Quality Training Program

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

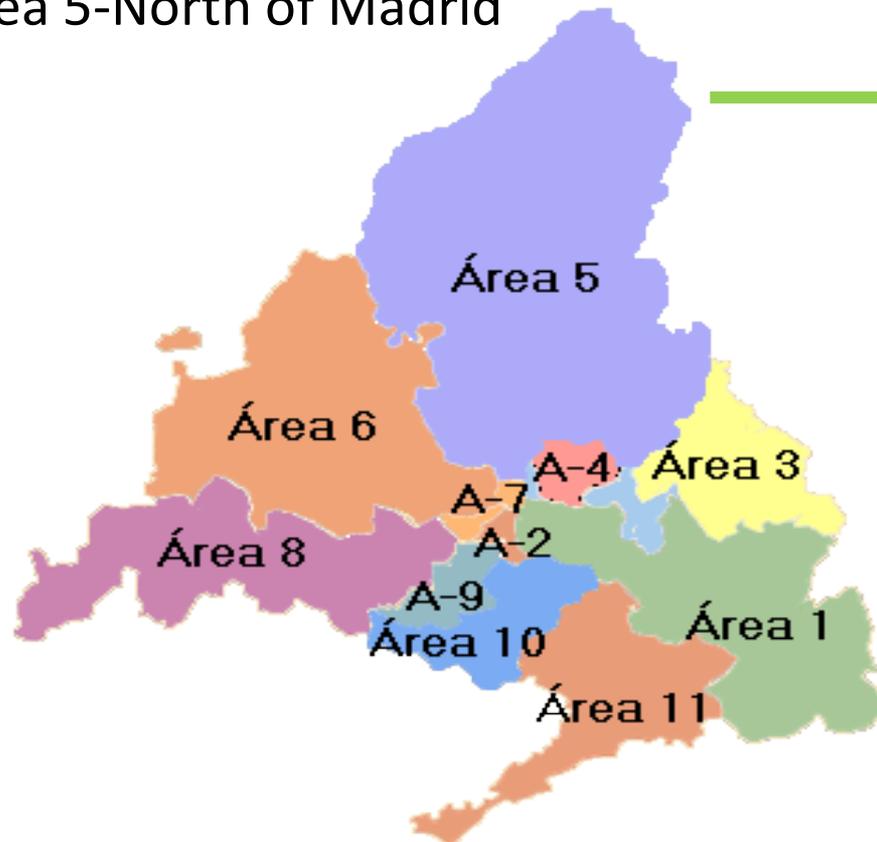**Presenter's Name:** Oliver Higuera and Lorena Ostios

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

14 Oncologist

15 Fellows (3 Fellows/year)

Units:

A: Breast, Gynecological, Genitourinary,, head and neck cancer, Melanoma, Sarcoma and brain tumors
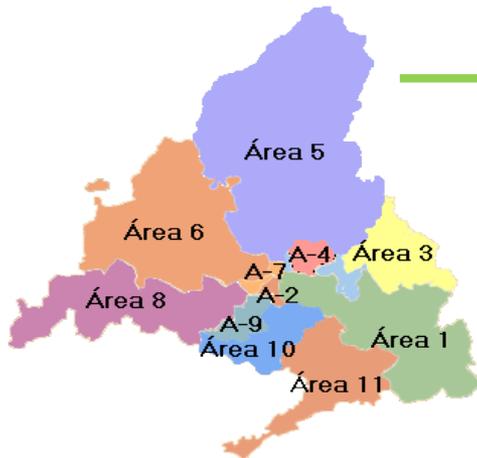
B: Digestive and thoracic tumors sections. Neuroendocrine tumors

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

Hospitalization

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Oncología

Institutional Overview

701,469 population

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

Problem Statement

Immune Checkpoint Inhibitors

Incorporation of a new therapeutic group

Different side effects

Variability in prevention and management of immune related side effects
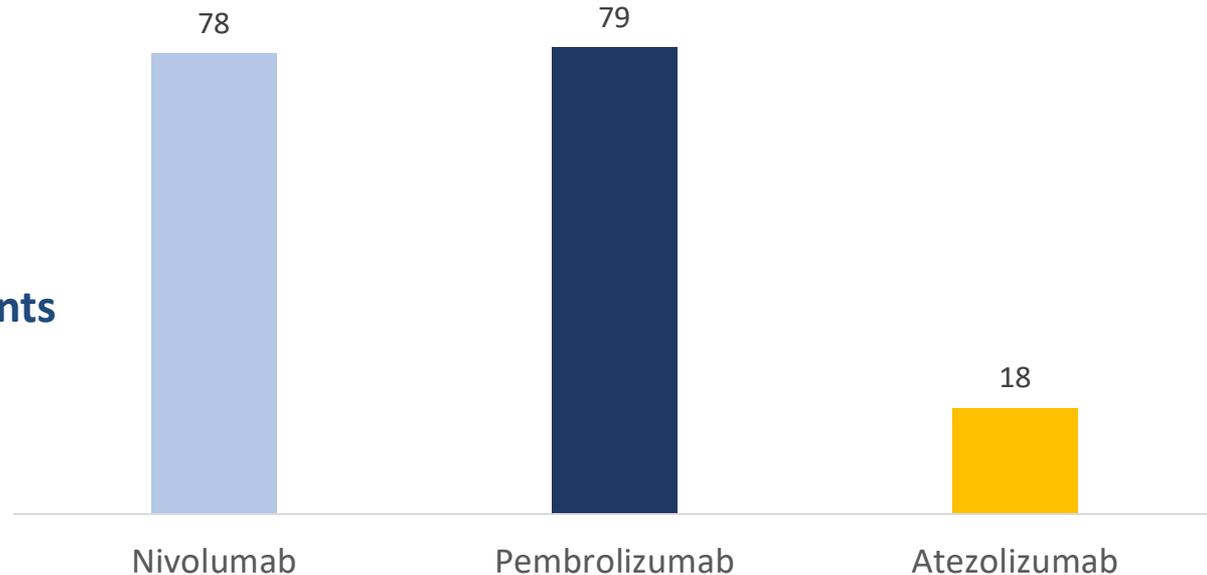
Implementation of protocols
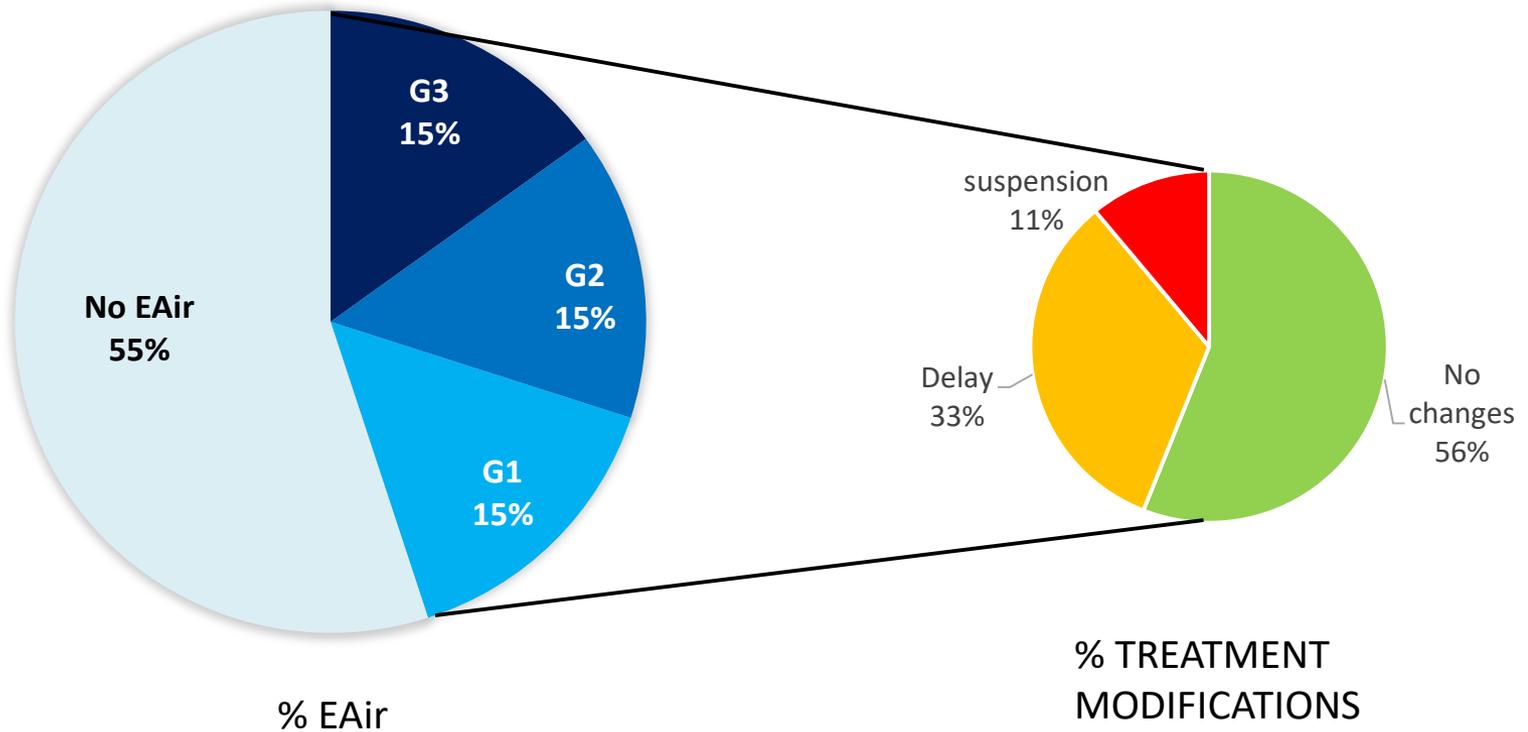
Problem Statement

ICPI, 2017-2018

175
patients

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

Patients treated with ICPI in 2017-2018

Nivolumab	Pembrolizumab	Atezolizumab
78	79	18

Problem Statement

% EAir

% TREATMENT MODIFICATIONS

Problem Statement

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
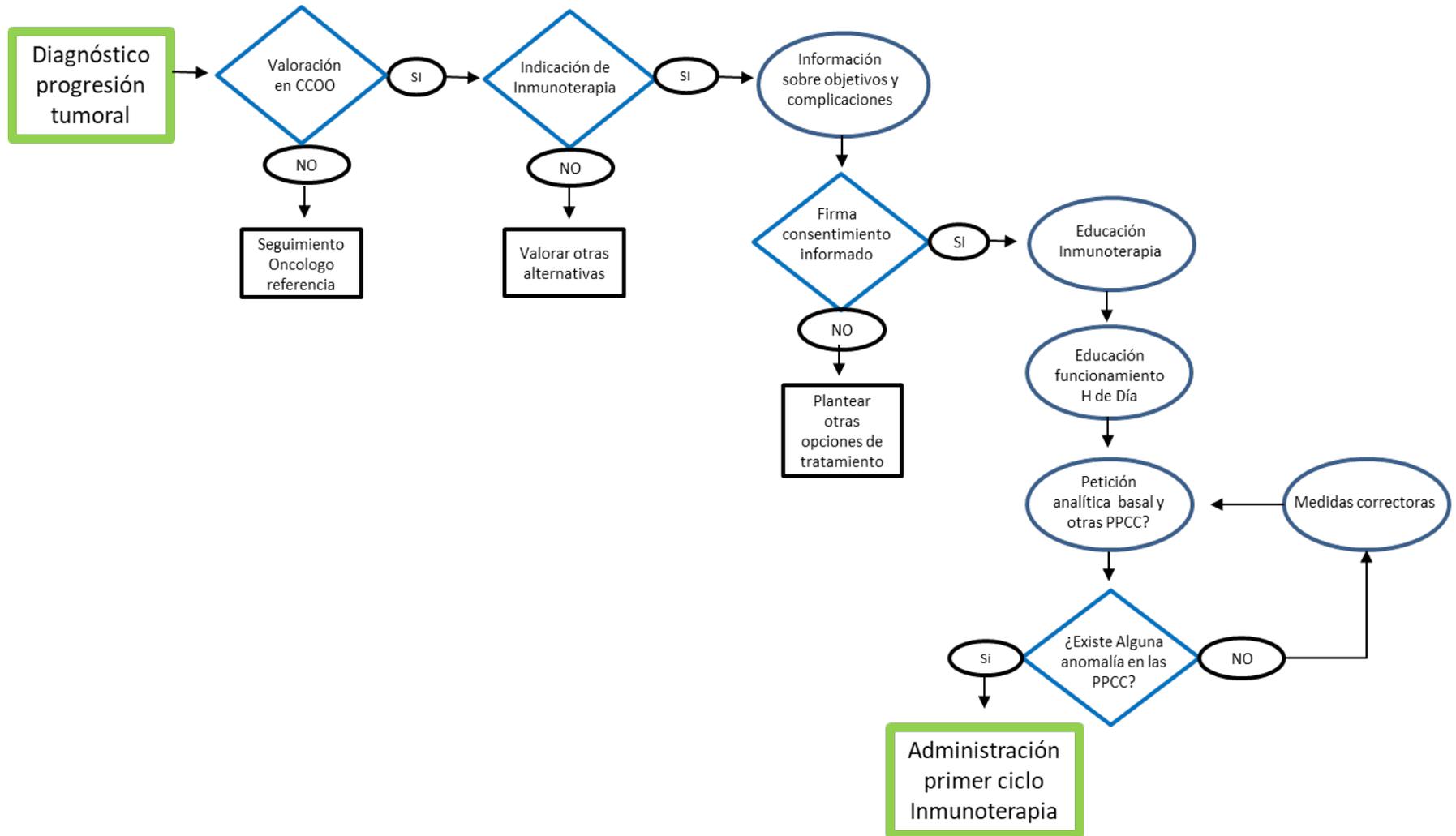- Patients dissatisfactions with the treatment administred

*CLINICAL TRIALS DATA:
Pembro 74% EAir, 26% G3-G5
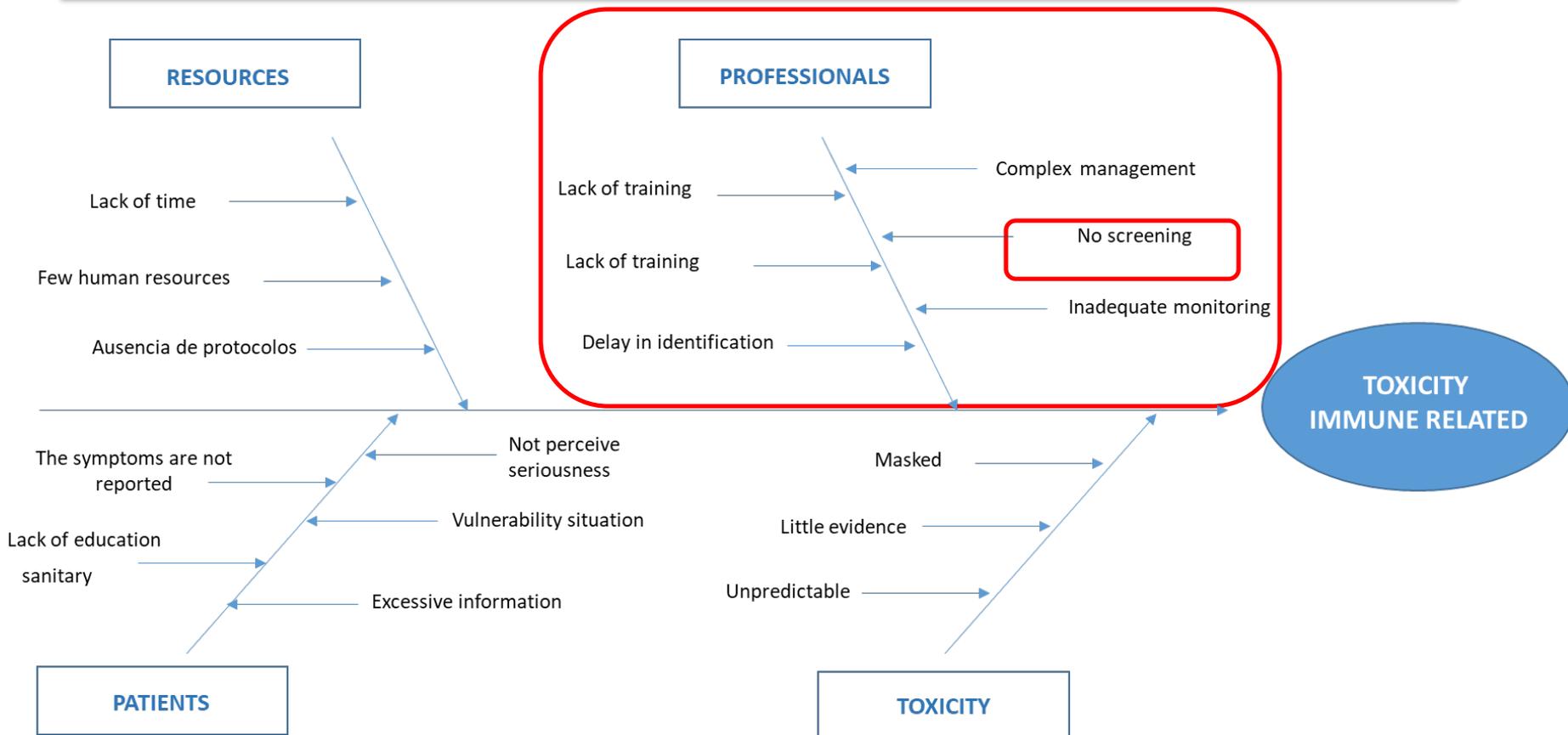Nivo 61% EAir, 15% G3-G4

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Problem Statement

An adequate baseline screening is performed before receiving treatment with ICPI ?
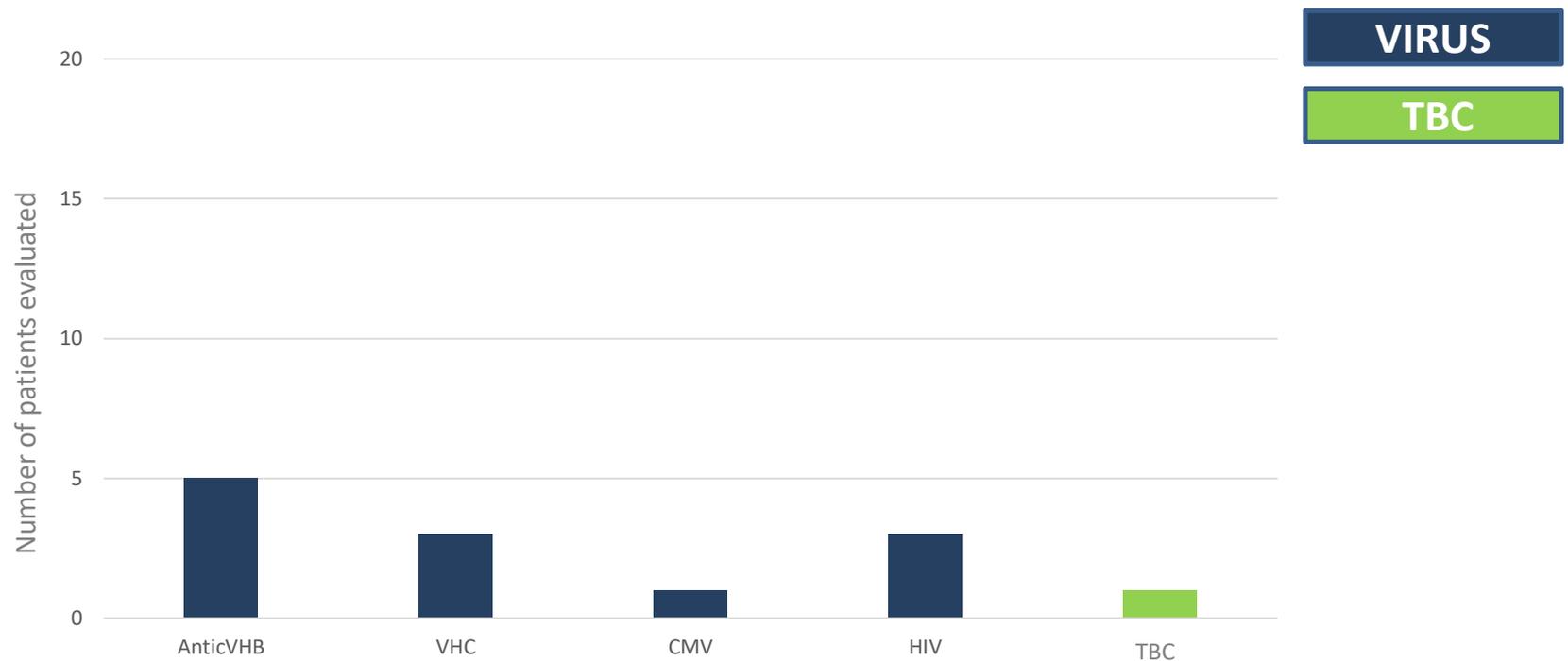
Process Map

Diagnóstico progresión tumoral → Valoración en CCOO
- SI → Indicación de Inmunoterapia
- NO → Seguimiento Oncologo referencia

Indicación de Inmunoterapia
- SI → Información sobre objetivos y complicaciones
- NO → Valorar otras alternativas

Información sobre objetivos y complicaciones → Firma consentimiento informado
- SI → Educación Inmunoterapia
- NO → Plantear otras opciones de tratamiento

Educación Inmunoterapia → Educación funcionamiento H de Día → Petición analítica basal y otras PPCC? → ¿Existe Alguna anomalía en las PPCC?
- Si → Administración primer ciclo Inmunoterapia
- NO → Medidas correctoras → (Petición analítica basal y otras PPCC?)

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Cause & Effect Diagram

RESOURCES

Lack of time

Few human resources

Ausencia de protocolos

PROFESSIONALS

Complex management

Lack of training

No screening

Lack of training

Inadequate monitoring

Delay in identification

TOXICITY IMMUNE RELATED

The symptoms are not reported

Not perceive seriousness

Masked

Vulnerability situation

Little evidence

Lack of education sanitary

Excessive information

Unpredictable

PATIENTS

TOXICITY

Diagnosis Data

Basal analysis of chronic infections

VIRUS

TBC

Diagnosis Data

Basal physical examination and heart function
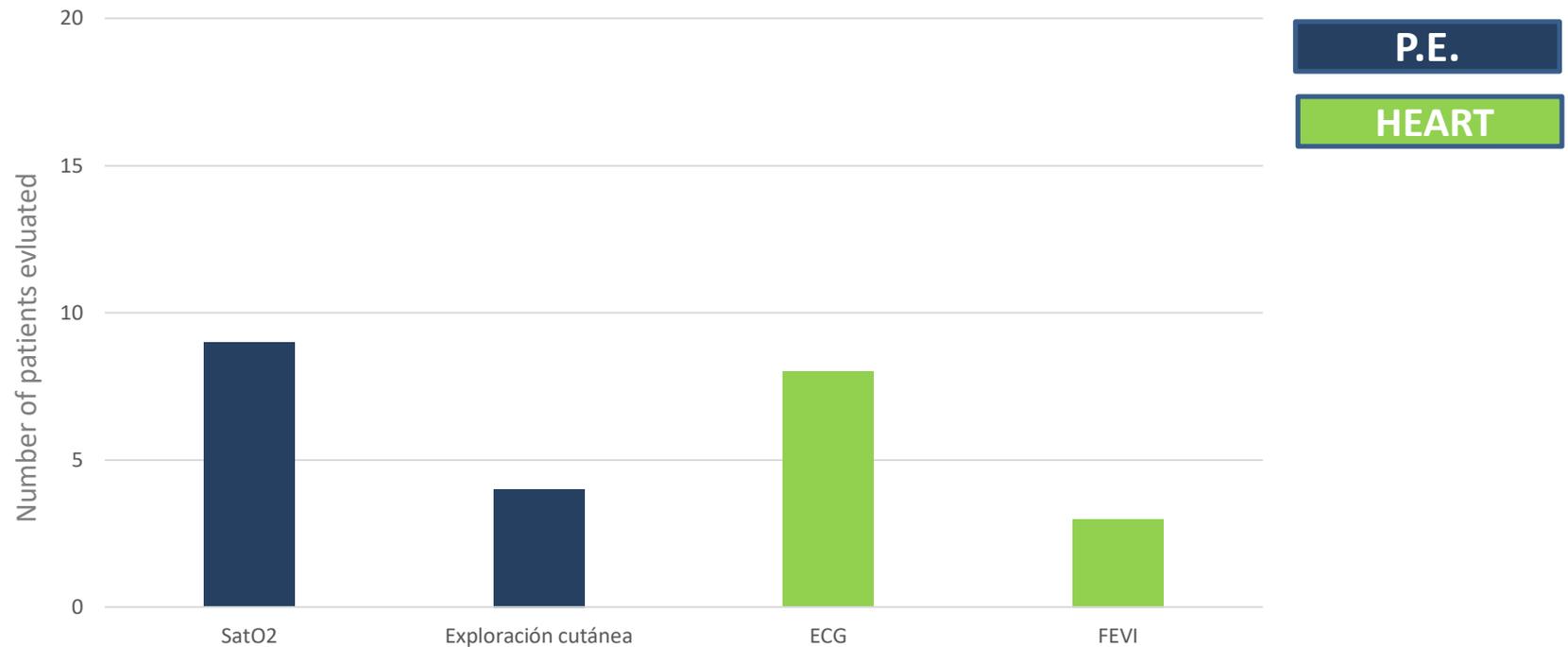
Diagnosis Data

PARETO CHART
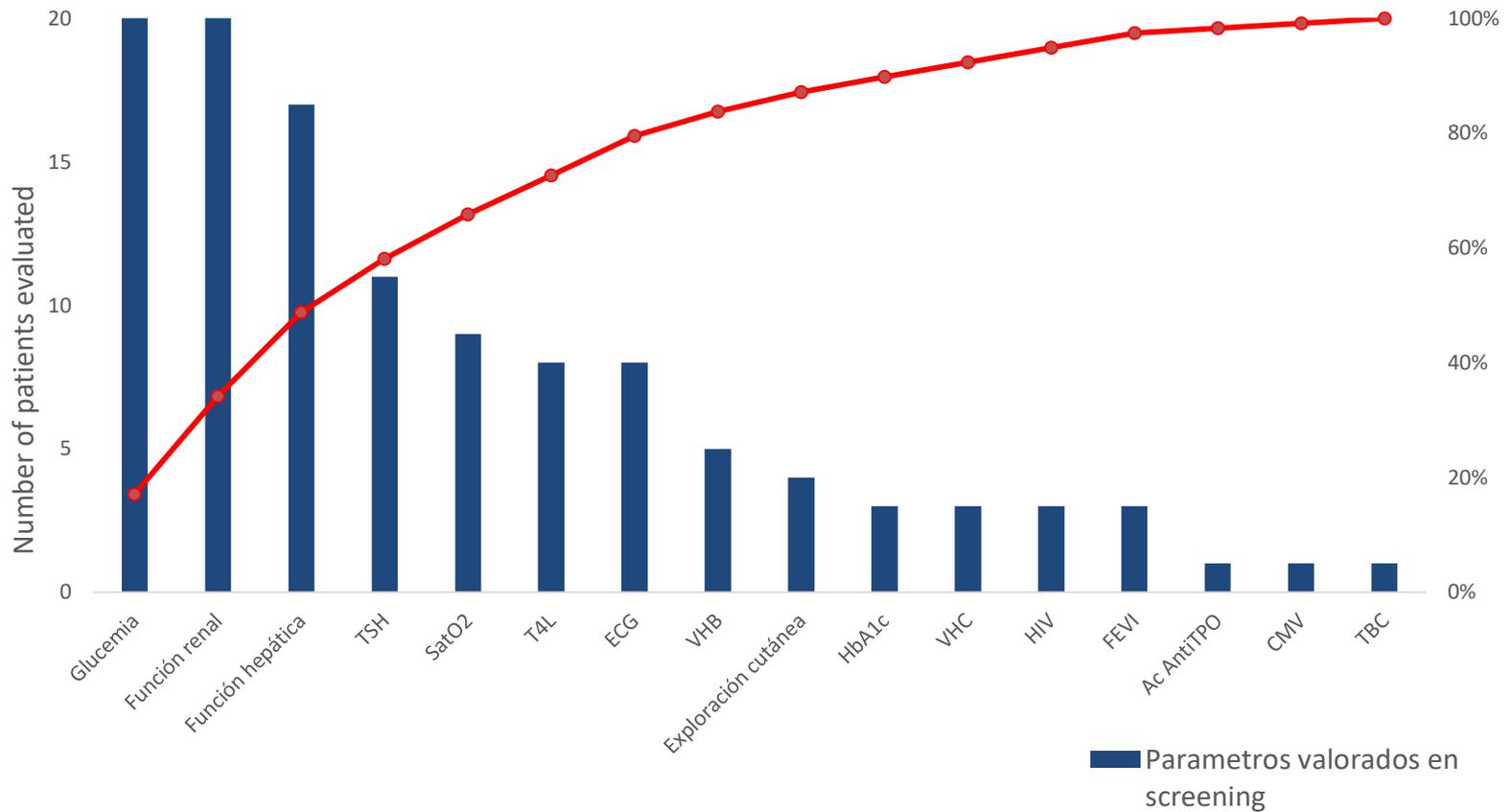
Process Improvement Team Members

- **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)

Impact

High

- Medical and Nurse team education.

- Early identification of patients eligible to receive immunotherapy.

- Implementation of standardized protocols (PNT) related to immunotherapy.

- Multidisciplinary board team

- Immuno-Oncology Unit

Low

- Patient education by oncologist and nurse.

- Provide written information and phone contact to patients.

- APP to record irAE

- Emergency Unit and Primary Care education

Easy   **Difficult**

**Ease of Implementation**

Measures PROCESS

- <u>Selection of patients:</u>
    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.

- <u>Process measurement steps</u>
    - 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 of immune mediated side effects.

PDSA Plan (Test of Change)

| Date of PDSA Cycle	Description of Intervention	Results
Jan-15 to Feb-1	1. Protocol design	
Feb-1 to Feb-20	1. Education to oncologist and nurses 2. Computer template design with data to be collected	(yellow)
Feb- 20 to Mar-31	1. Identification of candidates for immunotherapy. 2. Informative document with possible complications and advice for patients and relatives 3. Collection and evaluation of screening data. 4. Tracking complications irAE	(green)

Change Data

Run Chart
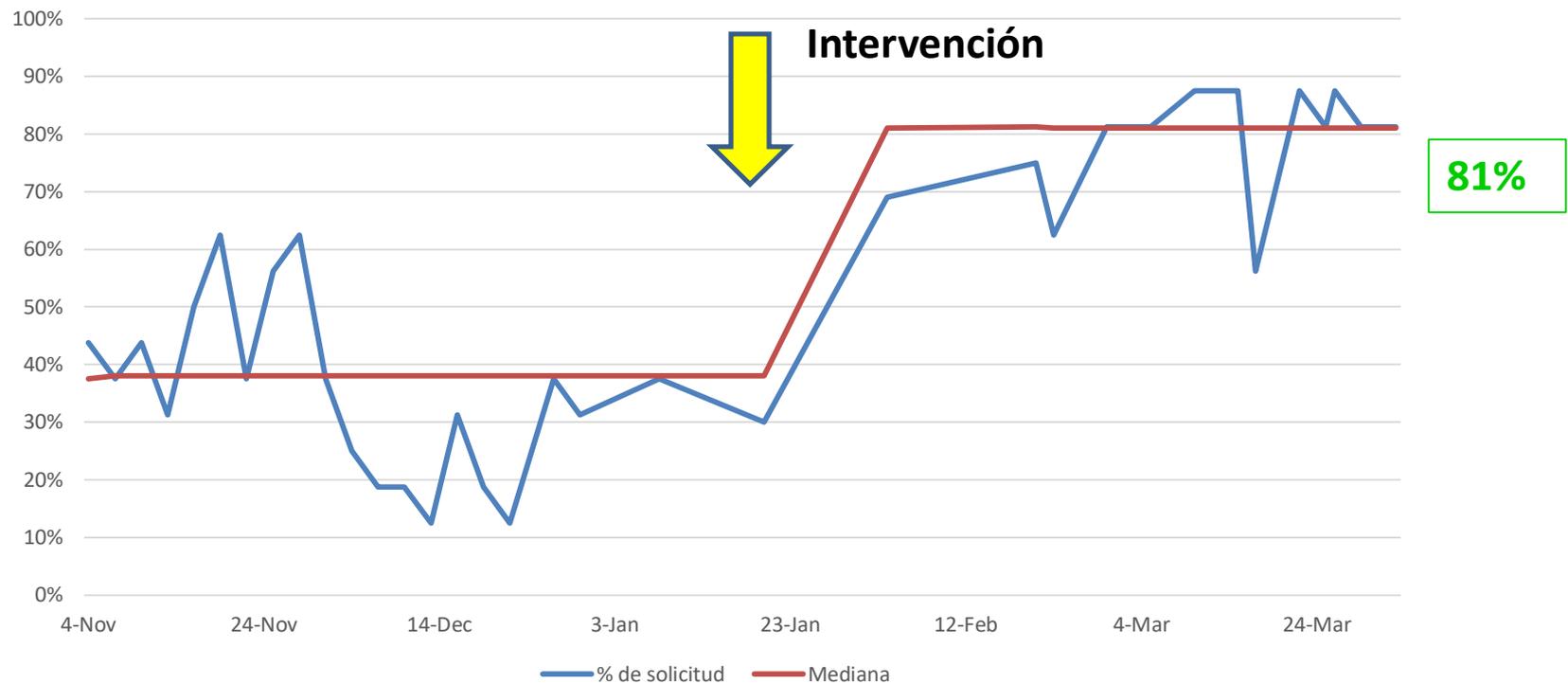
Change Data

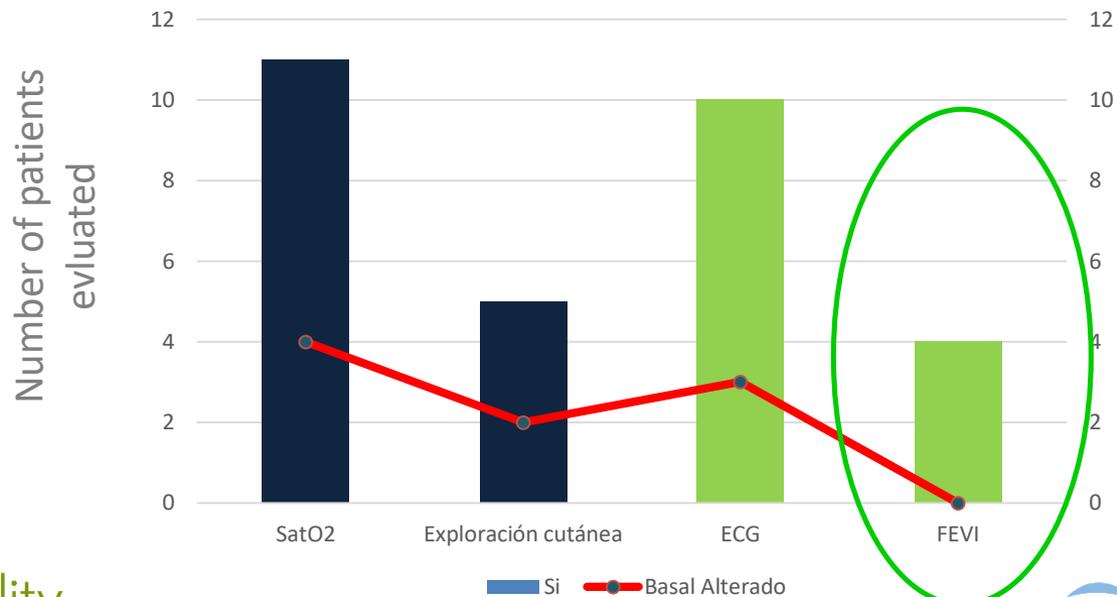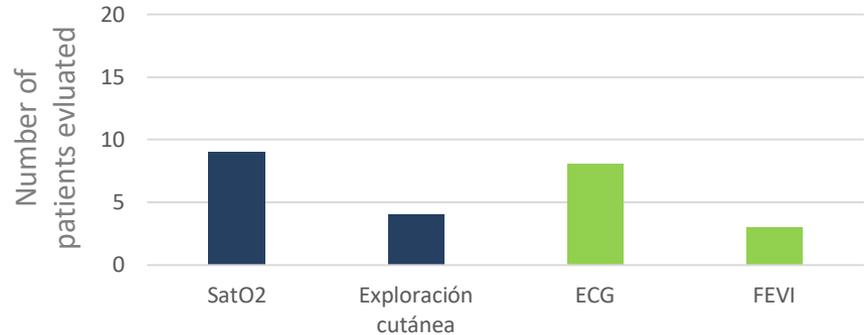Basal evaluation of liver, renal and endocrine function
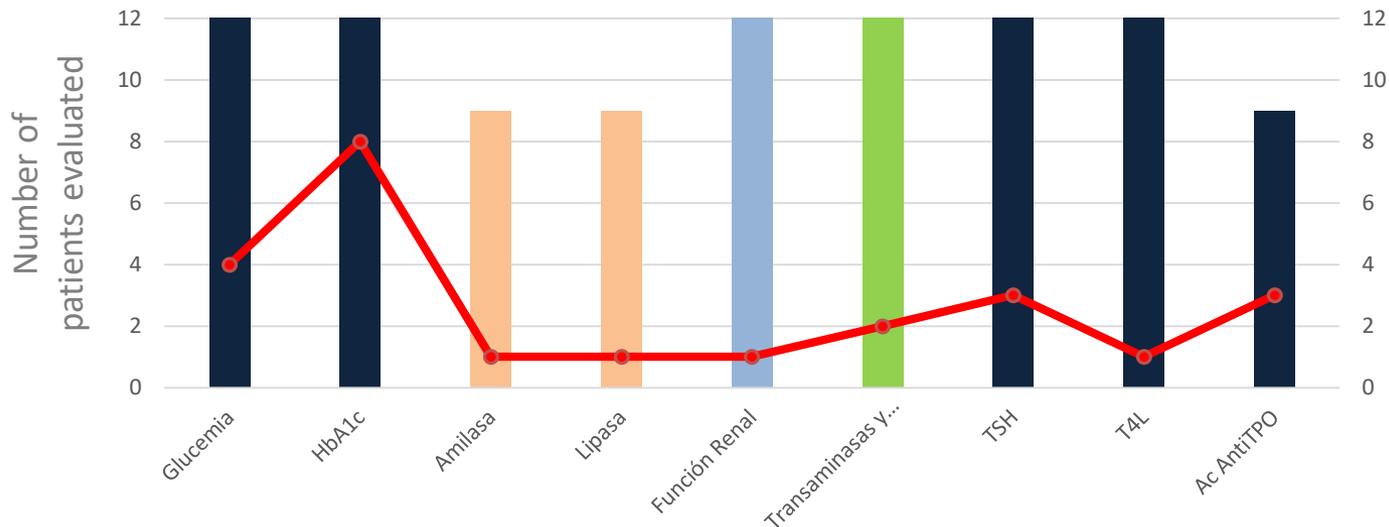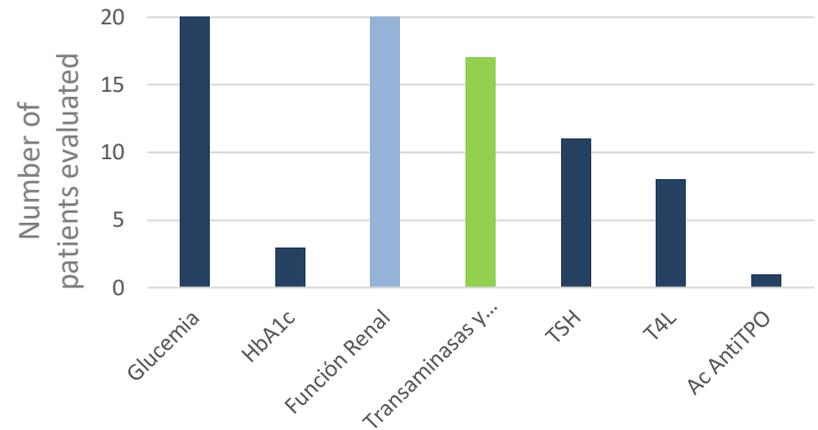
Change Data

Basal analysis of chronic infections
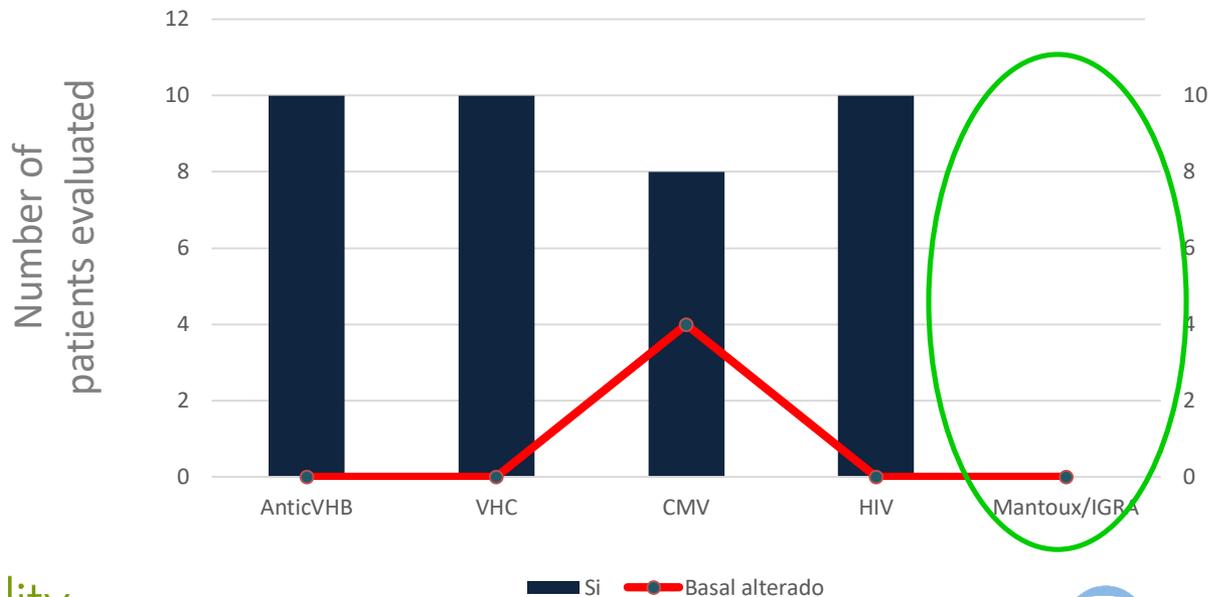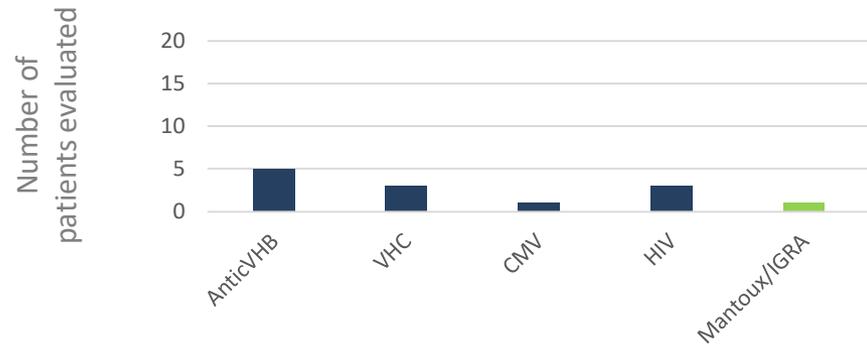
Change Data

Basal physical examination and heart function

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

	Easy	Difficult
High	- Medical and Nurse team education. - Early identification of patients eligible to receive immunotherapy. - Implementation of standardized protocols (PNT) related to immunotherapy.	**- Multidisciplinary board team** **- Immuno-Oncology Unit**
Low	- Patient education by oncologist and nurse. - Provide written information and phone contact to patients.	- APP to record irAE - Emergency Unit and Primary Care education

Impact

Ease of Implementation