

# EVOLUTION OF PARENTERAL PAEDIATRIC NUTRITION (PPN) PRODUCTION OVER 30 YEARS IN A UNIVERSITY HOSPITAL PHARMACY

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## BACKGROUND

Parenteral nutrition solutions are frequently prescribed in our institution for both the paediatrics and neonatal units. Since the middle of the 70's they have been produced à la carte in the HUG pharmacy. In the case of adults, the solutions are supplied ready-to-use by the pharmaceutical industry for the majority of cases. The number of PPN solutions has increased from 300 per year to over 2000 in 2003. Numerous manual stages were necessary until 2002 when a fully automated compounding device was introduced. The objective of this study was to show the constant improvements in both quality and security over the 30 year period.

## DESIGN & SETTING

A retrospective study and review of the development of the process.  
Aseptic Unit (3 sites since 1974), Pharmacy department, Paediatrics and Neonatal units HUG.

## MAIN OUTCOME MEASURES

Evolution of the equipment, materials and the transfer of medical orders is described. Determination of the number of prescriptions produced, the manufacturing time, the analytical methods used, cost effectiveness and the progress in environmental standards.

### Before 1980

#### Approximately 300 PPN per Year

- \* **Manual stages**
- Medical order
- Calculations double checked
- Solution measurement outside aseptic area
- Sterile filtration using a pressure vessel under laminar air flow (LAF)
- Filling by volume into glass bottles (LAF)
- \* No Clean Room environment
- \* No analytical controls performed
- \* Time consuming

### 1980 - 1985

#### Approximately 500 PPN per year

- \* **Manual stages**
- Medical order
- Solution measurement outside aseptic area
- Filling by volume : Bottles / syringes (LAF)
- \* **Semi-automatic stages**
- Electronic calculator Texas Ti 59 with memory card<sup>1</sup>
- Filtration with peristaltic pump and Ivex® single-use filter under LAF
- Labelling using Framework® program
- \* No clean room environment
- \* Analysis : Na, K and G5. Sterility test
- \* Faster filling time.
- \* Calculation time reduced by 6

### 1985 - 2000

#### 500 - 2000 PPN per year

- \* **Manual stages**
- Re-transcription of electronic medical order in the pharmacy
- Solution measurement outside aseptic area (Class C environment from 1997)
- \* **Automatic stages**
- The first computer based prescription program using DOS Quick-Base® used by the doctors (1988)<sup>2</sup>
- New labelling program using dBase® (1990)
- Filling by weight into EVA plastic bags with a programmable peristaltic pump under LAF using a single use / large capacity filter for daily use (with wash-out)
- \* Manufactured in Class B clean room since 1997
- \* Analysis (as 1980 - 1985)
- \* Even faster filling time
- \* Further reduction in calculation time
- \* Particulate matter reduction (EVA versus glass)

### After 2000

#### More than 2000 PPN per year

- \* **Automatic stages**
- Validation of a Baxa MM12 automated compounder (December 2000)<sup>3</sup>
- An integral prescription program was developed using Access® that generates the medical orders, prints the production sheet and the labels and also pilots the compounder
- \* Manufacture under LAF in atmosphere controlled Class B clean room<sup>5</sup>
- \* No solution measurements (automatic filling carried out from original packs)
- \* All materials supplied sterile to clean room using isolator transfer technology
- \* Analysis (as 1980 - 1985)
- \* Particulate load of PPN solutions determined (terminal filtration is not possible)<sup>6</sup>
- \* Risk analysis (AMDEC) has been performed<sup>7</sup>
- \* Reduction in both production time (50%) and costs have been seen

## CONCLUSIONS

Due to technological progress over the 30 year period, enormous steps have been made to reduce errors by avoiding re-transcription of medical orders. A significant gain in time and cost effectiveness has been seen and both working and environmental conditions have been improved. Considering both composition and technical complexity of PPN solutions, a safer process permitting an important risk reduction has been developed.

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