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EDITORIAL



# Expectations to Patient-Reported Outcome (PRO) in Oncology – PRO for a purpose, when and how?

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To improve survival (OS) and quality of life (QoL) for cancer patients is a driving goal for oncologists. Reaching this goal can be approached by several tracks; more sophisticated diagnostic procedures, enhanced cancer pathways, treatments with better effect, improved supportive care etc. An important component of supportive care may be the use of patient-reported outcome (PRO), but one may question when and how PRO can be used to achieve these goals.

In 2014 Kotronoulas reviewed the literature with focus on the ability of PROs to improve patient outcomes, processes of care and health service outcomes in cancer care [1]. The authors concluded that 24 controlled trials as a whole had found limited statistically significant impact of PRO, and that the effect sizes of interventional PROs were small to moderate. It was reported that PRO could improve symptom control, increase supportive care measures, and raise patient satisfaction, however it was already at that time stated that guidelines for clinicians' actions on PRO were warranted and could be crucial in order to achieve a meaningful effect of PRO [1]. More recent findings from a few larger randomized clinical trials with electronical PRO (ePRO) as an intervention have demonstrated that ePRO can improve QoL and increase survival in selected diagnostic groups and situations [2–4]. From these studies the use of PRO as an intervention seems to have the potential to influence the driving goal of oncologists, it might even be an important and strong tool in this context. However since the publication of these studies, no comparable data have been presented thus questioning how to achieve these goals. In a report from the 5th EORTC Quality of Life in Clinical Cancer Trials Conference, 2019, it was stated that even in clinical trials there were no standards for PRO measurement, analysis and reporting, and a major issue may be to ensure that 'the right questions are asked and the right answers are communicated' [5]. To overcome these hurdles several scientific collaborations have attempted to provide guidelines for the use and analysis of PROs [6–10]. The International Society of Quality of life (ISOQOL) and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) PRO extension have provided key elements for the planning of PRO studies while the Setting International Standards in Analyzing Patient-Reported Outcomes and Quality of Life Endpoint Data (SISAQOL) Consortium has suggested international standards for analysis of QoL and PRO data in clinical trials which may assure that the impact of PRO in such studies is better aligned and not lost [9]. We have previously demonstrated, how questionnaires developed to cover the same diagnosis and treatment situation may differ, leaving the risk of losing the potential of PROs [11] and have along with others suggested a systematic approach to following these guidelines in the question of item selection [12–15]. These studies therefore highlight the need to adhere to the proposed guidelines to ensure systematic use of the patient's voice through PRO data.

The use of PROs in clinical practice and challenges associated with this use has been explored by several groups during the past few years [16–20]. Stakeholder involvement and software resources pose as major elements in the optimal PRO delivery. Also, analysis of healthcare utilization when using PROs inhabits an important component for all health care systems. Howell et al. has reported on real-world experience with PRO in oncology from Canada showing some impact on healthcare utilization compared to standard care [20]. However, given the diversity of health care system world-wide such analyses need to be undertaken for every unique setting thus adding to the complexity of PRO immigration in health care. In a recent issue of Acta Oncologica Riis et al. show that individualized PRO-based follow-up in a breast cancer population resulted in fewer consultations while maintaining satisfaction with care and adherence to treatment [21]. The findings are important for administrators aiming at reducing costs of health care but also for patients and health care providers pursuing maintenance of the quality of care delivered despite reduced resources. The study was conducted as a single-center study for post-menopausal women receiving adjuvant endocrine treatment. As such the results may not be transferable to even a different treatment group of breast cancer women but may nonetheless inspire similar setups for other patient groups and it is vital that pursuit of the quality of care delivered remains a key element when exploring these PRO-based approaches.

In a recent review pronounced expectations of PRO having value for both individual patients and the society are communicated [8]. The authors propose 'an integrated evidence-based approach to data collection to meet multiple stakeholder needs', an approach which can have the

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drawback that a potential effect of PRO in a specific situation might be lost, e.g. by neglecting important group differences in universal analyses recommendations. This becomes evident in a recent publication by Nipp et al. in which the stunning data presenting improved survival in metastatic cancer patients of mixed diagnosis when applying ePRO with real-time feed-back as an intervention, has by sub-analysis shown positive impact only in the younger part of the population [22]. These results leave us with questions such as: can effect be lost when a PRO-tool is too generic? One size may not fit all.

Further, Nicklin and coauthors have recently raised the question 'who are we leaving behind?' [23]. Even though electronical devices are a natural part of most people's daily life, the introduction of tools such as ePRO might exclude some users and introduce age- or social inequality. This inequality risks enhancement if ePRO solutions are introduced prematurely and used as instruments in value-based health care. Very recently it has been suggested by Basch and colleagues that PRO can be added to Medicare's oncology value-based payment model, which seems feasible if meaningful questions reflecting the patient's situation are asked [24]. However, if the logistic challenges for the unique health care systems are not analyzed in advance, we will be measuring the value of health care for selected populations.

All in all, PRO in oncology can be a powerful tool in selected situations for selected populations, but the purpose of its introduction must always be thoroughly considered if an effect to the best of the patient is pursued– then we can have high expectations.

## Disclosure statement

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