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

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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

[Bar chart showing the number of adverse events (AE) by classification during 2017. The X-axis represents AE classification, and the Y-axis represents the number of AE with the corresponding classification. The chart shows the following categories and their respective counts: Asthenia (18), Respiratory infection (16), Cough (14), Rash (12), Diarrhea (11), Pruritus (9), Dysphagia (8), Dyspnea (7), Hypertiroidism (6), Pneumonitis (4), and Vomiting (2).]
Pareto chart - AE Grade

Pareto Chart (Nº of AE by Grade during 2017)

Quality Training Program

ASCO
Baseline Data Grade 2 & 3 AEs

Run chart % of AE Grade 2 and 3

% AEs grade 2

% AEs grade 3


%
Diagnostic Data

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

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

Inadequate patient knowledge

Restricted consultation time

Lack of communication with patients between visits

MEDICAL TEAM

Poor motivation

Precarious patient education

USV: Not recorded

Limited Infrastructure

ER saturation

Reduced human and economic resources

HOSPITAL

Stress

HIGH AMOUNT OF G2-3 ADVERSE EFFECTS

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

1. Schedule visit with referring Oncologist
2. Consultation
3. First dose is prescribed?
   - Yes: Patient Education by Oncologist
   - No: Treatment Prescribed and Delivered in Day Hospital
4. Is AE Experiences before next Visit?
   - Yes: Is accurate care needed?
     - No: Need to see Oncologist before next scheduled visit?
     - Yes: Emergency Room visit for control of the AE
   - No: Schedule next Visit
5. Color Legend
   - Stations for reporting symptoms

Quality Training Program
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- **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

Patients included on ASCO’s program

- Attends to 1st visit?
  - Yes: Patient Education for symptom control
  - No: Appearance of AEs between schedule visit?
    - Yes: Weekly questionnaire for symptom control until next schedule visit
    - No: Weekly questionnaire for symptom control until next schedule visit
      - Yes: It is necessary to visit the emergency room?
        - Yes: Patient will go to the ER
        - No: It is necessary another visit previous to schedule visit?
          - Yes: Patient will go to a schedule visit (visit programmed between treatment visit/schedule visit)
          - No: The team will control AE by phone or by Weekly questionnaire

Color legend
- Green identifies changes to be implemented
  All of them are stations for reporting symptoms.

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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)

<table>
<thead>
<tr>
<th>Impact</th>
<th>Ease</th>
<th>Implementation</th>
<th>Difficulty</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>● Patient education by oncologist</td>
<td>● Patient education by nurse</td>
<td>● Satisfaction questionnaire</td>
</tr>
<tr>
<td></td>
<td>● Patient education by nurse</td>
<td>● Education follow up</td>
<td>● Guidelines for patients</td>
</tr>
<tr>
<td></td>
<td>● Phone contact for AE control</td>
<td></td>
<td>● AE knowledge test for patients</td>
</tr>
<tr>
<td>Low</td>
<td>● Patient Symptom control questionnaire</td>
<td></td>
<td>● Email contact for AE</td>
</tr>
<tr>
<td></td>
<td>● Patient Symptom control questionnaire follow-up</td>
<td></td>
<td>● Primary Care Physicians education</td>
</tr>
</tbody>
</table>

The items conducted through June 2018 are marked in red.
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)

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

Change in AE Knowledge - Population Mean + SE

Mean Adverse Event
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

Run chart % of AE Grade 2 and 3

Aes %

% AEs grade 2
% AEs grade 3

Process Change Implemented

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.

• Differenciate 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.