The Investigation of Parenteral Nutrition-Aotearoa (IPNA) – setting up the 1st phase of a clinical audit of the delivery of parenteral nutrition (PN) in New Zealand (NZ)

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Abstract

Nutrition support administered as Parenteral Nutrition (PN) is given to patients that have a non-functioning gut. Parenteral nutrition is the administration of nutrients and fluids into the venous system and is potentially associated with life-threatening complications. It is therefore essential that the care and management of PN is co-ordinated by clinicians that have the specialist knowledge and expertise to ensure it is given safely and appropriately.

This is a Phase one regional pilot study which aims to examine the current standard of PN care in hospitals in New Zealand using a clinical audit process. A secondary aim is to identify if any remediable factors are found in the care of patients receiving PN which can then be used to improve patient care, focussing on the following themes:

- Indication for PN
- Type of PN
- Prescribing PN
- Catheter choice, insertion and care
- PN associated complications
- Nutrition teams

Six local hospitals from four large district health boards covering a population of 1.64 million were enrolled. Included were adult, paediatric (<16yrs), and neonates (<1yr) patients receiving PN in hospital during the period of Jan 1st to June 31st 2011. Patients receiving PN in the home were excluded, even if they were admitted into hospital within the study period.

620 cases of PN use (288 adult, 68 paediatric, 264 neonates) were identified within the study period. 151 cases (70 adult, 17 paediatric, 64 neonates) were purposely selected for expert peer review. There were, 66 adults (94%), 7 paediatric (41%), 49 neonates (76%) questionnaires returned, of these, de-Identified clinical records were also available for 100% of the adult and 41% of the neonate cases for expert review.

Data for 66 adults (34 male: 32 female) were returned and peer reviewed by advisor assessors however only 65 completed advisor assessor questionnaires were returned.

The results of the adult cases examined showed that only 12.7% of cases were deemed to involve Good Practice- defined as the standard for which advisors would consider being acceptable and in accordance to the recommended guidelines. Sixty five per cent of cases demonstrated that there was room for improvement in the care provided. Nineteen per cent of cases examined were considered to be of a less than satisfactory standard.

A limitation of this study included lack of sufficient paediatric/neonate experts available for peer review.

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List of Abbreviations

ADHB – Auckland District Health Board

AuSPEN – Australasian Society of Parenteral and Enteral Nutrition

BAPEN – British Society of Parenteral and Enteral Nutrition

BMI – Body Mass Index

CMDHB – Counties Manakau District Health Board

CPG- Clinical Practice Guidelines

CRP – C-reactive protein

CT – Computed Tomography

CVC – Central venous catheters

ESPEN – European Society of Parenteral and Enteral Nutrition

ESPGHAN - European Society of Paediatric Gastroenterology, Hepatology and Nutrition

GI – Gastro-Intestinal

ICU/HDU – Intensive Care Unit/High Dependency Unit

IPNA – Investigation of Parenteral Nutrition-Aotearoa

NCEPOD – National Confidential Enquiry into Patient Outcome and Deaths

NDHB – Northlands District Health Board

NHS – National Health System

NICE – National Institute of Clinical Excellence

NSN – Nutrition Support Nurse

NST – Nutrition Support Team

NZ – New Zealand

NZD – New Zealand Dollars

NZNO- New Zealand Nursing Organisation

NZSG – New Zealand Society of Gastroenterologist

Osm – Osmolarity

PDSA – Plan-Do-Study-Act

PICC – Peripherally Inserted Central Catheter

PN – Parenteral Nutrition

PPN- Peripheral Parenteral Nutrition

RCS – Royal College of Surgeons

RFS – Re-feeding syndrome

SIGN – Scottish Intercollegiate Guidelines Network

SIRS – Systemic Inflammatory Response Syndrome

UK – United Kingdom

USD – United State Dollars

WDHB – Waitemata District Health Board

1. Introduction

Parenteral nutrition (PN) is the administration of nutrients, fluid, minerals and electrolytes directly into the veins and is used in patients whose ability to absorb nutrients may be inadequate, unsafe or in whom the intestine may be inaccessible. Parenteral nutrition can be used long term (over a period of months to years) in patients that may have long term or irreversible intestinal failure; however, it is more commonly used short term (for a period of days to weeks) as nutritional support for a temporarily non-functioning intestine.

This thesis presents a regional pilot study (phase one) of a clinical audit examining current management of PN in the Auckland and Northland regions. The main aim of this study was to examine current practice in PN care, a secondary aim was to identify remediable factors which could lead to improved patient outcomes. PN care was audited using the European Society of Parenteral and Enteral Nutrition (ESPEN) clinical practice guidelines (CPG), and the National Institute for Health and Clinical Excellence (NICE) guideline; Nutrition support in adults. Several themes of PN care were examined in this audit; indication for PN, type of PN given, catheter choice, insertion and care, PN associated complications and finally, availability and role of nutrition support teams (NST). An overall grade of the PN care provided was then given by advisor assessors. Phase one of the study also determined the appropriateness of the data collection tools for the New Zealand setting. Learning from this a national audit (Phase two) is planned for a later date and will not form part of this thesis.

Chapter one provides a background of the rationale for this study and the study aims. Additional information on the consequences of malnutrition are described, together with information on what PN is, the role of PN as nutrition support, the context in which it should be administered and the significant potential complications associated with its administration. The researcher's interest in the study will be summarised followed by an overview of the remaining chapters of this thesis.

Background

Normal Function of the Gastrointestinal Tract and Consequences of Malnutrition

The primary function of the gastrointestinal (GI) tract is to provide the body with a supply of nutrients, electrolytes and fluid. The GI tract's function involves ingestion, digestion and absorption of food and fluid into the blood, and elimination of residue and waste products. The tract extends from the lips to the anus and includes the mouth, pharynx, oesophagus, stomach and the intestines. Each part of the GI tract has a unique function which is regulated by autonomic processes, endocrine secretions and local intrinsic controls.

Disruption of the GI tract, through excision, trauma, or malfunctioning of the tract can lead to malnutrition. Specific malnutrition issues often arise as a result of the disruption of specific parts of the GI tract. For example, the loss of a portion of small bowel affects the ability to absorb nutrients, while issues affecting the pharynx can have an effect on swallowing, thus reducing the ability to take in adequate food and water.

Barendregt, Soeters, & Allison discuss the consequences of malnutrition which can be considerable, affecting several biological systems (2004).

- Mental function - Anxiety and depression is seen to increase in malnutrition and decreases with re-feeding. In addition specific vitamin deficiencies and changes in calcium, magnesium and phosphate levels can result in impaired brain function.
- Muscle function – This declines after a few days of fasting, then worsens further as cell mass is lost.
- Cardiovascular and renal function – Loss of cardiac muscle decreases cardiac output, resulting in bradycardia and hypotension, and the resultant decrease in heart volume has been found to be proportional to the loss of body weight. Furthermore, mineral and electrolyte disorders can cause cardiac arrhythmias and specific vitamin deficiencies may cause cardiac failure. Severely malnourished patients may also develop peripheral circulatory failure. The ability to excrete excess salt and water is

also diminished as a consequence of malnutrition resulting in higher levels of extracellular fluid volumes, as evidenced by clinical oedema.

- Respiratory function – Protein depletion in the body of more than 20% affects respiratory muscle structure and function. It is associated with a decrease in diaphragmatic muscle mass and respiratory muscle strength, resulting in an inability to cough effectively and impaired resistance to microbes.
- Gastrointestinal function – In malnutrition there is impaired absorption of lipids, disaccharides, and glucose. There is also a decrease in the essential GI secretions which contribute to further malabsorption. In addition, changes in bacterial flora or intestinal infection may also increase malabsorption and diarrhoea. Gastrointestinal changes connected to malnutrition also impair intestinal barrier function, which is understood to exacerbate multiple organ failure.
- Thermoregulation – Severe weight loss impairs the thermogenic response to cold. A drop in core temperature of only 1-2^{o}C can cause impaired cognitive function, un-coordination, confusion and muscle weakness. With severe malnutrition the febrile response is lost and fever may be absent even when significant life threatening infection is present.
- Immune system – Malnutrition impairs cell mediated immunity and therefore lack of resistance to infection.
- Wound healing – Malnutrition delays healing, particularly the early stages of wound healing.

Options for Feeding the Malnourished Patient

There are several options for nutritional support to prevent or treat malnutrition. Oral or enteral methods of nutrition support are the preferred option over the parenteral route for a variety of reasons. These include maintenance of gut integrity and functioning (Sigalet, Mackenzie, & Hameed, 2004), reduction in potential risks associated with PN (Gramlich et al., 2004), and the far more favourable costs involved in this type of re-feeding (Michael, Hannah, & Joshua, 2011). Patients with difficulty swallowing or reduced levels of consciousness may require an enteral feeding tube in order to supplement their nutritional requirements. Choosing the best option for nutrition support is dependent on several factors: the anatomy

of the GI tract, the clinical indication for nutrition support, the expected duration of feeding and the accessibility and functioning of the GI tract.

Orogastric or nasogastric tubes are the most common tubes used for enteral feeding (Best, 2005). They are generally used for short term nutrition support (4-6 weeks). This method of feeding allows a nutritional supplement to be administered directly into the stomach, which then acts as a reservoir, releasing nutrition into the rest of the gut at a steady rate as it would normally. Complications of this type of nutrition support are the discomfort caused to patients during the insertion of the feeding tube and the high risks associated with aspiration. The correct positioning technique is important to reduce this risk. Patients with severe illnesses may experience delayed gastric emptying which often means this type of feeding is poorly tolerated in this group.

Naso-jejunal feeding tubes are inserted into the nose and pass through both the oesphagogastric and pyloric sphincter into the jejunum. This positioning is believed to reduce the risk of aspiration (Bankhead et al., 2009). Because this technique bypasses the stomach reservoir, patients are sometimes not able to tolerate large bolus volumes of feed. This type of feeding is often used in patients known to have delayed gastric emptying or those that have had upper gastrointestinal surgery where feeding is distal to any vulnerable anastomosis.

Gastrostomy and Jejunostomy tubes are passed directly through the skin either into the stomach (Gastrostomy), or the jejunum (Jejunostomy). Placement can be done endoscopically, radiologically or surgically. These types of tubes are generally utilised when longer term feeding is required. Associated risks are similar to orogastric and naso gastric tubes and are dependent on expert technique and correct placement (Smith, 2012).

Finally, if there is no access to the gut, or there is a non-functioning gut, PN can be used to supply nutrition directly into the bloodstream via a venous access device. However, PN is often associated with significant potential complications (Hartl, Jauch, Parhofer, & Rittler, 2009;

Montalvo-Jave, Zarraga, & Sarr, 2007; Ukleja & Romano, 2007). Therefore it should be used judiciously, and be managed by clinicians with the specific knowledge required in order to prevent any of the potentially fatal complications occurring (Nightingale, 2010; Wilson & Blackett, 2012).

Venous Access Options for Parenteral Nutrition

In order to administer PN, reliable venous access is required. Venous access is the placement of a catheter into a vein to administer fluids or medications directly into the bloodstream. Catheters can be short or long depending on the intended function of their use. Peripheral catheters are generally about 3 inches long and sit in small veins, these are typically used for administering fluids and non-irritant medications, mid-lines are usually approximately 8 inches long, sitting in slightly larger veins than peripheral catheters, therefore enabling the administration of slightly more potentially irritant fluids. Central venous access refers to placing a venous catheter that leads directly to the major veins connected to the heart or into the heart itself. These catheters can vary considerably in length, and those used for adults, from approximately 38cm to 120cm. They are usually used for longer term therapy, or when multiple different fluids are being administered or when the fluids being given are known to be extremely irritant to veins due to the osmolality of the solutions.

There are various administration options available for the delivery of PN, peripheral venous catheters, midlines or central venous catheters. ESPEN clinical guidelines, 'Central Venous Devices', recommend that PN be administered into the most clinically appropriate site via a central venous catheter (Pittiruti, Hamilton, Biffi, MacFie, & Pertkiewicz, 2009), the tip of which should be sited at the distal superior vena cava or upper third of the right atrium. Caution must be taken however, as there is evidence that placement into the right atrium can cause cardiac injury and arrhythmias (Austin & Stroud, 2007). To safely administer PN, reliable venous access is required. Initial assessment for which is the most appropriate venous access

device should include an assessment of vascular accessibility, vascular access history, co-morbidities, associated medication access requirements and the expected duration of therapy.

There has been a significant increase in the use of peripherally inserted central catheters (PICC) for administering short term (over a period of weeks to months) PN, which are thought to reduce the risks of complication (Gosbell, 2005). For longer term administration of PN (months-years), portacaths or tunnelled lines should be considered. Parenteral nutrition can also be administered peripherally via short cannula's or midlines for short periods (days) using a low osmolality formula (<850mOsm/L), however great care must be taken to ensure the correct formula is used to prevent complications such as phlebitis.

There are some routes of venous access that are not considered suitable for the administration of PN. Femoral catheters are not considered appropriate for PN use due to their higher associated risks of contamination at the exit site in the groin and potential for thrombosis. Likewise internal jugular placement is not recommended as the exit site is difficult to nurse, increasing risk of contamination and catheter related infection.

Complications of PN

There are well documented complications associated with PN and include:

1. Central Venous Catheter (CVC) complications - these can be relatively common and include mechanical complications, catheter related sepsis and central vein thrombosis. Complications such as pneumothorax, arterial puncture, bleeding and malposition can occur during placement. However these are more commonly associated with subclavian or internal jugular CVC placement, especially when ultra-sound guidance is not used (Crozier & McKee, 2005). Risks of pneumothorax are greater with subclavian CVC insertion compared with internal jugular CVC placement - A chest x-ray is therefore considered essential after upper body CVC placement to exclude pneumothorax and to confirm correct positioning (Amerasekera, Jones, Patel, & Cleasby, 2009).

Air emboli can also occur with both centrally inserted catheters as well as peripherally inserted catheters (PICC). These can be caused when the catheter is accidentally left open and the high blood flow in central vessels pulls significant amounts of air into the circulation. In addition, thrombosis can occur if the CVC is not inserted far enough into the superior vena cava or upper third of the right atrium, especially when using PN with >900mOsm/L. (Austin & Stroud, 2007).

Correct placement of the central venous access device (CVC) must be confirmed prior to use especially when using a higher osmolality formula (>900mOsm/L). A post insertion x-ray should be considered mandatory if the position has not been checked during insertion, however there is evidence that ultra-sounded guided venepuncture is associated with lower risk of complication (Gann Jr & Sardi, 2003; Palepu, Deven, Subrahmanyam, & Mohan, 2009).

Migration of the catheter tip can occur, more commonly during insertion however this can be rectified if identified during time of insertion (Geng, Bin, Li, & Yan, 2011). Migration can also occur during the dwell time of the CVC, often due to factors such as accidental tugging or during dressing changes. Finally, mechanical complications such as thrombosis and misplacement can be avoided by using standardized insertion and maintenance protocols (Pittiruti, et al., 2009). These protocols should include appropriate choice of CVC, technician experience, correct positioning of CVC and good maintenance procedures of flushing and observations.

2. Infections – A common complication because PN is an ideal growth medium for micro-organisms. Catheter related bacteraemia is one of the commonest complications of PN with its prevention and management being one of the key roles of nutrition support team (Wesley, 1995). Infection is usually attributable to either poor aseptic technique contaminating the lumen during accessing or at the point of insertion when skin infections can be introduced into the blood stream (Safdar & Maki, 2006).

Sepsis is often associated with indicators such as pyrexia, elevation of white blood cells and increase of inflammatory markers, for example, C - reactive protein (CRP) (Bickley, 2009). As the source of Infection is not always catheter related, determining the source of sepsis is absolutely essential to determine appropriate management. Other necessary investigations include the collection of samples such as urine, wound swabs, drainage and sputum specimens, and x-rays and/or computed tomography (CT) scans to exclude respiratory or abdominal causes. Blood cultures taken from the CVC along with a simultaneous blood sample taken peripherally can confirm or rule out catheter related sepsis and is generally accepted as standard practice.

Confirmation of CVC infection is unequivocal if a sample taken from the catheter lumen produces a colony count greater than 1000 times than that taken from a simultaneous peripheral blood sample. A positive CVC sample with a negative peripheral sample may suggest catheter related sepsis but may equally be caused by contamination. A negative catheter sample with a positive peripheral sample suggests a non- catheter related source of infection. It is recommended that central venous catheters used for short term PN that have been confirmed as infected are generally removed and replaced, together with antibiotic therapy. (O'Grady et al., 2011; Pittiruti, et al., 2009) Catheters inserted for long term PN use, such as tunnelled catheters or portacaths may be treated using an antibiotic lock technique in an attempt to save the catheter however in severe cases of sepsis, catheter removal may be required.

Catheter-related sepsis can be prevented by using cost effective evidence based practices that include education and training of staff who are accessing catheters (Dumont & Nesselrodt, 2012; O'Grady, et al., 2011; Pittiruti, et al., 2009; Scales, 2011). In particular adequate hand washing, correct choice of device and site of insertion, use of maximal barrier precautions during insertion, use of chlohexidine as antiseptic during insertion and to disinfect when accessing, appropriate choice of dressing, routine change of giving sets and timely removal on completion of PN.

3. Re-feeding syndrome (RFS) –is a potentially fatal, but entirely avoidable condition that can occur in malnourished patients who undergo rapid re-feeding, by oral, enteral or parenteral routes (Byrnes & Stangenes, 2011). It is a highly complex syndrome with hypophosphatemia as the main clinical feature as well as changes in glucose, protein and fat metabolism, sodium and fluid balance abnormalities, thiamine deficiency, hypokalaemia and hypomagnesaemia. Other metabolic complications include abnormal glucose metabolism, deficiencies of fatty acids and trace metals, hepatobiliary and gastrointestinal dysfunction and electrolyte abnormalities.

The main cause of RFS is rapid re-feeding following a period of starvation (Mehanna, Moledina, & Travis, 2008). As a result of the metabolic changes in early starvation, the body switches from using carbohydrate as the main energy source to using protein and fat. As fasting continues, the body aims to conserve muscle and protein by decreasing use of ketone bodies and tissues switch to using fatty acids for their energy source. An increase in blood levels of ketone bodies ensues, thereby stimulating the brain to convert to using ketone bodies as its main energy source; subsequently the liver decreases its rate of gluconeogenesis, thereby conserving muscle protein. As a result of these metabolic changes, several intracellular minerals such as phosphate, magnesium and potassium become severely depleted, even though the concentrations of these minerals may remain normal or near normal in serum (Mehanna et al.).

When feeding is restarted, the body metabolism suddenly changes from catabolism (a set of metabolic pathways that break down molecules into smaller units and release energy) to anabolism (the set of metabolic pathways that construct molecules from smaller units; these reactions require the energy produced during catabolism). The re-introduction of carbohydrates stimulates insulin release, leading to the uptake of glucose, potassium, magnesium phosphorus, and water into cells. Protein and fat synthesis are stimulated, further consuming minerals. In addition, more cells are produced, also using up the supply of minerals. The net result of these changes is a deficit in intra and extracellular mineral concentrations, leading to the clinical complications of re-feeding syndrome.

The most important step in preventing re-feeding syndrome is the early identification of high risk patients (Ahmed, Travis, & Mehanna, 2011; Barendregt, et al., 2004). These include patients with minimal food intake for a period of more than 5 days, those who have been chronically under-nourished and those who have diminished physiological reserve. Patients may have become malnourished due to reduced intake (e.g. dysphagia, anorexia nervosa, depression, and alcoholism) or reduced absorption of nutrition (e.g. inflammatory bowel disease and coeliac disease), or due to increased metabolic demands (e.g. in cancer and surgery).

In 2006 the National Institute for Health and Clinical Excellence (NICE) in the UK identified major and minor risk factors to help identify patients at risk of RFS and provided guidelines to prevent or reduce the risk of electrolyte disturbances (NICE, 2006). These factors include BMI, weight loss history, current nutritional status, and serum levels of specific substrates, and are summarised in table 1.1.

Table 1.1: NICE scoring system to identify patients at risk of Re-feeding Syndrome.

Major NICE Risk Factors[a]	Minor NICE Risk Factors[b]
BMI < 16 kg/^{m2}	BMI < 18.5 kg/^{m2}
Unintentional weight loss >15% in previous 3-6 months	Unintentional weight loss >10% in previous three to six months
Little/no nutrient intake for >10 days	Little or no nutritional intake for >5 days
Low levels of potassium, phosphate, magnesium prior to any feeding	History of alcohol misuse or drugs, including insulin, chemotherapy, antacids, or diuretics

Other strategies for the prevention of RFS include identification of patients at risk, correction of abnormal serum levels before commencement of artificial feeding, provision of thiamine and the slow introduction and advancement of artificial feeding. A lack of thiamine can be caused by malnutrition, and thiamine deficiency can lead to metabolic coma and death. Thiamine derivatives and thiamine-dependent enzymes are present in all cells of the body, thus a thiamine deficiency would seem to adversely affect all of the organ systems. However, the nervous system is particularly sensitive to thiamine deficiency, because of its dependence on oxidative metabolism. Continuous monitoring of serum levels of glucose, phosphate, potassium, magnesium, and sodium, and observing for indications of oedema throughout artificial feeding is essential. If patients have one major[a], or two minor[b] risk factors, NICE recommend a reduced PN prescription to lower the risk. Whilst the consequences of RFS are well documented, unfortunately the true incidence of re-feeding syndrome is not known, partly because there is no consensus on definitions and criteria for diagnosis (Stanga et al., 2008).

Significance of this Study

There is a need to examine current PN practice in New Zealand for several reasons. Firstly, there is a large compelling body of evidence suggesting that malnutrition prolongs length of hospital stay, increases inpatient hospital costs and raises the risk of complications (Chermesh, Papier, Karban, Kluger, & Eliakim, 2011; Jefferies, Johnson, & Ravens, 2011). Secondly, it has been observed that malnutrition remains prevalent in hospitals throughout developed countries despite increased awareness of its consequences (Pradignac et al., 2011; Webster, Healy, & Maud, 2009).

Registered nurses are the primary clinicians involved in the practical aspects of care given to hospitalised patients. While nurses are expected to demonstrate a significant and broad range of nursing skills to deliver evidence-based care, nutritional support is often under prioritised in nursing care. Understanding why there is an under prioritisation of nutrition support might be the case is not fully understood, however Ross et al. (2011) identified a lack of co-ordination and shared sense of responsibility amongst clinicians in general, in their examination of poor nutritional intake in older people.

Finally of greatest concern is that front line registered nurses tend to be the clinicians primarily involved in the practical delivery of PN, a complex procedure which requires specialised care (Bozzetti and Forbes, 2009). Seldom will these nurses have had an input in the decision to start PN, the type of PN that should be prescribed or how on-going management should be conducted. The consequences of poor management of PN care is well evidenced in the 'A Mixed bag' report conducted by the National Confidential Enquiry into Patient Outcome and Deaths (NCEPOD) in 2010 (Stewart, Mason, Smith, Protopapa, & Mason, 2010).

The Mixed Bag report examined the clinical care of patients receiving PN in United Kingdom (UK) hospitals. The audit was initiated because of on-going evidence of malnutrition in public hospital patients despite a number of initiatives that had been introduced to reduce this. In addition one area of nutrition research that was lacking robust review was PN administration.

The NCEPOD study was the first of its kind to examine the actual practice of PN management in the UK and found that quality of care was often unsatisfactory and in some instances of significant concern. Only 19% of adult and 23.5% of neonate care represented good clinical practice (deemed to be the standard of care that the advisers would accept themselves (Mason, Puntis, McCormick, & Smith, 2011). Tingle (2011) described the findings as depressing, shocking and unsatisfactory and cautioned that the results have significant safety and legal implications should negligence be established in similar cases. Adequate specialist explanation on how PN should be given and the importance of the close monitoring required is essential to prevent potentially fatal complications occurring.

Study Rationale

Parenteral nutrition is administered in a wide range of situations throughout New Zealand's public hospitals. The European Society for Parenteral and Enteral Nutrition (ESPEN) guidelines on PN recommends that a multi-disciplinary team is involved in all hospitals where PN is administered (Bozzetti & Forbes, 2009). However, in New Zealand it is known that PN is administered in regional hospitals with no or little specialist nutritional support input. It is essential that PN is appropriately prescribed, monitored and safely managed. Yet accurate data on the incidence of public hospital PN usage is not currently collated in New Zealand. This study will be the first in-depth analysis of PN usage in New Zealand.

The primary investigator is a Clinical Nurse Specialist working as part of a multi-disciplinary nutrition support team, responsible for the specialist clinical management of adult patients receiving PN. These patients frequently have the complexity of multiple co-morbidities. A significant part of the nurse specialist's role involves co-ordinating the quality of care delivered to these patients in order to ensure best practice is delivered at all times.

To this end, the primary investigator's nutrition support team constantly evaluates their own practice to ensure best practice is being followed based on Australasian and International guidelines. Regular audits are carried out using an established and now extensive database

that includes comprehensive data collection on, reasons for referral, co-morbidities, weight history and current clinical status. Following data collection, analysis is carried out and reported to the interdisciplinary team, including surgeons and anaesthetists on an annual basis. However, actual care delivered at the bedside has not yet been audited.

After reading the NCEPOD report, it was clear a similar and comprehensive New Zealand audit was needed to assess any gaps in PN practice and management. Anecdotally it was felt that the Waitemata district health board (WDHB) NST should perform better overall than the NCEPOD general findings suggested, as a truly interdisciplinary team of experts is utilised. The NST consists of a lead physician, a nurse specialist, a dietitian and a pharmacist. It was agreed however that to be of significant worth a wider audit of practice should be conducted to provide a true representation of New Zealand wide PN practice, and to identify any gaps in practice.

Research Question

The question to be answered in this study is: ***'What is the current practice of PN management throughout the Auckland/Northern region of New Zealand?'***

The objective of this study was to investigate the current practice of PN management, throughout the Auckland/Northern regions public hospitals. A clinical audit process was used. The hospitals that participated in this study were:

- Auckland City Hospital
- Middlemore Hospital
- Northshore Hospital
- Starship Children's Hospital

- Waitakere Hospital

- Whangarei Hospital

The primary aim of this study was to examine whether PN practice in New Zealand fares better under the same scrutiny as the study conducted by NCEPOD.

Secondary aims were: to determine if New Zealand has similar results to the NCEPOD study, benchmarking New Zealand PN practice against the ESPEN/AuSPEN and NICE guidelines, and to ensure the data collection methods used were appropriate for the New Zealand context.

Organisation of the Thesis – Chapter Overview

Chapter 1 - This chapter introduced the reader to the focus of the regional audit planned and examined some of the specific issues related to PN management. It began with an introduction to PN, its use in the context of nutrition support and some of the potential complications associated with its use. Finally the researcher's background and interest in the subject were also outlined.

Chapter 2 - Reviews key literature related to PN care. The literature search strategy is provided as well as an overview of the main literature found. The chapter discusses the 'Mixed bag' report in more detail as well as introducing the reader to the guidelines used in the clinical audit carried out. Any gaps in the literature are presented and a research question formulated.

Chapter 3 - Presents the audit process, as well as the methodology and methods used in this study. A review of the rationale as to why the chosen ethics process was followed is given, and other ethical considerations, rigour and trustworthiness of the study are reported. The data collection methods are also included in this chapter.

Chapter 4 - Presents how the data were analysed and the details the findings of the study.

Chapter 5 - Discusses the study findings, whether the aims of the study were achieved and the challenges and limitations of the study. This chapter concludes with further recommendations based on the results of this study.

Summary

Parenteral nutrition is essential nutritional support for some patients and its safe administration is one of the many skills that nurses require. In order to be able to identify if there are any remediable factors and improve the overall quality of care for patients, a clinical audit of current practice is necessary. The present study aimed to replicate the UK NCEPOD study. No clinical audit of PN management has been conducted in New Zealand to date.

The 2010 UK NCEPOD report 'A Mixed Bag', identified significant concern in the practice of PN management. Identifying the areas of concern and increasing awareness of the concerns highlighted in this report should result in improved patient care and greater safety in the administration of PN.

This thesis aims to critically examine the current practice of PN management throughout the Auckland/Northland region ensuring that the study methods as replicated from the NCEPOD study are transferable in the New Zealand population. Its secondary aim is to support the hypothesis that there is significant opportunity to improve the practice of parenteral nutrition which will result in improved patient outcomes.

2. Literature Review

Introduction

The benefits of PN are widely acknowledged, however it is accepted that the potential for serious complications mean that it is a complex therapy to administer. In addition to the well documented risk of complications associated with its use, PN is also a costly therapy to administer. In order to prevent complications occurring, appropriate and safe use of PN is essential.

To evaluate the current evidence on the management of PN, a search of published literature was carried out. Reviewing published literature is essential to uncover what is already known about the subject and to identify other studies that may have relevance to the audit planned. Efficiently searching literature is a critical part of conducting research (Foote, 2009). Searching the published literature on PN studies should eliminate the risk of repeating or replicating previously published research, or providing no new information.

This chapter presents the search strategies used to identify any previous research undertaken related to PN care. The literature reviewed will be discussed focussing on the themes that are examined in this study: indication for PN, type of PN, prescribing PN, catheter choice, insertion and care, PN associated complications and the availability and role of nutrition support teams. An overview of the clinical practice guidelines (CPG) that would be used to inform best practice for this audit is discussed. Finally, the NCEPOD study will be discussed in detail as the current study aims to replicate the methods used in NCEPOD.

Literature Search Strategy

Several search engines were chosen to identify research relevant to the administration and management of PN. These were, Medline, the primary database for medicine, nursing, veterinary medicine, biomedicine and other allied health fields. Scopus, this database provides broad international coverage of journals in health sciences. Finally CINAHL—the nursing and

allied health database covering all aspects of nursing, health education, occupational therapy, social services in health care, and other related disciplines from 1983. These search engines were chosen as they produce a broad range of results from all disciplines relevant to the topic. The search fields were parenteral nutrition AND nursing, parenteral nutrition AND/OR management, parenteral nutrition AND complications, nutrition support teams AND parenteral nutrition.

Medline yielded 732 articles on parenteral nutrition and nursing, and five articles on parenteral nutrition and management. These articles were then limited from 2005 to date and English articles only. This reduced the results to 91 articles, seven of which were selected as relevant PN related studies, as they examined the practice of PN management. Scopus provided 63 articles using the same criteria/limitations; eight were selected as relevant. CINAHL plus did not identify any relevant new literature not found by either Medline or Scopus. Articles were limited to these dates as it was felt recent research was required in order to make comparisons to current practice, however, as very few PN studies were found, references for each article chosen were manually examined and retrieved if found to be specific studies examining PN management, even if they were outside the dates initially used. Finally, Google scholar was used to review citations of the chosen articles examined and these were also manually searched. These searches included some older articles which the author felt were of interest on the subject of PN management.

A manual search of the international Journal of Parenteral and Enteral Nutrition (JPEN) and Clinical Nutrition was also conducted. These journals were chosen as they are internationally recognised by clinicians in the field of nutrition support as being at the forefront of nutrition research. JPEN were also found to have published all of the ESPEN guidelines that had been produced in order to guide clinicians on the safe use of PN.

Guidelines

Several affiliated professional organisations are considered to be at the forefront of PN expertise, all of which have produced CPGs outlining safe use of PN available to inform the clinician. These include: the British Society of Parenteral and Enteral Nutrition (BAPEN), the American Society of Parenteral and Enteral Nutrition (ASPEN), the European Society of Parenteral and Enteral Nutrition (ESPEN) and the Australasian Society of Parenteral and Enteral Nutrition (AuSPEN).

The ESPEN guidelines are a collection of individual guidelines outlining recommended best practice in specific clinical situations, central venous access devices, as well as general nutrition support recommendations. These ESPEN guidelines include;

- Parenteral Hepatology (Plauth & Schütz, 2011)
- Parenteral Nutrition: Surgery (Braga et al., 2009)
- Parenteral Nutrition: Pancreas (Gianotti et al., 2009)
- Parenteral Nutrition: On Cardiology and Pneumology (Anker et al., 2009)
- Parenteral Nutrition: Non-surgical oncology (Bozzetti et al., 2009)
- Parenteral Nutrition: Intensive care (Singer et al., 2009)
- Parenteral Nutrition: Geriatrics (Sobotka et al., 2009)
- Parenteral Nutrition: Gastroenterology (Van Gossum et al., 2009)
- Parenteral Nutrition: Adult Renal Failure (Cano et al., 2009)
- Parenteral Nutrition of the European Society of Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) (Koletzko, Goulet, Hunt, Krohn, & Shamir, 2005)
- Parenteral Nutrition: Central Venous Catheters (access, care, diagnosis and therapy of complications) (Pittiruti, et al., 2009)
- Parenteral Nutrition: Present status and perspectives for future research (Bozzetti & Forbes, 2009)

The CPG produced are intended to be a guideline for the safe and efficient use of PN. However, it is well recognised that such guidelines are not able to fully capture the complexities of all possible clinical situations, patient pathologies, and the variability in clinician's professional practice or governing organisations. They do however aim to at least provide a framework to guide clinicians in prescribing and administering PN safely to patients requiring this complex therapy.

NCEPOD published their extensive audit of PN care in 2010, which examined PN management in all public hospitals in the UK; the study presented here aims to replicate NCEPOD's study. A criticism of the NCEPOD study from local clinicians in New Zealand was the lack of explicit documentation demonstrating that evidence based guidelines were used in the review of cases. Evidenced based medicine can be defined as the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patient (Sackett, Rosenburg, Gray, .Hayes, & Richardson, 1996). The Australasian Society of Parenteral and Enteral Nutrition have adopted the ESPEN guidelines; hence the ESPEN guidelines will form the basis for the audit of practice of PN throughout New Zealand described in this study.

The quality and strength of the evidence supporting the ESPEN CPGs has been graded by the Scottish Intercollegiate Guidelines Network (SIGN) and the Agency for Health Care Policy and Research. This grading is based on a hierarchy of the evidence that has been produced, informing the guidelines produced. Level Ia evidence, such as meta-analyses of randomised clinical trials translated as a grade A recommendation. Level IIa, IIb and III evidence was defined as at least one well-designed controlled trial without randomisation, a well-designed comparative or case- controlled studies (Grade B recommendation). Level IV evidence was defined as expert opinion or clinical experience of respected authorities (Grade C recommendations) (Bozzetti & Forbes, 2009).

A limitation identified when producing these CPGs is the lack of Grade A evidence or even Grade B evidence in scientific literature. This is due in part to the difficulty to ethically justify randomised controlled trials that might with-hold or deny nutrition support to those most clinically in need. Indeed the ESPEN CPGs identify that 56% of the recommendations made are

based on expert opinion and clinical experience (Grade C). However, the ESPEN CPGs do seem however to have been robustly reviewed, involving 11 international committees, each co-ordinated by a chairman, comprising 87 experts from 16 European-Mediterranean countries. Bozzetti (2009) stated that clinical practice guidelines have been proven to be effective in changing clinical practice and improving outcomes, including improved patient selection, quality of life and minimisation of complications. Comparable to research informing CPGs, most of the studies found on PN practice in this literature review are observational surveys, relating to Grade B or C evidence.

A second limitation of the ESPEN guidelines is that they do not include specific guidelines on the management and prevention if RFS, which is a well-recognised potential complication of PN. Therefore, the NICE (2006) CPG recommendations for identifying patients at risk of RFS were used as the standard to audit against, in this study (An overview of these guidelines was provided in chapter 1, p 9).

Review of the Literature

Indication for PN

Enteral or oral nutrition should always be the first choices in providing specialist nutrition support to those patients who are malnourished or who are at risk of malnutrition (Phillips & Ponsky, 2011). Using the oral/enteral route has been shown to maintain gut function and promotes the immunological function of the intestine (Sudakin, 2006). Parenteral nutrition should be reserved only for those with a proven intestinal failure through which no other route for nutrition is available or appropriate (Bozzetti & Forbes, 2009). This includes patients with irreversible intestinal failure or who have had a temporary non-functioning gut for 7-10 days or who are expected to have a non-functioning gut for 7-10 days.

Early research demonstrates that inappropriate use of PN has been an on-going issue for some time. For example, Trujillo et al. (1999) found that only 56% of PN administration that was

started without NST consultation was appropriate in accordance to the ASPEN guidelines. However, this increased to 82% after a voluntary NST consult service was created. Maurer (1996) also reported similar findings when they completed a prospective study of 50 consecutive patients that were given PN in a 487 bedded community teaching hospital. They evaluated the appropriateness of PN use and found that all fifty patients received 469 days of PN in total, 49.7% of which was deemed to be avoidable (43% medical vs. 2% surgical). When formal approval for PN was introduced, PN days were reduced from 500 to 100 days per month again demonstrating a reduction in costs when a NST was present. However, despite guidance for the appropriate use of PN, further research consistently demonstrates that it is still often used inappropriately without the support of a NST.

Dellegge et al. (2007) found in his single centred prospective study of 139 surgical PN episodes that 40% of all PN cases were deemed to be inappropriate in accordance to the ASPEN guideline. However, the hospital in which this study was conducted actually had a NST available for voluntary consultation which is noted to be of concern. All patients started on PN were seen by a registered dietitian or a pharmacist with clinical nutrition expertise. However neither the dietitian nor pharmacist was directly responsible for the ordering of PN; this was done by the lead clinical team caring for the patient, demonstrating again a lack of compliance with CPGs.

Dellegge performed a later collaborative study with Martin (2011), who reported similar findings to his 2007 study discussed previously, when 278 randomly selected cases from four different tertiary hospitals were examined. Registered dietitians collected retrospective and prospective data over a three month period and found inappropriate PN use in 32% of cases. This study also highlighted the cost of inappropriate PN use, which resulted in a high cost of approximately $138,000 USD ($168,890NZD) of avoidable hospital costs.

However, both of the studies by Dellege are limited in their study design as they rely on the individual clinician's interpretation of inappropriate use. In addition, whilst the later study by Dellege examined randomly selected cases, there was no requirement to evenly match cases

by diagnosis or service. Therefore, it was unclear as to whether there was over or under-representation of particular diagnoses or services. Thus it was difficult to generalise the findings of these studies to all PN users in general practice.

Type of PN prescribed

All of the ESPEN guidelines state that patients requiring nutritional support must be screened to determine their current nutritional status and malnutrition risk. They also state that screening should include an evaluation of weight (current and history of weight loss/gain); metabolic functioning particularly levels of pre-albumin, sodium, potassium, magnesium and glucose levels, fluid status and anthropometric measurements.

Parenteral nutrition prescriptions need to be formulated to meet the individualised requirements of the patient. Although requirements can be calculated using standard international reference ranges for normal physiological requirements, the clinician prescribing PN needs to have a clear understanding of age, disease state, organ functioning, metabolic condition and medication usage as well as how to revise requirements accordingly.

Assessment of those patients who are deemed to be at nutritional risk is an important component of initial nutrition screening for PN. ASPEN's practice management task force (2010) surveyed all ASPEN members (M. DeLegge et al., 2010). There were 698 respondents that provided partial data and 200 surveys were completed which included answers to specific NST questions. The primary aim was to evaluate the state of nutrition support practice and utility of a NST in clinical practice. Forty two per cent of respondents had a NST, and 27% of NSTs included a nurse; however this was the least represented member in teams after pharmacists, dietitians and physicians. In only 40.5% of surveyed hospitals did all members of the NST perform nutritional assessments; these were completed predominately by dietitians in 91% of cases.

A cross-sectional survey of PN practice in acute-care adult hospitals across Australia was conducted by Ali, Chapman-Kiddell and Reeves (2007). Surveys were posted to 103 hospitals with a covering letter explaining the intention of the survey. A total of 67 hospitals (65.7% response rate) were included. The survey was completed by a health professional responsible for the delivery of PN in their hospital. Those hospitals with a PN team (n=27) reported that in over half of the cases (n=15, 55.6%) the NST determined the patients' suitability for PN, whereas for a quarter of the hospitals (n=7) determination of suitability was a combined decision between the NST and the referring medical unit. Almost all of the hospitals surveyed (n=66, 98.4%) reported that they assessed biochemical parameters before commencing PN.

Prescribing PN

Prescribing of PN is a complex issue requiring expertise and knowledge of all the components included and subsequent effects of administration (Mirtallo et al., 2004). Mirtallo's 2003 survey of PN practice (which was one of the few multi-centred studies found) was driven by the American Society of Parenteral and Enteral Nutrition (ASPEN) and aimed to provide an overview of the variance and consistency of safe PN prescribing in all health care settings. They had 667 responses mainly from hospitals (85%) and found that problems in prescribing PN often occurred. Prescriptions were predominantly the responsibility of physicians however pharmacists and dietitians were often involved, with pharmacists frequently 'overseeing' the prescriptions. Fifty five per cent of respondents dealt with 0-10 PN prescriptions daily whilst 15% had more than 30 PN prescriptions daily. Orders needed to be clarified <25% of the time for 88% of respondents and <10% of the time for 61% of the respondents. The most common reasons for PN orders requiring clarification were macronutrients prescribed, incorrect PN volume, content, illegible prescribing, incompatibility of components prescribed, nutrients prescribed outside the normal range, or the infusion rate not being prescribed. Fifty six per cent of respondents reported adverse events in the previous 2 years, 64% of which required no treatment or else increased monitoring was required. Of concern was the significance of harm reported, these were classified as: temporary (13%, n=61 responders) or permanent (2%, n=7 responders), near death (3%, n=16 responders) or death (2%, n=7 responders).

Intravenous fluids should be prescribed based on knowledge of the clinical effects that they will have on the patient, taking particular caution to assess the sodium, chloride, potassium and water requirements. A common issue when PN is being administered is the additional fluids prescribed; often by junior doctors who lack knowledge about the actual fluids they are responsible for prescribing as well as the subsequent consequences such as fluid overloading (Powell-Tuck et al., 2008).

Catheter Choice, Insertion and Care

Whilst PN is generally administered centrally, it is often given peripherally in some centres. Anderson et al. (2003) undertook a review of clinical trials relating to peripheral PN (PPN) use in adults. They found that PPN accounted for almost 20% of all PN administered in the UK and showed that in the absence of consensus guidelines, there was wide variance in practice. It concluded that PPN was an option for nutrition support if used appropriately. Peripheral PN is indicated in patients that are expected to require PN for a short period and also when nutrient solutions are being used in which the osmolality of the nutrient solution does not exceed 850mOsm/L. This avoids the risks associated with CVCs such as infection, simplifies nursing care, reduces costs significantly and may prevent the delay in initiation of nutrition support. However PPN is associated with a higher incidence of peripheral thrombophlebitis and is not suitable for patients with substantial fluid requirements, those with high output fistula (due to the increased requirements of replacement electrolytes therefore increasing Osm/L), or for those with suitable central access that could be used for PN (Osm/L (osmolarity) refers to the concentration of a solution in terms of osmoles of solutes per litre of solvent- the higher the Osm/L, the more concentrate the solution).

Catheter migration is a known complication which can occur following insertion (Vesely, 2003). Kowalski's (1997) prospective study evaluated the change in position of chest wall central venous devices inserted for chemotherapy and found migration was a common event occurring in 49/50 patients. The carina was chosen as the reference point for measurement in this study, with differences on immediate supine position and post procedure (within 24hrs) chest x-rays measured to determine migration. Although it is thought that left sided catheters

may demonstrate greater risk of migration due to the longer intravascular course compared to those inserted on the right, Kowalski did not find that this was statistically significant in this study, with right sided catheters migrating an average of 2.7cm +/- 1.9cm and left sided catheters migrated an average of 3.2cm +/- 2.1cm. A variety of catheters were used in their study, none of which demonstrated a statistically significant increase in the rate of catheter migration.

However, a study by DeChicco (2007) demonstrated a statistically significant occurrence of malpositioning when peripherally placed central catheters (PICC) were used in their clinic compared with other venous access devices such as Hickman lines, Groshong lines and implanted ports (34.2% vs. 9.0%; p<001). It should be noted that there were limitations with the study by DeChicco et al. (2007), which aimed to determine the prevalence of improper central access device tip position. A prospective study was conducted of 138 catheters in 124 adult patients with long term central venous access devices due to receive PN. The recommendation made in the ASPEN guidelines for catheter tip position to be in the superior vena cava adjacent to the right atrium was followed. However, their use of central venous access devices implies practice in direct contrast to another of ASPEN's recommendations. ASPEN state that infection complications are reduced when catheter access devices are dedicated solely for PN use or the designation of one port solely for PN use if a multi-lumen device is being used (Mirtallo, et al., 2004). The median catheter duration was 1.6 months in this study implying previous accessing of the devices, therefore considerably increasing infection risks in this situation. The second point of interest is that evidence suggests that PICC lines are associated with reduced rates of infectious complications in comparison to other central venous access devices (Maki, Kluger, & Crnich, 2006). However, if PICC lines are also associated with greater incidence of migration, then further study is essential to determine what the safest central venous device for PN use is (Cowl et al., 2000). Whilst the proposed study will examine choice of catheter, it is not the intention to explore this dichotomy further in this thesis.

ESPEN have specific recommendations for reducing the risk of catheter related infections including, catheter choice, hand-washing, barrier precautions during insertion, disinfection, regular changing of infusing sets and education for staff. All are intended to inform clinicians of

current recommendations for central venous access device care, however evidence suggests that these are sometimes not adhered to.

Despite CPGs, PN practice is often variable and does not adhere to recommendations made (Pittiruti, et al., 2009). Likewise the practice of CVC care also appears to vary considerably. A small prospective cross sectional nursing survey of 14 ICUs throughout Australia were surveyed about their infection control practices when using CVCs and responses compared to evidence based guidelines (Rickard, Courtney, & Webster, 2003). The study found a wide variety of responses demonstrating inconsistency in infection control practices. This nursing based study has a number of limitations. Firstly, each ICU included was telephoned and a questionnaire was completed by the researcher based on responses to questions asked. The person identified from each ICU was the charge nurse or senior nurse on duty. The author of the study noted that the responses given may be the opinion of the nurse questioned rather than standard practice in the unit in which they were working. Secondly, responses may have been based on what was considered to be the 'correct' answer. However, the study confirms that there is some variability in the infection control to CVC care, with some instances of non-adherence to CPGs. Why this should be the case was not investigated or identified if known.

PN associated Complications

Catheter-related infection is probably the most common serious potential complication associated with PN as the high concentration of glucose within the PN makes it an ideal environment for the colonisation of microbes. Beghetto et al. (2005) conducted a single centre concurrent cohort study of adult patients with a CVC, with or without exposure to PN. The aim of the study was to evaluate PN as a risk factor for CVC related infection in a general university hospital. For each patient receiving PN two others were randomly selected on the same day, one from the same ward and one from ICU. One hundred and fifty three patients were studied, 28 of which developed a CVAD infection. A multivariate cox analysis was carried out which demonstrated that PN was the only risk factor for CVAD infection (RR =3.30%; 95% CI, 1.30-8.34; p=0.012). Malnutrition, length of hospitalisation and sustained hyperglycaemia were of no significance.

Hyperglycaemia is a relatively common complication for patients receiving PN (Lin, Lin, Lee, Ma, & Lin, 2007). It is associated with increased infection rates as well as fluid and electrolyte imbalances. Studies demonstrate a correlation between PN, blood glucose levels and morbidity and mortality (Cheung, Napier, Zaccaria, & Fletcher, 2005; Pasquel et al., 2010). Cheung's (2005) retrospective single-centre study of 111 patients, (122 PN episodes) analysed outcome measures for patients receiving PN who developed hyperglycaemia. Increased blood glucose levels were associated with a significantly increased risk of cardiac complications (p=0.02), infection (p=0.01), systemic sepsis (p=0.05), acute renal failure (p=0.05) and death (p=<0.01). When data were examined by quartiles of blood glucose levels, patients in the highest quartile (>9.1mmol/L) were 10.9 times more likely to develop complications than patients in the lowest quartile (<6.9mmol/L) and the risk of developing any complication was 4.3 times higher (p=<0.01).

Whilst RFS is known to occur, Wagstaff (2011) in her survey of London based dietitians, suggests there is a universal lack of knowledge and/or a lack of compliance with the NICE re-feeding guidelines. Anonymous surveys distributed to dietetic service managers across all acute, community and mental health trusts in the London region yielded a 30.8% response rate. One hundred and sixty eight dietitians responded from 33 of the 62 NHS trusts surveyed. Similarly the patient identified at risk of RFS was fed initially at a reduced rate of 12.7kcals/kg suggesting lack of compliance with the NICE guidelines which recommends a starting rate of 5–10 kcal/kg depending on the patient's risk.

Availability and role of Nutrition Support Teams

Organised NSTs are associated with improved patient outcomes, decreased length of hospitalisation and improved cost effectiveness (Russell, Andrews, Brewer, Rogers, & Seidner, 2002). Russell et al. (2002) published standards for specialised nutrition support and identified that the function of nutrition support services is to assess and manage patients determined to be nutritionally at risk. They recommended that the NST should include a physician, nurse, pharmacist and dietitian who have undertaken specialist training in the administration of specialised nutrition support.

DeLegge et al. (2010) also suggests the benefit of a multi-disciplinary NST stating that "individually each member of the NST plays an important role in improving the nutrition status of patients, but the safety and efficiency of care are enhanced when they collaborate as a team". Labour costs constitute the greatest percentage of hospital expenditure. Nonrevenue producing and labour intensive NSTs have been frequently identified as targets for cost cutting (Bines, 2002). This is despite repeated evidence that specialised nutrition teams increase the quality of care and decrease the complications of nutrition support.

Kennedy et al. (2005) demonstrated that there was a reduction in costs as well as complication rates in the adult population when a NST was utilised. Comparative data was collected for two consecutive years – a retrospective pre-NST and a prospective NST year. Pre-NST there were 82 PN episodes (54 patients = 665 PN Days) and, with a NST there were 78 PN episodes (75 patients = 752 PN days). This single centre study found that catheter-related complications occurred in 71% of PN episodes compared with 29% when a NST was present (3 infections per 100 PN days, $p=<0.05$). Furthermore, 133 NST referrals were made however only 78 were provided PN, resulting in cost savings in 55 patients.

Evidence suggests that the employment of a nutrition support nurse specialist can significantly reduce the incidence of complications associated with PN as well as the costs associated with inappropriate PN usage. Kennedy (2005) conducted a study examining the tangible cost savings made by having a dedicated nutrition support nurse. This study was carried out by the Leicester Royal Infirmary in the UK after a nutrition support nurse role was established in 1999, working in all adult areas of a university hospital. Comparative data about all patients given PN were collected for two consecutive years (a retrospective pre-NST year and a prospective NST year). The study demonstrated that despite the number of PN days increasing with an NST, tangible cost savings of £50,715 (105,981NZD) were demonstrated within the NST year by avoided PN episodes and a decreased incidence of catheter related sepsis.

Goldstein (2000) conducted a quasi –experimental, reversal on-off, retrospective study of the medical and financial costs associated with termination of a nutrition support nurse (NSN).

They aimed to determine the effect of termination of a NSN responsible for patients receiving PN. This study examined 1,093 patients that received PN from fiscal years 1992-1998. The study compared the periods in which a NSN was employed to the period in which the role was disbanded and later re-instated. Costing's were estimated based on actual costs, cost of inappropriate use and as a result of complications incurred. This study found increased inappropriate usage in the period when no NSN was in post, a decrease in costs when the NSN was present and an increase in sepsis when no NSN was present. Although this was a single-centre study its strength was that it focused on the NSN role specifically.

The Mixed Bag Report

The NCEPOD organisation is an independent UK organisation run and overseen by the healthcare profession. Their aim is to undertake independent reviews of clinical practice and they have published over 28 reports on a range of diverse topics. These include: care of patients admitted to hospital as emergencies, care of the seriously injured patient, as well as specific disease and service topics such as sickle cell disease, thalassemia and therapeutic endoscopy. The aim of the 'Mixed bag' PN study was to examine the practice of PN management throughout public hospitals in the UK, and to identify remediable factors (Stewart, Mason, & Protopapa, 2010). The study was designed and carried out by a multi-disciplinary group of experts who also contributed to the review of the findings. These included gastroenterologists, paediatricians, dietitians, pharmacists, nutrition nurse specialists, a lay representative and a scientific advisor.

All National Health Service hospitals in England and Wales and Northern Ireland, hospitals in the independent sector and public hospitals in the Isle of Man, Guernsey and Jersey were expected to participate in the study. Patients that had received PN as an inpatient between 1 January 2008 and 31 March 2008 were included. Patients receiving home PN were excluded.

The study used three questionnaires to collect data. The first two included, a clinician patient care questionnaire used for individual patients and the other, an organisational questionnaire

was used for each hospital. The patient questionnaire was completed by either the clinician responsible for the patient at the time of PN administration, or if not, by the clinician responsible for the PN itself. The organisational questionnaire was based on the hospital policies and protocols for PN and the availability of NSTs. On completion of the patient questionnaire, clinical records were copied and all data was returned to NCEPOD. Advisor assessors then examined all cases and completed a third questionnaire based on their interpretation of the care provided. Finally an overall grade of care was provided.

A total of 5,527 patients from the 218 hospitals included were identified. The study sample was reduced to 3,305 when the number of patient per consultant was limited to two. Also those patients for whom a PN prescription was written but was not commenced on PN were excluded. For a further 167 cases NCEPOD were notified that the questionnaires could not be completed. Reasons for this included case notes being lost, the consultant having left the trust or wrongful identification. For the remaining 3138 patients included, patient questionnaires and/or case notes were received for 1948 cases (62%).

The findings were considered to be 'deeply depressing' by the advisors who found that too often the quality of care was unsatisfactory. Room for improvement was found to be predominantly in the areas of clinical care where cases were identified as receiving care that was considerably less than satisfactory. A number of worrying findings were identified: PN being administered for an inappropriate indication, inadequate clinical assessments, inadequate monitoring of patients receiving PN, poor biochemical/metabolic monitoring, having additional IV fluids/inappropriate volumes and types of fluids.

The value of peer review of the cases studied has been identified as both strength and a weakness of studies conducted by NCEPOD including this PN report. Stewart et al. (2010) stated that 'peer reviews of these processes on a case-by-case basis by a multidisciplinary group of healthcare professionals who work 'at the coal face' of PN care is a powerful tool'. Conversely they recognised that the report only reflects the opinions and values of the expert

advisors based on the information received. In addition, there is the assumption made that the findings can be generalised to reflect the current state of PN across the whole of the UK.

Significance of the Literature for this Study

The studies discussed demonstrate that despite the existence of CPGs to guide clinicians on the safe use of PN, care is widely variable between institutions with little evidence that CPGs are consistently used. Why this may be the case is unknown. It is intended that this study will establish whether New Zealand PN care is similar or if in fact differs, from that of our peers in other countries. If it is found that our practice is similar it is imperative that further research is conducted to establish what the barriers to clinicians using the CPGs available are.

It is recognised that nutrition support research can often be limited to small studies with limited power. In order to get significant results to inform the wider nutritional knowledge base larger multi-centred collaborative studies are essential (Wischmeyer, 2008). Although this thesis presents phase one, a fraction of PN practice in New Zealand, examining PN in the Auckland/Northland region only, it is hoped that phase two which will be completed at a later date and will examine PN care throughout all of NZ, will generate more significant findings.

Summary

This chapter has presented an overview of the current literature on the care and management of PN. The literature review has demonstrated that PN is often administered inappropriately. Complications can frequently occur without adequate monitoring and processes in place to prevent and identify complications early. Parenteral nutrition care is often not co-ordinated by clinicians that have specialist knowledge and expertise required to administer it safely.

The studies presented have illustrated that significant improvements in patient care are often demonstrated by establishing nutrition support specialists trained in the care of PN; it has also shown that considerable cost savings can be made by the implementation of a NST. The

following chapter will outline the clinical audit framework that informed this study. It will discuss the audit cycle, as well as some of the strengths and limitations of the research method chosen for this study.

3. Methodology and methods

Introduction

This chapter begins by describing the research design and the methods used for this study. Secondly, it will give an overview of the approach and rationale for the methodology chosen. Thirdly, it will discuss methods for participant selection, the research setting, data collection, and data analysis. Fourthly, the ethical considerations involved with this study are discussed. Finally, the process of establishing and maintaining rigour and trustworthiness will be considered.

To examine the current use of PN throughout the Auckland/Northern region, a clinical audit was conducted. The aim of the audit was to identify the current management of PN care in the Auckland/Northland region, examining specific themes, indication for PN, type of PN, prescribing PN, catheter choice, insertion and care, PN associated complications and the availability and role of NSTs. A secondary aim was to determine if the NCEPOD methodology used was transferable in the NZ population. This chapter will introduce the reader to the clinical audit process and will explain how audit can contribute to understanding how PN care is currently provided and any associated benefits and/or limitations of audit.

Research Methodological Framework

Quality improvement is the responsibility of all health professionals and is best done using a multi-disciplinary approach; nurses are often expected to participate in quality initiatives within their workplaces (Bowie, Bradley, & Rushmer, 2012). Clinicians need to demonstrate the effectiveness and efficiency of service provision, focusing on ensuring evidence based practice is at the cornerstone of care delivery. This requires the examination of care through research, service review and audit activities. Differentiating between these activities is complex, however Mawson et al. (2007) offer the following simple rules for defining the activities of research, audit and service review (See Table 3. 1).

Table 3.1 Defining activities of research, audit and service review

Activity	Simple rule
Clinical Audit	Measures existing practice against evidence-based, best practice, clinical standards.
Research	Generates new knowledge where there is *no or limited research evidence* available and which has the potential to be *generalisable or transferable*.
Service Review	Incorporates both *service/practice development and service/practice evaluation*. *Service/practice development* – introduces a change in service delivery or practice for which there is evidence derived from research or from other health/social care settings that have already introduced and evaluated the change. New developments should always be evaluated. *Service/practice evaluation*– evaluates the *effectiveness or efficiency* of existing or new service/practice with the intention of generating information to inform local decision making. This type of activity has sometimes been referred to as a clinical effectiveness study, baseline audit, activity analysis and organisational audit.

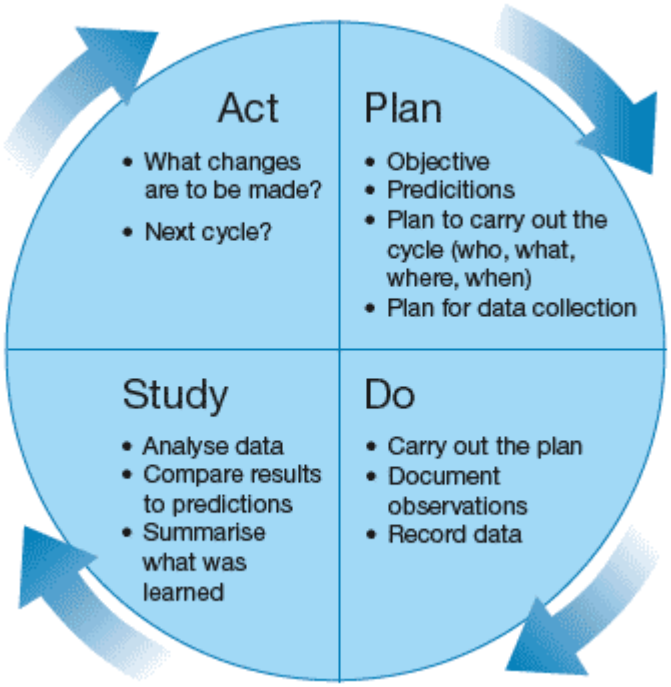
Ashmore and Ruthven (2008) also offer the novice clinical investigator very clear definitions between research and clinical audit. Both research and audit are systematic processes that involve statistical analysis and topic selection, and both can lead to change in clinical practice. However there is a definitive difference. Research attempts to derive generalisable, new knowledge by addressing clearly defined questions with systematic and rigorous methods. Clinical audit on the other hand investigates whether best practice, as defined by clinical research, is being implemented.

Hill and Small (2006) characterise the difference between research and audit as “research is finding out what you ought to be doing; audit on the other hand is whether you are doing what you ought to be doing” (p.99). At present the most widely used definition was developed ten years ago by NICE.

NICE (2002) defines clinical audit as a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery.

Clinical audit is one of the key elements of clinical governance, which has been acknowledged as the driving force behind National Health Service (NHS) reform since the government white paper outlined a new style NHS in the UK in 1997 (Taylor & Jones, 2006). It is described as a framework through which organisations are accountable to continue to improve the quality of the service and safeguard high standards of care by creating an environment in which excellence in clinical care would flourish. The processes involved in clinical audit are often represented diagrammatically; one of the most widely adopted within the United Kingdoms’ NHS as well as New Zealand’s Ministry of Health (MOH) is the Plan-Do-Study-Act (PDSA) cycle (2002). See Figure 3.1

Figure 3.1: Audit cycle



Boult and Maddern (2007) identify several factors which enable successful audit. These include mechanisms to make data collection easy, effective information technology, dedicated staff and protected time to release the burden on clinician's clinical workload. As well as these, a supportive organisational environment, sound leadership and direction of audit programmes, strategy and planning of audit programmes, monitoring and reporting of audit activity, commitment and participation, and high levels of audit activity, which can be seen as relevant and to involve participants.

However, clinical audit is not without its limitations. There is a belief that healthcare professionals are prompted to modify their practice, when given performance feedback showing that their clinical practice is inconsistent with a desirable target. Some authors have disputed the certainty of action, and question the effectiveness of audit and feedback in improving healthcare practice. The characteristics of audit and feedback that are believed to

lead to greater impact, are detailed planning of the audit and timely feedback following audit (Ivers et al., 2012).

Bowie et al. (2012) conducted semi-structured interviews, and used focus groups to examine the views and opinions of clinical audit advisors from two large Scottish district health boards. The advisors reported that work pressures and lack of time were frequently cited as barriers by clinicians involved with audit activity, but believed these may hide other reasons. Bowie et al. (2012) found that audit is perceived to be time-consuming, an additional chore and is often associated with a belief in hidden political agendas driven by management.

In order for audit to be effective, the tools and methods used for data collection must deal with the potential for bias arising from coverage, sampling, measurement and non-response errors (Boult & Maddern, 2007). An often noted criticism of the audit cycle in practice is the failure to complete the cycle following evaluation, by implementing recommendations for change and re-auditing the effects changes may have had. Without the subsequent evaluative re-audit, it is not possible to learn whether the quality improvements recommended have been made are sustainable, and what the effects of these changes on patient care are (Farrell & Hill, 2012).

As discussed, clinical audit allows the clinician to monitor service delivery through the collection of information. It leads to an increased awareness of how things actually are, encourages improvement initiatives and should result in sustainable improvements in patient care. Clinical audit relies on the collection of data which provides information on the subject being audited. Prospective audit is based on the collection of information about patients during their process of care. It permits more reliable and complete clinical data collection since the data required is pre-defined and can be validated and errors corrected while the data collection is in progress (Schneider and Elliott, 2008, p. 181). A possible disadvantage is that practice may be altered if clinicians are aware that they are being observed and that data is being collected. Retrospective audit is generally based on review of records of discharged patients. This may provide information that is more representative of day-to-day practice, but

it is more difficult to obtain complete data on every subject in the sample. Retrospective audit may make use of computer databases provide the data they contain is of adequate quality.

The investigator of this study considered conducting a prospective audit; however the potential for this to prompt clinicians to modify their practice was recognised, hence would not reflect the true state of PN management in NZ. Therefore, to examine current practice of PN management and to identify remediable factors, a retrospective audit was considered the appropriate method to meet the study aims. A key factor for clinical audit is that care provided is audited against specific evidence based criteria; in this study, PN care was audited against the ESPEN and NICE clinical practice guidelines.

Methods

Planning

The project was first considered in mid-2010 subsequent to the release of the NCEPOD report (See pg. 27 for an overview of the NCEPOD report). A meeting was convened with colleagues that work in the field of nutrition support, and included representatives from local hospitals and PN industry providers. A review of the NCEPOD findings was presented and a discussion was had as to whether practice in New Zealand was likely to be any different. It was known, through anecdotal evidence, that PN is administered in some areas without specialist nutrition support, which led the group to believe that NZ may have as similarly disappointing results as the NCEPOD study. The consensus from the meeting was that an audit, based on NCEPOD methods with amendments as necessary, would be worthwhile.

Cognisant of the commonly held criticisms of NCEPOD's use of subjective expert opinion alone to determine good practice, it was felt that a study conducted in New Zealand should first agree the guidelines to be used as standards that local practice would be audited against. The comprehensive ESPEN guidelines were under review by AuSPEN at the time, and it was anticipated that these would be adopted as recommended best practice for Australasia. Other

guidelines suggested were the NICE guidelines, which are internationally recognised, however, these are not specific to the management of parenteral nutrition. The ESPEN guidelines were, therefore, chosen as the overall standard measure. However, as the ESPEN guidelines did not include specific recommendations on managing the risk of RFS, the recommendations given in the NICE guidelines for identifying patients at risk of RFS were used. The NICE recommendations on re-introducing feeding were also used as the standard for the audit (See pg. 9 for an overview of the NICE guidelines).

There was also significant discussion amongst the group as to what the definition of RFS should be for the study, as although it is known to occur, agreement on the exact diagnosing features is lacking in published literature (Stanga et al., 2008). A clinical definition which the co-investigator of this study has developed following another study (yet to be published) was accepted by the group as the standard by which cases would be audited again. Roas and Walmsley (2012) conducted a retrospective study of our database at North Shore Hospital in Auckland, New Zealand. Two hundred and ninety two consecutive episodes of PN in 272 patients were analysed that received PN between Jan 2005 and December 2009. Re-feeding syndrome was defined as 'probable' if there was a drop in serum phosphate combined with evidence of pathological development of extracellular fluid shift and 'possible' if there was a fall in serum potassium, magnesium with development of oedema (Roas, Z., Walmsley, R. 2012, personal communication).

It was suggested and agreed that the study should be conducted in two phases. Phase one, a smaller regional study, followed by phase two, a national study to be carried out at a later date. The initial phase one of the study would examine practice throughout the Northern Region District Health Boards (DHBs) of Auckland, Counties Manukau, Waitemata and Northland DHBs. The aim of this smaller regional study was to test the suitability of the NCEPOD methodology in NZ. Phase one is presented in this thesis.

A multi-disciplinary group of six local clinicians were identified to be invited to participate in case reviews and to assign an overall grade of care provided. Local clinicians were chosen for

phase one of this study for ease of access, to enable regular meetings and to reduce any costs associated with the study. These clinicians were all experienced PN users; they were known regionally, nationally or in some cases internationally for their expertise in nutrition support. Many of them were members of AuSPEN and/or ESPEN, so were very well versed with the ESPEN guidelines. All were currently involved in the provision of clinical nutrition, education and research. The group consisted of both adult & paediatric gastroenterologists, dietitians and a nutrition nurse specialist.

Although the primary aim was to identify current PN management in NZ, a secondary aim was to assess the NCEPOD methods and identify whether there were areas, such as methods of data capture that would need to be adapted in the NZ setting. In order to make a comparison between the management of PN in NZ to that in the UK, it was agreed to use the already validated NCEPOD data collection tools, using the three questionnaires they had developed.

The patient care and advisor assessor questionnaires were both divided into sections examining specific themes of PN care; indication for PN, type of PN, CVC care, PN associated complications and the availability and role of NSTs. Within each section several questions were asked about that specific aspect of PN care. On completion of the advisor assessor questionnaire, the advisors were asked to assign a final grade based on their overall assessment of PN care provided. The assessment grades used in the NCEPOD questionnaires were; good, room for improvement or less than satisfactory. Advisors were then asked to record a rationale for the grade assigned.

NCEPOD were contacted for permission to use their questionnaires and we were informed that they produce a 'study pack' which includes the questionnaires on their webpage which is accessible for other centres to audit their own practice against - http://www.ncepod.org.uk/. The study protocol was framed following further consultation with a project advisory group comprising of the participating hospitals nutrition support teams. This thesis is based on phase one, the regional audit conducted.

To publicise the study to a wider and more diverse audience, and gain support for the proposed audit, endorsement was requested from the various affiliated professional bodies of the clinicians assisting with the study. Endorsement included publication in the professional journals and newsletter. Such endorsement is hoped to raise awareness of the study and encourage later participation in phase two of the audit. Endorsement was received from; the Australasian Society of Parenteral and Enteral Nutrition (AuSPEN), the New Zealand Nursing Organisation (NZNO), the New Zealand Society of Gastroenterologists (NZSG) and the Royal College of Surgeons (RCS).

Ethical Issues & Cultural Responsibilities

Even though audits are considered low risk activities and often do not require the same stringent ethical regulation as other forms of research, clinical audit must be conducted within an ethical framework (MOH, 2012). By definition, clinical audit should provide a beneficial outcome and do no harm. A clinical audit should not involve anything being done to a patient that is beyond the normal clinical management. For this reason, in New Zealand, clinical audit does not necessarily require formal ethical approval by a full human research ethics committee, especially when undertaken as part of academic study as is phase one of this study.

All clinicians involved with an audit activity have an ethical responsibility for good study conduct (MOH, 2012). Investigators conducting, or involved in conducting, observational studies (or audit) are responsible for ensuring these studies meet ethical standards. This is the case whether or not ethics committee review is also required. When there is more than one investigator, the principal investigator has the overall responsibility for the ethics of the activity. The NZ Ministry of Health state that the following considerations are particularly important: respect for people, Māori and ethical considerations, justice, beneficence and non-maleficence, integrity and diversity.

As this audit involved the collection of previously recorded information from multiple health care providers, an expedited application was made to the Northern X Regional New Zealand Health and Disability Ethics committee. The application was made for both phase one (the smaller regional study presented in this thesis) and phase two (a national study to be carried out at a later date which does not inform this thesis) of the audit. This process was appropriate due to the intent of the clinical audit:

a) A retrospective chart audit (secondary use of data) which would all be de-identified by the participating hospital's local reporter and

b) The outcomes of this investigation may potentially impact the care of future patients.

Expedited ethics approval was granted, approval number - 16/9/11 - NTX/11/EXP/218 (Appendix 4)

All research should be conducted with awareness of, and with the upmost respect for Maori as the indigenous population of New Zealand (Hudson & Russell, 2009). Article 3 of Te Tiriti O Waitangi, grants all Maori the rights and privileges of British subjects, which includes access to healthcare services required (Tupara, 2012). Health research, including this study, will help improve healthcare, thus improving the delivery of healthcare to Maori. Article 2 of Te Tiriti O Waitangi, guarantees Maori continuance of possession of their Taonga (treasures, things seen and unseen), of which, good health is included. A successful outcome of this research will lead to improved health status for all those that require PN. While not specifically aimed at Maori, this study has relevance to their on-going quest for improved health status. Following consultation with a Maori research advisor at WDHB, it was agreed that no further Maori consultation was necessary for this audit as there were no specific risks that needed to be addressed.

The chief investigator of this audit is an employee of WDHB therefore the audit was also registered with the WDHB Awhina health campus database and the Massey University Accredited Ethics committee as is required for research activity.

Data Collection

Data were collected using the three NCEPOD questionnaires (Appendix 1). The first, an organisational questionnaire examining the hospital's nutrition support practice. The second, a patient care questionnaire in which details of care provided were recorded for each patient. Finally, an advisor assessor questionnaire completed by an experienced PN user who reviewed the care provided and assigned an overall grade. The grades available were; good, room for Improvement or less than satisfactory. Both the patient questionnaire and advisor assessor questionnaires were divided into sections examining specific aspects of PN care, indication of PN, type of PN, central venous access devices, PN associated complications and availability and role of NSTs. The three questionnaires were distributed to the project advisory group for consultation and comments. Minor adjustments were made, generally in terminology or else to clarify the question being asked to ensure ambiguity was avoided.

Local Reporter

A local reporter was recruited from each public hospital participating in the study and was employed within the District Health Board. The role of the local reporter was to act as a point of liaison with the research group and to co-ordinate the collection of data in their particular hospital. This person was identified as either belonging to the NST or else being directly involved in PN management within their hospital. The local reporter from each hospital was asked to gain consent through their hospital research approval processes and with their appropriate managers. A consent form (Appendix 2) was provided which outlined the required consent as well as information on the right to withdraw participation at any time. Local reporters were asked to provide confirmation of consultation and consent to participate in the study to the primary investigator.

Once the required approval had been given, each hospital's local reporter provided minimal data set for patients of all ages that received PN during the period of January 1st to June 31st 2011. This included age and the consultant and speciality under which the patient received PN. Only hospital patients were included; home PN patients were excluded even if they were admitted to hospital and received PN within the study period. From the initial data provided purposive sampling was then used to select patients that reflected a diversity of clinician and specialities to ensure a representative sample of patients receiving PN in public hospitals. Purposive sampling is a type of non-probability sampling used in research to handpick cases which may be typical of a population to be included in the study, based on a variety of criteria, that they can generate the information required (Schneider & Elliott, 2008). In this instance patients that had received PN in public hospitals in NZ were selected in order to examine current care of PN administration and management. One out of four cases was selected by the primary investigator and co-investigator for peer review by expert advisor assessors.

The local reporter was then asked to complete a patient care questionnaire and provide detailed clinical data (which they de-identified) on each selected patient that received PN within the study period. If the patient selected was not managed directly by the local reporter, they coordinated completion of the questionnaire and the collection of de-identified clinical data with the appropriate clinician. Clinical data for each patient was copied and de-identified by the local reporter. These included clinical notes, nursing notes, nutrition notes, biochemistry/haematology results, fluid balance charts, observation charts, nutritional charts, weight chart, urinalysis, X-ray/CT results, operation notes and nutrition assessment records. The local reporter from each hospital co-ordinated the distribution/completion of questionnaires, collation of requested clinical information and acted as liaison with the main research team. Each participating hospital that requested was reimbursed for the printing costs associated with data collection.

The local reporter also completed the organisational questionnaire which examined each participating hospital's practice of PN management. The information requested in this questionnaire included topics such as who orders PN, where is PN manufactured and the availability of nutrition support teams.

Case Reviews

The patient questionnaires and de-identified documents were then sent to the primary researcher for anonymous retrospective review by expert advisor assessors. Cases were assigned by the primary investigator to ensure that the expert advisor assessors were not given cases from their own institution to examine. The role of the expert advisor assessor was to critically examine the de-identified clinical data and patient questionnaire on each of the selected cases. Based on the care provided and in accordance to compliance to the recommended ESPEN/AuSPEN and NICE guidelines, an advisor assessor questionnaire was to be completed. There was opportunity to record free text within the advisor assessor questionnaires to clarify care provided. Finally, an overall grade of the care provided was to be given.

A meeting was held with the invited advisor assessors to discuss their role, what was expected of them and a review of the questionnaire they would be completing. At this time it was identified that there was a lack of independent experienced paediatric and neonatal PN users regionally to review those cases. It was therefore agreed to suspend review of the paediatric and neonatal cases until the national study was conducted at a later date.

In addition to those invited to complete expert reviews it was agreed that opinions may have been sought from other clinicians if more specific expert advice was necessary during analysis of the clinical information for each case. This would have included advice from; a clinical biochemist, intensivists, a general surgeon, and pharmacist.

Reliability, Validity & Bias

Reliability refers to the consistency of results (measurement) obtained from the audit, based on the control, reduction, and/or elimination of measurement error. Validity is, the accuracy and appropriateness of the interpretations and inferences (evaluation) drawn from the results

of a measurement. Biases are systematic errors in how study subjects are selected or measured, which result in false inferences (Hartung & Touchette, 2009).

Although clinical audit is often not associated with the same risks of other types of research in terms of ensuring reliability, validity and addressing the potential for bias, there were still some issues noted for this study (MOH, 2012).

The participating hospitals chosen in phase one of the study all had a clinician or nutrition team that had indicated a commitment to the study in principal and were motivated to identify current practice within their own facilities and use the findings to improve practice where necessary. It was recognised by the primary investigator that selecting these particular hospitals to participate in this phase one audit may introduce an element of bias to the overall NZ findings. It is acknowledged that the Auckland region is an area of concentrated nutritional support expertise with four of the participating regional hospitals reporting an active nutrition support team. Therefore the findings of this audit (phase one) may not necessarily be transferable to all patients given PN throughout New Zealand (phase two) as not all hospitals have a dedicated nutrition support teams in their hospitals.

As previously described, to ensure reliability and validity for this investigation the analysis was underpinned by using recognised best practice guidelines. Advisor assessors were given bound copies of all of the ESPEN guidelines that would be used as the standard cases were audited against. The guidelines provide specific recommendations on how PN should be best managed in particular situations, recommendations on PN composition, specific disease related complications that may occur and monitoring required.

The principle aim of this study was to examine the practice of PN management in the Auckland/Northland region, however, a secondary aim of this phase one pilot study was to ensure the reliability and validity of the NCEPOD data collection tools, ensuring they were appropriate for the NZ setting. Measures were taken to minimise risks of reliability and validity of the data recorded.

It was acknowledged that there was a possibility for bias in the data returned by the advisor assessors, as they may grade standards of care inconsistently between cases, as well as between themselves. In order to minimise this, the author produced a 'test case' for examination by the expert advisors. All of the advisor assessors were convened and the test case was given to them for review. Following completion of the review, each question and response was then discussed in detail to establish a consensus on the consistency expected. A study guideline was produced to ensure consistency in analysis of case reviews based on the discussion generated completing the test case.

Advisor assessors were then asked to return their first completed case reviewed to the primary investigator for comparison review. Following this, meetings were held on an individual basis with each advisor assessor in order to discuss areas any of inconsistent completion of the third questionnaire.

On completion of the study, both local reporters and advisor assessors were asked to provide feedback on the processes involved in the audit, questionnaires, methodology and suggestions for improvements needed for phase two.

Data Analysis

Following completion of expert peer review by the advisor assessors all data were returned to the author, this included the patient care questionnaires, all de-identified clinical data, and the advisor assessor questionnaires. Data were then entered into a secure Microsoft Office Excel database by the primary investigator. All data entered was double checked at the point of entry and once all data was entered additional checks were made by the co-investigator. Following data entry, analysis was completed using Excel program. Clinical audit data is often presented purely as descriptive statistics, representative of practice at the time of data collection. There is often no attempt to draw significant statistical conclusions on the data collected. Due to the small sample size of patients and hospitals in this study, the results are reported descriptively, as numerically and percentage values only.

Summary

Clinical audit seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery.

This chapter has outlined audit activity, the underpinning methodology and methods used to complete this retrospective clinical audit. It has addressed the ethical considerations as well as the methods used to overcome the risks associated with bias, reliability and validity. How data was selected, collected and analysed is discussed.

The following chapter will presents the results of the investigation of parenteral nutrition, focussing on the themes examined in the questionnaires: indication for PN, type of PN, CVC care, PN associated complications and NSTs. In the final discussion chapter I will explore the final stage of the PDS - **A**CT cycle, the feedback process and the plans for re-audit following implementation of any recommendations made as a result of this audit.

4. Results

Introduction

Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. In order to examine the current practice of PN management throughout New Zealand a clinical audit was undertaken across four district health boards with six hospitals participating.

The question to be answered in this study is: ***'What is the current practice of PN management throughout the Auckland/Northern region of NZ?'***

The primary aim was to examine whether PN practice in New Zealand fares better under the same scrutiny as the study conducted by NCEPOD. Secondary aims were: firstly, to determine if New Zealand has similar results to the NCEPOD study by benchmarking New Zealand PN practice against the ESPEN/AuSPEN (2009)and NICE (2006) guidelines. Secondly, to ensure the data collection methods used were appropriate for a New Zealand study.

The main results presented in this chapter are from the adult population of patients that received PN in public hospitals throughout the Auckland/Northland region of NZ only. The themes examined were: indication for PN, type of PN, prescribing PN, CVC care, PN associated complications and the role and availability of NSTs. The results are expressed as a value of responses given; often many questions were not answered so rather than assume they were negative or positive responses they were not reported on. For example, the question "was this type of PN bag appropriate for the patient's needs?" elicited only 48 yes or no responses out of the 65 cases returned for analysis. There has been no assumption made by the author that a blank response meant that the advisor assessors felt the type of PN bag was appropriate for the patient's needs. Therefore the values and percentages provided were represented out of 48 in this case.

The data provided from the organisational questionnaires based on PN management in each hospital is also reported. It is presented as adult, paediatric and neonatal data. However it is a very limited sample so cannot be assumed to be representable of other hospitals throughout New Zealand.

Analysis of Data

Six hospitals from the Auckland and Northland regions were invited to participate in the study, covering a population of 1.64 million. Patients of all ages were included in the study; however home PN patients were excluded even if they had a period of hospitalisation during the study period. Six hundred and twenty cases (288 adults, 68 paediatric & 264 neonates) of PN use were identified within the study period of Jan 1st – June 31st 2011. A quarter of the sample, 151 (70 adult, 17 paediatric, 64 neonate) cases were then chosen purposively in order to capture a range of specialities and clinicians for review by advisor assessors. Sixty six adults (94%), 7 paediatric (41%), 49 neonates (76%), questionnaires were returned, of these de-Identified clinical records were available for 100% of adults and 41% of neonates for expert review.

Unfortunately as discussed previously, a limitation identified during the study was the lack of independent local experienced paediatric and neonatal PN users to peer review the paediatric and neonatal PN cases. It was therefore decided to suspend review of these cases. The results from the paediatric and neonatal patient questionnaires which were provided by the local reporter are provided as Appendix 3.

Sixty six adult cases were distributed to the advisor assessors for peer review. All 66 cases (patient questionnaire, clinical data and advisor assessor questionnaire) were returned to the primary investigator for data analysis; however one case was missing the patient questionnaire on its return and also one advisor assessor questionnaire was missing from a different case. These cases were therefore excluded from analysis. This chapter presents the results for 65 cases in total, however not all questions were answered in all of these 65 cases, hence the

number of total responses does vary for each individual question. Of the cases reviewed, thirty three patients were male, thirty two female.

The results of this audit are presented firstly as an overall grade assigned by the advisor assessors; following this, all of the descriptive data presented is from the responses given to each of the questions within the questionnaires. It is presented in the themes as per the questionnaires, indication for PN, type of PN, CVC care, PN associated complications and the role and availability of NSTs. In most cases the results are from the advisor assessor questionnaires unless otherwise stated.

Adult Data

Figure 4.1 outlines the age distribution of the study population. The mean age of patients that received PN is 61 (range 90-19). Over half of the patients receiving PN examined in this study were over the age of sixty (n=35) with nearly a third over the age of seventy (n=19).

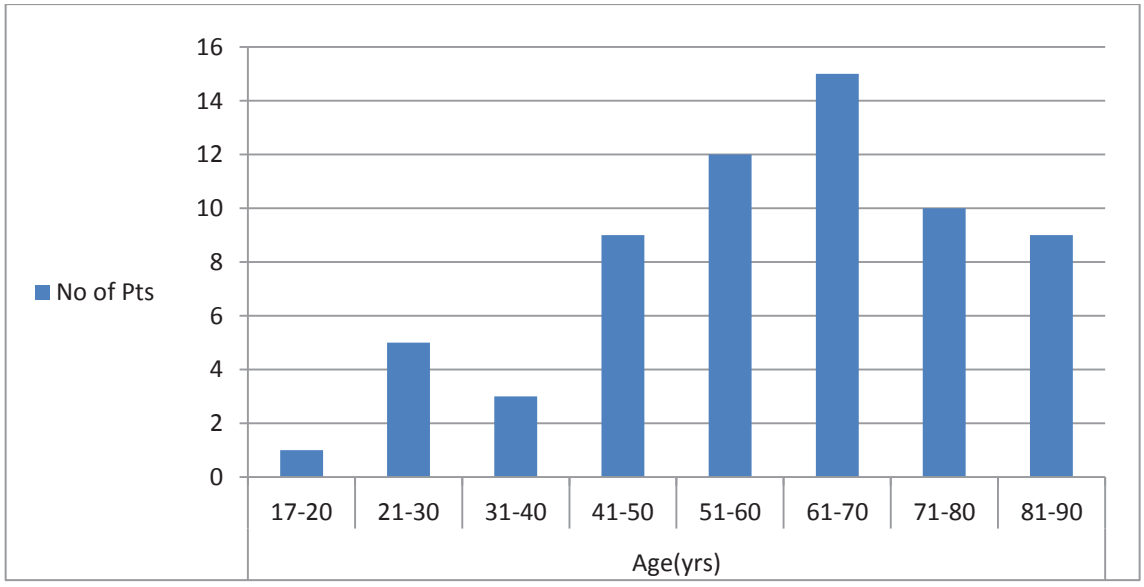


Figure 4.1 Age distribution of the study population

Overall Assessment of PN Care

Only 12.7% of cases examined demonstrated 'good practice'- the standard for which the advisor assessors would expect within their own practice (See table 4.1). 19% of the cases in this study were graded as a 'Less than satisfactory' standard, 65% of cases demonstrated aspects of care where there was 'room for improvement'.

Table 4.1 Overall of assessment of PN care- Advisor assessors

Overall Assessment	Number of Patients	%
Good Practice	8	12.7
Room for Improvement	41	65.1
Less than satisfactory	12	19
Combined (Room for Improvement/Good Practice)	1	1.6
Combined (Room for Improvement/Insufficient Data)	1	1.6
Total	63	

Examples of comments received on the grade allocated included:

Good Practice:

“Pre-empted risk of RFS and liaised with surgical team for additional phosphate. Patient put on 4-6kg during admission in association with PN administered,? secondary to Na+ content in PN and IV antibiotics (i.e. transport fluid). Excellent assessment”.

“Overall patient was managed well in a difficult situation”.

Room for Improvement:

“Peripheral PN not warranted in patient care/Little evidence of management of nutrition requirements/fluids/electrolytes”.

“Poor appreciation of fluid management by NST”.

“Some delay in recognition of need for PN”.

“Risk of RFS not documented in assessment. Unclear as to why patient’s requirements which were initially based on adjusted body weight of 136kgs then reduced to 100kgs. Same nutrition provided but based on different weights either 18.3kgs/kg or 25kcals/kg. Patient not weighed??? or data missing”.

Less than Satisfactory:

“No indication for PN to be initiated,/No trial of oral/enteral nutrition prior to PN starting,/Poor documentation around CVC insertion,/assessment is working on estimated weight of 65kg, recorded weight of 75kgs,/There is a clear documented plan of calories being provided in PN but not what actual requirements are”.

"No dietetic involvement for entire period/no evidence of nutrition assessment/no evidence that Enteral Feeding considered/no past medical history".

Administration of PN

Parenteral nutrition is administered in a variety of settings (See figure 4.2). The majority of patients requiring PN came from either general surgery 24/65 (36.9%) or critical/intensive Care medicine 22 (33.8%). Seven (10.8%) cases came from colorectal surgery, 5 (7.7%) from urology, 3 (4.6%) from upper gastrointestinal surgery and 2 (3%) were from vascular surgery. Only 1 (1.5%) case each was from nephrology and medical oncology. The complexity of patients that require PN is reflected in the type of ward where PN is generally administered with just over half being nursed in either HDU or ICU. The mean days on PN was 10.4 (range 1-109) (See figure 4.3)

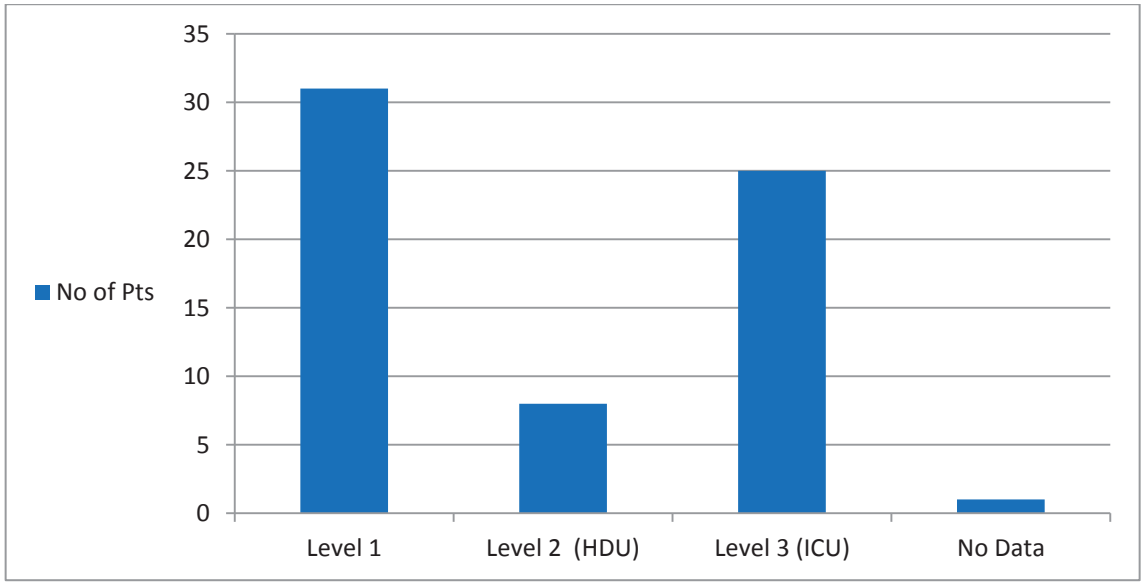


Figure 4.2 Ward level under which PN was administered (Patient care questionnaire

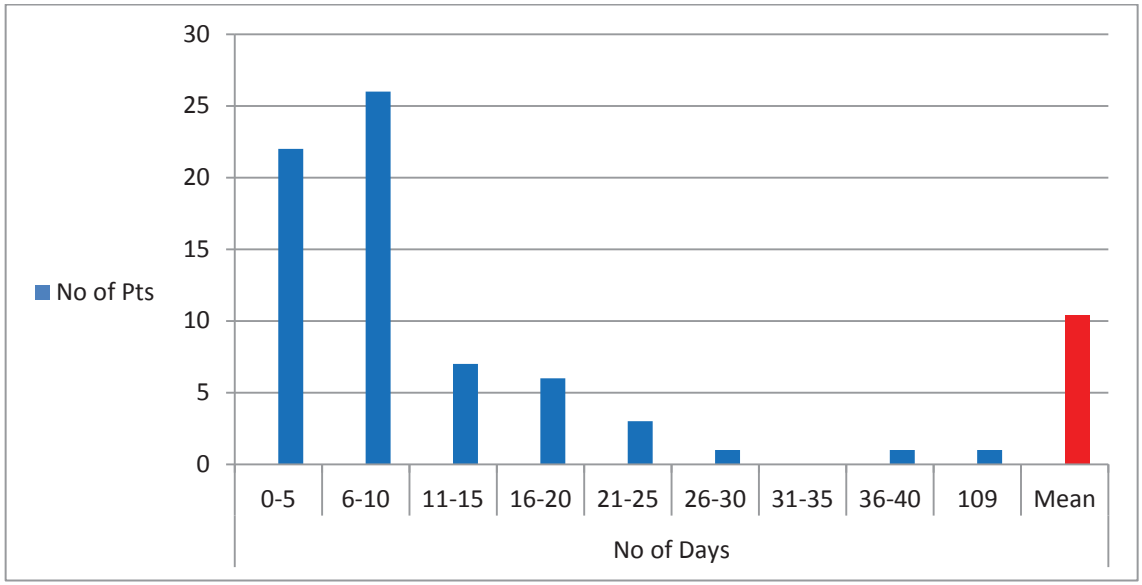


Figure 4.3 Number of days for which the patient received PN (Patient care questionnaire)

Indication for PN

Patients often have multiple indications for PN as a result of the complexities of their condition (See table 4.2). The most common reason documented indication for PN was for post - operative Ileus.

Table 4.2 Documented Indications for PN.

Documented Indication for PN	Number of Patients
Post Op Ileus	31
Other	11
Perforated/Leaking Gut	6
Failure of Enteral Nutrition	5
Post-Surgical Complications	4
Obstruction	4
Fistula	3
Chemotherapy	1
Short Bowel Syndrome	1
Pre-Operative Nutrition	1
Non-functioning Gut	1
No access for enteral Nutrition	1

No data recorded	12

More often than not, advisors agreed that PN was given for an appropriate indication 51/64 (79.9%), however there were still examples of PN administration in situations where it was not considered necessary. On examination of clinical records 3 of the remaining patients that received PN had no clear documentation recorded as to why PN was commenced, 1 reported high NG losses of 250mls in a patient receiving NG feeding, perhaps suggesting intolerance to enteral feeding. One patient was unable to have an enteral feeding tube inserted although the advisor assessor was unable to find a rationale for this.

The majority of PN was started during the weekdays, with very little being started over the weekend; PN is not considered to be an emergency intervention and benefits from timely assessment by experienced clinicians before its commencement. Thursday was the most common day to start PN with 16/64 cases (25%), followed by both Tuesday & Friday with 11 cases (17.2%) each (See figure 4.3). Monday & Wednesday were the least common days of the week to start PN with 8 cases (12.5%) each. Ten (15.6%) patients were started on PN over weekends, however advisors felt that 2/10 (20%) of the patients started on PN over the weekend, were inappropriate (See figure 4.4).

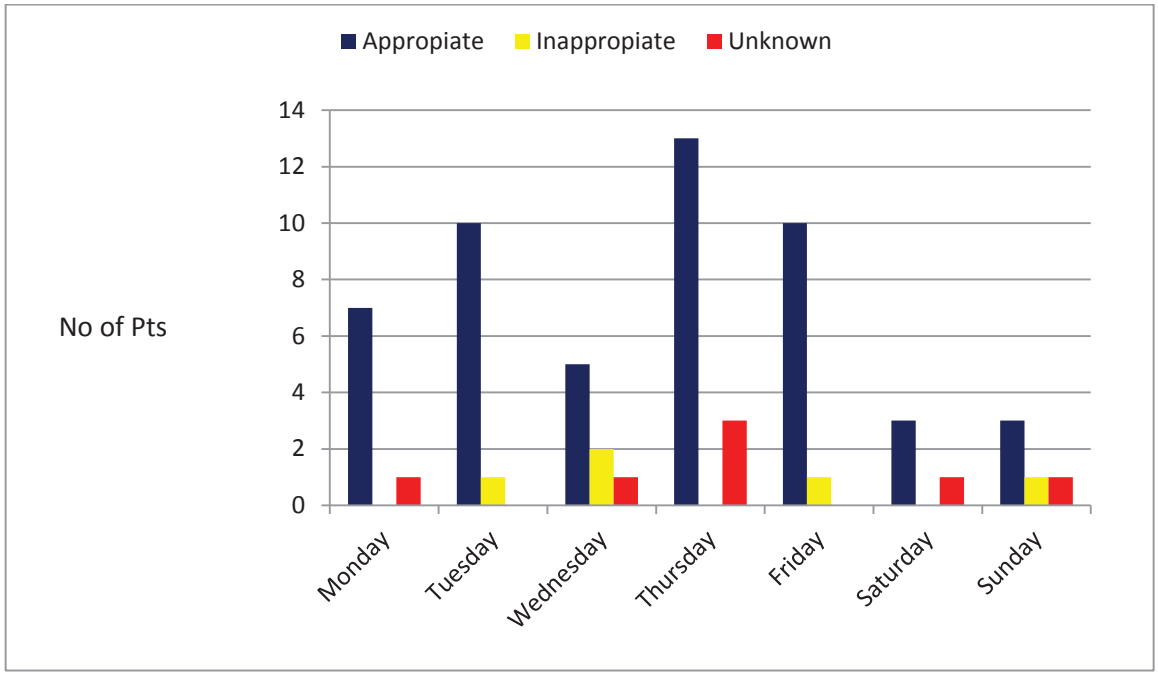


Figure 4.4 Day of the week on which PN was administered, and advisor's opinion on the appropriateness of PN being commenced.

The advisor assessors found that in 11/60 cases (18.3%) there was an unreasonable delay in recognising that the patient required PN by the clinicians caring for them. Once the need for PN was identified, only in 3/61 cases (4.9%), was it thought there was an unreasonable delay in starting the PN (More than 24hrs). Fifty eight cases out of sixty one (95.1%) were started within the 24hr period after the need was identified. The advisors felt that in 51/64 (79.7%) of the cases reviewed PN was indicated.

Over half of the patients 28/65 (43.1%) reviewed received no enteral feeding prior to commencing PN. Of the 37 that received some form of enteral feeding prior to commencing PN, 20 (30.8%) were receiving oral supplements with 1(1.5%) receiving both nasogastric feeding and oral supplementation. Nine patients (13.8%) were fed nasogastrically, 5 (7.7%) nasojejunally and 1 (1.5%) via a surgical jejunostomy. One patient (1.5%) was identified as eating and drinking prior to PN being commenced. Enteral nutrition was not adequately considered by the clinicians caring for the patient as an alternative means of nutrition support in 26.6% (17/64) of cases before PN was commenced according to the advisors.

Type of PN prescribed

The types of PN available are generally either 'standard multi-chamber off the shelf', 'standard multi-chamber with additional micronutrients' or 'tailored bags'. Standard PN bags are industry produced bags that have fixed components, these are cheaper to produce and can be kept in storage for long periods of time. Using standard bags with additional micronutrients allows the prescriber to tailor the micronutrient to the patient, however, standard bags do not allow any manipulation to the number of calories or the amount of fluids given. Tailored bags however are able to be fully tailored to the individual's calorie, micronutrient and fluid requirements as determined by the prescriber.

The majority of patients 34/61 (55.7%) received 'standard multi-chamber off the shelf' PN initially however this was closely followed by 27 (44.3%) of patients receiving 'tailored bags'. Only 6/34 (17.6%) of patients that received 'standard of the shelf' PN initially went on to have their formulas changed to 'tailored bags' specific for their individual requirements. Advisors did not feel that the first PN bag was appropriate for the patients' needs in 17/48 (35.4%) of the cases reviewed.

Prescribing of PN

Patients received adequate biochemical and nutritional assessment prior to commencing PN in 31/64 cases (48.4%) according to the advisor assessors. However 20 (31.2%) patients given PN were considered to have not been adequately assessed.

Clinicians completing the patient care questionnaire were asked to identify from a list of parameters what elements were included in their assessment of the patient prior to commencing PN. These were: clinical grounds (for PN), biochemical review, weight, mid-arm circumference, tricep circumference/skin fold thickness, grip strength and 'other'. The clinicians completing the questionnaires reported that 51/63 (81%) of patients assessments included clinical grounds, biochemical review and weight. Four (6.3%) assessments included just clinical grounds and biochemical review. In four (6.3%) cases only clinical grounds for PN

was assessed, two (3.2%) had clinical grounds, biochemical review, weight and grip strength assessed, with one (1.6%) patient having clinical grounds, biochemical review, weight and vascular access included in their assessment. Finally, one (1.6%) had just their weight and biochemical review on assessment.

Advisors were then asked to identify from a list of parameters the elements of assessment that were documented. The parameters in the advisor questionnaire were clinical assessment, biochemical review, weight, mid arm circumference, tricep circumference/skin fold thickness, grip strength, pre-albumin and 'other'. Only 29/62 (46.8%) of patients had documented evidence that their assessment included clinical assessment, biochemical review and weight. Two (3.2%) clinical assessment, biochemical review, weight, pre-albumin and BMI (body mass index), two (3.2%) clinical assessment, biochemical review, weight, and BMI, four (6.4%) clinical assessment, biochemical review, weight and pre-albumin, one (1.6%) clinical assessment, biochemical review and pre-albumin. Eight (12.9%) patients had documented evidence of just clinical assessment and weight being assessed, four (6.4%) clinical assessment and biochemical review, two (3.2%) a biochemical review and weight, two (3.2%) had just a clinical assessment documented and nine (14.5%) had only a biochemical review documented. Only six patients had a pre albumin recorded and in just 4 were a BMI recorded. Over half of the patients reviewed 35/64 (54.7%) did not have their nutritional requirements documented in their clinical notes.

Forty seven out of sixty four (73.4%) patients receiving PN were also given additional fluids. In the opinion of the advisors the type of fluid given was appropriate for 30 (63.8%) of those cases. The volume given was thought to be appropriate in 25 (53.2%) of cases, however not in 15 (31.9%). Of the 47 patients given additional fluid the advisors felt it was given inappropriately in 17 (36.2%) of cases.

PN Associated Complications

The advisors felt that in the majority of cases, 43/64 cases (67.2%) the patients received adequate clinical and biochemical monitoring whilst receiving PN. However there were deficiencies in monitoring identified (See figure 4.5).

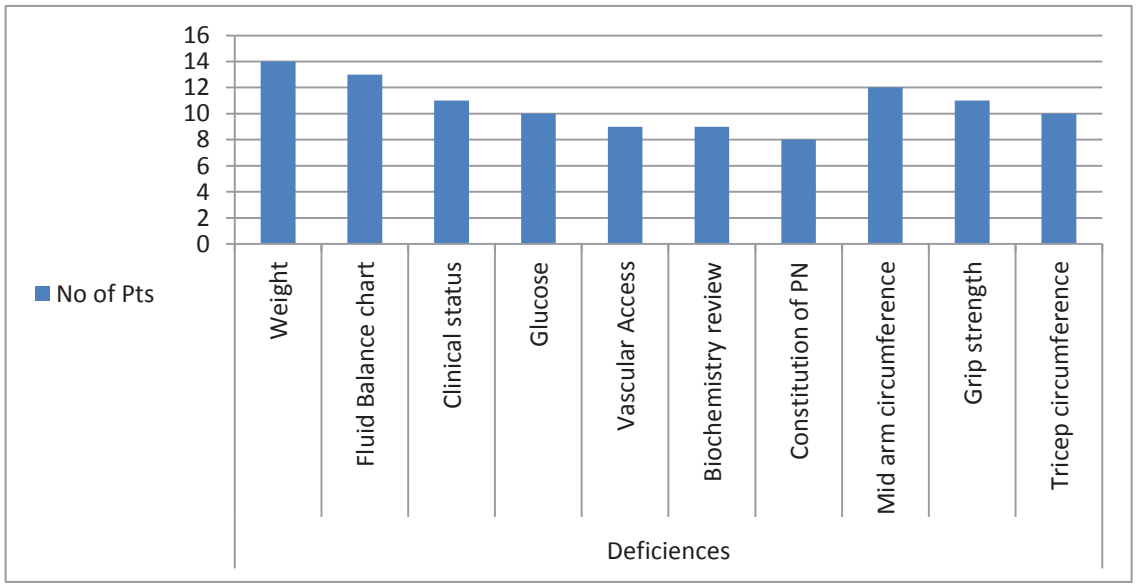


Figure 4.5 Deficiencies in monitoring (answers may be multiple)

There was evidence of metabolic complications occurring in most patients 34/64 (53.1%) while receiving PN (See figure 4.6). Advisors felt that in nearly half of the cases where metabolic complications occurred, 12/28 (42.9%) could have been avoided. The majority of the metabolic complications that occurred 23/27 (85.2%) were however managed appropriately in the advisors opinion. Twenty four patients (37.5%) did not develop any metabolic complications whilst receiving PN. The types of metabolic complications that occurred are displayed in figure 4.6.

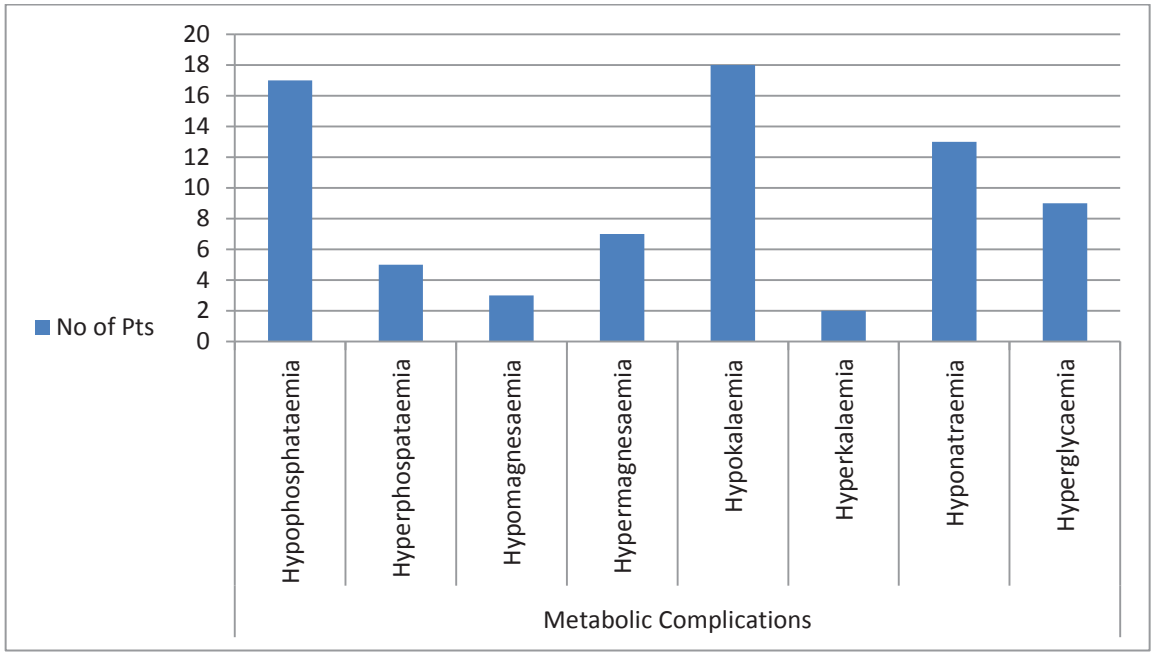


Figure 4.6 Types of metabolic complications that occurred (answers may be multiple)

Clinicians completing the patient questionnaires reported that 22/65 (33.8%) of the patients had documented evidence that they were at risk of re-feeding syndrome. However on review of the clinical data by the advisor assessors, documented evidence of the risk was only found in 8/65 (12.3%). Fifty six (86.2 %) cases had no documented evidence found by the advisors that the patients were or were not at risk of developing RFS. Following review of both the patient questionnaire and clinical data, in the opinion of the advisor assessors 24/57 (42.1%) of patients were at risk of RFS according the NICE RFS guidelines (NICE, 2006). Of the 8 patients with documented evidence that they were of risk of RFS which were found by the expert advisor assessors, 2 (25%) cases of RFS did actually occur (using the defining criteria provided by the co-investigator of this study).

Advisors also identified a further case of RFS and two cases of *probable* RFS, none of which had documented evidence found that they were even at risk of RFS. In 2 cases where there was evidence that RFS occurred, the advisors felt that adequate precautions to prevent it were taken on initiation of PN, however in 1 case where it occurred they did not feel that adequate precautions had been taken. In 2 of the cases where it was felt that RFS had *probably* occurred, advisors did not feel adequate precautions were taken to prevent it.

Catheter Choice, Insertion and Care

Forty one out of sixty five (63.1%) patients received their initial PN via a PICC (peripherally inserted central catheter), 23 (35.4%) via a non-tunnelled central line and only 1 patient (1.5%) via a peripheral line. Just over a third, 21/60 (35%) of patients were reported to have had their PN via a single lumen catheter. Thirty nine out of sixty five (65%) had multi-lumen catheters however exactly how many lumens was not recorded.

The type of catheter that was inserted for PN was documented in the clinical records most of the time, 53/64 (82.8%). However of 21/64 (32.8%) cases reviewed, the catheter insertion site was not documented. Only 24/64 (37.5%) of patients had the position of the catheter tip documented in their clinical records. In the advisor assessors opinion the type of catheter inserted was appropriate in nearly all cases, 49/53 (92.4%) and the insertion site was appropriate in 40/64 (62.5%) of cases.

Most of the time catheter care was assessed as being appropriate, with only 6/64 (9.4%) of cases demonstrating evidence of inappropriate care. There was evidence of central line complications in 18/64 (28.1%) of cases and in the advisors opinions these complications could have been avoided in 6/18 (33.3%) of the cases. Most of the time the advisors felt that the complications were managed appropriately when they did occur 12/18 (66.7%).

Advisors found that most 45/64 (70.3%) patients did not develop any central line complications whilst receiving PN. A suspected line infection occurred in 11/64 (17.2%) of patients receiving PN making it the most common complication of those that occurred. However the questionnaires did not reveal if these suspected infections were later confirmed or not. Line misplacement occurred in 4 cases (6.2%). There was also 1 (1.6%) case each that developed a confirmed line infection, haematoma or a thrombosis. Three (4.7%) cases of complication recorded as ‘other’ were also reported. However no further description was provided. The mean length of time that the initial PN catheter remained in place was 10.3 (range >1-39), although no data was recorded for 16/64 (25%) patients (See figure 4.7).

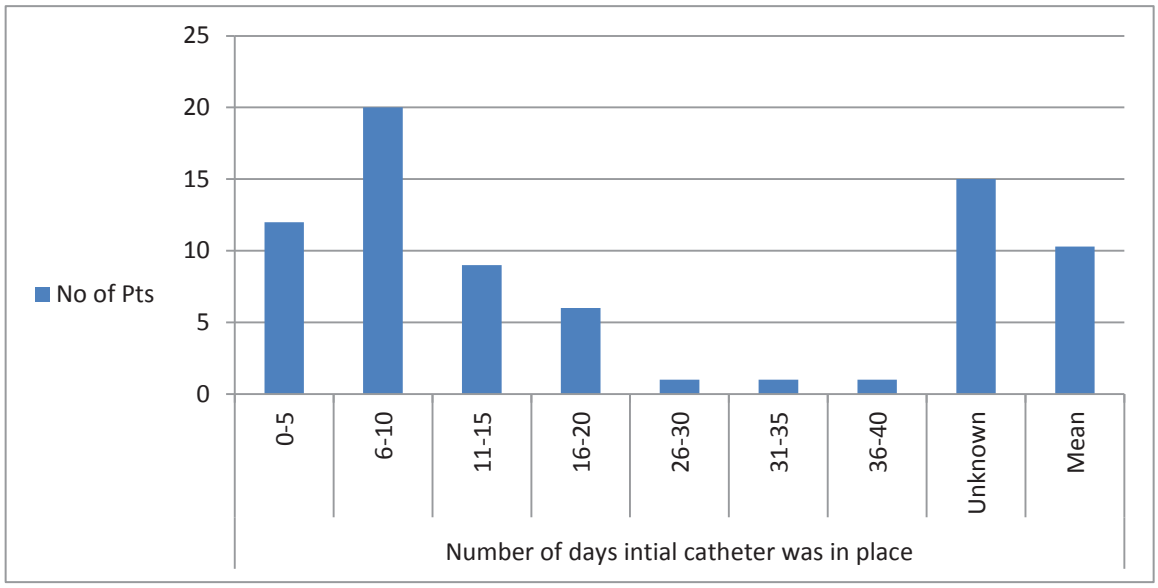


Figure 4.7 Length of time the initial PN catheter remained in place

Most patients 30/64 (46.9%), that had a reason for central line removal documented had their line removed as their period of PN was completed. Eight (12.5%) had their line removed due to infection (either confirmed or suspected), 4 (6.2%) patients had their central lines renewed, and one case (1.6%) each of thrombosis and accidental removal were reported. One case (1.6%) of lines was removed for 'other' unspecified reasons. Nineteen out of sixty four (29.7%) of all patients reviewed, had no documented reason given for their line removal. Some patients 10/63 (15.9%), developed both metabolic and CVC complications (See Table 4.3).

Table 4.3 presents cases where there was evidence of both CVC and/or metabolic complications occurring.

	Metabolic complications		
CVC Complications	Yes	No	**Total**
Yes	10	7	**17**
No	24	16	**40**
Total	**34**	**23**	**57**

Availability and role of Nutrition Support Teams

In well over half of the patients reviewed 40/65 (61.5%), a NST was involved in the decision to commence PN. The NST was also involved in determining the patient's nutritional requirements in 46/64 (71.8%) of cases.

The roles of NST's in the hospitals examined in this study are presented in more detail in the following organisational data.

Organisational Data

The following data were collected from the organizational questionnaires. It addressed the way in which nutrition support was managed within each of the participating hospitals, for example, what type of wards the hospital has, how PN care is managed, availability of PN and the presence of a NST or not.

Table 4.4 Designation of the person responsible for deciding the PN composition

	Type of ward						
Designation	Medical	Surgical	ICU	Paed Med	Paed Surg	Paed ICU	Neonatal ICU/SCBU
Dr/Dietitian/Pharmacist/ Nutrition nurse specialist	1	1	1	0	0	0	0
Dr/Dietitian/Pharmacist	1	1	1	1	1	1	0
Dr/Dietitian	0	0	1	0	0	0	1
Dr	0	0	0	0	0	0	2
Dietitian/Nurse	1	1	0	0	0	0	0
Dietitian	1	1	1	0	0	0	0
No data	0	0	0	0	0	0	1

Table 4.5 Designation of the person prescribing PN

	Type of ward						
Designation	Medical	Surgical	ICU	Paed Med	Paed Surg	Paed ICU	Neo natal ICU/SCB
Phar/Nut N Spec/Diet	1	1	1	0	0	0	0
Med S/Phar/Diet	0	0	0	1	1	1	0
Med S(NST Surg Cons)	1	0	0	0	0	0	0
Med S	1	2	2	0	0	0	3
Diet	1	1	1	0	0	0	0
Electronic/Medical Staff	0	0	0	0	0	0	1

Of the six hospitals examined in this study, four hospitals had both surgical and medical adult wards, and an adult intensive care unit. Three of the hospitals had both a surgical and medical paediatric ward with two having a paediatric intensive care unit. Five of the participating hospitals had a neonatal intensive care unit or a special care baby unit (See figure 4.8).

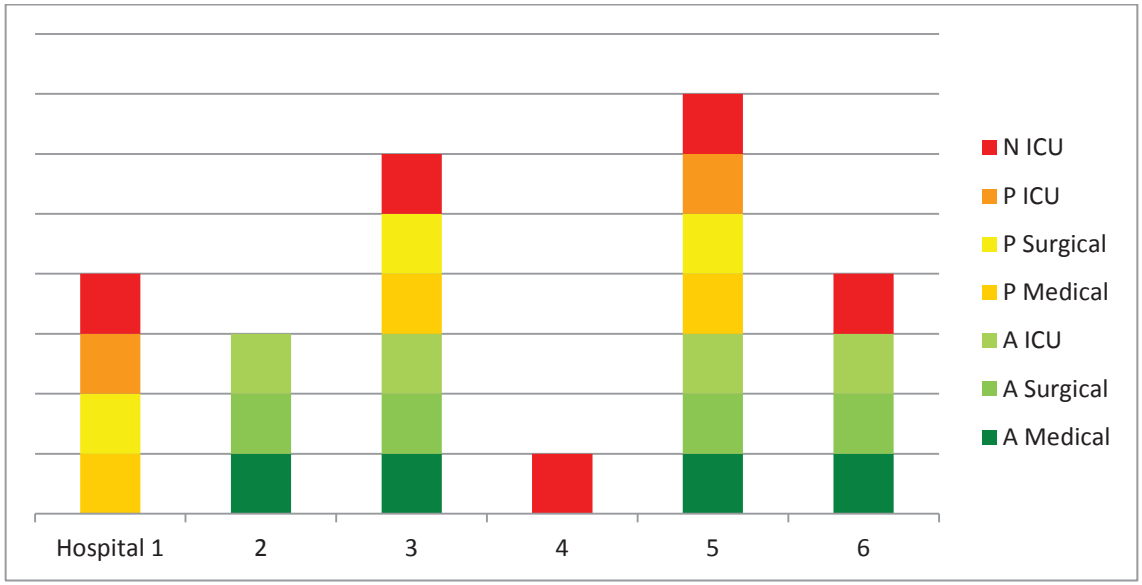


Figure 4.8 Types of wards in hospital

Three out of four hospitals that responded reported that a NST was involved in the PN care of adults, the NST were also involved in the prescribing of the PN. One in four hospitals reported that there was no NST involved. There was no data provided from two hospitals that provided adult PN. Of the hospitals that provided PN to paediatrics and neonates there was no reported NST involvement in their care.

No PN was prepared 'on site' in any of the participating hospitals that responded, all used an external manufacturer. Four hospitals that provided PN to adults, one hospital that provided PN to paediatrics and four hospitals that provided neonatal PN responded. PN turn around from prescription to being ready to administer generally took <6hrs in four hospitals that provided adult and four that provided neonatal PN. One paediatric PN provider reported a turn around time of >6hrs but less than 24hrs.

Four of the hospitals that provided PN to adults responded and reported that they were able to order 'bespoke' i.e. individualised made to order PN bags. One hospital that provided paediatric PN was also able to order 'bespoke' bags. Of the four hospitals that responded and provide PN to neonates only two were able to order 'bespoke' PN, the other two were only able to order standard 'off the shelf' PN. Two of the hospitals that provide adult PN and one

hospital that provided neonatal PN reported that they were able to order and be supplied 'bespoke' PN bags seven days a week. Two adult PN providers, one paediatric and one noenatal provider were limited to ordering and being supplied with 'bespoke' PN on five days of the week.

Maintenance stock of 'off the shelf' PN was kept on the ICU in three of the hospitals and on a surgical ward of another hospital that provided adult PN. Four neonatal units also kept a supply of 'off the shelf' standard solutions in their units. Only one hospital that provided 'off the shelf' maintenance stock kept a central record of who had received the PN. One neonatal unit from a different hospital also kept a central record of who had received the standard 'off the shelf' PN. None of the hospitals that provided paediatric PN maintained a stock on their wards.

Three out of the four hospitals that provide PN to adults in this study reported having a NST, the remaining hospital reported there was no NST. Only one hospital providing paediatric PN responded and reported it had a NST and 3/4 neonatal units that responded reported that there was no NST in their hospital for that patient group.

Of the adult patients who had their PN managed by a NST 7/40 (17.5%) were overall graded as 'Good Practice' by the advisor assessors, however only 1/25 (4%) that were not managed by a NST received a 'Good Practice' grade. Six out of twenty five (24%) of patients that were not managed by a NST received the grading 'Less than satisfactory' compared to 6/40 (15%) of those that were managed by a NST (See table 4.6).

Table 4.6 NST involvement in the decision to give PN, and overall assessment on PN care

(Adult data only).

	Nutrition team involved in the decision to give PN				
	Yes		No		
Overall Assessment	Number of patients	%	Number of patients	%	*No Data
Good Practice	7	17.5	1	4	
Room for Improvement	26	65	14	56	1
Less than satisfactory	6	15	6	24	
Room for Imp/Good Practice			1	4	
Room for Imp/Insufficient Data			1	4	
*No grade given	1	2.5	2	8	
TOTAL	**40**		**25**		**1**

Most of the hospitals that reported having a NST had both a doctor and a dietitian on their teams. Pharmacists were present in four of the NST's with only three having a nutrition nurse

specialist. One hospital's team included an IV nurse specialist and a surgical clinical nurse educator (See figure 4.9).

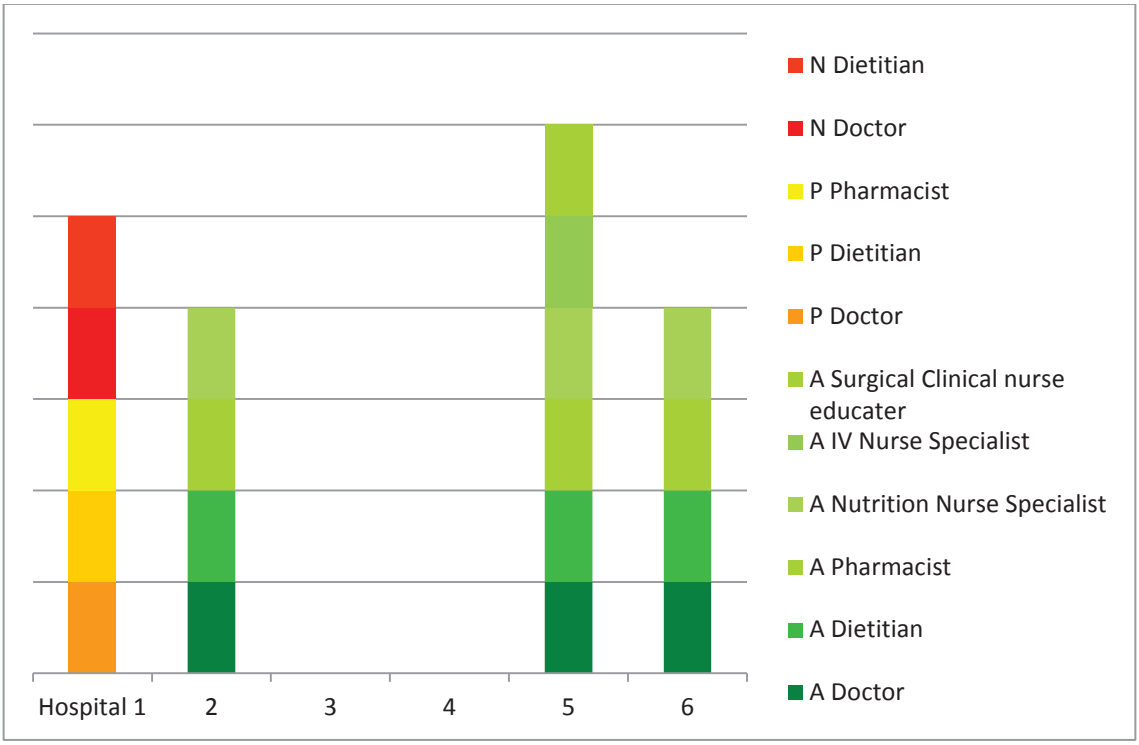


Figure 4.9 Compositions of NSTs

In the three hospitals that provided adult PN with an NST, the NST carried out daily (5dys/wk) ward rounds, with a full multi-disciplinary meeting weekly. The neonatal unit with a NST carried out a full multi-disciplinary ward round daily (5dys/wk.). The hospital that reported a paediatric NST only conducted a ward round and an MDT weekly.

NST's were asked to report on their function as a team. Two out of three of the adult PN providers, NST reported that they reviewed only PN referrals, the third reviewed both enteral and PN referrals. The paediatric NST reviewed PN referrals only. All nutrition referrals were seen by the neonate NST.

Two out of the three adult NST reported that they had complete autonomy when it came to provision of PN, i.e. they were able to say no to PN, however one of them then went on to state that clinicians can start 'standard formulas' on any patient they wish to do so without any NST involvement. The neonatal NST reported complete autonomy. The remaining adult NST and paediatric NST reported that they worked in an 'advisory role only', the lead clinician was able to overule a recommendation made by the NST should they wish to do so.

Five of the participating hospitals reported having specific guidelines for initiating PN, one hospital that provided PN had no guidelines. Four out of five hospitals that responded had specific policies related to changing and handling of PN bags.

Only two of the six participating hospitals had a dedicated CVL/PICC insertion service. Five hospitals had specific policies on insertion and care of CVL's, one had no policy. All six did however have a policy for the management of CVL infection.

Adult Outcome Data

All of the patients in this study had their PN discontinued, none went on the have home PN. The following data describes patient outcomes, PN indication and outcome, and PN duration and outcomes. Fifty seven out of sixty five (87.7%) patients were successfully weaned of their PN as they were able to either resume eating and drinking orally, or else were able to be enterally fed (See table 4.7). Of the eight patients that died, 75% (6) developed hyponatraemia, 50% (4) had CVC complications.

Table 4.7 Adult patient outcomes

Outcome	**Number of patients**
Weaned onto oral/enteral feeding	37
Weaned & transferred to other unit	2
Weaned, transferred to other unit & discharged home	9
Weaned & discharged home	8
Transferred to other unit & discharged home	1
Weaned & died	1
Died during hospital stay	7
Total	65

Table 4.8 PN indication and outcome

	Number of patients	
PN indication	Alive	Deceased
Post-operative Ileus	26	2
Perforated/leaking gut	5	1
Failure of Enteral nutrition	3	
Post-surgical complications	2	1
Obstruction	2	2
Fistulae	3	
Chemotherapy		1
Short Bowel	1	
Pre-op nutrition	1	
No access for enteral nutrition	1	
Failure of EF/Post Op Ileus	1	
Non-functioning gut/Failure of ent nut		1

Post Surg comp/Post op Ileus	1	
No data recorded	12	
Total	58 (88%)	8 (12%)

Table 4.9 PN duration and outcome

	Patient Outcome				
Number of days on PN	Alive	%	Deceased	%	Total
1-14	48	87.3	7	12.7	55
15-28	8	88.9	1	11.1	9
>28	2	100			2
Total	58		8		66

Summary

This chapter presented the findings of the clinical audit of the care provided to adult patients receiving PN in this phase one pilot study. The findings were presented in the themes of: indication for PN, type of PN, CVC care, PN associated complications and availability and role of NSTs. The results aim to answer the study question, 'What is the current practice of PN management throughout the Auckland/Northern region?'

In this study, overall care of PN was found to be of a disappointing standard (See table 4.1, p. 48). Only 12.7% of cases examined demonstrated 'good practice' (the standard for which the advisor assessors would expect within their own practice). Nineteen per cent of the cases in this study were graded as a 'Less than satisfactory 'standard, and 65% of cases demonstrated aspects of care where there was 'room for improvement'. The results demonstrate, like other studies conducted, that PN management varies considerably between different hospitals. Often it would appear that the clinical practice guidelines available are not adhered to.

A secondary aim of this study was to determine the suitability of the NCEPOD data collection tools used for this phase one regional study. Having presented the results, the following chapter will discuss the results in the context of the literature reviewed as well as whether the tools used, were or were not found to be suitable for the phase two national study planned. Study limitations, implications for practice and recommendations for further study are made.

5. Discussion

Introduction

This study aimed to critically examine the current practice on PN care throughout the Auckland/Northlands region using a clinical audit process. Secondary aims were to establish if New Zealand had similar findings to the NCEPOD 'Mixed bag' report and to ensure that the NCEPOD data collection tools were suitable for the New Zealand setting (Stewart, Mason, et al., 2010). The themes examined in this study were: indication for PN, type of PN, prescribing PN, CVC care, PN associated complications and the role and availability of NSTs.

In this chapter, a summary of the findings of the care provided to adults receiving PN are discussed in relation to the literature in an attempt to draw conclusions. Results are compared to those found by NCEPOD, with the aim of establishing whether NZ has similar findings to those of the NCEPOD study. The chapter will go on to discuss the suitability of the NCEPOD methods for a NZ national study. Weakness and limitations of the study are presented, before implications for New Zealand practice and recommendations for future research are made.

The Investigation of Parenteral Nutrition – Aotearoa

Similarly to the NCEPOD study (2010), the overall care of PN in this study was found to be of a disappointing standard (See table 4.1, p. 46). Only 12.7% of cases examined demonstrated 'good practice' (the standard for which the advisor assessors would expect within their own practice). Nineteen per cent of the cases in this study were graded as a 'Less than satisfactory' standard and 65% of cases demonstrated aspects of care where there was 'room for improvement'.

Indication for PN

Although literature suggests that PN is often administered inappropriately (DeLegge, et al., 2007; Maurer, et al., 1996), this study did not find that to be the case overall. In the hospitals

examined in this regional audit, 51/64 (79.7%) of patients that received PN were given it for an appropriate indication. NCEPODs study found that PN was given for an appropriate indication in 576/808 (71.3%) of cases (2010).

There were still however, some cases in this study when PN was prescribed, where no clinical indications of a non-functioning gut were found. Oral or enteral feeding should always be the first choices when providing nutritional support as it is associated with fewer complications than PN (Bankhead, et al., 2009). Parenteral nutrition is only indicated for those patients that have a non-functioning gut (Phillips & Ponsky, 2011). Of interest is that three of the six patients given PN for an inappropriate indication according to the advisor assessors, were from a hospital that reported no NST; this may suggest increased inappropriate PN use when no NST is involved (DeLegge, et al., 2007; Harbottle, Brache, & Clarke, 2009).

However, although it was agreed that PN was given for an appropriate indication, there was still significant evidence found in this study that alternative oral or enteral feeding options were not first considered and/or trialed in 26.6% (17/64) of cases. Whilst it was often difficult to find a documented rationale as to why oral or enteral feed was not considered, advisors examined clinical records and were able to draw a conclusion themselves in some cases. They found that in this study, PN was given inappropriately in some patients that appeared to have a functioning gut as demonstrated by the fact they were having their bowels opened and were not experiencing vomiting, bloating or any other indications of a non-functioning gut. Some patients received PN as it was anticipated that they may develop a post-operative ileus (3/17). Of concern is that for one patient given PN, the indication given was that they were not receiving sufficient volume of oral nutrition, strongly indicating a functioning gut. Clinicians also provided PN in patients that had had complicated surgeries, where the surgeon had advised gut rest to protect fragile surgical sites without any consideration as to whether feeding distal to the site of surgery may have been possible (3/17). For some patients 5/17, there was no rationale able to be found that oral or enteral feeding would not have been possible. The findings of this study are consistent with other studies that have demonstrated that PN is sometimes given inappropriately.

The findings of this audit are consistent with other studies that have demonstrated PN is sometimes given inappropriately and similar to the findings of NCEPOD (2010) where 32.7% (271/829) of cases did not receive adequate consideration of oral or enteral feeding before the commencement of PN (Harbottle, et al., 2009; Martin, et al., 2011; Maurer, et al., 1996; Stewart, Mason, et al., 2010). This inappropriate PN use could result in, increased costs, increased risk of potential complications and deny patients the benefits provided by feeding directly into the gut (Barendregt, et al., 2004; Reyes, 2002).

Type of PN prescribed

Most patients starting PN in this study were given a 'standard multi-chamber off the shelf' bag 34/61 (55.7%), very similarly to those in the NCEPOD study, 523/935 (56%). Many of the patients in this study continued to receive this type of PN bag, for the duration of PN. These bags have components that are fixed, therefore no manipulations can be made in order to match the patient's requirements in terms of macronutrients (calories/protein and nitrogen), fluids or electrolytes. Standard bags are considered to be cost effective, however ESPEN guidelines recommend that PN prescriptions be tailored specifically for the individual. Consideration must be given to protein, energy and micronutrient (electrolyte and minerals) requirements, disease state, co-morbidities and fluid status.

The data from this study suggests that more than half of the patients possibly received PN that did not fulfil their nutritional requirements, being either inadequate or in excess of their individual needs. Over provision of nutrition significantly increases the likelihood of PN associated metabolic complications occurring. Re-feeding syndrome is of particular concern following initiation of PN. Standardised PN bags does not allow adherence to the NICE re-feeding guidelines used in this audit, that make specific recommendations on how to initiate re-feeding in malnourished patients who may be at risk of RFS (Excellence., 2006).

Twenty seven out of sixty one (44.3%) patients were reported to have received tailored PN, however, two actually received PN bags that had 'standard' macronutrients but had tailored

micronutrients provided, hence they may also have received inadequate or excessive macronutrients.

Of concern is that according to advisors, 35.4% (17/48) of the first PN prescriptions in this study were inappropriate for the patient's needs. This is over double of that found in the NCEPOD study, where only 15% (75/500) of prescriptions were considered inappropriate.

Advisor assessors felt that on examination of the prescriptions provided (59/65) in this study, only 22 (37.3%) had fully 'tailored' bags. Tailored PN bags are able to be prescribed specifically to meet what the clinicians determine are the patient's requirements. It cannot however, be assumed in all cases, tailored PN bags are in fact correctly prescribed.

Indeed, three (17.6%) patients 'tailored' PN prescriptions (bags) examined in this study were considered to be inappropriate by the advisor assessors. One patient was prescribed in excess of their fluid requirements based on the advisors clinical assessment. Two patients were fed below their nutritional requirements, however one of these had been identified as at risk of RFS by the clinician caring for them and had purposively had their PN initiated with reduced macronutrients and additional vitamins. Advisors assessed the patients risk of RFS using the NICE guidelines discussed previously. Unfortunately the data tools used did not capture what clinicians felt were patients re-feeding risks when they initiated PN. The other patient fed below their requirements was not identified as being at risk of RFS, and no other reason for underfeeding is given. This highlights the importance of clinicians understanding the complexity of PN provision and clearly documenting decision rationale (DeLegge, 2012).

Prescribing PN

In this Auckland/Northland regional audit, PN requirements were generally calculated by a team of clinicians together, with a dietitian being present in 61/65 (93.8%) cases. The teams calculating PN requirements were usually part of a NST, unsurprisingly considering most

hospitals in the region studied reported having a NST. This cannot be assumed a typical scenario throughout the remainder of New Zealand. Of interest is that, 4/18 (22.2%) cases where a NST was not involved, the nutritional requirements were calculated by a doctor in the HDU/ICU of one participating hospital. This hospital had a NST which reported being involved in calculating requirements in level 1 and some level 2 area's (General wards & HDU) indicating that perhaps the NST in this hospital has less of a role in managing some level 2 & level 3 (ICU) patients. However, it could be expected that HDU/ICU critically ill patients, often with complex co-morbidities, would be the very cases to benefit from a multi-disciplinary NST prescribing. The remaining 14 (77.8%) of patients had their requirements calculated by a dietitian alone, and all came from one hospital that reported not having a NST.

Interestingly prescriptions of PN appear to be signed by a range of clinicians, although not always by the clinician or team that has determined the PN prescription. The hospital discussed above that has a NST but are not always involved in determining nutritional requirements in the HDU/ICU, reported occasions where they calculated nutritional requirements, however, the person signing the prescription was not a member of their NST. Unlike the UK where there are legal constraints on the prescribing of PN, here in New Zealand the Medicines Act places no such restrictions on who can legally prescribe PN, although it is considered 'good practice' to be done by a trained medical officer ("Medicines Act," 1981). Only 25/65 (38.5%) of the cases examined in this study had their prescriptions signed by a medical officer. Of the remaining forty, 26 (65%) had their PN prescriptions written by a dietitian with 14 (35%) being written by a pharmacist.

Catheter Choice, Insertion and Care

It is recommended in the ESPEN guidelines that most patients requiring short term PN be given their PN via a PICC line or non-tunnelled CVC (Pittiruti, et al., 2009). Peripherally inserted central catheters (PICC) are thought to be associated with decreased infective complications (Gunst et al., 2011; Maki, et al., 2006). Interestedly only 14.7% (153/1042) of patients in the NCEPOD study received their PN via PICCs, compared to 63.1% (41/65) of patients in this study. Why this variance in practice occurs between the UK and in New Zealand is unknown, however

it may be influenced by increasing evidence of specific PICC associated complications, such as mal-positioning and thrombosis (Jennings, Cann, & Smyth, 2011; Turcotte, Dubé, & Beauchamp, 2006).

There is evidence that suggests increased risks of thrombosis and mal-positioning associated with PICC lines, however PICC lines are associated with lower incidence of infective complications. The findings of this study appear to corroborate this, mal-positioning occurred in 2/41 (4.9%) of patients with a PICC line vs. 0/23 of those with other CVCs, thrombosis occurred in 1/41 (2.4%) vs. 0/23. There were however, only 4/41 (9.7%) infections (either suspected or confirmed) in PICCs vs. 6/23 (26.1%) with other CVCs.

Interestingly, despite evidence to suggest that mal-positioning occurs, and recommendations that the tip position of CVC should lie in the distal SVC for PN administration, this audit found that the position of the tip of the CVCs used was often not documented, 62.5% (40/64). It is therefore difficult to establish if checking the tip position of CVCs is part of the monitoring provided to those patients receiving PN, however the results of this audit would suggest not. This is of significant concern, considering checking the correct positioning of the CVC catheter following insertion can prevent many CVC related complications, particularly thrombophlebitis, thrombosis and mal-positioning.

Parenteral nutrition may be administered via a peripheral cannula as long as a solution of low osmolality is used and under close surveillance, as PPN is known to increase the risk of thrombophlebitis (Pittiruti, et al., 2009). Peripheral PN administration appears to be more commonly practised in the UK, where NCEPOD found that 12.2% (127/1042) of patients received their PN in this way compared with only 1/65 (1.5%) in this study.

Despite recommendations that a single lumen CVC may help to reduce the risk of infection in accordance to ESPEN guidelines, only 32.3% (21) of patients in this study had a single lumen catheter's inserted for their PN. However, this is more than those found in NCEPODs study,

where only 27.4% (283/1034) were given their PN via single lumen catheters. Multi-lumen CVCs are associated with increased risk of infection due to the increased handling of these lines while administering other fluids and medications (Maki, et al., 2006).

A limiting factor in the use of single lumen PN lines is that often patients requiring PN also often require significant additional intravenous therapy, for medications, blood products and other fluids. They also require frequent blood sampling as part of PN monitoring. Multi-lumens are preferred by clinicians because peripheral cannulas are notorious for lasting hours to a short number of days only. Furthermore, although no evidence has been found by the investigator of this study, neither have many clinicians questioned actually experienced this in their practice, but some clinicians report a theoretical risk of tangling, by having more than one CVC within the SVC. Due to this, the practicalities of inserting two CVC into the patient at the same time - a multi-lumen for intravenous therapies and a single lumen dedicated PN line is discouraged in practice.

PN Associated Complications

Like other PN studies conducted, this study also found that metabolic complications associated with PN occurred frequently. However, disappointingly in comparison to NCEPOD's study, in which 39.3% (249/634) of patients developed metabolic complications, in this study, 53.1% (34/64) of patients developed metabolic complications. This is surprising, considering this study found that there was adequate clinical and biochemical monitoring in 67.2% (43/64) of the cases reviewed, compared with only 56.7% (387/683) of the NCEPOD cases. Why this may be the case is not fully understood however, it is likely to be as a result of, a lack of consensus as to what constitutes adequate biochemical review, what biochemistry should be reviewed on initiation of PN and what on-going review is necessary.

Risk of RFS was found to be common in this study, although this risk was not always identified. Using the NICE (2006) guidelines to identify patients at risk of RFS, advisors found that nearly half of the patients in this study were at risk of RFS, 23/65 (35.4%). Of the twenty three

patients identified at risk of RFS, 4 (17.4%) went on to develop RFS, using the definition agreed as the standard to which RFS would be audited. Re-feeding was defined as 'probable' if there was a drop in serum phosphate combined with evidence of pathological development of extracellular fluid shift and as 'possible' if there was a fall in serum potassium, magnesium with development of such odema. Another one patient went on to develop RFS who had not been identified as being at risk of RFS by either the clinician caring for them or the advisor assessor.

As discussed previously there is a lack of consensus as to a clinical definition of RFS in current literature (Fleuret, Reidlinger, Whelan, & Rio, 2008). NCEPODs (2010) study state that for the purpose of their study they did not define RFS as a drop in phosphate only, however, they do not go on to state what their other defining criteria included. Therefore it is not possible to draw comparisons to the incidence of RFS between the two studies.

Of the eight deaths that occurred in this study, one was of a patient believed to have 'probably' developed RFS as well as a CVC complication. The overall grade assigned to this patient was one of 'room for improvement', the rationale for the grade given was that the PN prescription was not signed for. This suggests that patients requiring PN often have complex issues with several co-morbidities and that despite overall good management of their PN, poor outcomes can still occur.

Availability and role of Nutrition Support Teams

The administration of PN should be carried out in consultation with a specialised nutrition support team whenever possible (Bischoff et al., 2009). Interdisciplinary nutrition support teams should be established in hospitals because effectiveness and efficiency in the implementation of PN are increased, they have been found to reduce complications, reduce inappropriate PN use and reduce costs. In this study, three out of four hospitals that provided PN to adults reported having a NST.

This study demonstrated that 87.5% (7/8) of cases assigned an overall grading of 'good practice' had an NST involved in their care, vs. only 12.5% (1/8) of cases when no NST was involved. Disappointingly, of all the cases assigned the grade of 'room for improvement' 65% (26/40) of cases vs. 35% (14/40) had an NST present. Finally, there was no difference in those graded 'less than satisfactory' whether a NST was present or not, 50% (6/12) vs. 50% (6/12). These findings suggest that good care is more likely with a NST being present, however even with a NST there are still aspects of practice that are less than satisfactory or leave room for improvement. A limitation of these findings is, however, the grading system used which will be discussed later in the chapter.

Metabolic and CVC complications are known to occur with PN. Having a NST is believed to reduce the risk of complication occurring, however this study found that the incidence of such complications occurring remained high. One site with an NST demonstrated both metabolic and CVC complications occurring in 11/26 (42.3%) of cases, of these 4/11 (36.4%) had their complications managed appropriately. A second site reported 3/15 (20%) of cases where both metabolic and CVC complications occurred despite the presence of an NST, of these 33.3% (1/3) had their complications managed appropriately. A third site with an NST demonstrated only 1/26 (3.8%) case of both metabolic and CVC complications occurring which was then managed appropriately. The fourth site examined without an NST demonstrated both metabolic and CVC complications in 3/15 (20%) of cases, none of which were deemed to have been managed appropriately.

The incidence of metabolic and CVC complications occurring is in keeping with the known risks associated with PN. Whilst on appearance the findings discussed above may indicate that complications are prevalent whether or not a NST is present or not, this may not actually be the case. One advisor assessor discussed his findings when completing the questionnaires, *"If it wasn't for the fact that the NST documented incidents of complications occurring, I wouldn't know. It makes it look as if more complications happen but in actual fact it is just because they have been identified and we know about them"* It is hypothesised that the incidence of complications occurring when there is no NST present, may be higher than thought, however

they are not identified and the true incidence is therefore unknown. Of concern however, is the low incidence of managing complications that have occurred appropriately.

In summary, it would appear that whilst the current practice of PN management in the Auckland/Northland region is overall safe, there are several significant areas of concern identified where remedial action is necessary in order to improve patient care. In particular is, overall documentation, assessment of patients to ensure appropriate use of PN, monitoring and managing complications appropriately when they occur.

Validation of study tools

A secondary aim of this study was to see if the NCEPOD data collection tools were appropriate for the New Zealand setting. The three questionnaires were, a patient care questionnaire examining clinical care given, an advisor assessors questionnaire examining and grading the care provided in accordance to the ESPEN/NICE guidelines and an organisational questionnaire examining each hospitals nutrition support practice. Before data collection was commenced, the project advisory group reviewed and made some amendments to the questionnaires as it was felt that some questions were ambiguous. Yet on analysis of the data it was still often difficult to ascertain and determine some of the nuances of clinical care provided.

Validation of data tools is important when conducting audit in order to ensure results are as explicit and reliable as possible. For this study the tools produced by NCEPOD were used. On examination of the data collected in this audit, it was found that there were discrepancies in the way questions were asked between the patient care and advisor assessor questionnaires. An example of this is that when reporting the aspects of patient's assessment. The questions were worded differently, and the questionnaires listed a different set of parameters, therefore, making it difficult to draw a parallel between what was reported to have occurred and what was found to have occurred. For example, in the patient care questionnaire clinicians were asked: *Did the patient have an assessment made for the need for PN? – Y/N*, followed by, *If yes what were the elements of the assessment?* The advisor assessor questionnaire asked;

Was there adequate nutritional and biochemical assessment of the patient prior to commencement of PN? – Y/N. A list of options for what was included in the assessment were available on both questionnaires, however, the advisor assessor questionnaire included the option of pre albumin, which was not included on the patient care questionnaire.

In the case of RFS, clinicians were asked if there was documented evidence that the patient was at risk of RFS, however advisor assessors were asked if the patient was at risk of RFS in their opinion. Determining documented evidence is difficult with no real clarity of what documented evidence constitutes. For example, checking serum blood results before deciding on a formula is essential in order to ensure the correct formula is then prescribed. However just because a result was available does not mean it was sighted by the PN prescriber. If there was no documented evidence of a review in clinical case notes, it was considered to have not been done.

How NCEPOD validate the tools they use is unknown, no evidence was found of the process undertaken by their group. The findings of this study suggest that the NCEPOD questionnaires require some adjustment in order to ensure reliability and validity before phase two of this study is completed.

Adherence to guidelines

This Auckland/Northland region audit demonstrated that using ESPEN guidelines to grade PN care against was not adequate for this study. Whilst the ESPEN guidelines provide recommendations for best feeding options for specific groups of patients, they do not actually provide advisors with specific practical recommendations on the management of PN.

This audit found that there were variances in local practice that were based on experience, individual knowledge and the personal adoption of general practice recommendations. For example, one hospital in the audit added insulin directly into their PN bags for diabetic patients whilst none of the remainder hospitals did. There is no evidence in the ESPEN

guidelines as to whether this is safe to do so or not, however Austin et al. (2007) do not recommend the addition of components to the PN formula following compounding.

Limitations and Weaknesses of the study

Documentation

Retrospective clinical audit relies on the information that is required, being available for the audit. This study found many instances where documentation was missing, therefore making some aspects of this audit impossible to complete. There were generally two reasons for missing clinical data, it was either never recorded in the first place or else it was not copied and returned with the clinical data requested by the local reporters in this study. There was a consensus agreement that in probability some data were missing because it had not been copied, provided or had ineligible dates.

Blair et al. (2012) states that documentation is an important issue for nurses, however it is of paramount importance for all heath care clinicians to document the care they have provided, documenting the rationale and clinical thinking behind clinical decisions and interventions. As well as providing a factual chronological report about assessment and care of patients, it is also a legal requirement (NZNC, 2012). In many instances there was an implicit opinion that consideration/review of some aspects of practice were done however, there was no documented evidence of this. Of course there were also many instances of where there was no evidence of some aspects of practice because in fact it was not part of the clinicians care provided. For instance, documentation of catheter tip position was not recorded as it was often not reviewed as part of PN care.

Grading

A grading range of ‘Good practice’, Room for improvement’ and ‘Less than satisfactory’ was used to determine the standard of PN care in adherence to ESPEN guidelines throughout the

Auckland/ Northland region. Attempts to ensure consistency in overall grades assigned included a test case review and extensive discussion on each question asked. However, when it came to assigning an overall grade, a limitation of the system used was the inability to adequately capture a range of clinical care within each category. The grade of 'Room for improvement' was of particular concern as this grade was given for a variety of reasons ranging from *"Some delay in recognition of need for PN"* to *"SIRS is mentioned by team on review, but no prescription of fish-oil/Poor NST/nutrition reviews-lacking details……. /No mention of lipids- important (see ESPEN). /No note of PICC line in brachiocephalic-No change to PN or mention of re-siting"*

The range in variety of reasons for the grading given is important as it was intended that this could provide an overview of the current standard of PN care throughout the region. On completion of this study, it is believed that the grading system used, was inadequate to accurately reflect the current standard of practice as evidenced by the example given. Whilst a delay in recognising the need for PN is important as delays can exacerbate and increase the associated malnutrition complications, the issues raised in the second part of the example are numerous in comparison.

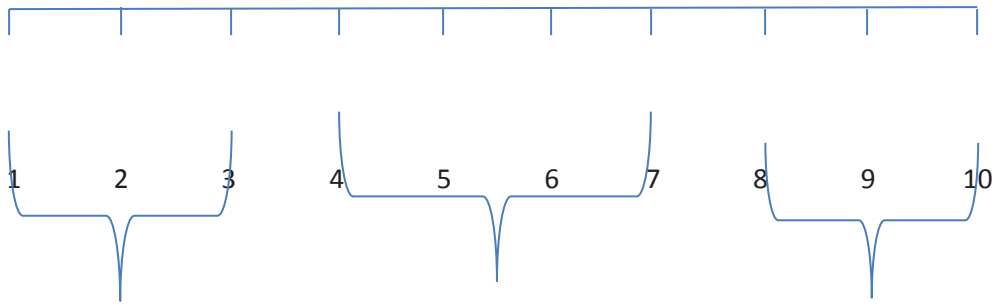
Recommendations from this study for phase two – IPNA

On completion of this phase one study the following recommendations are made for phase two of the IPNA study which aims to examine PN practice nationally.

1. In order to ensure reliability and validity of the outcomes measured in the phase two national study, revision of the data collection tools is essential to ensure consistency in the questions being asked by both the clinicians providing care as well as the advisors assessing care.
2. Phase Two of IPNA – a national study examining the practice of PN care throughout all of NZ public hospitals.

3. Grading – It is recommended that the planned phase two of this study uses a grading system such as a Likert scale. Using a Likert scale allows the researcher to capture variance around a specific point. An example of what may be used is figure 5.1;

Figure 5.1 Likert Scale



Less than Satisfactory Room for Improvement Good Practice

Suggested further research activity

1. NZ Standard of Practice for PN nutritional assessment – Standardised assessment criteria, what and how to assess patients for PN, recognising and responding to risk factors, on-going monitoring, and how to deal with complications appropriately.
2. NZ Standard NST daily review. For example, 'LIFEWRAP' an acronym currently used by the WDHB NST, as a reminder of the elements to be assessed on daily review. (LIFEWRAP -Line, Infection, Fluid, Examination & energy, Weight, Results and Action Plan.)
3. Further analysis of the literature is necessary to determine the safest CVC to be used for PN administration.

Concluding statement

This clinical audit examined PN care throughout the Auckland/ Northland region. The themes of, indication for PN, type of PN, prescribing PN, CVC care, PN associated complications and the role and availability of NSTs were examined. Secondary aims were to establish if New Zealand had similar findings to the NCEPOD 'Mixed bag' report and to ensure the NCEPOD data collection tools were suitable for the New Zealand setting.

Whilst the audit results presented are purely descriptive, with no attempt to draw any statistical significance, there are several trends that appear to correlate with the literature discussed. This study demonstrated a wide variance in local practice which is not necessarily evidence based or else not in accordance to ESPEN guidelines. Although in general, practice was deemed to be overall safe, there were still several areas of concern demonstrated in the standard of care provided. There is a lack of consensus as to the best way in which to care for patients on PN, how to initially assess patients, what to assess, what continuing monitoring is required and finally how best to manage any complications that may have occurred. Whilst there are guidelines available, they do not appear to be universally adopted. Why this might be the case is unknown.

The present study has demonstrated that national guidelines on the delivery of PN care are essential in order to reduce inappropriate PN use, reduce complications and improve overall care for the complex patients requiring this particular therapy. Provision of PN care requires a multi-disciplinary approach with input from clinicians, dietitians, nurses and pharmacists with specialist knowledge of the complexities of PN administration.

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Appendices

Appendix 1 – Questionnaires

PARENTERAL NUTRITION (PN) STUDY

Investigation of Parenteral Nutrition- Aotearoa (IPNA)

Patient Care Questionnaire

CONFIDENTIAL

IPNA Case Number: | | | | | | | | | | | | | | | |

Name of IPNA Local Reporter: _____

Specialty of doctor completing form: _____

What is this study about?

This study is examining the process of care of patients of all ages who received parenteral nutrition as an inpatient between 1st January 2011 and 30st June 2011. The study aims to identify areas where the care of these patients might have been improved (remediable factors). All public hospitals that admit both acute and elective admissions in New Zealand will be included in the study.

Exclusions - HPN

If you have any queries about the study or this questionnaire, please contact
Sue Larsen:
sue.larsen@waitematadhb.govt.nz

Telephone: 09 486 8920

How to complete this questionnaire?

Information will be collected using two methods: Box cross and free text, where your clinical opinion will be requested.

This form will be electronically scanned. Please use a black or blue pen. Please complete all questions with either block capitals or a bold cross inside the boxes provided e.g.

Had the patient previously received PN?

☒ Yes ☐ No

If you make a mistake, please "black-out" the incorrect box and re-enter the correct information, e.g.

■ Yes ☒ No

Thank you for taking the time to complete this questionnaire. The findings of the full study will be published in mid to late 2012.

FOR STUDY USE ONLY | | | | | | |

Please supply photocopies of the following case note extracts from admission to completion of PN.

Inpatient annotations (i.e. the main casenotes)

Nursing notes

Nutrition notes (these are sometimes filed separately)

Biochemistry results (e.g. LFT, U&Es)

Haematology results (e.g. FBC)
.
Fluid balance charts (including urine output)

Drug charts (including PN prescription chart)

Nutritional charts

Observation charts (including TPR, CVP)

Weight chart

Urinalysis

X-ray/CT/USS reports

Any operating notes

Please provide a clinical summary of the patient's care in hospital

A. PATIENT DETAILS

1. Age at time of admission ☐☐☐ years

If less than 2 years old ☐☐ months ☐☐ weeks ☐☐ days

If premature baby Gestation ☐☐ weeks ☐☐ days

2. Gender: ☐ Male ☐ Female

B. THE ADMISSION

3. What was the date of admission? ☐☐ ☐☐ ☐☐

d d m m y y

4. What was the time of admission? (Please use 24-hr clock) ☐☐ ☐☐

h h m m

5. a. Was the admission:

☐ A planned admission

☐ An emergency admission

☐ An Inter-hospital transfer

☐ Unknown

b. Specialty of consultant patient admitted under ☐☐☐

(Please see codes on page 11)

C. PARENTERAL NUTRITION INDICATION

6. Under what specialty was the patient when the decision was made to commence PN? ☐☐☐ ☐ Unknown

(Please see codes on page 11)

7. Under what specialty was the patient when PN was administered? ☐☐☐ ☐ Unknown

(Please see codes on page 11)

8. Had the patient previously been given PN? ☐ Yes ☐ No ☐ Unknown

9. a. On what type of ward was the PN initially administered?

- ☐ Adult Medical
- ☐ Adult Surgical
- ☐ Adult Critical Care
- ☐ Paediatric Medical
- ☐ Paediatric Surgical
- ☐ Paediatric Critical care
- ☐ Neonatal unit (SCBU)
- ☐ Dedicated Nutrition ward/area
- ☐ Other
- ☐ Unknown

b. What level of care was this ward? ☐ Level 1 ☐ Level 2 (e.g. HDU) ☐ Level 3 (e.g. ICU) ☐ Unknown

10. a. What was the indication for PN (answers may be multiple)?

- ☐ Immaturity of GI function
- ☐ Congenital anomalies; gut
- ☐ Congenital anomalies; non gut
- ☐ Necrotizing enterocolitis
- ☐ Non-functioning gut
- ☐ Perforated/leaking gut
- ☐ Short bowel
- ☐ Dysphagia
- ☐ Obstruction
- ☐ Dysmotility
- ☐ Fistulae
- ☐ Malabsorption
- ☐ Pre-operative nutrition
- ☐ No access for enteral nutrition
- ☐ Failure of enteral nutrition
- ☐ Radiation enteritis
- ☐ GVHD
- ☐ Infection (e.g. C. difficile)
- ☐ Chemotherapy
- ☐ Cancer
- ☐ Volvulus
- ☐ Crohn's disease
- ☐ Post-surgical complications
- ☐ Radiation damage
- ☐ Post-operative ileus
- ☐ Other (please specify)

11. a. Had the patient received any kind of enteral feeding in the week prior to the decision to commence PN? ☐ Yes ☐ No ☐ Unknown

b. If Yes, what:

- ☐ Oral supplements
- ☐ Nasogastric feeding
- ☐ Naso-jejunal feeding
- ☐ PEG
- ☐ RIG
- ☐ PEG-J
- ☐ Surgical jejunostomy
- ☐ Distal feeding

c. Why was it not possible to continue to feed the patient enterally?

12. If PN was the first method of nutritional support, how long had the patient been without adequate food or nutritional support before the PN was started? ☐☐ hrs/days ☐ Unknown

13. a. What was the interval between the decision to start PN and its commencement? ☐☐ hrs/days ☐ Unknown

b. If greater than 1 day, why was this?

14. a. Was a treatment goal documented? ☐ Yes ☐ No

b. If yes what was this? e.g. optimisation of nutrition pre-surgery

D. PATIENT ASSESSMENT

15. a. Did the patient have an assessment made for the need for PN ☐ Yes ☐ No ☐ Unknown

b. If yes what were the elements of the assessment?

- ☐ Clinical grounds
- ☐ Biochemical review
- ☐ Weight
- ☐ Mid-arm circumference
- ☐ Tricep circumference/skin fold thickness
- ☐ Grip strength
- ☐ Other **(specify)**

16. a. Who made the decision that PN should be commenced (answers may be multiple)?

- ☐ Nurse
- ☐ Dietitian
- ☐ Pharmacist
- ☐ Unknown
- ☐ Doctor
  - specialty (see page 11) ☐☐☐
  - grade (see page 11) ☐☐☐☐
- ☐ Other

b. Were they members of a nutrition team? ☐ Yes ☐ No ☐ Unknown

17. Was the decision to start the PN made in normal working hours (8am - 5pm, Mon - Fri)? ☐ Yes ☐ No ☐ Unknown

E. PARENTERAL NUTRITION PRESCRIPTION

18. What type of PN was first given?

- ☐ Multi-chamber bag ('off the shelf')
- ☐ Multi-chamber bag with micronutrients only
- ☐ Multi-chamber bag with micronutrients and tailored additions
- ☐ Tailored bag
- ☐ Unknown
- ☐ Other **(specify)**

19. If this was subsequently changed what was it to?

- ☐ Multi-chamber bag ('off the shelf')
- ☐ Multi-chamber bag with micronutrients only
- ☐ Multi-chamber bag with micronutrients and tailored additions
- ☐ Tailored bag
- ☐ PN not changed
- ☐ Other **(specify)**

20. a. Who determined the nutritional requirements of the patient (answers may be multiple)?

- ☐ Nurse
- ☐ Dietitian
- ☐ Pharmacist
- ☐ Other
- ☐ Doctor
  - specialty (see page 11) ☐☐☐
  - grade (see page 11) ☐☐☐☐
- ☐ Unknown

b. Were they part of a nutrition team? ☐ Yes ☐ No ☐ Unknown

21. a. Who signed the prescription?

- ☐ Nurse
- ☐ Doctor
- ☐ Pharmacist
- specialty ☐☐☐ (see page 11)
- ☐ Unknown
- grade ☐☐☐☐ (see page 11)
- ☐ Dietitian
- ☐ Other ☐

b. Were they part of a nutrition team? ☐ Yes ☐ No ☐ Unknown

c. Was this a different individual to the person(s) who determined the constitution? ☐ Yes ☐ No ☐ Unknown

22. a. Who reviewed the patient with respect to their PN (answers may be multiple)?

- ☐ Nurse
- ☐ Doctor
- ☐ Dietitian
- specialty ☐☐☐ (see page 11)
- ☐ Pharmacist
- grade ☐☐☐☐ (see page 11)
- ☐ Unknown
- ☐ Other ☐

b. Were they part of a nutrition team? ☐ Yes ☐ No ☐ Unknown

23. How often was the patient reviewed with respect to PN?

- ☐ Daily (7 days)
- ☐ 1-2 days/week
- ☐ Daily (working week)
- ☐ <1 day/week
- ☐ 3-5 days/week
- ☐ Unknown

24. What was reviewed (answers may be multiple)?

- ☐ Constitution of PN
- ☐ Tricep circumference/skin fold thickness
- ☐ Biochemical review
- ☐ Grip strength
- ☐ Clinical status
- ☐ Vascular access
- ☐ Ongoing need for PN
- ☐ Other ☐
- ☐ Weight
- ☐ Mid-arm circumference

25. How often was the PN prescription re-prescribed?

- ☐ Daily (7 days)
- ☐ Other ☐
- ☐ Daily (working week)
- ☐ Not re-prescribed
- ☐ Weekly
- ☐ Unknown

b. How many times was the prescription changed during this admission? ☐☐☐

☐ No changes

F. VENOUS ACCESS/LINE CARE

26. How many CVCs did this patient have for PN during this admission ? ☐☐ ☐ Unknown

Please answer the following questions with respect to the first **catheter** the patient received for PN

27. What was the initial mode of PN delivery

- ☐ Peripheral venous catheter
- ☐ Peripherally inserted central catheter
- ☐ Umbilical vein
- ☐ Implanted (e.g. Portacath)
- ☐ Centrally inserted venous catheter
  - ☐ Non-tunnelled
  - ☐ Tunelled
- ☐ Unknown

28. Type of catheter

- ☐ Multilumen
- ☐ Cuffed
- ☐ Uncuffed
- ☐ Single lumen
- ☐ Unknown

29. Was the catheter inserted?

- ☐ Solely for PN
- ☐ For general central venous access with one lumen for PN
- ☐ Unknown

30. Who inserted the catheter?

- ☐ Nurse
- ☐ Doctor
  - specialty ☐☐☐ (see page 11)
  - grade ☐☐☐☐ (see page 11)
- ☐ Other ☐
- ☐ Unknown

31. Where was the patient when the catheter was inserted?

- ☐ General ward
- ☐ Treatment room
- ☐ Critical care
- ☐ Radiology department
- ☐ Operating theatre
- ☐ Other ☐
- ☐ Unknown

32. What insertion technique was used? ☐ Open surgical ☐ Percutaneous ☐ Unknown

33. What asepsis precautions were used (answers may be muliple)?

- ☐ Gown & gloves
- ☐ Face mask
- ☐ Draping
- ☐ Not recorded
- ☐ Skin cleansing solution
  - ☐ Iodine
  - ☐ Chlorhexidine 0.5%
  - ☐ Chlorhexidine 2.0%

34. Were prophylactic antibiotics given during insertion of the catheter? ☐ Yes ☐ No ☐ Unknown

35. Where was the tip of the central catheter positioned?

- ☐ Superior vena cava
- ☐ Inferior vena cava
- ☐ Right atrium
- ☐ SVC/RA junction
- ☐ Other
- ☐ Not applicable
- ☐ Not documented

36. How was the position of the catheter verified?

- ☐ Image intensifier at time of insertion
- ☐ Post insertion CXR
- ☐ ECG
- ☐ Ultrasound
- ☐ Unknown

37. For how long was the initial catheter in place? ☐☐☐ days ☐ Unknown

38. If removed, what was the reason for removal (answers may be multiple)?

- ☐ End of PN
- ☐ Line renewal
- ☐ Infection
- ☐ Occlusion
- ☐ Thrombosis
- ☐ Malfunction
- ☐ Accidental
- ☐ Other

39. Who was responsible for changing the PN infusion bags (answers may be multiple)?

- ☐ General ward nurse
- ☐ Specifically PN trained nurse
- ☐ Other
- ☐ Unknown

40. Was access to catheter handling limited to PN-trained individuals? ☐ Yes ☐ No ☐ Unknown

G. NON-METABOLIC COMPLICATIONS

41. a. Did any non-metabolic complications occur with the first catheter inserted for PN?

☐ Yes ☐ No ☐ Unknown

b. If Yes which of the following non-metabolic complications occurred (answers may be muiltiple)?

☐ Line misplacement
☐ Suspected line infection
☐ Confirmed line infection
☐ Phlebitis
☐ Accidental line removal
☐ Line occlusion
☐ Line fracture/rupture
☐ Venous thrombosis
☐ Pneumothorax
☐ Haemothorax
☐ TPN-oma/extravasation
☐ Neurapraxia
☐ Other

H. METABOLIC COMPLICATIONS

42. a. Did any metabolic complications occur with the first PN catheter?

☐ Yes ☐ No ☐ Unknown

b. If Yes which of the following metabolic complications occurred (answers may be muiltiple)?

☐ Re-feeding syndrome
☐ abnormal liver function
☐ Oedema
☐ Hypophosphatemia (without re-feeding syndrome)
☐ Hypomagnesaemia
☐ Hypokalaemia
☐ Hyponatremia
☐ Hypernatraemia
☐ Hypermagnesaemia
☐ Hyperphosphatemia
☐ Hyperkalaemia
☐ Hyperglycaemia
☐ Other

43. a. Was there documented evidence that the patient was at risk from re-feeding syndrome?

☐ Yes ☐ No

b. If Yes what precautions were taken to prevent re-feeding syndrome?

☐ IV vitamins
☐ IV phosphate infusion
☐ Reduced initial rate of feeding
☐ Other
☐ None
☐ Unknown

I. MISCELLANEOUS

44. a. Was the patient given insulin? ☐ Yes ☐ No ☐ Unknown

b. If Yes was this: (answers may be multiple)

- ☐ Part of critical care standard protocol
- ☐ Response to PN induced hyperglycaemia
- ☐ Diabetic patient
- ☐ Other

45. a. Were IV fluids prescribed in addition to the PN? ☐ Yes ☐ No ☐ Unknown

b. If Yes was this: (answers may be multiple)

- ☐ To correct deficit
- ☐ To correct on-going losses
- ☐ Routine maintenance fluid provision
- ☐ Other

46. In total for how many days did the patient receive PN during this admission? ☐☐☐ days ☐ Unknown

47. a. Was feeding:

- ☐ Continuous
- ☐ Cyclical
- ☐ Unknown

b. If feeding was cyclical, how many hours/day did feeding last? ☐☐ hours ☐ Unknown

48. What was the eventual outcome for this patient?

- ☐ Weaned onto oral/enteral feeding
- ☐ Home parenteral nutrition
- ☐ Transferred to other unit
- ☐ Discharged home
- ☐ Died during hospital stay
- ☐ Other

Thank you for completing this questionnaire - the findings of the study will be published in mid to late 2012

NATIONAL SPECIALTY CODES

100 = General Surgery
101 = Urology
103 = Breast Surgery
104 = Colorectal Surgery
105 = Hepatobiliary & Pancreatic Surgery
106 = Upper Gastrointestinal Surgery
107 = Vascular Surgery
110 = Trauma & Orthopaedics
120 = Ear, Nose & Throat (ENT)
130 = Ophthamology
140 = Oral Surgery
145 = Maxillo-Facial Surgery
150 = Neurosurgery
160 = Plastic Surgery
161 = Burns Care
170 = Cardiothoracic Surgery
172 = Cardiac Surgery
173 = Thoracic Surgery
180 = Accident & Emergency
190 = Anaesthetics
192 = Critical/Intensive Care Medicine

300 = General Medicine
301 = Gastroenterology
302 = Endocrinology
303 = Clinical Haematology
306 = Hepatology
307 = Diabetic Medicine
314 = Rehabilitation
315 = Palliative Medicine
320 = Cardiology
340 = Respiratory Medicine
350 = Infectious Diseases
352 = Tropical Medicine
360 = Genito-Urinary Medicine
361 = Nephrology
370 = Medical Oncology
400 = Neurology
410 = Rheumatology
430 = Geriatric Medicine
500 = Obstetrics & Gynaecology
501 = Obstetrics
502 = Gynaecology
800 = Clinical Oncology
810 = Radiology
820 = General Pathology
823 = Haematology

171 = Paediatric Surgery
211 = Paediatric Urology
212 = Paediatric Transplantation Surgery
213 = Paediatric Gastrointestinal Surgery
214 = Paediatric Trauma & Orthopaedics
215 = Paediatric Ear, Nose & Throat
217 = Paediatric Maxillo-Facial Surgery
218 = Paediatric Neurosurgery
220 = Paediatric Burns Care
221 = Paediatric Cardiac Surgery
222 = Paediatric Thoracic Surgery
242 = Paediatric Intensive Care
251 = Paediatric Gastroenterology
252 = Paediatric Endocrinology
253 = Paediatric Clinical Haematology
258 = Paediatric Respiratory Medicine
260 = Paediatric Medical Oncology
321 = Paediatric Cardiology
420 = Paediatrics
421 = Paediatric Neurology
422 = Neonatology

CLINICIAN GRADES

When completing the questionnaire please use the codes below for the relevant clinician grades

Consultant = CONS

Non Consultant Career Grade = NCCG

Staff and Associate Specialist = SAS

Trainee with completed certifcate of training = CCT

Senior specialist trainee (SpR 3+ or ST3+) = ST3

Junior specialist trainee (SpR 1&2 or ST 1&2) = ST2

Basic grade (FY, HO's, SHO's or CT's) = FY

PARENTERAL NUTRITION STUDY

Investigation of Parenteral Nutrition in Aotearoa (IPNA)
Advisor Assessment Form (AF)

Questionnaire number ☐☐☐☐☐☐

INSTRUCTIONS FOR COMPLETION

Please complete all questions with either block capitals or a bold cross inside the boxes provided. If you make a mistake, please "black-out" the box and re-enter the correct information. Unless indicated, please mark only one box per question.

A. PATIENT AND ADMISSION DETAILS

1. Age at time of admission ☐☐☐ years

If less than 2 years old ☐☐ months ☐☐ weeks ☐☐ days

If premature baby Gestation ☐☐ weeks ☐☐ days

2. Gender: ☐ Male ☐ Female

3. Date of admission ☐☐ / ☐☐ / ☐☐☐☐
d d m m y y y y

Day of week ☐☐☐ (MON, TUE, etc)

B. INDICATION FOR PN

4. Time PN first administered (24hr clock) ☐☐ : ☐☐
h h m m

☐ Not recorded

Date ☐☐ / ☐☐ / ☐☐☐☐
d d m m y y y y

Day of week ☐☐☐ (MON, TUE, etc)

5. a. Was consideration given to using all other methods of enteral nutrition as an alternative to PN? ☐ Yes ☐ No ☐ Unknown

5. b. If no please expand on your answer

6. What indication for PN was **documented** (answers may be multiple)?

- ☐ Immaturity of GI function
- ☐ Congenital anomalies; gut
- ☐ Congenital anomalies; non gut
- ☐ Necrotizing enterocolitis
- ☐ Non-functioning gut
- ☐ Perforated/leaking gut
- ☐ Short bowel
- ☐ Dysphagia
- ☐ Obstruction
- ☐ Dysmotility
- ☐ Fistulae
- ☐ Malabsorption
- ☐ Pre-operative nutrition
- ☐ No access for enteral nutrition
- ☐ Failure of enteral nutrition
- ☐ Radiation enteritis
- ☐ GVHD
- ☐ Infection (e.g. C. difficile)
- ☐ Chemotherapy
- ☐ Post-surgical complications
- ☐ Volvulus
- ☐ Crohn's disease
- ☐ Cancer
- ☐ Radiation damage
- ☐ Post-op ileus

☐ Other (please specify

☐ No indication documented ☐ Insufficient data

7. Was the PN administered for an appropriate indication? ☐ Yes ☐ No ☐ Unknown

If No please expand on your answer

8. Was there an unreasonable delay in recognising that the patient required PN? ☐ Yes ☐ No ☐ Unknown

If Yes please expand on your answer

9. Was there an unreasonable delay between the **decision** the patient required PN and the commencement of PN? ☐ Yes ☐ No ☐ Unknown

If Yes please expand on your answer

10. Was the PN started at a reasonable time of day? ☐ Yes ☐ No ☐ Unknown

11. Was there adequate nutritional and biochemical assessment of the patient prior to commencement of PN?

☐ Yes ☐ No ☐ Unknown

b. What was included?

☐ Clinical assessment
☐ Tricep circumference/skin fold thickness
☐ Biochemical review
☐ Grip strength
☐ Weight
☐ Pre Albumin
☐ Mid-arm circumference
☐ Other

12. What type of PN bag was first given?

☐ Multi-chamber bag ('Off the shelf')
☐ Multi-chamber bag ('Off the shelf') with additives e.g. vitamins or electrolytes
☐ Tailored bag

13. Was this type of PN bag appropriate for the patient's needs?

☐ Yes ☐ No ☐ Unknown

If No please expand on your answer

14. a Were the patient's PN requirements documented in the case notes? (Cal/Energy/Electrolyte/Fluid/Vitamins etc.)

☐ Yes ☐ No

14. b If Yes please were these of adequate detail?

☐ Yes ☐ No

14. c If No to 14b, what additional information should have been included?

15. Was the PN prescription documentation adequate for the nursing staff to commence the PN infusion?

☐ Yes No ☐ Unknown

16. a. Was a treatment goal for PN documented?

☐ Yes ☐ No

16. b. If Yes was it appropriate for the patient's needs?

☐ Yes ☐ No

16. c If No to 16b, please expand on your answer

17. a. Was there adequate monitoring of the patient during PN? ☐ Yes ☐ No

17. b. If No what were the deficiencies?

- ☐ Constitution of PN
- ☐ Tricep circumference/skin fold thickness
- ☐ Biochemical review
- ☐ Grip strength
- ☐ Glucose
- ☐ Vascular access
- ☐ Fluid balance
- ☐ Weight
- ☐ Mid-arm circumference
- ☐ Other ☐ (please specify)
- ☐ Clinical status

18. a. Following initiation of PN did the patient have clinical reviews of their underlying condition? ☐ Yes ☐ No ☐

18. b. If Yes was the frequency of reviews adequate? ☐ Yes ☐ No

18. c. If Yes were the number of senior reviews adequate? ☐ Yes ☐ No

19. a. Was the type of central venous catheter (CVC) documented in the case notes? ☐ Yes ☐ No ☐

19. b. If Yes was this appropriate? ☐ Yes ☐ No

19. c If No to 19b please expand on your answer

20. a. Was the site of insertion documented in the casenotes? ☐ Yes ☐ No

20. b. If Yes was this appropriate? ☐ Yes ☐ No

20. c If No to 20b please expand on your answer

21. a. Was insertion of the CVC performed by an appropriate healthcare professional? ☐ Yes ☐ No ☐ Unknown

21. b If No please expand on your answer

22. a. Was position of the CVC tip documented in the casenotes? ☐ Yes ☐ No ☐

22. b. Was the tip in an appropriate position? ☐ Yes ☐ No

23. a. Was the insertion of the CVC adequately documented in the case notes? ☐ Yes ☐ No ☐

23. b If No which details were missing

24. a. Is there evidence of inappropriate CVC care? ☐ Yes ☐ No ☐

24. b If Yes please expand on your answer

25. a. Is there evidence of the CVC (PN lumen) being used for purposes other than PN? ☐ Yes ☐ No ☐

25. b If Yes what other purposes was the line used for

26. a. Did the patient develop any CVC-related complications? ☐ Yes ☐ No ☐

26. b. If Yes which complications?

- ☐ Line misplacement
- ☐ Line fracture/rupture
- ☐ Suspected line infection
- ☐ Venous thrombosis
- ☐ Confirmed line infection
- ☐ Pneumothorax
- ☐ Phlebitis
- ☐ Haemothorax
- ☐ Accidental removal
- ☐ TPN-oma/extravasation
- ☐ Line occlusion
- ☐ Neuropraxia
- ☐ Other

26. c. Were any of the complications avoidable? ☐ Yes ☐ No ☐ Unknown ☐ NA

26. d If Yes please expand on your answer

26. e. Were the complications managed appropriately ☐ Yes ☐ No ☐ Unknown ☐ NA

26. e If No please expand on your answer

27. a. Did the patient develop any metabolic complications? ☐ Yes ☐ No

27. b. If Yes which complications?

- ☐ Hypophosphataemia (without re-feeding syndrome)
- ☐ Hyperphosphataemia
- ☐ Hypomagnesaemia
- ☐ Hypermagnesaemia
- ☐ Hypokalaemia
- ☐ Hyperkalaemia
- ☐ Hypoglycaemia
- ☐ Hyperglycaemia
- ☐ Hyponatremia
- ☐ Hypernatraemia

27. c. Were any of the complications avoidable? ☐ Yes ☐ No ☐ Unknown NA

27. d. If Yes please expand on your answer

27. e. Were the complications managed appropriately ☐ Yes ☐ No ☐ Unknown ☐ NA

27. f. If No please expand on your answer

28. a. Did the patient develop abnormal LTF's ☐ Yes ☐ No ☐ Unknown

28. b. If Yes, in your opinion was this related to overfeeding? ☐ Yes ☐ No ☐ Unknown

29. a. In your opinion was the patient at risk of re-feeding syndrome? ☐ Yes ☐ No ☐ Unknown

29. b. If Yes was this documented by the clinical team? ☐ Yes ☐ No ☐

29. c. If Yes to 29a, were adequate precautions taken to prevent re-feeding syndrome? ☐ Yes ☐ No ☐

29. d. If No please expand on your answer

29. d. Did re-feeding syndrome occur? ☐ Yes ☐ No

30. a. Were fluids given in addition to the PN? ☐ Yes ☐ No

30. b. If Yes was this for an appropriate indication? ☐ Yes ☐ No

30. c. If No to 30b please expand on your answer

30. d. If fluid was given, was the type given appropriate? ☐ Yes ☐ No ☐ NA

30. e. If No to 30d please expand on your answer

30. f. If fluid was given, was the volume given appropriate? ☐ Yes ☐ No ☐ NA

30. g. If No to 30f please expand on your answer

I. OVERALL CLINICAL ASSESSMENT

31. Overall assessment of care for this patient (please select one category only)

- ☐ Good practice - a standard of care you would expect from yourself, your trainees and your institution
- ☐ Room for improvement: aspects of **clinical** care that could have been better
- ☐ Room for improvement: aspects of **organisational** care that could have been better
- ☐ Room for improvement: aspects of **clinical and organisational** care that could have been better
- ☐ Less than satisfactory: several aspects of **clinical and/or organisational** care that were well below a standard that you would expect from yourself, your trainees and institution
- ☐ Insufficient data

Please provide reasons for assigning this grade:

Are there any particular issues which you feel should be highlighted in the final report? ☐ Yes ☐ No

If yes, please specify:

PARENTERAL NUTRITION STUDY

Investigation of Parenteral Nutrition – Aotearoa (IPNA)

ORGANISATIONAL QUESTIONNAIRE

CONFIDENTIAL

PLEASE COMPLETE ONE ORGANISATIONAL QUESTIONNAIRE FOR EACH HOSPITAL IN YOUR DISTRICT HEALTH BOARD THAT ADMINISTERS PARENTERAL NUTRITION TO INPATIENTS

Name of DHB: _____

Name of Hospital: _____

Name of IPNA Local Reporter: _____

Position of person(s) completing the questionnaire : _____

What is this study about?

This study will examine the process of care of patients of all ages who received parenteral nutrition as an inpatient between 1st January 2011 and June 30th 2011. The study aims to identify areas where the care of these patients might have been improved (remediable factors). All hospitals that admit both acute and elective admissions throughout New Zealand will be included in the study.

Who should complete this questionnaire?

This questionnaire should be completed by a person nominated who will have the knowledge to complete it accurately or be able to seek help to complete it accurately.

To ensure confidentiality of the data, completed questionnaires must be returned directly to Sue Larsen, North Shore Hospital, Waitemata District Health Board.

Please use the SAE provided.

How to complete this questionnaire

Information will be collected using two methods: Box cross and free text, where your clinical opinion will be requested.

Please use a black or blue pen. Please complete all questions with either block capitals or a bold cross inside the boxes provided e.g.

Does your hospital have a nutrition team?

☒ Yes ☐ No

If you make a mistake, please "black-out" the incorrect box and re-enter the correct information, e.g.

■ Yes ☒ No

Unless indicated, please mark only one box per question.

Questions or help

If you have any queries about the study or this questionnaire, please contact Sue Larsen at:

sue.larsen@waitematadhb.govt.nz

Telephone 09 486 8920

Thank you for taking the time to complete this questionnaire. The findings of the full study will be published in mid to late 2012.

						FOR STUDY USE ONLY

HOSPITAL WARDS

1. Please indicate which wards your hospital has.

(i) Adult Medical ☐ Yes ☐ No

(ii) Adult Surgical ☐ Yes ☐ No

(iii) Adult ICU ☐ Yes ☐ No

*If a combined medical/surgical ward please mark both medical and surgical

(iv) Paediatric Medical ☐ Yes ☐ No

(v) Paediatric Surgical ☐ Yes ☐ No

(vi) Paediatric ICU ☐ Yes ☐ No

(vii) Neonatal ICU/ Special Care Baby Unit) ☐ Yes ☐ No

2. a. How many PN bags were prescribed in the 2010-11 financial year? ☐☐☐☐☐☐

b. How many patients received PN as an inpatient in the 2010-11 financial year? ☐☐☐☐☐☐

A. ADULT PATIENTS

Please answer questions 3 - 15 with respect to ADULT PATIENTS. If your hospital does not admit adult patients please go to section B on page 4

PRESCRIPTION

3. a. Who decides on the composition of PN (please answer this for each type of adult ward your hospital has, answers may be multiple)?

	(i) Adult Medical	(ii) Adult Surgical	(iii) Adult ICU
Medical staff	☐	☐	☐
Dietitian	☐	☐	☐
Pharmacist	☐	☐	☐
Nutrition nurse specialist	☐	☐	☐
Other (please specify)			
b. Would the above person(s) usually belong to the nutrition team?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

4. a. Who signs the prescription for PN in your hospital (please answer this for each type of ward your hospital has, answers may be multiple)?

	(i) Adult Medical	(ii) Adult Surgical	(iii) Adult ICU
Medical staff	☐	☐	☐
Pharmacist	☐	☐	☐
Nutrition nurse specialist	☐	☐	☐
Dietitian	☐	☐	☐
Other (please specify)			
Other (please specify)			
b. Would the above person(s) usually belong to the nutrition team?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

MANUFACTURE AND SUPPLY

5. Where is PN prepared?

- ☐ On-site
- ☐ External pharmacy (another hospital)
- ☐ External manufacturer

6. If PN is ordered during normal working hours how quickly can your pharmacy/manufacturer supply PN (turn around time)?

- ☐ < 6 hours
- ☐ > 6 hours but the same day
- ☐ Next day

7. What time does PN need to be ordered to be received the same day?

☐☐ ☐☐ (h h m m) ☐ Not available same day

8. a. Can your pharmacy/manufacturer supply tailored bags/bags with additives? ☐ Yes ☐ No

b. If Yes can you order these bags: ☐ 7 days/week ☐ 5 days/week ☐ Other ☐

9. a. Is PN supplied to the ward via the on-site pharmacy? ☐ Yes ☐ No

b. Is a stock of PN maintained on any adult ward? ☐ Yes ☐ No

c. If Yes on which wards? ☐ Adult Medical ☐ Adult Surgical ☐ Adult ICU

d. If Yes to 9b, is a record of patients receiving PN maintained centrally (e.g. with pharmacy)? ☐ Yes ☐ No

10. Is there an auditable trail from product to patient? i.e. if there was a product recall would it be possible to trace the batch? ☐ Yes ☐ No

NUTRITION TEAMS

11. a. Does your hospital have a nutrition team for adult patients? ☐ Yes ☐ No

(If No please go to section B on page 4)

b. If Yes who is in this team?

Doctor (* Please see page 11 for codes)
- * specialty ☐☐☐
- * grade ☐☐☐☐

Doctor
- * specialty ☐☐☐
- * grade ☐☐☐☐

Doctor
- * specialty ☐☐☐
- * grade ☐☐☐☐

- Dietitian ☐
- Pharmacist ☐
- Nutrition nurse specialist ☐
- Other (please specify) ☐
- Other (please specify) ☐

12. a. How often does the nutrition team have an MDT meeting?

☐ Weekly ☐ Monthly

☐ Fortnightly ☐ Other _____

(please specify)

b. How often does the nutrition team undertake rounds?

☐ Daily (7 days/week) ☐ Weekly

☐ Daily (5 days/week) ☐ Other _____

(please specify)

13. What is the function of the nutrition team?

☐ Review only Enteral Nutrition referrals

☐ Review only Parenteral Nutrition referrals

☐ Review both Enteral and Parenteral Nutrition referrals

14. With respect to ordering and administering PN, does the nutrition team have:

☐ Complete autonomy (i.e. can say no to PN)

☐ Advisory role only

15. Is there an over arching nutrition steering group/forum involved in the development and ratification of nutritional guidelines?

☐ Yes ☐ No

B. PAEDIATRIC PATIENTS

Please answer questions 16 - 28 with respect to PAEDIATRIC PATIENTS. If your hospital does not admit Paediatric patients you do not need to complete section B. Please go to section C on page 7.

PRESCRIPTION

16. a. Who decides on the composition of PN (please answer this for each type of paediatric ward your hospital has, answers may be multiple)?

	(i) Paediatric Medical	(ii) Paediatric Surgical	(iii) Paediatric ICU
Medical staff	☐	☐	☐
Dietitian	☐	☐	☐
Pharmacist	☐	☐	☐
Nutrition nurse specialist	☐	☐	☐
Dietitian	☐	☐	☐
Other (please specify)			
b. Would the above person(s) usually belong to the nutrition team?	☐ Yes ☐ No	Yes ☐ No	☐ Yes ☐ No

17. a. Who signs the prescription for PN in your hospital (please answer this for each type of ward your hospital has, answers may be multiple)?

	(i) Paediatric Medical	(ii) Paediatric Surgical	(iii) Paediatric ICU
Medical staff	☐	☐	☐
Pharmacist	☐	☐	☐
Nutrition nurse specialist	☐	☐	☐
Other (please specify)	☐	☐	☐
Other (please specify)	☐	☐	☐
b. Would the above person(s) usually belong to the nutrition team?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

MANUFACTURE AND SUPPLY

18. Where is PN made?
- ☐ On-site
- ☐ External pharmacy (another hospital)
- ☐ External manufacturer

19. If PN is ordered during normal working hours how quickly can your pharmacy/manufacturer supply PN (turn around time)??
- ☐ < 6 hours
- ☐ > 6 hours but the same day
- ☐ Next day

20. What time does PN need to be ordered to be received the same day?
☐☐ ☐☐ (h h m m) ☐ not available same day

21. a. Can your pharmacy/manufacturer supply tailored bags/bags with additives? ☐ Yes ☐ No

b. If Yes can you order these bags: ☐ 7 days/week ☐ 5 days/week ☐ Other ☐

22. a. Is PN supplied to the ward via the on-site pharmacy? ☐ Yes ☐ No

b. Is a stock of PN maintained on any ward? ☐ Yes ☐ No

c. If Yes on which wards?
- ☐ Paediatric Medical
- ☐ Paediatric ICU
- ☐ Paediatric Surgical

d. If Yes to 22b, is a record of patients receiving PN maintained centrally (e.g. with pharmacy)? ☐ Yes ☐ No

23. Is there an auditable trail from product to patient? i.e. if there was a product recall would it be possible to trace the batch? ☐ Yes ☐ No

NUTRITION TEAMS

24. a. Does your hospital have a nutrition team for paediatric patients? ☐ Yes ☐ No

(If No please go to section C on page 7)

b. If Yes who is in this team?

Doctor (* Please see page 11 for codes)

* specialty ☐☐☐
* grade ☐☐☐☐

Doctor

* specialty ☐☐☐
* grade ☐☐☐☐

Doctor

* specialty ☐☐☐
* grade ☐☐☐☐

Dietitian ☐

Pharmacist ☐

Nutrition nurse specialist ☐

Other (please specify) ☐

Other (please specify) ☐

25. a. How often does the nutrition team have an MDT meeting?

☐ Weekly ☐ Monthly

☐ Fortnightly ☐ Other ☐

(please specify)

b. How often does the nutrition team undertake rounds?

☐ Daily (7 days/week) ☐ Weekly

☐ Daily (5 days/week) ☐ Other ☐

(please specify)

26. What is the function of the nutrition team?

☐ Review only Enteral Nutrition referrals

☐ Review only Parenteral Nutrition referrals

☐ Review both Enteral and Parenteral Nutrition refferals

27. With respect to ordering and administering PN, does the nutrition team have:

☐ Complete autonomy (i.e. can say no to PN)

☐ Advisory role only

28. Is there an over arching nutrition steering group/forum involved in the development and ratification of nutritional guidelines?

☐ Yes ☐ No

C. NEONATAL PATIENTS

Please answer questions 29 - 41 with respect to NEONATAL PATIENTS. If your hospital does not admit Neonatal patients you do not need to complete section C. Please go to section D on page 9

PRESCRIPTION

29. a. Who decides on the composition of PN on the neonatal ICU/Special Care Baby Unit ?

- ☐ Medical staff
- ☐ Dietitian
- ☐ Pharmacist
- ☐ Nutrition nurse specialist
- ☐ Other (please specify) _____
- ☐ Other (please specify) _____

b. Would the above person(s) usually belong to the nutrition team? ☐ Yes ☐ No

30. a. Who signs the prescription for PN in your neonatal ICU/Special Care Baby Unit ?

- ☐ Medical staff
- ☐ Pharmacist
- ☐ Nutrition nurse specialist
- ☐ Other (please specify) _____
- ☐ Other (please specify) _____

b. Would the above person(s) usually belong to the nutrition team? ☐ Yes ☐ No

MANUFACTURE AND SUPPLY

31. Where is PN made?

- ☐ On-site
- ☐ External pharmacy (another hospital)
- ☐ External manufacturer

32. If PN is ordered during normal working hours how quickly can your pharmacy/manufacturer supply PN (turn around time)?

- ☐ < 6 hours
- ☐ > 6 hours but the same day
- ☐ Next day

33. What time does PN need to be ordered to be received the same day? ☐☐ ☐☐ (h h m m) ☐ not available same day

34. a. Can your pharmacy/manufacturer supply tailored bags/bags with additives? ☐ Yes ☐ No

b. If Yes can you order these bags: ☐ 7 days/week ☐ 5 days/week ☐ Other _____

35. a. Is PN supplied to the ward via the on-site pharmacy? ☐ Yes ☐ No

b. Is a stock of PN maintained on the ward? ☐ Yes ☐ No

c. If Yes to 35b, is a record of patients receiving PN maintained centrally (e.g. with pharmacy)? ☐ Yes ☐ No

36. Is there an auditable trail from product to patient? i.e. if there was a product recall would it be possible to trace the batch?

☐ Yes ☐ No

NUTRITION TEAMS

37. a. Does your hospital have a nutrition team for neonatal patients?

☐ Yes ☐ No

(If No please go to section D on page 9)

b. If Yes who is in this team?

Doctor (* Please see page 11 for codes)

* specialty ☐☐☐

* grade ☐☐☐☐

Doctor

* specialty ☐☐☐

* grade ☐☐☐☐

Doctor

* specialty ☐☐☐

* grade ☐☐☐☐

Dietitian ☐

Pharmacist ☐

Nutrition nurse specialist ☐

Other (please specify) ☐

Other (please specify) ☐

38. a. How often does the nutrition team have an MDT meeting?

☐ Weekly ☐ Monthly

☐ Fortnightly ☐ Other ☐ (please specify)

b. How often does the nutrition team undertake rounds?

☐ Daily (7days/week) ☐ Weekly

☐ Daily (5 days/week) ☐ Other ☐ (please specify)

39. What is the function of the nutrition team?

☐ Review only Enteral Nutrition referrals

☐ Review only Parenteral Nutrition referrals

☐ Review all Nutrition referrals

40. With respect to ordering and administering PN, does the nutrition team have:

☐ Complete autonomy (i.e. can say no to PN)

☐ Advisory role only

41. Is there an over-arching nutrition steering group/forum involved in the development and ratification of nutritional guidelines?

☐ Yes ☐ No

D. PARENTERAL NUTRITION PRACTICE

Please answer all questions (42 - 52) in section D

42. Are there hospital guidelines for initiating PN? ☐ Yes ☐ No

43. Is there a written hospital policy for the changing of PN bags/line handling? ☐ Yes ☐ No

44. Are there specialist nutrition nurses within your hospital? ☐ Yes ☐ No

45. a. Are the ward nurses given specific training in the care of patients who require PN? ☐ Yes ☐ No

b. If Yes, are they based on: ☐ Specific wards ☐ Distributed across the hospital

46. Are there dedicated areas where PN is only allowed to be given? ☐ Yes ☐ No

47. a. Is there audit of PN practice within your hospital? ☐ Yes ☐ No

b. If Yes how often is this repeated? ☐

LINE INSERTION

48. Is there a hospital policy on insertion and clinical care of central venous catheters? ☐ Yes ☐ No

49. a. Do you have a dedicated CVC/PICC insertion service? ☐ Yes ☐ No

b. If Yes who runs this service? (answers may be multiple)

☐ Nurse based team ☐ Surgeons

☐ Radiologists ☐ Nutrition team

☐ Anaesthetists ☐ Other ☐

CATHETER RELATED BLOOD STREAM INFECTIONS

50. Is there a written hospital policy for the management of CVC infection? ☐ Yes ☐ No

51a If a catheter infection is suspected which of the following investigations are done? (answers may be multiple)

☐ CRP ☐ Pour plates

☐ FBC ☐ Tip of line sent for culture (quantitative culture)

☐ Peripheral blood cultures ☐ Automated blood culture

☐ Central blood cultures ☐ Other ☐

b. Is Catheter routinely removed on suspicion of line infection? ☐ Yes ☐ No

52. a. Is antibiotic prophylaxis used to prevent line infection during line insertion? ☐ Yes ☐ No

b. If Yes is this for: ☐ Percutaneous ☐ Open surgical ☐ Both

Thank you for completing this questionnaire - the findings of the study will be published in mid to late 2012

If needed please use this page for providing additional information (please indicate the question number a response relates to).

NATIONAL SPECIALTY CODES

100 = General Surgery
101 = Urology
103 = Breast Surgery
104 = Colorectal Surgery
105 = Hepatobiliary & Pancreatic Surgery
106 = Upper Gastrointestinal Surgery
107 = Vascular Surgery
110 = Trauma & Orthopaedics
120 = Ear, Nose & Throat (ENT)
130 = Ophthamology
140 = Oral Surgery
145 = Maxillo-Facial Surgery
150 = Neurosurgery
160 = Plastic Surgery
161 = Burns Care
170 = Cardiothoracic Surgery
172 = Cardiac Surgery
173 = Thoracic Surgery
180 = Accident & Emergency
190 = Anaesthetics
192 = Critical/Intensive Care Medicine

300 = General Medicine
301 = Gastroenterology
302 = Endocrinology
303 = Clinical Haematology
306 = Hepatology
307 = Diabetic Medicine
314 = Rehabilitation
315 = Palliative Medicine
320 = Cardiology
340 = Respiratory Medicine
350 = Infectious Diseases
352 = Tropical Medicine
360 = Genito-Urinary Medicine
361 = Nephrology
370 = Medical Oncology
400 = Neurology
410 = Rheumatology
430 = Geriatric Medicine
500 = Obstetrics & Gynaecology
501 = Obstetrics
502 = Gynaecology
800 = Clinical Oncology
810 = Radiology
820 = General Pathology
823 = Haematology

171 = Paediatric Surgery
211 = Paediatric Urology
212 = Paediatric Transplantation Surgery
213 = Paediatric Gastrointestinal Surgery
214 = Paediatric Trauma & Orthopaedics
215 = Paediatric Ear, Nose & Throat
217 = Paediatric Maxillo-Facial Surgery
218 = Paediatric Neurosurgery
220 = Paediatric Burns Care
221 = Paediatric Cardiac Surgery
222 = Paediatric Thoracic Surgery
242 = Paediatric Intensive Care
251 = Paediatric Gastroenterology
252 = Paediatric Endocrinology
253 = Paediatric Clinical Haematology
258 = Paediatric Respiratory Medicine
260 = Paediatric Medical Oncology
321 = Paediatric Cardiology
420 = Paediatrics
421 = Paediatric Neurology
422 = Neonatology

CLINICIAN GRADES

When completing the questionnaire please use the codes below for the relevant clinician grades

Consultant = CONS

Non Consultant Career Grade = NCCG

Staff and Associate Specialist = SAS

Trainee with completed certifcate of training = CCT

Senior specialist trainee (SpR 3+ or ST3+) = ST3

Junior specialist trainee (SpR 1&2 or ST 1&2) = ST2

Basic grade (FY, HO's, SHO's or CT's) = FY

Appendix 2 - Consent Form

Consent Form

Confirmation of consent to participate in this study should be obtained from the appropriate hospital managers. Please return in the SAE provided to the primary researcher.

LOCAL REPORTER

Name

Designation

Signature

Date

MANAGER'S SIGNATURES

Name

Designation

Signature

Date

Name

Designation

Signature

Date

Name

Designation

Signature

Date

Appendix 3 - Pediatric/Neonatal Data

(Clinician Questionnaires only)

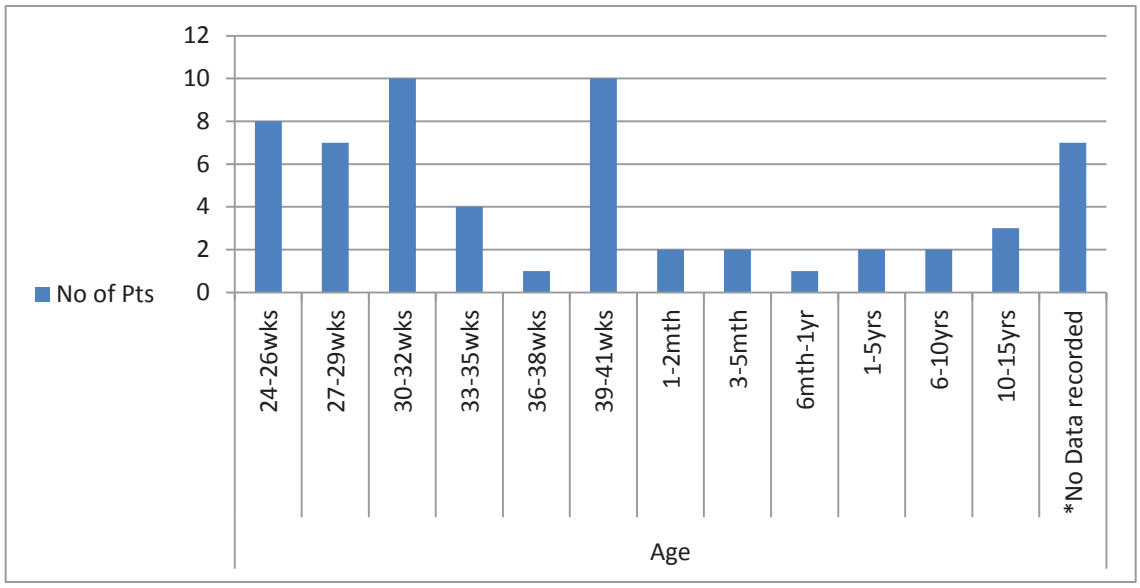

Figure 1.2.1 Age distribution of the paediatric/neonatal study population (at time of PN)

Table 1.2.1 Enteral feeding prior to commencing PN

Enteral feed	**Number of patients**	**%**
Yes	22	53.7
No	19	46.3
Total	**41**	
N/A	10	

Table 1.2.2 Assessment made prior to commencing PN

Assessment made	**Number of patients**
Yes	53
Unknown	2

Table 1.2.3 Type of ward where PN was administered

Type of ward	**Number of patients**	**%**
Paediatric Critical Care	8	14.5
Paediatric Surgical	4	7.3
Paediatric Medical	1	1.8
Paediatric Medical (Oncology)	2	3.6
Neonatal unit (SCBU)	39	71
NICU	1	1.8
Total	**55**	

Table 1.2.4 Level of ward on which PN was administered

Level of care	**Number of patients**	**%**
Level 3	38	76
Level 2	6	12
Level 1	6	12
Total	**50**	

Table 1.2.5 Indication for PN (answers may be multiple)

Indication for PN	**Number of patients**
Immaturity of GI function	27
Congenital anomalies: gut, ,	6
Congenital anomalies: non gut	2
Necrotizing enterocolitis	5
Non-functioning gut	3
Perforated/leaking gut	5
Post-operative ileus	5
Obstruction	1

Post-surgical complications	4
Failure of enteral nutrition	1
Chemotherapy	2
Fistulae	1
Infection	1

Table 1.2.6 Designation of the person responsible for making the decision to start PN

Designation	**Number of patients**
Doctor	20
Doctor, Dietitian	2
Doctor, Dietitian, Pharmacist	1
Doctor, Nurse	13
Nurse	4
Total	**40**
Unknown	15

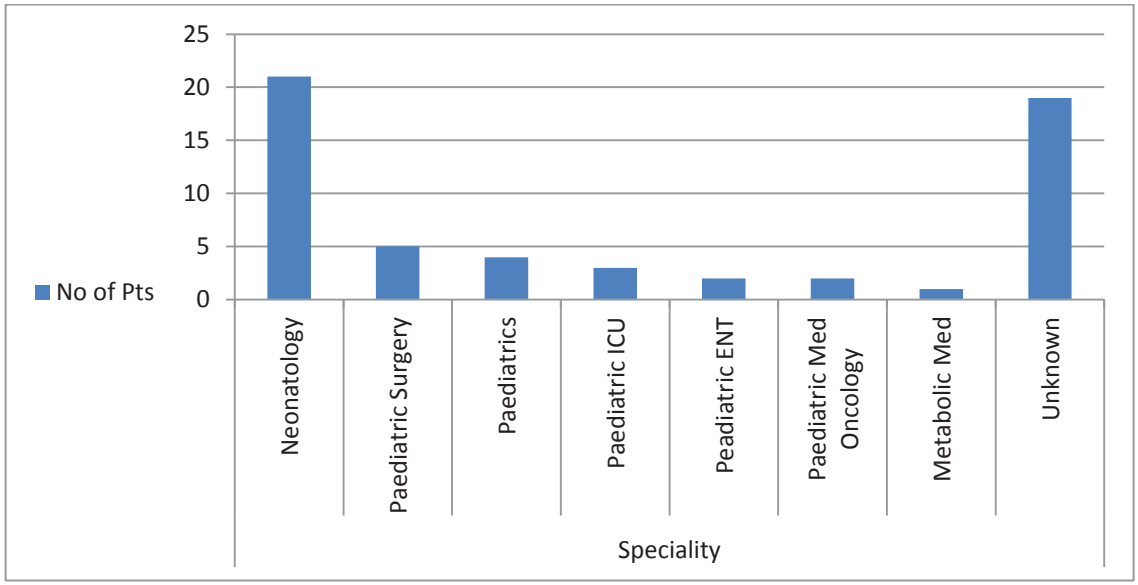

Figure 1.2.2 Specialty of doctor making the decision to commence PN

Table 1.2.7 Grade of doctor making the decision to commence PN

Grade of doctor	**Number of patients**	**%**
Consultant	20	74.1
Fellow	2	7.4
ST3 (Senior trainee)	4	14.8
ST2 (Junior trainee)	1	3.7
Total	**27**	
Unknown	5	

Table 1.2.8 Time between decision to start PN and its commencement

Time	**Number of patients**	**%**
0-1hr	13	42
<1-6 hours	8	25.8
<1day	9	29
<2day	1	3.2
Total	**31**	
Unknown	22	

Table 1.2.9 Specialty of doctor determining the patient's nutritional requirements

Speciality of doctor	**Number of patients**
Neonatology	18
Paediatric surgery	5
Paediatric ICU	4
Paediatrics	4
Paediatric Med Oncology/Paediatric Gastroenterology	1

Total	**32**	

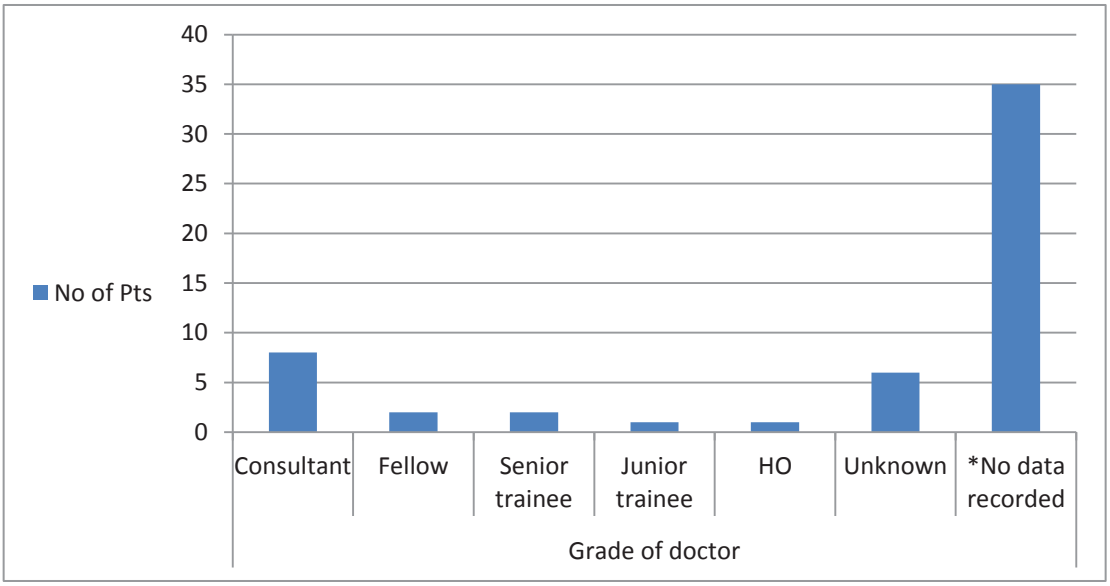

Figure 1.2.3 Grade of doctor determining the patients' nutritional requirements

Table 1.2.10 Specialty of doctor signing the prescription

Speciality of doctor	**Number of patients**	**%**
Neonatology	12	48
Paediatric surgery	4	16
Paediatrics	4	16
Paediatric ICU	2	8
Paediatric medical oncology	2	8
Paediatric gastroenterology	1	4
Total	**25**	

Table 1.2.11 Grade of doctor signing the prescription

Grade of doctor	**Number of patients**
Consultant	3
Fellow	1
ST3 (Senior trainee)	3
ST2 (Junior trainee)	1
HO	1

Total	**9**
Unknown	3

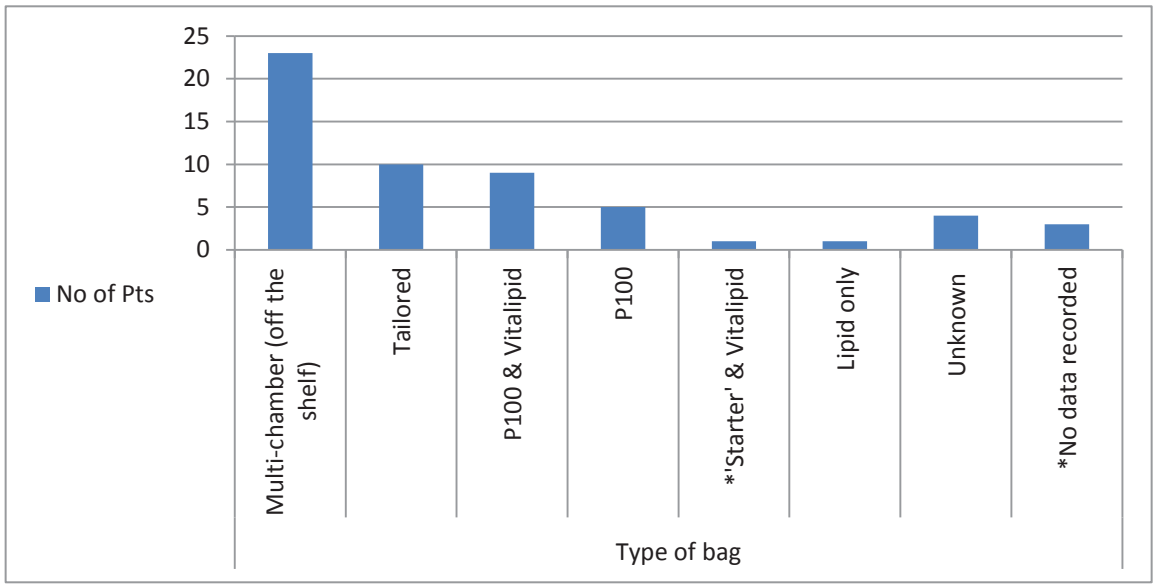

Figure 1.2.4 Type of PN first administered

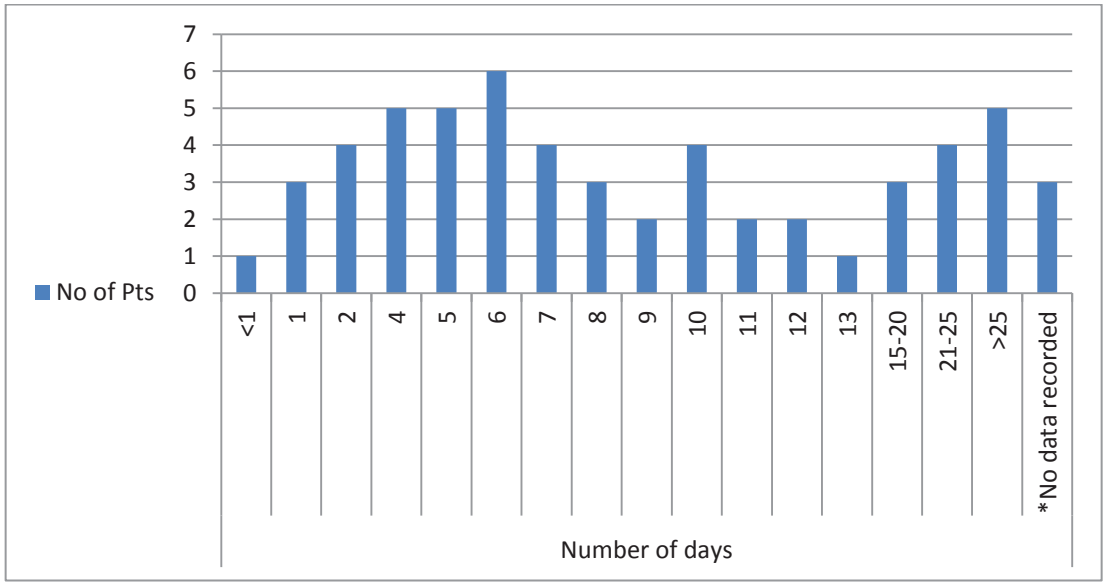

Figure 1.2.5 Number of days for which PN was received

Table 1.2.12 Patient outcome

Patient outcome	**Number of patients**	**%**
Weaned onto oral/enteral feeding	21	38.9
Weaned onto oral/enteral feeding, transferred to other unit	4	7.4
Weaned onto oral/enteral feeding, Discharged home	6	11.1
Weaned onto oral/enteral feeding, Died during hospital stay	2	3.7
Transfer to other unit	4	7.4
Transferred to other unit/Died during hospital stay	1	1.9
Died during hospital stay	3	5.6

Discharged home	13	24
Total	**54**	

Table 1.2.13 Evidence of metabolic complications

Metabolic complications	**Number of patients**	**%**
Yes	18	40
No	27	60
Total	**45**	
Unknown	3	

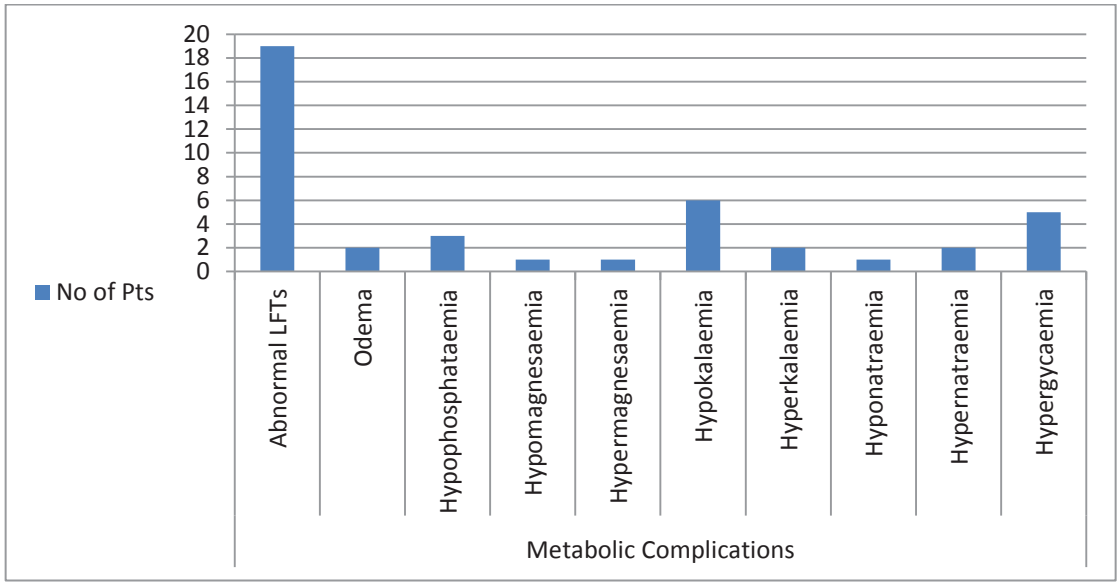

Figure 1.2.6 Types of metabolic complication (answers may be multiple)

Table 1.2.14 Evidence of additional types of fluids

Fluids given	**Number of patients**	**%**
Yes	33	63.5
No	19	36.5
Total	**52**	
Unknown	1	

Table 1.2.15 Initial mode of PN

PN delivery	**Number of**	**%**
Umbilical vein	21	41.2
Peripherally inserted central catheter	13	25.5
Centrally inserted venous catheter	10	19.6
Peripheral venous catheter	6	11.8
Implanted (e.g. portacath)	1	2
Total	**51**	
Unknown	2	

Table 1.2.16 Initial type of PN catheter

Type of catheter	Number of patients	%
Multi-lumen	21	55.3
Multi-lumen uncuffed	4	10.5
Single Lumen	13	34.2
Total	**38**	
Unknown	3	

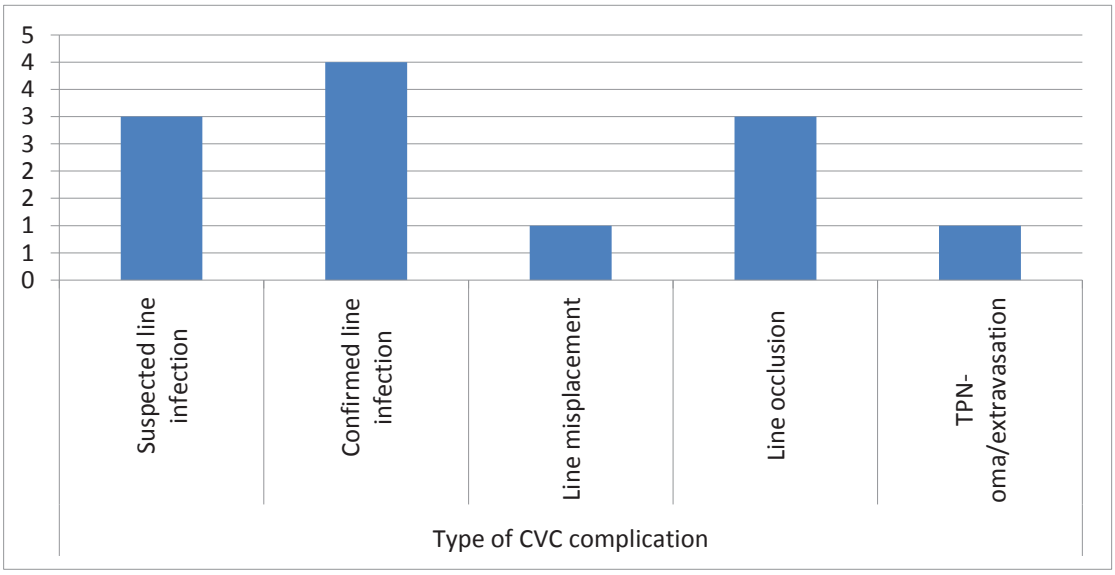

Figure 1.2.7 CVC complications

Appendix 4 - Ethical Approval

Health and Disability Ethics Committees

Northern X Regional Ethics Committee
c/- Ministry of Health
650 Great South Rd
Penrose
Auckland
Phone: (09) 580 9105
Email: northernx_ethicscommittee@moh.govt.nz

16 September 2011

Sue Larsen
North Shore Hospital
Shakespeare Road
Takapuna
AUCKLAND

Dear Sue

Ethics ref:	**NTX/11/EXP/218** (please quote in all correspondence)
Study title:	Investigation of parenteral nutrition - Aotearoa (IPNA)
Principal investigator:	Sue Larsen
Co-investigator:	Dr Russell Walmsley
Supervisor:	Dr Stephen Neville

Thank you for your application received 16 September 2011. This study was given ethical approval by the Chairperson of the Northern X Regional Ethics Committee on 16 September 2011.

Approved Documents

- Study Protocol [Draft Version one, undated, received 16/09/11]

This approval is valid until 30 October 2014, provided that Annual Progress Reports are submitted (see below).

Amendments and Protocol Deviations

All significant amendments to this proposal must receive prior approval from the Committee. Significant amendments include (but are not limited to) changes to:

- the researcher responsible for the conduct of the study at a study site
- the addition of an extra study site
- the design or duration of the study
- the method of recruitment
- information sheets and informed consent procedures.

Significant deviations from the approved protocol must be reported to the Committee as soon as possible.

Annual Progress Reports and Final Reports

The first Annual Progress Report for this study is due to the Committee by 16 September 2012. The Annual Report Form that should be used is available at www.ethicscommittees.health.govt.nz. Please note that if you do not provide a progress report by this date, ethical approval may be withdrawn.

A Final Report is also required at the conclusion of the study. The Final Report Form is also available at www.ethicscommittees.health.govt.nz.