PIioneer’s update and integration of a localised PCa core outcome set

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About PIONEER

• An IMI2 funded pan-European public private partnership consisting of 32 stakeholders from across 9 countries.
• PIONEER’s goal is to ensure the optimal care for all European men diagnosed with prostate cancer (PCa) by unlocking the potential of big data and big data analytics.
• Work package 2 aims to define core outcome sets (COS) for localised PCa in the context of the patient’s treatment pathway.

Introduction

Harmonising assessment of men with PCa is key for both clinical research and practice.

By collaborating with the original development groups, we aimed at updating the systematic reviews:

• A COS for localised PCa effectiveness trials (Maclellan et al., 2017).
• A standard set of outcomes for clinical audit developed by the International Consortium for Health Outcomes Measurement (ICHOM) have been published.

Methods

The methodology of the project is split into three phases:

We performed a systematic review of systematic reviews of any interventions for men with localised PCa (T1a-T2c N0 M0) published between 1st January 2013 and 23rd of October 2018.

We compared the identified outcomes with the outcomes in the two existing outcome sets.

The Williamson and Clarke taxonomy (2018) was used to integrate the outcome sets.

Results and Discussion

• 1,198 references were identified and 10 RCTs included.
• After comparing the identified outcomes with the two existing COS, we integrated the both following the Williamson and Clarke taxonomy (see Table 2).

Table 1: PRISMA flowchart

Table 2: Integrated COS

<table>
<thead>
<tr>
<th>Williamon/Clarke (revised)</th>
<th>COMPACTERS COS</th>
<th>ICHOM COS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Mortality/survival</td>
<td>Death from any cause</td>
<td>Overall survival</td>
</tr>
<tr>
<td>2. Blood and lymphatic system outcomes</td>
<td>Death from prostate cancer</td>
<td>Cause specific survival</td>
</tr>
<tr>
<td>3. Adverse events/effects</td>
<td>Local disease recurrence</td>
<td>Metastasis-free survival</td>
</tr>
<tr>
<td>4. Adverse events/effects</td>
<td>Distant disease recurrence/metastases</td>
<td>Biochemical recurrence-free survival</td>
</tr>
<tr>
<td>5. Endocrine outcomes</td>
<td>Need for salvage Therapy</td>
<td>N/A</td>
</tr>
<tr>
<td>6. Gastrointestinal outcomes</td>
<td>Treatment failure in ablative therapy</td>
<td>N/A</td>
</tr>
<tr>
<td>7. Urinary incontinence</td>
<td>Need for curative treatment in active surveillance</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Conclusions

Following work, we aim to develop a PIONEER outcome set with the support of a multidisciplinary expert group to incorporate all stakeholders to ensure optimal care for prostate cancer patients.