) + (A9 × 2) + (A10 × 3) + A11 + (A12 × 3) + (A5 × 2) + A13 + A14 + (A15 × 2) + (A16 × 2) + A1 + (A26 × 2) + A19 + (A20 × 2) + A27 + A28 + (A6 × 2) + A29 + (A30 × 3) + A18 + A4 + (2 × A9) + A29 + (2 × A15) + (3 × A12) + A11 + (4 × A8) + A4 + A28 + A13 + A14 + A16 + A17
Radiology charge	165.73	A52 × 1.333
Extra nursing time	12.81	A40 × 1
Total	306.07	

Costs of misplaced lines: remove/reinsert/nurse/single	**Cost**	**Ref.**
Hickman line insertion pack	90.00	A36 + A32
Nurses in X-ray	34.15	A40 × 1.333 × 2
Consumables	15.38	A1 + (A2 × 3) + A3 + (A8 × 4) + (A9 × 2) + (A10 × 3) + A11 + (A12 × 3) + \(A5 × 2) + A13 + A14 + (A15 × 2) + (A16 × 2) + A1 + (A26 × 2) + A19 + (A20 × 2) + A27 + A28 + (A6 × 2) + A29 + (A30 × 3) + A18 + A4 + (2 × A9) + A29 +

		(2 × A15) + (3 × A12) + A11 + (4 × A8) + A4 + A28 + A13 + A14 + A16 + A17
Radiology charge	165.73	A52 × 1.333
Extra nursing time	12.81	A40
Total	318.07	

Costs of pneumothorax	**Cost**	**Ref.**	**Event**	**Blind**	**Events**	**Image**	**Cost**
Consumables	25.09	A21 + A22 + A23 + A4 + (A5 × 2) + A28 + A12 + A11 + A15 + (A8 × 2) + A26 + A14 + A81	1	25.09	0	0	25.09
Overnight stay	130.00	A45	11	1430.00	0	0	1430.00
Chest X-ray	55.00	A47	17	935.00	6	330	1265.00
Nurse	1.28	A40 × 0.1	1	1.28	0	0	1.28
Specialist Registrar	7.58	A43 × 0.5	1	7.58	0	0	7.58
Extra nursing time	12.81	A40	7	89.67	2	25.62	115.29
Total				2488.62		355.62	2844.24

Costs of arterial puncture	**Cost**	**Ref.**
Overnight stay	130.00	A45

Cost of infection – single lumen	**Cost**	**Ref.**
Inpatient costs	780.00	6 × A45
Blood culture	42.00	3 × A55
Swab	8.00	A56
Consumables	3.93	A62 + (2 × A7) + (3 × A15) + A25 + (2 × A17) + (3 × 63) + A30
Antibiotics	228.21	((A57 + (5 × A58) + (6 × A59) + (6 × A60)) + ((6 × A61) + (6 × A62))/2
Total	1062.14	

Cost of infection – double lumen	**Cost**	**Ref.**
Inpatient costs	780.00	6 × A45
Blood culture	84.00	6 × A55
Swab	8.00	A56
Consumables	3.93	A62 + (2 × A7) + (3 × A15) + A25 + (2 × A17) + (3 × 63) + A30
Antibiotics	228.21	((A57 + (5 × A58) + (6 × A59) + (6 × A60)) + ((6 × A61) + (6 × A62))/2
Total	1104.14	

PICC insertion during basic procedure	**Cost**	**Ref.**
PICC insertion pack	49.48	A38
Extra nurse time	12.81	A40
PICC extra consumables	4.04	(2 × A2) + (2 × A8) + (3 × A15) + (2 × A31) + (2 × A5) + (2 × A9) + A82
Total	66.33	

PICC insertion during procedure/ insertion in jugular by radiologist	**Cost**	**Ref.**
PICC insertion pack	71.82	A39
PICC extra consumables	4.04	(2 × A2) + (2 × A8) + (3 × A15) + (2 × A31) + (2 × A5) + (2 × A9) + A82
Extra nurse time	12.81	A40
Jugular insertion – radiology charge	124.33	A52
Jugular line insertion pack	95.00	A33 + A36 + A37

Consumables	10.64	A1 + (A2 × 3) + A3 + (A8 × 4) + (A9 × 2) + (A10 × 3) + A11 + (A12 × 3) + A5 × 2) + A13 + A14 + (A15 × 2) + (A16 × 2) + A17 + (A26 × 2) + A19 + (A20 × 2) + A27 + A28 + (A6 × 2) + A29 + (A30 × 3) + A18 + A4
Radiologist	50.31	A41
Total	368.95	

PICC insertion during procedure/ insertion in femoral by oncologist at a later date/infection/PICC insertion	**Cost**	**Ref.**
Femoral insertion – radiology charge	124.33	A52
Femoral line insertion pack	95.00	A33 + A36 + A37
Femoral consumables	10.64	A1 + (A2 × 4) + A3 + A7 + (A8 × 4) + (A9 × 2) + (A10 × 3) + A11 + (A12 × 3) + A5 × 2 + A13 + A14 + (A15 × 2) + (A16 × 2) + A17 + (A26 × 2) + A19 + (A20 × 2) + A27 + A28 + (A6 × 2) + A29 + (A30 × 3) + A18 + A4
Oncologist	50.31	A41
Day ward costs	80.00	A44
Tests	42.00	A46 + A48 + A49
Double-lumen infection	1104.14	(((A57 + (5 × A58) + (6 × A59) + (6 × A60)) + ((6 × A61) + (6 × A62))/2) + (6 × A45) + (6 × A55) + A56 + A62 + (2 × A7) + (3 × A15) + A25 + (2 × A17) + (3 × 63) + A30
PICC insertion pack	71.82	A39
PICC consumables	10.64	A1 + (A2 × 3) + A3 + (A8 × 4) + (A9 × 2) + (A10 × 3) + A11 + (A12 × 3) + A5 × 2) + A13 + A14 + (A15 × 2) + (A16 × 2) + A1 + (A26 × 2) + A19 + (A20 × 2) + A27 + A28 + (A6 × 2) + A29 + (A30 × 3) + A18 + A4
Nursing time	12.81	A40
Day ward costs	80.00	A44
Tests	42.00	A46 + A48 + A49
Chest X-ray	55.00	A47
Total	1778.69	

Referred for femoral insertion by oncologist at a later date	**Cost**	**Ref.**
Femoral insertion – radiology charge	124.33	A52
Femoral insertion pack	95.00	A33 + A36 + A37
Consumables	10.64	A1 + (A2 × 4) + A3 + A7 + (A8 × 4) + (A9 × 2) + (A10 × 3) + A11 + (A12 × 3) + A5 × 2 + A13 + A14 + (A15 × 2) + (A16 × 2) + A17 + (A26 × 2) + A19 + (A20 × 2) + A27 + A28 + (A6 × 2) + A29 + (A30 × 3) + A18 + A4
Oncologist	50.31	A42
Day ward costs	80.00	A44
Tests	42.00	A46 + A48 + A49
Total	402.28	

Referred for femoral insertion by oncologist at a later date	**Cost**	**Ref.**
Femoral insertion – radiology charge	124.33	A52
Femoral insertion pack	83.00	A32 + A36 + A37
Consumables	10.64	A1 + (A2 × 4) + A3 + A7 + (A8 × 4) + (A9 × 2) + (A10 × 3) + A11 + (A12 × 3) + A5 × 2 + A13 + A14 + (A15 × 2) + (A16 × 2) + A17 + (A26 × 2) +

		A19 + (A20 × 2) + A27 + A28 + (A6 × 2) + A29 + (A30 × 3) + A18 + A4
Oncologist	50.31	A42
Day ward costs	80.00	A44
Tests	42.00	A46 + A48 + A49
Extra nursing cost	25.62	A40 × 2
Total	415.90	

PICC inserted during procedure/ Hickman inserted at a later date	**Cost**	**Ref.**
PICC insertion pack	49.48	A38
PICC extra consumables	4.04	(2 × A2) + (2 × A8) + (3 × A15) + (2 × A31) + (2 × A5) + (2 × A9) + A82
Extra nurse time	12.81	A40
Image single Hickman line insertion	378.40	A1 + (A2 × 3) + A3 + (A8 × 4) + (A9 × 2) + (A10 × 3) + A11 + (A12 × 3) + A5 × 2) + A13 + A14 + (A15 × 2) + (A16 × 2) + A1 + + (A26 × 2) + A19 + (A20 × 2) + A27 + A28 + (A6 × 2) + A29 + (A30 × 3) + A18 + A4 + A37 + A38 + A32 + (3 × A44) + A46 + A46 + A49 + A52
Total	444.73	

PICC insertion 2 days later/Hickman inserted at a later date	**Cost**	**Ref.**
PICC insertion pack	49.48	A38
PICC extra consumables	4.04	(2 × A2) + (2 × A8) + (3 × A15) + (2 × A31) + (2 × A5) + (2 × A9) + A82
Chest X-ray	55.00	A47
Day ward cost	80.00	A44
Nurse time	12.81	A40
Image single Hickman line insertion	378.40	A1 + (A2 × 3) + A3 + (A8 × 4) + (A9 × 2) + (A10 × 3) + A11 + (A12 × 3) + A5 × 2) + A13 + A14 + (A15 × 2) + (A16 × 2) + A1 + + (A26 × 2) + A19 + (A20 × 2) + A27 + A28 + (A6 × 2) + A29 + (A30 × 3) + A18 + A4 + A37 + A38 + A32 + (3 × A44) + A46 + A46 + A49 + A52
Total	579.73	

Rebooked for Hickman line insertion by nurse	**Cost**	**Ref.**
Image double Hickman line insertion	390.40	A1 + (A2 × 3) + A3 + (A8 × 4) + (A9 × 2) + (A10 × 3) + A11 + (A12 × 3) + A5 × 2) + A13 + A14 + (A15 × 2) + (A16 × 2) + A17 + (A26 × 2) + A19 + (A20 × 2) + A27 + A28 + (A6 × 2) + A29 + (A30 × 3) + A18 + A4 + A33 + A36 + A37 + (3 × A40) + A44 + A46 + A48 + A49 + A52
Total	390.40	

Assistance by health care professional	**Cost**	**Ref.**
Assistance by nurse	3.20	A40 × 0.25
Assistance by radiologist	12.58	A41 × 0.25
Assistance by oncologist	12.58	A42 × 0.25

Transfer from blind to image-guided	**Cost**	**Ref.**
Radiology charge	62.17	A52 × 0.5

Additional single-lumen pack	**Cost**	**Ref.**
Pack	78.00	A32 + A36

Appendix 5

Patient information leaflet

Wilmslow Road, Withington,
Manchester M20 4BX
Telephone: Direct: 0161 446
Hospital: 0161 446 3000

CHRISTIE HOSPITAL
NATIONAL HEALTH SERVICE TRUST

Central Line Insertion Project Trial

PATIENT INFORMATION

Your Doctor has referred you for the insertion of a central venous line, sometimes called a Hickman line, long line or central venous catheter.

What is a central line?
A central line is a long narrow hollow tube made of soft plastic with an opening at each end. One end remains outside the body and the other end lies in a large vein in the chest. It can remain in position for several months.

Why do you need a central line?
Central lines are usually inserted for one or more of the following reasons;

(a) Some chemotherapy drugs are not suitable to be given into small veins in the hand or arm, these drugs must be given into a larger vein.

(b) To allow some chemotherapy treatments to be continued at home, therefore these patients do not need to stay in hospital for all their treatment.

(c) When it is envisaged that patients will need prolonged chemotherapy treatment and frequent needle sticks to take blood samples.

(d) To provide venous access for patients when the veins in their hands or arms are not suitable, either because they are too small, or have been used too frequently.

(e) Central lines are sometimes inserted for patients who have a phobia of needles.

How are central lines inserted?
A local anaesthetic is given to numb the area where the line is to be inserted, a sedative may also be given to make you drowsy and relaxed throughout the procedure.

The central line is inserted by puncturing the vein just under the collar bone (the insertion site) and is secured by feeding it under the skin (the skin tunnel) so it exits above the nipple on the chest wall (the exit site). The line has a small dacron cuff around it which beds into the tissue in the skin tunnel to prevent it from falling out.

A small cut is made at both the insertion and exit sites requiring one or two stitches in each, these are removed after about 3 weeks when the cuff is secure and the skin has healed.

What are the risks of central line insertion?
As with most procedures there is a small risk of complications occurring, these include:

- Accidental puncture of the lung which allows air to leak into the chest, this occasionally requires the placement of a tube to drain off the air.

- The catheter not being in the correct position, approximately 5% of patients need to have the central line moved to a better position.

- Before the procedure blood samples will be taken to make sure your blood count is satisfactory and your blood is able to clot normally as occasionally excessive bleeding can occur.

The central line insertion project trial
You are invited to participate in a trial we are currently undertaking to compare inserting central venous lines either on the ward, or in the x-ray department by nurses who have been specially trained to perform this small operation.

Here at the Christie Hospital central lines are usually inserted while patients are on the ward and the position checked by taking an x-ray of the chest afterwards. In the central line insertion project trial 50% of the procedures are being undertaken on the ward and 50% in the x-ray department, with the position of the line being checked at the time it is put in.

The Department of Medical Statistics will be responsible for allocating where the procedure will take place in order to ensure an equal number of patients with various types of cancer are included in each group.

Your participation is voluntary
You should not feel under any pressure to enter the trial, your treatment will not be jeopardised in any way should you refuse. Similarly, you may withdraw from the study at any time prior to commencement of the procedure without having to give a reason.

Patients not entering the trial will have their central line placed by a specialist nurse on the ward and the position of the line checked by a chest x-ray which we routinely do at present.

Confidentiality
All information regarding your care will remain confidential and any published reference to this study will not identify individual patients. Should you agree to take part in the study you will be asked to complete a patient satisfaction questionnaire.

Please ensure you have received answers to all your questions before consenting to participate in the trial. If you have any problems or queries please contact;

Sister Lesley Fitzsimmons. Tel; 0161-446-3000 Bleep 12014
(Clinical Nurse Specialist)

Appendix 6

National survey responses

National survey responses

Introduction

There is a paucity of published information regarding the insertion of Hickman lines in adult cancer patients across England and Wales. This questionnaire was designed to elicit information from a mix of both medical and nursing staff across cancer centres and units that could add to the current body of knowledge in this area.

Methods

Questionnaires were sent to cancer centres and cancer units in England and Wales (n = 172) in early 2000. Addresses and contact details for the units and centres were requested from relevant regional health authorities. Two questionnaires were sent to each organisation; one questionnaire was addressed to the medical cancer lead and the other was addressed to the Director of Nursing.

Results

Survey response rate

Of 344 questionnaires sent out to cancer centres and cancer units across the UK NHS, there were 160 replies. Twenty-one organisations sent replies from both doctors and nurses. A decision was made to exclude the questionnaires returned by the doctors in order to avoid double counting. This means that from the 172 individual organisations targeted, there were 139 replies. This converts to a modified response rate of 81%. However, not all of the replies could be used in the analysis for a variety of reasons. For example, seven replies stated that only Groshong or Broviac central lines were used in their organisation and not Hickman lines, one questionnaire was returned blank and 11 questionnaires could not be included because the organisation identification code was removed. All of these questionnaires were re-introduced for analysis when individual responses to questions were sought, not organisational responses.

Organisational responses of interest

Does your hospital have a central line policy or written guidelines for central lines required by adult cancer patients?

Fifty out of 110 (45%) respondents replied that they have a central line policy or written guidelines for central lines required by adult cancer patients; 52% replied that they did not have a policy or written guidelines; three respondents stated that they did not know whether a policy or written guidelines existed.

Approximately how many Hickman lines in adult cancer patients are inserted within your hospital each week?

Of 107 respondents, 75 (70%) stated that between one and five Hickman lines per week were inserted within their hospital. A full breakdown of figures is presented in the following table.

Lines inserted per week	*n* = 107
0	23 (21%)
1–5	76 (71%)
6–15	3 (3%)
16–30	2 (2%)
31–45	0
>45	0
Don't know	3 (3%)

How often does your hospital insert Hickman lines in adult cancer patients for the following reasons?

	Frequently	Infrequently	Never	*n*
Chemotherapy	76	21	8	105
TPN	17	59	15	91
Blood products	24	50	19	93
Needle phobia	17	45	25	87
Poor venous access	38	48	10	96
Antibiotics	17	45	25	87

In your hospital, where and how often are Hickman lines for adult cancer patients inserted?

	Never	Occasionally	Regularly	Always	*n*
Theatre	8	25	15	50	98
X-ray	36	11	17	18	82
Bedside	59	7	3	0	69

In your hospital, how often do consultants insert Hickman lines in adult cancer patients?

Consultant	Never	Occasionally	Regularly	Always	*n*
Oncologist	42	3	1	5	51
Surgeon	13	18	9	38	78
Anaesthetist	26	8	6	20	60
Radiologist	28	6	12	21	67

In your hospital, how often do specialist registrars insert Hickman lines in adult cancer patients?

Specialist registrar	Never	Occasionally	Regularly	Always	*n*
Oncologist	44	3	2	4	53
Surgeon	19	15	11	17	62
Anaesthetist	34	16	4	5	59
Radiologist	40	2	3	5	50

In your hospital, how often do nurses insert Hickman lines in adult cancer patients?

Nurse	Never	Occasionally	Regularly	Always	*n*
Oncologist	65	0	3	0	68
Surgeon	33	0	0	0	33
Anaesthetist	66	0	0	0	66
Radiologist	66	0	0	0	66

In your hospital, how often do junior house officers insert Hickman lines in adult cancer patients? Only one respondent out of 107 stated that junior house officers occasionally insert Hickman lines in adult cancer patients. The remainder (99%) stated that junior house officers never insert Hickman lines in adult cancer patients.

In your hospital, how often do senior house officers insert Hickman lines in adult cancer patients? Thirteen respondents out of 109 stated that senior house officers occasionally insert Hickman lines in adult cancer patients. The remainder (88%) stated that senior house officers never insert Hickman lines in adult cancer patients.

In your hospital, do nurses insert Hickman lines in adult cancer patients?
Three (3%) respondents out of 110 stated that nurses do insert Hickman lines in adult cancer patients.

On average, how long does a cancer patient in your hospital have to wait, after treatment is agreed before a Hickman line is inserted?

Average wait for insertion	*n* = 102
<1 day	8 (8%)
1–3 days	46 (45%)
4–7 days	35 (34%)
>7 days	13 (13%)

In your hospital, over the past year, what is the longest time an adult cancer patient has had to wait for a Hickman line?

Longest wait for treatment	*n* = 94
<8 days	52 (55%)
8–14 days	24 (26%)
15–21 days	9 (10%)
22–28 days	2 (2%)
<1 month	7 (7%)

If a formal training programme was available for medical and nursing staff to gain/refresh technical skills on Hickman line insertions, how many staff in your hospital do you think might be trained in the first year?

Training programme	Medical staff	Nurses
0	11 (12%)	25 (25%)
1–10	59 (64%)	59 (59%)
11–20	0	2 (2%)
>20	0	0
Don't know	22 (24%)	14 (14%)
Total	92	100

Individual responses of interest

Do you support nurse insertion of Hickman lines?
Eighty-four out of 160 (53%) respondents replied that they were in favour of Hickman line insertions by nurses, 35 (22%) said that they were not in favour of Hickman line insertions by nurses, 21 (13%) stated that they did not know and 20 respondents did not complete this question. There was no statistically significant difference in the results between nursing staff and medical staff.

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We look forward to hearing from you.

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ISSN 1366-5278