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REVIEW

# Enhancing Shared Decision Making between Patients and Providers in Breast Radiation Oncology

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## Abstract

**Purpose of Review** The goal of this review is to highlight the value of the patient voice in clinical decision-making regarding breast radiation. We seek to discuss ways in which the patient's voice may be amplified both in the clinic and in clinical trials.

**Recent Findings** Breast radiation discussions are nuanced and complex, particularly when physicians have equipoise amongst recommendations. Several tools including decision aids can help guide physicians and patients through this process. Instruments exist for analyzing patient's priorities influencing their decisions, which are essential for guiding future encounters. Several recent clinical trials have used patient reported outcomes as primary or secondary endpoints, providing invaluable datapoints for physicians to share with patients to aid in their decision.

**Summary** A shared decision-making approach involves eliciting a patient's preferences and values so that a sound recommendation can be given and a preference-sensitive decision can be made in settings of clinical equipoise.

**Keywords** Shared Decision-Making · Patient reported outcomes · Breast cancer · Patient autonomy · Breast cancer questionnaires · Preference sensitive

## Introduction

The treatment of breast cancer and DCIS is multifaceted and constantly evolving. Currently, several reasonable and acceptable treatment options exist for the majority of breast cancer cases, which allows for personalization and individual choice. At the same time, these choices can also be overwhelming for patients. For some patients, their decision may be straightforward, while for others it may be nuanced and involve input from family, friends, and the clinician. For this reason, determining how best to integrate and highlight a patient's preferences and values into their treatment plan for optimal shared decision-making is critical in breast cancer care. In addition to clinical practice, clinical research can augment shared decision-making by amplifying the patient voice, largely through greater incorporation of patient-reported outcomes (PROs) in trials including treatment-related toxicity, cost, and impact on quality of life (QOL).

### Preference-Sensitive Decisions

The landscape of breast radiation includes several scenarios in which providers have clinical equipoise in treatment recommendations. Depending on baseline patient characteristics and clinicopathologic factors such as stage, hormone receptor (HR) status, grade, age, etc., there may be a range of acceptable options available. While this offers flexibility and the opportunity for personalizing medicine to fit an individual patient's needs, it can also lead to complex discussions, difficult decisions in which there is no "right" answer, and sometimes overwhelming amounts of clinical information and choices. The patient's decision regarding therapy may be shaped by factors such as personal values, differential prioritization of therapeutic risk and benefit, convenience and length of treatment, and cost. In other words, each individual may have a unique analysis of their own risk versus benefit of treatment including both subjective and objective personal information. Appropriately characterizing that risk and benefit both qualitatively and quantitatively can be challenging for provider and patient alike.

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In some cases, oncologic outcomes may be similar or comparable across different therapeutic options. In other cases, while oncologic outcomes may have slight differences, some patients may accept a risk of slightly inferior outcomes for a slightly superior QOL or reduced toxicity profile. The term "preference-sensitive decision" has become more widespread and is particularly important for the challenging conversations and decisions that occur in oncology. Elwyn et al. defines preference-sensitive decisions by "equipoise: situations where options need to be deliberated. Moreover, where both healthcare professionals and patients agree that equipoise exists, situations may be regarded as having 'dual equipoise" [1]. Alcorn et al expand on this type of preference-sensitive decision as one in which there is a high-quality informed consent process, and the decision is aligned with the patient's values [2]. Of course, a multitude of factors may influence and shape a patient's decision regarding these values. For example, access to medical care, prior experiences with the medical field, and social and cultural factors can play a key role in a patient's decision. Factors such as transportation access, occupational status, and access to caregivers can also shape the ability to make certain decisions. Patients may also have their own perception of their personal health, life expectancy and goals of care that can influence their choice. Some patients may take into account which treatment option provides them with the most mental comfort or peace. The patient's perception of these factors and values determines how these items are triaged in terms of importance and thus, will likely directly impact what treatment decision is made.

Shared decision-making is "a strategy that aims to maximize patient autonomy by integrating the values and preferences of the patient with the biomedical expertise of the physician" [3]. A patient-centered approach is one in which the patient will be well informed of their treatment options and what to expect, including treatment details and logistics, side effects and toxicities, outcomes data if desired, and alternative therapies. In a shared decision-making format, a patient may be able to share their values and preferences and the clinician can help them navigate the decision. Here we will review decision-making preferences including identifying the preferred decision maker, gaining a sense for the extent to which the patient prefers maximal or minimal medical intervention, and understanding the patient's general health and life expectancy, all of which can help shape the shared decision-making process.

Baseline knowledge of a patient's general preferences regarding healthcare interventions and utilization can be helpful for guiding the visit and decision-making. The Maximizer-Minimizer Scale (MMS) is a patient-facing questionnaire focused on the patient's desire for more or less aggressive treatments and healthcare decisions [4]. Qualitative interview-based data has demonstrated that maximizers are more likely to pursue medical intervention and more aggressive adjuvant therapy for breast cancer, even when guidelines suggest that such therapy is not necessary [5]. Originally 10 items in length, there is now a validated single-item version in which "When making decisions about medical care, do you tend to lean toward doing only what is necessary or do you lean toward doing everything possible?" strongly correlated with radiotherapy choice [4, 6].

Understanding the extent to which the patient desires physician involvement in the decision-making may help provide insight into navigating the discussion. For some patients, there are several external inputs into their decision including friends, family, or caregivers but for many, the decision is mostly made by the patient themselves, albeit with some level of involvement from the physician. In a systematic review of 115 studies regarding medical decision-making, the majority of patients preferred sharing decisions with physicians [7]. When patients were asked to rate physician autonomy support amongst their providers, they found that perceptions of autonomy supportive communication (providing with choices, understanding, confident, etc.) varied between different providers including medical oncologists, surgeons, and radiation oncologists [8]. The decision autonomy preference score (DAPS) or control preference scale (CPS) is a questionnaire that can help determine how a patient prefers that treatment decisions are made, regarding personal and physician involvement ranging from patient-only (active), shared (collaborative), to physician-only (passive) [9].

During certain breast cancer treatment discussions, particularly in those regarding elderly patients who may be candidates for radiation omission, the risk of breast cancer recurrence may be competing with other sources of morbidity and mortality. Thus, estimating a patient's general life expectancy is an informative consideration in the decision-making process. However, estimating life expectancy can be challenging even for skilled physicians, in addition to being subject to bias. E-Prognosis is an available online calculator with 15 questions regarding other risk factors, medical comorbidities, and functional status that estimates 10-year mortality risk using Lee and Schonberg indices, not including the current breast cancer diagnosis [10, 12]. One clinic found that including e-Prognosis and a Vulnerable Elderly Scale into their assessments impacted subsequent surgical and adjuvant therapy decision-making [13]. A survey of women age 65–79 with early-stage breast cancer as well as their surgeons found that factors such as age, grade, HR status were associated with omission of RT, while extent of comorbidities were not [14]. When weighing risks and benefits and incorporating comorbidities, it is important for patients to understand their risk of local recurrence, which patients often rely on their physician to share. To this end, the aforementioned survey found that all patients overestimated the risk of local recurrence, indicating the importance of clear communication during consultation [14].

Shared decision-making may be optimally facilitated in multidisciplinary clinics (MDCs) in which breast surgeons, medical oncologists, and radiation oncologists see patients on the same day, ideally in close proximity and having conferred regarding nuances with patient care. Compared to a standard clinic format, one group prospectively administered the DAPS, e-Prognosis, and MMS in patients over 65 in a MDC and found no difference in radiation or hormone receipt, but a difference in radiation fractionation, suggesting there may be patterns associated with the results of these questionnaires to be explored [15]. To this end, they found that all patients who favored mostly patient autonomy underwent RT while those favoring mostly doctor autonomy chose no radiation, had lower odds of radiation for higher e-Prognosis mortality risk, and more use of RT with “maximizer” category scores on the MMS [15]. A subsequent study using the DAPS, MMS, and e-prognosis in 95 patients ≥ 65 with stage I HR + breast cancer found that older age, higher mortality risk, and preference for patient autonomy correlated with omission of therapy and that “maximizers” often chose RT or RT + endocrine therapy. [16].

Finally, when reviewing risks and benefits of radiation, it is important to ensure that a patient has grasped the nuances of the conversation and ultimately the physician recommendation. In one survey of patients who were deciding on postmastectomy radiation (PMRT) and were grouped by RT indicated, medical opinion divided, or not indicated, only ~ 1/3 of patients in the group with equipoise indicated they had been recommended radiation and ultimately received radiation [17]. The most common reasons cited for not pursuing radiation were lack of physician recommendation and perceived lack of need [17].

## Decision-Making Aids and Guides

In an attempt to guide the conversation regarding adjuvant radiation, several decision-making aids have been developed. Some patient-facing tools help inform the physician regarding the patient’s preferences, while others aim to inform the patient. Several tools also exist for analyzing the perception of the decision-making process, both during and after a decision has been made.

Attempts have been made to simplify the decision itself through the way in which information is delivered. There are several decision aids, not all of which are able to be covered comprehensively in this review. A systematic review from 2021 found 21 clinical decision tools for breast cancer treatment decision-making, majority of which used clinicopathologic factors to determine outcome and risk information rather than side effects [18]. The Decision Board was an instrument developed in 1999 for sharing risks and benefits of lumpectomy and radiation therapy and mastectomy and 81% of patients felt this helped with their decision [19]. More recently, the BRASA patient decision aid (BRASA-PtDA) was developed to help shared decision-making in radiation by providing information on local recurrence risk and side effects. An analysis of this aid showed patients desired more quantitative information on side effects such as those that impact daily life and QOL such as energy, arm function, and pain [20]. The Breast Cancer Surveillance Patient Decision Aid (BCS-PtDA) includes risk for recurrence and outcome information on fear of cancer recurrence (FCR). The prospective SHOUT-BC study implemented the BCS-PtDA in over 500 patients and found it improved patient-reported shared decision-making and decision-making quality [21]. The currently ongoing Alliance A231901CD trial is evaluating knowledge, self-efficacy, and cancer worry with the use of the Shared Decision Engagement System (SharES) which includes decision tools called iCanDecide and an emotional support module as well as a clinician-facing dashboard [22]. The Navya Patient Preference Tool (PPT) provides an informative module for patients reviewing trade-offs of cosmesis, adverse effects, and additional cost of breast conserving surgery followed by radiation vs. mastectomy. This decision aid was tested in a randomized controlled trial (RCT) in India using the Decisional Conflict Scale (DCS) which found that adding Navya significantly reduced decisional conflict compared with standard of care [23]. Another clinical trial examining an in-consultation “Decision Helper” on decision making results from the Shared Decision-Making Questionnaire (SDM-Q-9) found that there was higher patient-reported and oncologist-reported patient engagement with the aid [24]. Finally, the IMPACTT trial is an ongoing RCT assessing the impact of an in-consult paper-based patient decision aid or a pre-consult digital patient aid on patient and clinician-reported shared decision-making engagement for patients with early-stage breast cancer [25].

Instruments also exist that evaluate the decision-making process as well as the decision itself, including queries on patient satisfaction, conflict, extent and experience of shared decision-making, and decisional regret. The Decisional Conflict Scale (DCS) elicits patient’s response regarding uncertainty in health-related decisions, factors contributing to the uncertainty, and perceived effective decision making [26]. The Shared Decision-Making Questionnaire (SDM-Q-9) evaluates the shared decision-making experience with 9 items related to the role of the physicians in the decision, sharing risks and benefits, informing the patient and helping to weigh options, engaging the patient in the decision and selecting a treatment [27]. The Satisfaction with Decision (SWD) scale initially had six questions including satisfaction with being adequately informed with issues important to the decision, the best decision for oneself, consistency with personal values, expecting to successfully carry out the decision, feeling the decision was one's own to make, and ultimately being satisfied with the decision [28]. The Decision Regret Scale (DRS) has 5 items and involves questions pertaining to feeling if the decision was the right one, regretting the choice, whether one would make the same decision again, feeling the decision did them harm, or feeling the decision was wise [29]. One population-based study of patients over the age of 67 found that 24% reported local therapy decision regret [30]. A cross-sectional study used the Ottawa DRS and found that only ~ 14% of patients experienced high decision regret up to 4 years after RT, while certain factors such as chest wall RT were associated with higher regret [31]. These tools can be used in future studies examining the decision-making process and the information they provide can be helpful for guiding patients in their decisions.

## Patient Reported Outcomes and Patient Voices

PROs in research have allowed patients to provide important details of their experience with different therapies, which provide invaluable insight for the shared decision-making process. Recently, there has been a shift in clinical trial endpoint selection, from more classically reported outcomes-based endpoints (i.e. locoregional recurrence rate, progression free survival, overall survival, etc.), to endpoints that reflect PROs or toxicity data. PROs represent a way to systematically collect, track, and intervene on metrics from the patient's lens. In this way, PROs amplify patient voices and serve as valuable information to share with patients who are deciding on breast RT.

There are a number of PRO instruments available, varying from more general health-related QOL to more specific breast radiation questions. PROs can assess any aspect of the care process including but not limited to cost, side effects, or the aforementioned decision-making process. Previously, toxicity data was often physician-reported, but data has shown that this can underestimate the impact of toxicity on patients compared to PROs [32, 34]. There exist scales for standardized toxicity rating and reporting amongst physicians, such as the Common Terminology Criteria for Adverse Events (CTCAE) and those from Radiation Therapy Oncology Group (RTOG) and more recently, the PRO-CTCAE was developed as a consistent PRO form [35].

As not all breast cancer PROs have been developed for each unique treatment option, it can be difficult to compare PRO results across studies, especially when different instruments are used. Some instruments were specifically developed to assess outcomes after surgery as opposed to RT or endocrine therapy, but there can be vastly different experiences more specific to these treatment options such as fatigue and skin changes with radiation or joint aches and sexual well-being with endocrine therapy. The BREAST-Q is a commonly used breast-specific PRO with multiple available modules such as reconstruction, breast conserving therapy, and QOL and includes scales for expectations, outcomes, experience with their healthcare, physical and psychosocial well-being, sexual well-being, satisfaction, emotional outcomes, as well as functional outcomes [36, 37]. Another frequently used instrument is the Breast Cancer Treatment Outcome Scale (BCTOS) which has 22 questions focusing on breast cosmetic status, functional status, and breast pain in the treated area compared to the untreated area[38]. The BCTOS has been validated for BCS and adjuvant RT in patients with early-stage breast cancer. A shorter version, BCTOS 12, consolidated the number of questions but has only been validated in BCS, while the Dutch BCTOS 13 also includes skin outcomes pertinent to adjuvant RT [39, 40].

For more global QOL and health related QOL, frequently used instruments include PROMIS, EORTC QLQ-C30, FACT-G (and B), and others. The Patient Reported Outcomes Measurement Information System (PROMIS) is also PRO for physical, mental and social health and global health [41]. The European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 assesses general healthcare related QOL (HRQOL) in cancer patients and has an updated breast specific module (BR45) which can be used in conjunction with the QLQ-C30 module [42, 43]. The Functional Assessment of Cancer Therapy (FACT) has a general health (FACT-G) with 27 core items and a breast specific (FACT-B) module which measures domains of HRQOL including physical, social, emotional, and functional well-being in 37 items [44]. For greater details regarding commonly used PROs in breast cancer research please see the reviews by Alcorn et al. and McCammack et al [2, 45].

Clinical trials including EUROPA, FABREC, and CAMERAN have started to use PROs as a primary or co-primary endpoint. EUROPA was a non-inferiority phase III RCT that randomized patients over 70 with early-stage breast cancer to endocrine therapy or radiation [46]. One of the co-primary endpoints was change in HRQOL evaluated by EORTC QLQ-C30 at 2 years, with interim results demonstrating a greater reduction in HRQOL with endocrine therapy [46]. FABREC was a RCT comparing standard to hypofractionated postmastectomy radiation (PMRT) with a primary endpoint of physical well-being (PWB) domain of

FACT-B at six months and finding no significant difference between the two groups [47]. The CAMERAN trial is an ongoing phase II trial comparing endocrine therapy to partial breast irradiation for early stage breast cancer in patients over the age of 65 after breast conserving surgery with a primary endpoint of QOL at 1 year (NCT05472792). Other major trials including DEBRA (NCT04852887), EXPERT (NCT02889874), RT CHARM, IMPORT-LOW, COMET, INSEMA, TAILOR RT (NCT03488693) have PRO data as at least a secondary endpoint in their analyses [48, 51]. The phase III RCT, IMPORT-LOW, reported PROs at 5 years with whole or partial breast radiation and found that the average number of adverse effects (AEs) per person was lower in the partial breast and reduced-dose groups but that these decreased over time in all groups. They also identified baseline predictors for subsequent AE reporting including younger age, larger breast size/surgical deficit, lymph node positivity and higher levels of anxiety/depression [48]. The patient-reported information from these trials comparing types of treatments is essential for guiding patients through different options during the shared decision-making process.

Apart from being informative, providers have questioned whether PROs may also be actionable and/or predictive of certain behaviors or outcomes, and ultimately able to improve care. Do certain PRO responses suggest groups of people who may have greater difficulty tolerating certain therapies? Are others with a given PRO response at a higher risk for worsened toxicity based on their current experience or their baseline PRO? The STAR trial remotely tracked PRO-CTCAE data in patients with metastatic cancer and alerted clinic staff based on certain response criteria indicating worsening or severe side effects. Patients with PRO tracking had improved HRQOL and fewer hospitalizations [52]. Subsequently, PRO-TECT was a cluster randomized trial at 52 oncology practices which administered electronic PROs (ePROs) with PRO-CTCAE to patients with metastatic cancer on systemic therapy. While there was no difference in survival, time to first emergency visit and deterioration was delayed with PROs and both symptoms and HRQOL (by the EORTC QLQ-C30) were more favorable in the PRO group [53]. Approximately 77% of participants also felt that PROs improved discussions with the care team, 84% said PROs made them feel more in control of their care, and 91.5% would recommend PRO survey completion to other patients [53, 54]. Among oncologists, 91% found PRO information useful and 65% used these outcomes to guide discussions or make treatment decisions [55].

The IMPROVE trial was a single-arm prospective trial in which patients with thoracic or gastrointestinal cancer completed PRO questionnaires before their RT on treatment visit (OTV). Their physician also clinically assessed toxicity and then re-rated this after PRO review. In this trial, radiation oncologists changed their toxicity burden assessment in 75% of patients and their on-treatment management in 50% of their patients [56]. Using the BREAST-Q, one analysis of survey data found that there was worsened long-term sexual well-being in mastectomy + reconstruction (Mast + Recon) than BCS + RT but that patients $\geq 65$ with BCS + RT reported greater QOL while patients $< 50$ reported greater QOL with mast + recon [57, 58]. A systematic review and meta-analysis of 45 RCTs between 1996 and 2022 found that PRO inclusion likely reduced risk of overall mortality and improved HRQOL at 12 weeks [59]. Another meta-analysis of PROs from 2013 to 2018 including any research design (138 studies) found that majority had at least 1 PRO statistically significantly prognostic for OS. They found EORTC QLQ-C30 was most frequently used and physical functioning scale was the most frequently independent prognostic PRO [60]. Patient experience of the consultation also seems to make a difference as a higher patient reported experience of care including communication, care coordination, and other aspects of care were more likely to receive any type of radiation [61]. Knowledge of this data can help inform physicians of differences in PROs that may influence decision making and can be particularly helpful in situations that otherwise have clinical equipoise.

Finally, the financial burden and cost of treatment also plays a key role in informing decisions. Financial toxicity is frequently assessed with the PRO instrument Functional Assessment of Chronic Illness Therapy-COmprehensive Score for financial Toxicity (FACIT-COST) [62, 63]. This was developed with 12 items but a single-item screener of “My illness has been a financial hardship to my family and me,” has also been utilized [64]. In one survey, higher financial toxicity was associated with lower HRQOL (by FACT-G) and greater psychological distress [65].

## Clinical Scenarios

**Adjuvant therapy for early-stage HR + breast cancer in patients over 65** The option for radiation omission is supported by data from CALGB 9343 and PRIME II, which demonstrated slightly increased risk of locoregional recurrence with endocrine therapy alone but without effect on overall survival, breast cancer mortality, and distant metastasis [66, 68]. In our experience, these conversations can be particularly overwhelming as we discuss the options for surgery, radiation, endocrine therapy alone, or the possibility of radiation alone on the aforementioned CAMERAN trial at our institution. The above decision aids could be helpful for patients to help guide through options and weigh risks and benefits for a preference-sensitive decision. Instruments such as the MMS and CPS also could help inform the physician as to how the patient typically prefers to make medical decisions. Further, e-Prognosis could be particularly helpful in this scenario to help both the physician and patient understand their baseline comorbidity risk. Using these tools as well as PRO data such as that from EUROPA and to come from CAMERAN, one could be equipped to help patients make a preference-sensitive decision.

**Treatment for ductal carcinoma in situ (DCIS)** DCIS treatment also has many reasonable options and thus enhancing shared decision-making and amplifying the patient's voice and preferences is critical. There have been efforts to risk stratify DCIS, which previously largely included clinicopathologic factors such as age, HR status, grade, size, margins, etc. Nomograms exist to help estimate risk of ipsilateral breast tumor recurrence (IBTR) in different scenarios, however, even with nomograms and clinicopathologic factors, it can be difficult to identify low-risk groups who do not have a clinically meaningful benefit to RT [69]. Thus, there have been efforts to create tools to better identify and stratify low-risk DCIS using genomic and biomarker information in addition to clinicopathologic factors, such as Exact Sciences Oncotype DCIS score and the PreludeDx DCISion RT [70, 75]. Apart from influencing treatment recommendations, one study of the Oncotype DCIS score found that the tool also reduced treatment decisional conflict and anxiety in patients (by the DCS) and the State-Trait Anxiety Inventory (STAI) [76]. The Comparing an Operation to Monitoring, With or Without Endocrine Therapy for Low-Risk DCIS (COMET) Trial is a randomized prospective noninferiority trial comparing active monitoring with guideline-concordant care [51]. Interestingly, by 6 months of randomization, over half of >900 enrolled patients had opted against their randomized treatment, with majority coming from those randomized to guideline-concordant care [51]. One could speculate that based on this information alone, there may be a strong patient interest in non-surgical or non-invasive management options even if there could be some associated risk (or if, in a trial setting, that risk may be not entirely known or quantified). The LORD-trial is a non-randomized patient preference trial for women with low-risk DCIS to choose between active surveillance and conventional treatment. As participants had the ability to choose their arm, distribution was compared to look for patterns of motives and preferences. Majority of the women chose active surveillance (AS) with the most cited reasons being "treatment is not (yet) necessary)" and "trust in the plan" [77]. Those opting for AS reported experiencing shared decision-making more frequently than those choosing conventional therapy [77]. These trials highlight the importance of shared decision-making in the setting of DCIS treatment, both on and off trial.

## Conclusion

When sorting through multiple appropriate and reasonable options, it is of utmost importance to engage patients and elicit their values and priorities. However, while seemingly straightforward, this task can be challenging to adequately perform in single, usually time-limited, appointments that are often times emotionally charged and overwhelmingly dense with new information for patients. This review sought to discuss the importance of patient-centered encounters and discussions, define preference-sensitive decision making and guidance, and reflect on some of the ways in which the patient's voice plays a role in breast cancer treatment at both an individual level in the clinic and a population level in the form of patient reported outcomes on trials, and introduce tools such as questionnaires that may be able to inform clinicians of patient preference.

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