# IMPROVING PRACTICE AND REDUCING RISK IN THE PROVISION OF PARENTERAL NUTRITION FOR NEONATES & CHILDREN

# A REPORT FROM THE PAEDIATRIC CHIEF PHARMACISTS GROUP

November 2011

Endorsed by:





# IMPROVING PRACTICE AND REDUCING RISK IN THE PROVISION OF PARENTERAL NUTRITION FOR NEONATES & CHILDREN:

# Report from the Paediatric Chief Pharmacists Group 2011

# **Foreword**

Parenteral Nutrition (PN) is a vital part of the care of patients who are unable to eat or absorb adequate nutrition from the GI tract, but it is fraught with potential complications. Following some serious incidents, the Chief Pharmacists from specialist children's hospitals (the Paediatric Chief Pharmacists Group) were asked by the four UK Chief Pharmaceutical Officers to scope current practice across the UK and to make recommendations to improve practice and reduce risks in the provision of PN for neonates and children.

All acute hospitals in the UK were asked to provide information on, and insights into, the whole pathway of care (from initiation and prescribing, through preparation to administration and monitoring) for their PN patients. This work provided powerful data, which enabled technical and clinical reference groups to make recommendations for the service, health departments, industry, professional bodies, academia and legislators. It has also been agreed to produce a good practice guide/standards document based on this report.

Since this report was prepared the results of the first national observational study on PN ever carried out in the UK in a report by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) has been published This report found very similar concerns and issues in the prescribing and administration of PN as our exercise One common theme in both reports was the unnecessary variation in neonatal PN practice between units, particularly for extremely low birth weight neonates. Obtaining a greater consensus in best PN neonatal practice should be a priority for all those involved in the care of this group of patients. Greater use of standardised PN solutions has an important role to play in facilitating change in practice and maintaining capacity to provide PN within the NHS.

This report looks to put some detail into the issues from an NHS perspective and to try to define the minimum standards required to deliver PN following review of the literature and professional judgement on best practice. It looks at the whole pathway of care for a PN patient and the issues from a clinical and technical point of view.

I would like to thank the four UK Chief Pharmaceutical Officers for their encouragement and support and the very many individuals who contributed to this report and who are named elsewhere.

Anthony Sinclair Chairman Paediatric Chief Pharmacists Group

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# **Executive Summary**

# Background

Nutritional support is a fundamental element of care for many infants and children with a great variety of medical and surgical diagnoses. When nutritional requirements cannot be met using the gastrointestinal tract (enteral nutrition), nutrients must be given intravenously as parenteral nutrition (PN). The clinical and nutritional need for PN requires careful assessment; any decision to start PN will depend on the underlying clinical condition and nutritional status of the patient.

Prescribing, compounding and administration of PN are tasks that demand meticulous planning, effective communication and a breadth of specialist expertise from multidisciplinary teams of doctors, pharmacists and other members of the pharmacy team, dietitians, nurses and clinical scientists. Every stage of the process carries risks, and although large numbers of patients are fed intravenously without adverse events every year, occasionally serious incidents have occurred, some of which have resulted in patient deaths.

The Chief Pharmacists from specialist children's hospitals (the Paediatric Chief Pharmacists Group) were asked by the UK Chief Pharmaceutical Officers to review the current provision of PN for neonates and children in the UK and to prepare guidance to support safe and effective practice in this important area of clinical work.

The purpose of this report is to promote the safety and effectiveness of PN provision, and to clarify (and where possible simplify) the complicated pathway of events that begins with a decision to feed a patient intravenously and ends with the infusion of nutrients directly into the circulation.

It should be noted that this report has been written to apply across the whole UK. The term "Chief Pharmacist" is therefore used as a generic description for senior pharmacy manager and "Hospital" for Health Boards and NHS Trusts

The Paediatric Chief pharmacists assembled a multi-disciplinary project team and two reference groups (technical and clinical) to oversee this work and to assess the evidence collected in three national surveys of current parenteral nutrition provision across the UK. The following recommendations have been made.

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# What Must the Hospital Executive Group Do?

- Produce a corporate parenteral nutrition capacity plan. The capacity plan must include a risk assessment of all processes and practices associated with Parenteral Nutrition therapy and the procedure to be followed if demand exceeds the agreed capacity [Recommendation 1]
- Agree the corporate parenteral nutrition capacity plan and facilitate its execution and delivery by all stakeholders [Recommendation 3]
- Ensure activity is reviewed annually against the parenteral nutrition capacity plan. Where the Pharmacy Aseptic Unit routinely operates at or above 90% of their planned capacity hospitals should consider whether any additional measures are needed to assure product quality and patient safety both within the Pharmacy and on the wards. These may include increased staffing, use of a validated, automated compounding device or outsourcing all or part of the workload [Recommendation 4]
- Ensure a risk assessment is carried out and alternative service provision considered if
  the parenteral nutrition workload is not sufficient for the Hospital Executive Group to be
  assured that all staff achieve and maintain competence in their respective roles. This
  includes both the initiation of parenteral nutrition and acceptance of patients already
  receiving parenteral nutrition [Recommendation 5]
- Ensure that staff are trained to meet a local set of competencies that relate to their role in the provision of parenteral nutrition. Hospitals **must** hold training records, which demonstrate this competence of those individuals involved in the process [Recommendation 6]
- Ensure that all children on parenteral nutrition have access to a competent multidisciplinary team with a minimum composition of doctor, pharmacist, nurse and dietitian [Recommendation 8]
- Ensure all decisions to initiate parenteral nutrition are made by a senior clinician [Recommendation 9]
- Ensure that a standardised request form for parenteral nutrition is used such that there is a controlled, validated system of documentation [Recommendation 12]
- Ensure there are agreed guidelines in place for the provision of parenteral nutrition based on and referenced to published evidence and/or guidelines which are ratified by their Clinical Governance Committee who agree any significant deviations [Recommendation 15]
- Ensure that a yearly review of the clinical guidelines for the provision of parenteral nutrition is carried out to ensure guidelines are regularly updated and take into account the accumulation of any new data [Recommendation 16]

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- Ensure that nursing staff perform a final safety check at the point of administration of parenteral nutrition which includes checking the labels of parenteral nutrition solutions against the request form for:
  - o Name of patient and identifying number
  - o Route of administration (central or peripheral)
  - Date for infusion
  - o Rate of infusion
  - Expiry date
  - o Appearance of the parenteral nutrition solutions

and that any additional checks requested are practical and clearly defined in local policy guidelines [Recommendation 22]

- Ensure clinicians record any change in infusion rate, from that originally stated on the label of the parenteral nutrition solution, on the patient's prescription chart [Recommendation 23]
- Have agreed written guidelines for biochemical monitoring which take account of length of time on parenteral nutrition, prematurity, co-morbidities and other medicines [Recommendation 24]
- Ensure that clinical guidelines for biochemical monitoring identify who is responsible for reviewing results and taking appropriate action when abnormal values are observed [Recommendation 25]
- Ensure additions to parenteral nutrition solutions (aqueous or lipid phase) contained in infusion bags and/or syringes are only made in a Pharmacy Aseptic Unit [Recommendation 26]
- Ensure that there are arrangements for the provision of parenteral nutrition when the Pharmacy Aseptic Unit is closed and that ward based preparation or additional manipulation of parenteral nutrition components does not occur [Recommendation 27]
- Ensure that PN is quality assured to the same standards regardless of scale or whether it is prepared under a Section 10 exemption or prepared under a Manufacturers Specials Licence [Recommendation 28]
- Ensure there are written guidelines for the alternative administration of vitamins or other micro-nutrients contained within the lipid phase of parenteral nutrition, when lipid administration is interrupted [Recommendation 45]

# What Should the Hospital Executive Group Do?

- Ensure the clinician accountable for deciding on nutrient needs and parenteral nutrition formulation also signs the prescription [Recommendation 11]
- Ensure that electronic prescribing and medicines administration and/or pharmacy compounding systems are used to prescribe and/or order parenteral nutrition in order

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to eliminate transcription errors and provide legible, accurate and complete patient medication and/or dispensing records [Recommendation 13]

- Give due regard to the risks of repetitive strain injury (RSI) if their pharmacy staff are
  routinely preparing parenteral nutrition solutions manually. Where a risk is identified,
  outsourcing and/or automation should be considered [Recommendation 36]
- Ensure that in-line filters are used in accordance with published British Parenteral Nutrition Group (BPNG) guidance [Recommendation 55]

#### What Must the Chief Pharmacist Do?

- Help the hospital executive group produce a corporate parenteral nutrition capacity
  plan. The capacity plan must include a risk assessment of all processes and practices
  associated with parenteral nutrition therapy and the procedure to be followed if
  demand exceeds the agreed capacity [Recommendation 1]
- Ensure that the parenteral nutrition capacity plan clearly identifies safe limits of parenteral nutrition compounding workload and steps to be taken if these limits seem likely to be exceeded. This **must** be set in the context of the overall aseptic services capacity management plan. Significant outstanding or unmanaged risks must be documented in the Hospital's risk register [Recommendation 2]
- Ensure that whenever the formulation of parenteral nutrition has been changed within
  the Pharmacy Aseptic Unit, a pharmacist familiar with parenteral nutrition carries out a
  final clinical validation of the amended regimen, discusses any changes with the
  prescriber if necessary and ensures they are recorded in the prescription
  [Recommendation 14]
- Ensure that the hospital's prescribing policy mandates the use of standard parenteral nutrition solutions in preference to individualised parenteral nutrition solutions whenever it is clinically appropriate [Recommendation 19]
- Agree locally the maximum concentration of glucose that can be infused in peripheral veins and must ensure the Pharmacy Aseptic Unit's labels all parenteral nutrition solutions which contain glucose solutions in excess of this 'to be given by central line only' [Recommendation 20]
- Ensure the development and implementation of an action plan to eliminate handwritten documentation and minimise the use of pre-printed and photocopied worksheets [Recommendation 29]
- Ensure that software used in the Pharmacy Aseptic Unit to produce documentation and labels is validated according to standards specified within The Guide to Good Manufacturing Practice (GMP) [Recommendation 30]
- Ensure that the Pharmacy Aseptic Unit lists all ingredients on the master worksheet in a logical order which follows the sequence of the compounding process to facilitate checking and reconciliation of ingredients used [Recommendation 31]

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- Ensure that appropriate training is provided for all staff involved in the compounding process. This must include training in the use of compounding devices where used [Recommendation 32]
- Ensure the Pharmacy Aseptic Units reviews the range of ingredients held as stock. The Pharmacy Aseptic Unit **must** be able to justify the use of more than one strength or salt of the same electrolyte and if clinically appropriate, use must be subject to a risk assessment [Recommendation 37]
- Ensure the Pharmacy Aseptic Unit carries out pre-process checks including as a minimum worksheet, formula, ingredients, disposables and label details [Recommendation 38]
- Ensure the Pharmacy Aseptic Unit carries out checks at critical stages of the compounding process and that the roles of 'operator' and 'checker' are always clearly separated and understood [Recommendation 39]
- Ensure the Pharmacy Aseptic Unit carries out a range of final product checks to
  assure the quality of the product. As a minimum this **must** include reconciliation of
  ingredients, physical check on parenteral nutrition solutions (particulates, precipitation,
  and integrity), weight check and full documentation checking including labelling
  [Recommendation 40]
- Ensure that all staff undertaking checking activities have been formally authorised to do so via an accreditation process which complies with the principles of the National Frameworks for Pre-, In-Process- and Final Technical Checks in NHS Aseptic Services [Recommendation 42]
- Ensure that the Pharmacy only purchases unlicensed parenteral nutrition from a supplier approved by an NHS Pharmaceutical QA pharmacist [Recommendation 51]
- Ensure the Pharmacy Aseptic Unit records and reports errors that occur at any stage
  of the preparation process according to local hospital procedures [Recommendation
  57]
- Ensure the Pharmacy Aseptic Unit carries out regular reviews of error trends and has an effective recording and review system which will ensure corrective and preventative actions are taken in response to incidents and non conformances [Recommendation 58]
- Ensure that the Pharmacy Aseptic Unit contributes data to the National Aseptic Error Reporting Scheme [Recommendation 59]

#### What Should the Chief Pharmacist Do?

Ensure that when parenteral nutrition solutions are made individually or when additions
are made to individualise standard parenteral nutrition solutions in the Pharmacy
Aseptic Unit, ingredients are not shared between parenteral nutrition solutions unless
accurate reconciliation of ingredients supplied against ingredients used for each
parenteral solution can be assured [Recommendation 34]

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- Use the annual risk assessment of their parenteral nutrition service to help identify local training needs [Recommendation 49]
- Ensure that the Pharmacy Aseptic Unit only dispenses parenteral nutrition solutions compounded under Section 10 exemption to external customers only if it is part of a registered Pharmacy on a small scale and infrequent basis [Recommendation 53]

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# **Recommendation Checklist for External Organisations**

# British Association of Parenteral and Enteral Nutrition (BAPEN)

 A multi disciplinary body such as the British Association of Parenteral and Enteral Nutrition (BAPEN) should lead the preparation of a minimum set of competencies for the various disciplines involved in the provision of parenteral nutrition [Recommendation 7]

# National Advisory Board for NHS Hospitals' Medicines Manufacturing and Preparative Services (NAB)

- NAB must investigate the feasibility of end product testing before or during the early stages of administration with or without early patient monitoring [Recommendation 41]
- The NAB and appropriate NHS Pharmaceutical Committees must initiate a
  programme of work to scope the requirement and agree standards for stability data to
  support the provision of PN and make recommendations to Chief Pharmacists and the
  UK Health departments (UKHD) [Recommendation 46]
- The NAB should work with NHS Pharmacy Education & Development Committee and Higher Education Institutions to further develop current initiatives to enhance the education and training for the specialist technical services workforce [Recommendation 48]
- The NAB **should** be asked to provide guidance for hospitals on acceptable activity limits to ensure that Pharmacy Aseptic Units only dispense parenteral nutrition solutions compounded under Section 10 exemption to external customers on a small scale and infrequent basis [Recommendation 52]
- The NAB **should** consider the introduction of a needleless connector, which would result in a much more secure connection than the traditional "spike" systems [Recommendation 56]

# National Pharmaceutical Quality Assurance Committee (NPQAC)

- The NPQAC **must** develop comprehensive guidance on validation and maintenance of compounding devices [**Recommendation 33**]
- The NPQAC **must** define the quality standards to be applied when unlicensed parenteral nutrition is purchased **[Recommendation 50]**
- The NPQAC must make recommendations and/or commission research on the practice of attaching giving sets to parenteral nutrition solutions in the Pharmacy Aseptic Unit [Recommendation 54]

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# National Pharmaceutical Supplies Group (NPSG)

 The NPSG should work with the pharmaceutical industry to ensure that products are available in pack sizes and concentrations which simplify compounding and minimise risk [Recommendation 35]

# Neonatal and Paediatric Pharmacists Group (NPPG) and Royal College of Paediatrics and Child Health (RCPCH)

- The NPPG and RCPCH **should** work together to facilitate the development of a national consensus for parenteral nutrition requirements for neonates and children through a UK prospective registry of all treated patients **[Recommendation 17]**
- The NPPG and RCPCH should develop research proposals for clinical trials to improve the treatment of neonates and children with parenteral nutrition. The proposals should be presented to the UK Coordinating Centre for the Medicines for Children Research network for consideration [Recommendation 18]
- The NPPG and RCPCH should develop research proposals for establishing the factors affecting peripheral line life, patency and risks when parenteral nutrition is administered and issue best practice guidance based on the outcomes [Recommendation 21]

# Pharmaceutical Industry (PI)

- The pharmaceutical industry **should** work together with multi-disciplinary experts in the field of children's parenteral nutrition to develop a range of licensed standard parenteral nutrition solutions that will meet the requirements of children of all ages [Recommendation 43]
- The pharmaceutical industry should investigate the feasibility of including trace elements and vitamins into licensed standard parenteral nutrition solutions and explore ways of maximising shelf life [Recommendation 44]

## United Kingdom Health Departments (UKHD)

- The UKHD **should** initiate changes in legislation to allow the prescribing of parenteral nutrition by independent non-medical prescribers<sup>1</sup> [**Recommendation 10**]
- The UKHD must ensure there is a career structure and sufficient capacity to ensure the continued provision of pharmacy aseptic services [Recommendation 47]

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<sup>&</sup>lt;sup>1</sup> Since drafting this report the MHRA has amended medicines legislation which address the prescribing issues relating to mixing and combining medicines: Mixing of medicines prior to administration in clinical practice: medical and non-medical prescribing guidance (Gateway ref. 14330, May 2010).

# **Background and Introduction**

## **Background**

Nutritional support is a fundamental element of care for many infants and children with a great variety of medical and surgical diagnoses. When nutritional requirements cannot be met, using the gastrointestinal tract (enteral nutrition), nutrients must be given intravenously as parenteral nutrition (PN). The clinical and nutritional need for PN requires careful assessment; any decision to start PN will depend on the underlying clinical condition and nutritional status of the patient.

Prescribing, compounding and administration of PN are tasks that demand meticulous planning, effective communication and a breadth of specialist expertise from multidisciplinary teams of doctors, pharmacists and other members of the pharmacy team, dieticians, nurses and clinical scientists. Every stage of the process carries risks, and although large numbers of patients are fed intravenously without adverse events every year, occasionally serious incidents have occurred, some of which have resulted in patient deaths.

The Chief Pharmacists from specialist children's hospitals (the Paediatric Chief Pharmacists Group) were asked by the UK Chief Pharmaceutical Officers to review the current provision of PN for neonates and children in the UK and to prepare guidance to support safe and effective practice in this important area of clinical work.

#### Introduction

Successful long term PN in an infant with short bowel syndrome was first described by Wilmore and Dudrick in 1968. Since then provision of PN for children has become widespread practice in hospitals across the UK. PN also plays a key role in the management of the extremely premature newborn with minimal nutritional reserve at birth and an immaturity of gastrointestinal function precluding full enteral feeding until adaptation to postnatal life has occurred.

Across the whole paediatric age range, PN may be used when it is not feasible to meet nutritional needs by the enteral route alone. This includes children with conditions such as inflammatory bowel disease, malignancy, abdominal trauma, post-operative ileus and those requiring intensive care. In some circumstances, such as long-term intestinal failure, PN is a life saving intervention.

As with any medical and technical intervention, PN is associated with a risk of adverse consequences. Most commonly, these include central venous catheter related bloodstream infection, metabolic imbalance and intestinal failure associated liver disease, together with complications of intravenous cannulation (e.g. phlebitis, thrombosis, catheter malposition, blockage, fracture or accidental removal). PN is a complex therapy and consequently medication errors remain an additional important hazard. In the current state of our knowledge, such risks can be minimised but not completely eliminated.

Preparation of PN solutions is a complex process undertaken in pharmacy aseptic units (PAUs) and requiring the formulation of a wide range of ingredients including both macrosolutions (amino acids, glucose, electrolytes and water) and micro-solutions (vitamins and trace elements) into stable, sterile solutions. Formulations need to meet the needs of individual patients ranging from 500g to 50kg or more in weight and with a variety of Improving practice and reducing risk in the provision of parenteral nutrition for neonates and children: Report of the Paediatric Chief Pharmacists Group

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complicating medical conditions. The daily challenge is to achieve the best possible fit of ingredients into the available fluid volume for any individual patient.

Many prescriptions represent a careful compromise between meeting nutritional goals in full within the limitations imposed by stability constraints and the patient's clinical status. Unlike PN for adult patients, all-in-one fat emulsion containing preparations are rarely used in younger children or infants, mainly because of stability problems. Technological innovations such as prescribing software and automated compounding systems are available to aid the compounding process within aseptic units and rigorous quality assurance systems are the key to their safe operation.

Rationalisation and standardisation, as far as is possible, of the content of individual PN solutions have an important part to play in simplifying both the prescribing and compounding processes for those patients where it is appropriate. In addition standardisation may also allow preparation of PN solutions in advance, facilitating end-product testing and quality assurance by the supplier, whether a hospital pharmacy or commercial manufacturer. This is only one of many factors, which may contribute to improved risk management of the PN process.

Organisation and management of PN services must therefore include a critical approach to planning and implementation that seeks to reduce risk at every stage in the process -from initial assessment of clinical need through prescribing, compounding, administration and monitoring.

The purpose of this report is to promote the safety and effectiveness of PN provision, and to clarify (and where possible simplify) the complicated pathway of events that begins with a decision to feed a patient intravenously and ends with the infusion of nutrients directly into the circulation.

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# **Project governance and methods**

# **Project Governance**

This work was overseen by a Multi-disciplinary Project Team and informed by two specialist reference Groups advising on clinical and technical aspects of the provision of parenteral nutrition (PN) to neonates and children. Details of the membership of the governance groups for the work are provided in Annex 1.

#### Methods

To assist and inform the project team and reference groups the following approaches to evidence gathering were undertaken.

#### Literature review

Professor Wong et al (Centre for Paediatric Pharmacy Research, The School of Pharmacy, University of London) undertook a literature search to identify the available published clinical evidence comparing the use of individualised and standard PN solutions in neonates and children.

# Surveys

Three surveys were conducted in hospitals across the UK using pre-piloted web based questionnaires:

Survey 1: Background Survey

Sent to all UK hospitals with a 96% response rate and generated information about provision of PN to neonates and children in each hospital and capacity planning where PN was provided.

Survey 2: Clinical Survey

Sent to all UK hospitals providing PN services for neonates and children with a response rate of 78% neonates and 81% children, generated information about numbers of patients treated; availability of specialist nutrition teams; processes for initiating and prescribing PN; interface with the pharmacy team; use of clinical guidelines and processes for administering and monitoring PN.

Survey 3: Technical Survey

Sent to all UK hospitals involved in the compounding and supply of PN for neonates and children with a response rate of 82% generated information about the compounding process, documentation, quality control; workload and use of individualised and standardised PN solutions and making additions of vitamins, trace elements and electrolytes.

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Having analysed the results from the surveys and literature review the Project Team made a number of recommendations under three headings:

- General Guidance (Page 4)Clinical Guidance (Pages 6)
- Technical Guidance (Pages 12)

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#### **General Guidance**

# Capacity Planning

Monitoring and management of the PN workload within a hospital is very important. If demand is unmanaged and allowed to exceed the capacity, which the nutritional support service was designed and resourced to provide, the risk of harm to patients as a result of errors, become more likely. Whilst management of the service capacity of the PAU may be considered the responsibility of the Chief Pharmacist, effective management of the overall demand for PN solutions needs input from a wide range of stakeholders and should be seen as part of a hospital's corporate responsibility for patient safety.

The availability of adequate numbers of competent individuals is the key element of any capacity plan. Hospitals must hold training records, which demonstrate the competence of those individuals involved in the process.

Hospital PAUs have, for many years, been required to formally assess their capacity and to document systems for monitoring workload. If workload threatens to exceed "safe" levels, predetermined steps should be taken to increase capacity or reduce demand.

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- 1. The Hospital Executive Group and Chief Pharmacist **must** produce a corporate PN capacity plan. The capacity plan **must** include a risk assessment of all processes and practices associated with PN therapy and the procedure to be followed if demand exceeds the agreed capacity.
- 2. The Chief Pharmacist **must** ensure that the PN capacity plan clearly identifies safe limits of PN compounding workload and steps to be taken if these limits seem likely to be exceeded. This **must** be set in the context of the overall aseptic services capacity management plan. Significant outstanding or unmanaged risks **must** be documented in the Hospital's risk register.
- 3. The Hospital Executive Group **must** agree the corporate PN capacity plan and facilitate its execution and delivery by all stakeholders.
- 4. The Hospital Executive Group **must** ensure activity is reviewed annually against the PN capacity plan. Where the PAU routinely operates at or above 90% of their planned capacity hospitals should consider whether any additional measures are needed to assure product quality and patient safety both within the Pharmacy and on the wards. These may include increased staffing, use of a validated, automated compounding device or outsourcing all or part of the workload
- 5. The Hospital Executive Group **must** ensure a risk assessment is carried out and alternative service provision considered if the PN workload is not sufficient for the Hospital Executive Group to be assured that all staff achieve and maintain competence in their respective roles. This includes both the initiation of PN and acceptance of patients already receiving PN.
- 6. The Hospital Executive Group **must** ensure that staff are trained to meet a local set of competencies that relate to their role in the provision of PN. Hospitals **must** hold training records, which demonstrate this competence of those individuals, involved in the process.
- 7. A multi disciplinary body such as the British Association of Parenteral and Enteral Nutrition (BAPEN) **should** lead the preparation of a minimum set of competencies for the various disciplines involved in the provision of PN.

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#### **Clinical Guidance**

# **Nutrition Support Teams**

The importance of the Nutritional Support Team (NST) in relation to safe and effective PN services has been frequently emphasised in the literature. While endorsing the potential importance of an NST in any hospital undertaking PN, it is acknowledged that the composition of teams will vary according to availability of personnel with particular expertise. In the absence of a specific and identified NST, recognition of the multidisciplinary nature of support required for clinicians prescribing PN and the need for ready access to expert knowledge is of overriding importance. It is worth noting that the management of children receiving PN at home is best supervised through an NST and by staff experienced in dealing with long term PN.

#### Recommendations

8. The Hospital Executive Group **must** ensure that all children on PN have access to a competent multidisciplinary team with a minimum composition of doctor, pharmacist, nurse and dietitian.

#### Initiation of parenteral nutrition

Given the balance of benefits to risks and the costs involved, the decision to initiate PN should be at a senior level. There are potential benefits for patients if prescribing is in the hands of a skilled and experienced member of staff who undertakes this role as part of an NST. This improves communication and allows the team to develop sufficient expertise in prescribing in addition to gaining a shared understanding of, and familiarity with, the process of compounding, administering and monitoring components of a PN service.

Prescribing should be done in conjunction with the clinical team looking after the patient, the necessary dialogue provides opportunities for teaching and learning in relation to nutrition and the use of PN as well as ensuring that the NST is fully sighted in relation to the overall care of the patient.

There are two aspects to prescribing: defining the nutrient content and the prescribing of PN on a prescription chart. In principle, it would seem desirable that whoever is deemed competent to decide on nutrient needs and prescription content should also take legal responsibility for signing the prescription.

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- 9. The Hospital Executive Group **must** ensure all decisions to initiate PN are made by a senior clinician
- 10. The MHRA/UKHD **should** initiate changes in legislation to allow the prescribing of PN by independent non-medical prescribers.<sup>2</sup>
- 11. The Hospital Executive Group **should** ensure the clinician accountable for deciding on nutrient needs and PN formulation also signs the prescription.

# Pharmacy Provision of Parenteral Nutrition

Rewriting and transcribing of prescriptions should be kept to a minimum. The use of standardised request forms should be a minimum accepted standard, such that there is a controlled, validated system of documentation. There is evidence to suggest that repeated transcribing of data increases the risk of error. Standardised request forms will facilitate the accurate documentation of the prescription and avoidance of transcribing should be the main aim. Transcription errors will be eliminated by the use of electronic prescribing and/or pharmacy compounding software. Use of such electronic systems will provide legible, accurate and complete prescriptions and/or orders for PN, which will be readily available within the patient's electronic medication and/or dispensing record.

If the prescriber is able to appreciate the issues affecting compounding (such as compatibility) at the time of prescribing then fewer subsequent changes to a prescription are likely to be needed. One stop requesting (where the prescriber is responsible for the final regimen to be prepared and is provided with information that allows stability issues to be taken into account) is probably the most desirable option. Locally agreed guidelines will enable the PAU to make automatic substitution of items when appropriate e.g. acetate if chloride loads are too high or putting water-soluble vitamins in the aqueous solution if a lipid solution is not being used.

Technical issues such as the stability of components may require a modification of the prescription in the PAU. A pharmacist familiar with PN must carry out the final clinical validation of the amended regimen, discuss any changes with the prescriber if necessary and ensure they are recorded in the prescription.

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<sup>&</sup>lt;sup>2</sup> Since drafting this report the MHRA has amended medicines legislation which address the prescribing issues relating to mixing and combining medicines: Mixing of medicines prior to administration in clinical practice: medical and non-medical prescribing guidance (Gateway ref. 14330, May 2010).

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- 12. The Hospital Executive Group **must** ensure that a standardised request form for PN is used such that there is a controlled, validated system of documentation.
- 13. The Hospital Executive Group **should** ensure that electronic prescribing and medicines administration and/or pharmacy compounding systems are used to prescribe and/or order PN in order to eliminate transcription errors and provide legible, accurate and complete patient medication and/or dispensing records.
- 14. The Chief Pharmacist **must** ensure that whenever the formulation of PN has been changed within the PAU, a pharmacist familiar with PN carries out a final clinical validation of the amended regimen, discusses any changes with the prescriber if necessary and ensures they are recorded in the prescription.

#### Parenteral Nutrition Content

It is clearly desirable to have agreed guidelines for PN, including not only nutrient intakes, but also covering technical aspects such as venous access, appropriate monitoring and organisational issues. Guidelines should be based on and referenced to published evidence and/or guidelines and should be regularly updated to take into account the accumulation of new evidence. Any changes in practice will require dedicated resource and focus as both the clinical and technical aspects of PN are highly complex. Significant deviations should be agreed within a hospital's clinical governance structures.

Comprehensive guidelines for both newborn and older children have been published by the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) in conjunction with the European Society of Clinical Nutrition and Metabolism (ESPEN). These are freely available over the internet and are based on a review of all relevant literature by paediatricians, pharmacists and nurses working with PN across all age ranges.

A number of other suitable references are also available. It should be noted, however, that these guidelines contain many recommendations that are based on a relatively low quality of evidence, highlighting the importance both for guidelines to be regularly updated to take into account the accumulation of new data, and the need for robust clinical trials in paediatric PN.

Although it is well recognised that preterm neonates accumulate significant nutrient deficits in the early weeks of postnatal life that are difficult to make up, there is no clear consensus regarding optimal nutritional regimens for pre-term neonates receiving PN.

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- 15. The Hospital Executive Group **must** ensure there are agreed guidelines in place for the provision of PN based on and referenced to published evidence and/or guidelines which are ratified by their Clinical Governance Committee who agree any significant deviations.
- 16. The Hospital Executive Group **must** ensure that a yearly review of the clinical guidelines for the provision of PN is carried out to ensure guidelines are regularly updated and take into account the accumulation of any new data.
- 17. The NPPG and RCPCH **should** work together to facilitate the development of a national consensus for PN requirements for neonates and children through a UK prospective registry of all treated patients.
- 18. The NPPG and RCPCH **should** develop research proposals for clinical trials to improve the treatment of neonates and children with PN for consideration by the UK Coordinating Centre for the Medicines for Children Research network.

#### Standard Parenteral Nutrition Solutions

Through removing the need for multiple additions during the process of compounding, the use of standard PN solutions may be associated with a lower risk of error. Data suggest that about 80% of prescriptions could be based on a standard PN solution rather than being prepared on an individualised basis. Although there is no definitive data to suggest clinical superiority for individualised over more standardised PN solutions there will be some patients in who individualised PN solutions will be appropriate. These will include those who are clinically unstable, with hyperglycaemia, abnormal fluid and electrolyte losses, multiple additional infusions or organ failure.

Studies have found that standardised solutions enable the improvement of early nutrient supplies, and these may be appropriate for a large proportion of clinically stable patients. There does not appear to be any significant clinical and biochemical differences in preterm and newborn infants given standardised PN compared with individualised prescriptions. (Cade A. et al., 1997; Yeung et al., 2003; Krohn et al., 2005; Lenclen et al., 2006) One study estimated the costs of using standardised solution to be 30% lower than when compared to individualised solutions (Yeung et al., 2003). Dice et al (1981) found the pharmacist-monitored individualised solution to be cost effective and weight gain was significant compared to the standardised group. The study by Krohn et al (2005) suggested that a wider range of standard PN solutions than those used in adults would be necessary to meet the different range of requirements across the paediatric age range.

Standard PN solutions generally appear to be more cost effective. However, due to poor methodology no conclusions can be reached on the adequacy of nutrition provided. An advantage of standard PN solutions is availability out of hours enabling PN to be started early, of particular benefit to pre-term neonates. Potential disadvantages include a lack of flexibility in meeting nutritional needs in those patients whose requirements fall outside the norm and the current lack of nutritionally complete standard PN solutions.

It is likely that in hospitals regularly providing PN to newborns and children, the ability to provide both individually tailored and standard PN solutions would need to be maintained. For any individual patient the question should be 'how can nutritional requirements best be

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met?' The answer to this question may well vary at different times in the course of the child's illness.

A standard PN solution with marketing authorisation provides the highest level of quality assurance to the patient. Standard PN solutions manufactured in a licensed manufacturing unit with end product testing offer assurance of pharmaceutical quality. The benefits from improved levels of quality assurance may be offset by less flexibility for the clinical needs of certain patients. PN solutions prepared for individual patients must be subject to agreed quality assurance procedures

#### Recommendations

19. The Chief Pharmacist **must** ensure that the hospital's medicines policy mandates the use of standard PN solutions in preference to individualised PN solutions whenever it is clinically appropriate.

# Routes of Parenteral Nutrition Delivery

Best practice in this respect is well summarised in available guidelines (i.e. ESPGHAN/ESPEN). Complications of central venous access can be reduced through involvement of the NST and staff training is likely to be an important element.

Peripheral venous access for short term PN is often feasible, but limits the concentration of glucose that can be given (often to a maximum of 12.5%) because of phlebitis, and can be associated with severe tissue injury if PN fluids extravasate. It is essential that hospitals have policies to ensure that PN, only suitable for central venous administration, is in fact given by this route. Due to the variety of venous access devices used in newborns, policies must define which catheters constitute central venous access. The importance of ensuring correct catheter tip position needs to be emphasised.

While catheter related blood stream infection (BSI) remains the most common complication of central venous access, mechanical problems are well described. The risks of atrial perforation in the premature newborn have previously been highlighted. It must also be noted that in extremely preterm newborns, PN is an independent risk factor for BSI making its judicious use a priority. Central venous delivery of nutrients remains the most reliable method for providing long term PN in the newborn and children.

#### Recommendations

- 20. The Chief Pharmacist **must** agree locally the maximum concentration of glucose that can be infused in peripheral veins and **must** ensure the PAU labels all PN solutions which contain glucose solutions in excess of this 'to be given by central line only'.
- 21. The NPPG and RCPCH **should** develop research proposals for establishing the factors affecting peripheral line life, patency and risks when PN is administered and issue best practice guidance based on the outcomes.

# Safety checks & Biochemical Monitoring

If enteral feeds are increasing or fluid requirements are changing it is not uncommon for infusion rates of PN to change. When this occurs and the new rate of infusion no longer matches that stated on the label of the PN solution, hospitals must ensure that the change in rate is recorded on the patient's prescription chart.

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At the point of administration it is rarely possible to fully check the content of the PN solution against the prescription. For example the prescription may indicate that the patient requires 3mmol/kg of sodium but the label on the PN solution may state the volume and concentration of sodium chloride that has been used to make the PN. The bag label may also define all nutrients in mmol/kg including items such as chloride, which was not prescribed as an essential nutrient. In these circumstances it would be impossible to check the label of the PN solution, item for item, against the prescription or request at the point of administration.

Hospitals must ensure that all required checks are practical and clearly defined in local policy guidelines. Failure to do so puts checkers at risk through no fault of their own.

# Routine Biochemical Monitoring

Clinical and biochemical monitoring of patients receiving PN is crucial, although there is no universally agreed protocol. Serious and unexpected biochemical instability as a consequence of PN is rare but potentially fatal if it goes unchecked.

Tests that are difficult to interpret and unlikely to change clinical management (such as plasma amino acid profile) should be avoided or kept to long term monitoring only. It is essential that abnormal results are acted upon appropriately.

An assessment of nutritional requirements and nutrient intake actually achieved should be carried out on a daily basis. The use of agreed written guidelines for monitoring of PN patients must be utilised.

#### Administration of Vitamins

Clearly problems may occur if lipid emulsions (as the medium for supplying vitamins) are discontinued. Hospitals must have an agreed policy on how to monitor vitamin status or supply vitamins by an alternative route when this situation occurs. These decisions should be based on the clinical requirements of the child, the routes available and the time frame over which the administration problems may occur.

#### Additions to PN Solutions

It should never be acceptable practice to have additions being made directly to the PN (aqueous or lipid phase) outside of a PAU. Incompatibilities, calculation errors and microbial contamination can all potentially compromise the quality of PN. Preparation inside a dedicated PAU provides a higher level of quality assurance minimising the risk to patients.

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22. The Hospital Executive Group **must** ensure that nursing staff perform a final safety check at the point of administration of PN, which includes checking the labels of PN solutions against the prescription for:

Name of patient and identifying number Route of administration (central or peripheral) Date for infusion Rate of infusion Expiry date Appearance of the PN solutions

Hospitals **must** ensure that any additional checks requested are practical and clearly defined in local policy guidelines.

- 23. The Hospital Executive Group **must** ensure clinicians record any change in infusion rate, from that originally stated on the label of the PN solution, on the patient's prescription chart.
- 24. The Hospital Executive Group **must** have agreed written guidelines for biochemical monitoring which take account of length of time on PN, prematurity, co-morbidities and other medicines.
- 25. The Hospital Executive Group **must** ensure that clinical guidelines for biochemical monitoring identify who is responsible for reviewing results and taking appropriate action when abnormal values are observed.
- 26. The Hospital Executive Group **must** ensure additions to PN solutions (aqueous or lipid phase) contained in infusion bags and/or syringes are only made in a PAU.

#### **Out of Hours Service**

Ideally, expert advice should be available out of normal working hours and where this is currently not possible, the importance of written guidelines is crucial. "Outside normal hours" refers to extended periods of time when the PAU is not available i.e. weekends rather than just over night. PN is not an emergency supply issue but should be available for the newborn within 24 hours.

Ward based additions must not be made to PN solutions.

#### Recommendations

27. The Hospital Executive Group **must** ensure that there are arrangements for the provision of PN when the PAU is closed and that ward based preparation or additional manipulation of PN components does not occur.

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#### **Technical Guidance**

#### Introduction

The provision of a PN preparation service requires appropriate facilities, equipment, trained staff and safe systems of work as part of a quality management system. To provide PN on any significant scale requires two critical technological elements to be in place.

- · Prescribing and compounding software including decision support
- · Automation of the compounding process

The challenge for the compounding pharmacist is to achieve the optimal formulation of ingredients. Many prescriptions are a compromise of nutritional goals, stability constraints and volume restrictions often experienced in this patient group.

# **Process and Quality Control**

Whilst the scale and specifics of the compounding process may differ, the underlying principle must be that, regardless of whether the process is carried out under a Manufacturers Specials Licence or under Section 10 exemption, the same quality assurance systems must apply.

#### Recommendations

28. The Hospital Executive Group **must** ensure that PN is quality assured to the same standards regardless of scale or whether it is prepared under a Section 10 exemption or prepared under a Manufacturers Specials Licence.

#### **Documentation**

Validated software with decision support can significantly reduce risks of transcription, calculation, preparation and labelling errors.

The use of handwritten, pre-printed or photocopied documentation is a source of risk.

#### Recommendations

29. The Chief Pharmacist **must** ensure the development and implementation of an action plan to eliminate handwritten documentation and minimise the use of pre-printed and photocopied worksheets.

30. The Chief Pharmacist **must** ensure that software used in the PAU to produce documentation and labels is validated according to standards specified within The Guide to Good Manufacturing Practice (GMP).

# Methods of Compounding

At present a simple compounding device would meet the need for process automation in most hospital PAUs but no such device exists. Those currently available are complex and very difficult to validate for small volumes and multiple combinations of additive additions. All

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the potential risks should be carefully evaluated prior to use. The expertise, staff time and other resources needed for the validation of compounding devices should not be underestimated.

There are important differences between batch manufacture and compounding individual PN solutions. Batch manufacture lends itself to using multi-dose ingredient containers, since it is safer not to keep changing containers, particularly where automation is in use. Sharing of ingredients to compound a batch may also be seen as convenient and to minimise wastage especially if the pack size does not reflect commonly used quantities. When compounding individual PN solutions manually, however, container sharing increases the risk of undetected measuring errors and should be avoided.

#### Recommendations

- 31. The Chief Pharmacist **must** ensure that the PAU lists all ingredients on the master worksheet in a logical order, which follows the sequence of the compounding process to facilitate checking and reconciliation of ingredients used.
- 32. The Chief Pharmacist **must** ensure that appropriate training is provided for all staff involved in the compounding process. This **must** include training in the use of compounding devices where used.
- 33. The NPQAC **must** develop comprehensive guidance on validation and maintenance of compounding devices.
- 34. The Chief Pharmacist **should** ensure that when PN solutions are made individually or when additions are made to individualise standard PN solutions in the PAU, ingredients are not shared between PN solutions unless accurate reconciliation of ingredients supplied against ingredients used for each PN solution can be assured.
- 35. The NPSG **should** work with the PI to ensure that products are available in pack sizes and concentrations, which simplify compounding and minimise risk.
- 36. The Hospital Executive Group **should** give due regard to the risks of RSI if their Pharmacy staff are routinely preparing PN solutions manually. Where a risk is identified, outsourcing and/or automation **should** be considered.

## Compounding Processes and Process Controls

There are significant risks of selection error where multiple strengths of the same ingredient or different salts of the same electrolyte are in use. Numerous incidents of these types of errors have been reported. Packaging design and labelling does not always differentiate different strengths of glucose solution and strengths and salts of electrolytes clearly. These products may be sourced as marketed licensed products or as specials from commercial or NHS sources.

Only a properly risk-assessed process that incorporates relevant checks at appropriate stages can deliver the high degree of quality assurance needed. Comprehensive final product checking is essential. All checks must be carried out by trained, accredited staff that have the required underpinning knowledge and a thorough understanding of the process and what they are checking. Weighing the finished PN solution is essential: this simple test is a very useful tool to alert those checking the process to some potential errors in compounding. It should not, however, be seen as the only checking answer.

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- 37. The Chief Pharmacist **must** ensure the PAU reviews the range of ingredients held as stock. The PAU **must** be able to justify the use of more than one strength or salt of the same electrolyte and if clinically appropriate, use must be subject to a risk assessment.
- 38. The Chief Pharmacist **must** ensure the PAU carries out pre-process checks including as a minimum worksheet, formula, ingredients, disposables and label details.
- 39. The Chief Pharmacist **must** ensure the PAU carries out checks at critical stages of the compounding process and that the roles of 'operator' and 'checker' are always clearly separated and understood.
- 40. The Chief Pharmacist **must** ensure the PAU carries out a range of final product checks to assure the quality of the product. As a minimum this **must** include reconciliation of ingredients, physical check on PN solutions (particulates, precipitation, and integrity), weight check and full documentation checking including labelling.
- 41. NAB **must** investigate the feasibility of end product testing before or during the early stages of administration with or without early patient monitoring.
- 42. The Chief Pharmacist **must** ensure that all staff undertaking checking activities have been formally authorised to do so via an accreditation process, which complies with the principles of the National Frameworks for Pre-, In-Process and Final Technical Checks in NHS Aseptic Services.

#### Workload

Individualised PN will always be required for certain patients. The two main groups are those who require concentrated nutrition in restricted volumes e.g. when in Paediatric ICU, and those who are on long-term PN for longer than 1 month e.g. patients with short bowel syndrome who require very specific nutrition, usually based on higher than normal nutritional requirements.

Most other newborn and children are not fluid restricted and do not require prolonged PN. In theory these patients are suitable for standardisation. Their nutritional and volume requirements fall into broad categories and by following guidelines such as those produced by ESPGHAN, the development of age-related standard formulae is possible and has been implemented in some UK hospitals.

Standardisation offers a variety of advantages compared to individualisation, all contributing to a safer overall process and higher quality product. Advantages include:

- Simplified prescribing with reduced error potential
- Simplified dispensing/compounding processes with reduced error potential
- Opportunity for end-product testing and enhanced level of product quality assurance
- Reduction in the risk of RSI due to the reduced number of aseptic manipulations for compounding unit staff.
- Increased system capacity
- Improved quality of care for patients needing PN support.

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43. The Pharmaceutical Industry **should** work together with multi-disciplinary experts in the field of children's PN to develop a range of licensed standard PN solutions that will meet the requirements of children of all ages.

#### Additions to Standard PN Solutions

Although most standard PN solutions already contain electrolytes and occasionally micronutrients, there is a requirement in the majority of hospitals to further tailor the solutions in the pharmacy. Electrolytes are frequently added because patients have widely differing needs depending on their clinical condition.

Lack of stability precludes extended shelf life and the addition of trace elements and vitamins to standard regimens at source by the manufacturer and thus necessitates local addition in the pharmacy prior to administration.

As trace elements and vitamins have critical functions in metabolism, they should be viewed as essential components of a complete PN regimen and their incorporation into standard (and individualised) regimens desirable for all patients for every day of PN.

Hospitals must have an agreed multi-disciplinary policy for monitoring of micronutrient levels in all patients receiving, or expected to receive, PN for longer than one month. The policy must include advice on monitoring of vitamin status and, if vitamins are normally administered in the lipid phase of a PN infusion, the policy should also provide guidance on supply by an alternative route if lipid administration is interrupted or stopped altogether.

#### Recommendations

44. The Pharmaceutical Industry **should** investigate the feasibility of including trace elements and vitamins into licensed standard PN solutions and explore ways of maximising shelf life.

45. The Hospital Executive Group **must** ensure there are written guidelines for the alternative administration of vitamins or other micro-nutrients contained within the lipid phase of PN, when lipid administration is interrupted.

# Stability Data

Heavy reliance is currently placed on the Pharmaceutical Industry to provide stability data but the quality and level of detail provided can be very variable. The NHS needs to recognise this as a source of significant risk, which should be addressed through the production of standards for the content and presentation of stability data as a high priority.

#### Recommendations

46. The NAB and appropriate NHS Pharmaceutical Committees **must** initiate a programme of work to scope the requirement, and agree standards, for stability data to support the provision of PN and make recommendations to Chief Pharmacists and the UKHD.

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# Workforce Planning

Data from the technical survey suggests that NHS PAUs are struggling to meet demand and in some places may be under resourced for their current workload. This is a source of potential risk to product quality and patient safety.

Longstanding difficulties with recruiting and maintaining an appropriately skilled pharmacy technical services workforce are widely recognised by Chief Pharmacists. This has major implications for development and sustainability of NHS PN services.

#### Recommendations

- 47. The UK Health Departments (UKHD) **must** ensure there is a career structure and sufficient capacity to ensure the continued provision of pharmacy aseptic services.
- 48. The NAB **should** work with NHS Pharmacy Education & Development Committee and Higher Education Institutions to further develop current initiatives to enhance the education and training

for the specialist technical services workforce.

49. The Chief Pharmacist **should** use the annual risk assessment of their PN service to help identify local training needs.

## Quality Assurance of Purchased Parenteral Nutrition Solutions

The great majority of PN solutions are unlicensed medicines and should be managed as such. PN solutions are complex, large-volume injectable medicines presenting many pharmaceutical challenges in terms of physical and chemical stability and are thus a significant source of pharmaceutical risk. The clinical risks of PN and particularly the fatal consequences of administration of sub-standard solutions are well recognised and documented. It is therefore essential that all appropriate steps are taken to assure the quality of PN products whether compounded locally or externally, by NHS or other providers.

#### Recommendations

- 50. The NPQAC **must** define the quality standards to be applied when unlicensed PN is purchased.
- 51. The Chief Pharmacist **must** ensure that the Pharmacy only purchases unlicensed PN from a supplier approved by the NHS Pharmaceutical QA service.
- 52. The NAB **should** be asked to provide guidance for hospitals on acceptable activity limits to ensure that PAUs only dispense PN solutions compounded under Section 10 exemption to external customers on a small scale and infrequent basis.
- 53. The Chief Pharmacist **should** ensure that the PAU only dispenses PN solutions compounded under Section 10 exemption to external customers only if it is part of a registered Pharmacy on a small scale and infrequent basis.

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# Giving Sets and Filters

Significant risks are associated with the process of attaching giving sets to PN solutions in the PAU and this practice has the potential to compromise the microbiological integrity of the PN solution and set once it leaves the unit. Subsequent packing and transport operations will further compound any risks and, as a result, there are considerable difficulties associated with the validation of the microbiological integrity of such systems.

#### Recommendations

- 54. The NPQAC **must** make recommendations and/or commission research on the practice of attaching giving sets to PN solutions in the PAU.
- 55. The Hospital Executive Group **should** ensure that in-line filters are used in accordance with published BPNG guidance.
- 56. The NAB **should** consider the introduction of a needleless connector, which would result in a much more secure connection than the traditional "spike" systems.

# **Error Reporting**

Recording and analysing error and near-miss data is invaluable for identifying potential risks and failure modes in the compounding process. Pooling of these data further enhances the ability to identify new and emerging risks both on a local and national basis.

#### Recommendations

- 57. The Chief Pharmacist **must** ensure the PAU records and reports errors that occur at any stage of the preparation process according to local hospital procedures.
- 58. The Chief Pharmacist **must** ensure the PAU carries out regular reviews of error trends and has an effective recording and review system, which will ensure corrective and preventative actions are taken in response to incidents and non conformances.
- 59. The Chief Pharmacist **must** ensure that the PAU contributes data to the National Aseptic Error Reporting Scheme.

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# **Appendix 1 - Project Governance: Membership Lists**

# Project Team

James Wallace (Chairman), Previous Chief Pharmacist, Yorkhill Hospitals, NHS Greater Glasgow and Clyde

Dr John Puntis, Consultant Paediatric Gastroenterologist, Leeds Teaching Hospitals NHS Trust Alastair Gibson, Director of Pharmacy, Blackpool Fylde and Wyre NHS Foundation Trust

Julian Smith, All Wales QA Specialist Pharmacist

Bruce McElroy, Head of Pharmacy, Shrewsbury and Telford Hospital NHS Trust

Liz Kay, Clinical Director Medicines Management & Pharmacy Services, Leeds Teaching Hospitals NHS Trust

Eamon Mullaney, Senior Pharmacist, Technical Services Belfast Hospitals NHS Trust

Professor David Upton, Pharmacy Practice and Research, De Montfort University

Sue Conner, Project Manager, Great Ormond Street Hospital for Children

Antje Neubert, Researcher at the Paediatric Medicines Research Centre for Paediatric Pharmacy Research

# Clinical reference group

Dr. John Puntis (Chairman), Consultant Paediatric Gastroenterologist, Leeds Teaching Hospitals NHS Trust

James Wallace, Chief Pharmacist, Yorkhill Hospitals, NHS Greater Glasgow and Clyde

Dr Sabita Uthaya, Consultant Neonatologist, Chelsea and Westminster Hospital Foundation Trust

Anthony Lewis, Clinical Pharmacist, Cardiff and Vale NHS Trust

Venetia Horn, BPNG, Great Ormond Street Hospital for Children NHS Trust

Linda Matthew, Senior Pharmacist, National Patient Safety Agency

Steve Tomlin, FNPP and NPPG, Guys and St Thomas' NHS Trust

Sylvia Cottee, NNNG, Cambridge University Hospitals NHS Trust

Jacqui Lowdon, Dietician, Central Manchester and Manchester Children's University Hospitals NHS

Sue Conner, Project Manager for Electronic Prescribing, Great Ormond Street Hospital for Children, NHS Trust

# Technical reference group

Alastair Gibson (Chairman), Director of Pharmacy, Blackpool Fylde and Wyre NHS Foundation Trust James Wallace, Chief Pharmacist, Yorkhill Hospitals, NHS Greater Glasgow and Clyde

Trevor Munton, NHS QA Committee Representative, Bristol Hospitals NHS Trust

David Hoole, NPPG Representative, Royal Hospital for Sick Children, Edinburgh

Ian Smeaton, Senior Production Pharmacist, Royal Victoria Infirmary, Newcastle Upon Tyne NHS Foundation Trust

Tim Root, Hospital Pharmacists' Group

Neil Fisher, NHS Production Committee and Aseptic Services Group, Barking, Havering and Redbridge NHS Trust

Richard Bateman, NHS QA Committee Representative, Guys and St. Thomas' NHS Foundation Trust Sue Conner, Project Manager for Electronic Prescribing, Great Ormond Street Hospital for Children NHS Trust

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# Appendix 2 - Glossary of Terms

Accreditation Validation of competence to undertake specific tasks

Ad-hoc worksheet Worksheet produced by a word processor using non

validated software or other manual method

**Biochemical monitoring**Blood level monitoring of constituent ingredients

administered as PN

**Clinical monitoring** Monitoring the clinical status of the patient e.g.

temperature, condition of access site

Clinical validation Check to ensure the formula is appropriate for the

patient's condition and biochemical status

**Compounding** The process of producing un-licensed standard PN

solutions under the terms of a specials licence or an individualised PN solution under the terms of a

section 10 exemption

**Decision support**Rule based software, which ensures consistency

within the compounding process, compliant with

safe systems and guidelines

**FNPP** Faculty of Neonatal and Paediatric Pharmacists

Formally agreed guidelines Clinical guidelines which have been formally

approved by the Drugs and Therapeutic Committee

**Homecare** Supply of PN (with/without other medicines) direct

to the patient for ongoing care & administration at

home/outside hospital

Individualised PN solution PN solution prepared specifically for an individual

patient

Ingredients Raw materials used in the manufacturing of PN

**In-house computer programme** Computer programme designed and written in-

house to support the production of PN, which calculates the quantity of ingredients and produces

worksheets and labels

**Licensed standard solution** A medicinal product manufactured in batches by a

commercial manufacturer providing nutrients

required for a specified age range

Macro compounding Compounding from separate individual ingredients

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Master worksheet Approved documentation on which only minor details

> are amended, such as date of manufacture, expiry date and batch number. The formula of the solution

remains constant.

**MHRA** Medicines and Healthcare products Regulatory Agency

Micro compounding Addition of micro nutrients to a pre-compounded

standard base solution

**NAB** National Advisory Board for NHS Hospitals' Medicines

Manufacturing and Preparative Services

Neonate From birth to 1 month corrected age

**NNNG** National Nurse Nutrition Group

**NPPG** Neonatal and Paediatric Pharmacists Group

**NPQAC** National Pharmaceutical Quality Assurance Committee

**NPSG** National Pharmaceutical Supplies Group

**NST Nutrition Support Team** 

**Nutritional Support Team** Multi-disciplinary team who assesses the need and

subsequently prescribes the PN for patients

**Paediatric** From 1 month to 18 years

**PAU** Pharmacy Aseptic Unit

PΙ Pharmaceutical Industry

PN Parenteral nutrition

Pro-forma prescription/

Worksheet A pre-printed formatted document template listing

core, non-variable prescription information, such as main PN components and additives, with the aim of minimising the amount of handwritten detail

which has to be added.

QA **Quality Assurance** 

**RCPCH** Royal College of Paediatrics and Child Health

Reconciliation The process of comparing, at the end of the

> compounding process, identities and amounts of residual ingredients & containers against those specified on the worksheet and initially issue to technical staff as an indirect, retrospective check of

the identity and amounts of ingredients used.

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November 2011 34 **SOP** Standard operating procedure

Standard PN solution A PN infusion pre-compounded to an agreed, non-

individualised formula, intended to meet the full nutritional requirements of a defined group or

groups of patients.

**UKHD** United Kingdom Health Departments

Un-licensed standard PN solution

A medicinal product manufactured by a third party (commercial manufacturer or hospital pharmacy aseptic unit) as batch manufactured specials to which

micro nutrients are added by Pharmacy

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# Appendix 3 - Bibliography

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