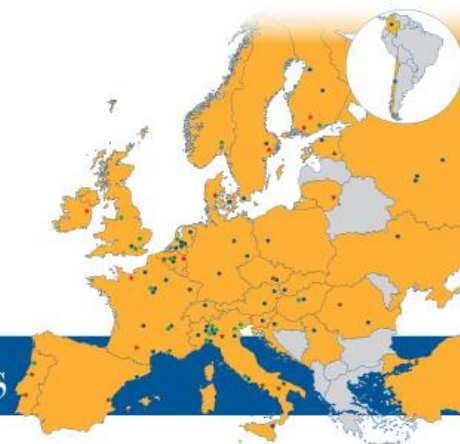


OECI

Working Group on Cancer Outcomes Research

Patient Reported Measures (PRM) in Oncology Clinical Practice and Research

Giovanni Apolone
Scientific Director INT
Vice President OECI
Milano, May 26 2021



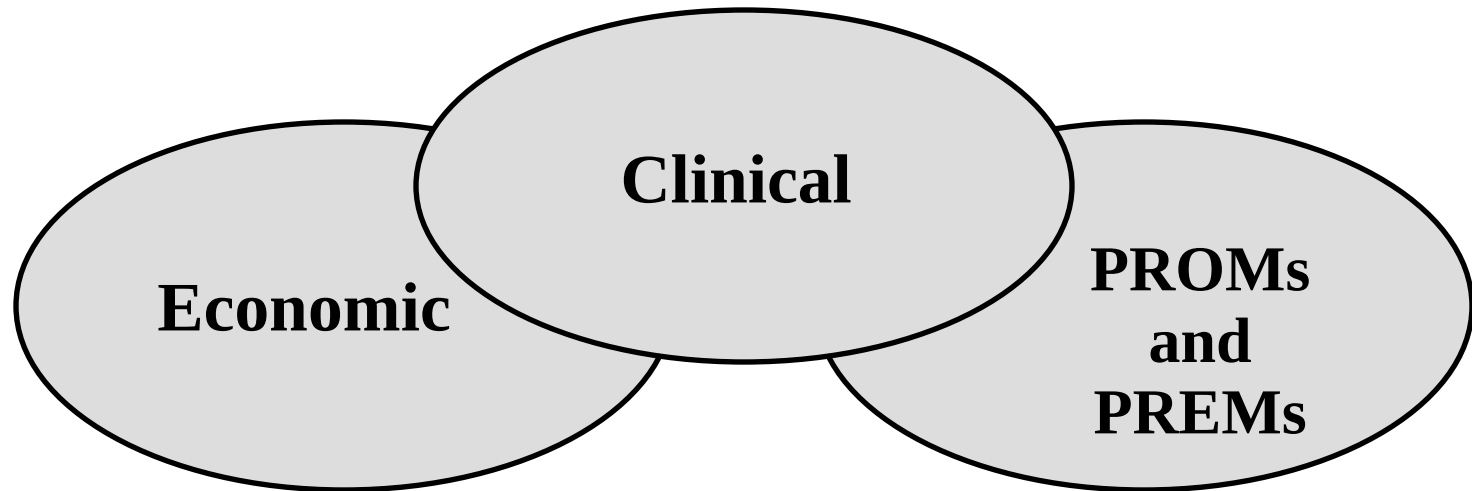
Overview

- The context
- A few definitions: OR, RWD and RWE
- Patients Reported Measures (PRO and PRE)
- Focus on the Cancer Mission
- The OECl Initiative
- The kick off meeting

Outcome Research

A scientific discipline that describes, interprets and predicts the impact of health care intervention on final outcomes that matter for decision makers”

The Consequences of Health Care and Medical Interventions



The context

- Need of RWD and RWE to complement evidence from (efficacy) CT
- Central role of citizens and patients in decision making
- Well established role of PRM (PROMs and PREMs) in clinical research
- Increasing interest to integrate collection of PRM in routine practice to improve health care and quality
- Despite potential benefits, obstacles with the integration into practice
- Challenges are for costs, administrative and technical issues

A few references



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ANALYSIS

Maximising the impact of patient reported outcome assessment for patients and society

Patient reported outcome measures can help drive global patient centred healthcare reform, but we need a more efficient coordinated approach to assessment if we are to fully realise benefits for patients and society, say **Melanie Calvert and colleagues**

Melanie Calvert *professor of outcomes methodology*¹, Derek Kyte *lecturer in health research methods and NIHR fellow*¹, Gary Price *patient partner, member of CPROR executive*¹, Jose M Valderas *professor of health services and policy research*², Niels Henrik Hjollund *clinical professor*³

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Qualität und Sicherheit in der Gesundheitsversorgung / Quality and Safety in Health Care

Implementation of patient-reported outcome assessment in routine cancer care: A systematic review of multicentric programs in Europe

Implementierung der Erfassung von Patient-Reported Outcomes in der Routineversorgung von Krebspatientinnen und -patienten: ein systematischer Überblick zu multizentrischen Programmen in Europa

Madlen Scheibe^{a,1}, Alina Herrmann^{a,1}, Jochen Schmitt², Natascha Einhart², Brita Sedlmayr², Christoph Kowalski^{b,*}

BASCH ET AL

Implementation of Patient-Reported Outcomes in Routine Medical Care

Ethan Basch, MD, MSc, Lisa Barbera, MD, Carolyn L. Kerrigan, MD, MHCDs, and Galina Velikova, MD, PhD

OVERVIEW

There is increasing interest to integrate collection of patient-reported outcomes (PROs) in routine practice to enhance clinical care. Multiple studies show that systematic monitoring of patients using PROs improves patient-clinician communication, clinician awareness of symptoms, symptom management, patient satisfaction, quality of life, and overall survival. The general approach includes a brief electronic survey, administered via the Web or an app or an automated telephone system, with alerts to clinicians for concerning or worsening issues. Patients have generally been asked to self-report on a regular basis (remotely between visits and/or at visits), with reminders prompting patients to self-report that are sent via email, text, or automated phone message. More recently, care management pathways for patients and clinicians have been triggered by PRO system alerts. PRO systems may be free-standing, integrated into electronic health record systems or patient portals, or native functionality of an electronic health record. Despite potential benefits, there are challenges with integrating PROs into practice for monitoring patient status, as there are with any modifications to existing clinical processes. These challenges range from administrative to technical to workflow. A session at the 2018 ASCO Annual Meeting was dedicated to the implementation of PROs in clinical practice. The session focused on practical examples of PRO implementations, with honest reflections on barriers and strategies that may be generalizable to other systems looking to implement PROs. Panelists for that session are the authors of this paper, which describes their respective experiences implementing PROs in practice settings.

RWD and RWE

According to an inclusive definition from the FDA *"Real-world data are the data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. RWD can come from a number of sources, for example:*

- *Electronic health records (EHRs)*
- *Claims and billing activities*
- *Product and disease registries*
- *Patient-generated data including in home-use settings*
- *Data gathered from other sources that can inform on health status, such as mobile devices"*

RWD may be used to produce Real World Evidences (RWEs), that ". RWEs can be generated by different study designs or analyses, including but not limited to, randomized trials, including large simple trials, pragmatic trials, and observational studies (prospective and/or retrospective).

Patient Reported Measures

PRO, Patients Reported Outcomes: are health outcomes directly reported by the patient (self-reporting) who experienced it (in contrast to an outcome reported by someone else)

PREMs, Patient Reported Experience: are measure of a patient's perception of their personal experience of the health care they have received.

**Adaptation to climate
change, including societal
transformation**



**Healthy
oceans,
seas,
coastal
and inland
waters**



**Mission
areas**



Cancer

**Climate-neutral
and smart cities**



**Soil health
and food**



Proposed Mission
**CONQUERING CANCER:
MISSION POSSIBLE**
Report of the Mission Board for Cancer

Independent
Expert
Report



Research and
Innovation



Conquering cancer: mission possible



Five intervention areas:

1. understanding
2. prevention
3. diagnosis and treatment
4. quality of life
5. equitable access

13 recommendations for bold actions

The EU Cancer Mission

Goal:

“By 2030, more than 3 million lives saved, living longer and better”

ANNEX III: CITIZEN ENGAGEMENT ACTIVITIES

As explained in this Draft Mission outline, the Mission on Cancer aims to generate a substantial impact on the lives of all European citizens exposed to cancer. Therefore, it is of utmost importance that the Mission is being developed together with citizens and cancer patients, survivors and their families or carers (hereafter, citizens and patients), and that it reflects the voice of these people.

13 Recommendations for bold actions

- 1 Launch **UNCAN.eu** – a European Initiative to Understand Cancer
- 2 Develop an EU-wide research programme to identify **(poly-) genic risk scores**
- 3 Support the development and implementation of **effective cancer prevention strategies** and policies within Member States and the EU
- 4 Optimise existing screening programmes and develop **novel approaches for screening and early detection**
- 5 Advance and implement **personalised medicine approaches** for all cancer patients in Europe
- 6 Develop an EU-wide research programme on **early diagnostic and minimally invasive treatment technologies**
- 7 Develop an EU-wide research programme and policy support to improve the **quality of life of cancer patients and survivors, family members and carers**, and all persons with an increased risk of cancer
- 8 Create a **European Cancer Patient Digital Centre** where cancer patients and survivors can deposit and share their data for personalised care
- 9 Achieve **Cancer Health Equity** in the EU across the continuum of the disease
- 10 Set up a network of **Comprehensive Cancer Infrastructures** within and across all EU Member States to increase quality of research and care
- 11 **Childhood cancers** and cancers in adolescents and young adults: cure more and cure better
- 12 Accelerate innovation and implementation of new technologies and **create Oncology-focused Living Labs** to conquer cancer
- 13 **Transform cancer culture**, communication and capacity building

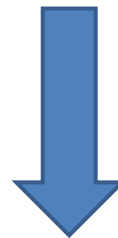
The First Cancer Mission Call (UCAN)

☛ Recommendation 1: Launch UNCAN.eu – a European Initiative to Understand Cancer

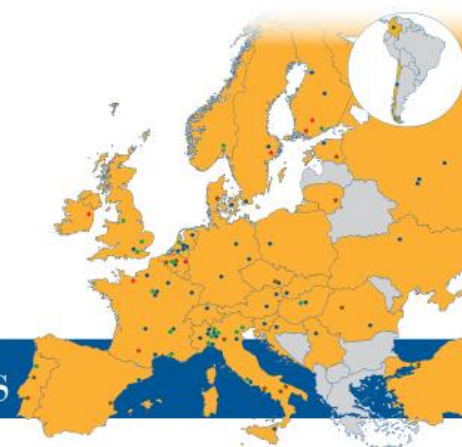
Despite tremendous progress in deciphering the genetic and biological basis of cancer, our understanding of the molecular processes at the cancer cell level and the interactions of the tumour and its host is still very limited. This holds in particular for cancers for which understanding is lacking and rare cancers. The potential for increasing our understanding in this area is demonstrated by the significant benefit obtained through targeted therapies and host immune activation against some tumours. Recent technological developments and European collaborations provide an excellent opportunity for realising this potential through obtaining a comprehensive and dynamic view of how certain cancers initiate, develop and spread in the context of the host.

This requires a new level of investment in innovative research, including high-potential/high-risk projects. Therefore, the Mission Board proposes a Europe-wide platform, UNCAN.eu, utilising relevant research infrastructure and investing in the development of new models and technologies interrogating the interactions of cancers and their host. UNCAN.eu would encompass relevant stakeholders and enable integration of innovative models and technologies with longitudinal patient data, samples and biomarkers for identification and translation to patients. UNCAN.eu would provide breakthroughs in understanding how cancers initiate, develop and spread in the context of the host and thereby provide a basis for saving millions of European citizens' lives in synergy with actions related to recommendations 2-6 and 11-12 of this Mission outline as well as actions related to the Europe's Beating Cancer Plan and other EU Research and Innovation Missions (see Annex I).

Cancer Mission has the goal to reduce mortality, improve survival and the quality of life of patients and citizens, and many of the actions that are expected to be undertaken and made operative with specific calls, involve the active participation of patients and citizens. Each project concerning future calls will need to equip themselves with the best tools relating to PROMs and PREMs and with expertise in their implementation in clinical practice, research and electronic records.



OECI One Shot Project on PR Measures



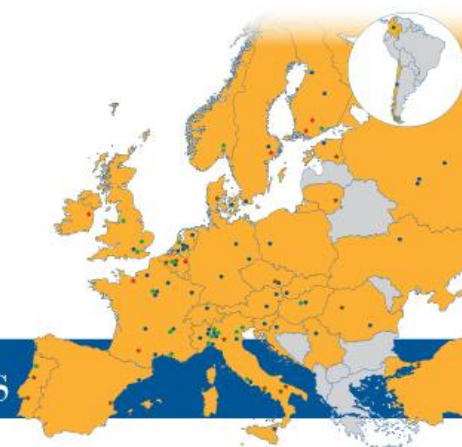
The OECI Initiative on PRM (2)



- Establish OECI priority of promoting implementation of PROMs and PREMs stepping from rhetoric to practice.
- Underline the role of PROMs and PREMs implementation as one step towards patient centred approach in clinical practice and research.
- Identify PROMs and PREMs that fit the needs of different patient populations: those undergoing treatment with curative intent, patients with advanced or metastatic disease (palliative care population) and disease free long term survivors.
- Propose implementation strategies (use of e-devices for the assesement, stakeholder engagement, organizational and reimbursement issues).
- Scope feasibility/implementation experiences within selected collaborating centers.

Panel composition

1. **Giovanni Apolone** Scientific Director- Fondazione IRCCS Istituto Nazionale Tumori-Milano
2. **Augusto Caraceni** Head of Palliative Care, Palliative Care, Pain therapy and Rehabilitation Department - Fondazione IRCCS Istituto Nazionale Tumori-Milano
3. **Cinzia Brunelli** Senior Researcher Palliative Care, Palliative Care, Pain therapy and Rehabilitation Department - Fondazione IRCCS Istituto Nazionale Tumori-Milano PI of "Patient voices " project.
4. **Dominique de Valeriola** Chairperson of "Collaboration for good practices with patients"- OECI Working group"
5. **Patrick Miqueu** "Collaboration for good practices with patients"- OECI Working group"
6. **Wim H. van Harten** Chairperson of "Cancer Economics and benchmarking"- OECI Working group
7. **Giuseppe Recchia** Co-Founder and CEO daVinci Digital Therapeutics, Milano, Italy.
8. **Stein Kaasa** Chair department of Oncology Oslo University Hospital , Chair European Palliative Care research Center, Norway.
9. **Marianne Jensen Hjermstad** Senior researcher/PhD, Regional Advisory Unit for Palliative Care, Dept. of Oncology, Oslo University Hospital.
10. **Camilla Zimmermann** Head, Division of Palliative Care Princess Margaret Cancer Centre, Toronto, Canada.
11. **Alex Gilbert** Leeds Cancer Centre, United Kingdom.
12. **Helle Pappot** Oncology Centre Rigshospitalet Copenhagen, Denmark.



The Agenda

- **2.30 pm - 2.45 pm*** The Why – *Giovanni Apolone* (rationale and aims)
- **2.45 pm - 3.00 pm*** The What – *Augusto Caraceni* (choice of tools)
- The How – electronic assessment & implementation strategies:
 - **3.00 pm -3.15 pm*** The experience of Fond. IRCCS Istituto Nazionale Tumori: PTVOICES project - *Brunelli Cinzia*
 - **3.15 pm - 3.30 pm*** The experience of Princess Margaret Cancer Center Toronto - *Camilla Zimmermann*
 - **3.30 pm - 3.45 pm*** The experience of Oslo University Hospital - *Stein Kaasa, Marianne Jensen Hjermstad*
 - **3.45 pm - 4.00 pm*** The experience of the Rigshospitalet of Copenhagen - *Helle Pappot*
- **4.00 pm - 4.15 pm*** The role of patients and their advocates in the implementation of PROMs and PREMs – *Patrick Miqueu*
- **4.15 pm - 4.30 pm*** PROMs and PREMs for health economic decision-making - *Wim H. van Harten*
- **4.30 pm - 5.30 pm*** Discussion elaboration of OECl initiative future plans

Giovanni Apolone	Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy
Augusto Caraceni	Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy
Cinzia Brunelli	Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy
Dominique de Valeriola	Institut Jules Bordet, Brussels, Belgium Chair of OECI Collaboration for Good Practices with Patients Working Group
Patrick Miqueu	Institut Jules Bordet, Brussels, Belgium Coordinator of OECI Collaboration for Good Practices with Patients Working Group
Wim H. van Harten	Rijnstate, Arnhem, The Netherlands Chair of OECI Cancer Economics and Benchmarking Working Group
Camilla Zimmermann	Princess Margaret Cancer Centre, University Health Network, Toronto, Canada
Stein Kaasa	Oslo University Hospital, Oslo, Norway European Palliative Care Research Centre
Marianne Jensen Hjermstad	Oslo University Hospital, Oslo, Norway
Helle Pappot	Oncology Centre, Rigshospitalet, Copenhagen, Denmark
Alex Gilbert	Leeds Cancer Centre, Leeds, United Kingdom
Giuseppe Recchia	daVinci Digital Therapeutics, Milan, Italy



Participants



Proposed lines of activity/objectives

- include other centres and experts to identify a common set of valid, reliable and robust PRM
- develop standards guidelines
- to scope the adoption of a common platform for routine data collection within the OEI network.



The final aims are to evolve the quality of care delivered and offering a common framework and a platform database for future European research initiative in the context of the future Cancer Mission calls.