ANALYSIS OF MATERIOVIGILANCE BOTTOM UP ALERTS RELATED TO MEDICAL PERFUSION DEVICES

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Contexte
Materiovigilance (MV) bottom up alerts related to medical perfusion devices represent 14% of all received alerts. They include several types of medical devices (MD) and may instigate incidents or risks of serious incidents.

Objective
The purpose of this investigation is to realize a risk mapping of infusion based on materiovigilance bottom up alerts in order to prioritize our preventive actions.

Methode
A retrospective study of MV bottom up alerts in our establishment was conducted from October 2015 to September 2016. We applied a failure modes and effects analysis method for each bottom up alert. We quoted frequency and severity to determine the net criticality and classify them in minor, major or critical.

Results
80 incidents or risks of incident in our MV service
- 26.25% perfusion sets
- 40% extensions
- 33.75% catheter

Main critical risks identified:
- gas embolism
- infectious risk

Causes of the incident:
- 8 cases: the device itself
- 19 cases: not identified

MV bottom up alert incidents or risks of incident

Discussion
Also materiovigilance deals with a default of a device, the bottom up alerts received most often are related to a misused of the device. Training concentrated on prevention of gas embolism and infectious risks in infusion will be set up in partnership with our hygiene service and the nursing directorate of our institution.