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The role of patient-reported outcome measures in the continuum of cancer clinical care: ESMO Clinical Practice Guideline†

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Highlights:

• This ESMO Guideline provides key recommendations on the role of PROMs during the care of patients with cancer.
• It covers the use of PROMs in patients with cancer from the start of active treatment during follow-up and at the end of life.
• Recommendations are based on available scientific evidence and the authors’ collective expert consensus.
• Authorship includes a multidisciplinary group of experts from Europe, North America, Asia & Australia.
INTRODUCTION

Patients with cancer frequently experience symptoms related to their disease or treatment-related toxicities. Symptom management through optimal supportive care is a foundation of quality care. While objective toxicities and laboratory results are amenable to reporting by healthcare personnel, subjective experiences such as symptoms are best reported by patients themselves.\textsuperscript{1} Traditionally, patients are relied upon to discuss symptoms and side-effects with the clinical team during hospital and clinic visits, when contacting their healthcare team between visits via telephone or, more recently, electronic messaging.

Prior research indicates that healthcare providers often under-detect symptoms or underestimate their severity.\textsuperscript{2-6} This is especially true when side-effects or symptoms are not life-threatening\textsuperscript{4} although impacting quality of life (QoL). Prior publications demonstrate a lack of concordance between symptom recognition by clinicians and patient self-reporting.\textsuperscript{3,7-9} For instance, in one large clinical trial patients rated several tamoxifen-related symptoms (hot flushes, weight gain, night sweats, sleeping difficulties and loss of libido) as severe, but concordance of these with clinicians’ recordings at any severity was less than expected by chance.\textsuperscript{8} Likewise, in over 1000 patients with breast or lung cancer included in three randomised trials, the reporting of significant chemotherapy (ChT)-related toxicity, (all symptoms analysed) e.g. diarrhoea, nausea, anorexia were under-reported by clinicians in terms of incidence and severity.\textsuperscript{9} Suboptimal symptom detection by clinicians can potentially lead to delayed or suboptimal management and may affect adherence to therapies, symptom control, patient QoL and survival.

Reasons for discrepancies between reports by clinicians and patients may include a failure to ask questions systematically, time constraints of busy clinic visits and attribution bias (focusing only on expected or serious adverse events rather than symptoms the patient may be experiencing).\textsuperscript{10} Additionally, patients may feel hesitant to mention certain symptoms or worry that treatment might be stopped if they express complaints.\textsuperscript{11} Patients also report difficulty remembering symptoms experienced between clinic visits.\textsuperscript{12,13}
Symptom monitoring via patient-reported outcomes (PROs) offers an evidence-based approach to detecting symptoms which can provide critical information to clinicians, thereby improving clinical management. PROs are defined as ‘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’. Patient-reported outcome measures (PROMs) are tools and/or instruments used to report PROs, usually questionnaires (although they can include standardised interview schedules), to assess elements of their experience such as symptom burden, functional status, psychological and emotional well-being. In clinical practice, PROMs can be used to foster communication between patients and clinicians, assist in the detection and management of treatment toxicities and disease progression or recurrence and facilitate optimal delivery of supportive care.

The opportunity to use PROMs completed by patients and received by nurses and/or doctors enables timely and systematic assessment of clinical trends of symptoms and side-effects. The use of electronic systems for administering PROMs to patients with cancer and communicating this information back to their clinicians has been shown to improve symptom control, physical function, QoL, adherence to treatment, reduction in emergency room and hospital admissions and survival.

**USE OF PROMS IN PATIENTS UNDERGOING ACTIVE CANCER TREATMENT**

*Clinical scenarios*

For patients receiving curative therapy (e.g. definitive, adjuvant or neoadjuvant), the treatment goal is to eradicate the disease. In such patients, combined modality therapy is common, and patients often receive intensive treatments that produce considerable toxicity. These include organ-preserving regimens, such as definitive radiotherapy (RT) combined with radio-sensitising ChT (as in the treatment of head and neck, anal, lung and cervix cancers), adjuvant therapy following radical surgery (as in breast, colon and lung cancers) or neoadjuvant chemoradiotherapy preceding radical surgery (as in oesophageal and rectal cancer). The morbidity of each treatment is often magnified because of overlapping toxicity. In this setting, however, clinicians and patients may be willing to tolerate the intensity and severity of symptoms in hopes of
achieving a cure. Using PROMs to describe the severity and type of symptoms can help identify symptoms that would benefit from supportive interventions, determine the recovery time needed to return to usual activities and prepare future patients for what to expect during and after treatment. Automated advice feedback to the patient can facilitate self-management at home, particularly for milder symptoms detected by PROMs.23

Patients receiving RT with curative or palliative intent can experience acute toxicities, depending on the dose and schedule of treatment. These primarily occur in the field of treatment and can be severe. Fatigue can be a debilitating symptom during the later phases of RT treatments. PROMs could be used to monitor physical functioning and ability to complete usual activities in this setting and to anticipate and intervene in patients who may be deteriorating during the treatment and/or immediately following treatment.

In the setting of advanced or metastatic disease, measurement of PROs is valuable for detecting symptoms and functional impairment associated with both disease and treatment. In these patients, for whom palliation is the primary goal of any intervention, regular assessment of PROs is central to informing clinical supportive management. Increasingly, patients with cancer are receiving systemic treatment over an extended period. These therapies include maintenance ChT or biological agents, endocrine therapies, targeted therapies, immunotherapy and a combination of these. When treatments are expected to last for many months or even years, side-effects that impact QoL, even at a low level, are more likely to result in non-adherence. Regular measurement of PROs permits early identification of the difficulties patients are experiencing and offers opportunities to discuss modified dosing and supportive care.

PROMs that monitor symptoms and physical functioning can also address post-treatment and survivorship concerns. Some persisting symptoms such as pain, fatigue, sleep disturbance, cognitive difficulties, distress, depression and sexual issues are important to measure in the post-treatment period.

**Evidence supporting the adoption of PROMs in clinical practice**

Prospective trials and population-based studies have demonstrated improved outcomes when electronic PROMs are implemented for monitoring patients during
routine cancer treatment with systemic therapies, including improvements in physical function, symptom control, health-related QoL, hospitalisations, overall survival (OS), patient satisfaction and cost-effectiveness\textsuperscript{15,18-26} (Figure 1). Common features of the electronic PROM systems used in these studies include the availability of PRO questions via the web, handheld devices and/or automated telephone systems, inclusion of questions for common cross-cutting PROs from prior research (e.g. pain, nausea, vomiting, constipation, diarrhoea, dyspnoea, insomnia, depression and physical function), electronic prompts and reminders to self-report via email, text or automated telephone, use of validated symptom questions based on prior research and automated alerts to clinicians for severe or worsening symptoms. Multiple academic and commercial systems are available that include these features.

A 2014 systematic review of controlled trials evaluated whether the inclusion of PROMs in routine clinical practice was associated with improvements in patient outcomes, processes of care and health service outcomes during active cancer treatment.\textsuperscript{24} Studies were heterogeneous in terms of settings and methods: some used paper-based tools in the clinic, while others used electronic tools at home. In some studies, the use of PROMs was associated with improved symptom control, increased supportive care measures and patient satisfaction, although with limited statistically significant findings and predominantly small-to-moderate effect sizes.

Subsequently, several randomised controlled trials (RCTs) tested remote monitoring by electronic PROM web applications in patients undergoing active cancer treatment of different types of cancer\textsuperscript{18-20,23,27-30} (see Table 1 for details on the questionnaires and software used within each trial).

In the seminal trial conducted at Memorial Sloan Kettering Cancer Center, 766 patients receiving routine outpatient ChT for advanced solid tumours were randomised to either receive usual care (consisting of symptom monitoring at clinicians’ discretion) or to report 12 common symptoms via a remote system at home or on tablets or computers in the hospital waiting room.\textsuperscript{18} Self-reporting was conducted via the web-based interface STAR (Symptom Tracking and Reporting), and included questions adapted for patient use from the National Cancer Institute’s Common Terminology Criteria for Adverse Events (CTCAE), pertaining to 12 common symptoms experienced during ChT, graded on a five-point scale from 0 (not present) to 4 (disabling). STAR did not
allow skipped questions or free-text responses. Nurses received e-mail alerts when participants reported severe or worsening symptoms, and treating physicians received symptom printouts at visits. Symptom monitoring was associated with significantly improved QoL, reduction in emergency room admissions and hospitalisations. In addition, analysis of OS found a significant prolongation of life with the use of the reporting system. 19

The PRO-TECT cluster randomised trial, conducted at 52 USA community oncology practice centres, compared digital symptom monitoring with PROMs (treatment arm) with usual care (control) in 1191 patients with metastatic cancer receiving active treatment. 20 Patients in the treatment arm were invited to complete a weekly survey via the web or an automated telephone system for up to 1 year, which included items from the PRO version of the CTCAE about common symptoms, as well as performance status, financial toxicity and falls. The digital PRO-TECT electronic PRO (ePRO) system used in the study was built by the University of North Carolina’s PROs Core. Severe or worsening symptoms triggered electronic alerts to care team nurses and reports showing the trend of symptoms over time were available to oncologists at visits. Mean changes from baseline were significantly better with digital monitoring for physical function, symptom control and health-related QoL. Clinically meaningful benefits were experienced by 13.8% more patients with digital monitoring versus control in physical function, 16.1% in symptom control and 13.4% in QoL. Additional outcomes such as effects on hospitalisations and survival have not yet been reported.

Although RCTs represent the highest level of evidence supporting the efficacy of PROM implementation, important evidence comes also from real-world data and non-randomised studies. A population-based, retrospective, matched cohort analysis examined the effect of the exposure to the Edmonton Symptom Assessment System (ESAS) on patient survival, rates of emergency visits and hospitalisation. ESAS is a validated instrument to measure symptoms among ambulatory cancer patients, whose use has been standardised in the Ontario cancer practice network. 21, 22 The analysis, conducted in 128 893 pairs of patients with cancer between 2007 and 2015, showed improved survival and reduced rates of emergency visits and hospitalisations for patients exposed to ESAS.

Recommendations
Digital symptom monitoring with PROMs in routine clinical care during systemic cancer treatment is recommended, based on evidence of benefits on communication, satisfaction, treatment adherence, symptom control, QoL, emergency room and hospital admissions and survival [I, A].

The use of an electronic PRO system or device with the following key features is recommended: availability of PRO questions to patients via the web, a handheld device and/or an automated telephone system, inclusion of questions for common cross-cutting PROs from prior research (e.g. pain, nausea, vomiting, constipation, diarrhoea, dyspnoea, insomnia, depression and physical function), electronic prompts and reminders to patients to self-report via email, text or automated telephone, use of validated symptom questions based on prior research and automated alerts to clinicians for severe or worsening symptoms [I, A].

- Considering that multiple academic and commercial systems are available that include these features, the use of systems that have produced compelling evidence of benefit within randomised trials [such as STAR, PRO-TECT, electronic patient self-reporting of adverse-events (eRAPID) and other systems listed in Table 1] are recommended [I, A].

- Other systems could be recommended only if they have similar functionality and item content as the systems above [V, B].

- See Supplementary file Table S1 for relevant references and information on electronic medical record (EMR) systems that have been used for symptom monitoring during usual care.

**PROMS IN CLINICAL PRACTICE**

When implementing PROMs in practice, decision-makers must select: the outcomes to be elicited (i.e. what specific symptoms, functional domains or other PROs); the instrument to be administered (i.e. what questionnaire or item library will be used for patients to report on the selected outcomes); and the mode of data collection (i.e. web-
based, downloadable application, automated telephone call with interactive voice response, which does not require internet access or paper).

**Selection of outcomes**

A caution to decision-makers is not to start their process by choosing a particular instrument, but rather to consider what outcomes are important in a given population. This is particularly useful when validated item libraries are used, which allow building a PROM with a restricted subgroup of items from the whole library set. Outcomes to be assessed in a routine clinical care setting should be meaningful in the target population (i.e. prevalent and/or impactful on function or QoL) and clinically actionable (i.e. a management approach exists for clinicians to address the problem(s) through action, such as modifying cancer treatment or adding a supportive therapy). Patient input should be incorporated, and item selection should be broad enough to allow for the representation of patient values, even if they do not overlap with physician views.

A decision must be made whether the same outcomes will be elicited from all patients completing PROMs, or if there will be customisation based on variable characteristics of patient subpopulations, e.g. based on cancer type or disease stage (localised or advanced/metastatic disease status), active treatment versus survivorship, treatment type (ChT, immunotherapy, targeted agents, RT, surgery) or other variables. Some items, like pain, constipation and performance status are meaningful across most cancer populations, however, in contrast, erectile dysfunction may be a meaningful and actionable outcome in men following curative surgery for localised prostate cancer, but it may be less informative for other cancers. Fatigue is common in patients with cancer, irrespective of tumour site. Psychological morbidity—especially anxiety and depression—is a ubiquitous feature across most patients. Suicide is a rare but relevant issue; questions about this are often not included, due to insufficient monitoring by clinicians to assure a timely response.

Other variables best known by the patient that may impact care delivery can also be considered, such as social determinants of health (availability of a caregiver, transportation access, financial barriers or toxicity, social function, etc.). When administering the same PROM or instrument across the entire population, a cross-cutting ‘core set’ of common symptoms can be selected, as well as additional common domains such as patient-reported performance status or physical function.
Although management of free text is not standardised, an open ‘free-text’ option can be included for patients to add in any additional symptoms they are experiencing that are not in the selected outcomes.34

**Selection of instruments**

Once the appropriate outcomes for a given population have been identified, an optimal instrument must be selected that can elicit them. Choice of the tool should be made from existing questionnaires, or grouping of individual items taken from a well-developed item library [e.g. European Organisation for Research and Treatment of Cancer (EORTC), ESAS, Functional Assessment of Cancer Therapy (FACT), the MD Anderson Symptom Inventory (MDASI), PRO-CTCAE, Patient-Reported Outcomes Measurement Information System (PROMIS) and Symptoms Distress Scale (SDS-15)], or locally created using robust methodology35 or a combination of these.

It is recommended that instruments have established measurement properties, including qualitative and quantitative validity, reliability, responsiveness/sensitivity, and an acceptable recall period, in accordance with existing best practices for developing and evaluating PROMs.14,36-41 Once PROMs with adequate psychometric properties are identified, final instrument(s) can be selected by comparing item content (e.g. symptom types) to best fit the patient population and goal of the assessment. Many existing instruments were initially developed for research purposes; their appropriateness when used in a non-research context such as supporting clinical care should be examined.

To avoid patient burden and to increase completion rates, the number of items in any PROM should be reasonably limited. Although there is no strict rule regarding the number of items, the more often an instrument is administered to a patient, the shorter the application should be. For weekly administration, many successful experiences have adopted 10-20 items.18,20 When selecting instruments, the feasibility of administering items electronically should be considered, e.g. avoiding lengthy questions or response options that may not be compatible with mobile device screens or automated telephone administration. The responses should be easily interpretable by clinicians when visualised in alerts or reports.
The desirable characteristics of tools to use for remote symptom monitoring are described in Supplementary Table S2.

**Modes of administration**

Models based on paper tools—reviewed and discussed at hospital visits by clinicians able to interpret these types of data—allow improvements in symptom assessment and evaluation of ameliorative interventions. Models based on remote monitoring and electronic tools have the added value of providing alerts between visits and allowing for an earlier management of critical clinical issues. Prior research and consensus recommendations suggest similar performance of PROMs regardless of method of administration if only minor alterations of the instrument have been made between different modes. Thus, formal equivalence evaluation is generally not necessary when adapting or converting between modes.42 Patients may self-report at clinic visits via clinic-based devices and/or from home between visits using their own devices.

Based on the available body of evidence, a general approach has evolved to allow the remote electronic completion of PROMs, not only at clinic visits but also between visits. This involves loading a PROM into a software system and enabling patient self-reporting by the web, a downloadable mobile application or an automated telephone call on a regular basis.

Electronic platforms are preferable to paper for data flow and timeliness, although paper administration or staff-administered questionnaires may serve as a backup data collection approach for patients unwilling or unable to report for themselves (this issue can be particularly relevant in some clinical settings or some geographic or socio-economic contexts). Some patients may experience access barriers, increased age (although the use of electronic devices, e.g. mobile phones is increasing substantially even among older patients), a medical barrier to using a screen or limited internet connectivity. Although paper questionnaires do not allow for real-time communication between visits or an automated interface with EMRs, they have shown benefits in reducing under-reporting and improving QoL of patients undergoing active treatment, particularly when systematically shared with providers at visits.43 For those participants who are not able to use electronic devices, family or caregivers should have the ability
to report on behalf of the patient, with software capturing who completed the PROM in the system (e.g. with an item asking who completed the PROM).

Patient preferences and potential limitations should be considered when selecting mode(s) of administration. Prior research shows that patients have varying preferences for mode of PROM completion. For example, in a USA study using home PROM reporting, >35% of patients receiving systemic cancer therapy preferred interactive voice response over the web, a choice associated with lower education and older age.44 Therefore, when feasible, more than one mode should be offered to assure that vulnerable populations are able to have access to a survey platform.

Some key functionalities of electronic PROM systems that add value include: the generation of reports or visualisations for clinicians to review the longitudinal trajectory of PROs; the generation of automated patient self-care advice on actions they can take for the management of mild symptoms; and the ability to alert clinicians when patients report symptoms or physical function impairments of a magnitude or level of worsening that warrants clinical attention. When implementing any PROM system, workflow and staff capacity must be considered to assure that clinicians have ample time allocated for reviewing alerts and reports.

**Software considerations**

Once an instrument is selected, it must be loaded into the mode(s) for administration. In recent years, multiple academic and commercial PROM software systems have been developed and are available for adoption in clinical practice. Integration into the EMR is also possible for some vendors. A variety of instruments have produced data of acceptable usability by both patients and clinicians, and some have produced data of efficacy from randomised trials to support their use (e.g. ESAS, PRO-CTCAE).

PROM software system functionality should have a mechanism for registering patients, clinicians and administrative staff into the system, be able to trigger a prompt to patients to report at specified time points, administer instrument items to patients, trigger alerts to clinicians when patient responses reach specified thresholds for magnitude or worsening and generate reports for clinicians to view.45
Software should undergo usability testing to assure ease of use for patients and providers and comprehensibility of navigation. Testing should assure that patients with limited health literacy are able to understand and navigate the system. Barriers to patient adherence include complex passwords, difficult navigation and lack of a prompt functionality. Access and affordability in the population must be considered; for example, reliance on smartphones in a setting where patients face challenges with internet connectivity or the cost of data plans may threaten the feasibility of a PROM programme. Access by clinicians should also be considered to assure that the system can be integrated into existing information flow and workflow without inconvenience to users.

A single software system containing the multiple key functionalities of PROMs for all cancer types is ideal to avoid multiple platforms for a single patient and to minimise technology burden on the clinical team. There is an increasing interest in integrating PROM systems with EMRs to enable data visualisation, storage and management within a single clinical system, although these integrations can be technically challenging.

Optional functionalities may include skip-patterns for items, ability to show results to patients within the platform, capacity to provide educational materials or advice to patients on self-management, an open free-text box for patients to provide information not contained in the instrument and integration with EMR.

Because patient information is conveyed and stored by these systems, attention to privacy and security is essential. A balance must be struck between privacy, security and ease of use. Privacy and security must be assured, but access cannot be overly cumbersome, or patients and clinicians will not use the system. If a system is only collecting information from patients but not showing results back to patients, security precaution levels could be lower, as unidirectional data flow may reduce the risk of third parties accessing patient information. If users are prompted to participate by messages (text, email or telephone call) on their own password-protected devices, additional passwords may not be necessary. This is not acceptable in Europe, however, where two-factor authentication is mandatory. PROM software systems often include a disclaimer statement to patients, developed with legal consultation, stating that information entered in the system might not be rapidly reviewed by
clinicians, and, therefore, for urgent problems patients should call the office or seek emergency assistance.

Specific regulation in Europe for these instruments is reported in Section 1 Supplementary material.

**Recommendations**

- Outcomes assessed by PROMs in clinical care should be meaningful and clinically actionable in the target population [I, A].
- PROM questionnaires or items should have demonstrated measurement properties including validity, reliability and responsiveness to change [I, A].
- Administering the same PROMs across an entire population of patients is suggested, by employing a cross-cutting ‘core set’ of common symptoms and optionally a modular approach with additional items, based on cancer type or other variables [V, B].
- Limiting the number of items to avoid burden on patients and to assure patient participation is suggested [V, B].
- When feasible, more than one mode of administration should be offered to assure that vulnerable populations are able to have access to a survey platform [V, B].

**RESPONDING TO PROMS DATA AND REMOTE MONITORING ALERTS**

The use of PROMs in routine care is shaped by clinician relationships with patients, professional roles and workflow. Essential to the effectiveness of programmes is a clear delineation of responsibilities and expectations of team members; training in analysis, interpretation and actions in response to PROMs data; and thoughtful design of workflow for various users. Determining which clinician(s) will have primary responsibility for reviewing and acting upon collected data for patient management is paramount for meaningful integration into routine clinical care. Nurses, psychologists, allied health team members and physicians may all have roles and responsibilities in responding to PROMs data (e.g. psychologists or social workers may be designated to act upon emotional distress data based on severity). Teams
may need to develop new ways of working together to ensure an effective and efficient response to PROM data from a multidisciplinary perspective.

Evidence-based symptom management algorithms and pathways can also facilitate a quality response to PROM data. It should be recognised that PRO monitoring can detect a problem and its severity, however, further focused assessment and dialogue with the patient is still necessary to guide the selection of interventions and a supportive care plan (see Figure 2). Patients and caregivers can also play a role in yielding benefits of PRO monitoring, e.g. by following self-management advice from a PROM digital system. Patients require clear direction on the self-management actions they can take in response to PROM data as an integral component of patient management.

Nurses—who frequently represent the first line of clinical contact in oncology care—value PROM data for clinical practice and can assume a central role in reviewing and acting upon these data. Systematic reviews of RCTs and quasi-experimental studies show that the involvement of oncologists and expert nurses in the provision of information, education and supportive counselling has beneficial effects on physical, psychological and QoL outcomes across the continuum of cancer care. These nursing roles are well aligned to act on PROM data to improve patient outcomes.

Specific to acting on PROM data, RCTs of remote symptom monitoring during cancer treatment have shown that oncology nurses and/or nurse practitioners can effectively manage moderate and severe symptom alerts between clinic visits, with evidence of benefits on symptom burden, QoL, healthcare utilisation and survival. A trial of remote symptom monitoring showed that nurse-led coaching in symptom self-management reduced symptom distress, whereas PRO feedback to the clinical team without explicit designation of who or how to act upon these data did not show a similar effect. In PROM implementation studies in routine care, nurses were expected to use these data to initiate discussions on the most concerning patient symptoms or problems; to apply best practice interventions; to manage symptoms and other problems; and to identify and refer patients whose symptoms require escalation to oncologists and/or psychosocial specialists. The role of nurses as first responders can then be followed by oncologists’ responses (e.g. changes in treatment/prescriptions) as required. Although nurse impact on outcomes in
response to acting upon PROM data is synergistic to actions taken by the clinical team overall, studies show reduced symptom distress, healthcare utilisation and improved patient activation when nurses are designated and trained to act upon PROM data. Research is now focused on PROM-driven nurse-led consultations in feasibility and acceptability, with multiple smaller studies and recent large-scale trials demonstrating effectiveness.  

In order for nurses and other personnel to address PROM data, adequate resources should be allocated to this responsibility, rather than adding it on top of other duties. Nurses involved in PRO programmes have provided feedback saying that they value the information, but need to have dedicated time to address patient needs resulting from symptom monitoring.

In summary, there is evidence that nurses play a central role in reviewing and acting upon PROM data in routine care to improve symptom management and QoL. PRO monitoring in the absence of clinical integration and designated personnel to act on the PROM data likely will not yield substantial clinical benefits.

**Recommendations**

- Clinical personnel at sites routinely collecting PROMs should receive training on the review and interpretation of PROMs data [I, A].
- Provider organisations and clinical teams should clarify personnel roles and responsibilities and redesign workflow to ensure PROMs data are reviewed and acted upon [I, A].
- Oncology nurses or other allied health support (e.g., social workers) with appropriate training should serve as first responders to PRO alerts [I, A].

**USE OF PROMS POST TREATMENT IN PATIENTS AT HIGH RISK OF RECURRENCE AND/OR TREATMENT-RELATED SIDE-EFFECTS**

Some therapies are administered for a limited number of cycles, and patients without progressive disease at the end of treatment undergo periodic follow-ups to check for progression. For these patients, the use of PROMs may play a role in the detection of
recurrence and late effects, as well as management of residual toxicities and disease symptoms (Figure 1).

In a French multicentre randomised trial conducted in 133 patients with advanced-stage lung cancer (72% had stage IIIB/IV cancer), PROMs were used in the experimental arm with the aim of early detection of symptomatic complications and relapse after the end of their first-line or maintenance treatment. Patients underwent imaging every 3-6 months and reported symptoms weekly via a web system. Nurses were alerted by email in the case of new or changed symptoms. Survival was the primary outcome of the study. The study showed that, due to the alerts from the remote monitoring web application, more patients attended unscheduled visits in the experimental arm (58.3%) than in the control arm (24.6%, \( P = 0.008 \)). Use of remote monitoring was associated with a better performance status at the time of relapse: the performance status at first relapse was 0-1 in 75.9% of the patients in the experimental arm and 32.5% in the control arm (\( P < 0.001 \)), leading to optimal treatment in 72.4% of the patients in the experimental arm and in 32.5% in the control arm (\( P < 0.001 \)). A median survival benefit of 7 months was observed after 2 years of follow-up. Study procedures (the rules for medical team notifications) were created in 2013 and have not been tested with new drugs and standards of care, such as combined immuno-ChT maintenance. A randomised trial is ongoing with new standards of lung cancer care to assess the validity of this approach (Netherlands Trial register Trial NL7897).

Research on PRO monitoring in other cancer types following treatment is warranted.

**Recommendations**

- Symptom monitoring with PROMs is suggested for patients with stage IIIIB/IV lung cancer who have completed initial or maintenance treatment [II, B].
- Symptom monitoring with PROMs to manage persisting or new symptoms such as pain, fatigue, sleep disturbance, distress, depression, sexual health and cognitive difficulties, can be useful in the post-treatment period of patients with cancer [V, C].

**USE OF PROMS IN END-OF-LIFE CARE**
End-of-life care is defined as care for people with advanced disease once they have reached a point of rapid physical decline, typically the last few weeks or months before an inevitable death as a natural result of a disease.78

In these patients the main objective of care is QoL, and active cancer treatment should be discontinued. Monitoring should be focused on symptoms of disease and residual toxicities, although completion of PROMs in seriously ill patients can be a challenge.

Unfortunately, few studies have specifically focused on the use of PROMs in this setting. Many experiences in the palliative care setting include end-of-life care but also patients with advanced disease, who are still on active treatment.79 A study evaluating remote monitoring, including a distress thermometer and the Chemotherapy Symptom Assessment Scale, found it was feasible and acceptable by patients being cared for at home in the advanced stage of their illness.80

Research on PRO monitoring in end-of-life care is warranted.

**Recommendation**

- The use of symptom monitoring with PROMs in patients with cancer near the end of life, which may support symptom control should be considered [III, C].

**USE OF PROMS IN FOLLOW-UP AND SURVIVORSHIP**

There is limited evidence on the use of PROMs in post-treatment cancer survivorship. Assessment of core symptoms—including depression, anxiety, pain, fatigue, cognitive problems, fear of cancer recurrence or progression, QoL, health status and/or financial distress—could improve patient-clinician communication and avoid suboptimal symptom management.81,82 Other PROs may also be helpful to measure parameters such as self-efficacy and/or self-management capacity, health behaviours, physical functioning and sexual health, in order to alert care providers to the need for rehabilitation services.

Implementation of PROMs in survivorship care for longitudinal surveillance may be challenging due to variation in follow-up schedules; thus, standardised timeframes using remote monitoring may be needed. Research is warranted in this area.
Recommendation

- The use of PROMs in survivorship care of patients post-treatment for cancer, to improve communication and identify late toxicities, symptoms or functional impairment warranting supportive care, should be considered [V, C].

BEST PRACTICE AND IMPLEMENTATION OF PROMS IN THE HEALTHCARE SYSTEM

Given the demonstrated clinical benefits of digital symptom monitoring with PROMs in clinical practice, oncology practices are increasingly interested in implementing PROMs in clinics for usual care. Several resources are available to help cancer centres think through barriers and implementation solutions, although the evidence level is still not high. Supplementary Table S1 lists several PROM implementation guides that are available open access, and describe established best practices in both academic cancer centres and community oncology practices.

Across these implementation guides, general PROM implementation steps include:

- Pre-implementation planning: stakeholder engagement, identifying champion(s), technology solution, determining barriers and discussion about additional resources and capacity needs
- Delineating and/or revising clinic workflow for the care team to respond to PROMs as part of patient management
- Training care teams and staff to interpret and use PROMs during discussions with patients
- Testing, go-live and identifying and solving problems
- Evaluating and course corrections
- Monitoring and maintaining high-quality PROM use through continued engagement with clinics

Success rates of PROM implementation programmes have been variable and are dependent on the level of organisational commitment and available resources—planning, technology usability, engagement of clinic stakeholders, training, monitoring and oversight. Assuring that personnel (particularly nurses) have protected
time for handling PROM alerts is necessary. Like other clinical informatics and care enhancement programmes, PROM implementation has a high risk of failure if key principles are missing. Implementing and sustaining PROMs requires the engagement of clinical and administrative staff and leadership, as well as patients. Therefore, a systematic approach with tailored implementation support and effective oversight is critical.

Barriers to implementing PROMs in routine care are consistent across patient populations, care settings and even countries, but facilitating factors are specific to each clinic’s resources and needs. Systematic reviews show that barriers occur at the clinic, clinician and patient levels. At the clinic level, common barriers are inadequate information technology infrastructure and integration into clinical workflow, insufficient time to review and act on PROMs responses and lack of payer/insurance reimbursement. Resources available to clinics for PROM implementation are highly variable and may include technology infrastructure, leadership in the clinic to champion the use of PROMs and access to palliative care clinicians. Common barriers for care teams are lack of training on interpreting and using PROMs during discussions with patients, lack of perceived usefulness and liability concerns. Patients may have difficulty completing PROMs in the waiting room or remotely between visits (e.g. lack of technology access or experience, unavailable translations, physical impairment) and may be unclear about the perceived usefulness if the care team does not review PROM responses with patients.

To overcome these barriers, tailored implementation support is needed based on local resources, clinic culture and PROM characteristics (e.g. PROMs completed in the waiting room or remotely). Approaches from both implementation science and quality improvement have been successful when robust planning phases and a systematic approach were used. The planning stage can last several years but active implementation is typically shorter (weeks to months). Several RCTs conducting head-to-head comparisons of different PROM implementation strategies in oncology clinics are in progress. Few examples of maintaining high-quality PROM use clinic-wide are available in the literature, but promising strategies are local champions with change facilitation skills (physicians, nurses or staff who provide leadership support for using PROMs in their clinic), audit and feedback (monthly feedback to clinics on
the percentage of their patients completing PROMs and whether symptom burden is improving) and ongoing outreach to clinics.72

In summary, the evidence for optimal PROM implementation and support strategies is at a nascent stage, reflecting Level III-V evidence. An international consortium has been funded to disseminate open access resources and expert recommendations for PROM implementation in health systems—‘PROM Tools: Engaging Users and Stakeholders’ (PROTEUS-practice), available at https://more.bham.ac.uk/proteus/.

Recommendations

- PROM implementation should include engagement with clinic personnel, systematic training and ongoing monitoring and oversight [III, A].
- PROM implementation should include an initial assessment of barriers for both the clinic (e.g. whether the EMR vendor supports PROMs, availability of clinic resources for responding to alerts) and the patient level (preferred language(s), availability and comfort with internet access at home, literacy) and socio-cultural context [III, A].
- PROM implementation support should be tailored based on clinic resources and culture, clinical needs and the patient population, and PROM characteristics (e.g. PROMs completed in the waiting room or remotely) [III, A].

USE OF PROMS AS A QUALITY METRIC

In addition to individual patient management, aggregated PROM data can be used for quality assessment and improvement in clinical care.98-101 Data can be compared between organisations, clinics or providers, e.g. focusing on the proportion of patients with adequate pain control, nausea management or constipation during treatment.102 This can be followed by an improvement effort, e.g. using a ‘plan-do-check-act’ scheme or approaches of mutual learning.103

Like other quality metrics, to allow for fair clinician comparisons, PROMs may need to be adjusted by case mix or population risk.104,105 PROM use for quality improvement is endorsed by multiple initiatives as part of standard data sets,106 including large-scale
voluntary or national cancer quality initiatives\textsuperscript{107,108} and is well-established in fields outside oncology\textsuperscript{109-111}. Nevertheless, tangible evidence for the benefits of such approaches in oncology is still limited.

**Recommendation**

- The use of aggregated PROM data should be considered to inform quality metrics for quality-of-care initiatives [V, B].

**APPLICABILITY AND LIMITATIONS**

There is substantial evidence supporting the benefits and feasibility of implementing PROMs in outpatient cancer clinical care, particularly for patients receiving active therapy or during observation of therapy with a high risk of recurrence. Evidence related to PROM monitoring during long-term survivorship, hospital admissions and during hospice or end-of-life care is emerging.

There is less evidence about strategies for optimising patient participation during the entirety of the cancer trajectory, adherence with PROM reporting (especially in older patients), integration of software into care processes and assignment of personnel roles; these areas warrant future research. Information on barriers and facilitators to PRO integration is largely based on research studies or pilots under strictly controlled conditions, rather than attempting to integrate PROs into routine clinical care.

A recent survey of oncology practitioners familiar with PROs from 41 countries identified a ‘lack of technological support’ and the ‘absence of a robust workflow to integrate PROs in clinical care’ as central barriers from a provider perspective\textsuperscript{112}. These findings echo results from earlier research and implementation guidelines that highlight time constraints, PROM interpretation and liability issues and lack of resources/funding as major barriers for PRO implementation\textsuperscript{54}. Patient-level barriers when electronic PROMs are used include instrument complexity and relevance, degree of patient disability and patient technological savvy\textsuperscript{54}.

As with other care enhancements, strong facilitators to adoption include funding and mandates\textsuperscript{113}. Establishing PROs in routine care means that a certain amount of money
and resources are allocated. Payers and health authorities are, therefore, well
positioned to enable uptake of PRO monitoring in routine cancer clinical care to
improve clinical outcomes, quality of care and patient experience. Convincing
stakeholders and payers to invest in PROs requires the discussion of the robust
evidence that PRO collection adds value. The current evidence, however, is largely
limited to patient monitoring at the acute stage of the disease when the cancer is
systemically treated and the use of PROs for the patient–provider encounter to
improve interaction, diagnosis and disease management. Evidence is less robust in
other settings, such as when a patient is on oral cancer therapy, undergoing only RT,
in follow-up care after surgery or no longer eligible for active treatment due to disease
progression and/or worsening condition. Similarly, the evidence base for PROs as
performance measures is rather slim, though acknowledged by several expert groups
including this author group.

The authors recommend supporting research in these areas, particularly regarding the
use of PROs in routine care as compared with the application in trials within dedicated
projects and selected centres.

**Recommendation**

- The allocation of funds for validated software reimbursement, dedicated
resources (nurses, physicians, etc.) and systematic evaluation of PRO
implementation programmes in oncology clinics is recommended [V, A].

**METHODOLOGY**

This Clinical Practice Guideline was developed in accordance with the European
Society for Medical Oncology (ESMO) standard operating procedures for Clinical
Practice Guideline development (http://www.esmo.org/Guidelines/ESMO-
Guidelines-Methodology). The relevant literature has been selected by the expert
authors. Levels of evidence and grades of recommendation have been applied
using the system shown in Supplementary Table S3.114,115 Statements without
grading were considered justified standard clinical practice by the authors.
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Maguire R, McCann L, Kotronoulas G et al. Real time remote symptom monitoring during chemotherapy for cancer: European multicentre randomised controlled trial (eSMART). BMJ 2021; 374: n1647-n1647.


<table>
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<tr>
<th><strong>Author, year</strong></th>
<th><strong>Number of patients</strong></th>
<th><strong>Setting</strong></th>
<th><strong>Questionnaires used</strong></th>
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<td>Absolom K, 2021&lt;sup&gt;23&lt;/sup&gt;</td>
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CAPRI RPMS, Cancerologie Parcours Région Ile de France Remote Patient Monitoring Systems; ChT, chemotherapy; E-MOSAIC, electronic monitoring of symptoms and syndromes associated with cancer; ePRO, electronic patient-reported outcomes; eRAPID, electronic patient self-reporting of adverse-events: patient information and advice; ESRA-C Electronic Self-Report Assessment-Cancer; ESAS, Edmonton Symptom Assessment System; LoMoS, longitudinal monitoring sheet; MDASI, MD Anderson Symptom Inventory; NCI-CTCAE, National Cancer Institute-Common Terminology Criteria for Adverse Events; NIH PROMIS, National Institute of Health Patient-Reported Outcomes Measurement Information System OS, overall survival; PRO-CTCAE, Patient-Reported
Outcomes version of the Common Terminology Criteria for Adverse Events; QoL, quality of life; RT, radiotherapy; SCH, Symptom Care at Home; SDS, Symptom Distress Scale; STAR, Symptom Tracking and Reporting.

\(^a\) See supplementary file Table S1 for relevant references and information on electronic medical record systems that have been used for symptom monitoring during usual care.
Figure 1.

Therapeutic benefits of optimal implementation of PROMs in routine and remote cancer care

ED, emergency department; PROM, patient-reported outcome measure; QoC, quality of care; QoL, quality of life.

Figure 2.

Model for PRO use in routine patient management and for handling remote symptom alerts

ED, emergency department; EMR, electronic medical record; PRO, patient-reported outcome; PROM, patient-reported outcome measure.

a Other reviewers may include non-medical personnel, typically nurses