

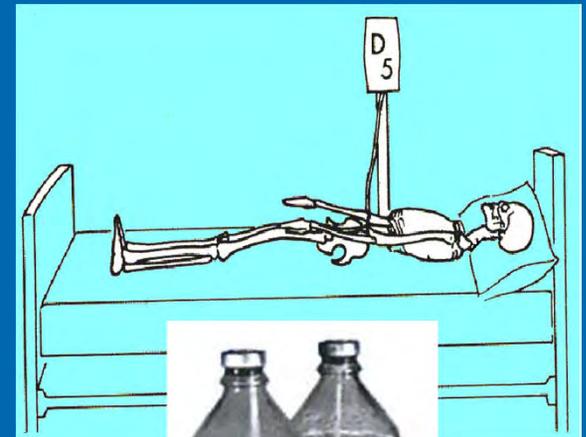
TPN

Past, Present & Future



Past

- Early 1900's
 - glucose, saline and few IV fluids
- 1940's
 - amino acid (protein) solutions
 - lipid emulsion (soya oil based)



1st Generation

- Christmas Tree TPN



- High clinical error and infections

2nd Generation

- dual and multi-chamber bags,
- customised '*2 in 1*' or '*All in One (AIO)*'



2nd Generation

- TPN solutions
 - made from various ingredients:



- Dispensing: carried out in a certified 'clean-room'



2nd Generation

➤ Essential Requirements for Setting up a Dispensing (Compounding) Facility:

- Certified Clean Room (ISO 14644) and a Quality Managing Systems (ISO 13485). *Standard of compliance may vary from country to country.*
- Availability of macronutrients (critical)
- Availability of micronutrients (not critical but highly desirable)
- Trained personnel (pharmacists & technicians)
- Appropriate equipment and consumables (sourcing)

2nd Generation

➤ Overview of Process:

1. Preparing stock solutions
2. Sterilisation by Autoclave



2nd Generation

3. Standard Stock Solutions
which don't need further
compounding

4. Compounding
in clean room
with LAF Hoods



Compounded TPN

- By aseptic compounding



3rd Generation

- In 95% individualised formulation may not be needed.
- Use of Standard PN solutions is likely to be more beneficial
- adult patients:
 - OliClinomel (Baxter)
 - SMOFKabiven (Fresenius Kabi).
- For paediatrics, Numeta (Baxter Europe)
- For neonatal, *NICU (NSW) Consensus Solution (currently compounded by Baxter)*

3rd Generation

- Triple chamber bags
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3rd Generation

- Similar to 2nd generation
- filling machine is designed to fill 2 or more different solutions into separate chambers simultaneously,
- sterilised by autoclaving.



3rd Generation

- Currently, ready to use TPN is limited to adult formulations
- Market size and regulatory requirements make it almost prohibitive, economically speaking.
- At present, PN for neonates remains half way between 2nd and 3rd.
- For 2nd to 3rd Generation through ANZ then need to have this same formulation around Asia Pac region as well in terms of going to 4th Generation: 'mass production'.
- Standard PN for paediatrics (for ANZ) has yet to be developed.

Opportunities & Options

- It may take some years to see '*ready to use*' neonatal and paediatric PN manufactured by the major companies.
 - Companies will take on only if the volume is high
 - Development and registration will take several years.
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Opportunities & Options

- In the interim
- small compounding unit(s) can be set up by using basic ingredients available.
- Consultation with local regulatory bodies
- Opportunity exist for our team to assist in making 3rd generation TPN