PROPHECY: Patient Reported Outcomes in Prostate Cancer, a mobile-Health Experience in radiotherapy

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Definition of PRO: Patient Reported Outcome

➢ Definition of PRO concept: “any report of the status of a patient’s health condition that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else”

➢ PRO includes symptoms not obvious to the observer, frequency, severity, impact of daily activities and emotional burden

➢ PROs tend to give a view of the Health-Related Quality of Life (HRQL)

➢ QoL is seen as providing an overall assessment of the effect of both illness and its treatment on the patient

Role of mobile-Health (mHealth)


GREEN PAPER on mobile Health (“mHealth”); EUROPEAN COMMISSION; 2014
Differences between patient and physician reported outcomes in prostate cancer

- 1,366 identified men from the CaPSURE database who had been diagnosed in 1995 to 2007 and treated with prostatectomy, BT or EBRT

- Disease specific quality of life was assessed by patients with UCLA-PCI and by physicians independently

- Physicians underestimated the degree of participant reported impairment for all domains with a worse scores in late follow-ups

- All patients and physicians documented quality of life using different instruments therefore, patients and physicians might have not been assessing the exact same issue

Need to develop a specific app

- Difference between patient and physician in reporting symptoms
- Role of mHealth
- Importance of PROs
Materials and Methods

The module development process consists of four phases according to EORTC:

1) generation of relevant QL issues
   Development
   (Literature, patients, Health care professionals)
2) conversion of the QL issues into a set of items

3) pre-testing the item list or preliminary module questionnaire

4) large-scale international field-testing

Validation

EORTC QUALITY OF LIFE GROUP – Guidelines for developing Questionnaire Modules, 2011
Materials and Methods: Diagram and conceptual framework of a PRO instrument

Graphical rendering

Conversion of the QL issues into a set of items

Conceptual framework → FDA

Generation of relevant issues → EORTC

Application specialist

Psycho-oncologist

Radiation oncologist
## Generation of relevant issues

<table>
<thead>
<tr>
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<tbody>
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<td>0</td>
<td>0</td>
<td>0</td>
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<td>1</td>
<td>4</td>
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<td>1</td>
<td>1</td>
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<td>1</td>
<td>18</td>
<td>25</td>
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<td><strong>UCLA - PCI</strong></td>
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<td>1</td>
<td>3</td>
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<td>4</td>
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<td>1/4</td>
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</tbody>
</table>


# Generation of relevant issues

As shown in the table the number of possible choices for the patients vary significantly from questionnaire to questionnaire and in some cases even within the very same questionnaire.

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Range</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>EORTC-PR25</td>
<td>1→4</td>
<td>1=no symptom, 4=worst</td>
</tr>
<tr>
<td>UCLA-PCI</td>
<td>0→6</td>
<td>with a range of 3 to 6 answers and no fixed correlation between severity and number</td>
</tr>
<tr>
<td>EPIC</td>
<td>0→5</td>
<td>with a range of 3 to 5 answers and correlation between severity and increasing number</td>
</tr>
<tr>
<td>FACT-P</td>
<td>0→4</td>
<td>With correlation between severity and increasing number</td>
</tr>
<tr>
<td>PORPUS</td>
<td>No definite number of answers</td>
<td></td>
</tr>
<tr>
<td>PC-QoL</td>
<td>1→7</td>
<td>with a range of 3 to 7 answers and correlation between severity and increasing number</td>
</tr>
<tr>
<td>PCSI-SDS</td>
<td>1→5</td>
<td>1=no symptom, 5=worst</td>
</tr>
</tbody>
</table>
Generation of relevant issues

This generates at least two orders of problems:

➢ The first problem is for the patients’ perspective because in responding the questions patients face a diversity in the range of possible answers which might in theory be a confounding factor in attributing the choice of the severity of the symptoms.

➢ The second problem is related to the difficulty to compare the results from the different questionnaires.
Symptoms related to radiation treatment in prostate cancer patient

**Urinary symptoms**
- Hematuria
- Urinary incontinence
- Urinary tract pain
- Urinary frequency

**Bowel symptoms**
- Abdominal pain
- Diarrhea
- Rectal haemorrhage
- Proctitis

**Sexual function/Hormonal therapy**
- Sexual desire reduction
- Hot flashes
- Breast pain
- Memory or concentration problems
- Erection problems
- Ejaculatory problems

**Radiation oncologist**
Conversion of the QL issues into a set of items

- Choice of CTCAE V 4.03 (Common Terminology Criteria for Adverse Events)
- Most used scale in scientific literature for adverse events reporting
- Linked to medical intervention
- Exclusion of grades 4 and 5

Grade refers to the severity of the AE. The CTCAE displays Grades 1 through 5 with unique clinical descriptions of severity for each AE based on this general guideline:

- **Grade 1**: Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
- **Grade 2**: Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL*.
- **Grade 3**: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL**.
- **Grade 4**: Life-threatening consequences; urgent intervention indicated.
- **Grade 5**: Death related to AE.
Conversion of the QL issues into a set of items

- Wording carried out limiting medical terms and number of words
- Possibility to generate alert signal
- Chance to verify correspondence between PRO and physician
- Possibility of early medical supportive care
- Same event for acute and late
Da quando hai iniziato la radioterapia hai notato delle variazioni nelle tue funzioni urinarie?

**Graphical rendering**

- Domain 1
- General Concept
- Domain 2
- Domain n

- Item 1
- Item 2
- Item 3
- Item 4
- Item 5
- Item 6
- Item 7
- Item 8
- Item n

**Application specialist**

**Psycho-oncologist**

**Radiation oncologist**

**Conversion of the QoL issues into a set of items**

**Conceptual framework**
- FDA

**Generation of relevant issues**
- EORTC

**Graphical rendering**
Graphical rendering

Grado 1 → Si, leggermente
Grado 2 → Si, moderatamente
Grado 3 → Si, molto
Grado 4 → Non presente
Grado 5 → Non presente

No (assenza sintomo)
Si, leggermente (G1)
Si, moderatamente (G2) → Alert
Si, molto (G3)
Conclusions

➢ We developed a HRQoL questionnaire for prostate cancer patients specifically intended for mHealth (app)

➢ The validation might fill-up the gap between PRO and physicians adverse events reporting documented in literature

➢ This might help collect toxicity data

➢ Improve patients’ HRQoL
Thank you for your attention