Patient-Reported Outcome Measures in Cancer Care: A Review of the Scientific Evidence
Executive summary

The importance of truly hearing the voice of the patient is growing as health systems strive to position patients at the center of care. Among the key solutions for more patient-centered clinical practice are electronic patient-reported outcome measures, ePROMs. These digitally implemented, validated questionnaires reveal patients’ views on how health care interventions impact their quality of life.

In cancer care, using patient-reported outcome measures has particular advantages. Cancer patients experience substantial physical and psychosocial consequences of the disease and its treatment, and much of the symptom burden occurs outside the hospital. Research suggests, however, that these consequences may be under-recognized and under-treated in oncology practice. Recent studies have shown that routine collection of PROMs as part of cancer therapy and follow-up may positively impact the survival and quality of life of cancer patients.

In this white paper, we present the benefits of collecting and using PROMs in routine cancer care and follow-up, relying on scientific literature. We also introduce a framework for defining a PROM collection protocol and applying it in practice. While the scope of this paper is limited to cancer care, many of the points raised here are general in nature, and may apply in other specialties, too.

ePROMs are a powerful tool in assessing and understanding the patient experience, as they provide data about patient symptoms and needs throughout the many phases of cancer care, including treatment, palliative care, survivorship, and hospice. This real-time data can be used to complement clinical data and support clinicians in identifying and tracking symptom progression, as well as in integrating patient-specific intervention opportunities into routine clinical care.
The power of PROMs lies in their ability to turn subjective experiences into numerical scores that can easily be utilized for quantifying how effective health care interventions are, both on an individual and a larger population level. This allows the data to also be used for strategic and analytical purposes, including health policy decisions, quality improvement and comparison of clinical practices, even across different countries.

The scientific evidence in support of using ePROMs in routine clinical care is robust. A large part of the benefits can be traced back to improvements in patient-clinician communication caused by the increase in timely, automated and systematically collected patient-reported information. For patients, key benefits include improved quality of life, symptom management and satisfaction with care. For health care professionals, the main advantage is gaining a better awareness of the patient’s experience on care outcomes. ePROM data help the clinician to focus on symptoms that need attention, both during and between clinic visits and without prolonging consultation time or interfering with workflows.

In a situation where the number of cancer patients is predicted to increase but resources available for treatment and care are not expected to grow, digital solutions such as ePROMs that have the potential to improve the quality, effectiveness and efficiency of care are welcomed by many health care professionals. Nevertheless, the uptake of ePROM systems in clinical care settings is still faced with implementation barriers, such as planning and designing the system infrastructure, training users, and engaging staff. This is partly because the body of research demonstrating the benefits of using ePROMs in clinical care has only started growing in recent years. Further research is therefore still warranted.

This whitepaper is a call-to-action for hospital and health care system decision makers to consider how PROMs could be applied to their area of specialty. Despite the implementation challenges, the potential of ePROMs in improving cancer care is significant and PRO data utilization continues to become increasingly common. The more hands-on experience from applying PROMs we accumulate, the better protocols and ePROM tools we can design. Most importantly, the insight provided by ePROMs help professionals focus on what matters to cancer patients, provide better and more personalized care – and ultimately, make more of a difference to patients’ health status and quality of life.
What are patient-reported outcomes (PROs)?

Patient-reported outcomes (PROs) are reports that come directly from the patient about the status of his or her own health condition, without interpretation of the patient’s response by a clinician or anyone else.\(^{10}\)

PROs are essential to understanding whether health care services and interventions make a difference to patients’ health status and quality of life.\(^{11}\) This data provides insight on the effectiveness and outcomes of care from the patient’s perspective – as opposed to the patient’s experience of the care process.\(^{12}\)

Examples of PROs include:
- health-related quality of life,
- symptoms (e.g. nausea, fatigue, diarrhea, or pain),
- physical functioning (e.g. difficulty climbing stairs or fastening buttons),
- mental health (e.g. anxiety, fear, or worry),
- satisfaction with care or symptoms,
- adherence to prescribed medicine or therapy, and
- perceived value of treatment.\(^{5,13}\)

Patient-reported outcomes typically include information about changes in health status that occur as a result of a health care intervention. This information complements clinical data, and can only be obtained from the patient, not measured directly. PROs are ideally collected without unnecessary delays to ensure accurate perception.

PROs were initially used in clinical trials, national audits and registers, but their routine use as part of clinical practice has become widespread. Disease-specific validated questionnaires have been developed for a variety of cancer types and for use in different stages of care. Efforts to standardize these questionnaires and promote the global use of health outcomes data are currently led by the International Consortium for Health Outcomes Measurement (ICHOM).
What are electronic patient-reported outcome measures (ePROMs)?

Electronic patient-reported outcome measures (ePROMs) are digitally implemented, standardized and validated questionnaires that capture the patient’s perspective on how health care interventions impact their quality of life. 

PROMs are meant to solely represent the patients’ perspective and be independent of the views and interpretation of the clinical team providing their care. The method of data collection must therefore ensure that patients complete their questionnaire unobserved and unaided by care providers.  

For decades, questionnaires were collected via the traditional pen and paper format, but PROMs are now increasingly collected electronically. Extensive evidence indicates that PROMs administered on paper are quantitatively comparable with measures administered on an electronic device. Compared to paper-administered PROMs, electronic PROMs are more efficient and less time-consuming to use, the data they provide is more complete and accurate, easier to scale and more adaptable.

Electronic PRO applications ensure fast, patient-driven reporting.

A variety of applications exist for different devices, including smart phones, tablets, personal computers, and wearable medical devices, as well as web-based portals. Research has confirmed patient preference for electronic administration of PROs, even among patients with low computer literacy.

In this paper, the term PROMs is used to refer to patient-reported outcome measures in general, and is understood to include outcomes collected electronically. The term ePROMs is used when highlighting the electronic collection method.
Why are PROMs used?

Understanding the patient experience is particularly important within cancer care, as cancer patients go through substantial physical, mental and social consequences of both the disease itself and its treatment. Despite time spent in hospital during active cancer care, much of the treatment side effects and treatment-related symptom burden occur outside the hospital. \(^{21}\)

Research suggests these consequences may be under-recognized and under-treated in oncology practice, resulting in greater morbidity that is costly to patients and the health care system. \(^{2}\) Studies have also found that compared to clinicians, patients detect subjective symptoms, such as fatigue, earlier and report them with more detail and a higher severity. Health care providers assessing cancer patients’ symptoms tend to underestimate symptom intensity; yet are better at predicting unfavorable clinical outcomes. Both perspectives are needed, as both provide clinically meaningful information. \(^{8,22}\)

In this context, PROMs provide a patient-focused, clinically relevant, and reliable perspective on the patient symptom experience. \(^{5}\) The scientific evidence supporting the use of PROMs both on an individual and a population level is ever increasing, and has revealed a variety of benefits for patients and health care professionals. Importantly, using PROMs in everyday practice can improve clinicians’ understanding of the effect of disease and treatment on patients’ daily lives, and has the potential to narrow the gap between clinical reality and the patient world. \(^{23}\)
How are PROMs used?

There are two main ways of utilizing data provided by PROMs. Firstly, the data can be used during clinical care processes to inform and guide patient-centered care and clinical decisions. This includes adjusting or changing treatment to better suit the patient, discussing and treating patient-specific symptoms, inviting the patient to additional appointments or tests, or cancelling unnecessary appointments.

Secondly, PROMs can be used for a variety of analytical and strategic purposes. As these subjective measures are asked in a consistent manner at particular points in time during an illness, they can be analyzed, scored and used to inform health services programming, planning and policies, performance measurement, comparative effectiveness analysis, and quality improvement initiatives.11

The population level data can also be utilized to inform individual patients of how others have experienced the disease and treatments. This allows them to be better prepared, and supports them in making informed decisions regarding their own care.24 Using PROMs in this way is particularly warranted in the case of certain cancer types where the patient is actively involved in choosing treatment. Having access to information on what kind of outcomes and side effects other patients have experienced related to e.g. chemotherapy vs. surgery can be crucial in this process.
What benefits do (e)PROMs have for patients?

The evidence in favor of self-reporting by patients is robust. From the point of view of the patient, PROMs shift part of the clinical care focus and place them more at the center of care. Being heard in this way can have an empowering and engaging effect.

According to research, the use of PROMs as part of routine clinical care:

- increases patient satisfaction with care,
- improves patient-provider communication,
- improves overall quality of life,
- improves symptom management,
- leads to less frequent hospitalization and admission to the ER,
- enables longer continuation of chemotherapy, and
- better survival rates for cancer patients.

Perhaps most importantly, PROMs enhance communication between patients and care providers and improve patient involvement in care planning and decision making. PROMs provide an opportunity for patients to provide input from their perspective and to be more aware of expected outcomes and how they compare.

Being systematically asked about symptoms can also train patients to better identify, track and report their symptoms. This can significantly improve quality of life and satisfaction with care, particularly among patients with less-developed health communication skills. PROMs can also help patients deal better with their symptoms. Some ePROM systems are designed to provide educational material to patients, tailored to their reported symptoms and needs, right after they complete a survey.

There is some evidence that clinical outcome measures seem to improve after patients start measuring, reporting, and sharing responsibility for the management of their condition with their physician. However, high-quality research on the impact of routine PROMs collection on health outcomes is still warranted.
What benefits do ePROMs have for health care professionals?

For health care professionals, the key benefit of using ePROMs is gaining a better, more systematic understanding of the patient’s experience on care outcomes. ePROM data can help the clinician to focus on symptoms that need attention and quickly determine whether symptoms are worsening or improving over time.\(^5\) This insight can be used to modify the care path for the patient and to improve or maintain a high level of care and expected outcomes.\(^{25}\)

**Several studies have provided evidence that the regular use of PROMs**

- facilitates and improves communication between patients and health care professionals,\(^7\)
- increases awareness of patients’ functioning and wellbeing,\(^7\)
- does not adversely affect clinic workflow or visit length,\(^7\)
- facilitates shared medical decision-making as patient participation is enhanced\(^{21}\) and
- makes discussion of more intimate issues more likely.\(^{21}\)

Furthermore, alert systems enable clinicians to recognize occurring symptoms in real time despite the geographic distance between the patient and medical services.\(^{21}\) Because patients track their outcomes between clinic visits and can communicate electronically when there is a change, the timing of appointments and their duration and content can be preplanned by staff, guided by patients’ needs and priorities. Registry data can also be aggregated to examine population health, improve quality of care and provide transparent public reports on patient outcomes.\(^{23}\)
Challenges in ePROM use

The benefits and clinical utility of PRO measures have prompted supporters to call for routine PRO collection in clinical care, yet significant barriers to initiating and implementing this remain – widespread physician acceptance has been lacking and adoption of PROMs by large health care systems has been slow due to several common challenges.\(^\text{13}\) These challenges include ensuring there are enough resources available for system implementation; planning and designing the system infrastructure adequately; training all users; and engagement of clinical staff.

The addition of ePROM systems into clinical care requires a significant investment of resources and planning at the outset. Proper planning, design and management of the system at the initial stage will however pay off later, as the added value of an ePROM system is very dependent on the type of outcomes it was designed to achieve and on how well it was designed for its purpose and context of use.\(^\text{5}\)

A wide variety of ePROM solutions exist, and it may be challenging to select the most appropriate one. An ePROM system requires comprehensive IT infrastructure, including technical devices for data collection and output, appropriate software solutions and network facilities for data transmission, storage and back-up, technical support and updates.\(^\text{21}\)

Design challenges include integrating the system into the clinic workflow and interpreting clinical relevance. Integrating PRO reports into the electronic medical record and other pre-existing IT systems is essential, as it significantly streamlines PRO review and use by clinicians.\(^\text{5}\) The user interface as well as PRO reports and alerts presented to clinicians must be clear and provide actionable data. It can, however, be difficult to identify the appropriate thresholds for PRO-based clinical alerts.\(^\text{5}\)
One of the major barriers to ePROM implementation – as with introducing any major organizational change – is reluctance to change. Using electronic systems to record patient feedback requires a certain mindset and a certain level of IT skills from all users: clinicians, staff, and patients.

According to research, clinicians are often reluctant to use PROMs routinely because they fear it will add to their workload and disturb already hectic workflows rather than make them more efficient and effective. Furthermore, many clinicians who do spend time talking to patients contend that they already understand their patients’ problems and do not need additional information from them. Clinicians may also require training on areas such as reviewing ePRO reports and alerts, score interpretation, and the discussion of ePRO scores with patients.

One of the reasons behind clinicians’ lack of acceptance is that the scientific proof supporting ePROMs is not yet widely known and acknowledged. This is partly because the body of research demonstrating the benefits of using ePROMs in clinical care has only started growing in recent years. Further research is therefore still warranted.

Comprehensive and role-specific training for all users can help tackle technical and mindset challenges. To ensure the engagement of clinical staff, and ultimately the uptake of the ePROM system, it is crucial to allocate adequate resources to training and other activities that will focus on overcoming the implementation barriers identified by research.
A framework for using ePROMs in cancer care

ePROM systems need to be planned, designed and applied in a way that optimally streamlines the combination of digital information, human contact and professional expertise, while supporting the clinician’s workflow and enabling better communication between patients and caregivers. The ultimate objective is to improve the quality, effectiveness and efficiency of care, and this must be considered throughout the process of planning, implementing and using ePROM systems.

The planning phase of ePROM use includes making several strategic decisions that will define the practical setup of the system and its integration into clinical practice. This involves selecting which standards to use, which tools to utilize, which patient groups to monitor and defining how the current clinical care paths and practices will be adapted to the use of ePROMs.
Methods of utilizing ePROMs can and should be scaled to the specific objectives and available resources of each setting. An important aspect to consider is that the uptake of ePROM systems may require adjusting existing processes and practices to make use of the new tools. The best design will vary for different patient populations, practice types, and clinical settings.

Many organizations that have successfully implemented ePROMs in cancer care have chosen to follow internationally validated standards. ICHOM and EORTC are examples of organizations that have collaborated with several cancer centers to develop standards for different cancer types. Scientific validation and standardization ensures that the outcomes being measured are relevant and support high quality care. Following international standards also enables outcome reporting and comparison between cancer centers in different countries.

The practical setup of ePROMs depends on the possibilities offered by the ePROM system in use, and many different parameters can be configured based on the PROM collection protocol. For instance, the configuration possibilities may include automatic feedback to the patient (e.g. self-care instructions), defining alerts and alert thresholds, adaptability and integration into existing IT systems.

As part of setting up the use of PROMs, their role in the clinical pathway needs to be defined. This includes deciding how to respond to the reported data, who will assess the data, and how patients who are not able to or do not want to use an electronic system will be considered. These processes need to be continuously assessed and updated as experience from the use of ePROMs accumulates.

After the various strategic decisions regarding ePROM use have been made, the practical framework can be designed and implemented. A simplified example framework for using ePROMs as a routine part of clinical cancer care is described in the next image.

The best design will vary for different patient populations, practice types, and clinical settings.
The process starts when cancer patients are enrolled at the clinic, and each patient is registered into the ePROM system and a follow-up protocol is activated for them (1). This will ensure they receive invitations and reminders to report quality of life and symptom information. The frequency of follow-up is defined according to each patient’s treatment plan.

Patients can complete symptom assessments anywhere and at any time using their own devices (2). The digitally collected information is automatically scored, and depending on the scoring, can lead to pre-defined, clinically relevant actions (3).

For example, results can be added to the patient’s electronic medical record, alerts generated to notify clinical staff of acute patient needs, or patients provided with educational material or routine self-care instructions tailored to their needs. The patient’s PROM collection protocol may be changed based on the patient’s answers.
Clinicians can use the PROM data immediately, during patient meetings, or return to the data later for more strategic purposes. When used before or during patient appointments, the information guides the content of patient-provider discussions and less time is needed for investigating the patient’s situation. Using this evidence-based insight can make the treatment process significantly more focused and efficient.

In addition to this typical ePROM use of collecting patient feedback as part of routine cancer care, ePROMs can be utilized in several other ways. One option that requires fewer resources during daily clinical practice is to use outcome data to analyze treatment results and efficiency on a population and health system level or as part of clinical trials. ePROMs can also be applied to standardize care and prioritize resources. The use of validated questionnaires ensures that all patients with the same disease and treatment are asked the same questions related to symptoms and quality of life. Patients who report symptoms requiring acute care can easily be identified and attended to in a prioritized manner, whereas those who do not require immediate attention can be given appointment times later or in some cases unnecessary appointments can even be cancelled or rescheduled.

Furthermore, ePROMs can be used to support the development of patients’ health communication skills – to train patients to better identify, track and report symptoms. With the help of smart algorithms, the right questions can be asked at the right time, enabling the collection of specific symptom information that patients otherwise may not report or pay attention to. This can have a significant positive impact on quality of life and satisfaction with care, particularly for patients with lessdeveloped health communication skills. ePROM results can also be used to visualize the treatment process, helping patients to understand how symptoms evolve throughout the disease – this in turn creates a feeling of safety and preparedness.

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The future of ePROMs in cancer care

The care of a cancer patient does not end with the completion of the treatment, it continues with a follow-up phase that typically lasts for years. The follow-up protocol varies depending on the type of disease and treatment, and the protocols are different in different parts of the world, but it typically involves scheduled check-ups and investigations. The goal of follow-up is to detect recurrence of cancer as early as possible and to manage possible long-term side effects of the treatment.

The rationale behind and efficiency of the follow-up schemes relying on long-term hospital follow-up has been challenged for different cancer types: the protocol may not be effective and can burden the health care system. The problem is further exacerbated by the projected increase in cancer incidence in the near future. Moreover, improvements in cancer treatments mean that patients live longer than before, which also contributes to the increase in the number of cancer survivors. Health care systems in developed countries are under pressure to decrease costs. Due to these reasons, new solutions for cancer follow-up are needed.
Electronically collected patient-reported outcomes may play a significant role in transforming cancer follow-up. PROMs complement clinical data in the assessment of the physical, psychological and social well-being of a cancer survivor. ePROM systems are an essential tool in enabling efficient collection, and, in part, also analysis, of patient-reported outcome information on a large scale. Based on our experience in working with caregivers, implementing an ePROM solution decreases the need for phone calls and makes the preparation for and the clinical appointment itself more efficient.

Another key driver for adoption of PROMs is the mounting scientific evidence for the benefits of collection of PROMs during routine cancer therapy and follow-up. Recent studies have found that the collection of PROMs in routine care and follow-up may have a positive impact even on patient survival and quality of life. Collecting PROMs will become mainstream practice, no longer an option for clinicians.

To fully exploit the promise of PROMs, specific PROM collection protocols, integrated into the clinical workflows, must be developed. The protocols should strive to make the best use of the available technology. Today, internationally validated questionnaires used in ePROMs are generally little more than paper questionnaires adapted to digital format.
ePROM systems allow for a greater adaptability of PROM collection than traditional pen-and-paper forms: the questionnaire can change based on the patient’s previous responses and other individual factors. Moreover, the emergence of wearable sensors allows the collection of almost real-time clinical data, opening a completely new data stream. As the volume of incoming PROM data increases, the techniques used to process and analyze it must improve accordingly. Already today, ePROM systems may give patients automated feedback, such as self-care instructions, but more sophisticated algorithms are needed.

A value-based (or outcome-based) health care model is expected to gradually replace the existing transaction based model. Patients have an increasing freedom to choose where, how and by whom they are treated. In this new environment, hospitals need to be able to show the patient the impact and expected outcomes of different treatment options the hospital offers. Moreover, as new cancer treatments are developed, the pharmaceutical industry needs to be able to show improvement in outcomes. PROMs and health-related quality of life are important components in the outcome dataset that will be essential for hospitals and pharmaceutical manufacturers alike. As we continue to learn to exploit big data, the existence of an extensive PROM dataset may bring benefits we cannot even predict yet.

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This whitepaper is a call-to-action for hospital and health care system decision makers to consider how PROMs could be applied to their area of specialty. We have presented the benefits of collecting PROMs in routine cancer care and follow-up, relying on scientific literature. We have introduced a framework for defining a PROM collection protocol and applying it in practice, based on our professional experience. While the scope of this paper is limited to cancer care, many of the points raised here are general in nature, and may apply in other specialties, too. We recognize there are barriers to PROM implementation, but they are not insurmountable. The more hands-on experience from applying PROMs we accumulate, the better protocols and ePROM tools we can design.
About the authors

Joel Lehikoinen M.Sc.Tech. and Henri Virtanen B.Sc.Tech. have been developing and implementing ePROM protocols for several cancer types and treatment methods in cooperation with leading European oncologists. Lehikoinen and Virtanen are co-founders of Netmedi Ltd and developers of Kaiku® Health ePROM solution.
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