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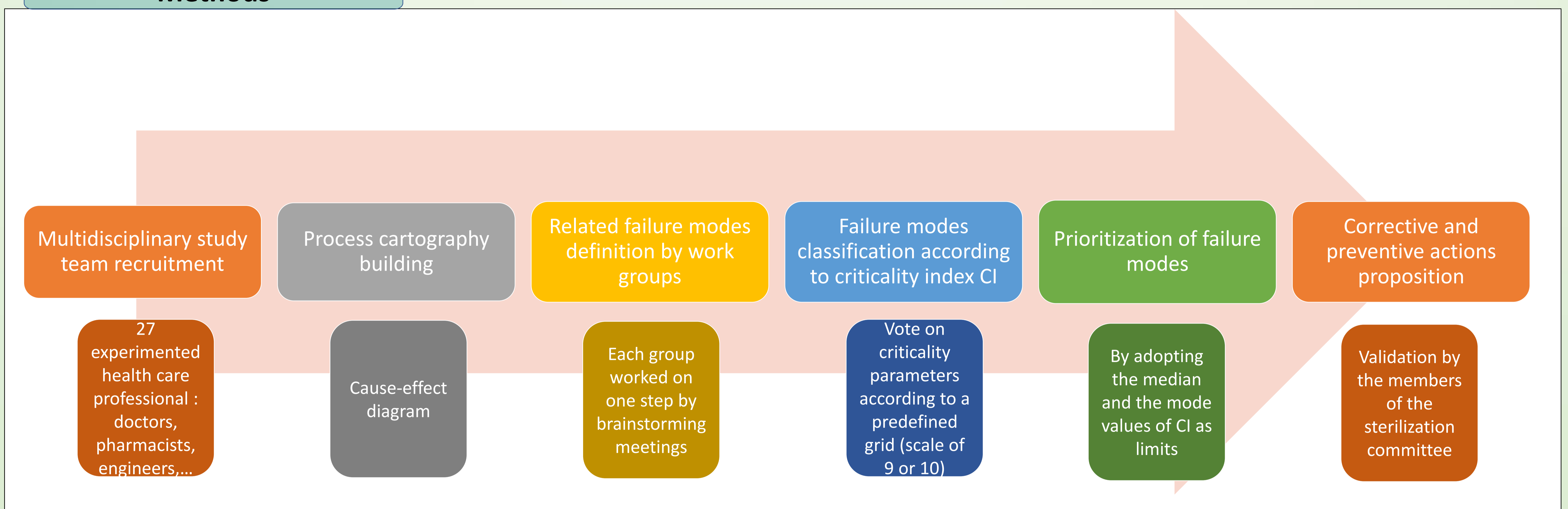
Background and Importance

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



Results

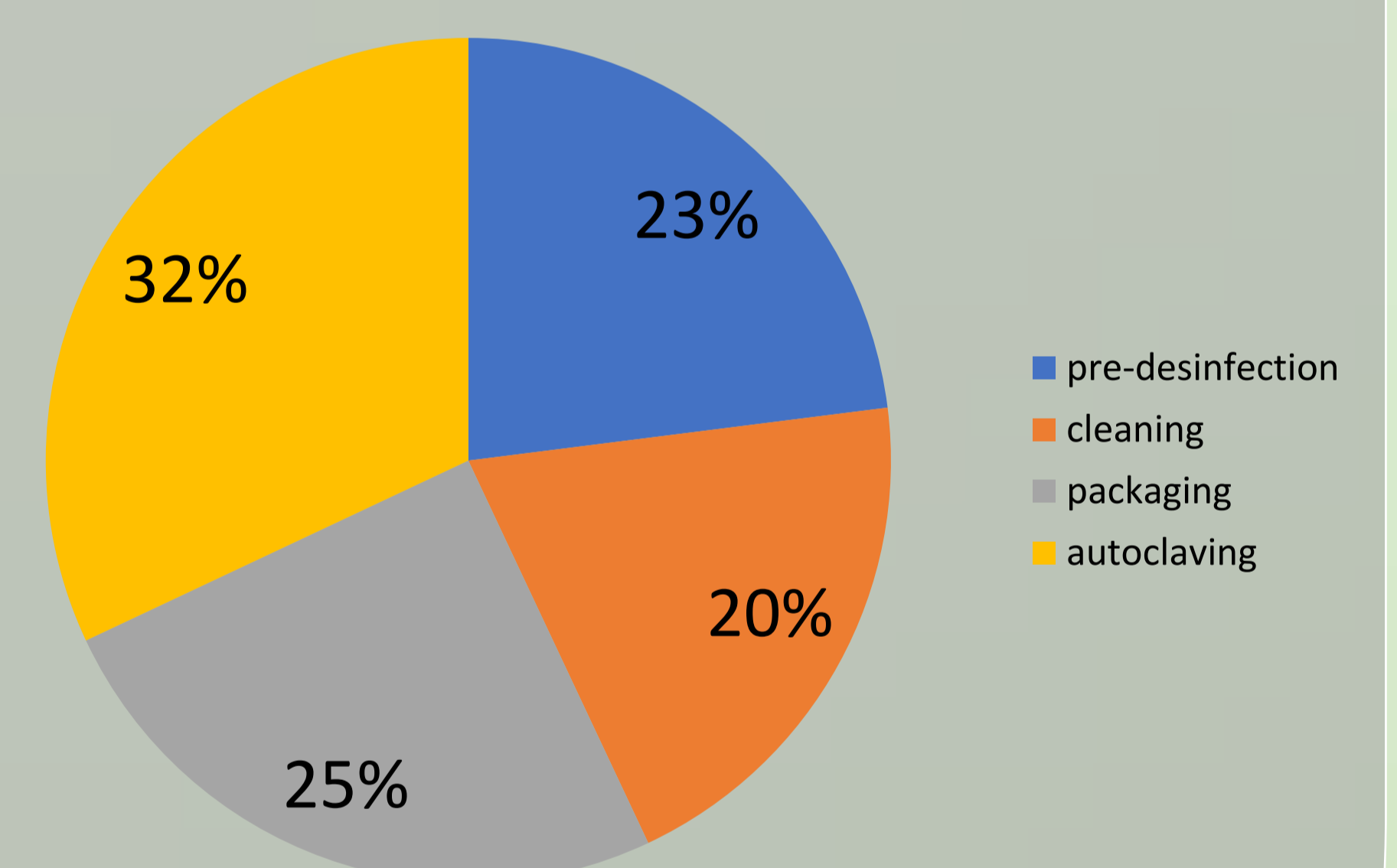
General statistics

Variable	Value
N failure modes	135
Total CI	17790
Pre-desinfection median CI	145
Cleaning median CI	164
Packaging median CI	184
Autoclaving median CI	228

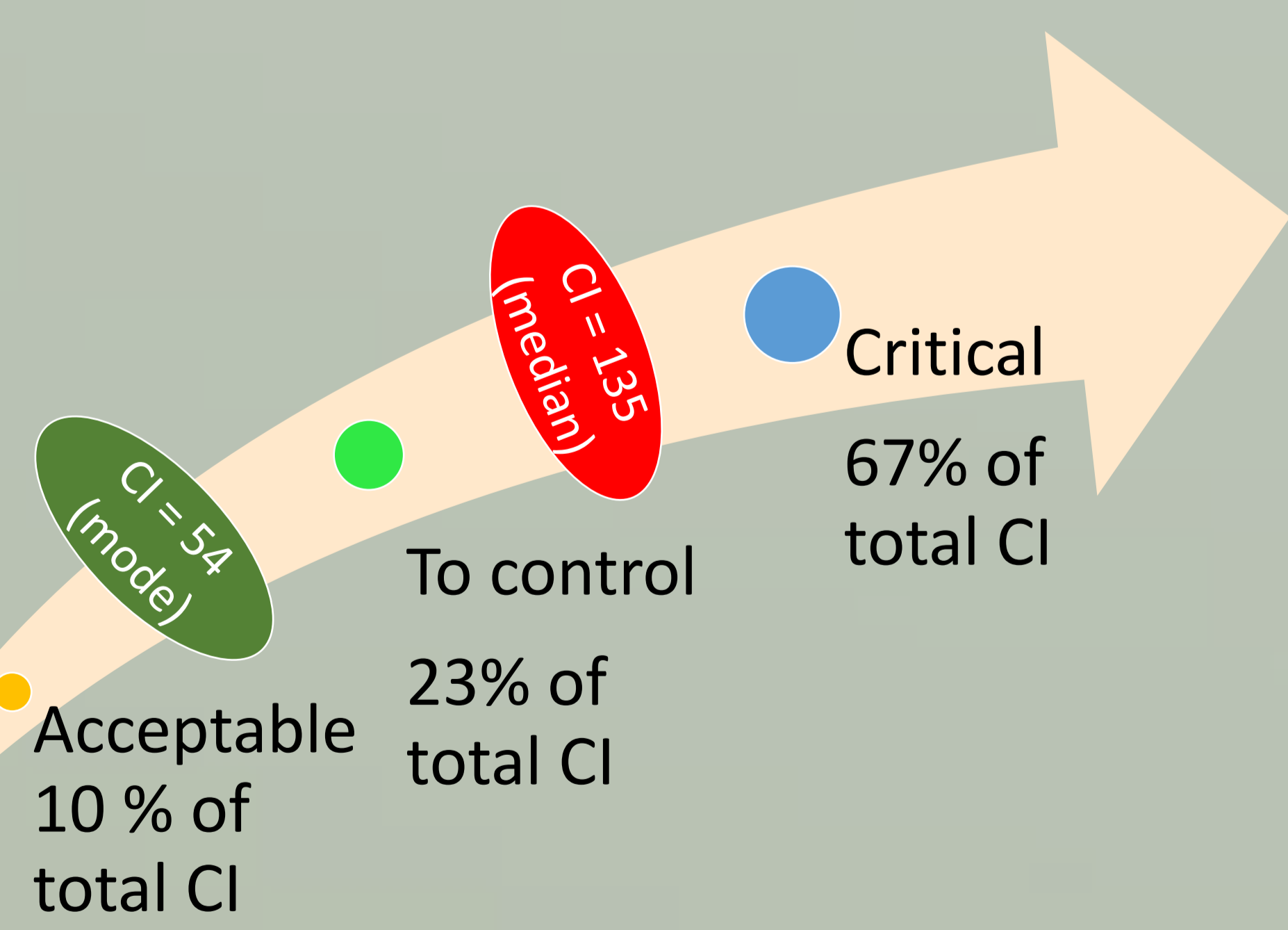
Higher CI failure modes

Step	Failure mode	CI
Autoclaving	Non-performing autoclave	288
Autoclaving	Damaged packaging	280
Packaging	Damaged containers not ensuring closure	245
Pre-desinfection	Inadequate concentration of the pre-desinfection solution	240
Autoclaving	Bowie-Dick test not done	240
Autoclaving	Non-compliant storage time	240
Pre-desinfection	Medical device not properly treated	224
Autoclaving	Wet packaging	224
Autoclaving	Inappropriate cycle type	210
Packaging	Unsealed container	196
Packaging	Incorrect quantitative / qualitative composition	192
Packaging	Filter not changed	192
Packaging	Inappropriate folding	192
Packaging	Unclean containers	192
Autoclaving	Damaged packaging	192
Autoclaving	Unverified integrators	192
Autoclaving	Unused integrators	180
Packaging	Container leakage not checked	175
Packaging	Non-conforming weld (sheath, bag)	175
Autoclaving	loading of the load	168

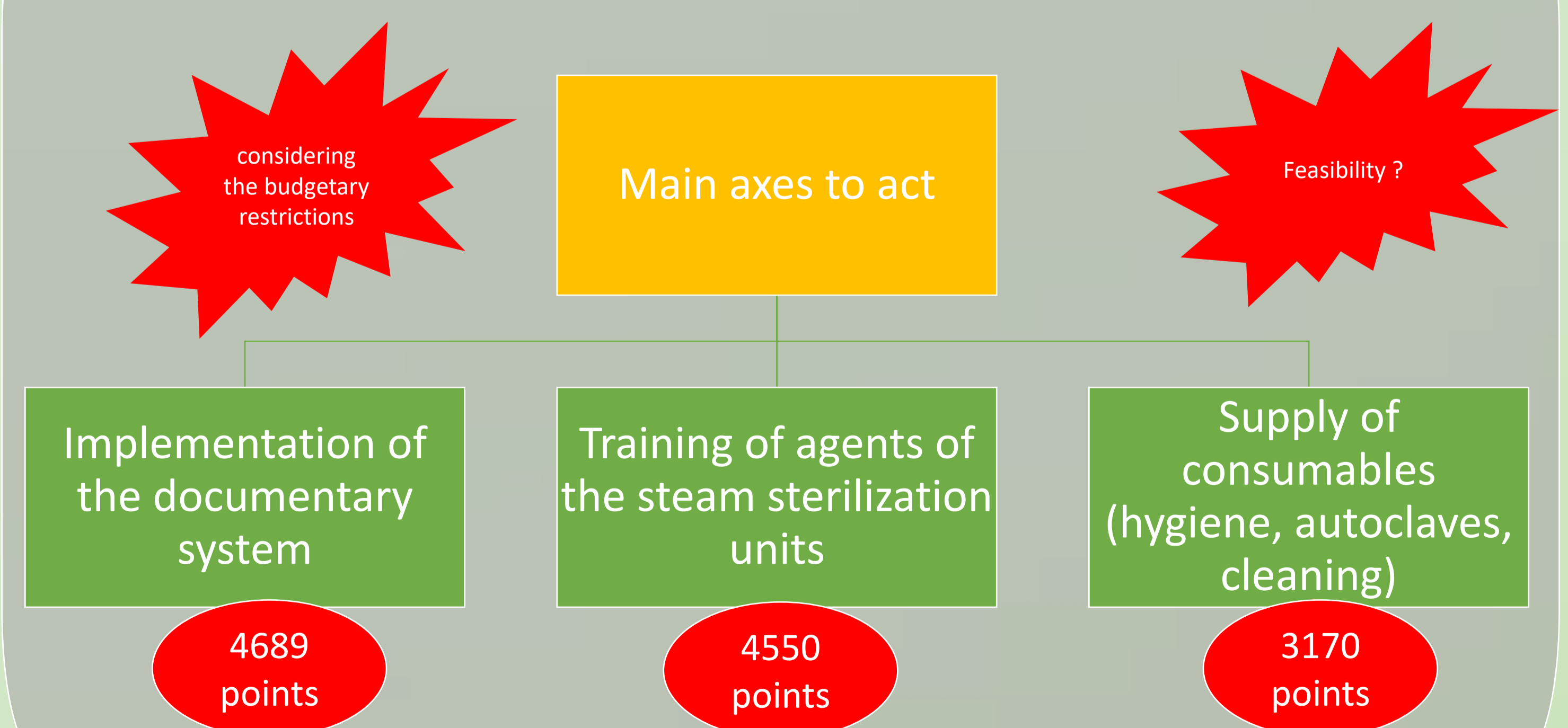
Failure modes typology



Prioritization



Corrective and preventive actions



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

AORN J. A Practical Guide to Performance Improvement: Failure Mode and Effects Analysis. 2019 Sep;110(3):282-287.

