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Translation of Patient-Reported Outcomes in Oncology Clinical Trials to Everyday Practice

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Abstract

Background/Purpose: Clinical trials in oncology evaluating the effects of patient reported outcomes (PRO) collection have found that monitoring of symptoms with PROs is associated with improved clinical care through reduced acute care utilization and decreased patient symptom burden. This educational review will evaluate strategies for systematic PRO integration into everyday oncology clinical practice.

Methods: We outline key considerations for using PROs in clinical practice, highlighting evidence from published studies. We also discuss the benefits and challenges of PRO implementation in oncology.

Results: Implementing PRO collection in clinical practice can improve care delivery and facilitate patient-centered clinical research. Considerations for using PROs in clinical practice include choice of instrument, method of delivery, and frequency of query. Challenges with implementing systematic PRO collection include the costs and resources needed for implementation, impact on clinical workflow, and controlling/monitoring physician burnout.

Discussion: While challenges exist in terms of financial resources and staff participation/burnout, patient reported outcomes in clinical practice provide a number of benefits including symptom monitoring, clinical research, and potential real-time personalized clinical decision support.

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Introduction:

Patient reported outcome (PRO) refers to “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.”[1] Clinical trials in oncology evaluating the effects of PRO collection/symptom monitoring have found that PROs are associated with improved clinical care through reduced acute care utilization and decreased patient symptom burden as well as increased patient satisfaction, increased physician/patient communication, increased patient activation, improved survival, and improved quality of life. In one of the earliest studies comparing PRO to usual care in the oncology population, Basch et al showed that PRO-based intervention for symptom control prolonged time on systemic therapy (8.2 months versus 6.3 months, p 0.002) and improved survival (31.2 months versus 26.0 months, p 0.03). It was postulated better symptom control with early response by the clinical team prevented downstream adverse events and allowed longer toleration of chemotherapy with the presumed benefit of the therapy.[2–8] Challenges with implementing systematic PRO collection include the costs and resources needed for implementation, impact on clinical workflow, and preventing physician (and staff) burnout. This educational review will evaluate strategies for systematic PRO integration into everyday clinical practice.

Instrument Choice (Table 1):

Choosing a PRO instrument or instruments for use in clinical practice is dependent on the intent of the PRO collection. It is important to define the purpose of the PRO data in order to distinguish the patient population for whom PRO collection is to benefit. For example, PROs can benefit current patients by tracking symptom burden for detection of impactful clinical change in the reporting patient’s course of care. Alternatively, PROs can benefit future patients through the collection of quality of life, symptom-specific, and disease-specific measures for evaluating comparative effectiveness of treatment and for understanding patient experience and quality of life outcomes. There are three classes of measure to discuss: general measures (non-cancer specific instruments), cancer-specific instruments, and disease-specific instruments.

General Measures:

The use of general measures, sometimes called legacy measures, for PRO data collection in clinical practice has a number of benefits. First, these instruments are widely accepted and have had the longest use in clinical practice. Next, these instruments have been used in both the cancer as well as the non-cancer populations allowing for comparison among different patient groups. Lastly, this broad scope of measurements allows for wider institutional implementation of PROs in clinical practice. This is especially applicable in institutions where PRO measurement is completed electronically with electronic health record (EHR) integration. The challenge with using general measures is that there may be a lack of question specificity to understand the true symptom burden of the cancer patient.

Cancer-Specific (General Measures Specific for Cancer Patients):

The use of cancer-specific instruments in clinical practice provides many of the benefits of the general instruments and addresses their limitations. These instruments are well-validated in the cancer population and they measure quality of life, symptom burden, and specific body components (e.g. bowel function). Many of these instruments have supplementary subscales that allow for disease-specific PRO queries such as EORTC QLQ-C30 as the quality of life measure for cancer patients with additional modules available for disease-specific considerations.[9] This modular approach for cancer-specific instruments provides the benefit of general implementation in a cancer center with each disease group adding their disease-specific module(s) as supplementary PRO query; however, this may result in a large burden of questions for the patient to answer leading to burnout and/or instrument non-completion.[10]

Site-Specific (Measures for Specific Cancer Types):

The use of site-specific instruments in clinical practice continues to address the limitations of the other measures by providing the most granularity of disease-specific PRO. These questionnaires are less burdensome than cancer-specific instruments because they tend to lack the quality of life components that are part of the disease-specific module. The granularity of these instruments, such as the EPIC-CP for prostate cancer, make them better questionnaires to use when comparing disease-specific treatments, especially in those cancer sites where treatment side-effects, surgical complications, and symptom burden are unique and not captured in a more general measure.[11] The lack of question generality and the narrow-scope of the applicable patient population are the limitations of these measures, but this can be rectified by combining them with other general measures for comprehensive collection.[12]

Method of Instrument Delivery (Table 2):

As with choice of instrument, method of delivery is another vital component of PRO collection. Each method imparts differing impact on resources needed, effect on clinical workflow, ability to aggregate data including EHR integration, and barriers to completion. Additionally, there is an expanding ability to query patients with the growth of health information technology including more robust EHRs, patient portals, and health-related apps for mobile devices.[13,14]

Method of Instrument Delivery - Paper:

Patients are most familiar with completion of information on paper, especially older patients; however, data is conflicted regarding older cancer patients' ability to complete paper forms and electronic ones.[15,16] Galliher et al noted that while response rates for a paper survey exceeded that of electronic collection among adults age 65 or older in a primary care clinic, electronic forms were less likely to have missing items indicating feasibility of electronic data collection in this population.[15] Further, McCleary et al. evaluated feasibility of computer-based cancer-specific geriatric assessment among adults age 75 or older diagnosed with gastrointestinal cancer noting that ½ of the cohort required assistance.[16] Both studies acknowledge the need for patient training as well as consideration of advancements in

technology that may mitigate challenges with electronic data collection. For a cancer center or clinic, resources likely already exist that would allow it to start with paper instrument delivery with minimal additional outlay. Moreover, many of the instruments are open source, free-for-use, and can be downloaded and printed/copied for near immediate use. Paper instruments also have the benefit of being integrated into clinical workflow in multiple places such as at the time of clinic intake or after visitation by the care team as well as being mailed to patients prior to clinical visits (although there is variability in completion rates for mailed questionnaires[17]).

The benefits of paper instruments are countered by their inability to be automatically scored or meaningfully integrated into the EHR as paper instruments are typically scanned into the medical record in a static form. This leads to delays in symptom tracking, data aggregation by hand, as well as a need for clinical resources to accomplish just-in-time scoring such as Scantron[18]. Clinicians would need to make a concerted effort to include scores into the chart when completing clinical documentation, leading to barriers for meaningful clinical use.

Method of Delivery – Electronic (Computer/Tablet)

Electronic delivery of PRO (ePRO) instruments represents the use of technology to collect and aggregate PRO. Most commonly, computer workstations and tablets are used to facilitate completion of PRO, and electronic delivery is integrated with the EHR allowing for responses to be scored and integrated into clinical practice such as showing patients their changing score trends through treatment. While workstation completion of electronic PRO can negatively impact clinical workflow, tablet completion offers the benefit of a more mobile device that is relatively inexpensive and allows for completion in the waiting room or exam room while waiting for a clinician.[19] For those patients with access to an online patient portal, electronic PRO completion can be divorced from clinical visits allowing for routine symptom tracking without the need for physical presence. Data aggregation is more readily accomplished with electronic PRO instruments compared with paper instrument.

The limitations of electronic PRO instruments include the need for significant resources to develop and integrate new measures into the EHR if desired measures do not already exist and/or are inadequate. Resources are also necessary for the electronic tools (e.g. tablets, workstations), coordination with clinic workflow, and the technological expertise to pull completed measures from the EHR for data aggregation.[20] Lastly, some patients may have decreased technological literacy leading to incomplete or inadequate capture of PRO.

Method of Delivery – Electronic (Smartphone)

Smartphones have become ubiquitous in the United States with over 75% of Americans owning smartphones in 2016.[21] Moreover, the use of smartphone health apps has the potential to assist with health needs regardless of age, race, socioeconomic status, and language although some users have reported refraining from health app use due to concerns about cost and data privacy.[22] The use of smartphones for instrument completion provides the benefits of electronic delivery with the use of patients' own electronic resources. Additionally, there is minimal effect on workflow as PROs can be delivered through push notification for completion at the patient's convenience. Similar resource and technological

literacy issues exist with smartphone instrument delivery as in computer/tablet delivery with additional challenges of local smartphone penetrance and mobile internet coverage.

Frequency of Query (Table 3):

The third important aspect of PRO integration into clinical practice is the frequency of patient query. The ideal frequency is the timing of queries that capture a patient's symptoms such that clinicians can make actionable change resulting in a positive impact on the patient's clinical course. It is vital that this frequency not represent an undue burden on the patient, staff or the clinician. It is also vital that the PRO completion by the patient is monitored by the clinical team in order to understand the patient's condition and make appropriate adjustments to treatment.

Frequency of Query - At Clinical Visits

PRO collection at clinical visits represents the natural starting point for query for those beginning to integrate PRO collection into clinical practice. In-person queries can be integrated into the clinical workflow and need not impose a significant burden on the patient or clinician. Clinicians can also have a starting point for clinical discussion if PROs are completed before the patient is seen by the clinician. For example, our postoperative patients' PRO scores represent the effect of their cancer operation on quality of life and bowel function with changes observed from respective scores captured at baseline.

However, if query is only done at clinical visits, there is the potential to miss important PRO data that may alter a patient's treatment plan. Additionally, some clinical encounters may already result in clinician capture of symptoms and current clinical condition resulting in meaningful clinical changes although there is substantial evidence that clinical visit PRO collection augments clinical visits with symptom monitoring and data capture.

Frequency of Query - Set Timepoints (Paper)

In order to capture symptom burden between clinical visits, PRO collection can also occur through query of patients through mailing of paper instruments to complete and return. In this way patients' symptoms are tracked routinely and score changes can signal a need for clinical contact and/or earlier clinical visit. This approach is limited by a higher patient and administrative burden to send, track, obtain, and act on responses. Moreover, there is also delayed actionability by the clinician as many of the clinical symptoms represented in score changes may have resolved or already been identified in the time it takes for the responses to be obtained and processed.

Frequency of Query - Push Notifications (Electronic)

A more novel and potentially effective way to monitor symptom burden between clinical visits is to use push notifications electronically for PRO completion. This represents a nice way to monitor patients between visits and allow for early detection of changes through symptom monitoring. Queries can be triggered based on timing of frequency, care intervention, or specific time point. This method is particularly effective for those patients who are technologically savvy. The key is to optimize the frequency of query in order to

prevent survey fatigue from the patient while maintaining acquisition of meaningful data trends. However, there is a higher burden on the clinical team to monitor these changes and act on concerning findings, which risks the possibility of data overload and burnout. There is also unclear clinician liability in monitoring and acting on the symptom changes identified between clinic visits by PRO measurement.

Frequency of Query - Continuous Communication

Although not a PRO instrument per se, wearable devices represent the newest generation of patient monitoring and data reporting. Continuous data capture from these devices provides the potential of very early detection of clinical changes before the patient notices a subjective change. The use of these devices in clinical practice, in theory, requires the need for a robust infrastructure for data capture, monitoring, and management that results in a very high clinical staff burden. There is also the real issue of patient compliance with wearing the device and, again, there are unclear implications for clinician liability.

Please see Table 4 for supplemental references for further reading.

Benefits of PRO Collection in Surgical Patients:

PRO data may be collected from surgical patients for the purposes of facilitating management of individual patients, for systematic quality measurement, for making generalizable observations (research), or for multiple simultaneous purposes. In routine practice, PROs may be used as part of the clinical encounter, serving as a standardized assessment tool to inform decisions about individual patient management. At a higher level of sophistication, observations collected from PROs could be used to feed into decision aids or clinical decision support symptoms. For example, the SPORT trial used measures of bodily pain, physical function, and disability to assess the longitudinal outcomes of operative vs non-operative management for multiple spinal conditions.[23] Building on their findings, the study authors published an on-line calculator which uses PRO instruments to present patient-specific numerical estimates of the likelihood of reaching treatment goals with operative or non-operative treatment.[24] To date the availability of PRO-driven clinical decision support tools for specific surgical conditions is limited, though this is a promising area of development.

More specific to the surgical oncology population, thoracic surgeons appear to have led the way. Traditionally as therapies evolve, the focuses of research are on the impact that the advancement has on the health care system, recurrence, and survival as a means of validation; however, the impact of change on patient quality of life and other measures has not always been the primary focus. In a study published by Alberts et al, PROs were used to compare patient quality of life (QoL) in the post-treatment period in the surgical and the SBRT population for lung cancer. The authors matched 41 SBRT and surgical patients and gave them QoL questionnaires at baseline and then at 3m, 6m, and 12 months post treatment. The surgical group had a lower baseline QoL but at one year there was no difference in the QoL scores.[25]

PROs represent the patient's voice, a vital topic that is historically lacking in the broad surgical oncology literature to date; however, the medical community is now recognizing this as significant and valuable. In fact, the American College of Chest Physicians (ACCP) includes PROs as part of their guidelines for treating lung cancer.[26] Other national agencies such as the National Institutes of Health, National Quality Forum, National Cancer Institute, Federal Drug Administration and the American College of Surgeons all advocate for the use of PROs in clinical outcomes measures.

Additional ancillary benefits of collecting PROs in surgical care include programmatic quality assessment and facilitation of surgical outcomes research. By routinely collecting clinically relevant PROs at different points in the trajectory of surgical management, surgeons and surgical practices can benchmark their own patient outcomes, evaluate changes in outcomes over time, and compare outcomes across centers. PRO data collected in the course of routine care may also be used for surgical outcomes research, with appropriate institutional approvals and permissions. Surgical outcomes research may evaluate the association between presenting symptoms and other baseline characteristics with post-operative outcomes. As the medical community continues to strive to minimize surgical therapy for the treatment of malignancies, the use of PROs will become ever-present to include the patient's quality of life, not just length of stay and cost savings, as an indicator of success of new therapies,

Uses of PRO Data:

While the potential uses of PRO data are many, it is important to be clear with patients about the objectives of PRO collection. Without a clear strategy for incorporating PROs into care delivery, the staff and patient efforts associated with PRO collection may distract from other aspects of the clinical interaction. Furthermore, patients are likely to have lower compliance with longitudinal PRO collection when the usefulness of the activity is not apparent. In the case of research, it is imperative that patients provide informed consent when their data is being collected as part of a prospective or pre-planned research study. Standards for ethical use of PRO data in retrospective or quality improvement research do not always require patient consent; however, clinicians should take care to respect patient privacy and to be transparent about the intended use of PRO data.

Challenges of ePRO Implementation:

Moving PROs from its first iteration, pen and paper, into an electronic version with integration into the EHR invites numerous challenges including but not limited to cost and resource allocation, patient acceptance and participation as well as physician and support staff acceptance.

Cost and Resource allocation for electronic PRO:

Broadly speaking, ePRO can be implemented via (1) custom/institutionally built systems (2) independently built commercial products (3) EHR-embedded products. In the first instance, custom-built ePRO systems can be costly. Baumhauer and colleagues estimated the yearly cost for ePRO maintenance alone to be over $600,000. Launch and upkeep of the system

includes the device purchase and maintenance, the cost of information technology services, data server maintenance and a physician champion to guide implementation and continued usage.[20] While expensive, the advantage of a customized system is immediate adaptability and modifications based on the patient population involved. Similarly, the second way to integrate ePRO, commercial products, provides the advantage of customizability; however, system maintenance responsibilities lie with the vendor. Additionally, commercial systems are independent of the EHR and thus require clinicians to access the data via a separate login, complicating clinical workflow and limiting PRO usability. Lastly, large EHR-based ePRO systems provide the advantage of seamless integration into the patient's record thereby minimizing or eliminating the need for added steps. The convenience of EHR-embedded PROs comes at the price of customization of the questionnaires and the potential for slow system updates required to maintain the ePRO system.

The cost of PRO development, implementation and integration must have financial incentives. At this time, clinical actions taken on PRO data is not reimbursable. However, in healthcare, the trend continues towards pay-for-performance. In most of the pay-for-performance oncology models, PROs or some other measure of patient voice is a quality metric for reimbursement. This will continue to drive the integration of PROs into routine oncology practice. Development of a mature, integrated ePRO system is resource intensive and is likely to stay in its infancy until federal mandates require vendors and institutions to routinely report PROs as part of patient care.

Patient acceptance/participation:

Many studies have shown that patients who have real-time involvement in their care report increased patient satisfaction and often this leads to improved outcomes. With this said, there can be significant barriers to implementation of PROs including literacy, health literacy, language barriers, WiFi/internet access, and burnout due to length of questionnaire. The most readily modifiable factor is questionnaire length and content. Rolstad et al published a meta-analysis looking at response rates and questionnaire length. There was a significant association between questionnaire length and response rates/completion in the 20 studies included in the meta-analysis. However, the authors cautioned that it is impossible to separate out applicability of the content questions and questionnaire length with this meta-analysis.[10] General literacy and health literacy can, in part, be overcome by modifications to the language used in the questionnaires to allow for generalized implementation. Wired and mobile broadband access can be a potential problem in many rural areas of the United States and can only be improved by expanded coverage. Communication of the importance and the impact of an intervention is essential to implementation. Patient response and participation is higher and more valuable if patients understand the value of PRO for their care and those like them especially if the content of the questions asked are appropriate.

Physician/Support Staff participation and burnout:

Implementation of a PRO system must not excessively burden the physician and the support staff involved in patient care. Indeed, direct flow of the PRO into the patient's chart is essential to gain clinic clinician participation and reduce burnout. In its prior pen and paper iteration, PROs needed to be upload or translated into the patient's chart; a labor-intensive

process often met with opposition due to increased workflow, a contributor to physician burn out. It is already well-known that the implementation of the EHR has negatively impacted face-to-face patient interactions and contributed to physician burnout. A time motion study reported by Sinksy et al showed that almost 50% of clinician's time is spent at their desk working on the EHR. In fact, in this survey of 4 different specialists in 4 different states, over 50% of physician's time in the examination room with a patient is spent on the EHR. Time documenting in the EHR significantly increased the stressors related to physician burnout and job dissatisfaction.[27] Thus, if an ePRO system is to be used, it is essential its impact on daily workflow be minimized if not help streamline patient care between clinic encounters. As we have become accustomed to pain as the 5th vital sign without much impact on daily workflow, we can similarly develop an ePRO system that minimizes additional time allocation and becomes as important as all other vital signs necessary for patient care.

Conclusion

In this educational review, translation of patient reported outcomes in oncology clinical trials to everyday clinical practice requires the identification of the intended purpose for querying cancer patients to inform instrument choice, type of instrument delivery, and frequency of query. While challenges exist in terms of financial resources and staff participation/burnout, patient reported outcomes in clinical practice provide a number of benefits including symptom monitoring, clinical research, and potential real-time personalized clinical decision support.

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Synopsis:

Clinical trials in oncology have shown that patient reported outcome measure collection and monitoring have a number of benefits. This educational review article will discuss the integration of patient reported outcomes measures into clinical practice.

Table 1 -

Instrument Choice:

Instrument Choice	Representative Examples	Benefits	Challenges
General	PROMIS Measures SF-36	Routinely used and accepted in clinical practice Comparison to general population or other cancer/non-cancer cohorts Broad scope of patient population for wider institutional implementation	Lack of question specificity to capture desired PRO
Cancer-Specific	PRO-CTCAE EORTC	Well-validated instruments for patients with cancer Instrument supplements can query for site-specific PRO	Some instruments have a significant number of questions to answer
Site-Specific	EPIC-CP (Prostate Cancer)	Instruments measure the most specific elements for cancer site Instruments measure disease specific outcomes to facilitate comparative effectiveness of disease specific treatments	Lack of question generality Narrow scope of patient population

Table 2 -

Method of Instrument Delivery:

Method of Delivery	Resources	Effect on Clinical Workflow	Electronic Health Record Integration	Ability to Aggregate Data	Barriers
Paper	Minimal additional resources	Can be sent to patients prior to their visits Can be placed in clinic workflow at multiple timepoints	Response sheets can be scanned into the electronic medical record	Data aggregation occurs by hand or through machine aggregation (e.g. Scantron)	Smaller barriers as paper form completion is common among the general population
Electronic - Computer/ Tablet	Resources necessary include electronic tablets or workstations for PRO completion in the clinic and/or EHR infrastructure such as patient portal	Tablet PRO completion can be placed in clinic workflow at multiple timepoints Workstation PRO completion may disrupt normal clinic workflow due to the need for presence in front of the workstation to complete	Can be integrated into the EHR and responses/scores can be placed in clinical documentation	Data aggregation occurs through the electronic system and in many cases is integrated into the EHR such that PRO on responses can be aggregated by individual question	Technological literacy Cost of physical resources, development, integration
Electronic - Smartphone	Minimal additional resources from the clinician/ institution	Minimal effect on clinical workflow as PRO can be sent and patients can complete at a convenient time	Can be integrated into the EHR and responses/scores can be placed in clinical documentation	Data aggregation occurs through the electronic system and in many cases is integrated into the EHR such that PRO on responses can be aggregated by individual question	Technological literacy Cost of development/ integration Local population penetrance of smartphones

Table 3 -

Frequency of Query:

	Benefits	Pitfalls
Clinical Visits	Can be integrated into existing clinic workflow Patients physically present to complete PRO and to be given reminders	PRO query at defined clinical encounters miss symptom changes between visits Symptoms already assessed by clinician during clinical visit
Set Timepoints (Paper)	Obtain PRO at set timepoints not associated with clinical visits	Higher patient burden to complete and return Higher administrative staff burden to reliably obtain and give to clinician Delayed clinician actionability due to delayed receipt
Push Notification (Electronic, Smartphone)	Obtain PRO at set timepoints not associated with clinical visits Higher likelihood for completion with technological facile patients Frequent symptom monitoring may result in early detection of clinical changes	Too frequent query will result in survey fatigue Higher clinical staff burden to monitor PRO with potential of data overload Unclear effects on clinical liability
Continuous Communication	Continuous patient data capture using wearable devices Just-in-time symptom monitoring may result in early detection of clinical changes	Need for robust infrastructure for data capture, monitoring, and management Higher clinical staff burden Patient compliance with wearable devices Unclear effects of clinical liability

Table 4 –

Supplemental References:

Authors	Brief Description	PMID
Valderas, et al.	Systematic Review of Measuring PRO in Clinical Practice	18175207
Mooney, et al.	Overview of PRO in Clinical Practice	28561859
Lohr, et al.	Overview of PRO in Clinical Practice	19034690
Snyder, et al.	Summary of ISOQOL User's Guide for PRO Implementation	22048932
Osoba	Analysis of the Science of PRO Assessment	17951224
Haverman, et al.	Evaluation of Web-based PRO Monitoring for Health-Related Quality of Life	23296436
Bennett, et al.	Review of Electronic PRO Systems in Oncology Clinical Practice	22811342
Donaldson	Analysis of Implementation of PRO in Clinical Practice	18991021
Cella, et al.	Analysis of Adaptive PRO Assessment	17401637
Basch, et al.	Summary of 2018 ASCO Session on PRO Implementation with Practical Examples	30231381