British Specialist Nutrition Association Ltd

bsna

# Parenteral Nutrition: ensuring high quality throughout preparation, supply and administration

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The process of producing Parenteral Nutrition (PN) is a complex one involving multiple, carefully controlled and regulated steps. These steps are essential to ensure the quality of products is maintained during production, processing, delivery and administration.

## Stage One: Preparation of Parenteral Nutrition

### 1. Licensing

- Parenteral nutrition is governed by pharmaceutical law.
- The Medicines and Healthcare Regulatory Authority (MHRA) is the UK body responsible for the authorisation and regulation of products and associated devices.

The individual components that PN is comprised of and ready-made multi-chamber bags (MCBs) are licensed and regulated by the MHRA. An unlicensed product is made when PN is compounded from individual, licensed components or when additions are made to a MCB.

An **unlicensed medicine** is one that is manufactured without a Marketing Authorisation (MA) from the MHRA. Manufacturers of these products hold a Manufacturing Specials (MS) license. The MHRA are responsible for granting an MS license and the holder is subject to regular audits to maintain high quality standards to retain their license.

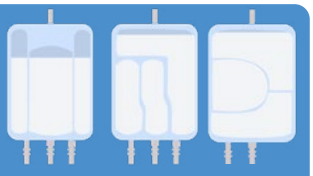
### 2. Aseptic compounding

PN solutions are prepared using aseptic techniques and processes to prevent contamination of pathogenic organisms during manufacturing, including:

- use of sterile production facilities
- sterile clothing
- non-touch techniques
- environmental air filtration
- automated compounded devices
- vacuum fill chambers
- gravity fill in appropriate sterile cabinets or isolators.

### 3. Stability

PN can contain over fifty separate chemical entities. The complexity of such admixtures requires careful consideration of factors that may affect stability. Key techniques are used to prevent destabilisation and slow down chemical reactions. Consideration of the mixing sequence, as well as the maximum levels of each component, are vital to ensure stability when combining PN ingredients.



MCBs provide a physical barrier between components to prevent adverse chemical reactions before activation, delivering a significantly longer shelf life. Once the MCB is activated and components are mixed there is a limited period of time in which its contents must be infused.

## 4. Quality Control

Licensed MCBs must undergo extensive chemical and sterility testing before release from the manufacturer into the market. For unlicensed compounded PN and compounded additions to MCBs, it is the responsibility of the manufacturer to ensure that adequate quality control measures are in place and carried out. The extent of local chemical and sterility testing is dependent on the compounding unit and the shelf life of the product. Compounding units are regularly audited by the MHRA.

## 5. Transport/distribution/storage

- Shelf life can be influenced by the type of bag used i.e. an oxygen barrier bag will prolong the shelf life.
- MCBs do not require refrigeration until the chambers have been activated.
- Compounded PN is almost always refrigerated as part of an end-to-end cold chain process.
- Good Distribution Practice will see temperature controlled storage maintained throughout transport for both ambient and cold chain requirements.


# Stage Two: Administration of Parenteral Nutrition

## 1. Screening for Nutritional Status

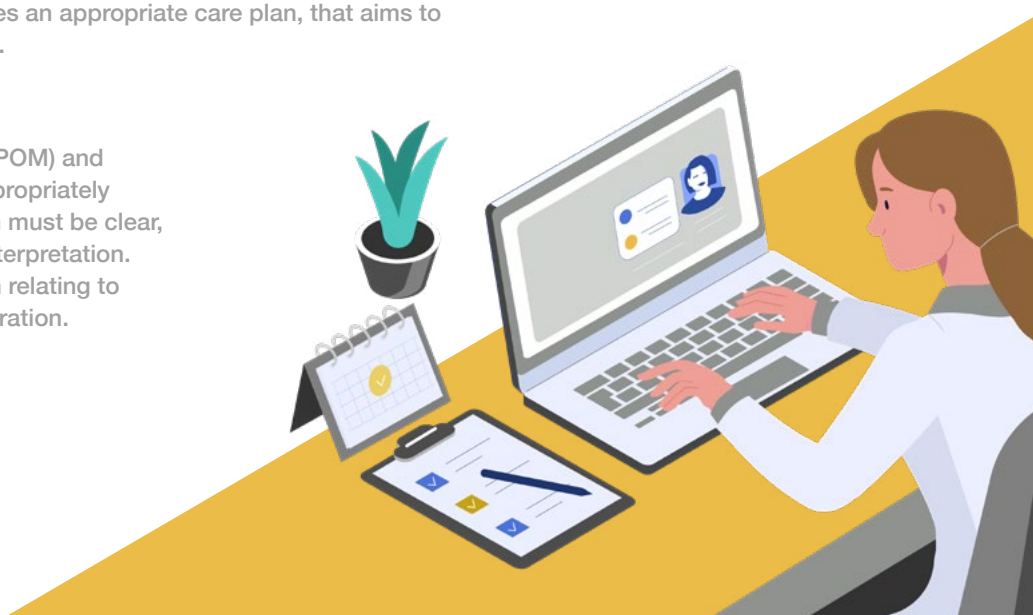
All patients should be screened to allow early identification of malnutrition and those at risk of malnutrition.[1] There are multiple screening tools, including the Malnutrition Universal Screening Tool (MUST). [2]

## 2. Assessment

It is essential to perform a comprehensive assessment prior to commencing PN. Detailed examination of metabolic, nutritional or functional variables should be carried out by a dietitian. This ensures an appropriate care plan, that aims to optimise clinical nutrition, is devised.

## 3. Prescription

PN is a prescription-only-medicine (POM) and must be legally prescribed by an appropriately qualified prescriber. The prescription must be clear, legible, complete and not open to interpretation. It must contain sufficient information relating to dose, duration and route of administration.



## 4. Administration

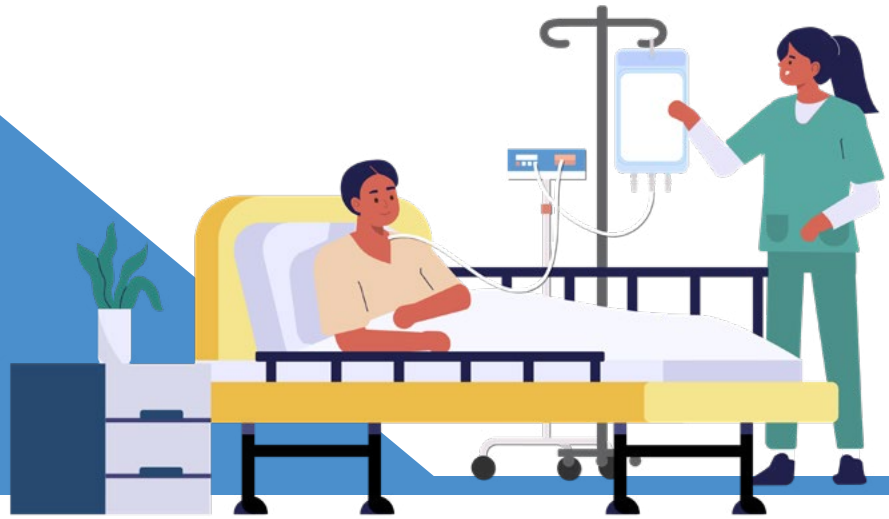
PN should only be administered by a suitable, qualified professional. There are a number of considerations when providing PN:

- **Route of administration:** there are two different routes through which intravenous nutrition can be delivered: central and peripheral.
- **Filtering:** PN delivered via an administration set that incorporates a filter is advocated.
- **Light protection:** the European Medicines agency (EMA) recommends that when delivering PN to neonates and children below 2 years of age, the PN bag and administration set should be protected from light exposure until administration is complete. [3]
- **Care of lines:** lines should be handled using an aseptic technique and according to locally approved protocols.

## 5. Monitoring

Ongoing monitoring of patients on PN is essential to minimise potential complications and to ensure the appropriate amount of electrolytes, nutrition and fluid are provided. As a patient's condition stabilises and improves, PN treatment may be ceased or the patient may transition to other forms of nutritional therapy.

Healthcare professionals should familiarise themselves with NICE Guidelines: Nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition.[1]



*This document has been created to provide an overview of the processes involved in the development and administration of parenteral nutrition. It is not intended to replace advice from a qualified healthcare professional.*


1. National Institute for Clinical Excellence (NICE) (2006) Nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition (clinical guideline CG32). Updated August 2016. Available at: https://www.nice.org.uk/guidance/cg32 [Accessed: 29 January 2020]
2. Malnutrition Advisory Group (MAG) (2003) Malnutrition Universal Screening Tool. Redditch: British Association of Parenteral and Enteral Nutrition (BAPEN). Available at: https://www.bapen.org.uk/pdfs/must/must_full.pdf [Accessed: 29 January 2020]
3. Pharmacovigilance Risk Assessment Committee (PRAC) (2019) PRAC recommendations on signals. Amsterdam: European Medicines Agency. Available at: https://www.ema.europa.eu/en/documents/prac-recommendation/prac-recommendations-signals-adopted-8-11-july-2019-prac-meeting_en.pdf [Accessed: 29 January 2020]