Background and Importance

In case of non-centralized sterilization units, there is a lack of understanding of the effectiveness of different steam sterilization processes. In such case, the risk of failure is major. This may lead to the non-sterility of treated medical devices which can affect heavily the patient health.

Objectives

The present study aimed to determine risks related to the steam sterilization processes in non-centralized sterilization units of the teaching Charles Nicolle hospital of Tunis in Tunisia according to a failure mode and effects analysis (FMEA) method.

Methods

- Multidisciplinary study team recruitment
- Process cartography building
- Related failure modes definition by work groups
- Failure modes classification according to criticality index CI
- Prioritization of failure modes
- Corrective and preventive actions proposition
- Cause-effect diagram
- Each group worked on one step by brainstorming meetings
- Vote on criticality parameters according to a predefined grid (scale of 9 or 10)
- By adopting the medium and the mode values of CI as limits
- Validation by the members of the sterilization committee

Results

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N failure modes</td>
<td>135</td>
</tr>
<tr>
<td>Total CI</td>
<td>17790</td>
</tr>
<tr>
<td>Pre-desinfection median CI</td>
<td>145</td>
</tr>
<tr>
<td>Cleaning median CI</td>
<td>164</td>
</tr>
<tr>
<td>Packaging median CI</td>
<td>184</td>
</tr>
<tr>
<td>Autoclaving median CI</td>
<td>228</td>
</tr>
</tbody>
</table>

Failure modes typology

- 32% - Pre-desinfection
- 25% - Cleaning
- 23% - Packaging
- 20% - Autoclaving

Prioritization

- Critical 67% of total CI
- Acceptable 10% of total CI

To control 23% of total CI

Corrective and preventive actions

- Implementation of the documentary system 4689 points
- Training of agents of the steam sterilization units 4550 points
- Supply of consumables (hygiene, autoclaves, cleaning) 3170 points

Conclusions

Applied FMEA method was useful to prioritize actions in order to efficiently minimize risks related to the steam sterilization process. Training the personnel on steam sterilization units, strengthen their knowledge on hazards and good practices, are essential to guarantee the safety of both personnel and patient.

References