

Quality Training Program

Project Title: Minimize the risk of patients with phase I trials treatment.

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Institution: Institut Català d'Oncologia, H Duran i Reynals (L'Hospitalet-Barcelona)

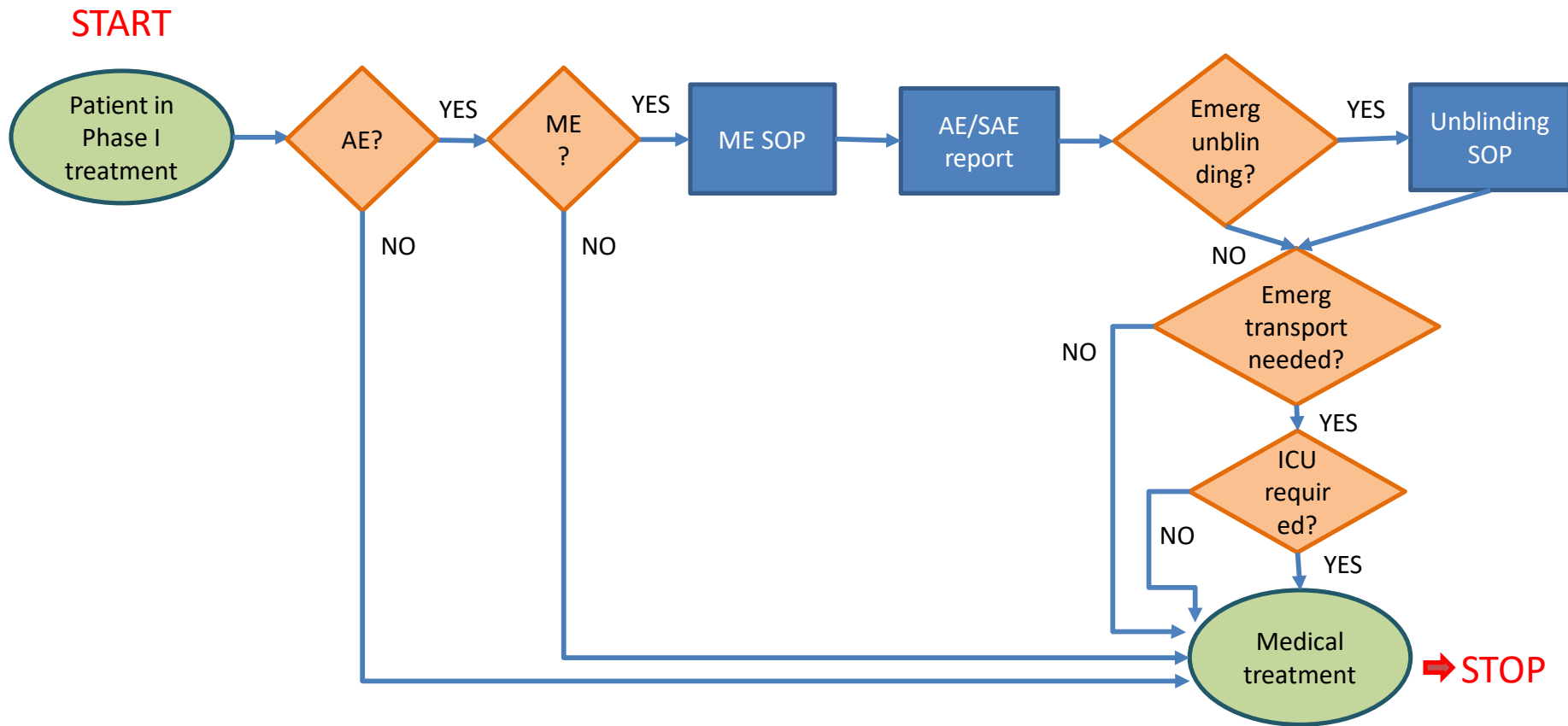
Date: January 2019.

Problem Statement

Since the recent Phase I Unit beginning, with the risk of some adverse events that could be potentially severe and unexpected, and the ICU located in other hospital building, a standard operating procedures (SOPs) have been created to minimize the risk. In general, there is a risk of 5-30% of severe adverse events in phase I trials.

PROBLEM: Medical Emergency SOP accomplishment in spite of the several necessary services, especially the ambulance activation and ICU admission.

Process Map



Institutional Overview

The Institut Català d'Oncologia (ICO) Hospital Duran i Reynals, is an onco-hematological monographic centre in the Barcelona metropolitan area, that assists the 40% of catalan population. The centre is part of a university hospital (Ciudad Sanitaria de Bellvitge) that has all medical and surgical specialities, except for pediatry. It's associated with a research lab (IDIBELL) with translational aims and close relationship with the clinical part of the centre.

The ICO has specialists in Medical Oncology, Radiation Oncology, Hematology, Blood progenitor cell transplantation Unit, Palliative Care, Radiology, Radiophysics, and other collaborator specialities (Pneumology, Neurology,...). There are clinical trials in all stages and the Phase I unit was inaugurated in December 2017.

Team Members

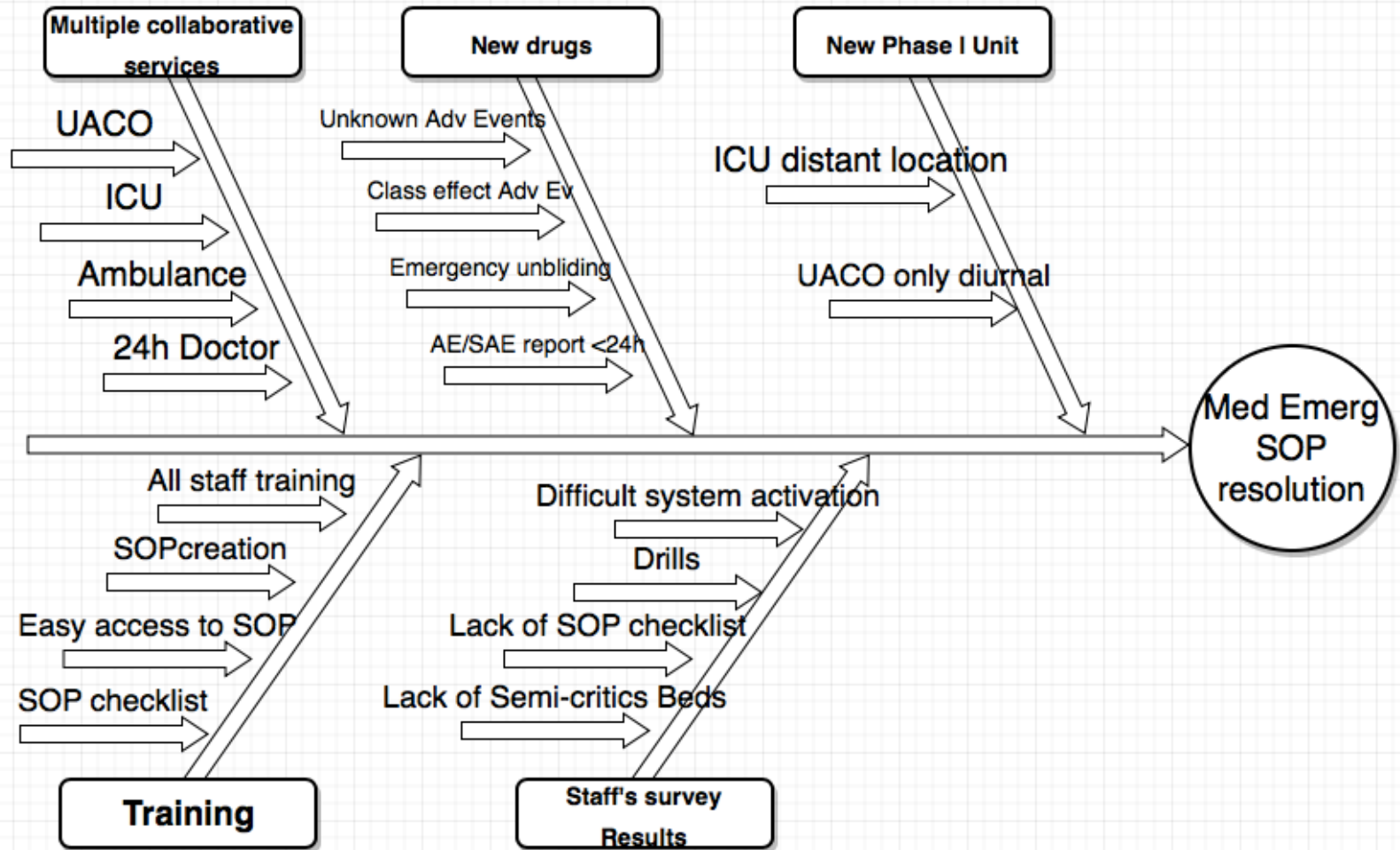
Team Responsible: MARTA GIL MARTIN (MD)

Team Members: MIGUEL GIL GIL (MD), CARMEN CUADRA (Research Nurse)

Project Promoters: RAMON SALAZAR (Medical Oncology Dpt Chief)/ MARGARITA GARCIA (Clinical Research Unit Director)

Patients / Relatives: there is no sanitary education, no patient intervention.

Cause & Effect Diagram



Measures

- Measure:
 1. Number of emergencies/month / all phase I trial patients
 2. SOP accomplishment
 3. Staff surveys
- Patient population: phase I treatment patients since Dec2017.
 - Exclusions (if any) those patients that call to communicate an event but are treated in other centres, so they are excluded because the SOP activation cannot be evaluated. The calls are not registered. The information is recorded in the electronic medical story. When solved or contacting with the patient or relatives.
- Calculation methodology: -Numerator & Denominator (if applicable)
- Data source: hospital database in the clinical research unit.
- Data collection frequency: monthly
- Data quality (any limitations): those patients treated in other centres.

Diagnostic Data

Medical Emergency Records	N=7
Gender	6 M (86%) / 1 F (14%)
Cancer type (solid tumor or hematological)	4 S (57%) / 3 H (43%)
Cancer stage	100% metastatic
Event Grade	1 G2 (14%) / 6 G3 (86%)
Shift	3 morning (43%) / 4 evening (57%)
¿Quick staff activation? (Nurses, Doctors) – No / Yes / NA	Nurses 100% Y ; Doctors 100% Y
¿Quick staff/system activation? Ambulance	3 Y (43%) / 3 NA (43%) / 1 N (14%)
¿Quick staff/system activation? ICU	2 Y (28%) / 4 NA (57%) / 1 N (14%)
¿Was the SOP correctly followed?	100% yes
¿Problems?	1 case of difficulty to coordinate ambulance & UCI (the patient was palliative in spite of being on phase I treatment) – it supposes 25% of failure in the system

Diagnostic Data

STAFF SURVEY RESULTS: 11 members (doctors, nurses, study coordinators).

Do you know that a Medical Emergency SOP exists in Phase I Unit? **Yes (100%)**

Do you know where you can find it? **Yes (100%)**

Do you know the procedures of the SOP? **Yes (100%)**

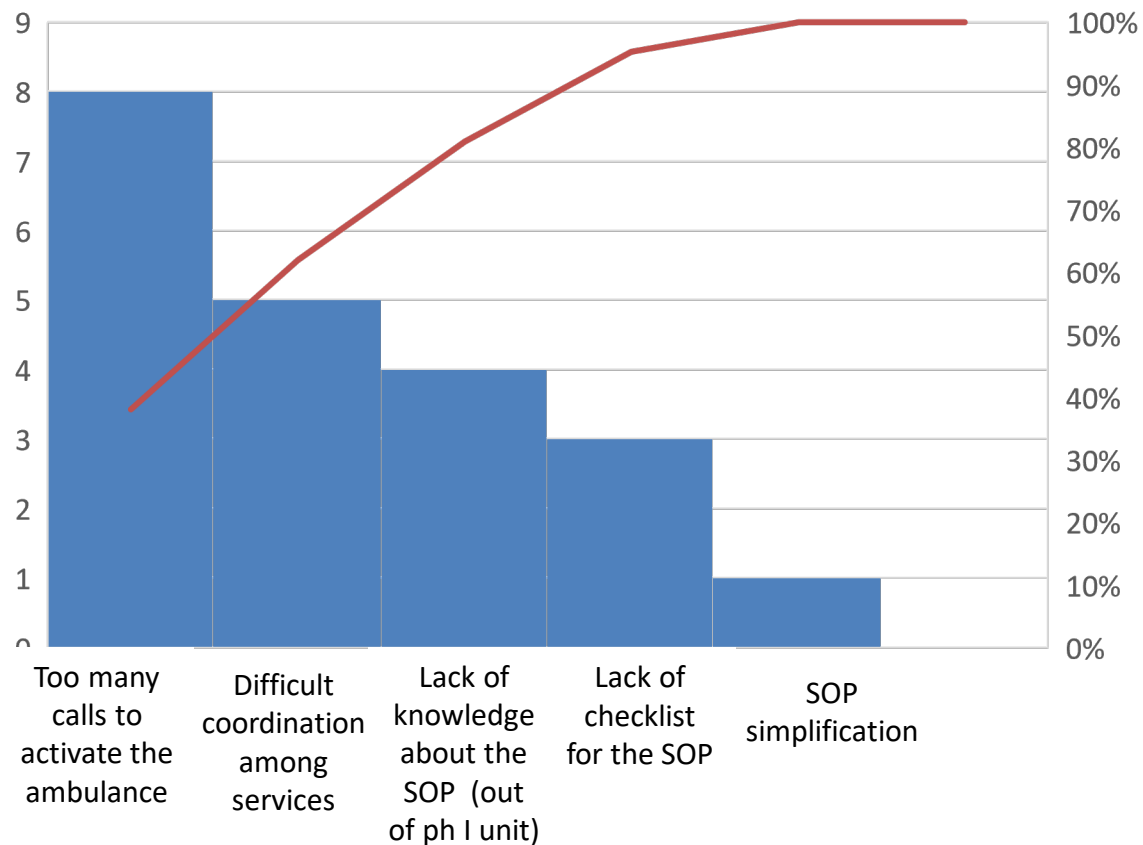
If you have participated in a medical emergency:

- Have been it solved following the SOP? **Yes (100%)**
- Have you felt confident with your knowledge of the SOP? **Yes (100%)**

Diagnostic Data

Number of surveys

Survey answers about main problems that the staff identify



Aim Statement

- To optimize the transfer system (ambulance) in the medical emergency SOP: improving to the 85%-90% of direct transfer, by 1/APR/2019.

Baseline Data

7 events (medical emergency) in 13 months

69 patients were treated in the Phase I unit in that period of time

7 events / 69 patients = 0,1 → 10,1%

The main problem in the SOP is the transport system, the ambulance activation and the ICU admission.

There is a 25% of failure in this System.

Prioritized List of Changes (Priority/Pay –Off Matrix)

Impact	High	<ul style="list-style-type: none"> • Theoretical drill • SOP simplification • Records for the continuous improvement • To optimize the coordination with the ambulance and ICU 	<ul style="list-style-type: none"> • Multidisciplinary working Team to create and review the SOPs • Specific SOPs for high complexity trials • Real drill
	Low		<ul style="list-style-type: none"> • Continuous training for all the staff who is frequently changing
		Easy	Difficult
		Ease of Implementation	

PDSA Plan (Test of Change)

Date PDSA Cycle	Description of Intervention	Results	Action Steps
21/01/2019 31/01/2019	1. Retrospective analysis of medical emergencies. 2. Checklist implementation	1. 7 cases: ph I unit staff is well-trained. 25% of deficient coordination in ambulance transfer 2. Ongoing.	1. NA 2. Ongoing. Continuous review and improvement.
01/02/2019 28/02/2019	3. Multidisciplinary working team	3. Improvement of multiple services coordination and training.	Periodic meetings
18/01/2019 ongoing	4. Continuous training for the staff	4. Improvement the training of a high mobility staff (in the admission area, ICU, ambulances, emergency room)	Training plan in the different groups of staff
21/01/2019 31/03/2019	5. Prospective analysis of the medical emergencies in 2019	No new EM in 2019	--
01/02/2019 31/03/2019	6. Theoretical drill to evaluate the staff training and all the emergency and transfer system	ongoing	Continous training

Materials Developed (optional)

- Medical Emergency Checklist.
- Medical Emergency Phase I Record to optimize continuous improvement.

Change Data

- No new events to measure and compare.
- A new proposal to compare before and after the action plan: measure the time since ambulance activation and the transfer to the ICU/Emergency room.

Conclusions

- ✓ Phase I unit staff is well-trained in the Medical Emergency SOP.
- ✓ Retrospective analysis and staff surveys show that the problem is the coordination and quick transfer with the ambulance.
- ✓ No formal comparison has been possible, but the new material (Medical Emergency Checklist and Medical Emergency Phase I Record) have been implemented.

Next Steps/Plan for Sustainability

- Medical emergency records for those patients treated in the general emergency room or other centres.
- Record all patients' calls that are frequent during the day to the study coordinators and phase I nurses.
- Drills.
- A survey for the phase I patients in order to evaluate if they understand the warning signs and symptoms, especially if they are isolated during the admission.

Project Title Minimize the risk of patients with phase I trials treatment

AIM: To optimize the transfer system (ambulance) in the medical emergency SOP: improving to the 85%-90% of direct transfer, for the 1/JUN/2019.

INTERVENTION:

- Retrospective analysis of medical emergencies.
- Checklist implementation
- Multidisciplinary working team to create and review the SOPs
- Continuous training for the staff
- Prospective analysis of the medical emergencies in 2019
- Theoretical drill to evaluate the staff training and all the emergency and transfer system

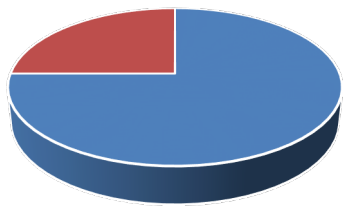
TEAM:

- Department 1: MGM & MGG (Medical Onc)
- Department 2: Carmen Cuadra (Phase I Unit)
- Department 3: Clinical Research Unit

PROJECT SPONSORS:

- RAMON SALAZAR (Medical Oncology Dpt Chief)
- MARGARITA GARCIA (Clinical Research Unit Director)

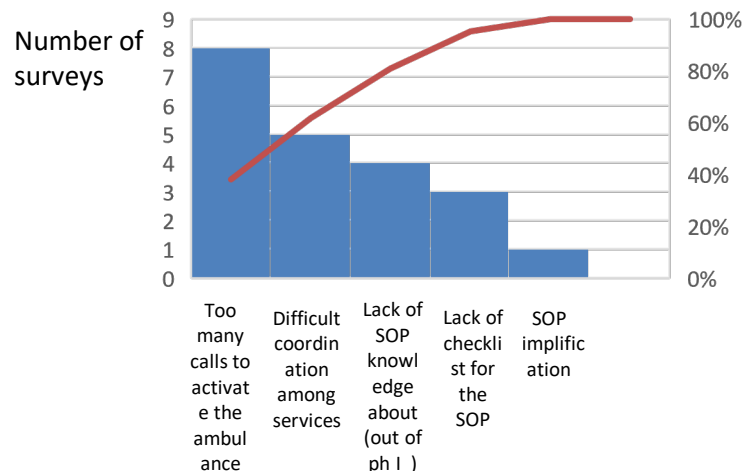
RESULTS: 7 medical emergencies (ME) in the retrospective study (2018). Four cases required transfer to the ICU, and in 1 patient this transport was delayed. So, it supposes 25% of cases with difficult SOP activation (75% of optimal transfer).



■ quick ■ slow

No new data in 2019 to compare

Survey answers about main problems that the staff identify



CONCLUSIONS:

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NEXT STEPS:

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- Record all patients' calls.
- A survey for the phase I patients to evaluate if they understand the warning signs/symptoms.
- Drills.