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# Patient-reported outcome measure to implement routine assessment of cancer survivors' unmet needs: An overview of reviews and COSMIN analysis

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ABSTRACT

As the number of cancer survivors (CSs) is increasing worldwide, providing services relevant to the specific, unmet needs of these individuals is crucial. There are currently various patient-reported outcome measures (PROMs) whose aim is to identify the unmet needs of CSs. Still, limited guidance supports healthcare providers in choosing the most valid and reliable PROMs for this purpose.

We conducted this overview of systematic reviews (SRs) on the psychometric properties of PROMs addressing the unmet needs of adult CSs suffering from non-cutaneous cancers. We searched databases for SRs published between 2012 and January 2023.

Two SRs were included, covering 14 PROMs tested on 19,151 CSs. These were assessed according to the COSMIN methodology for SRs of PROMs for the quality of their measurement properties and risk of bias, thus providing guidance in selecting PROMs that appropriately reflect the unmet needs of CSs.

## Introduction

The number of cancer survivors (CSs) worldwide is increasing as a consequence of improved screening and early detection, advances in treatment and technology, enhanced follow-up care, and world population aging [1–4]. Individuals are considered 'cancer survivor' from the moment of their diagnosis on, for the rest of their life [5].

The World Health Organization's World Cancer Report estimated that there were approximately 25 million CSs in 2008 and that this figure would increase to 75 million by 2030 [6].

There is global recognition that CSs experience a range of physical, psychosocial, spiritual, informational, and practical issues that may result in unmet needs, which are often neither identified nor addressed [7,8]. Unmet needs are those needs that lack the level of service an individual perceives as necessary to achieve optimal well-being, and that can thus be described as unsatisfied needs for which CSs would like to receive more assistance or support [9,10]. Understanding and measuring CSs' unmet needs helps to identify gaps in patients' care

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experiences, which in turn provides the opportunity to deliver patient-centred services [11]. Appropriate care delivery improves patient outcomes and quality of life as well as patients' level of satisfaction with care, which may result in a decrease in the demand for health and social care services [12,13].

There is growing recognition of the importance of assessing the patient's perspective of the quality of the care received through patient-reported outcome measures (PROMs) [14,15]. These standardized, validated tools reflect and give value to the information patients provide regarding their symptoms, functional well-being, and health status [16,17].

PROMs therefore lend themselves to measuring patients' unmet needs; so far, a wide range has been developed to assess those of CSs. However, there is currently limited guidance for healthcare providers on how to select the most valid and reliable PROMs to reflect the unmet needs of this population.

In this overview of reviews, we analysed the systematic reviews (SRs) focusing on the PROMs directed at adult CSs suffering from non-cutaneous cancer. We also examined the dimensions and the domains assessed and the psychometric properties of the included PROMs selected to provide guidance on their selection.

## Methods

The protocol of this review, registered on Prospero [CRD42022348107], was reported according to both the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA, see appendix pp 31–33) and to the Cochrane Overview of Reviews guidelines [18,19]. Given that the latter does not provide a rigorous methodology to describe the psychometric properties of PROMs, the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) guidelines were also used [20].

An overview of SRs integrates evidence from evidence syntheses focusing on a topic of relevance [21]. It can be useful when a wide array of literature needs to be summarized and when there is a substantial pool of SRs addressing the topic of interest.

### *Search strategy and selection criteria*

The search strategy was devised to retrieve SRs published on validation studies of PROMs aimed at identifying the unmet needs of CSs. Relevant key search terms were identified through the literature in the field. The search was conducted in collaboration with a health sciences librarian to ensure that the search strategy embraced the necessary and most appropriate keywords.

The search terms 'cancer', 'survivors', 'PROMs,' and 'unmet needs' were adapted for use in the electronic databases PubMed, EMBASE, the Cochrane Database of Systematic Reviews, and CINAHL and were filtered for SRs and/or meta-analyses published between 01 January 2012 and 08 February 2022. We subsequently updated the search to 20 January 2023 to ensure maximum currency of this overview. No language restrictions were set.

More details about methods and the complete search strategy used for all the consulted databases are reported in the appendix (pp 1–3).

SRs were deemed eligible according to the following inclusion criteria: (1) primary study population must be CSs aged $\geq$ 18 years affected by non-cutaneous cancer; (2) SRs reporting at least one psychometric property of PROMs aimed at identifying the unmet needs of CSs.

Exclusion criteria: PROMs assessing only unidimensional care needs and those targeting children and adolescents, palliative or end-of-life care patients, ethnic or cultural minorities, samples affected by a site-specific cancer, and PROMs addressing to the unmet needs of partners and/or caregivers.

All the records retrieved by the search were imported into Rayyan, and duplicates were removed [22]. Records were independently screened by two researchers (AC and SC), and relevant reports were retrieved [23]. The reference lists of eligible SRs were hand searched, and further relevant evidence syntheses were screened for eligibility by the two independent researchers. In cases of disagreement, a third researcher was consulted (SP). Consensus agreement was sought for the list of the eligible SRs selected for this overview. All the potentially relevant studies that were read in full text but excluded from this overview of reviews are listed, and a justification for the exclusion is provided (appendix pp 3–4).

The PRISMA 2020 flow diagram guided the selection process [23].

A priori, we decided not to exclude SRs from the overview based on a minimum standard of quality in order to adopt an inclusive approach that would allow us to intercept the greatest number of PROMs of interest.

The risk of bias of the SRs was assessed by two independent researchers (AC e SC) using A MeaSurement Tool to Assess systematic Reviews (AMSTAR-2) by Shea et al. [24] According to the AMSTAR-2 developers and given the type of primary studies included in the SRs, we identified a priori the first, fourth, fifth, sixth, ninth, and sixteenth as the critical items to appraise, since they could affect the validity of an SR of PROMs [24]. Cohen's kappa was used to measure agreement between the two raters, and discrepancies were resolved by consensus [25].

The appendix (pp 5–8) shows the AMSTAR-2 critical appraisal tool, its critical items as identified for this overview, and rating instructions.

The COSMIN guideline for SRs of PROMs was used to achieve an integrated assessment of both the methodological quality of the primary studies that investigated PROM properties and the quality of the PROM itself (i.e., its psychometric properties) [20]. This supports the development of evidence-based recommendations on PROM quality and facilitates the selection of valid and reliable PROMs for use in clinical practice or research.

The methodological quality of each primary study selected for this overview was assessed through the COSMIN Risk of Bias checklist, and the psychometric properties of any PROM were rated against COSMIN updated quality criteria for good measurement properties, reported in the appendix (pp 9–10) by two reviewers (AC and MT) independently [20,26,27].

Cross-cultural validity was not considered because the original English version of each PROM was assessed. Criterion validity was also omitted since there is no gold standard for the assessment of perceived needs, which are subjective by nature.

The evidence was then summarized, and the same two reviewers independently graded its quality by means of the modified GRADE approach for grading the quality of the evidence in SRs of PROMs, as described by Prinsen et al. and reported in the appendix (pp 11) [20,28]. Consensus agreement was sought through discussion.

Two data extraction templates on an Excel spreadsheet were created, one to extract data from the SRs covered by this overview, and the other to extract data from the primary studies included therein. The extraction of descriptive data from the SRs was performed in accordance with both the Cochrane Handbook and the COSMIN guidelines [19,20]. After achieving consensus between the researchers regarding the data to be extracted, data collection was completed by one researcher (AC). Once input, data was re-reviewed and cleaned by a second researcher (SC).

Where relevant, additional development and/or validation data of the PROMs examined, published in other studies, were identified and added to the data extracted.

In cases of missing or inadequately reported data, the gap in data coverage is clearly stated. If the data were reported inconsistently in the SRs, extraction was done directly from the primary studies.

The summaries of results are grouped into a narrative synthesis.

The International Classification of Functioning, Disability and Health (ICF), created by the World Health Organization, provides an internationally recognized framework, definitions, and coding language to describe the impact of health conditions on body functioning, activities limitation, and restrictions in participation [29]. Based on the ICF

framework and through a standardized coding procedure, two researchers (AC and SC) independently analysed all the items of the PROMs examined and linked them to the ICF components, which are expressed in a universal language [30–32]. This facilitates reliable identification of the areas of impact on health encompassed by these PROMs, providing an additional basis for the selection of a specific PROM based on content comparison [33].

*Role of the funding source*

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

## Results

The retrieval and screening process of the SRs eligible for this overview is presented through the PRISMA flow diagram in the appendix (p 12).

The electronic search resulted in a total of 1157 records. After deleting duplicates, 748 records were screened for inclusion, and 33 reports were retrieved and assessed. Thirty-one reports were excluded at this stage because they did not focus on the population of interest (n = 17), because they did not assess the psychometric properties of a PROM (n = 8), or because they were not an SR (n = 6).

The appendix (pp 3–4) shows all the potentially relevant studies whose full text were read but which were excluded from this overview of reviews and the justification for their exclusion.

At the end of this process, two SRs, published in 2019 [34] and in 2021 [35] in peer-reviewed journals, were deemed eligible for this overview. Their characteristics are summarized in Table 1.

One SR [34] was reported following the PRISMA guidelines [23], while the second [35] did not report according to standardized methodology; nonetheless, the PRISMA flow diagram was used to describe the selection process of the included studies.

The protocol of one SR [34] was prospectively registered with independent verification (PROSPERO register), and no potential sources of conflict of interest were declared by the authors of either review.

The PICO framework was used to describe the reviews' aim and to specify their inclusion criteria [36].

At least two bibliographic databases were searched by each SR; the keywords and search strategy used were reported, and any publication restrictions were justified. However, neither SR searched the reference list or any ongoing study register, nor consulted experts in the field. In both the reviews, the screening for eligibility of studies and data extraction were performed by two independent researchers.

The eleventh, twelfth, and fifteenth components of the AMSTAR-2, which describe the methods and possible biases arising from the development of a meta-analysis, were rated as 'not applicable' for both the reviews as neither had performed one.

The agreement (Cohen's kappa) between the two raters of both the SRs on the risk of bias assessment was nearly perfect ($\kappa = 0.88$). As a result of this rating process, the overall confidence in the results provided was rated 'moderate' for one SR [34] and 'low' for the other [35].

The appendix (p 13) shows the details of the AMSTAR-2 ratings.

Nineteen primary studies of the 67 included in the two SRs met the inclusion criteria, i.e., reported at least one psychometric property of a PROMs aimed at identifying the unmet needs of adult CSs affected by non-cutaneous cancer. Their study designs were observational, mostly cross-sectional.

The primary studies included 19,151 patients. The specific cancer diagnosis was specified for 52.8% (n = 10,119) of individuals, with the largest percentages of diagnoses attributable to breast (30.4%), colorectal (24.1%), lung (16.3%), and prostate (16.2%) cancers.

Table 2 shows the characteristics of the primary studies included in the two SRs.

After removing duplicates, 19 different PROMs were examined for their psychometric properties by the primary studies included in the two SRs. Of these 19 PROMs, 14 PROMs were selected for this overview as they applied to CSs affected by non-cutaneous cancer.

The degree of overlap between these PROMs, according to the corrected covered area calculation described in Hennessy et al. guidelines, was 43% and is presented in the appendix (p 14) [57]. The small differences among the results of the two reviews are likely due to differences in their PICOs and the consequent search strategies.

Five PROMs were developed in Australia (CaSUN [41], CNQ-SF [44], SCNS-LF59 [50], SCNS-SF34 [51] SCNS-ST9) [52], three in the USA (CANDI [37], CARES [38,39], CARES-SF) [40], two in the UK (eHNA [45], PNI) [49], two in Canada (SUNS [53,54], SUNS-SF) [55] one in the Republic of Korea (CNAT) [42,43], and one in Italy (NEQ) [46–48].

The appendix (p 14) shows the full names of the 14 PROMs retrieved and their abbreviations.

The 14 PROMs included from 9 [52] to 139 [39] items. Patients were asked to recall their needs during the following time periods: the last month [39–42,50–53,55], the last two weeks [37], 'last few weeks' [49], 'recently' [45] or 'currently' [48]. One PROM did not specify any recall period [44]. The response formats used to assess cancer care needs varied: most of the PROMs adopted a five-point rating scale [37,39,40,44,49–53,55], while others used a four-point rating scale [42], a three-option scale [41], a dichotomous scale [48], or a 0-to-10 scale [45]. Four PROMs included a free-text space to allow the respondents to describe other unmet needs not foreseen by the scale [39–41,53]. Five PROMs used a combination of approaches to better delineate the burden of the need (e.g., indicating whether there was an unmet need, followed by how much help was needed or how pressing the need was) [37,39–41,49].

All but two PROMs [37,49] were analysed by means of factorial analysis to detect the number of factors describing the underlying interrelationships and mutual variability between their items and showed a multidimensional nature: nine PROMs [39–42,48,50–53] had five higher-order factors, while the other three had four, [55], seven [42], and 12 [45] factors each.

One PROM was interviewer-administered [42] while all the others were self-administered. For the ten PROMs that reported completion time [37,39–41,44,45,48,50,51,53], this ranged from 5 [48] to 26 [53] minutes. Copyright was reported for six PROMs [39,40,45,50–52].

Eight PROMs were validated in languages other than English [37,39,41,42,44,48,51,52]. Of these eight, the SCNS-SF34 [51] is the one with the most cross-cultural adaptations, having so far been translated into 13 different languages [58–70].

The characteristics of the 14 PROMs are presented in Table 3, and their detailed description is presented in the appendix (pp 15–17).

All but one PROM [45] reported the item generation process. Seven PROMs relied on more than one item generation technique [37,39–42,49,53]. The most frequently used techniques were amending items from an existing PROM (n = 7 PROMs) [39,40,44,50–52,55] and/or building on information from patient interviews/focus groups (n = 6) [37,39,42,48,49,53] or from the literature (n = 5) [37,39,41,49,53].

Twelve PROMs [37,39–42,44,48,50–53,55] reported an item reduction process, six of which reported more than one technique [39,40,42,50,52,55]. The most common techniques were factor analysis (n = 7) [39–41,51–53,55], patient review (n = 4) [37,39,42,50], and/or expert review (n = 4) [39,40,42,50].

The appendix (pp. 18) shows item generation and item reduction mapping among the included PROMs.

The COSMIN checklist was used to assess the risk of bias of the primary studies [20,26,27,79].

As none of the studies clearly described the full PROM development process, none of the PROMs could be considered 'very good' or 'acceptable'. In particular, four PROMs [37,41,45,49] were considered 'inadequate' due to a lack of pilot testing, and the other ten 'doubtful', mainly because it was not reported whether the two researchers were independently involved in the coding process of qualitative data that fed

**Table 1**
Characteristics of The included systematic reviews.

| Review | Studies, n (total/ eligible for the overview) | Study Population * | Inclusion Criteria | Exclusion Criteria | AMSTAR-2 quality | Patient-Reported Outcomes Measures† | Study Aims | Results | Conclusions | Source of Funding |
|---|---|---|---|---|---|---|---|---|---|---|
| Rimmer et al., 2021 [34] | 30/12 | Advanced cancer patients | Studies in English reporting the development and/or validation of an instrument to measure unmet needs for cancer patients measuring more than one dimension of unmet need where advanced cancer patients were included in the process of development or validation. | Instrument targeted at childhood/ adolescent cancer patients; Not reporting any validation for the instrument; Where the patient was not the respondent; If $\geq$ 50% of the items and response options did not allow patients to indicate a desire for help or support. | Moderate | CANDI, CNAT, CNQ-SF, eHNA, NEQ, PNI, SCNS-LF59, SCNS-SF34, SCNS-ST9 | Examine what instruments are available to measure unmet needs in people with advanced cancer and assess instrument development, content, and quality, in terms of clinimetric properties. | 30 studies reporting 24 instruments were identified. | Many instruments are available to assess unmet needs in advanced cancer. There is extensive heterogeneity in their development, content, and quality. Given the growth of precision and biological therapies, research needs to explore how these instruments perform in capturing the needs of people using such therapies. | Funding from the Macmillan Cancer Support and the Brain Tumour Charity |
| Tian et al., 2019 [35] | 37/16 | Adults with cancer | Studies in English aimed to develop instruments to measure comprehensive care needs specifically for multiple cancer patients, reporting the psychometric properties of these instruments. | Studies aimed to develop tools originally to test care needs in single site cancer patients or in other chronic illnesses; Only assessing unidimensional care needs; Interventional study, qualitative study, cross-sectional descriptive study, discussion paper, literature review, and guideline. | Low | CANDI, CARES, CARES-SF, CaSUN, CNAT, CNQ-SF, NEQ, SCNS-SF34, SCNS-ST9, SUNS, SUNS-SF | Perform a SR on the quality of psychometric properties of needs assessment tools among cancer patients in order to make recommendations on the most appropriate instruments for care needs assessment for cancer patients through collecting evidence from previous studies. | 37 studies which assessed the psychometric properties of 20 needs assessment tools were identified. | Despite several needs assessment tools exist to assess care needs in cancer patients, further improvement of already existing and promising instruments is recommended. | No specific funding |

* Included study populations within the eligible studies of the review. †Referable to the population examined by this overview.

**Table 2**
Characteristics of the primary studies.

| First Author, Year | Instrument | Instrument Administration | | | | Study Design | Was the PROM created with the active participation of survivors? | Literally addressed to assess Unmet Needs? | Does the word 'survivorship' (or similar) appear in the text? |
|---|---|---|---|---|---|---|---|---|---|
| | | Country | Study population | Survivorship Stage of the original† sample | Country and Health System Model* | | | | |
| Lowery et al., 2012 | CaNDI[37] | USA | Mixed cancer patients (n = 100): Breast – n = 31 (31%); Chronic lymphocytic leukaemia – n = 10 (10%); Colorectal – n = 14 (14%); Lung – n = 6 (6%); Myeloma – n = 4 (4%); Gynaecologic – n = 11 (11%); Other – n = 24 (24%) | No staging details of participants were reported. | Private Health System | Cross-sectional | Yes | No | No |
| Schag et al., 1990 Ganz et al., 1992 | CARES [38,39] | USA | 2 samples of mixed cancer patients (n = 479,[39] 779 [38]): Colorectal – n = 82 (17%), 277 (36%); Lung – n = 57 (12%), 214 (27%); Prostate – n = 101 (21%), 288 (37%); Breast – n = 86 (18%), -; Other – n = 153 (32%), - | Adjuvant treatment n = 24 (5%); Follow-up, no active disease n = 177 (37%); Care for local primary/recurrence n = 105 (22%) Care for widespread disease n = 173 (36%) | Private Health System | Cross-sectional Longitudinal [38] | Yes | No | No |
| Schag et al., 1991 | CARES-SF [40] | USA | 4 samples of mixed cancer patients (n = 479, 1047, 114, 109): Colorectal – n = 82 (17%), 277 (26%), -, -; Lung – n = 57 (12%), 214 (20%), -, -; Prostate – n = 101 (21%), 288 (28%), -, -; Breast – n = 86 (18%), -, 114 (100%), 109 (100%); Other – n = 153 (32%), 268 (26%), - | The 109 newly diagnosed breast cancer patients involved in the responsiveness evaluation were in the first year after diagnosis, at 32 days after surgery as mean. | Private Health System | Mixed: Cross-sectional and Longitudinal | Yes | No | No |
| Hodgkinson et al., 2007 | CASUN [41] | Australia | Mixed cancer patients (n = 353): Breast – n = 209 (59.2%); Gynaecologic – n = 60 (16.9%); Prostate – n = 43 (12.2%); Colorectal – n = 32 (9.1%); Other – n = 9 (2.6%) | Participants were at least 4 months since diagnosis, and currently receiving treatment or follow-up. | National Health Insurance | Cross-sectional | Yes | Yes | Yes |
| Shim et al., 2011 Yang et al., 2019 | CNAT [42,43] | Republic of Korea [42] Singapore [43] | 2 samples of mixed cancer patients (n = 2661,[42] 328 [43]): Stomach – n = 399 (15%); -; Lung – n = 287 (10.8%); 54 | Patients were at least 4 months since diagnosis, and currently receiving treatment or follow-up. Mean of months | Etatist Social Health Insurance | Cross-sectional | Yes | Probably Yes | Yes |

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**Table 2** (*continued*)

| First Author, Year | Instrument | Instrument Administration | | | | Study Design | Was the PROM created with the active participation of survivors? | Literally addressed to assess Unmet Needs? | Does the word 'survivorship' (or similar) appear in the text? |
|---|---|---|---|---|---|---|---|---|---|
| | | Country | Study population | Survivorship Stage of the original† sample | Country and Health System Model* | | | | |
| | | | (16.5%); Colorectal – n = 324 (12.2%); 62 (18.9%); Breast – n = 325 (12.2%); 57 (17.4%); Cervix – n = 98 (3.7%); -; Other – n = 1008 (37.9%); 155 (47.3%) | since diagnosis was 31.6 (±36.2) | | | | | |
| Cossich et al., 2004 | CNQ-sf [44] | Australia | Mixed cancer patients (n = 450): Lung – n = 132 (29%); Head and neck – n = 95 (21%); Gynaecologic – n = 77 (17%); Haematological/ Lymphoma – n = 45 (10%); Melanoma – n = 45 (10%); Other – n = 54 (12%) | – | National Health Insurance | Cross-sectional | Yes | Probably Yes | No |
| Snowden et al., 2015 | eHNA[45] | UK | Mixed cancer patients (n = 5421) | Newly diagnosed n = 1860 (35%) On follow up n = 1259 (23%) On treatment n = 1212 (22%) End of treatment n = 935 (17%) Not specified n = 155 (3%) | National Health Service | Cross-sectional | – | Yes | Yes |
| Tamburini et al., 2000 Annunziata et al., 2009 Bonacchi et al., 2016 | NEQ [46–48] | Italy | 3 Mixed cancer patients' groups (n = 423,[48] 600, [46] 783[47]): Colorectal – n = 114 (27%); 168 (28%); 85 (12%) Genitourinary – n = 114 (27%); -; -; Breast – n = 93 (22%); -; 316 (43%); Haematological – n=-; 120 (20%); Respiratory – n=-; 66 (11%); 102 (14%); Other – n = 102 (24%); 246 (41%); 238 (34%) | Data relative to the 600 patients' group: [46] Patients were within 6 months from diagnosis. | National Health Insurance | Cross-sectional | Yes | Yes[47] | No |
| McIllmurray et al., 2001 | PNI[49] | UK | Mixed cancer patients (n = 402): Breast – n = 183 (46%); Colorectal – n = 121 (30%); Lung – n = 62 (15%); Lymphoma – n = 36 (9%) | Patients at a key moment (1 month from): Diagnosis n = 222 (55%) End of first treatment n = 75 (19%) First Recurrence n = 44 (11%) Move to palliative only n = 61 (15%) | National Health Service | Cross-sectional | Yes | No | No |
| Bonevski et al., 2000 | SCNS-LF59 [50] | Australia | Mixed cancer patients (n = 888): Breast – n = 280 | No staging details of participants were reported. | National Health Insurance | Cross-sectional | Yes | Yes | No |

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**Table 2** (*continued*)

| First Author, Year | Instrument | Instrument Administration | | | | Study Design | Was the PROM created with the active participation of survivors? | Literally addressed to assess Unmet Needs? | Does the word 'survivorship' (or similar) appear in the text? |
|---|---|---|---|---|---|---|---|---|---|
| | | Country | Study population | Survivorship Stage of the original† sample | Country and Health System Model* | | | | |
| | | | (32%);<br>Colorectal – n = 150 (17%);<br>Prostate – n = 80 (9%);<br>Lung – n = 67 (8%);<br>Skin/melanoma – n = 43 (5%);<br>Don't know – n = 14 (2%);<br>Other – n = 217 (24%) | Patients were diagnosed with cancer at least 3 months prior to the conduct of the study. | | | | | |
| Boyes et al., 2009 | SCNS-SF34 [51] | Australia | 3 samples of mixed cancer patients (n = 444, 444, 250):<br>Breast – n = 137 (31%), 139 (31%), 14 (6%);<br>Colorectal – n = 74 (17%), 70 (16%), 21 (8%);<br>Prostate – n = 39 (9%), 35 (8%), 82 (33%);<br>Lung – n = 31 (7%), 32 (7%), 23 (9%);<br>Other – n = 137 (31%), 142 (32%), 110 (44%) | No staging details of participants were reported. | National Health Insurance | Cross-sectional | Yes | Yes | No |
| Girgis et al., 2012 | SCNS-ST9 [52] | Australia | 2 samples of mixed cancer patients (n = 977 development, 481 validation):<br>Current cancer site (s) reported in n = 1345: Breast – n = 232 (25.6%), 117 (26.9%);<br>Colorectal – n = 99 (10.9%), 49 (11.3%);<br>Lung – n = 84 (9.3%), 35 (8%);<br>Prostate – n = 66 (7.3%), 40 (9.2%);<br>Melanoma/skin – n = 42 (4.6%), 14 (3.2%);<br>Cervical/ovarian – n = 33 (3.6%), 15 (3.4%);<br>Brain tumour – n = 28 (3.1%), 13 (3%);<br>Other – n = 323 (35.6%), 152 (34.9%) | 894 (61%) patients were diagnosed with cancer 0–12 months prior to the study, 349 (24%) 1–5 years and 141 (10%) > 5 years prior to the study. | National Health Insurance | Cross-sectional | Yes | Yes | No |
| Campbell et al., 2010 Hall et al., 2014 | SUNS [53,54] | Canada | 2 cancer patients groups (n = 550, [53] 529[54]):<br>Breast – n = 142 (25.8%); -;<br>Prostate – n = 110 (18.2%); -;<br>Colorectal – n = 75 (13.6%); -;<br>Lung – n = 34 (6.2%); -;<br>Lymphoma – n = 31 (5.6%); -; | Patients were 1–5 years post-diagnosis. | National Health Insurance | Cross-sectional | Yes | Yes | Yes |

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**Table 2** (*continued*)

| First Author, Year | Instrument | Instrument Administration | | | | Study Design | Was the PROM created with the active participation of survivors? | Literally addressed to assess Unmet Needs? | Does the word 'survivorship' (or similar) appear in the text? |
|---|---|---|---|---|---|---|---|---|---|
| | | Country | Study population | Survivorship Stage of the original† sample | Country and Health System Model* | | | | |
| Campbell et al., 2014 | SUNS-SF [55] | Canada | Haematological – n=-; 529 (100%) Other – n = 168 (30.6%); - Mixed cancer patients (n = 1589): Breast – n = 356 (22%); Prostate – n = 338 (21%); Colorectal – n = 230 (14%); Non-Hodgkin's lymphoma – n = 84 (5.3%); Lung – n = 67 (4.2%); Other – n = 514 (32%) | All patients had a histologically confirmed cancer diagnosis in the preceding 12 to 60 months. | National Health Insurance | Cross-sectional | No | Yes | Yes |

| **Current cancer site(s) reported:** | N° | % |
|---|---|---|
| Breast | 3026 | 30.4 |
| Colorectal | 2406 | 24.1 |
| Prostate | 1611 | 16.2 |
| Lung | 1624 | 16.3 |
| Stomach | 399 | 4.0 |
| Cervical/Gynaecological | 294 | 3.0 |
| Lymphoma/Haematological | 210 | 2.1 |
| Melanoma | 144 | 1.4 |
| Genitourinary | 114 | 1.1 |
| Head and neck | 95 | 1.0 |
| Brain | 41 | 0.4 |
| **TOT.** | **9964** | **100.0** |

- Data not available.
* Refers to Böhm et al., 2013 classification[56] presented in the appendix (p 15)
† Refers to the original sample of the oldest primary study unless otherwise stated

the generation process.

The methodological quality of internal consistency was rated as 'very good' for 13 (93%), and 'inadequate' for one [52] of the PROMs, since no appropriate statistic for the subscales or for the item-total correlations was calculated. The methodological quality of reliability was rated 'adequate' for three PROMs [37,40,48], 'doubtful' for one [39] because the time interval between test and re-test was not stated, and 'inadequate' for ten [41,42,44,45,49–53,55] (71%) because they failed to test patients at different time points or because the time interval was not appropriate. The NEQ [48] was the only PROM considered 'adequate' for the methodological quality of measurement error; the others (n = 13, 93%) were rated 'inadequate' for not having calculated the standard error of measurement, the smallest detectable change, the limits of agreement, or the percentage of agreement.

The methodological quality of content validity was rated 'adequate' for the CNAT [42], 'doubtful' for ten PROMs (71%) [37,39–41,44,50–53,55], primarily due to insufficient sampling, and 'inadequate' for the remaining three PROMs (21%) [45,48,49] as the methods used were mostly inappropriate. The methodological quality of structural validity was rated 'very good' for four PROMs (29%) [40,42,48,51] and 'adequate' for eight (57%) [39,41,44,45,50,52,53,55], while the CANDI [37] and the PNI [49] were considered 'inadequate' for failing to have conducted a factor analysis. Nine PROMs (64%) [37,39–42,44,51,53,55] were rated 'very good' for the methodological quality of hypotheses testing; the remaining five (36%) [45,48–50,52] were rated 'inadequate' since convergent validity was not assessed. Responsiveness was assessed for two PROMs [38,40] (14%), and their methodological quality was rated as 'doubtful'.

By applying the 'worst score count' rule, the methodological quality of all the PROMs was rated 'inadequate', in most cases because they failed to adequately assess the measurement error [37,39–42,44,45,49–53,55].

The COSMIN updated criteria (appendix pp 9–10) were applied to rate the quality of the psychometric properties of the PROMs [20,26]. Of note, there was inconsistent reporting of these properties between studies, and several psychometric properties were not reported.

As regards the reliability domain, which is composed of internal consistency, reliability itself, and measurement error, eight PROMs [39,41,42,44,50,51,53,55] (57%) were rated 'sufficient' in the internal consistency property, while the other six [37,40,45,48,49,52] were rated 'indeterminate', mostly due to the high degree of uncertainty in the measurements. Reliability was rated 'sufficient' for one PROM [37], 'insufficient' for another [53], and 'indeterminate' in the remaining 12, which lack the reporting of appropriate statistics. Measurement error was rated 'indeterminate' for all of the PROMs, since none reported values for the smallest detectable change, limits of agreement, or minimal important change.

As regards the validity domain, which is composed of structural validity and hypothesis testing, two PROMs [42,48] (14%) were rated 'sufficient' in the structural validity property, while all the others [37,39–41,44,45,49–53,55] were rated 'indeterminate' because none of the criteria that rate this property was reported. The hypothesis testing property was rated 'sufficient' for the majority of the PROMs [37–39,41,42,44,51,53,55] (n = 9, 64%) and 'indeterminate' in the five [45,48–50,52] that did not define any hypothesis a priori.

**Table 3**
PROM characteristics.

| Instrument | Purpose | N of items | Domains/ Subscales | Question format | Response Options | Range of scores/ Scoring | Original language | Readability index (original language) | Administration | Completion time (minutes) | Available translations |
|---|---|---|---|---|---|---|---|---|---|---|---|
| *CaNDI* [37] | To identify distressed patients in need of intervention. | 39 | 7:<br>Depression<br>Anxiety<br>Emotion<br>Social<br>Healthcare<br>Practical<br>Physical | A – Rate the extent to which each item has been a problem in the past 2 weeks<br>B – Would you like to discuss each concern with a specific health-care professional? | A: 'Not a problem' (1);<br>'Mild problem' (2);<br>'Moderate problem' (3);<br>'Severe problem' (4);<br>'Very severe problem' (5);<br>'Prefer not to answer';<br>'Do not know'.<br>B: 'Yes';<br>'Prefer not to' | 39 – 195 | English | 5.5<br>Flesch-Kincaid Grade Level | Pen-and-paper<br>Touchscreen tablet | 8 | Turkish [71] |
| *CARES* [38,39] | To assess the day-to-day problems and rehabilitation needs of patients with cancer | 139 | 5:<br>Physical<br>Psychosocial<br>Medical Interaction<br>Marital<br>Sexual<br>+1 Miscellaneous subscale | A – Circle the number that best describes how each statement applies to you during the past month, including today<br>B – For any problem statement that you rate between 1 and 4, indicate whether it is a problem with which you would like help<br>C – Please list any additional cancer or treatment-related problems that may not have been addressed | A: 'Not at all' (0);<br>'A little' (1);<br>'A fair amount' (2);<br>'Much' (3);<br>'Very much' (4).<br>B: 'Yes'; 'No'<br>C: Free text | 0 – 556 | English | – | Pen-and-paper | 18 | Flemish [72] |
| *CARES-SF* [40] | To assess the day-to-day problems and rehabilitation needs of patients with cancer | 59 | 5:<br>Physical Psychosocial<br>Medical Interaction<br>Marital<br>Sexual<br>+1 Miscellaneous subscale | A – Circle the number that best describes how each statement applies to you during the past month, including today<br>B – For any problem statement that you rate between 1 and 4, indicate whether it is a problem with which you would like help<br>C – Please list any additional cancer or treatment-related problems that may not have been addressed | A: 'Not at all' (0);<br>'A little' (1);<br>'A fair amount' (2);<br>'Much' (3);<br>'Very much' (4).<br>B: 'Yes'; 'No'<br>C: Free text | 0 – 236 | English | – | Pen-and-paper | 10 | – |
| *CASUN* [41] | To identify cancer survivors' supportive care needs | 35 (+6 + 1)* | 5:<br>Existential survivorship<br>Comprehensive care<br>Information<br>Quality of life<br>Relationships | A – Please tick the answer that best describes your experience, thinking at the last month.<br>B – If the need is currently unmet: how strong is your need?<br>C – Please list any other needs that you have experienced in the last month<br>D – Positive changes in the last month | A: 'No need, or is not applicable'<br>'Have need, but need is being met'<br>'Need is currently unmet'<br>B: 'Weak'<br>'Moderate'<br>'Strong'<br>C: Free text<br>D: 'Yes, but I have always been like this' | 0 – 35 | English | 5.6<br>Flesch-Kincaid Grade Level | Pen-and-paper | 10 | Dutch[73]<br>Chinese[74] |

(*continued on next page*)

**Table 3** (*continued*)

| Instrument | Purpose | N of items | Domains/ Subscales | Question format | Response Options | Range of scores/ Scoring | Original language | Readability index (original language) | Administration | Completion time (minutes) | Available translations |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 'Yes, this has been a positive outcome'<br>'No, and I would like help to achieve this'<br>'No, and this is not important to me' | | | | | | |
| *CNAT* [15,42] | To cover cancer patients' needs in a comprehensive way throughout all phases of the cancer experience, from diagnosis to recovery or palliative care | 59 | 8:<br>Information<br>Psychological problems Health care staff<br>Physical symptoms<br>Hospital facilities and service<br>Family/interpersonal problems<br>Spiritual/religious concerns<br>Social support | Rate the extent to which you have felt the need for the followings in the past month | No need' (0)<br>'Low need' (1)<br>'Moderate need' (2)<br>'High need' (3) | 0 – 100 | Korean | – | Pen-and-paper | – | English<br>Chinese[75] |
| *CNQ-sf* [44] | To assess cancer patient's needs across several domains. | 32 | 5:<br>Psychological<br>Health information<br>Physical and daily living Patient care and support<br>Interpersonal communication needs | Rate the level of need for help on a 5-point scale | No need: not applicable'(1)<br>'No need: already satisfied'(2)<br>'Low need for help'(3)<br>'Moderate need for help'(4)<br>'High need for help'(5) | 0 – 100 | English | 4 – 5 Flesch-Kincaid Grade Level | Touch-screen tablet | 20 | Arabic[76]<br>Chinese[77] |
| *eHNA*[45] | To help people living with cancer express all their needs and help those helping them better target support. | 48 | 5:<br>Physical<br>Practical<br>Social<br>Emotional<br>Spiritual | Select any areas that may have caused you concern recently and you would like to discuss with your key worker.<br>When selecting please score each concern between 1 and 10, with 1 being low level of concern and 10 the highest. | Each item is scored from zero (no problem) to 10 (maximum concern) | 0 – 480 | English | – | Touch-screen tablet | 7 | – |
| *NEQ* [46–48] | To evaluate needs expressed by (hospitalised [46,48] or outpatients [47]) cancer patients. | 23 | 5:<br>Informative needs<br>Needs related to assistance/care<br>Material needs<br>Needs for a psychoemotional support<br>Relational needs | Answer the questions listed below regard your current needs and state of mind your current needs and state of mind | 'Yes' (1) vs. 'No' (0) response scale. | 0 – 23 | Italian | – | Pen-and-paper | 5 | Greek [67] |
| *PNI* [49] | To identify the psychosocial needs of cancer patients, and the | 48 | 7:<br>Needs associated with health professionals | A – Iindicate for each need item on a scale of 1–5 'how important' it had<br>been for you over the past few | A: 'Not applicable' (0)<br>'Not important' (1)<br>?? (2) | A: 0 – 240<br>B: 48 – 240 | English | – | Pen-and-paper | – | – |

(*continued on next page*)

**Table 3** (*continued*)

| Instrument | Purpose | N of items | Domains/ Subscales | Question format | Response Options | Range of scores/ Scoring | Original language | Readability index (original language) | Administration | Completion time (minutes) | Available translations |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | contributory factors to need. | | Information needs<br>Needs related to Social support networks<br>Identity needs<br>Emotional and Spiritual needs<br>Practical needs<br>Need for childcare | weeks<br>B – 'How satisfied' are you that the need had been addressed? | ?? (3)<br>'Important' (4)<br>'Very important' (5)<br>'B: 'Not at all satisfied' (1)<br>'Not very satisfied' (2)<br>'Neither satisfied nor unsatisfied' (3)<br>'Satisfied' (4)<br>'Very satisfied' (5) | | | | | | |
| *SCNS-LF59* [50] | To assess the generic needs of patients with cancer. | 59 | 5:<br>Psychologic<br>Health system and information<br>Physical and daily living Patient care and support Sexuality | For every item on the following pages, indicate whether you have needed help with this issue within the last month as a result of having cancer. Put a circle around the number which best describes whether you have needed help with this in the last month. | 'No need-not applicable' (1) 'No need-already satisfied' (2)<br>'Low need' (3)<br>'Moderate need' (4)<br>'High need' (5) | 0 – 100 | English | 4 to 5 Flesch-Kincaid Grade Level | Pen-and-paper<br>Touchscreen tablet<br>Telephone | 15–20 | – |
| *SCNS-SF34* [51] | To measure cancer patients' perceived needs across a range of domains. | 34 | 5:<br>Psychologic<br>Health system and information<br>Physical and daily living Patient care and support Sexuality | For every item on the following pages, indicate whether you have needed help with this issue within the last month as a result of having cancer. Put a circle around the number which best describes whether you have needed help with this in the last month. | 'No need, not applicable' (1);<br>'No need, satisfied' (2);<br>'Low need' (3);<br>'Moderate need' (4);<br>'High need' (5) | 1 – 100 | English | 7 to 8 Flesch-Kincaid Grade Level | Pen-and-paper<br>Touchscreen tablet<br>Telephone | 10 | French[58]<br>German[59]<br>Japanese[60]<br>Traditional Chinese[61]<br>Mandarin[62]<br>Mandarin and Cantonese[63]<br>Mexican-Spanish[64]<br>Dutch[65]<br>Italian[66]<br>Nepali[67]<br>Amharic[69]<br>Turkish[68]<br>Brazilian[70] |
| *SCNS-ST9* [52] | A brief screening tool to assess the perceived needs of people with cancer. | 9 | 5:<br>Psychologic<br>Health system and information<br>Physical and daily living Patient care and support Sexuality | In the last month, what was your level of need for help with… | 'No need, not applicable' (1);<br>'No need, satisfied' (2);<br>'Low need' (3);<br>'Moderate need' (4);<br>'High need' (5) | 2 – 100 | English | – | Pen-and-paper<br>Touchscreen tablet<br>Telephone | – | Chinese[78] |
| *SUNS* [53,54] | To assess the generic needs of patients with cancer. | 89 | 5:<br>Emotional Health<br>Access and continuity of care<br>Relationships<br>Financial Concerns<br>Information | A – Indicate, for each item, your level of unmet need in the last month.<br>B – Are there any other problems or needs that you needed help with, in the last month? | A – 'No unmet need' (0)<br>'Low unmet need' (1) 'Moderate unmet need' (2)<br>'High unmet need' (3) | 0 – 356 | English | 4 to 5 Flesch-Kincaid Grade Level | Pen-and-paper | 26 | – |

(*continued on next page*)

**Table 3** (*continued*)

| Instrument | Purpose | N of items | Domains/ Subscales | Question format | Response Options | Range of scores/ Scoring | Original language | Readability index (original language) | Administration | Completion time (minutes) | Available translations |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 'Very high unmet need' (4)<br>B – Free text | | | | | | |
| *SUNS-SF* [55] | To assess the generic needs of patients with cancer. | 30 | 4:<br>Information<br>Financial concerns<br>Access and continuity of care<br>Relationships and emotional health | Indicate, for each item, your level of unmet need in the last month. | A – 'No unmet need' (0)<br>'Low unmet need' (1) 'Moderate unmet need' (2)<br>'High unmet need' (3)<br>'Very high unmet need' (4) | 0 – 120 | English | – | Pen-and-paper | – | – |

† In case of more than one validation study, those data refer only to the original sample group.
N = number. - = information not available.
* 35 unmet need items + 6 positive change items + 1 open-ended question.

Lastly, regarding responsiveness property of its homonymous domain, one PROM [39] (7%) was rated as 'sufficient' because its results were in accordance with the hypothesis, while the other 13 were 'doubtful', since no hypothesis was defined.

The CARES [38,39] was the PROM with the highest level of evidence according to the GRADE approach [20,28,80] (see appendix pp 11 and 26–28), with seven properties graded as 'high' or 'moderate' quality, followed by CARES-SF [40] and NEQ [46–48]. The PNI [49] and the eHNA [45] showed the worst psychometric performances, having been graded 'very low' in seven and six properties, respectively.

Table 4 shows a summary of the assessments for COSMIN Risk of Bias, quality of psychometric properties, and GRADE level of evidence attributed to the PROMs covered by this overview. In the appendix (pp 18–28) the details of each assessment are shown.

A brief description of the psychometrics properties of each PROM is also presented in the appendix (pp 29–30).

Although with a wide range of variability and different proportions, each of the 14 PROMs covered the three ICF components of body functions, activities and participation, and environmental factors, as shown in Table 5.

In ten PROMs [39,40,44,49–53,55], most of the items could be traced back to the component of activity and participation and in three [41,42,48] to the component of environmental factors, while in the last two [37,45], most of the items referred to the component of body functions.

## Discussion

This overview examined SRs focusing on the PROMs addressing unmet needs of adult CSs and identified 14 PROMs directed towards CSs suffering from non-cutaneous cancers.

We limited our search to reviews published in the last decade because recent advances in cancer treatment have changed the expectations and the quality of life of CSs enormously. The growing interest in survivorship has given impetus to the development of care plans focusing on CSs' unmet needs, which has led to the development of PROMs to identify them. This overview describes the PROMs currently validated for this purpose to facilitate their choice by clinicians and researchers in this field.

In 2022, the European Society for Medical Oncology (ESMO) developed a clinical practice guideline that emphasized the emerging evidence supporting the implementation of PROM monitoring during long-term survivorship to improve communication and identify late toxicities, symptoms, or functional impairment warranting supportive care, stressing the need for further research is this area [81]. This overview of reviews, which was implemented accordingly to the COSMIN guidelines for SRs of outcome measures, contributes to filling the knowledge gap in this area by comparing the evidence associated with the measurement properties of PROMs that address the unmet needs of CSs. Therefore, this overview supports the identification of the strengths and limitations of PROMs and assists in their selection for a reliable assessment of CSs' unmet needs.

Overall, two SRs and 14 PROMs were identified. They were originally tested in mixed cancer populations that included cancers with high survival rates (breast, prostate, colorectal, bladder non-Hodgkin's lymphoma) and/or incidence (breast, prostate, lung, colorectum) [82]. For this reason, these PROMs may be particularly useful to inform patient-centred survivorship care services.

Although the SRs covered in this overview were of moderate-to-low methodological quality according to the AMSTAR-2, it is our opinion that the AMSTAR-2 may not adequately capture quality aspects of SRs assessing the psychometric properties of PROMs. The use of clear, more specific criteria for this purpose would enable a more reliable comparison between the findings.

The selection of the most appropriate PROMs to assess a domain of interest should be informed by the psychometric properties and should

**Table 4**
Summary of the assessments for COSMIN Risk of Bias, quality of psychometric properties and GRADE level of evidence attributed to the PROMs covered by this overview.

PROMs COSMIN and GRADE evaluations

| Instrument | PROM Development | *Reliability* | | | *Validity* | | | *Responsiveness* | Overall RoB "the worst score counts" |
|---|---|---|---|---|---|---|---|---|---|
| | | *Internal consistency* | *Reliability* | *Measurement error* | *Content validity* | *Structural validity* | *Hypotheses testing* | *Responsiveness* | |
| *CaNDI* | ⊕◯◯◯ | ? ⊕⊕⊕⊕ | + ⊕⊕⊕◯ | ? ⊕◯◯◯ | ⊕⊕◯◯ | ? ⊕◯◯◯ | + ⊕⊕⊕⊕ | ? ⊕◯◯◯ | Inadequate |
| *CARES* | ⊕⊕⊕◯ | + ⊕⊕⊕⊕ | ? ⊕⊕⊕◯ | ? ⊕◯◯◯ | ⊕⊕⊕◯ | ? ⊕⊕⊕⊕ | + ⊕⊕⊕⊕ | + ⊕⊕⊕◯ | Inadequate |
| *CARES-SF* | ⊕⊕◯◯ | ? ⊕⊕⊕⊕ | ? ⊕⊕⊕◯ | ? ⊕◯◯◯ | ⊕⊕◯◯ | ? ⊕⊕⊕⊕ | + ⊕⊕⊕⊕ | ? ⊕⊕◯◯ | Inadequate |
| *CASUN* | ⊕◯◯◯ | + ⊕⊕⊕⊕ | ? ⊕◯◯◯ | ? ⊕◯◯◯ | ⊕⊕◯◯ | ? ⊕⊕⊕◯ | + ⊕⊕⊕⊕ | ? ⊕◯◯◯ | Inadequate |
| *CNAT* | ⊕⊕⊕◯ | + ⊕⊕⊕⊕ | ? ⊕◯◯◯ | ? ⊕◯◯◯ | ⊕⊕⊕◯ | + ⊕⊕⊕⊕ | + ⊕⊕⊕⊕ | ? ⊕◯◯◯ | Inadequate |
| *CNQ-sf* | ⊕⊕◯◯ | + ⊕⊕⊕⊕ | ? ⊕◯◯◯ | ? ⊕◯◯◯ | ⊕⊕◯◯ | ? ⊕⊕⊕◯ | + ⊕⊕⊕⊕ | ? ⊕◯◯◯ | Inadequate |
| *eHNA* | ⊕◯◯◯ | ? ⊕⊕⊕⊕ | ? ⊕◯◯◯ | ? ⊕◯◯◯ | ⊕◯◯◯ | ? ⊕⊕⊕◯ | ? ⊕◯◯◯ | ? ⊕◯◯◯ | Inadequate |
| *NEQ* | ⊕⊕⊕◯ | ? ⊕⊕⊕⊕ | ? ⊕⊕⊕⊕ | ? ⊕⊕⊕⊕ | ⊕◯◯◯ | + ⊕⊕⊕⊕ | ? ⊕◯◯◯ | ? ⊕◯◯◯ | Inadequate |
| *PNI* | ⊕◯◯◯ | ? ⊕⊕⊕⊕ | ? ⊕◯◯◯ | ? ⊕◯◯◯ | ⊕◯◯◯ | ? ⊕◯◯◯ | ? ⊕◯◯◯ | ? ⊕◯◯◯ | Inadequate |
| *SCNS-LF59* | ⊕⊕◯◯ | + ⊕⊕⊕⊕ | ? ⊕◯◯◯ | ? ⊕◯◯◯ | ⊕⊕◯◯ | ? ⊕⊕⊕◯ | ? ⊕◯◯◯ | ? ⊕◯◯◯ | Inadequate |
| *SCNS-SF34* | ⊕⊕◯◯ | + ⊕⊕⊕⊕ | ? ⊕◯◯◯ | ? ⊕◯◯◯ | ⊕⊕◯◯ | ? ⊕⊕⊕⊕ | + ⊕⊕⊕⊕ | ? ⊕◯◯◯ | Inadequate |
| *SCNS-ST9* | ⊕⊕◯◯ | ? ⊕◯◯◯ | ? ⊕◯◯◯ | ? ⊕◯◯◯ | ⊕⊕◯◯ | ? ⊕⊕⊕◯ | ? ⊕◯◯◯ | ? ⊕◯◯◯ | Inadequate |
| *SUNS* | ⊕⊕⊕◯ | + ⊕⊕⊕⊕ | - ⊕◯◯◯ | ? ⊕◯◯◯ | ⊕⊕◯◯ | ? ⊕⊕⊕⊕ | + ⊕⊕⊕⊕ | ? ⊕◯◯◯ | Inadequate |
| *SUNS-SF* | ⊕⊕◯◯ | + ⊕⊕⊕⊕ | ? ⊕◯◯◯ | ? ⊕◯◯◯ | ⊕⊕◯◯ | ? ⊕⊕⊕◯ | + ⊕⊕⊕⊕ | ? ⊕◯◯◯ | Inadequate |

*RoB = Risk of Bias*

Colours refers to COSMIN Risk of Bias appraisal:
= Very good
= Adequate
= Doubtful
= Inadequate
= Not Applicable

Symbols refers to the quality of psychometric properties (see updated criteria for good measurement properties COSMIN table in Appendix E)
+ = Sufficient
- = Insufficient
? = Indeterminate

Dots refers to the GRADE approach
⊕◯◯◯ = Very Low
⊕⊕◯◯ = Low
⊕⊕⊕◯ = Moderate
⊕⊕⊕⊕ = High

**Table 5**
Linking to the ICF framework

Linking to the International Classification of Functioning, Health and Disability Network

| Name of the Instrument | Number of Domains/Items | ICF Categories† | | | |
|---|---|---|---|---|---|
| | | Body Function Y/N (%) | Body Structures Y/N (%) | Activity and Participation Y/N (%) | Environmental Factors Y/N (%) |
| CaNDI | 7/39 | Y (47,6%) | N | Y (35,4%) | Y (17,1%) |
| CARES | 5/139 | Y (36,8%) | N | Y (50%) | Y (13,2%) |
| CARES-SF | 6/59 | Y (34,8%) | N | Y (50%) | Y (15,2%) |
| CaSUN | 5/35+6+1* | Y (11,8%) | N | Y (34,2%) | Y (53,9%) |
| CNAT | 7/59 | Y (26,1%) | N | Y (24,6%) | Y (49,3%) |
| CNQ-SF | 5/32 | Y (39,5%) | N | Y (48,8%) | Y (11,6%) |
| eHNA | 5/48 | Y (53,7%) | N | Y (37%) | Y (9,3%) |
| NEQ | 4/23 | Y (3,3%) | N | Y (36,7%) | Y (60%) |
| PNI | 6/48 | Y (21%) | N | Y (40,3%) | Y (38,7) |
| SCNS-LF59 | 5/59 | Y (29,2%) | N | Y (46,9%) | Y (24%) |
| SCNS-SF34 | 5/34 | Y(27,8%) | N | Y(46,3%) | Y (25,9%) |
| SCNS-ST9 | 5/9 | Y (30%) | N | Y (50%) | Y (20%) |
| SUNS | 5/89 | Y (23,2%) | N | Y (42,4%) | Y (34,4%) |
| SUNS-SF | 4/30 | Y (26,6%) | N | Y (42,2%) | Y (31,3%) |

* = 35 unmet need items + 6 positive change items + 1 open-ended question. Y = yes. N = no
†For each tool a different shade of green was used to highlight the different frequencies of the questions related to each ICF category, where darker is the highest frequency

go beyond statistics. The context in which PROMs are applied is perhaps the most crucial factor in determining their validity. Context not only refers to the pathology stage and the environmental factors but also to the geographical location, age, language, educational level, and socioeconomic and cultural background of the target population.

The adequate performance of a PROM is guaranteed by its content validity, that is, the relevance, completeness, and comprehensibility of items with respect to the construct of interest and the target population

[26]. Moreover, content validity is fundamental in clinical application, where clinicians should always consider whether the items of a PROM are likely be interpreted correctly by their patients and whether the information deriving from the response options will be useful to making healthcare decisions. Although content validity is considered the most important psychometric property, only one PROM [15,42] in this overview was rated as 'adequate' for its methodological quality, and 71% were 'doubtful' [20]. Future studies should further investigate the content validity in the target population to support the use of these PROMs in clinical care and research.

Only one PROM [48] reported information on interpretability, that is, the degree to which a qualitative meaning can be assigned to a PROM's quantitative score or change in score [79]. Future studies should assess the minimal important difference or minimal important change as well as the floor and ceiling effects of the PROMs investigated in this overview to guide the clinical interpretation of their scores.

Considering the assessment of the quality of the psychometric properties, the CARES [38,39] and the CNAT [42,43] were the two PROMs with the highest number of 'sufficient' properties (3/6), and none rated 'insufficient'. However, by combining these ratings with those obtained from the quality grading of the evidence, what emerges is that the most reliable PROM is the CARES [38,39], followed by the CARES-SF [40] and the NEQ [46–48]. Since these three PROMs would seem to be the ones with the most promising qualities, we suggest further studies to investigate their psychometric properties and their feasibility and interpretability more in depth.

A way to standardize PROMs by construct would be to link the content of their items to the ICF components in order to determine the health-related construct that is being captured. Identifying the most critical domains of CSs' unmet needs would be of crucial importance to guiding the development of a core of outcomes that are relevant to CSs and expressed in a universal language. Despite this, none of the PROMs examined was linked to the ICF in any of the primary studies analysed.

The main strength of this overview of reviews is that we independently applied the COSMIN guidelines to synthesize the risk of bias and psychometric properties of the PROMs aimed at assessing the unmet needs of CSs. We also linked the PROM domains to ICF components to facilitate the adoption of a universal language that could assist clinicians and researchers in their choice. Future studies should perform a complete mapping of PROMs according to the ICF framework to assist in the choice of the most suitable PROMs to assess different domains.

The main limitations are that SRs before the year 2012 were not included, which may have caused the misdetection of some reviews of interest. However, the authors deemed it appropriate to focus on recent studies, as the interest in CSs' needs is relatively recent, given that their life expectancy has drastically increased over the last decade. Moreover, recommendations for appropriate statistical methods and interpretation of psychometric properties assessment have changed over time. Another limitation is that SRs with low methodological quality were not excluded, which could have led to the detection of PROMs not accurately validated for their purpose. However, as both the primary studies and the PROMs were accurately assessed, this overview provides comprehensive information on existing PROMs and their validity. A third limitation is that, according to the timeframe of publication, the various primary studies used different statistical approaches and terminology of criteria to assess and report measurement properties. This means that the application of the most up-to-date COSMIN criteria often required an interpretation process to adapt the terminology used by some authors to the COSMIN lexis, which may have altered their original meaning. A final limitation is that the PROMs identified in this overview of reviews are measures of the comprehensive care needs tested in a mixed cancer population mostly living in Western countries. Indeed, specific contexts or cancer diagnoses would yield more precise needs that must be captured by suitably validated PROMs.

To conclude, this overview of reviews provides a comprehensive evidence synthesis of the properties and context in which PROMs addressing CSs' unmet needs have been developed and validated. It can therefore facilitate choosing the most valid and reliable PROMs to identify unmet needs, and it may facilitate a more appropriate resource allocation to survivorship care plans. Furthermore, this overview goes beyond the assessment and reporting of the psychometric properties of each PROM investigated; it illustrates the connections between the domains expressed by each PROM and the components of the ICF. This allows clinicians and researchers to choose the PROMs that comprehensively assess the various components of health that may be affected in cancer survivors.

**Contributors**

SC and AC were responsible for study concept and design. MCB performed the literature search. AC, SC and SP were responsible for records and reports screening. AC and SC performed data extraction and risk of bias assessment of the SRs. AC and MT performed the assessments for risk of bias, psychometric properties, and grading of the PROMs. AC wrote the original draft. Accuracy checks were performed by SC and SF. EM, MG, LG and IC reviewed and edited the article. SC supervised the study. All authors approved the final version to be published.

**Data sharing**

This overview of systematic reviews collected only aggregated data, which are presented in the manuscript. No individual participants data nor identifiable information was used. The primary studies included in the systematic reviews which are included in this overview are published and indexed in MEDLINE and/or Embase.

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**Research in context**

Evidence before this study

The number of cancer survivors (CSs) worldwide is increasing as a consequence of improved screening and early detection, advances in treatment and technology, enhanced follow-up care, and world population aging. There is global recognition that CSs experience a range of physical, psychosocial, spiritual, informational, and practical issues that may result in unmet needs, which are often neither identified nor addressed. Patient-reported outcome measures (PROMs) can help assessing the patient's unmet needs, with a wide range having been developed for this purpose. However, there is currently limited guidance for healthcare providers on how to select the most valid and reliable PROMs to reflect the unmet needs of this population. In this overview of reviews, we searched the terms 'cancer', 'survivors', 'PROMs,' and 'unmet needs' in the following electronic databases: PubMed, EMBASE, the Cochrane Database of Systematic Reviews, and CINAHL, filtering for systematic reviews (SRs) and/or *meta*-analyses published between 01 January 2012 and 20 January 2023. No language restriction was set. SRs were deemed eligible according to the following inclusion criteria: (1) primary study population must be CSs aged $\geq$ 18 years, affected by non-cutaneous cancer; (2) at least one psychometric property of PROMs aimed at identifying the unmet needs of CSs should have been reported. The risk of bias of the SRs was assessed using the AMSTAR-2 tool, while the methodological quality of each primary study was assessed through the COSMIN Risk of Bias checklist, and the psychometric properties of each PROM were rated against COSMIN updated quality criteria for good measurement properties. The quality of the evidence was then graded by means of the modified GRADE approach for grading the quality of the evidence in SRs of PROMs. We used a standardized coding procedure based on the ICF framework to link all the items of the PROMs analysed to the ICF components.

Added value of this study

Data from two SRs, which included 19 primary studies and 19151 CSs with several diagnoses, allowed us to identify 14 PROMs addressing the unmet needs of CSs, and they provided elements to facilitate the choice of the most valid and reliable PROMs to assess the unmet needs of

this population, considering both their psychometric properties and the context in which they can be applied. This overview of reviews provides a comprehensive evidence synthesis of the properties and contexts in which PROMs addressing CSs' unmet needs have been developed and validated. It can therefore guide the best allocation of the resources for survivorship care.

Implications of all the available evidence

Future studies should further investigate the interpretability of PROM score(s) and their content validity in the target population to better support their use in clinical care and research. A future, complete mapping of PROMs according to the ICF framework will further assist in the choice of suitable PROMs to assess different domains.

## CRediT authorship contribution statement

**Angela Contri:** Conceptualization, Data curation, Formal analysis, Investigation, Writing – original draft. **Sara Paltrinieri:** Investigation. **Martina Torreggiani:** Formal analysis. **Maria Chiara Bassi:** Investigation. **Elisa Mazzini:** Writing – review & editing. **Monica Guberti:** Writing – review & editing. **Isabella Campanini:** Writing – review & editing. **Luca Ghirotto:** Writing – review & editing. **Stefania Fugazzaro:** Writing – review & editing. **Stefania Costi:** Conceptualization, Data curation, Formal analysis, Investigation, Writing – review & editing, Supervision.

## Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

## Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ctrv.2023.102622.

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