PSQ13554

SECURING THE MANAGEMENT OF EXPERIMENTAL PRODUCT IN INVESTIGATOR SERVICES IN CASE OF NON-NOMINATIVE DISPENSING: A RISK-BASED APPROACH

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WHAT WAS DONE?

A **risk analysis** of **non nominative dispensation of experimental drugs process** was conducted to streamline, secure, optimize, and standardize the dispensation process.

WHY WAS IT DONE?

Clinical trials in critical care involve:
- Inclusion and administration **24H/24h** possible
- **Emergency** inclusions can required

→ To allow these possibilities we can do:
Non nominative dispensation
=
dotation of experimental drugs directly in clinical departments

→ But the dispensation process is considered as :
- **Suboptimal**
- **Less secured**
- **Uncontrolled**

Risk analysis for the dispensation process
→ Securing the management of experimental product in case of non nominative dispensation

HOW WAS IT DONE?

1. DEFINE THE SYSTEM

From reception at the pharmacy department to the administration of the experimental product (including returns)

2. DEFINE THE STAKEHOLDERS

3 Pilot clinical departments

- **Surgical Intensive care**
- **Post-Interventional recovery room**
- **Cardiology**

Pharmacy

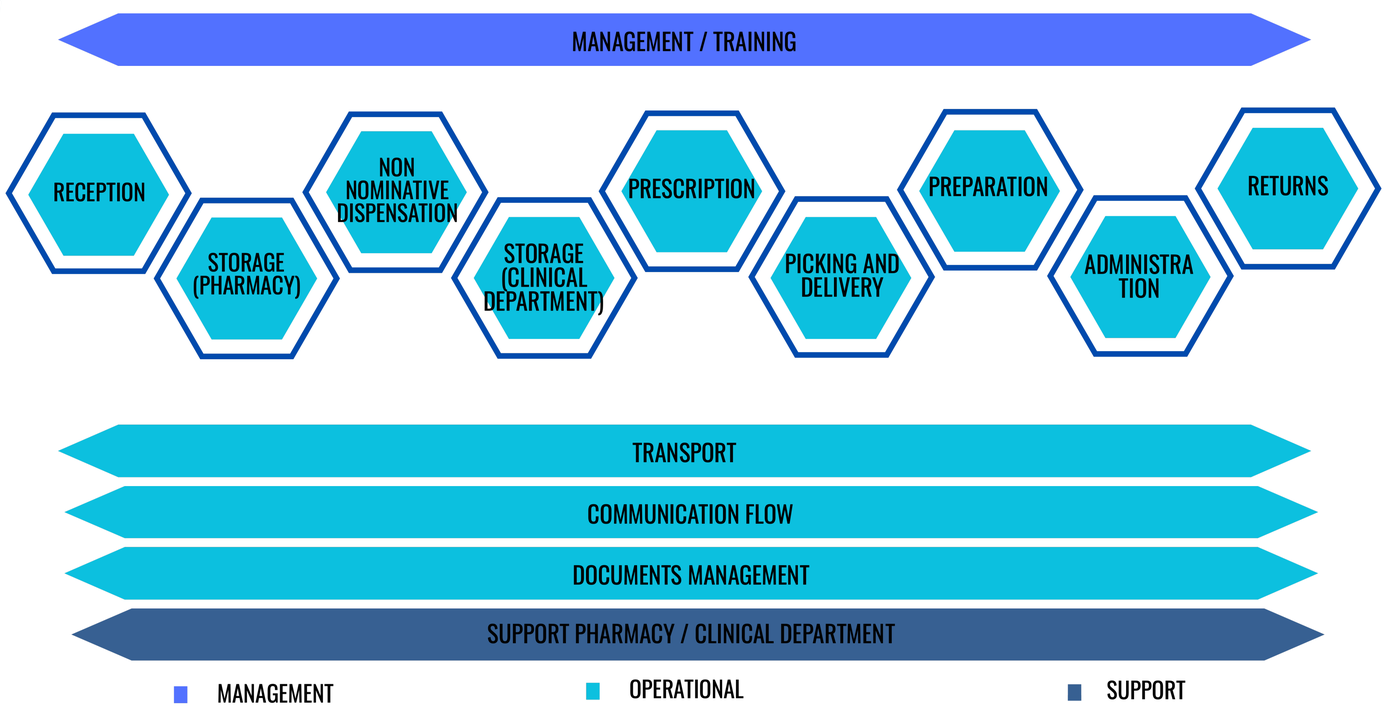
3. FMECA

Failure Mode, Effects, and Criticality Analysis

1. SYSTEM PROCESSUS CARTOGRAPHY
2. IDENTIFY RISKS
3. ANALYSE RISKS — Frequency, Detectability and Severity
4. CLASSIFY RISKS — Criticality
5. ACTION PLAN

WHAT HAS BEEN ACHIEVED?

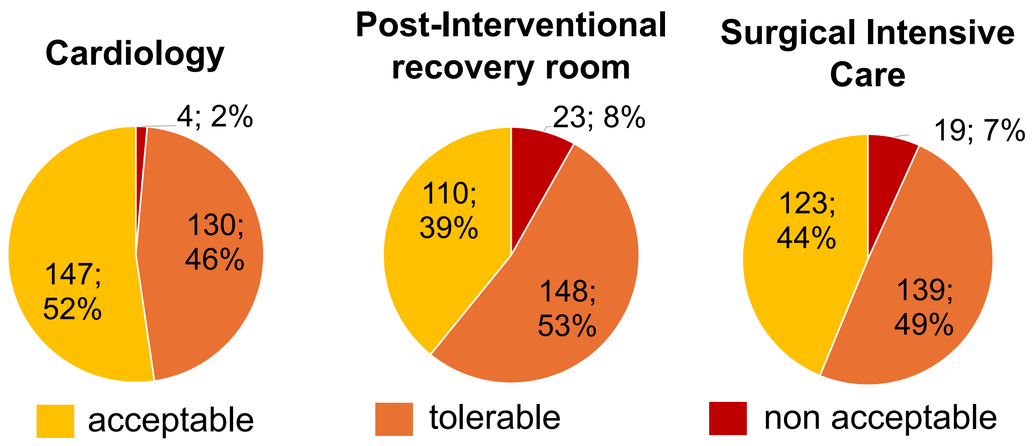
1 SYSTEM PROCESSUS CARTOGRAPHY



2 281 RISKS IDENTIFIED

3 4 ANALYSE AND CLASSIFY RISKS

- **Communication, the most critical for all three clinical departments** (ex : lack of communication between departments)
- **Administration** (ex: traceability)
- **Prescription** (ex: error)
- **Support** (ex :absence temperature monitoring)
- …



5 ACTION PLAN = 17 ACTIONS

Training/Qualifications
- Training programs (nurses and physicians) x2
- Hire qualified personnal
- Systematic tutorials for departments where transfering is frequent
- Binomials investigator/nurse specific

Equipment
- Installation of temperature monitoring system
- Procedures for temperature excursions

Documentation/Cognitive Aid
- Creation of specific form by protocol with
- Thinking the accessibility of specifics forms
- Checklist before starting clinical trials x2

Communication tool
- Sharing info between intensive surgical care and SSPI
- Panel with clinical trials on going accessible
- Flowchart with clinical trials on going
- Flashy labels

Standardization
- Standardization of informations noted in clinical file
- Standardization of prescription

WHAT NEXT?

This risk analysis demonstrated that control over the non nominative dispensation process is **achievable**. Once the actions are in place, a **reduction in criticality is anticipated due to a decrease in the frequency**. **Theoretically** all risks are now tolerable or acceptable. In the long term, this project has the potential to **improve the care of patients enrolled in emergency clinical trials and boost research in the concerned departments**.