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 labelling.
- 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

<table>
<thead>
<tr>
<th>STEPS</th>
<th>OLD PROCESS</th>
<th>CURRENT PROCESS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Prescription</td>
<td>Manual</td>
<td>Computer software (Nutriwin®)</td>
</tr>
<tr>
<td>2. Transmission to Pharmacy</td>
<td>Fax</td>
<td>Prescription chart saved in Nutriwin®</td>
</tr>
<tr>
<td>3. Validation</td>
<td>By comparison with protocol and transcription to Excel</td>
<td>Comparing to previous days through Nutriwin® Alerting of Ca-P precipitation and osmolality</td>
</tr>
<tr>
<td>4. Label production</td>
<td>Electronic (Excel)</td>
<td>Electronic (Nutriwin®)</td>
</tr>
<tr>
<td>5. PN compounding</td>
<td>Initial double-check: person who prepares material is different from the person who prepares PN</td>
<td>Double-checking throughout the process: supervision of the process by a person different from PN performer</td>
</tr>
<tr>
<td>6. Quality control</td>
<td>Visual analysis of the bags to detect precipitation</td>
<td>Biochemical analysis Weight control of the bags</td>
</tr>
<tr>
<td>7. Labeling</td>
<td>Assistant</td>
<td>Assistant</td>
</tr>
</tbody>
</table>

RESULTS

Main critical points detected (Total = 31): Prescription, Transmission to Pharmacy, Validation, Compounding, Quality control, Labeling.

Effect on neonate

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

Graph 1: Criticality Index according to stage in both processes

Difference = CI Past Process - CI Current process = 3249
Risk Reduction (RR) = (Difference/CI Past process) x 100 = 65.5%

Graph 2: RR distribution among the main changes carried out

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.