PS-042

PARENTERAL NUTRITION (PN) IN PREMATURE INFANTS: RISK ANALYSIS AFTER REDESIGNING A PRODUCTION PROCESS

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OBJECTIVE

Quantifying the risk reduction derived from redesigning the prescription and compounding process of parenteral nutrition (PN) for preterm infants, identifying residual risks in the current process and planning measures to solve them

METHODS

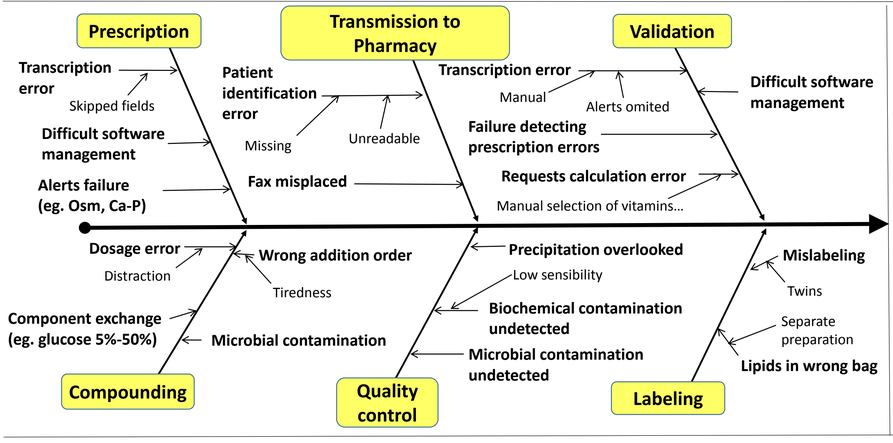
- Failure mode, effects and criticality analysis (**FMECA**) to determine the risk of PN performance process.
- **Brainstorming sessions** in order to agree and discuss the **critical points** in the different phases of the process: prescription, validation, processing, quality control and labeling.
- Errors were qualified in terms of its probability of occurrence (O), severity (S) and detection capacity (D) in the process, assigning values from 1 to 10.
- **Criticality Index (CI)** = Occurrence (O) x Severity (S) x Detection capacity (D)
- The **difference** between previous and current CI's processes allowed us **to compare the risk** management in both processes and prioritize those points which required immediate action.

Table 1: Comparative summary of old and current processes of neonate parenteral nutrition

STEPS	OLD PROCESS	CURRENT PROCESS
1. Prescription	Manual	Computer software (Nutriwin®)
2. Transmission to Pharmacy	Fax	Prescription chart saved in Nutriwin®
3. Validation	By comparison with protocol and transcription to Excel → Ca-P precipitation, not osmolarity	Comparing to previous days through Nutriwin® Alerts of Ca-P precipitation and osmolarity
4. Label production	Electronic (Excel)	Electronic (Nutriwin®)
5. PN compounding	Initial double-check: person who prepares material is different from the person who prepares PN	Double-checking throughout the process: supervision of the process by a person different from PN performer
6. Quality control	Visual analysis of the bags to detect precipitation	Visual analysis of the bags to detect precipitation Biochemical analysis Weight control of the bags
7. Labeling	Assistant	Assistant

RESULTS

Main critical points detected (Total = 31)



Effect on neonate

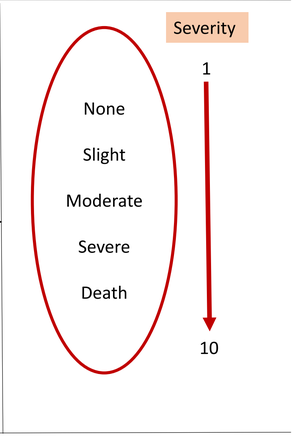
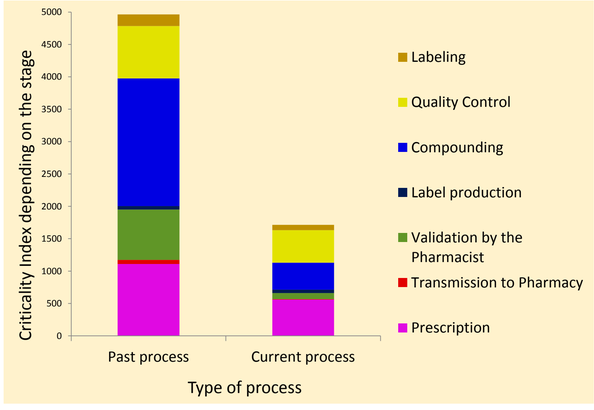
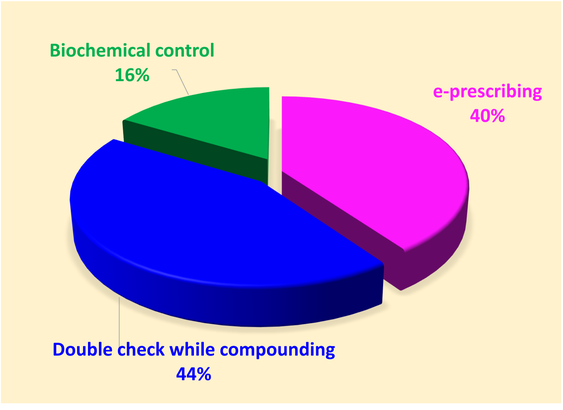


Figure 1: Ishikawa cause-effect diagram based on the PN production process



Graphic 1: Criticality Index according to stage in both processes



Graphic 2: RR distribution among the main changes carried out

Difference = CI Past Process – CI Current process = 3249

Risk Reduction (RR) = (Difference/CI Past process) x 100 = **65,5%**

Remaining risk (nearly 30%) is related in part to the management of a new computer system, for which a user manual and a training program have been developed. Future automation of the compounding process could also help in reducing the risk.

CONCLUSIONS

- PN prescription and compounding process for preterm infants is considered a critical process in Hospital Pharmacies, and so, it is necessary to re-evaluate it frequently.
- The implementation of e-prescribing, double-checking and biochemical control has allowed to achieve an **important overall risk reduction**.
- It is necessary to evaluate residual risk and establish suitable corrective measures
- Risk management applied to Hospital Pharmacy processes is a valuable tool in order to improve quality and safety.

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Authors declare no conflicts of interest