Automated nominative preparation of treatments : formalize corrective actions in case of non-conformities

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BACKGROUND

In our hospital pharmacy equipped with a repackaging robot, the **management of production non-conformities** (NCs) and their **associated corrective actions** relied on pharmacists' verbal instructions. This led to **heterogeneous practices, inefficiency, and insufficient process safety.**

OBJECTIVES

Formalize corrective actions associated with production NCs
→ harmonize practices, improve efficiency and strengthen process safety

MATERIAL AND METHODS

Step 1

Analysis of NCs reported in 2024/2025
→ revision of the criticality rating grid for production NCs

CRITICALITY	POTENTIAL CLINICAL IMPACT
Minor	No consequence
Moderate	Treatment delay or omission
Major	Overdose or inappropriate administration

Step 2

Collaborative work + literature review
→ definition of the corrective actions associated with the production NCs

RESULTS

Revision of the criticality rating grid for production NCs

2023 CRITICALITY RATING GRID

Step	Sub-step	Non-conformities		Criticality
Pill dispenser control	Distribution control	NC1	Missing unit dose	moderate
		NC2	Additional unit dose detected by the robot	minor
		NC3	Additional unit dose NOT detected by the robot	moderate
		NC4	Dose unit placed at the wrong time/day of administration	moderate
	Unit Dose control	NC5	Damaged tablet	moderate
		NC6	Damaged blister pack	minor
		NC7	Wrong tablet in the sachet	major
		NC8	Empty sachet	moderate
		NC9	Several tablets in the sachet	moderate
		NC10	Sachet poorly sealed	minor
		NC11	Mandatory information on the sachet illegible	minor

2025 CRITICALITY RATING GRID

Step	Sub-step	Non-conformities		Criticality
Pill dispenser control	Labelling control	NC1	Several patient names on the same tray	major
		NC2	Chronological order not followed	moderate
	Distribution control	NC3	Missing unit dose	moderate
		NC4	Additional unit dose detected by the robot	minor
		NC5	Additional unit dose NOT detected by the robot	moderate
		NC6	Dose unit placed at the wrong time/day of administration	moderate
	Unit Dose control	NC7	Damaged tablet	moderate
		NC8	Damaged blister pack	minor
		NC9	Wrong tablet in the sachet	major
		NC10	Empty sachet	moderate
		NC11	Several IDENTICAL tablets in the sachet	moderate
		NC12	Several DIFFERENT tablets in the sachet	major
		NC13	Sachet poorly sealed	minor
		NC14	Mandatory information on the sachet illegible	minor
Medication pouches control	Identification control	NC15	Unidentified pouch	moderate
		NC16	Identification error	moderate
	Dispensing control	NC17	Omission of a drug	moderate
		NC18	Medication dispensing error	moderate
		NC19	Error in dispensed quantities	minor
Pill dispenser cabinets control		NC20	Omission of production of a pill dispenser	moderate
		NC21	Pill dispenser stored in the wrong cabinet	minor

Extension of NCs monitoring to the entire production process including the preparation of pill dispenser cabinets and the manual preparation of patient-specific medication pouches for treatments outside the robot

Definition of the corrective actions

NON-CONFORMITIES	CORRECTIVE ACTIONS ASSOCIATED
NC1, NC9, NC12	Interrupt the control and notify the pharmacist
NC2, NC6, NC21	Return the unit dose/pill dispenser/tray to the correct place
NC3, NC7, NC10 ± NC8, NC11, NC14	Replace the unit dose
NC4, NC5	Remove the unit dose
NC8, NC11, NC13, NC14	Keep the unit dose
NC15, NC16, NC17, NC18, NC19, NC20	Notify the pharmacy technician for correction

6 general corrective actions →

Flowchart → specific corrective actions for each NCs

For majors NCs : contact immediatly the supplier
For minors/moderates NCs : contact the supplier if the rate of NCs > 4‰

CONCLUSION

Formalizing procedures for managing NCs **standardizes handling, reduces decision variability**, and **promotes staff autonomy**. This approach enhances the **reliability of the final control step** in Automated Dose Dispensing, thereby **strengthening overall process safety.**

References : Armand-Branger S. et al. (2021). Recommandations de bonnes pratiques de préparation des doses à administrer en pharmacie hospitalière à l'aide d'automates de surconditionnement ou d'automates de reconditionnement des formes orales sèches. Le Pharmacien Hospitalier et Clinicien, 56(1), pp. 98-110.