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Patient-reported outcome measures to improve care for patients with metastatic breast cancer: opportunities and implications for nursing practice

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Abstract

Objectives: The Advanced Breast Cancer (ABC) Global Alliance has identified ten urgent and actionable goals for the decade between 2015 and 2025 to achieve substantial improvement in the lives of patients living with ABC, including metastatic breast cancer (MBC). Enhancements for MBC patients are needed for health-related quality of life (HRQoL), research, quality of care, and survival. We explore the potential of patient reported outcome measures (PROMs) in addressing these gaps and aim to describe opportunities and current initiatives for improving MBC care through PROMs.

Data sources: Recent literature on MBC and PROMs is described narratively.

Conclusion: Based on findings in the literature, we believe PROMs have the potential to make valuable contributions to seven of the ten goals described: 1) improving HRQoL; 2) enhancing the understanding of MBC through the collection of high quality data; 3) contributing to increasing survival; 4) supporting communication between healthcare providers (HCPs) and MBC patients; 5) increasing patients' awareness and referral to non-clinical support services; 6) encouraging improvements in access to healthcare; 7) supporting meeting the informational needs of patients with MBC.

Implications for Nursing Practice: Maximizing the benefits of PROMs requires effective implementation strategies. As nurses and nurse practitioners are at the forefront of care, they can offer a comprehensive understanding of patients' needs and play a crucial role in facilitating the integration of PROMs into routine care for MBC patients and ultimately optimizing patient outcomes.

Keywords: Metastatic breast cancer, health-related quality of life, patient-reported outcome measures, quality of care, advanced breast cancer, ABC global alliance

With yearly 2.2 million new patients, breast cancer is the most commonly diagnosed cancer worldwide [1]. Although it is the leading cause of cancer-related deaths in women (685.000 deaths in 2020 [1]), the five-year survival rates are generally high (99% for localized, 83-86% for regional breast cancer) [2, 3]. Eventually, 20-30% of these patients will develop metastatic breast cancer (MBC) [4, 5]. In high income countries, 5-10% of patients are already diagnosed with de novo MBC; in low-middle income countries, this can reach percentages as high as 60-80% [3, 6]. MBC remains incurable, albeit treatable, and survival rates remain poor (five-year survival: 25-34%; estimated median survival: 2-3 years [3, 5, 7]). The last few years, survival rates have substantially improved for two of three main MBC subtypes, HER2-positive and ER+/HER2-negative MBC, which now have a median OS of about 5 years [8, 9]. Although MBC treatment is primarily focused on extending survival, there is always a trade-off with managing adverse effects and health-related quality of life (HRQoL) [10], because MBC and its treatment often lead to adverse effects that affect HRQoL [11]. Furthermore, patients need to confront the reality that they will not be cured [5, 12, 13], and because MBC progresses, decisions are time-sensitive and outcomes uncertain [5, 14]. Disease control and progression, fear and hope, and fluctuations in HRQoL alternate constantly [14, 15]. As HRQoL is also associated with overall survival [16], optimizing HRQoL in MBC patients is vital.

There is an urgent need for improvement of care for MBC patients [14, 15, 17, 18]. The Advanced Breast Cancer (ABC) Global alliance [18], a non-profit multi-stakeholder organization that aims to improve the lives of all patients living with ABC worldwide, published the ABC Global Charter in 2017 and updated it in 2022. The charter was based on the findings of a comprehensive report, the Decade Report [5], developed through multi-stakeholder discussions, involving patients, patient advocates, healthcare providers, commercial partners, and policymakers. The ABC Global Charter defines 10 urgent and actionable goals for the decade between 2015 and 2025 to achieve substantial improvement in the lives of patients living with ABC **(Figure 1)**, which include enhancing HRQoL, improving survival, ensuring quality of care through better healthcare access, communication, and information provision, and boosting research. In their commentary on metastatic cancer survivorship care, Lai-Kwon et al. [15] propose to expand the survivorship care agenda beyond curatively treated patients to include those with metastatic cancer. Like the ABC Global Alliance, they pose the understanding of the metastatic cancer survivorship experience is incomplete, communication and

care coordination should be improved, and healthcare and healthcare practitioners' (HCPs) capacities should be aligned with metastatic cancer patients' needs.

Both only briefly acknowledge patient reported outcome measures (PROMs) as a means of improvement [15, 18]. PROMs are instruments that capture measurements of health status directly from the patient, without the interpretation of third parties [19]. Initially developed to measure HRQoL in trials and research, PROMs are now implemented in routine clinical practice. Patients typically complete PROMs electronically as part of their care, and receive feedback on their scores from their HCP during clinical consultations or directly via patient dashboards or tools [20, 21]. PROMs can be used for screening, monitoring, treatment decision-making, and to facilitate communication about HRQoL [20, 22]. Nurses play a vital role in the implementation and utilization of PROMs, as they can actively engage with patients, using PROMs as a basis for discussion and shared-decision making. We believe that PROMs could play an important role in achieving improvements in HRQoL, research, quality of care, and survival for MBC patients. In this opinion paper, we describe opportunities and initiatives for improving MBC care through PROMs following the 10 goals of the ABC Global Charter.

PROMs could promote health-related quality of life

PROMs in clinical practice could improve HRQoL **(goal 3)**. In a Cochrane systematic review, Gibbons et al. [23] outline the effectiveness of PROMs in clinical practice in improving oncology care processes and/or outcomes, summarizing 116 randomized trials conducted before 2020. PROMs were found to improve HRQoL (standardized mean difference (SMD): 0.15, 95% confidence interval (CI) 0.05-0.26; 11 studies; 2687 participants). Notably, the study by Basch et al. in metastatic cancer reported a SMD of 0.31 (CI: 0.12-0.50) patients [24, 25]). After six months, significantly more patients who completed PROMs registered clinically meaningful HRQoL improvements compared to usual care (21% vs. 11%; $p<0.001$) [25]. Conducted after 2020, the PRO-TECT trial provisionally concluded that after 3 months, symptom control (on a scale 0-100: PRO: 77.67 to 80.03 points; usual care: 76.75 to 76.55 points; mean difference, 2.56 [95%-CI, 0.95-4.17]; P=.002) and HRQOL (PRO: 78.11 to 80.03 points; usual care: 77.00 to 76.50 points; mean difference, 2.43 [95%-CI, 0.90-3.96]; P=.002) were significantly improved in metastatic cancer patients who regularly completed PROMs compared to usual care [26].

These effects rely on proper implementation of PROMs. It is crucial to ensure regular completion and participation, which was proven achievable in research settings, even in relatively ill patients or those

with limited digital experience [26, 27]. Partially, limited utilization of PROMs in MBC care could be attributed to inadequate measurement tools that do not fully capture issues specifically relevant for MBC patients. Therefore, the European Organisation for Research and Treatment of Cancer (EORTC) and the ABC Global Alliance are developing an MBC-specific PROM [28], which is expected to be finalized in 2025.

With dedicated attention and resources, implementation outside research settings is achievable [20, 29, 30]. Nurses emphasized the need for a shared strategy on how and towards what goal they should integrate PROMs into their workflows, considering time constraints and prioritization of PROMs within their responsibilities. Furthermore, outcomes were not always easily accessible in electronic health records (EHR) [31], adding to the time constraints nurses face. Streamlining documentation processes and ensuring easy access to PROM data can help address these constraints.

Research supported by PROMs data collection

The understanding of MBC could be enhanced by increasing the collection of high quality data **(goal 2),** as burden and unmet needs of MBC patients are difficult to measure due to lack of accurate, population-based data. Therefore, it is essential that HRQoL, PROMs, and patient-reported experience measures (PREMs) are systematically collected in clinical research and practice [17, 18]. Towards systemic data collection, the Health Outcomes Observatory initiative [32] recently developed an MBC-specific core outcome set (COS). This is a sample of carefully selected and validated measurements for standardized measurement of disease and treatment, which can include PROMs. It comprises comprehensive recommendations for standardized tracking of survival and disease progression, patient, disease, and treatment characteristics, and adverse events and HRQoL. It followed from consensus reached with 141 international stakeholders in a modified Delphi procedure, in which especially the opinion of the 45 included patients and patient advocates weight in [33]. Specifically, it includes 26 outcomes covering aspects of HRQoL that can be measured with the EORTC MBC-specific PROM, such as daily functioning, ability to work, psychosocial functioning, emotional functioning, relationships, and sexual functioning. This ensures a holistic and multidisciplinary approach to evaluate patients' well-being, a view already practiced by nurses [21]. To boost implementation, the International Consortium for Health Outcomes Measurement (ICHOM) accredited the MBC COS.

Increased survival through PROM symptom monitoring

PROM symptom monitoring during treatment could contribute to increasing survival of MBC patients **(goal 1)**. In a systematic literature review, Lizán et al. [34] summarized evidence of trials on PROM symptom monitoring in clinical cancer care in Europa, North America, and Australia between 2011-2021. Eight of 16 identified reports included metastatic cancer patients; 4 included large populations of MBC patients. Thirteen studies compared electronic PROM symptom monitoring to regular care (i.e. where patients discussed symptoms with HCPs during clinical consultations). Significantly improved survival was reported in studies about metastatic cancer: overall survival benefit: 6% and 5.2 months [24, 25]; overall survival benefit: 5.5% after one year of survival [35]. These results likely stem from improved symptom notation (risk ratio (RR) 1.73, 95% CI 1.44-2.08; 21 studies; 7223 participants), disease control (RR 1.25, 95% CI 1.10-1.41; 14 studies; 2806 participants) [23], early detection of tumor recurrence, and prolonged chemotherapy use [34].

Extrapolation of trial results to clinical practice should be done with caution [34]. Studying the effects of PROM symptom monitoring in routine care would be worthwhile: this may be especially important for patients undergoing continuous treatment [35], which typically applies to MBC patients. Although doubling median overall survival, as aimed by the ABC global charter, relies on the development of more effective treatments and the wider accessibility to existent ones, a contribution of several extra months of survival with improved HRQoL is substantial for patients with a median survival of two to three years [3, 5, 7]. Even if effects for individuals are small, they may have a profound effect on care for the MBC population as a whole [36].

The MBC COS recommends measurement of 24 adverse effects during treatment cycles [33]. More than any other HCP, nurses spend time with their patients during treatment administration. This creates opportunities to discuss PROMs with their patients: as illustrated by Pereira et al. [37], 85% of nurses compared to 61% of physicians frequently discussed PROMs with patients using a symptom monitoring system implemented in 14 hospitals in Canada.

PROMs towards improvements in quality of care

Effective communication between HCPs and patients is critical for metastatic cancer patients [12, 15]. To improve this aspect of care, the ABC proposes communication training for HCPs and patients **(goal 5)**. Hart et al. [17] systematically summarized 81 studies published between 2002 and 2022 about the

unmet supportive care needs of cancer patients. Forty-five percent (26–67%) of MBC patients reported an unmet health system and information need. In advanced solid cancer patients, 35% lacked information about 'things you can do to stay well', and 31% reported lack of one appointed HCP to talk about all aspects of your condition, treatment, and follow-up. PROMs in clinical practice has shown potential in improving patient-physician communication (SMD 0.36, 95% CI 0.21-0.52; 5 studies; 658 participants) [23]. However, a crucial element here is the feedback of results to patients [38]. HCPs require training on how to interpret and communicate about PROMs effectively and use these to inform patient management [20]. While this requires more attention [20], several training programs have been developed and tested that could be disseminated to hospital practice [39, 40].

PROMs can support the referral to and awareness about (non-clinical) supportive care services **(goal 7)**. As reported in a Dutch survey and UK interview study among MBC patients, patients were unaware of or did not receive the supportive care they needed [14, 41]. Nurses acknowledged that PROMs offer valuable and personalized information about their patients, supporting identification of supportive care needs [31, 42].

PROMs generates outcome data that are urgently needed for health policymaking [15, 22] The MBC COS contributes to this by measuring patients' access to healthcare and the relationship between the patient and the medical team, both aimed at improving quality of care by encouraging that all MBC patients have access to care from a multidisciplinary team **(goal 4)**, which is crucial in addressing the complex needs of advanced cancer patients [17].

Finally, PROMs data is an important resource for patient education, decision aids, and information provision [22]. Presentation of PROMs aligned with patients' needs and preferences [43] can support meeting the informational needs of patients with MBC **(goal 6)**.

Discussion

This work presents how PROMs could contribute to the fulfillment of many of the ABC Global Charter goals and, by doing so, improve care for MBC patients. This includes: 1) improving HRQoL; 2) enhancing the understanding of MBC through high quality data collection; 3) contributing to increasing survival; 4) supporting HCP-patient communication; 5) assisting patients' awareness and referral to

supportive care; 6) promoting access to healthcare; 7) supporting the informational needs of MBC patients.

Additionally to the development of new, more effective and/or less toxicity therapeutic agents, implementing PROMs in clinical practice is an opportunity already at hand. Importantly, new agents for MBC are substantially more expensive than PROMs [44]. Although annual costs of PROMs symptom monitoring are higher than usual care, these are counterbalanced by the survival benefits [34]. PROMs can contribute to value-based healthcare (VBHC), by ensuring patients receive care they value and get 'the right care in the right place' through better understanding of their needs and preferences. Nurses play an important part in VBHC: they work close with the patient and are therefore strong advocates of patient-centered care, which could facilitate bottom-up restructuring of care [45]. Specialized nurses, in particular, possess specialized knowledge that enhances their understanding of patient needs, supporting the shift towards patient-centered care and evolving focus from "living after cancer" to "living with cancer" [15].

Even after the introduction of new therapies for MBC patients, PROMs remain valuable. Managing new therapies, like immunotherapies and targeted therapies, poses unique new challenges linked to new and sometimes unexpected side effects, on top of managing uncertainty and fear of cancer progression in a new treatment setting [15]. That is, anxiety, stress, depression, and decreased HRQoL and social support are associated with unmet care needs in patients with solid advanced tumors [17]. Managing these symptoms, which are inherently present in the uncertain disease trajectories of MBC patients, will therefore always be important.

The care of metastatic cancer patients is marked by increasing inequalities worldwide between and within countries [15]. PROMs may unfortunately add to the inequalities: studies presenting trials and clinical practice examples of mainly administered electronically PROMs [34] were generally conducted in high income countries [20, 23, 34]. Electronic PROMs may not be easy to implement in low-middle income countries, creating an even larger lag to high income countries. Furthermore, older MBC patients, and patients with lower HRQoL and less technical skills frequently report barriers for electronic PROM completion [46]. This widens the 'digital divide' between those who can and cannot participate in and thus benefit from eHealth applications [47]. Efforts should be made to include all patients, regardless of literacy, health literacy, digital literacy, and access to technology and care [48].

Further research is required to establish real-world evidence to complement research in trial settings, cost-effectiveness [34], and the mechanisms trough which PROMs work in different clinical contexts [22, 23]. Large cluster-randomized trials of PROMs remain necessary, as current studies display a considerable variation in participants, settings, interventions, and measures [23].

PROMs implementation requires investments in terms of efforts, time, and resources. It comprises more than building an electronic portal for PROMs completion, and should be supported by a technical briefing, technical telephone support, and on-site support services [46]. Providing feedback of the results to patients by HCPs is crucial. By ensuring that all involved HCPs have access to a patient's PROMs, including nurses and nurse practitioners, a more multidisciplinary and holistic perspective can be provided. Nurses could play a vital role in successful PROMs implementation, as they work at the forefront of patient care.

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Conceptualization: KdL, BdR, LK, LvdPF, GV, FC;

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Figure 1 Goals for improvement of ABC patients