Project title: Evaluation of the inclusion rate in clinical trials of bladder cancer patients evaluated for first time in Oncology Department

Presenter`s name: Fernando Moreno

Institution: Hospital Clínico San Carlos

Date: 8 April 2019
Team Members

- **Fernando Moreno**: Medical Oncologist.
- **Mª del Rosario Alfonso**: Oncologist. Coordinator of Clinical Research in Oncology Department
- **Lydia Suárez**: Study Coordinator in the Department of GU tumors
- **Javier Puente**: Medical Oncologist. Secretary of the genitourinary tumors board (GU board)
- **Pedro Pérez Segura**: Medical Oncologist. Head of Oncology Department
- **Concha Vila**: Oncology nurse
- **Marta Vigara**: Geriatrician
Institution Overview

- Public University Hospital
- Madrid, Spain.
- Population area: 364,345 habitants

<table>
<thead>
<tr>
<th>Role</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians</td>
<td>31</td>
</tr>
<tr>
<td>- Head of Department</td>
<td>1</td>
</tr>
<tr>
<td>- Head of Section</td>
<td>1</td>
</tr>
<tr>
<td>- Physicians</td>
<td>14</td>
</tr>
<tr>
<td>- Residents</td>
<td>15</td>
</tr>
<tr>
<td>Nurses</td>
<td>66</td>
</tr>
<tr>
<td>Administrative staff</td>
<td>3</td>
</tr>
<tr>
<td>Study coordinators</td>
<td>8</td>
</tr>
<tr>
<td>Laboratory members</td>
<td>8</td>
</tr>
</tbody>
</table>
## Problem Statement

<table>
<thead>
<tr>
<th>Cancer location</th>
<th>First visits (n)</th>
<th>Enrolled patients (n)</th>
<th>Ratio %</th>
</tr>
</thead>
<tbody>
<tr>
<td>H&amp;N</td>
<td>41</td>
<td>2</td>
<td>4.87</td>
</tr>
<tr>
<td>Brain</td>
<td>23</td>
<td>2</td>
<td>4.87</td>
</tr>
<tr>
<td>Gynecologic</td>
<td>77</td>
<td>17</td>
<td>22.07</td>
</tr>
<tr>
<td>Sarcomas &amp; GIST</td>
<td>34</td>
<td>3</td>
<td>8.82</td>
</tr>
<tr>
<td>Thyroid</td>
<td>5</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Unknown</td>
<td>12</td>
<td>3</td>
<td>25</td>
</tr>
<tr>
<td>Breast</td>
<td>290</td>
<td>63</td>
<td>21.72</td>
</tr>
<tr>
<td>Lung</td>
<td>152</td>
<td>29</td>
<td>19</td>
</tr>
<tr>
<td>Mesothelioma</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Genitourinary</td>
<td>131</td>
<td>51</td>
<td>38.93</td>
</tr>
<tr>
<td>Melanoma</td>
<td>34</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Colorectal</td>
<td>178</td>
<td>19</td>
<td>10.68</td>
</tr>
<tr>
<td>Digestive (non colorectal)</td>
<td>118</td>
<td>8</td>
<td>7.62</td>
</tr>
<tr>
<td>Others</td>
<td>16</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>1113</td>
<td>197</td>
<td>17.68</td>
</tr>
</tbody>
</table>
Between January and November 2018 the percentage of patients with GU tumors enrolled in clinical trials was 39%

Lower percentage of enrollment in clinical trials in Bladder cancer compared to other GU tumors.

- Prostate cancer 43%
- Kidney cancer 47%
- Bladder cancer 24%
✓ **Measure:** Enrollment rate in clinical trials.
✓ **Population:** Bladder cancer patients evaluated for the first time in the Oncology Department of HCSC
✓ **Methodology (metrics):**
  • Proposals of clinical trials (n)
  • Available trials (n)
  • Patients evaluated for the first time (n)
  • Patients enrolled in clinical trials (n)
  • Causes of non-enrollment & screening failures
  • Enrollment rate (patients enrolled/patients evaluated)
✓ **Data source:** Medical records and data base of clinical trials in the department of clinical research unit.
✓ **Data collection frequency:** January-october 2018.
✓ **Data quality:** Paper medical record
Diagnostic data: Available Clinical Trials

Clinical Trials (January-October 2018)

- Advanced disease 2nd line
- Maintenance
- Advanced disease 1st line
- Advanced disease 1st line
- Adjuvant
- Pre-invasive
- Neoadjuvant

Jan-18 - Oct-18
Diagnostic data: Clinical Trial Proposals (January-October 2018)

N = 14 proposals
Average: 1.5 proposals/month

Accepted Trials N = 5
Cancelled Trials N = 9
Cancellation rate: 64%

Number of proposals

- Adjuvant
- Neoadjuvant
- Advanced 1st line
- Advanced 2nd-3rd line

Accepted
Cancelled by Promotor
Cancelled by Center
Diagnostic data: Patients Enrolled (January-October 2018)

**Average: 2.1 patients/month**

**Enrollment rate: 23%**

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**Patients candidate for treatment (N=26)**

- **Enrolled patients**: 6
- **Not enrolled patients**: 20

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**Patients not included in clinical trial (N=20)**

- **Elegibility criteria**: 12
- **Not available clinical trial**: 7
- **Patient refusal**: 1

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Pareto Chart

Patients Not-enrolled in clinical trials Jan-Oct 2018 (N=20)

Reason for Not-enrollment

- Patient eligibility criteria
- Lack of clinical trial available
- Patient Refusal

Clinical Trial enrollment failure

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ASCO Quality Training Program

eco

Fundación para la Excelencia y la Calidad de la Oncología
Patient with bladder cancer in oncology department

1. Indication of systemic treatment?
   - No
   - Yes

2. Clinical trial available?
   - Yes
   - No

3. Candidate to clinical trial?
   - Yes
   - No

4. Does the investigator offer clinical trial?
   - Yes
   - No

5. Does the patient accept clinical trial?
   - Yes
   - No

6. Does the patient meet eligibility criteria?
   - Yes
   - No

7. Is patient enrolled in clinical trial?
   - Yes
   - No

8. Treatment according to guidelines

9. Treatment in clinical trial
To increase patients enrollment rate in bladder cancer clinical trials in Oncology Department of Hospital Clinico San Carlos, between November 2018 and March 2019 up to 30%.
Patient`s rejection

- Elderly population
- Need of Additional test

Transport and meals

- Mistrust

Elegibility criteria

- Sample not available or insufficient
- Comorbidities

Geriatric evaluation

Oncology nurse

Enrollment in clinical trials

- Out of range results
- Study not offered
- Clinical trial cancelled

Optimization of CT*

- Initiation Phase

Pre-opening phase

Clinical criteria

- Overwork
- Center not interested
- Rejection of the center

Diffusion of CT* in the team & GU board

- Lack of knowledge

Planification of agenda

Investigator`s responsibility

Not available clinical trial

(*) CT: Clinical Trials
## Prioritized List of Changes
(Priority/Pay-Off Matrix)

<table>
<thead>
<tr>
<th>Impact</th>
<th>Ease of Implementation</th>
<th>High</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Supportive care (nurses)</td>
<td>Improvements in GU board</td>
</tr>
<tr>
<td>Easy</td>
<td></td>
<td>Geriatric assessment</td>
<td>Active search of CT</td>
</tr>
<tr>
<td>Diffusion of Clinical Trials (other units, other centers)</td>
<td>Optimization of CT Initiation Phase</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diffusion of CT (Oncology Department)</td>
<td>Planification of Agenda</td>
<td>Logistics: transport and meals</td>
<td></td>
</tr>
</tbody>
</table>
List of Changes:
Support Program for cancer patients

Supportive care (nurses)
First visit:
✓ Evaluation
  • Symptoms
  • Comorbidities
  • Nutrition
  • Pain
  • Emotional situation
  • Medication
  • Family support
  • Social needs
✓ Treatment Plan
Follow-up visits
✓ Revision and update

Geriatric Oncology
Criteria:
✓ Age > 75 years
✓ Advanced disease
✓ Functional status ECOG ≤2
✓ Barthel Index >60
✓ Caregiver
First Visit
✓ Full Geriatric assessment
✓ Inform
  • Robust patient
  • pre-frail patient
  • Frail patient
✓ Improvement plan
Follow-up visits
**PDSA Plan**

**Improvement in Performance Status of patients**

<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>From 01-11-2018 to 31-03-2019</td>
<td>Oncology nurse support</td>
<td>18 patients submitted</td>
<td>Maintain</td>
</tr>
<tr>
<td>From 08-01-2019 to 31-03-2019</td>
<td>Geriatric evaluation</td>
<td>4 patients submitted</td>
<td>Maintain</td>
</tr>
</tbody>
</table>
## PDSA Plan
### Increment available candidates

### Diffusion of Clinical Trials

<table>
<thead>
<tr>
<th>Date of PDSA Cycle</th>
<th>Description of Intervention</th>
<th>Results</th>
<th>Action Steps</th>
</tr>
</thead>
</table>
| 01-11-2018 to 31-03-2019 | **Review of clinical trials in the Investigation Unit**  
**Indicators:** Active CT *, Follow-up CT*, New CT*, Proposals  
**Tools:** Data base of Clinical Research Unit | ✓ Active CT*: 4  
✓ Follow-up CT*: 2  
✓ New CT*: 2  
✓ Proposals: 14 | Maintain |
| 22-11-2018 to 31-03-2019 | **Presentation of CT* in GU** board  
**Indicators:** Updates of CT*, new CT*  
**Tools:** Monthly report of GU** board | ✓ Updates CT*: 5  
✓ New CT*: 2  
✓ Proposals (localized disease): 2 | Maintain |

(*)CT: Clinical Trials  
(**) GU board: Genitourinary tumors board
# PDSA Plan

**Increment available candidates**

## Improvements in GU board

<table>
<thead>
<tr>
<th>Date of PDSA Cycle</th>
<th>Description of Intervention</th>
<th>Results</th>
<th>Action Steps</th>
</tr>
</thead>
</table>
| From 01-12-2018 to 27-03-2019 | **Indicator:** number of patients with bladder cancer.  
**Tools:** Review of pathology report (weekly) | ✓ 16 weekly reviews of pathology reports  
✓ 26 patients with bladder cancer | Maintain |
| From 22-11-2018 to 28-03-2019 | **Indicator:** number of patients with bladder cancer.  
**Tools:** Review GU board* minutes | ✓ 17 weekly minutes  
✓ 21 patients with bladder cancer | Maintain |
| From 22-11-2018 to 28-03-2019 | **Indicator:** number of patients with bladder cancer candidates to Clinical trial  
**Tools:** Review of GU board* minutes | ✓ 17 weekly minutes  
✓ 14 patients candidates to clinical trial | Maintain |

(*) GU board: Genitourinary tumors board
Indicators: Active clinical trials (November 2018-March 2019)

- **Advanced 2nd line**
- **Maintenance 1st line**
- **Advanced 1st line**
- **Advanced 1st line**
- **Neoadjuvant**
- **Pre-invasive**
- **Adjuvant**

<table>
<thead>
<tr>
<th>Nov-18</th>
<th>Dec-18</th>
<th>Feb-19</th>
<th>Mar-19</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
Indicators: Clinical Trials proposals (November 2018-march 2019)

N= 14 proposals
Average: 2,8 proposals/month

Accepted Trials N=12
Cancelled Trails N=2
Cancelation rate: 14%

- Adjuvant
  - Accepted
  - Cancelled by promotor
  - Cancelled by center

- Neoadjuvant
  - Accepted
  - Cancelled by promotor
  - Cancelled by center

- Advanced 1st line
  - Accepted
  - Cancelled by promotor
  - Cancelled by center

- Avanced 2nd-3rd line
  - Accepted
  - Cancelled by promotor
  - Cancelled by center

Average: 2,8 proposals/month
Change data (March 2019)

Average: 3.2 patients/month

Enrollment rate 43.75%

Patients candidate for treatment n=16

- Enrolled patients: 9
- Not enrolled patients: 7

Patients not included in clinical trials (n=7)

- Elegibility criteria: 4
- Not available clinical trials: 3
- Patient refusal: 3

Average: 3.2 patients/month
Evolution of enrollment rate (Jan 2018-march 2019)

Evolution of enrollment rate

- Patients Enrolled in Clinical Trials
- Patient Not enrolled in Clinical Trials
- Patients evaluated for first time
After the introduction of changes we have observed:

- An increase of clinical trials monthly proposal rate 1.4 vs 2.8
- A decrease of clinical trials cancellation rate 64% vs 14%
- An increase in the number of first time evaluated patients with indication of systemic treatment 2.6 vs 3.2
- A decrease in the percentage of not eligible patients 60% vs 25%
- An increase in the percentage of patient`s rejection 5% vs 18%
- An increase in the enrollment rate 23% vs 43.75%