PROSPECTIVE RISK ANALYSIS ABOUT THE OSTEOSYNTHESIS IMPLANTS SUPPLY PROCESS

E.Jouhanneau, A.Champier, M.Hehn, L.Bertrand, R.Gervais
Centre Hospitalser de Saint-Denis, 2 Rue du Dr Delafontaine, Service Pharmacie, Saint-Denis

CH Saint-Denis

16th World Sterilization Congress

INTRODUCTION

The study is following several declarations of nonconformities from surgeons. Two main dysfunctions were identified: a delay to stock up on osteosynthesis implants and orders' mistakes. The objectives were first the achievement of a risk mapping related to the process of osteosynthesis implants and, second, the implementation of corrective measures to reduce identified risks.

MATERIALS AND METHODS

A multidisciplinary team, formed in October 2014, validated results at each step of the study. The method of preliminary risks analysis (PRA) allowed us to describe the supply system of implants to identify risks and to seek improvement actions.

Step 1 : Constitution of a multidisciplinary team → Step 2 : System description → Step 3 : Definition of different classes → Step 4 : Mapping of hazardous situations and scenarios → Step 5 : Risk ranking and follow-up actions

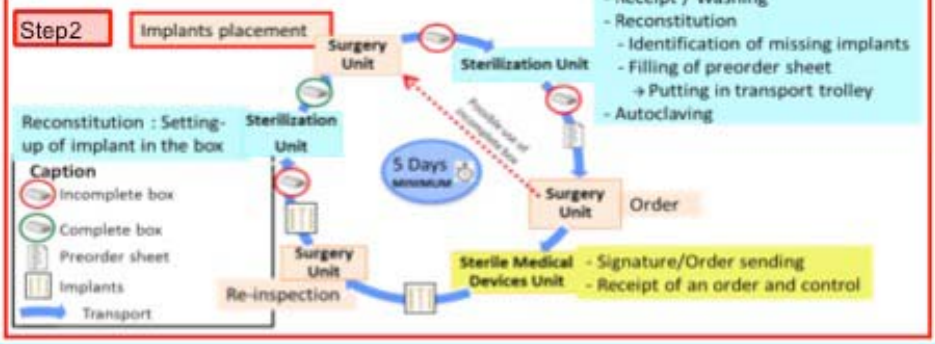
RESULTATS

Step 1

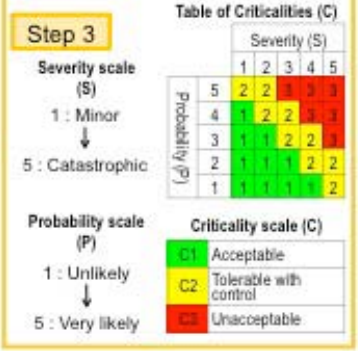
Working group

- Quality Unit
- Surgery Unit
- Sterilization Unit

Step2



Step 3



Step 4

During the analysis, 47 hazardous situations were identified, among which, 40 were quoted first in priority and led to the description of 48 risk scenarios.

Exemples of 3 scenarios (out of 48) which has led to follow-up actions

X Y	Dangers	System	Dangerous situation	Contact cause	Feared event	Primer cause	Existing treatments whose detection procedures	Consequences	S i	P i	C i	Risk reduction actions and identification of deciding authority	LE	S r	P r	C r
8	MAN	B3	Training failure of the person who fills preorder sheet	*Lack of training*	Ordered implant' s mistake	*Misidentified missing implant*	Generic preorder sheets	52 Cancellation during surgery or non ideal implant placement	5	3	3	Action 5 : Review of preorder sheets to help the reconstitution Deciding authority: Pharmacist, Supervisor, Operating room nurse	2	4	1	1
11	MAN	B6	Training failure of the person who puts the preorder sheet in transport trolley	*Lack of training*	Delay in ordering	*Not transmited sheet*		41 Disruption of activity which lead of >48hours delay	4	3	2	Action 8 : Information about the modified step: sheet must be given to sterilization supervisor Deciding authority: Pharmacist, Supervisor	1	2	1	1
15	MAN	B1	Implementation difficulties or insufficient skills during the identification of missing implants	*Very complex operations*	Ordered implant' s mistake	*Complex denominations (a lot of references, important resemblance)*	Trained person can help with implants	41 Disruption of activity which lead of >48hours delay	4	3	2	Action 9 : Establish a risk culture, the « no go » Deciding authority: Pharmacist, Supervisor, Operating room nurse	3	3	1	1

MAN : Management | i : initial | LE : LossEffort | r : residual

Step 5

► 3 Exemples of follow-up actions (out of 23)

SECURING BENEFIT

Action 5 : Creation of helping tools for reconstitution

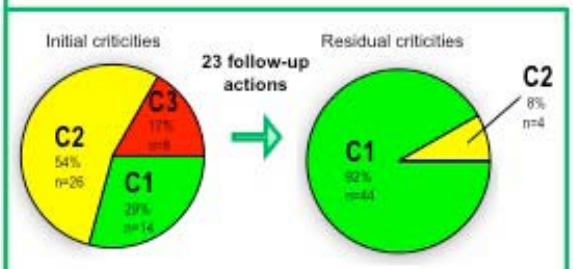
- Denominations revision with orthopaedic surgeons
- Implementation of preorder sheets which are individualized for each box
- Implants storage improvement with clear identification of each drawers and boxes

Action 9 : Establishment of a risk culture, the « no go »

SAVING OF TIME

Action 8 : Command activity transfer towards sterilization

Removal transport steps (preorder sheets + implants)
Delivery:
✓ By hand
✓ Without delay
✓ In a single service (pharmacy)



If 23 follow-up actions are realized, risks will be acceptable or tolerable with control.

NEW SYSTEM

DISCUSSION / CONCLUSION

Both dysfunctions are under control. Ten action measures are realised and 5 are in progress. The study has led us to realize the complexity of initial system. The PRA allowed us to involve all process actors in the development of a risk management policy.
The new system has led to new risks that would require a new assessment. It is necessary to continue the ongoing actions and assess their impact. The PRA constitutes an appropriate tool for assessing quality-improvement policy and safety in healthcare facilities like the sterile processing department.

elsa.jouhanneau@gmail.com