Home Parenteral Support for Type 2 and Type 3 Intestinal Failure Patients

An overview of the NHS England commissioning statement

Martha Jackson,
Medical Nutrition Manager, BSNA

Parenteral nutrition (PN) is a lifeline for patients who are unable to consume nutrition and/or fluid orally or enterally due to intestinal failure (IF). Over the decades the NHS has moved to a mixed model of PN, using both compounded and multi-chamber bags (MCB). More recently NHS England has published a commissioning statement setting out the pathway of the treatment of adults and children with Type 2 and Type 3 IF with home parenteral support (HPS).[1] This article aims to explain this pathway for these patients along with the different types of parenteral nutrition.

Parenteral nutrition

PN is the provision of nutrition via the intravenous route. A patient may receive PN on either a short- or long-term basis if their gastrointestinal system is inaccessible or non-functioning and oral intake is inadequate or unsafe. A patient may also receive PN for other reasons, for example, as part of pre-operative care to improve post-operative outcomes.

In 2023, NHS England published a commissioning statement[1] setting out the treatment pathway for patients of all ages with Type 2 and Type 3 IF who require HPS, including home parenteral nutrition (HPN), providing a treatment algorithm of current commissioned treatments.

Intestinal failure

IF is defined as *'the reduction of gut function below the minimum necessary for the absorption of macronutrients and/or water and electrolytes, such that intravenous supplementation is required to maintain health and/or growth'*.[2] IF is classified as Type 1-acute, Type 2-prolonged acute and Type 3-chronic.[3] There are various conditions which can cause IF, including inflammatory bowel disease, mesenteric ischaemia, surgical complications, and radiation enteritis. This article will focus on Type 2 and Type 3 IF, described in **Table 1**.

Table 1: Types of IF

	Description
Type 2	Type 2 IF describes patients with changing metabolic or nutritional needs. It is usually a reversible form of IF requiring longer than 28 days of PN. It commonly arises as a consequence of abdominal sepsis and enterocutaneous fistula(s), bowel obstruction/ileus, and may be associated with metabolic problems. Patients may be discharged on HPN.
Type 3	Type 3 IF describes patients with a chronic condition requiring long-term PN at home due to non-functioning gut and therefore the patient cannot absorb nutrients and/or fluid via the intestinal tract.

Home parenteral support

Over the last decade, there has been an increased combination of nutrition requirements with fluid required for IF patients. This has led to the gradual increase in the size of PN bags. This clinical development has resulted in the term HPS becoming more commonly used over HPN, as HPS includes fluids alone, fluids and electrolytes or macro- and micronutrients, whereas HPN refers to the intravenous administration of macro- and micronutrients only.[4] Patients who are discharged from hospital still requiring parenteral support are discharged on HPS. Currently, patients are discharged home on either compounded PN tailor-made to the patient's individual requirements or commercially available PN in the form of MCBs, or a combination of the two, known as the hybrid approach.[1] **Table 2** contains a summary comparison of the different types of PN.

The number of patients in England on HPN is approximately 2500, with around 30% of these patients being on long-term HPN (>5 years).[5] There has been an increase in the number of Type 2 IF patients and the number of patients being managed long-term at home.[5] The prevalence of HPN has been increasing at a rate of approximately 20% per annum and the demand for compounded PN continues to exceed the capacity of the service. However, for most patients, their individual needs can be met with licensed treatments in the form of a standard MCB either as a short-, medium- or long-term alternative to a compounded product. The NHS commissioning statement suggests that:[1]

Table 2: Comparison of PN Products

	Quality control and compounding risk	Sterility assurance	Stability/ shelf-life	Compatibility	Clinical utility	Cost*
Licensed, commercially available MCB	Content guaranteed	Guaranteed	18-24 months	N/A	Limited to patients who can have micronutrients via another route or lumen	Low
Commercially available MCB with additions made in batch in a licensed compounding unit to a standardised fixed formula	Content assured; some ingredient concentrations may be tested before release depending on supplier. Template order entry mitigates some risks. Risks associated with aseptic manipulation	Assured, risk dependant on number of additions and environment. Sterility testing is unlikely	4 weeks to 89 days	MCB parameters are fixed, stability matrix more robust	Suitable for most patients	Moderate
Unlicensed compounded formulation made from individual components to a fixed formula	Assured, some ingredient concentrations may be tested before release. Template order entry mitigates some risks. Risks associated with aseptic manipulation. Automated compounding may reduce errors when compared to manual compounding	Assured, risk dependent on operator and environment. Sterility testing is unlikely	1 week to 89 days depending on composition, with or without micronutrients, and bag type, e.g. EVA, or oxygen barrier	Data based on matrix design, higher degree of uncertainty	Suitable for most patients	Moderate
Commercially available MCB with additions made individually in a compounding unit for a specific patient	Assured, some ingredient concentrations may be tested before release. Individualised order entry may increase risk or error. Risks associated with aseptic manipulation	Assured, risk dependant on number of additions and environment. Sterility testing unlikely as usually made for immediate use	7 days. An overwrap may need to be applied to permit a longer shelf-life	MCB parameters are fixed, stability matrix more robust	Suitable for most patients	Moderate
Unlicensed compounded formulation made from individual components to a patient specific formulation	Assured, some ingredient concentrations may be tested before release. Individualised order entry may increase risk or error. Risks associated with aseptic manipulation. Automated compounding may reduce errors when compared to manual compounding	Assured, risk dependant on number of additions and environment. Sterility testing unlikely as usually made for immediate use.	7-89 days depending on composition and bag type, e.g. EVA, or oxygen barrier	Data based on matrix design, higher degree of uncertainty	Suitable for most patients	High

*Considering product acquisition costs and associate resource use

For adults and children with Type 2/3 IF starting on HPS the treatment options are as follows:

- **First-line:** MCBs/supplemented MCBs +/- additional IV fluids.
- **Second-line:** Hybrid approach. A hybrid approach may involve a combination of MCBs, fluids and compounded bags across a week. It describes a situation where not all the PN and fluids need to be compounded in order to meet a patient's need.
- **Third-line:** Fully compounded regime.

The commissioning statement is in line with the European Society for Clinical Nutrition and Metabolism (ESPEN) guideline on HPN,[6] which states that either MCBs or customised compounded bags can be used. The third line treatment of a fully compounded regimen should only be used on adults or children starting HPS if the first two lines of treatment are not possible or have been tried and did not meet the needs of the patient. Where patients are on established HPS, they should be considered for a trial of a non-compounded regimen and monitored.

When making a decision on the type of PN a patient should receive, the multidisciplinary team (MDT) should consider:[1]

- Compatibility
- Burden of treatment regimen
- Risk assessment of treatment regimen, including home environmental and social factors
- Whether the patient is being treated post-operatively following reconstructive surgery for IF and is already being weaned off PN
- Clinical and nutritional history and assessment.

The evidence supporting the commissioning statement

Each method of PN solution provision has its own risks and challenges. These include quality control, sterility assurance, stability and compatibility, shelf-life and supply chain, resource availability, clinical suitability and timeliness of formulation change and cost.

Three papers were reviewed by NHS England to support MCBs as a first line treatment for adults and children with Type 2 and Type 3 IF requiring HPS. These were:

- Nagelkerke, *et al.* (2020). Standardized and individualized parenteral nutrition mixtures in a pediatric home parenteral nutrition population.[7]
- Crooks, *et al.* (2022). Catheter-related infection rates in patients receiving customized home parenteral nutrition compared with multi-chamber bags.[8]
- Cogle, *et al.* (2021). Multi-center prospective evaluation of parenteral nutrition preparation time and resource utilization: 3-chamber bags compared with hospital pharmacy–compounded bags.[9]

NHS England reviewed the papers for effectiveness, looking specifically at growth, calorie intake, preparation time and cost, along with safety, specifically looking at catheter-related bloodstream infections (CRBSI) and biochemical values, before concluding that MCBs were safe and effective for the majority of patients.

Standardised solutions

Over the last 30 years, there has been more research and development into standardised solutions. A recent study looking at an increased use of standardised solutions from a baseline of 48% to 86% demonstrated a reduction in costs by nearly 20% without impacting quality criteria such as nutrient delivery.[10] The same research group also demonstrated that alongside significantly short preparation times, the use of MCBs may have a beneficial effect on the economic burden associated with PN, as well as a possible reduction in errors related to PN preparation.[11]

In summary

MCBs should be seen as a first-line treatment of adults and children with Type 2 and Type 3 IF requiring HPS, as outlined in the NHS England commissioning statement. MCBs are available in a wide range of nutrition dose, volume and electrolyte options, licensed for use in adults and children. With the right range of standardised solutions aligned to the needs of the local patient cohort a standardised approach may be effective to reduce waste, improve supply efficiency and simplify purchasing options without compromising clinical requirements. Whilst there are a number of benefits to MCBs, clinical complications, co-clinical issues and patient requirements may require a bespoke compounded bag supporting an individual's complex needs. Therefore, it is important for the MDT to assess each patient as in individual to decide which form of PN most benefits the patient.

References: **1.** NHS England (2023). Commissioning Statement: Parenteral nutrition for the treatment of adults and children with Type 2 and Type 3 intestinal failure requiring home parenteral support. Accessed online: www.england.nhs.uk/wp-content/uploads/2023/10/2267-hpn-commissioning-statement.pdf (Aug 2024). **2.** Pironi L, *et al.* (2018). Intestinal failure in adults: Recommendations from the ESPEN expert groups. Clin Nutr.; 37(6 Pt A): 1798-1809. **3.** Pironi L (2016). Definitions of intestinal failure and the short bowel syndrome. Best Pract Res Clin Gastroenterol.; 30(2): 173-185. **4.** Pironi L, *et al.* (2015). ESPEN endorsed recommendations. Definition and classification of intestinal failure in adults. Clin Nutr.; 34(2): 171-180. **5.** NHS England, Internal Medicine Programme of Care (2023). Severe Intestinal Failure Service (Adults). Accessed online: www.england.nhs.uk/wp-content/uploads/2019/07/170077-230701S-intestinal-failure-adults-serv-spec-v1.3.pdf (Aug 2024). **6.** Pironi L, *et al.* (2020). ESPEN guideline on home parenteral nutrition. Clin Nutr.; 39(6): 1645-1666. **7.** Nagelkerke SCJ, *et al.* (2020). Standardized and individualized parenteral nutrition mixtures in a pediatric home parenteral nutrition population. J Pediatr Gastroenterol Nutr.; 70(2): 269-274. **8.** Crooks B, *et al.* (2022). Catheter-related infection rates in patients receiving customized home parenteral nutrition compared with multichamber bags. J Parenter Enteral Nutr.; 46(1): 254-257. **9.** Cogle SV, *et al.* (2021). Multicenter prospective evaluation of parenteral nutrition preparation time and resource utilization: 3-chamber gags compared with hospital pharmacy–compounded bags. JPEN J Parenter Enteral Nutr.; 45(7): 1552-1558. **10.** Berlana D, *et al.* (2014). Impact of parenteral nutrition standardization on costs and quality in adult patients. Nutr Hosp.; 30(2): 351-358. **11.** Berlana D, *et al.* (2019). Cost, time, and error assessment during preparation of parenteral nutrition: multichamber bags versus hospital-compounded bags. JPEN J Parenter Enteral Nutr.; 43(4): 557-565.