



**21<sup>ST</sup>**   
WORLD  
**STERILIZATION**  
CONGRESS



*Like a flight recorder: Identification of risks  
in reprocessing medical device*

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17 / 20 NOVEMBER 2021  
CICG, GENEVA, SWITZERLAND

In Canada, more than 250,000 patients contract a nosocomial infection;

1. Surgical site infection is the second most common nosocomial infection (in the United States);
2. 77% of postoperative deaths are related to infection;
3. Costs \$1.6 to \$3 billion USD annually. CAN \$ 30,000 to 60,000 / ISO (ICSP 2019).

Factors:

1. patient-related (diabetes);
2. surgical procedures (brushing-asepsis);
3. environmental and organizational (sterilization).

**June 5, 2013** More than 1,000 patients recalled to Hôtel-Dieu de Lévis for HIV and hepatitis B and C testing due to improperly disinfected echo-endoscope

<https://ici.radio-canada.ca/nouvelle/617256/hotel-dieu-levis-rappel-patients>

**September 24, 2014** Recall of more than 1,600 patients in Rimouski who had undergone a prostate biopsy. Sterilization of the housing of the handpiece used to make these non-compliant reprocessed biopsies.

<https://ici.radio-canada.ca/nouvelle/686071/rappel-patients-csss-rimouski-biopsie-prostate-pas-de-panique>

**November 2, 2016** Recall of more than 2,600 patients at the Montreal Heart Institute operated on since May 8, 2014, due to possible contamination of some equipment used during open heart surgery. And at least five other hospitals in the province also recalled patients shortly thereafter.

[http://plus.lapresse.ca/screens/978bc233-9d89-49d2-bc0e-130786b5620a\\_7C\\_0.html](http://plus.lapresse.ca/screens/978bc233-9d89-49d2-bc0e-130786b5620a_7C_0.html)

During the 4th year of surveillance (2017-2018), a total of **4694 adverse events** related to MDR were reported as of June 15, 2018. Of these, **4206 (90%)** were **incidents** and **488 (10%)** were **accidents**, of which 4% with risk of infection.

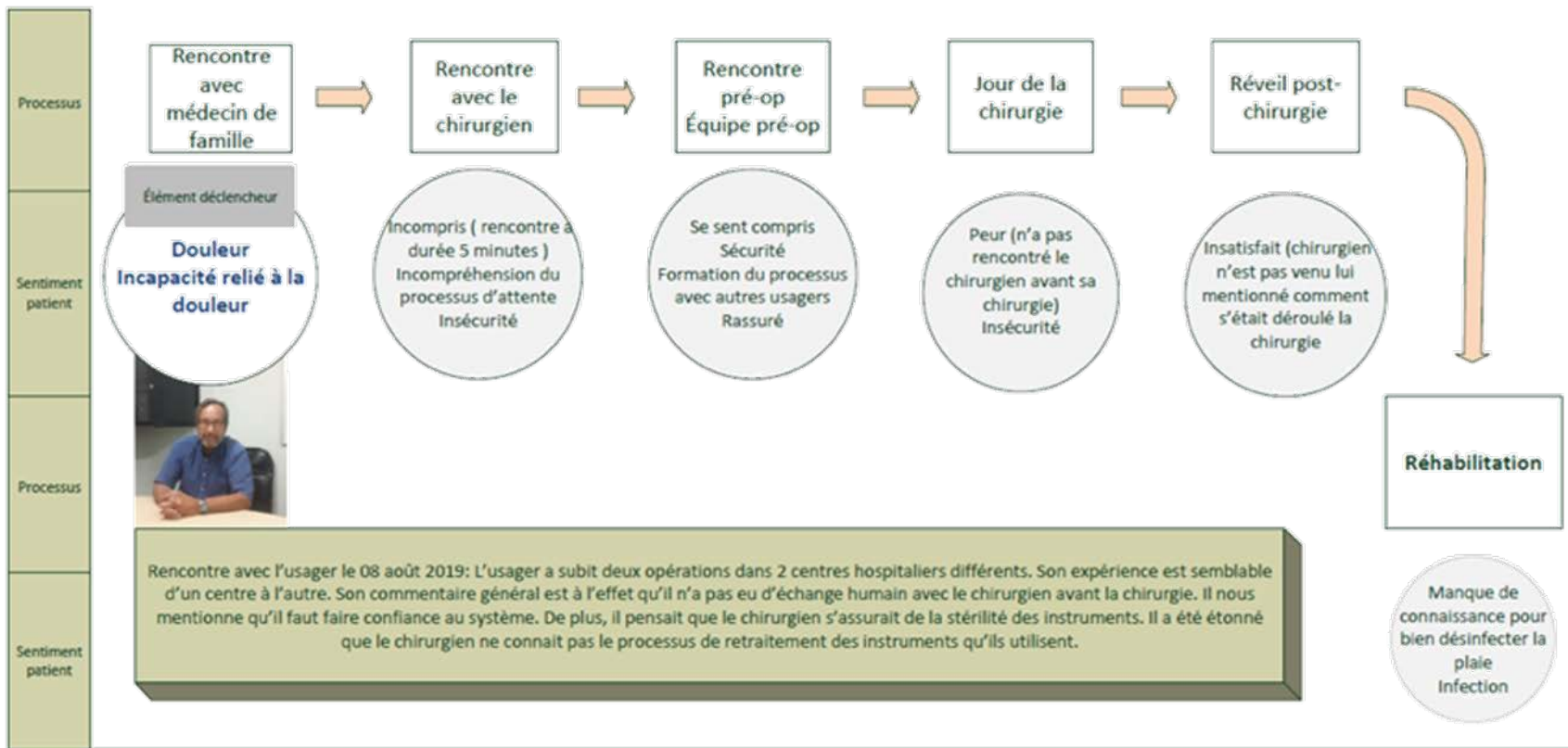
Of the incidents, 90% were related to an interruption in the reprocessing line, mainly in assembly or packaging:

- ✓ **33 at assembly level**
- ✓ **29 at packaging level**

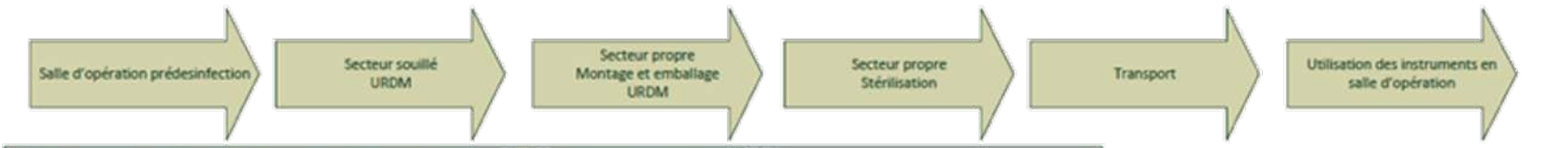
Among accident cases: 30% related mainly to emergency sterilization:

- ✓ Due to unavailability of MDs
- ✓ Lack of work organization

## Cartographie expérience-patient 20 août 2019

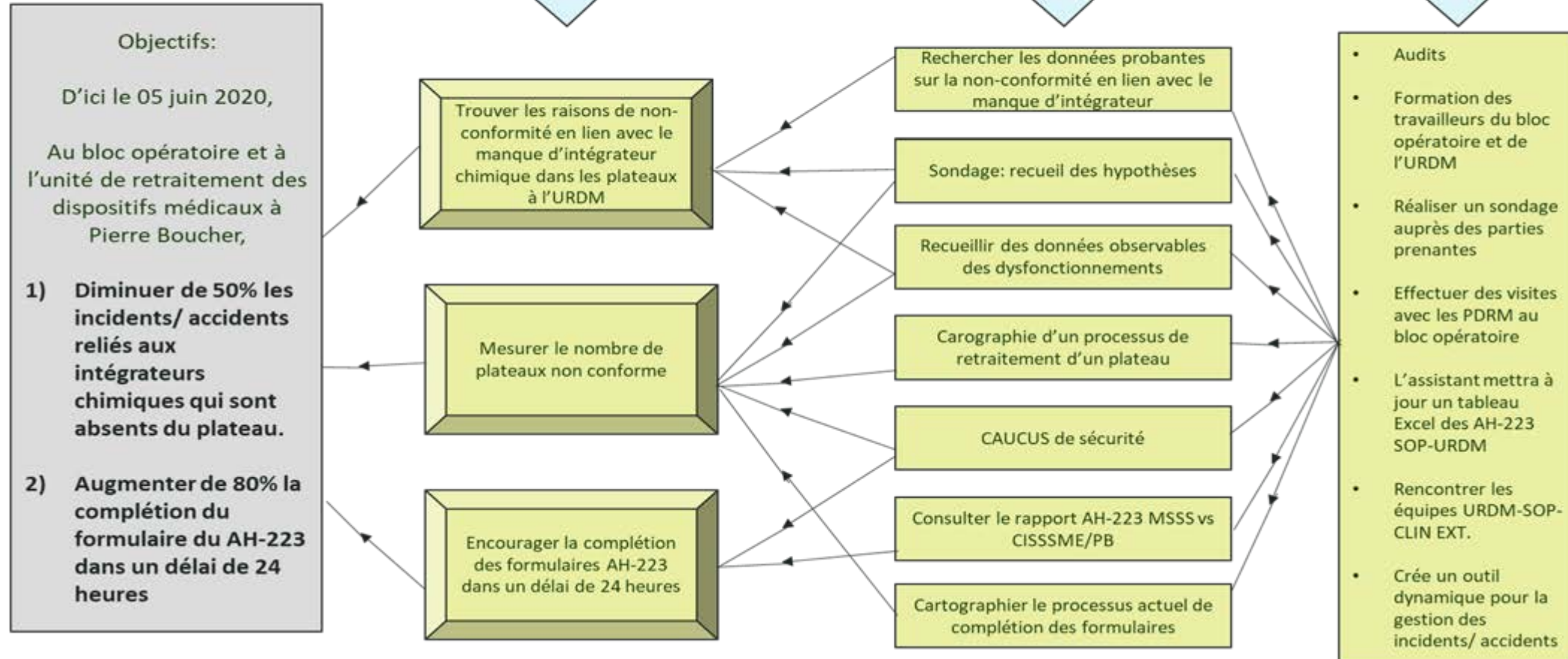


### Processus de retraitement des dispositifs médicaux au bloc opératoire



Légende: Processus d'expérience: [ ] Expérience patient: [ ] transition [ ] Processus de retraitement [ ]

## Cartographie du processus de retraitement des dispositifs médicaux



## Outcome Measures:

### 1) Integrators: **Non-compliant chemical integrators.**

Operational definition: Number of incidents/accidents related to chemical integrators that are missing from the sterile packaging

**Target: reduce by 50% by June 2020**

### 2) Integrator: **Form AH-223**

Operational definition: Number of total incidents/accidents reported in the operating room

Target: Increase by 80% by June 2020

## Process measures :

### 1) Integrator: **assessment of the completion of form AH-223 by sampling**

Operational definition: percentage of causes of completion of form AH-223

**Target: 80% completion of survey by employees by September 2019**

### 2) Integrator: **Form AH-223 on chemical integrator**

Operational definition: Percentage of forms filled within 24 hours of the incident

**Target: 90% filling form AH-223 within 24 hrs by June 2020**

## Balance measures:

### 1) **Average cost of the incident, cost of the operating room (team working on the technical platform)**

## Infections profondes sur prothèse de genou et hanche

	Infection profonde PTG-PTH ( Enquête lavage de prothèses)		
	2017-2018	2018-2019	2019-2020
Nombre de cas	5	8	14
Heures de salles	8,24	20,25	32
Coût en salaire en salle	7875,42	17392,88	30 589

## Tâches observées :

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1. Inspection instrument



2. Scan instrument



3. Click Écran « ajouter »

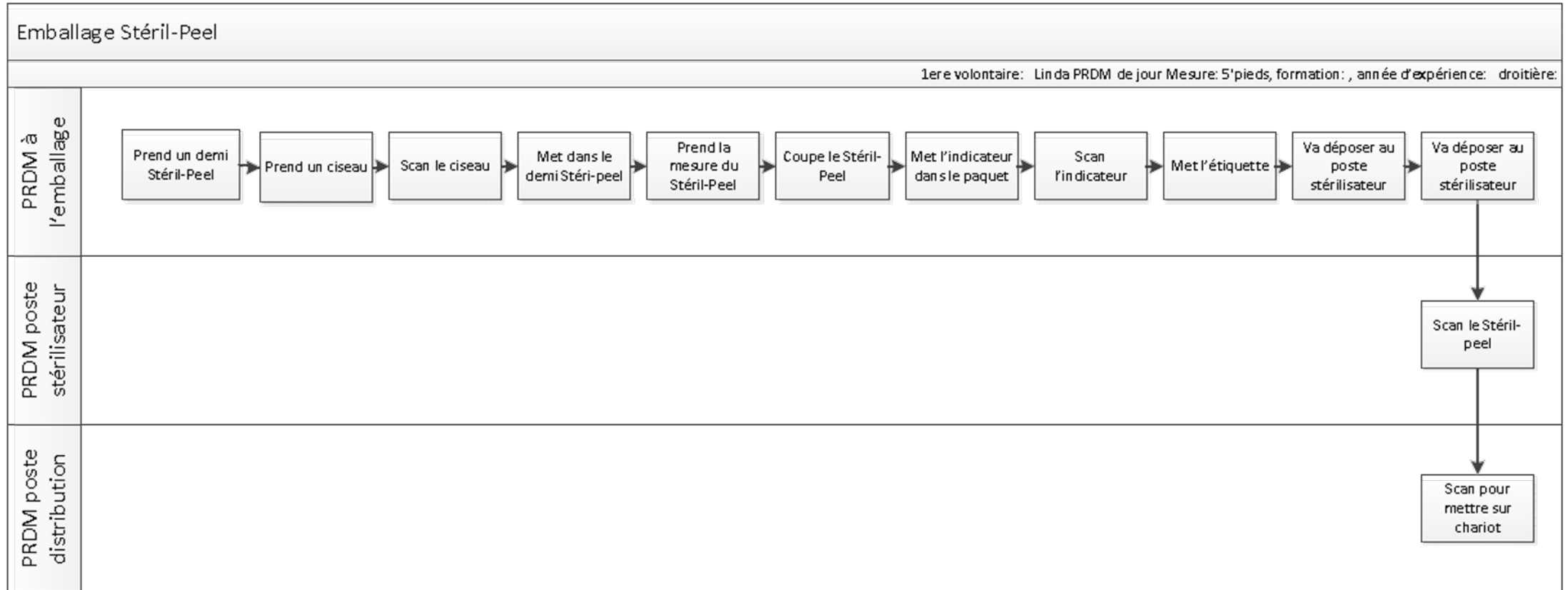


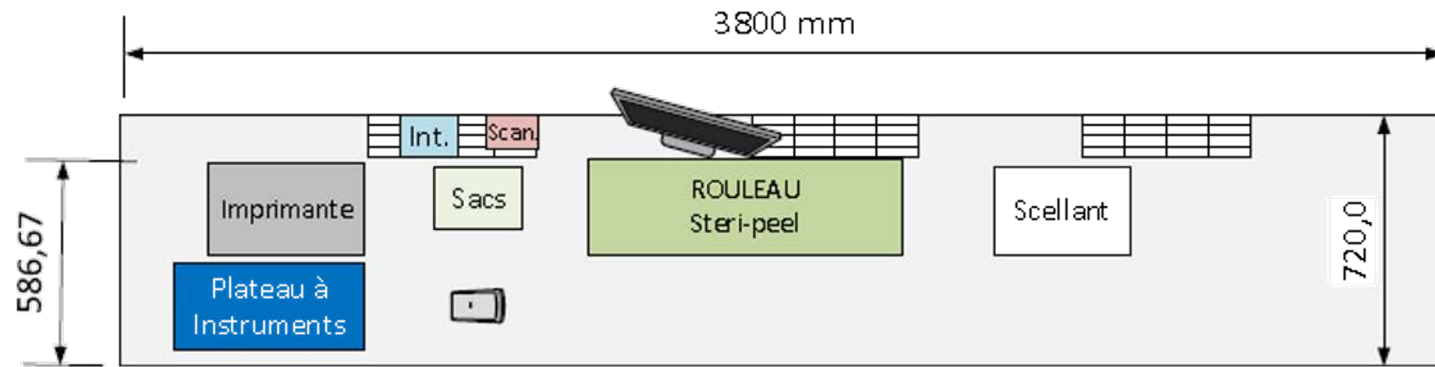
4. Prends Demi Steri-peel



5. Prends l'intégrateur







Scénario actuel

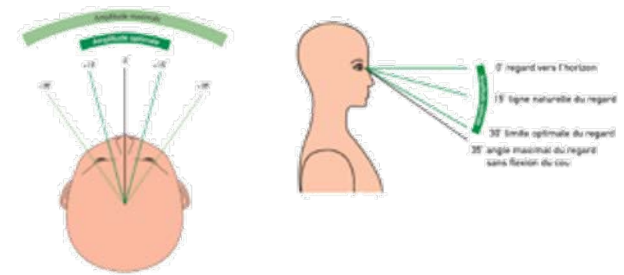
## Contraintes

- Écran localisé en diagonale
  - Torsion du cou

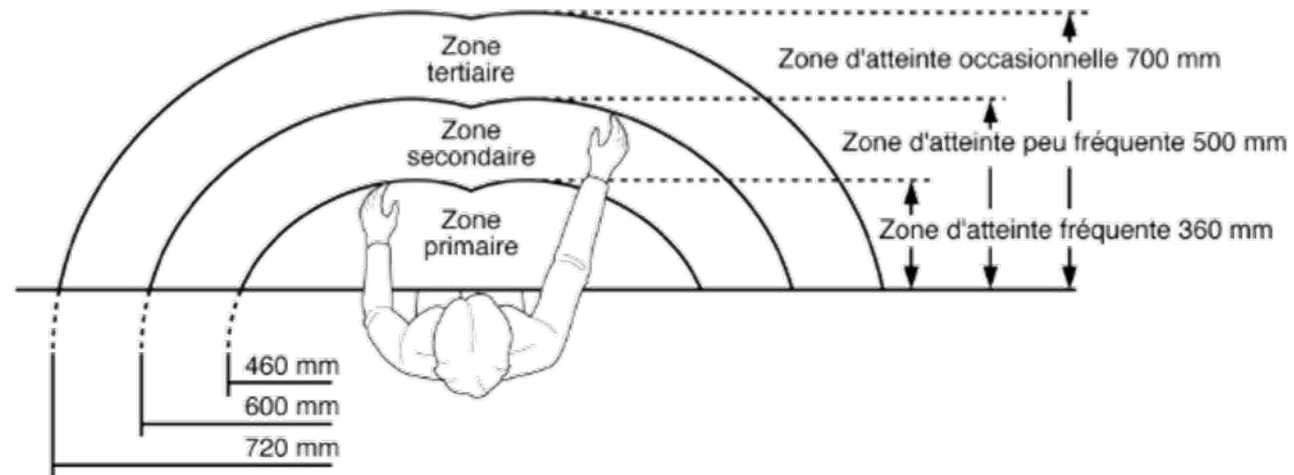


## Postures « neutres » pour le cou

- L'amplitude des mouvements de flexion et de rotation ne dépasse pas 15°

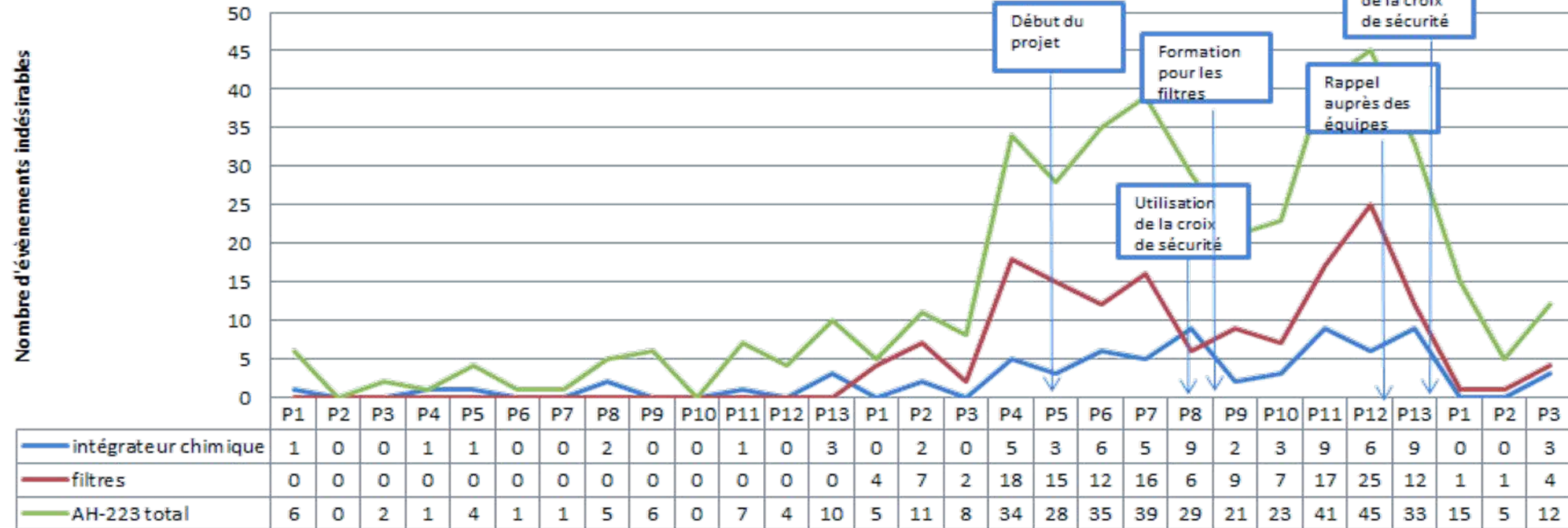


## Zones d'atteinte

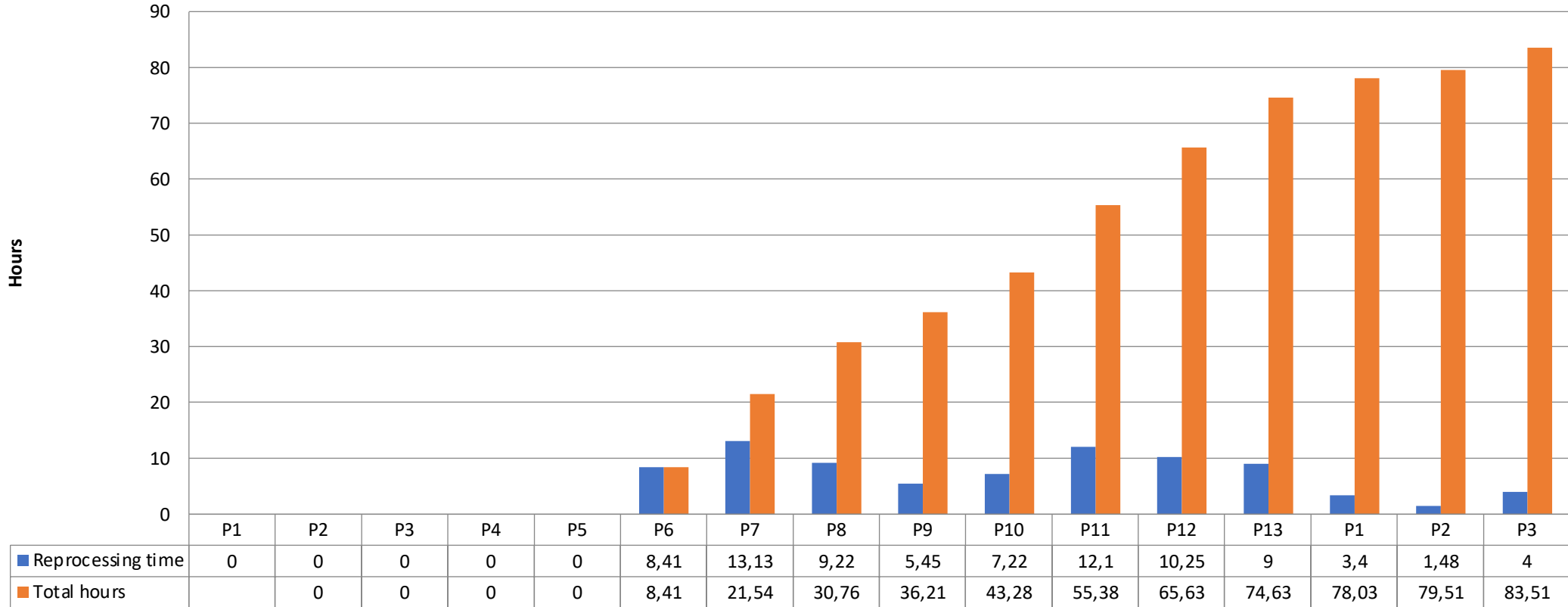


- Fréquente : 360-460 mm (14-18 po)
- Peu fréquente : 500-600 mm (20-24 po)
- Occasionnelle : 700-720 mm (27,5-28 po)

### Graphique d'évènements indésirables



## Excess reprocessing time



1. Commitment of the management to the project
2. Involvement of stakeholders and users
3. Include a patient-partner
4. Realistic project in a given time frame
5. Important to carry out structured projects

In the context of the current pandemic, it is difficult to establish a definitive correlation between the progress achieved before the current situation.

With the decrease in OR activity by 78% in the early FY 2020-2021 period 1-3, a decrease in incidents/accidents was observed.

Nevertheless, measures have been taken to achieve the initial objectives:

1. ASSTSAS assessment (MDRU ergonomic stress assessment);
2. Purchase of the caissons value of \$100 for the first year with a recurring amount for subsequent years;
3. Integration of the MDRU team leader in the operating room control room;
4. Effective communication system between the two departments;
5. Presentation to MSSS with regular follow-ups for process optimization in Quebec;
6. Development and application of a quality tool.



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