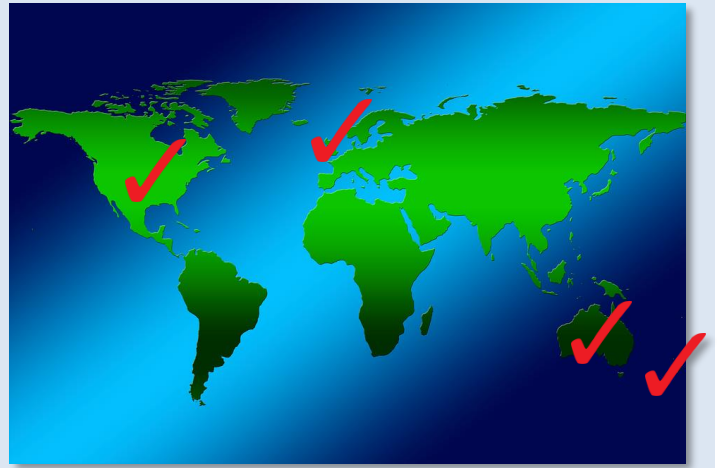


Homecare Around The World ...

Australia and New Zealand, United Kingdom, and the USA



Observations about living at home with HPN and the services received from the PN manufacturers and delivery/support services.

This document is not intended to imply what's 'right' or 'wrong' but to showcase the variations.

Overview of HPN provision

Australia/New Zealand

- Approximately 250-260 HPNers in Australia AND NZ (adults and children).
- Australia – 8 states & territories, all with own medical systems. Only South Australia and Western Australia have a dedicated, centralised HPN hospital (one for adults/1 for paediatrics). NSW has possibly 11 HPN centres. No federal system for HPN care – all different, depending on state and hospital. HealthPACT 2014 government review recommended a national system with centres of excellence in each state/territory.
- Australia – 1 homecare company – Baxter; New Zealand – 2 homecare companies – Baxter (adults), Biomed (paediatrics).
- Australia and New Zealand have very different laws and regulations regarding pharmaceutical companies – Australia there can be no direct marketing to consumers; New Zealand they can. Results in homecare functioning slightly differently. Unless otherwise stated, the following information is in relation to Australia.
- Hospitals are responsible for clinical care, not Baxter, including in the transition to home.
- Patients are taught HPN care in hospital before going home (usually 1-2 weeks of training).
- All communication (except ancillary ordering or PN/ancillary delivery problems) must be directly with hospital.
- Homecare in Australia is dependent on the individual hospital's contract – some hospitals contract Baxter for PN only, others contract Baxter for the whole package (i.e. PN, pump + ancillaries).
- If the hospital contract with Baxter is for whole HPN package, it includes:
 - Delivery of ancillaries 4 weekly to home by a courier.
 - Pump and accessories (24 hr emergency phone service) – pump replacements are only in business hours. Baxter currently has 1 pump available – the Bodyguard 323.
- (Dedicated fridges in NZ only).
- Holiday service – everything must be organised through the hospital, not directly with Baxter.

- Baxter provide PN delivery to any domestic holiday destinations (including split deliveries) if possible within delivery timeframe; delivery to cruise departure ports (not airports/trains); provide letters on pumps/PN formulation, if requested.
- Baxter only organise ancillary deliveries to home, not to holiday destinations.
- Baxter/hospital organise compounding/supply of PN in other countries (depending on destination).

United Kingdom

- Homecare has evolved in the UK over the years, part of the NHS with no cost to patients.
- The homecare company are there to carry out the service in line with what the clinical team prescribe.
- Currently it's governed under a national HPN Framework in England. Scotland have a national contract and as do Wales, which covers all aspects of home parenteral nutrition homecare.
- The safety of the PN is everyone's priority – that includes the patient.
- Seven approved homecare companies in England.
- Approximately 1,800 HPNers (adults and children).
- Allocated a homecare company by the HPN centre, usually due to individual needs or capacity. If anyone has problems, then in consultation with hospital another can be used if they have capacity.
- All seven homecare companies cover England. Scotland has a national contract with one company so does Wales. Ireland has two.
- All pumps must be reviewed by LITRE, Looking into the Requirements for Equipment (sub-committee of PINNT – products and services) before available for home patient use in England. It's a user assessment; not clinical nor technical. It's part of the National framework process for England. Wales and Scotland also refer to LITRE/PINNT. One pump does not suit all patients. Ambulatory pumps are required for home use.
- The pump choice is primarily a clinical choice in conjunction with the user. All homecare companies must provide the pump of choice as prescribed by the HPN centre.
- Approximately seventy hospitals with HPNers; two centres of excellence. These two have been centrally funded. A new regional network is due to be announced in England very soon.
- Homecare in the UK can include:
 - PN + ancils delivered to the home by a dedicated driver who has been trained about the treatment and ancillaries they will see. They are not there to deal with any aspects of the homecare service.
 - Deliveries must be made in un-marked vans.
 - Some companies used specially validated boxes to transport the PN and other used refrigerated vans.
 - As part of the package the patient will receive: PN, ancils, dedicated fridge, pump + accessories – everything needed to carry out HPN.
 - Self-caring patients only communicate with the homecare company on a needs basis.
 - Patients unable to carry out their own treatment will have a nursing service which provides them with a nurse for two visits a day. They are allocated a time slot; usually a two-hour window.
 - All offer a travel service – deliver to a departure port, airport, dock, station etc. ... compounding abroad is no longer permitted. Countries with reciprocal healthcare may be possible but this will depend upon the compounding facilities.
 - Travel service – they provide labels for boxes and specific letters for each episode of travel.
 - Offer a 24-hour support service to patients.
 - All must have Freephone numbers.
 - Most patients in the UK, except some paediatrics, are taught their procedures at home by homecare nurses, this reduces the length of stay in hospital. For those who go on to self-care they are usually signed off within a given time framework.

USA

- Approximately 40,000 PN patients (adults and children).
- PN is usually referred to as Total Parenteral Nutrition (TPN).
- Multiple PN providers in the USA. There are 6 major nationwide companies as well as local/regional companies. In Massachusetts, there are 29 homecare companies capable of manufacturing PN.
- Some companies operate with the combined efforts of a pharmacist and a nutritionist while some rely solely on the pharmacist.
- Most nationwide companies that have offices set up in suburbs or smaller cities are in close proximity to larger cities. They will cater to the larger cities and the smaller cities surrounding it, sometimes driving hours away from the office's location.
- Multiple PN payers- Medicare is a federal national program serving the elderly and disabled, Medicaid is a federal/state partnership program that is different for every state and serving low income and disabled and commercial companies serve persons who are employed and/or have reasonable levels of income.
- There are no federal guidelines to PN manufacturing. The FDA approves initial approval of PN related products and will inform pharmacies of shortages. The American Society for Parenteral and Enteral Nutrition (ASPEN) is a national organization and a PN information network for prescribers. ASPEN provides recommended guidelines for PN manufacturing, updates on supply shortages, and keeps a registry of all PN patients.
- PN is considered a prescription medication. The prescribing physician, based on the patient's needs, determines the PN formula. Physicians differ on the specificity of PN manufacturing. Some physicians prefer frequent lab work and altering of formula while some do not find it as necessary.
- Emergency PN is available for patients who live in very rural areas that are difficult to access. This type of PN is not custom made, but an FDA approved PN containing basic supplementary nutrition. It has a long shelf life and does not require refrigeration.
- Hospital involvement is generally limited to employing the PN prescribing physician. Only through the prescribing physician can PN changes be made or other supplementary fluids prescribed. During patient hospitalizations, the hospital provides its own PN from its pharmacy and all deliveries from PN providers cease until discharge.
- PN pharmacy
 - 24 hour on-call services in case of emergencies.
 - The PN pharmacy supplies the pumps and ancillary supplies. This includes pickup and disposal of hypodermic needles, pump batteries, and supplementary fluids. The most common pumps used are Body Guard, Curlin, and CADD.
 - Deliveries are on an as needed basis and worked out between the PN pharmacy and the patient by phone or email.
 - PN pharmacy will coordinate the delivery of PN to holiday destinations. Nationwide companies can easily fax PN formulas to office closest to holiday destination. That office will then carry out the PN manufacturing and delivery.
 - No speciality fridge provided, it is recommended to store PN in a fridge that does not store food.
 - Custom mix includes lipids mixed in, as needed or, in a chamber bag that separates the lipids from the TPN until prior to use. Custom mix PN must refrigerated and used within seven days of delivery.
 - The patient will need to inject the vile of vitamin solutions and occasionally other additives immediately prior to use.
 - PN patients are taught how to set up PN in the hospital and then are visited multiple times by a homehealth nurse to ensure perfection of method and proper hygiene techniques.
 - PN pharmacies recommend the presence of a homehealth nurse for any central line/port dressing change or even PN set up.
 - PN pharmacy will send out homehealth nurse to draw labs for prescribing physician as he/she sees fit. This could be weekly all the way to bi-monthly.

PN packaging and delivery

Australia/New Zealand

- Various types of PN bags and formulations received. Most HPNers receive refrigerated customised formulations in dual chamber bags with rod to be removed just before infusion to mix in lipids.
- Bags are single thickness.
- PN is usually delivered weekly. Only delivered in business hours Tues-Fri (plus Mondays in Sydney, Perth and Melbourne). No out-of-hours deliveries except in any emergency. Patient must be home to receive delivery.
- Except for a small number of Baxter contract couriers, most deliveries made by external courier drivers.
- Outside of Sydney/Perth/Melbourne deliveries, PN is transported overnight by plane or refrigerated trucks, then by local courier drivers.
- Cold chain begins once PN is delivered to HPNer – PN is compounded at room temperature, with a certain timeframe (dependent on formulation) before PN needs to be at/kept at 2-8°C. Deliveries are made in this timeframe. It's the responsibility of the HPNer to begin and maintain cold chain.
- Boxes (i.e. icebricks, insulation, boxes) are only to protect PN from being affected by extreme temperatures; not to maintain 2-8°C.
- Packaging is not collected by Baxter.

United Kingdom

- We have temperature controlled boxes which allow us to maintain 2-8°C for up to 34 hours (big boxes) for transporting compounded PN. Good for travelling, used by some homecare companies.
- Some companies have refrigerated vans rather than boxes.
- Each of the seven companies offer different packaging – validation, size and ability to store different volume and number of bags will vary.
- In extreme circumstances PN may arrive at room temperature, HPN will usually, 99.9% if the time be delivered via a cold chain process. Only happens if compounding is on the day of delivery for an extreme reason.
- Re-use boxes and packaging, saves waste – HCC will remove unwanted packaging as it is rather excessive
- Deliveries usually fortnightly for feeds, four weekly for ancils, all companies must offer a key holding service, it's mandatory but not everyone elects to use it. Good so don't have to stay at home.
- Deliveries on weekends/out of hours, if required but certainly not encouraged.
- Multilayer PN bags for HPNers. Extends stability also prevents champagne effect. Come in various sizes, most suitable size used for volume of feed.
- Lipids come ready-mixed in formulations where relevant, multi-chamber bags used for travelling, mixing rules apply.
- Stability on PN bags vary per regime but usually 7 – 21 days. Use within 24 hours once out the fridge.

USA

- Various types of PN bags including chamber bags to separate lipids from PN until right before use.
- Bags are double thickness
- Deliveries can only be scheduled on weekdays, Mon-Fri, with the exception of some holidays. Deliveries can be carried out past office hours into the evening.
- Deliveries can be carried on weekends for emergencies.
- Regular deliveries can be made once or twice a week. Days of delivery are pre-agreed upon by PH pharmacy and patient.
- PN is home delivered by the PN pharmacy. If they know that someone is home waiting for the delivery it will be sent in a cardboard box with cooler packs. If it is dropped off at the home will be in a cooler with cold packs. Courier usually requires a signature from patient or PN receiver.
- Once PN is delivered to home, it must be refrigerated as soon as possible. Custom mix PN is good for 9 days in the fridge, 24 hours outside the fridge.
- Packaging is recollected and re-sterilized by some PN pharmacies.