Project Title: Optimization of screening tools in patients eligible to receive Immune Checkpoint Inhibitors (ICPI)

Presenter’s Name: Oliver Higuera and Lorena Ostios

Institution: La Paz University Hospital, Madrid-Spain

Date: April 8, 2019
Institutional Overview

La Paz University Hospital:
Area 5 - North of Madrid

701,469 population
Institutional Overview

Medical Oncology Department

Units:

A: Breast, Gynecological, Genitourinary, head and neck cancer, Melanoma, Sarcoma and brain tumors

B: Digestive and thoracic tumors sections. Neuroendocrine tumors

Cross – sectional consultations:
- Hereditary Cancer
- Long survivors
- VTD in cancer patients

Hospitalization
Institutional Overview

Nº visits/year: 53,763
- 36,261 I.V. treatments/year

Out-Patients
- 54 armchairs
- 6 beds

In-Patients: 28 beds
24 hours, 7 day a week availability to an on-call medical oncologist

701,469 population
Problem Statement

Immune Checkpoint Inhibitors

Incorporation of a new therapeutic group

Different side effects

Variability in prevention and management of immune related side effects

Implementation of protocols
ICPI, 2017-2018

175 patients

We analyzed 20 patients treated with ICPI (10 pembro-10 nivo)

Patients treated with ICPI in 2017-2018

- Nivolumab: 78 patients
- Pembrolizumab: 79 patients
- Atezolizumab: 18 patients
Problem Statement

- No EAir: 55%
- G1: 15%
- G2: 15%
- G3: 15%

% TREATMENT MODIFICATIONS
- No changes: 56%
- Delay: 33%
- Suspension: 11%

% EAir
45% immune related side effects*:

Impact on Quality of care

- Delay in treatment administration (33%)
- Definitive suspension of treatment (11%)
- Increase in the number of visits to the emergency room and Unscheduled visits
- Interconsultations another medical specialists
- Increase of costs
- Patients dissatisfactions with the treatment administered

*CLINICAL TRIALS DATA:
Pembro 74% EAir, 26% G3-G5
Nivo 61% EAir, 15% G3-G4
An adequate baseline screening is performed before receiving treatment with ICPI?
Proceso de tratamiento:

1. **Diagnóstico progresión tumoral**
   - Valoración en CCOO
     - SI: Indicación de Inmunoterapia
       - SI: Información sobre objetivos y complicaciones
         - SI: Firma consentimiento informado
           - SI: Educación Inmunoterapia
             - NO: Educación funcionamiento H de Día
               - NO: Petición analítica basal y otras PPCC?
                 - SI: Medidas correctoras
                 - NO: ¿Existe alguna anomalía en las PPCC?
                   - SI: Administración primer ciclo Inmunoterapia
                   - NO: Seguimiento Oncólogo referencia

2. NO: Valorar otras alternativas
   - NO: Seguimiento Oncólogo referencia
Basal evaluation of liver, renal and endocrine function

- Glucemia
- HbA1c
- Función Renal
- Transaminasas y Bilirrubina (ALT, AST y GGT)
- TSH
- T4L
- Ac AntiTPO

Number of patients evaluated
Diagnosis Data

Basal analysis of chronic infections

Number of patients evaluated

- AnticVHB: 5
- VHC: 3
- CMV: 1
- HIV: 4
- TBC: 1

VIRUS
TBC
Basal physical examination and heart function

Number of patients evaluated

- SatO2
- Exploración cutánea
- ECG
- FEVI
• **Sponsor:** Dr. Feliu

• **Medical Team:**
  - Dr. Higuera, Dra. Ostios.  
    *In charge of identification of the problem, design of the program, analysis and monitoring of the results*
  - Medical oncologist Day Hospital  
    *In charge of recruitment of patients treated with ICPI*

• **Nurse team:**
  - *In charge of processing samples*
### Prioritized List of Changes (Priority/Pay –Off Matrix)

<table>
<thead>
<tr>
<th>High Impact</th>
<th>Low Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Easy</td>
<td>Difficult</td>
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<tr>
<td>- Medical and Nurse team education.</td>
<td>- Multidisciplinary board team</td>
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<td>- Early identification of patients eligible to receive immunotherapy.</td>
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<td>- Implementation of standardized protocols (PNT) related to immunotherapy.</td>
<td>- APP to record irAE</td>
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<td>- Patient education by oncologist and nurse.</td>
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**Ease of Implementation**

**High Impact**
- Medical and Nurse team education.
- Early identification of patients eligible to receive immunotherapy.
- Implementation of standardized protocols (PNT) related to immunotherapy.

**Low Impact**
- Patient education by oncologist and nurse.
- Provide written information and phone contact to patients.

**Easy**

**Difficult**
Measures PROCESS

- **Selection of patients:**
  1. **Inclusion criteria:** Adult patients who, for the first time, will receive immunotherapy regardless the line of treatment and type of tumor.
  2. **Exclusion criteria:** Patients who are participating in clinical trials.

- **Process measurement steps**
  - Develop a **profile of screening tests** in the electronic medical.
  - **Selection of candidates** for ICPI during the period January-April 2019.
  - **Review of screening tests** before administration of the first dose of immunotherapy.
  - Implementation of **standardized protocols (PNT)** related to immune mediated side effects.
## PDSA Plan (Test of Change)

<table>
<thead>
<tr>
<th>Date of PDSA Cycle</th>
<th>Description of Intervention</th>
<th>Results</th>
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<tbody>
<tr>
<td>Jan-15 to Feb-1</td>
<td>1. Protocol design</td>
<td></td>
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<td>Feb-1 to Feb-20</td>
<td>1. Education to oncologist and nurses</td>
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<td>2. Computer template design with data to be collected</td>
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<td>Feb-20 to Mar-31</td>
<td>1. Identification of candidates for immunotherapy.</td>
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<td>2. Informative document with possible complications and advice for patients and relatives</td>
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<td>3. Collection and evaluation of screening data.</td>
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<td>4. Tracking complications irAE</td>
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Basal evaluation of liver, renal and endocrine function
Change Data

Basal analysis of chronic infections

![Bar chart showing the number of patients evaluated for different infections.](image)
Basal physical examination and heart function

Number of patients evaluated:

- SatO2
- Exploración cutánea
- ECG
- FEVI
Conclusions

• Improvement in the collection of screening data.

• Tests that depend on interventionism or collaboration with other specialties (mantoux, echocardiogram ...) are not performed.

• Alterations in the tests prior to immunotherapy in a significant number of patients, which could lead to possible toxicities or interactions with the immunological treatment.

• We are on the right track, but it is still necessary to continue improving.
NEXT STEP
# Next Steps/Plan for Sustainability

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