

# ASCO's Quality Training Program

**Project Title: Control of Adverse Events (AE) in Lung Cancer Patients Receiving Immune Checkpoint Inhibitors (ICPI) Through a Multidisciplinary Education Program**

**Presenter's Name: Ana Gómez, Elena Ruiz & Paloma Gómez**

**Institution: Ramón y Cajal Hospital, Madrid - Spain**

**Date: June 29, 2018**

# Institutional Overview

- **Adult Day Hospital, Medical Oncology Department and Pharmacy** have been certified by ASCO-QOPI (2017) and ISO 9001 (2008, last re-certification 2018).
- **Medical Oncology Department:**
  - 21 medical oncologists.
  - 15 residents (3 residents each year).
- **Day Hospital:** Six beds plus 30 armchairs, all with programmable pumps. 25,000 I.V. annual treatments.
- **Hospitalization:** 35 beds.
- 24 hours, 7 days a week availability to an on-call medical oncologist.
- **Phase I Unit:** 8 armchairs and 1 bed.

# Institutional Overview

- **Medical Oncology Department sections:**
  - Breast, Gynecologic Tumors & Familial cancer.
  - Digestive Tumors Section & Familial Cancer, Sarcomas & Brain Tumor.
  - Genitourinary & Endocrine, ENT, Melanoma & Thoracic Tumors Section.

# Problem Statement

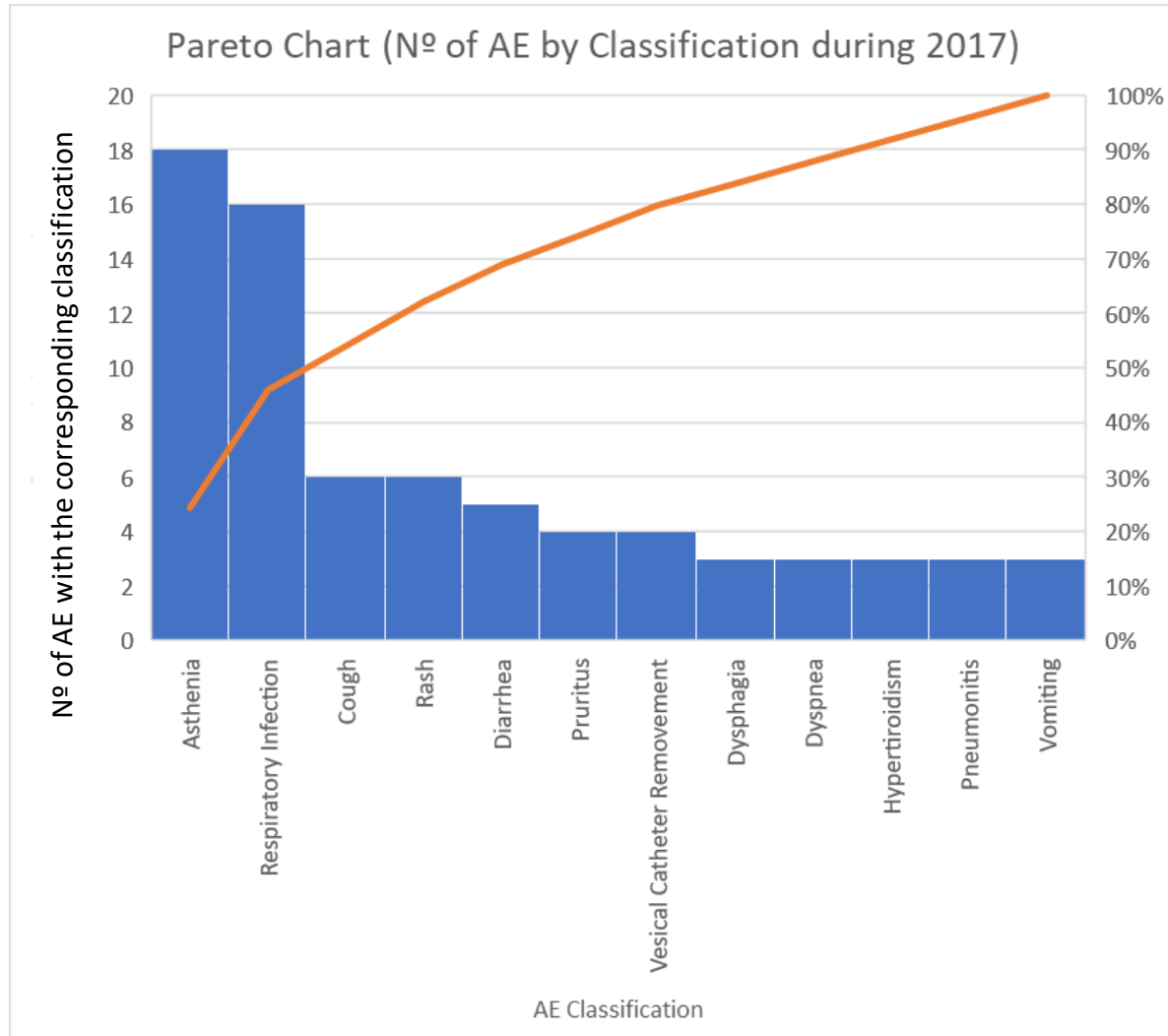
We analyzed 45 patients with lung cancer, treated with ICPI, during 2017.

We detected 55% of moderate-severe AEs (33% G2 AEs and 12% of G3 AEs), related and not related to these drugs.

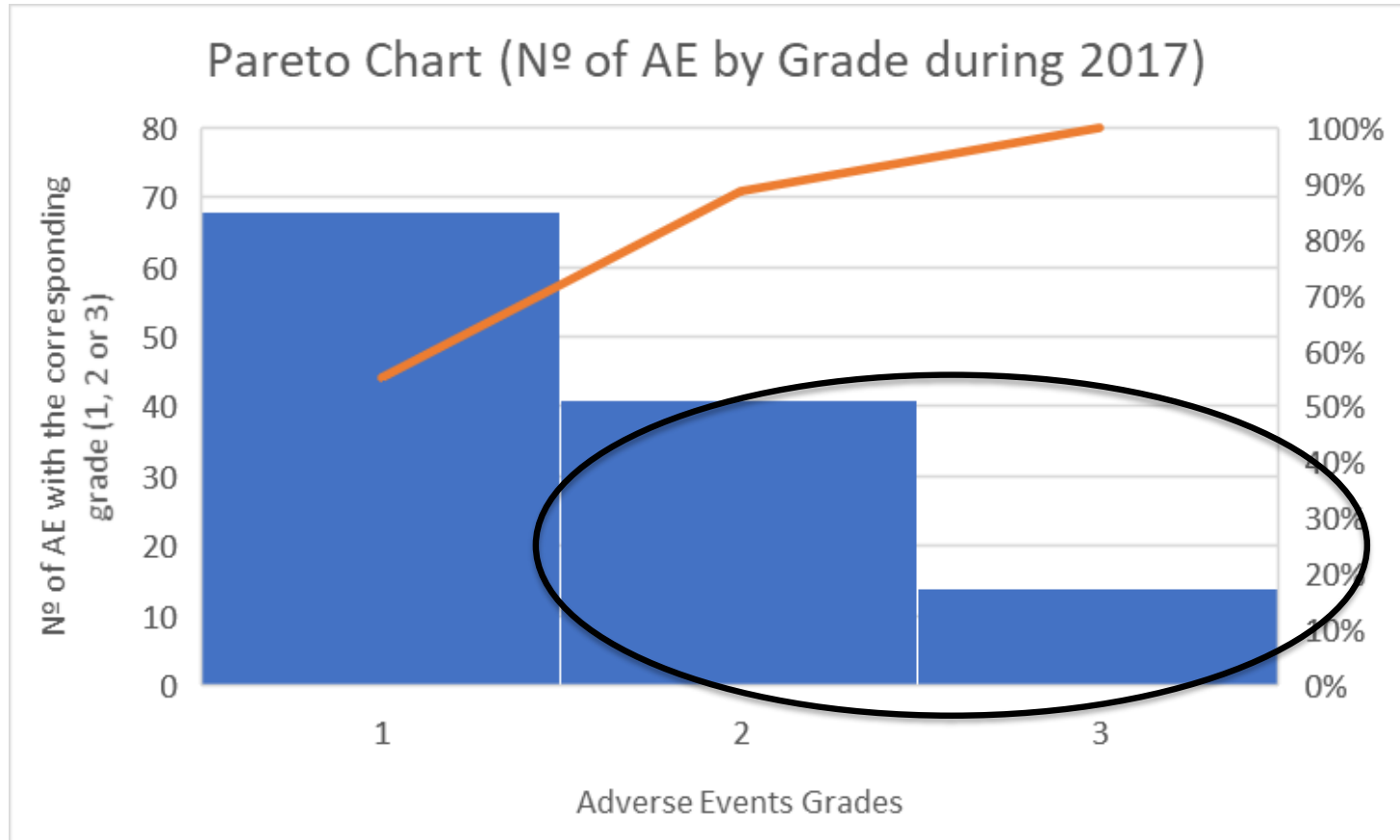
## **GRADE 2-3 AE IMPACT ON QUALITY OF CARE**

- Delay in treatment: 31% of total AEs.
- Unscheduled visits: 19% of total AEs (emergency room and visits without annotation).
- Serious complication: 11% of total AEs.
- Patient dissatisfaction with access to Symptom Control Providers: Not quantified (informal patient statements).

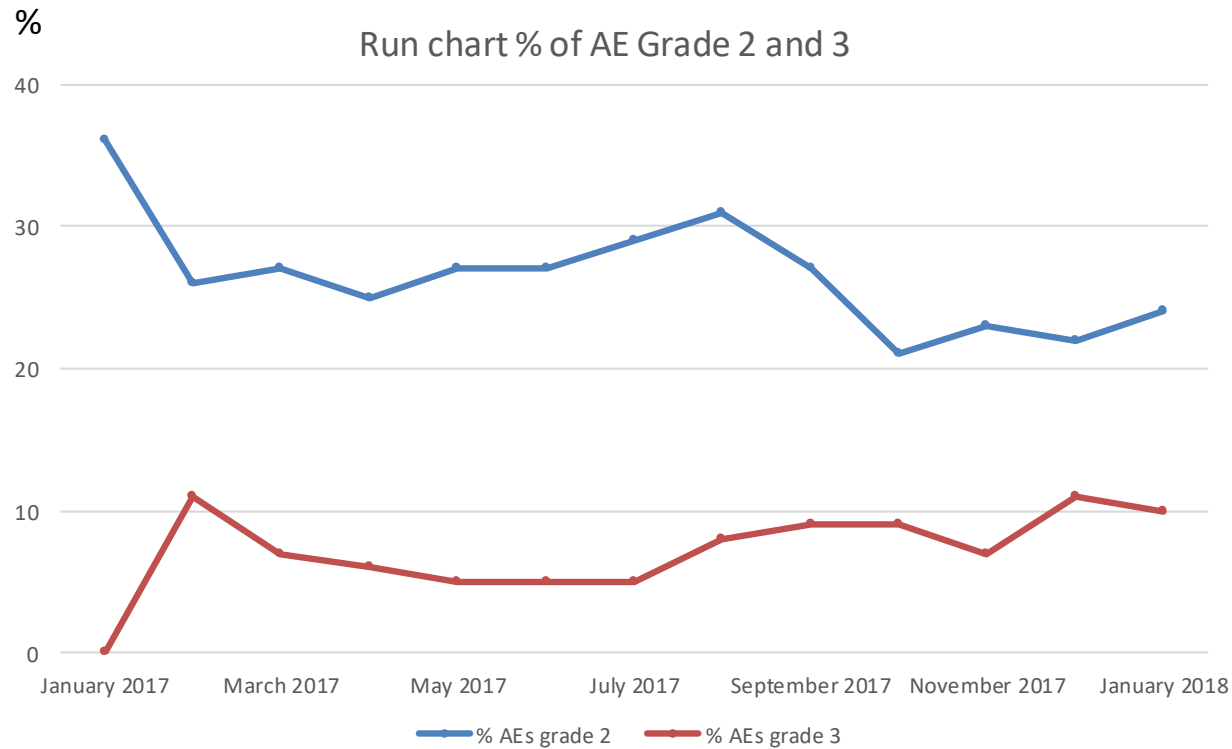
# Pareto chart-AE Spectrum



# Pareto chart- AE Grade



# Baseline Data Grade 2 & 3 AEs



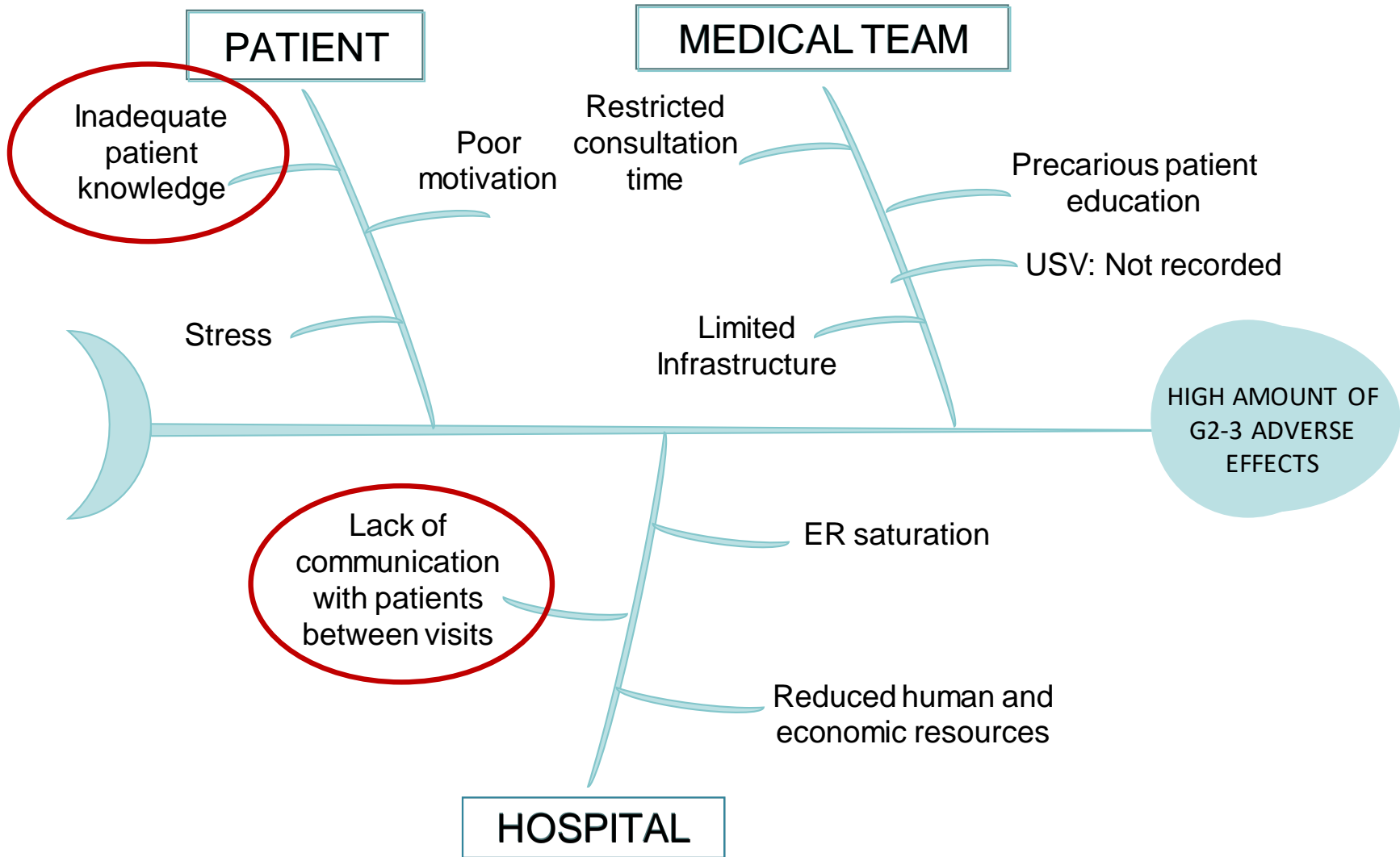
# Diagnostic Data

Diagnostic Data	Number of AEs (%)
Total #	123
Grade 2-3 (related and not)	55 (44.7)
Grade 2-3 (related with ICPI)	21 (17)
Scheduled Encounters	73 (59)
Unscheduled Encounters	4 (3)*
Emergency Service Visits	19 (15)
Treatment Delay	16 (13)

\*Most of unscheduled visits at consultations are not recorded due to the absence of a computerized medical record.

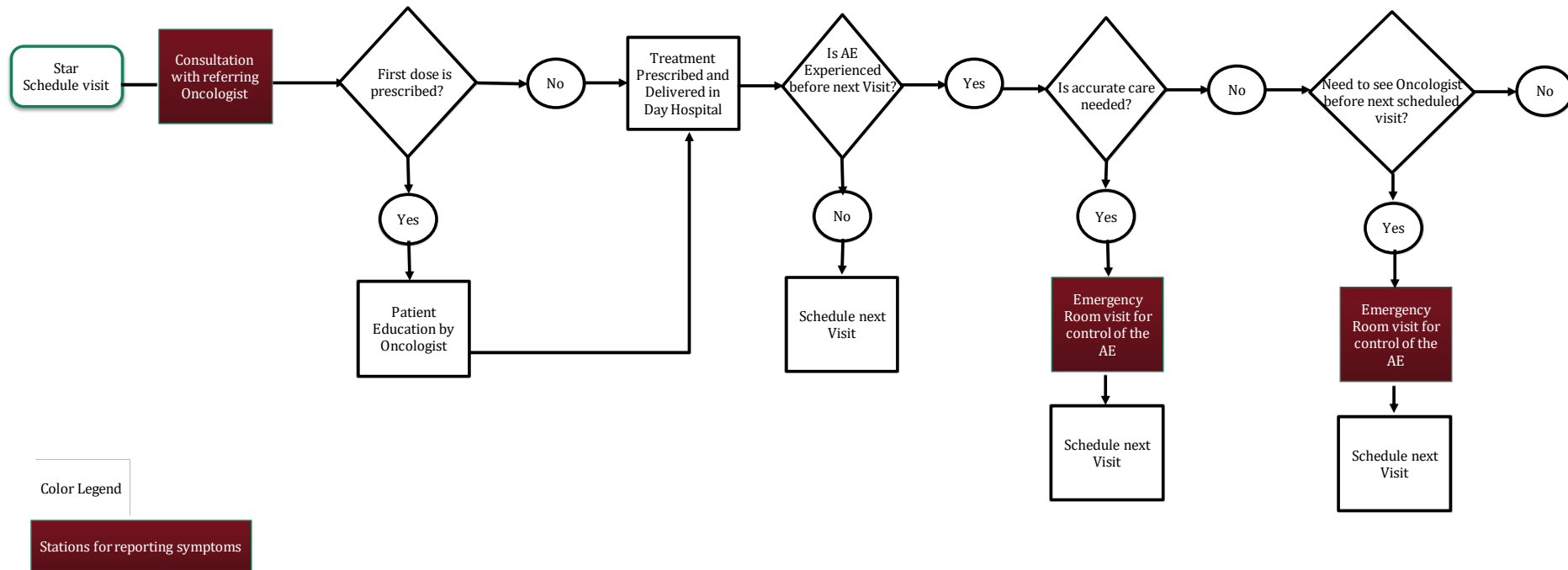


# Cause & Effect Diagram



Highlighted areas: These were identified as being the ones with the highest impact; these are within our control to change and are achievable within the amount of time of the course.

# Process Map Pre-existing Patient-Provider Communication-Education

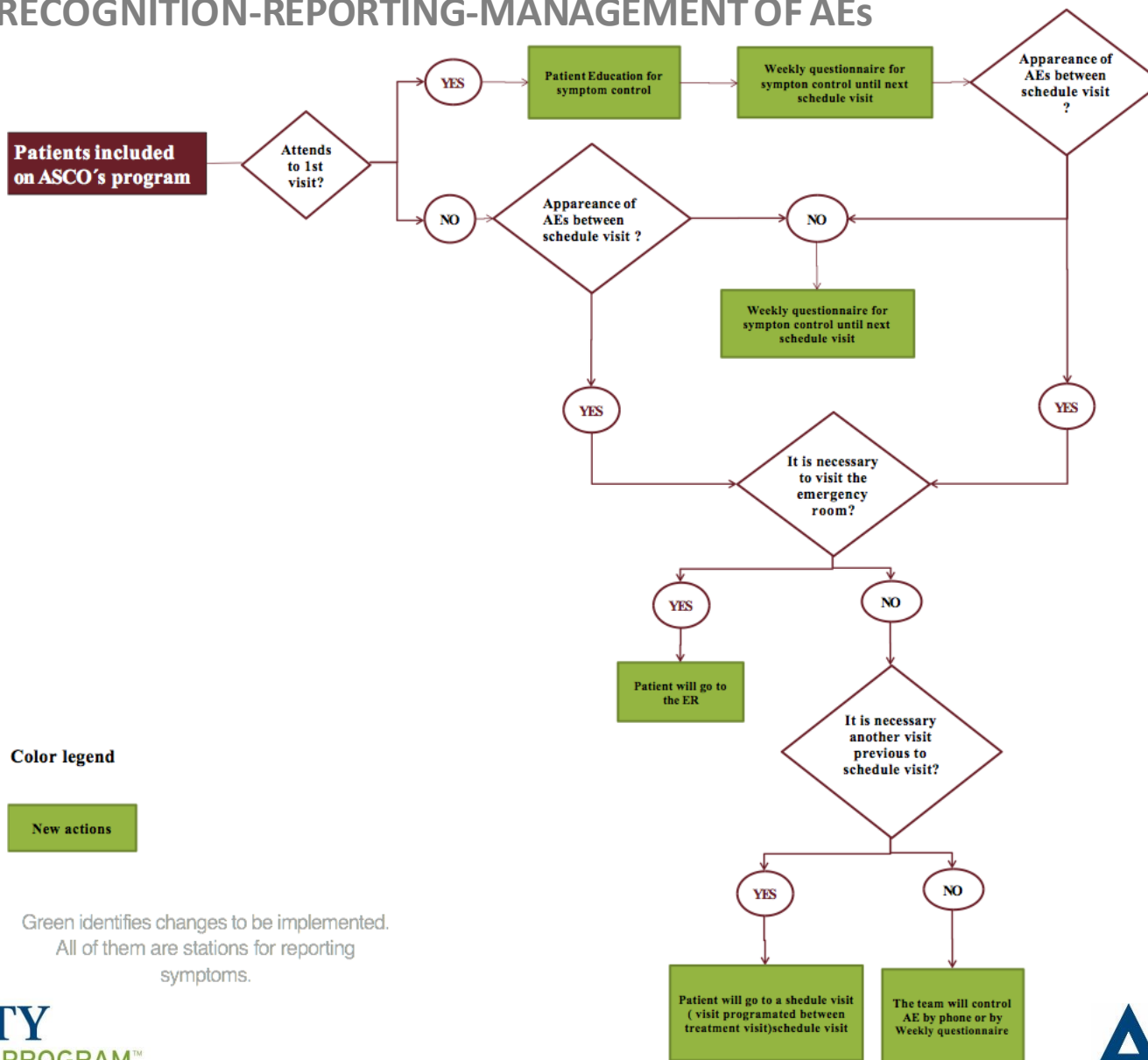


# Process Improvement Team Members

- **Sponsor:** Dr. Carrato
- **Medical Team:** Ana Gómez, Cristina Saavedra, Roberto Martín  
*In charge of giving the first education of the patient regarding symptom control.*
- **Nurse Team:** Paloma Gómez, Tamara Jimenez and Mario Cano.  
*In charge of strengthening the patient education regarding symptom control.*  
*Review and alert in case of high grade AEs.*
- **Study Coordinator:** Elena Ruiz  
*Control of patient data and their analysis*
- **Patient Advocate:** Ángel Gaitán.

# Process Map New Communication-Education

## RECOGNITION-REPORTING-MANAGEMENT OF AEs



# Aim Statement

25% Reduction in grade 2-3 AEs over a period of 2 months (April-May).

# Prioritized List of Changes (Priority/Pay-Off Matrix)

<b>Impact</b>	<b>High</b>	<ul style="list-style-type: none"> <li>• Patient education by oncologist</li> <li>• Patient education by nurse</li> <li>• Education follow up</li> <li>• <b>Phone contact for AE control</b></li> </ul>	<ul style="list-style-type: none"> <li>• Satisfaction questionnaire</li> <li>• Guidelines for patients</li> <li>• AE knowledge test for patients</li> </ul>
	<b>Low</b>	<ul style="list-style-type: none"> <li>• Patient Symptom control questionnaire</li> <li>• Patient Symptom control questionnaire follow-up</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Email contact for AE</b></li> <li>• <b>Primary Care Physicians education</b></li> </ul>

**Ease**

**Implementation**

**Difficulty**

# Developed Materials

- Patients AEs management guide.
- Patients AEs management test.
- Developed AE management reference tool for providers based on ASCO guidelines.

# PDSA Plan (Test of Change)

Date of PDSA Cycle	Description of Intervention	Results	Action Steps
9-Apr-2018	Prepare patients materials		Reviewed by patient advocate
16-Apr-2018	Create checklist	Not clear with ASCO <i>guidelines</i> and patient treatment dates	
26-Apr-2018	Modify checklist	Increase quality of data and easier management	
30-Apr-2018	Modify checklist	Adding trainer perception about patient knowledge	



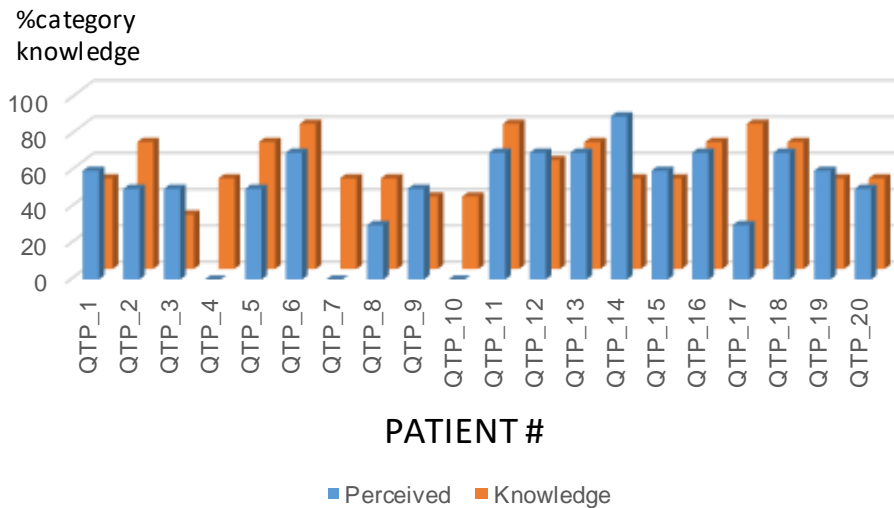
# Measures: PROCESS

- Calculation methodology:
  1. Inclusion criteria: Adult patients with lung cancer who will receive or are receiving immunotherapy that participate in Education Sessions.
  2. Exclusion criteria: Patients who are participating in clinical trials.
- Process measurement steps: Two provided patient education sessions, one before treatment and the second session after two cycles of immunotherapy.
  1. 10 categories of AEs outlined for patients and reviewed altogether with the team.
  2. Patients are asked about their confidence in the acquired knowledge in the 10 AEs categories.
  3. Patients have to pass a test about the level of acquired knowledge in the 10 AEs categories.
  4. Patients' perception, before and after.

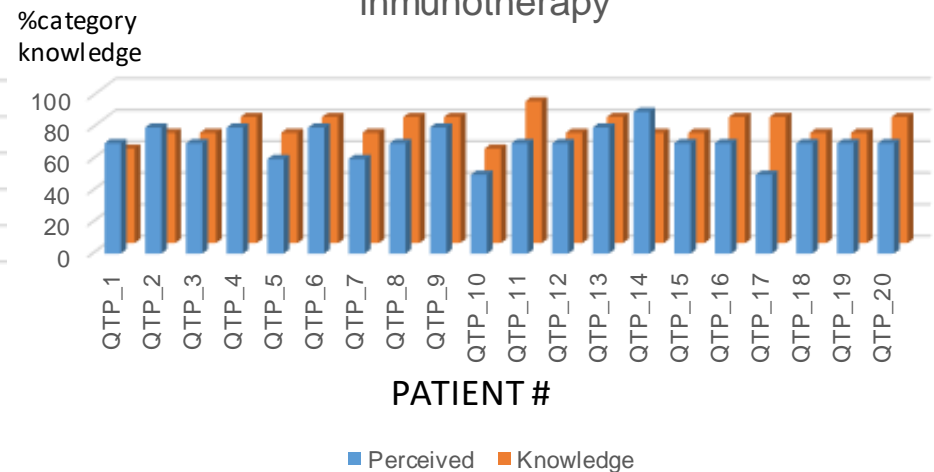
# Measures: PROCESS

- Patient education test results: knowledge and perception
- 10 Adverse event categories

Session #1: before educational program

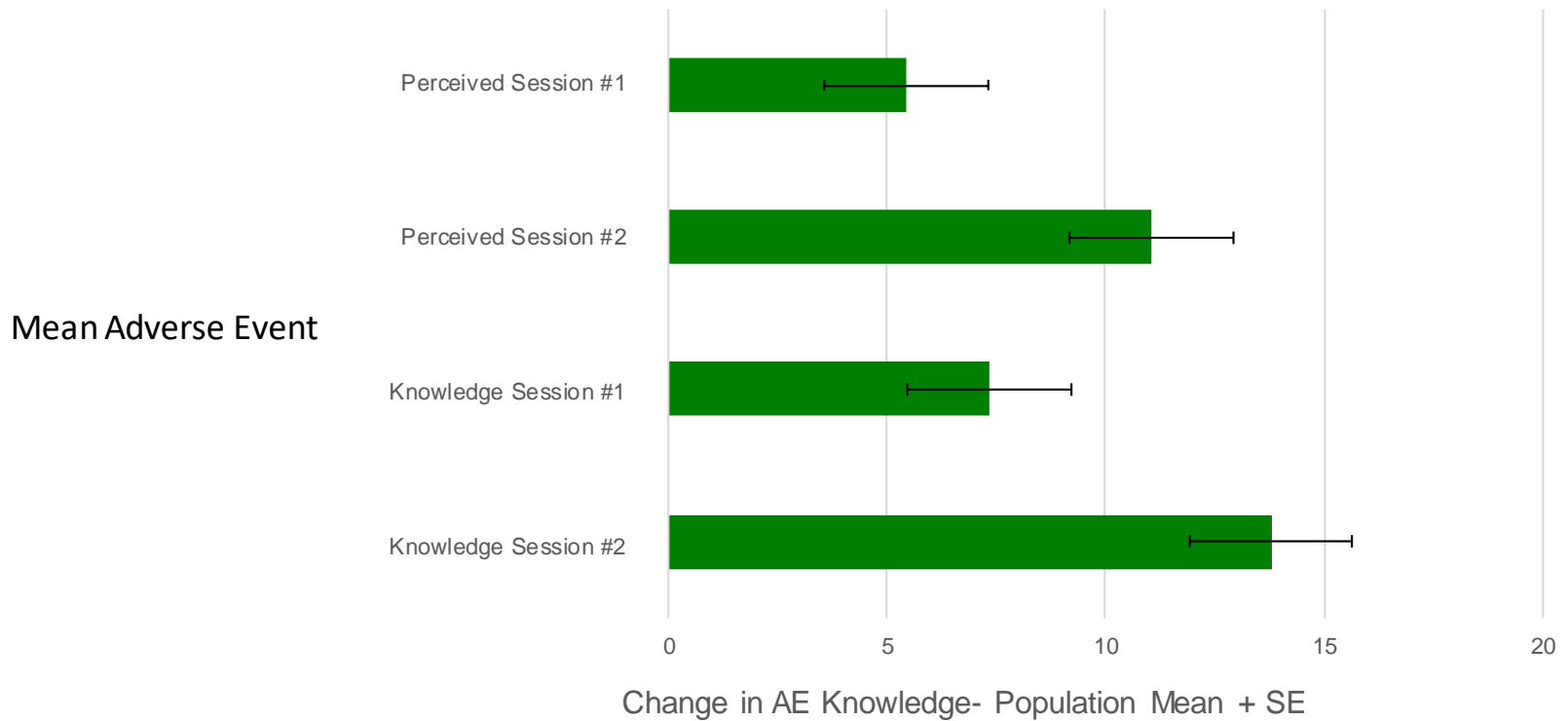


Session #2: after two cycles of immunotherapy



# Measures: PROCESS

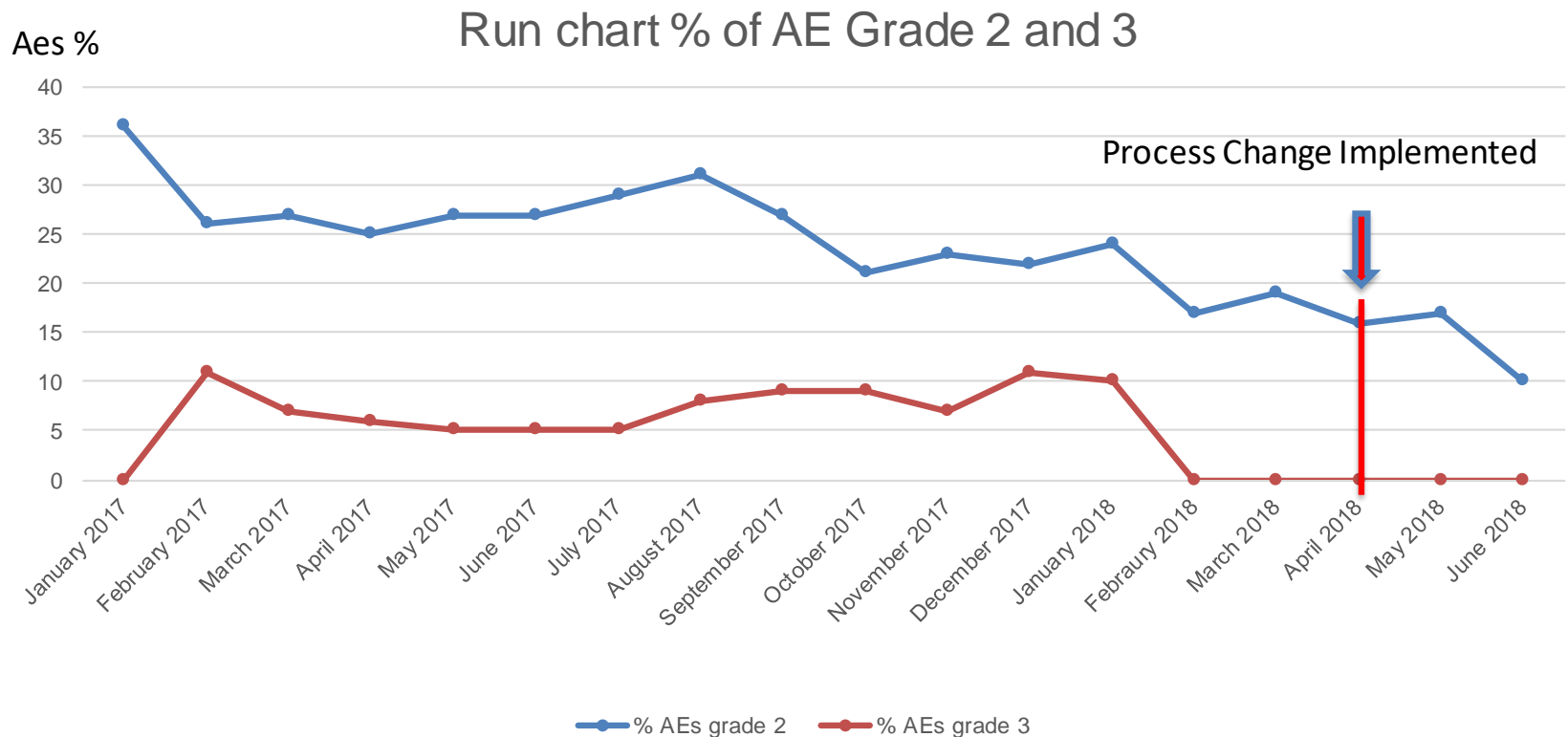
Comparison of Mean change between Session #1 vs #2



# Measures: Outcome

- **Calculation methodology:** data compilation of patients who enter in the program and contrast them with the data recorded in 2017
- **Data source:** patient's clinical charts
- **Data collection frequency:** AEs taken continuously.
- **Data quality (any limitations):** visits not recorded, patient's adherence, patient's not returned questionnaire

# Measures: Outcome



# Conclusions

- A Cancer Clinic-team-based process for Adverse Event education, recognition, and reporting was successfully changed and implemented.
- Introducing a test module in the educational process appears to improve patient knowledge base about AEs. The test module helps to identify areas for educational reinforcement. Patients are better educated after second session (“Learning through repetition”).
- The incidence of AEs, in particular grade 2, has decreased since the implementation of process change. The data collection is not mature enough in order to re-assess a new Cause and Effect analysis regarding factors contributing to improvement

# Next Steps/Plan for Sustainability

- Continue collecting data, patient tests, AEs grade 2 and 3 incidence, to support the aim of the project.
- Differentiate patients by groups. Those who have been receiving immunotherapy for a long period of time and those who have started the treatment with the program.
- Perform knowledge reassessment visits every 3 months.
- Export project to additional units in the Oncology Department.