

Quality Training Program

Project Title: Adherence to International Guidelines in the management of patients with immune-related adverse events treated at Hospital Clínico San Carlos (Madrid, Spain).

Presenter's Name: Mónica Antoñanzas

Institution: Hospital Clínico San Carlos

Date: 14th November 2020

Institutional Overview

- Public University Hospital
- Madrid. Spain.
- Population area: 364.345 habitants

Physicians	30
Head of Department	1
Head of Section	2
Physicians	12
Residents	15
Nurses	66
Administrative staff	3
Study coordinators	9
Laboratory members	8



Team Members

- ✓ **Sponsor:** Dr. Pedro Pérez-Segura (Medical Oncology Chief)
- ✓ **Coach:** Dr. Ana Blasco (Medical Oncologist)
- ✓ **Team Leaders:**
 - ✓ Dr. Aranzazu Manzano (Medical Oncologist)
 - ✓ Dr. Mónica Antoñanzas (Medical Oncologist)
 - ✓ Dr. Natalia Vidal (Medical Oncologist)
- ✓ **Other members:**
 - ✓ Mónica Zabala (Outpatients Oncology Nurse)
 - ✓ Sara Gil Useros (Inpatients Oncology Nurse)
 - ✓ Julia Arcones (General Practitioner)
 - ✓ Dra. Paloma Flores (Resident and In-patient Attending Physician)

Why?

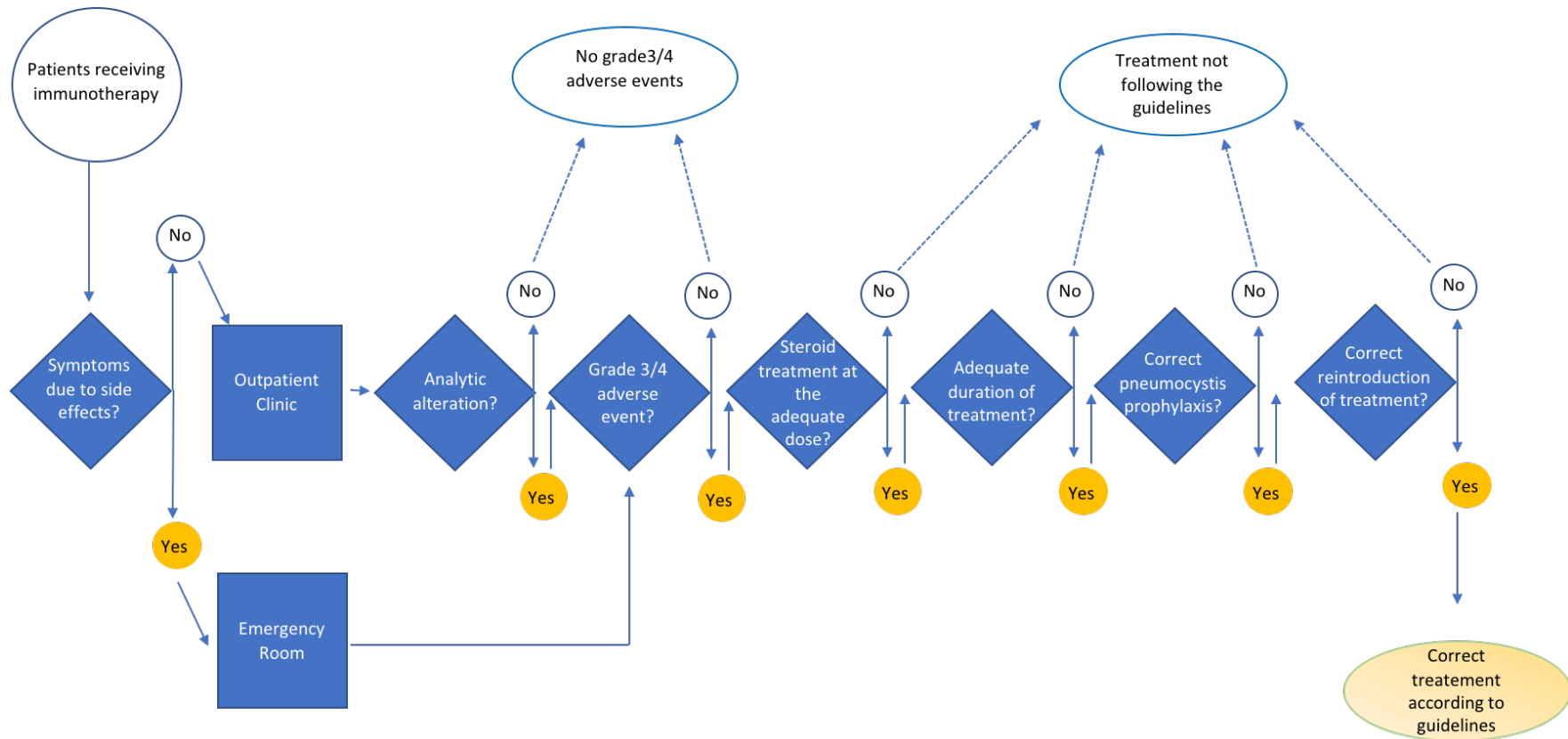
- Checkpoint inhibitors are used in almost all types of cancer.
- Immune- related adverse events (iAEs) are now frequently seen in our regular practice.
- G3 and G4 iAEs can be life threatening.
- Its essential a prompt diagnosis and an adequate treatment from the onset of the toxicity.

We decided to evaluate if our institution had an adequate management of this iAEs according to international standard of treatment.

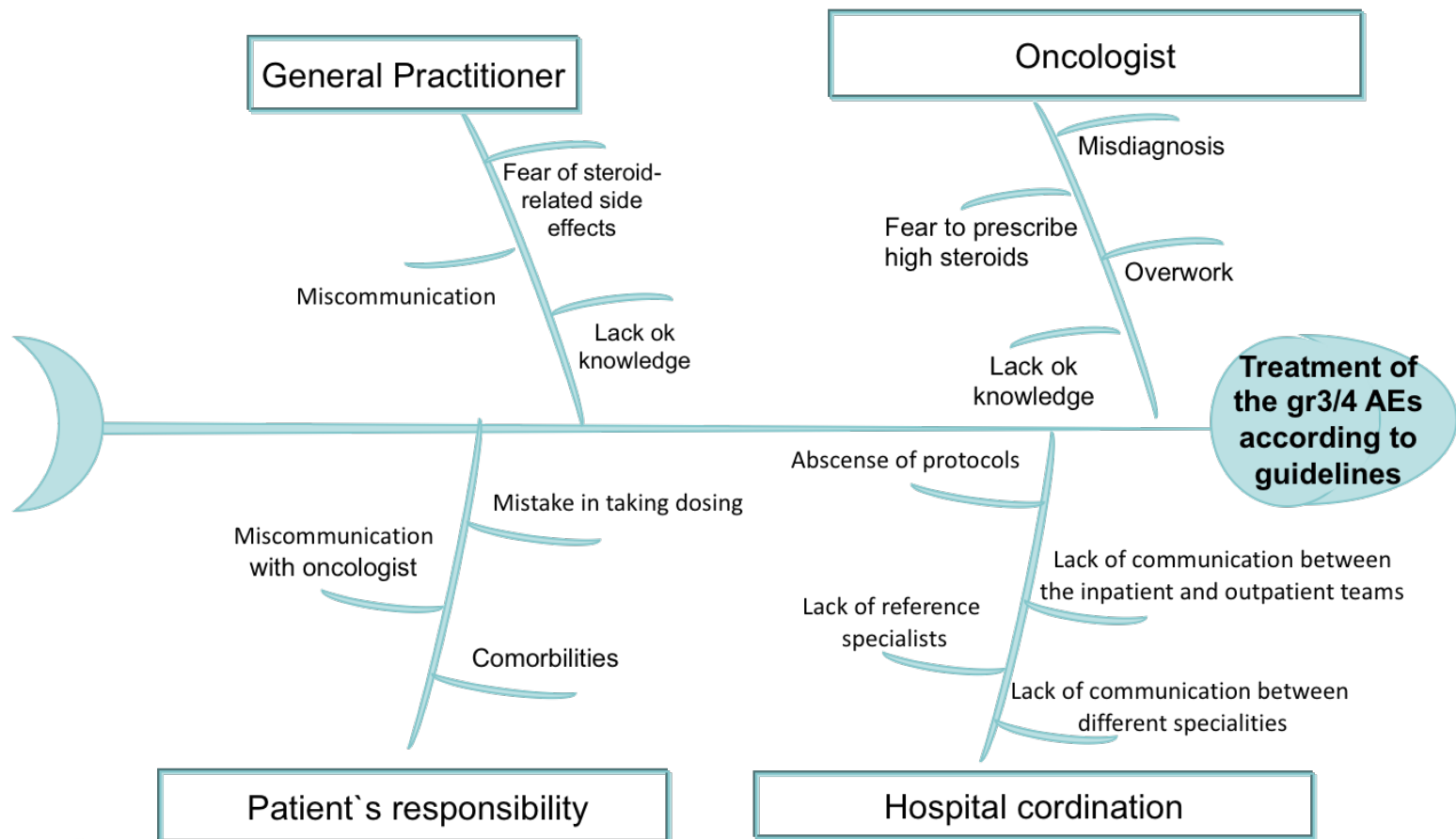
Problem Statement

Between October 2019 and June 2020, only **21%** of patients with G3 and G4 immune-related adverse events at Hospital Clínico San Carlos received the proper management of toxicity according to International Guidelines (dose and duration of steroid therapy, supportive treatment and follow-up), which could increase the risk of a new outbreak of the same toxicity or complications due to steroid treatment

Process Map



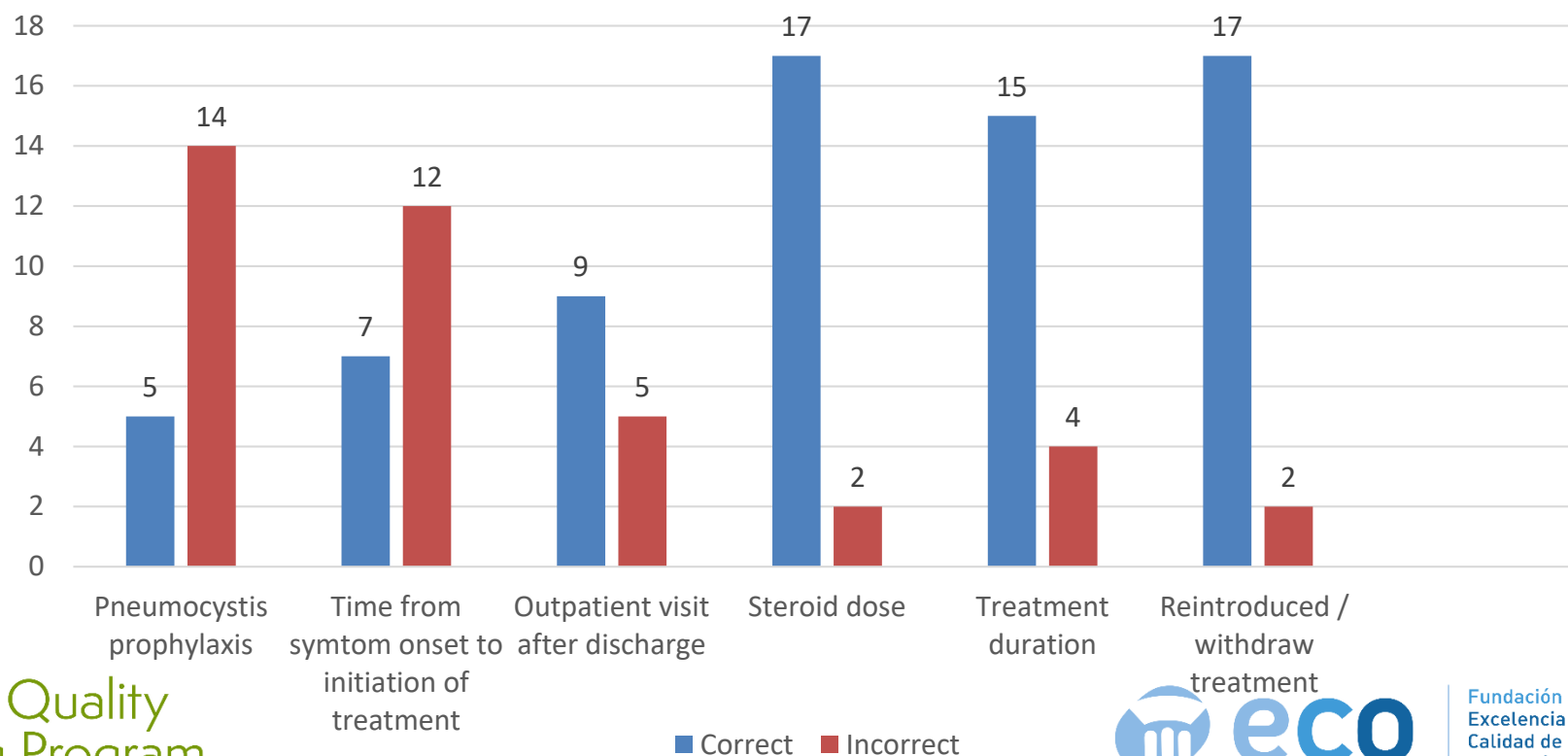
Cause & Effect Diagram



Diagnostic Data

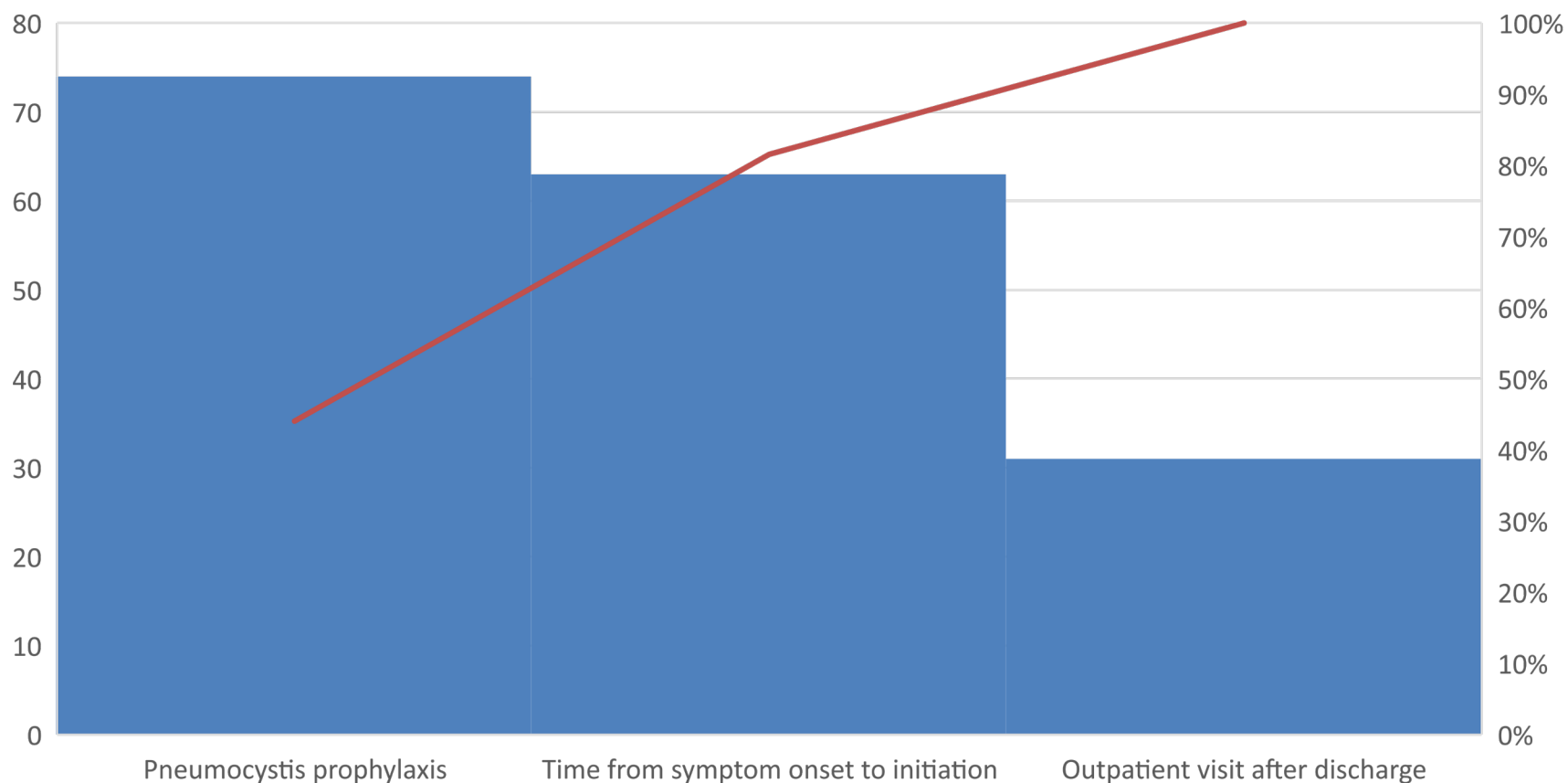
n=19 pts with G3/4 iAEs

Pts treated according to guidelines: 4
% pts treated according to guidelines: 21%



Diagnostic Data

Causes for failing to commit to guidelines



Aim Statement

To increase to **70%** the number of patients with immune-related adverse events who are treated with steroid therapy according to International guidelines between September and November 2020 in Hospital Clínico San Carlos, in order to improve the Quality of Life by decreasing the risk of new outbreak immune toxicity and associated complications.

Measures

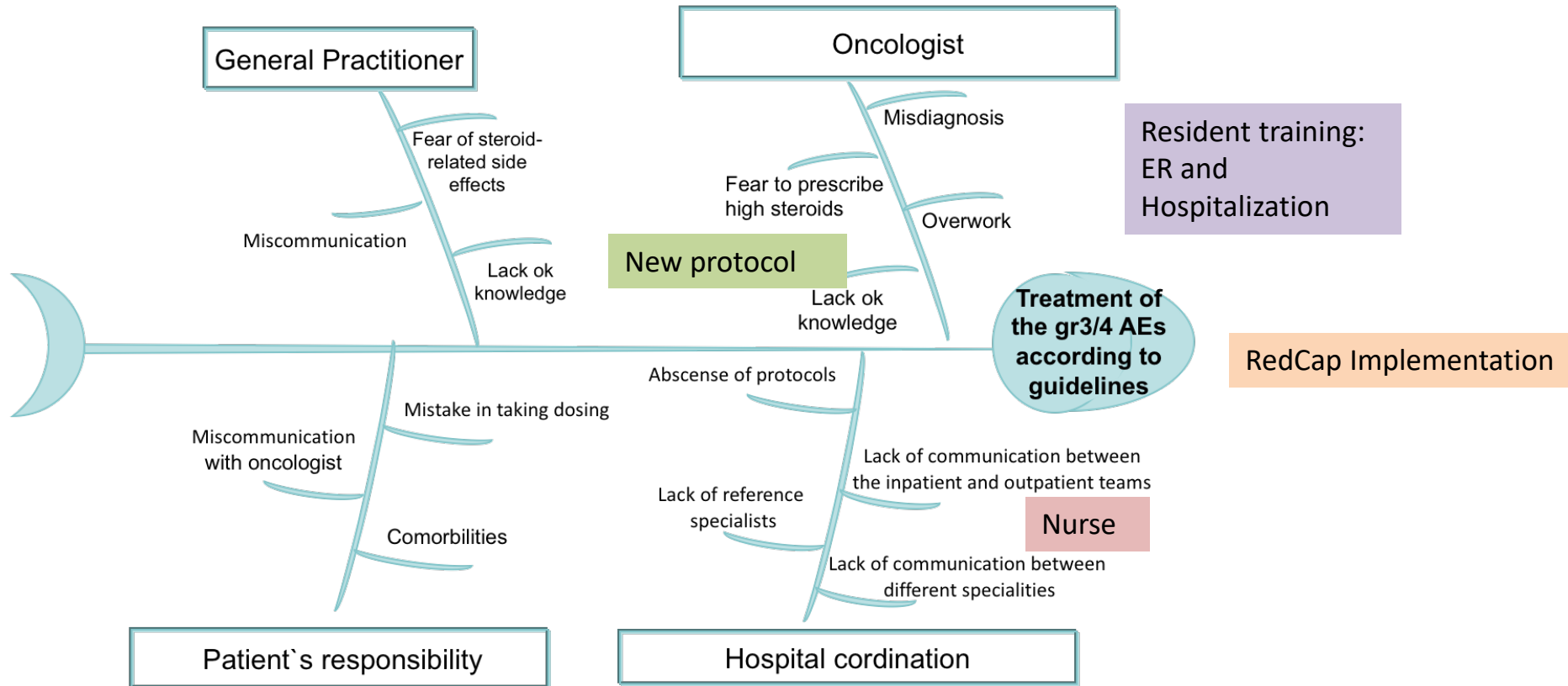
- **Measure:** % of patients with G3/4 immune-related adverse events who are treated with the recommended schedule of corticosteroids according to guidelines.
- **Patient population:** Patients with grade 3-4 immune-related adverse events
- **Calculation methodology (number of patients):**
 - Patients that received the initial correct steroid dose according to International guidelines
 - Patients that received steroids during the correct amount of time according to International guidelines
 - Inpatients that visit the outpatient clinic within two weeks after being discharge
 - Steroid treatment modifications by GP with out consulting the oncology team.
 - Patients that did not take the adequate dose of steroids due to mistake
 - Patients that reintroduced / withdraw treatment correctly according to guidelines
 - Patients treated < 48h from suspected diagnosis
 - Patients that received pneumocystis prophylaxis according to guidelines
 - Balance measure: Glucemic discontrol
- **Data source:** Medical oncology data bases (RedCap), HCSC medical records , Madrid online GP's medical chart (HORUS)
- **Data collection frequency:** Oct 2019-June 2020.
- **Data quality (any limitations):** paper oncology medical records

Baseline Data

- **Measure:** 21% of patients with G3/4 immune-related adverse events who are treated with the recommended schedule of corticosteroids according to guidelines.
- **Patient population:** 19 patients with grade 3-4 immune-related adverse events
- **Baseline data:**
 - Pts that received the initial correct steroid dose according to International guidelines: 17/19 (89%)
 - Pts that received steroids during the correct amount of time according to International guidelines: 15/19 (79%)
 - Inpatients that visit the outpatient clinic within two weeks after being discharge: 9/14 (**64%**)
 - Steroid treatment modifications by GP with out consulting the oncology team: 0/19 (0%)
 - Pts that did not take the adequate dose of steroids due to mistake: 0/19 (0%)
 - Pts that reintroduced / withdraw treatment correctly according to guidelines: 17/19 (89%)
 - Pts treated < 48h from suspected diagnosis: 7/19 (**37%**)
 - Pts that received pneumocystis prophylaxis according to guidelines: 5/19 (**26%**)
 - Balance measure: patients with glucemic discontrol: 4/19 (23,5%)

Cause & Effect Diagram

Cause and effect



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

High Impact	Nurse adherence control Nurse follow up	Quick flow chart and protocol for oncologists Resident ER training
	Include Autoimmune Toxicity in our Cancer patient's Registry (RedCAp)	GP coordination
Low		

Easy

Difficult

List of Changes

All Oncologist Staff

- Implement easy Flow-chart & MiniProtocol
- P. jiroveci Prophylaxis
- SLOW Tapering (4-6 weeks)

Resident training: ER and Hospitalization

- First line in the ER (alone)
- Focus on suspect diagnosis
- Prompt steroids initiation

Nurse control

- Adherence control
- BOTH steroids and Septrim®
- Early correction of mistakes
- Phone accessibility

RedCap Implementation

- New drop down list
- Informatic follow-up

PDSA Plan (Test of Change)

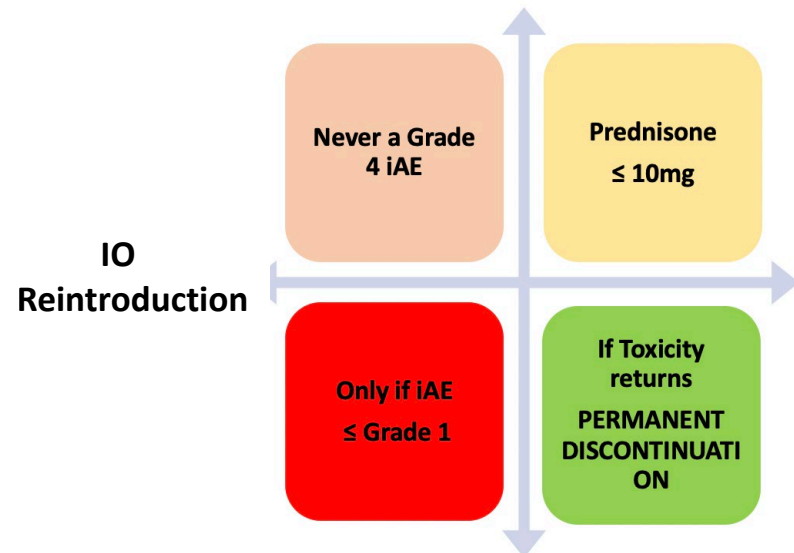
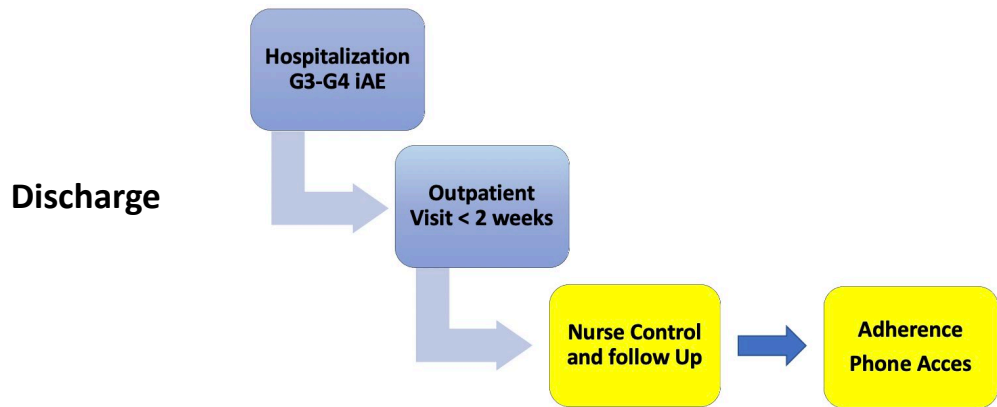
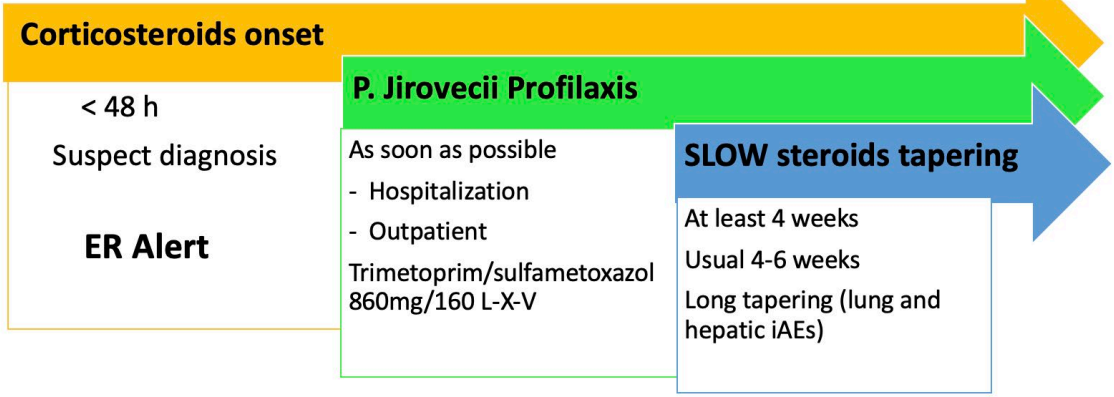
Date of PDSA Cycle	Description of Intervention	Results	Action Steps
1 Sept – 30 Sept	Easy Flow Chart & Mini Protocol	Distributed and implemented	Maintain
1 Oct– 30 Oct	Resident Training	On going	MAINTAIN
1 Nov – 30 Nov	Nurse Adherence control	2 patients Both patients satisfied	Maintain

Materials Developed



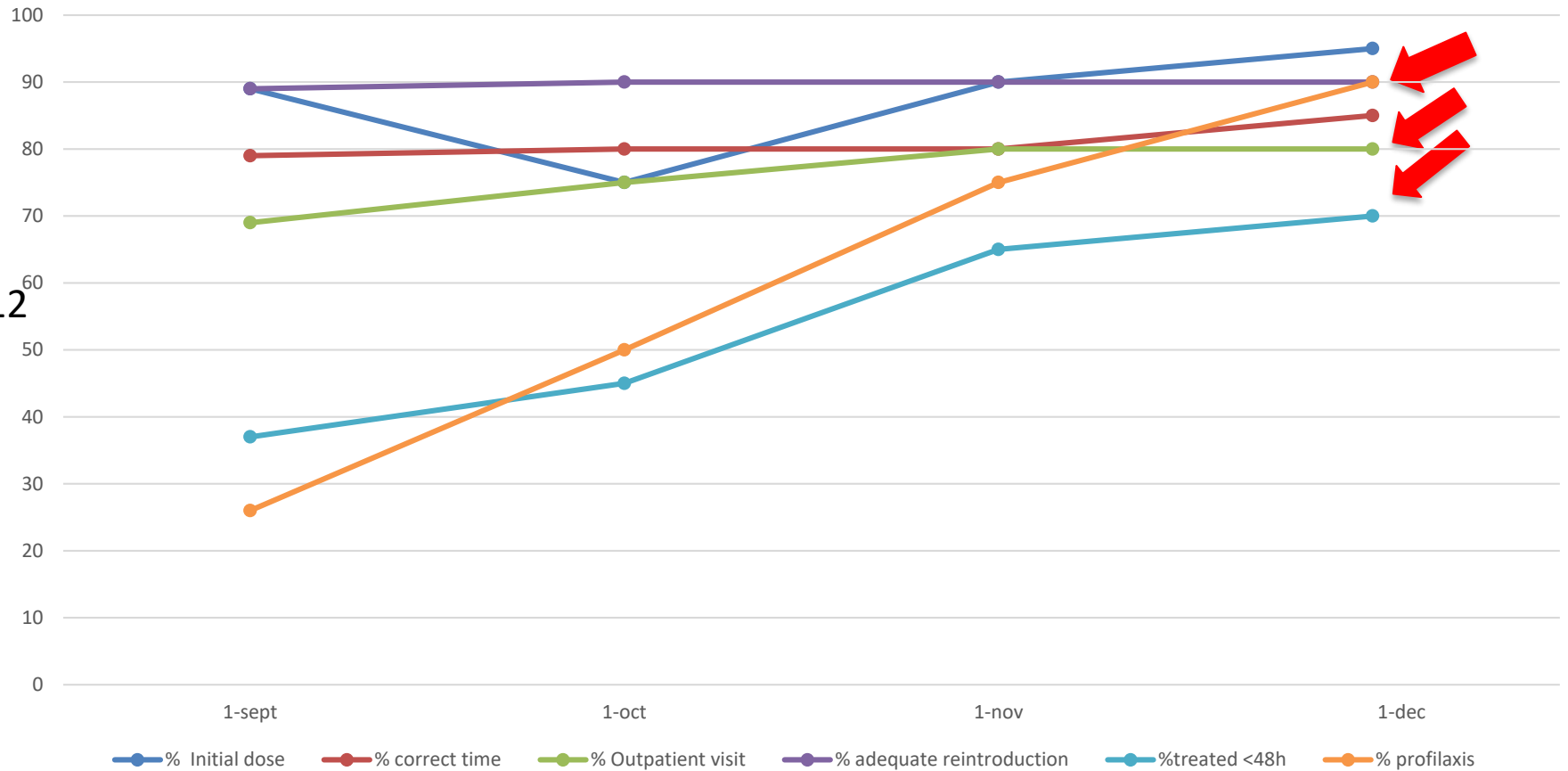
Protocolo Rápido
Efectos adversos
Inmunomediados (iAEs)

2020-2021



Change Data. Run chart

Results



N: 12

Conclusions

- These data indicate the need to continue looking forward to implement new projects in oncology care.

Quality Project = Better patient care

- Limited time to evaluate the impact in the iAEs management
- These results suggest we have implemented correct changes
- We will continue collecting data to support this results.

Next Steps/Plan for Sustainability

Maintain Long term improvements: Challenge

- Challenge: Check monthly with residents KEY POINTS of Flow Chart
- Challenge: Motivate STAFF to continue to follow miniprotocol & guidelines
- RedCap Implementation is done: Automatic Maintenance with resident involvement
- Maintain Nurse Disponibility (could be difficult if employee template decreases)

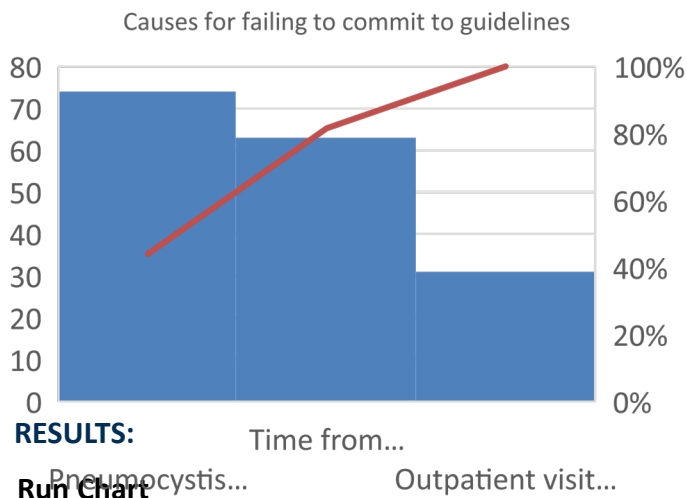
Project T Adherence to International Guidelines in the management of patients with immune-related adverse events treated at Hospital Clínico San Carlos (Madrid, Spain).

AIM: To increase to **70 %** of patients with immune-related adverse events who are treated with steroid therapy according to International guidelines between September and November 2020 in Hospital Clínico San Carlos, in order to improve the Quality of Life by decreasing the risk of new outbreak immune toxicity and associated complications.

TEAM:

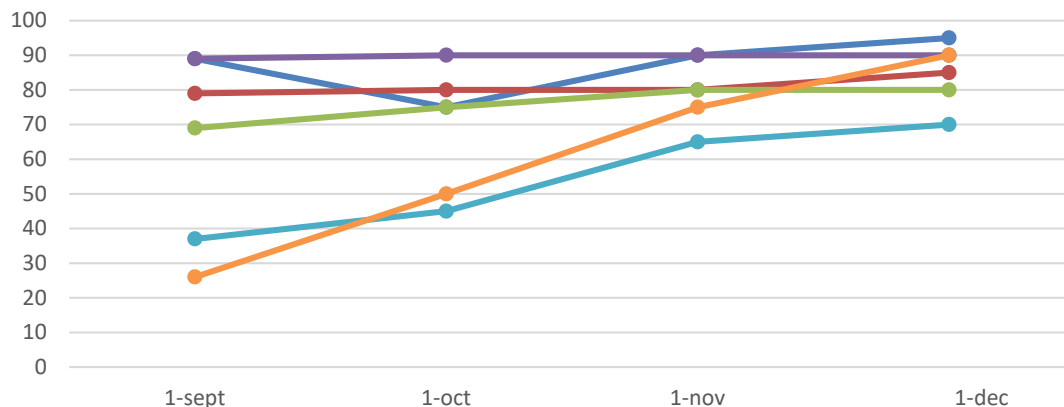
- Medical Oncology: STAFF Residents
- Outpatients Oncology Nurse: Mónica Zabala

PROJECT SPONSORS:
Dr. Pedro Perez Natalia



Date of PDSA Cycle	Description of Intervention	Results	Action Steps
1 Sept – 30 Sept	Easy Flow Chart & Mini Protocol	Distributed and implemented	Maintain
1 Oct– 30 Oct	Resident Training	On going	MAINTAIN
1 Nov – 30 Nov	Nurse Adherence control	2 patients Both patients satisfied	Maintain

Run Chart



CONCLUSIONS:

- These data indicate the need to continue looking forward to implement new projects in oncology care.
- Limited time to evaluate the impact in the iAEs management
- These results suggest we have implemented correct changes

NEXT STEPS:

- Check monthly with residents KEY POINTS of Flow Chart
- Motivate STAFF to continue to follow miniprotocol & guidelines
- RedCap Implementation is done: Automatic Maintenance with resident involvement
- Maintain Nurse Disponibility (could be difficult if employee template decreases)