The Development of a Comprehensive Archive of Patient-Reported Outcome Measures (PROMS) for Clinical Research and Clinical Practice in Oncology

Malandrini F[I] , Meregaglia M[I] Pinto C [2], Di Maio M [3], Ciani O [I]

[I] Centre for Research on Health and Social Care Management (CERGAS), SDA Bocconi School of Management, Milan, Italy; [2] Department of Medical Oncology, S. Maria Hospital - IRCCS, Reggio Emilia, Italy; [3] University of Turin, Torino, TO, Italy

BACKGROUND

- **Patient-reported outcomes (PROs)** are health or treatment outcomes reported **directly by the patient** without added interpretation of a healthcare professional or anyone else [1].
- PROs chosen in suitable and accurate manners can help to identify symptoms that might benefit from supportive interventions, determine the recovery time needed to return to usual activities, and prepare **future cancer patients** for what to expect during and after treatment.
- The advantage of using PROs in clinical practice and research is that they provide a more comprehensive interpretation of the benefits of the intervention delivered or under investigation. However, **choosing the most adequate measure of PROs** in clinical trials, clinical practice, and post-authorization studies is not straightforward [2].

RESEARCH OBJECTIVES

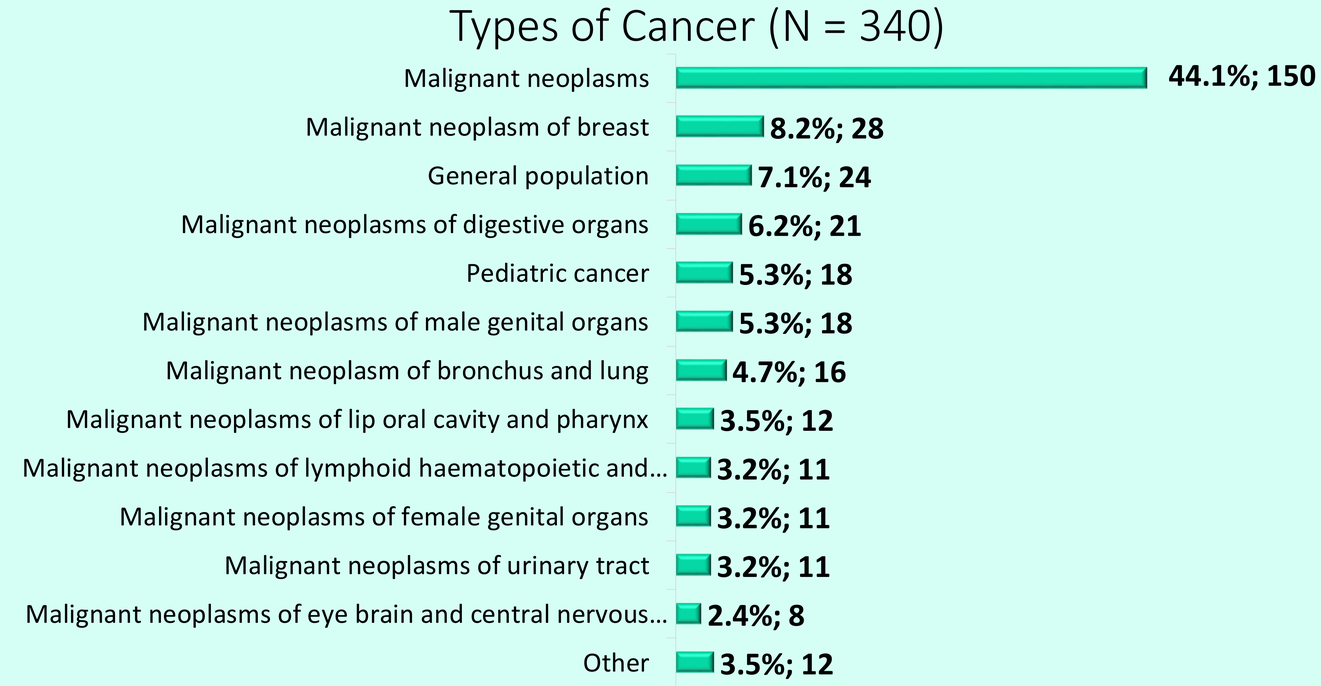
- Identifying the **different measures** that exist in **oncology** and classifying them according to their characteristics and properties is the first step in getting a clear picture of the **instruments available** to measure the quality of life of cancer patients.
- This study aims to develop a comprehensive **archive of patient-reported outcome measures (PROMs)** in oncology and identify their main characteristics and target outcome domains.

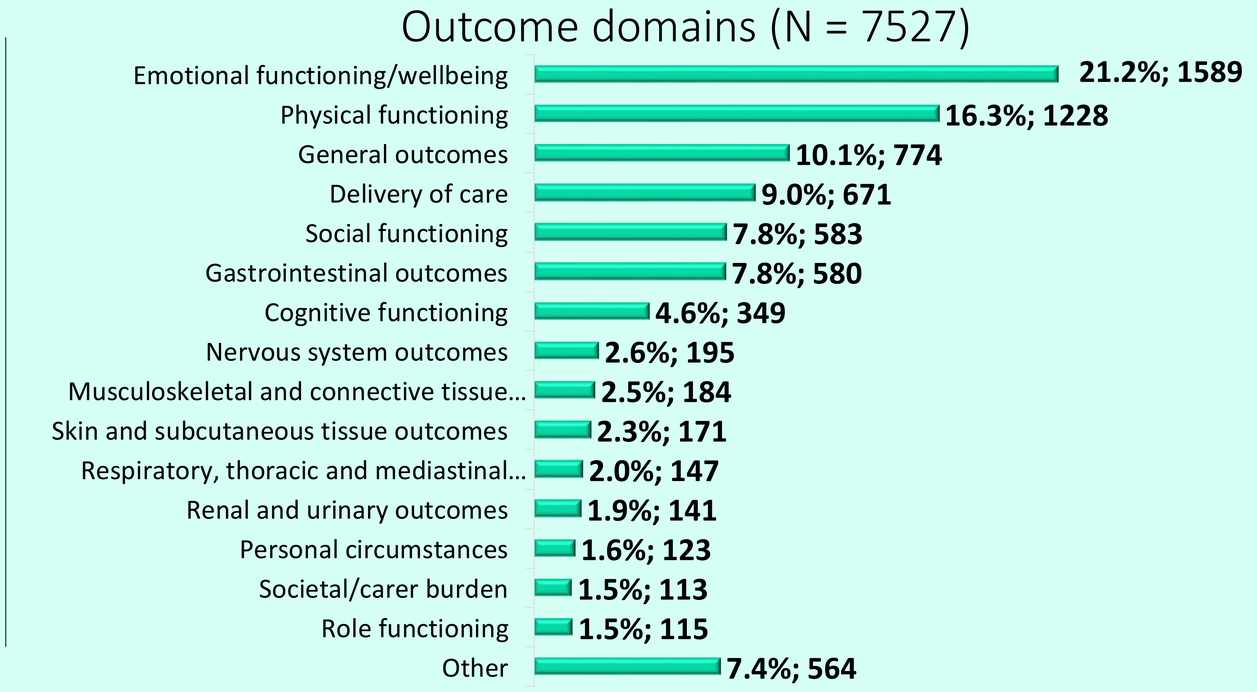
METHODS

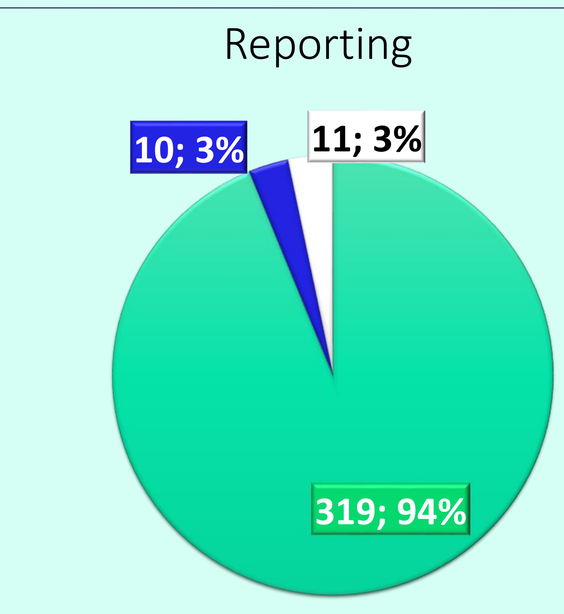
As part of the **PRO4All project**, we retrieved the available PROMs in **oncology** by searching websites (e.g., facit.org, eortc.org, eprovide.mapi-trust.org), ema.europa.eu (European Public Assessment Reports), and published reviews. We developed a data extraction form to collect information on: PROM name, cancer area (based on ICD-10), type of questionnaire (i.e., self-reported, proxy-reported or caregiver's report), questionnaire variant(s), recall period (e.g., last week), validation and MCID (Minimal Clinically Important Difference) studies, number of items and types of scoring. Moreover, we assigned **each item** a **specific domain** according to a predefined 38-item taxonomy for outcome classification [3].

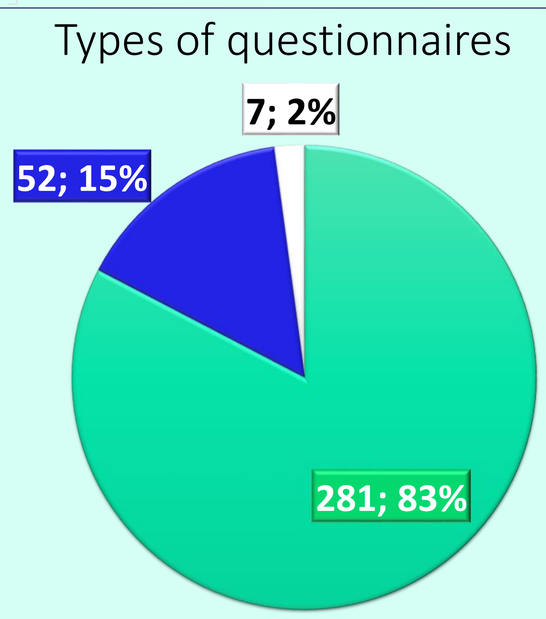
RESULTS

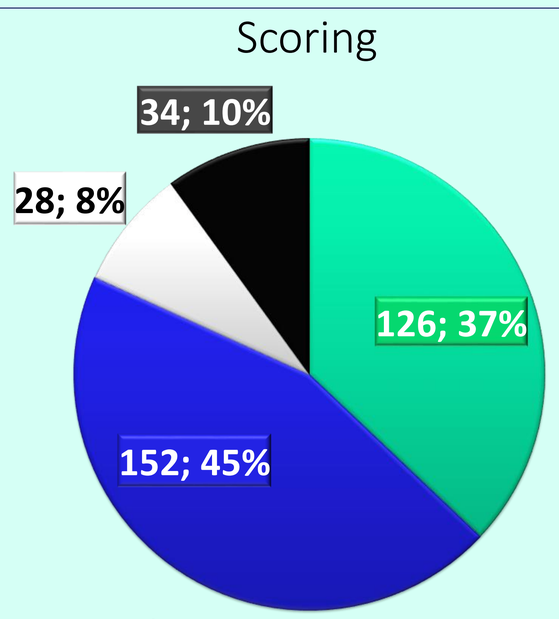
A total of **340 PROMs** were identified and fully analyzed. Over half (n=166, **48.8%**) were cancer type-specific, 150 (**44.1%**) were generic for cancer and 24 (**7.1%**) were intended for the general population but also recommended or used for cancer patients. Half of the instruments (**50.3%**) indicated 'last week' as recall period. In the great majority of cases (**94%**), the questionnaire was self-reported and in the remaining **6%** reported by proxy (e.g., caregiver, parent) or focused on caregiver's health or situation. Besides original questionnaires (**83%**), we identified **52** variants (e.g., short versions, parental versions) and **11** duplicates (i.e., same items). The mean number of items per questionnaire was **22.1** (range: 1- 130). In total, **7527** items were assigned an outcome domain, which was emotional functioning/wellbeing in **21.1%** of cases, physical functioning/wellbeing in **16.3%** and general outcomes in **10.1%**.

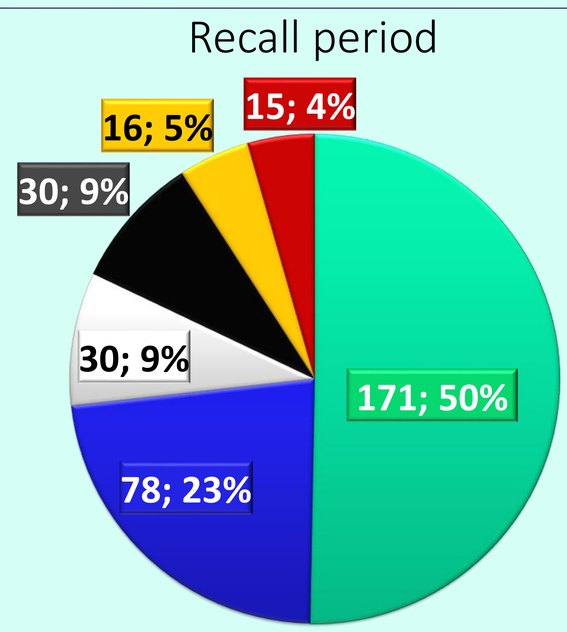












DISCUSSION

This review study highlighted a significant number and heterogeneity of PROMs in oncology, even within the same cancer area. The newly developed archive represents a useful tool for guiding researchers and practitioners in selecting the most suitable measures for cancer patients and fostering a patient-centered approach in oncology.

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PRESENTING AUTHOR: Francesco Malandrini; francesco.malandrini@sdabocconi.it

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