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Developing a patient decision aid for women aged 70 and older with early stage, estrogen receptor positive, HER2 negative, breast cancer

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ABSTRACT

Objectives: Since women ≥70 years with early stage, estrogen receptor positive (ER+), HER2 negative breast cancer face several preference-sensitive treatment decisions, the investigative team aimed to develop a pamphlet decision aid (DA) for such women.
Materials and methods: The content of the DA was informed by literature review, international criteria, and expert feedback, and includes information on benefits and risks of lumpectomy versus mastectomy, lymph node surgery, radiotherapy after lumpectomy, and endocrine therapy. It considers women's overall health and was written using low literacy principles. Women from two Boston-based hospitals who were diagnosed in the past 6–24 months were recruited to provide feedback on the DA and its acceptability. The DA was iteratively revised based on their qualitative input.
Results: Of 48 eligible women contacted, 35 (73%) agreed to participate. Their mean age was 74.3 years; 33 (94%) were non-Hispanic white; and 24 (67%) were college graduates. Overall, 26 (74%) thought the length of the DA was just right, 29 (83%) thought all or most of the information was clear, 32 (91%) found the DA helpful, and 33 (94%) would recommend it. In open ended comments, participants noted that the DA was clear, well-organized, and would help women prepare for and participate in treatment decision-making.
Conclusions: The investigative team developed a novel breast cancer treatment DA that is acceptable to women ≥70 years with a history of ER+, HER2-, early stage breast cancer. Next, the DA's efficacy needs to be tested with diverse older women newly diagnosed with breast cancer.

1. Introduction

About 30% of all breast cancers in the United States now occur in women age 70 years or older due to population aging and breast cancer incidence increasing with age [1]. The majority of these women are diagnosed with small (less than three centimeters [cm]), estrogen receptor (ER) positive, human epidermal growth factor receptor two negative (HER2-), clinically lymph node negative breast cancers [2]. Standard treatment options for these individuals in the past were mastectomy or breast-conserving surgery (BCS) with axillary node surgery (dissection or sentinel node biopsy), with BCS followed by radiotherapy (RT). Locoregional therapy was followed by hormonal therapy (HT). However, recent prospective and randomized trials have found that RT after BCS or lymph node surgery may often be omitted without impacting older women's survival, especially for those patients with multiple comorbidities, and omitting these therapies can help reduce treatment morbidity [3–5].

Despite this, approximately two-thirds of such older women receive RT after BCS and approximately three-fourths receive lymph node surgery, including many with short life expectancy and little chance of benefit [6–10]. One reason that these older women may agree to such treatments despite little chance of benefit is the challenge of understanding and weighing the benefits and risks of their treatment options. Many patients also overestimate their risk of recurrence [11,12].

Decision aids (DAs) are educational tools used to inform patients about the benefits and risks of treatment options. DAs have been shown to increase patient knowledge, participation in decision-making, and decision quality [13]. They also reduce overtreatment, since well-informed patients often choose not to receive care associated

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with little benefit [14]. However, there are no DAs specifically designed to help women age 70 years or older incorporate their health and preferences into their breast cancer treatment decisions.

The investigative team developed a workbook DA on breast cancer treatment for women age 70 years or older newly diagnosed with ER positive, HER2 negative, clinically lymph node negative breast cancers smaller than three centimeters to fill this gap and then tested the DA's comprehensibility and acceptability among older women with a history of these types of breast cancers.

2. Materials and Methods

2.1. DA Development

Development of the breast cancer treatment DA was guided by the Ottawa Decision Support Framework, which incorporates theories from psychology, the decision sciences, and economics [15,16]. A paper format was chosen for the DA based on older women's expressed preferences and since paper-based DAs have been shown to have equivalent effects on behavior and tend to be associated with greater satisfaction and use than web-based DAs among adults older than 50 years [17,18].

Following low literacy principles, the DA uses plain-language, short sentences, large fonts (fourteen point or greater size font), color, an abundance of white space, and avoids medical jargon [19,20]. Based on expert recommendations for supporting decision-making in older adults, the DA uses lists to present information; makes the "gist" or meaning of numerical information clear; focuses on the most critical information to avoid information overload; and repeats essential information [21–23]. To convey risk information, the DA uses words, numbers, and pictographs. The pictograph is the graphical format most recommended for patients with low numeracy [24,25]. The pictographs used in the DA shade the number of patients out of 100 women likely to experience an event over ten years. All pictographs use the same denominator and time period for each outcome to maximize comprehension [24]. The DA also uses simple diagrams rather than photographs of actual women to show post-operative scars, based on older women's preferences [26]. The DA is written at a sixth grade reading level as measured by the Flesch-Kinkaid Grade Level scale.

Since older women face multiple interconnected treatment choices, the DA was designed to be comprehensive. Therefore, it includes information on surgical, radiation, and endocrine therapy choices. Data from randomized controlled trials that included older women and (when possible) meta-analyses of such trials were used to inform the content of the DA. When such data were not available, data from observational studies were used (e.g., the frequency of experiencing treatment side effects). The DA is available in the Appendix, with justification and references for the included information.

The DA also includes a validated mortality index (ten items) so that users may calculate their health score and consider their health in treatment decisions [27]. This index has been used successfully by older women in a DA on mammography screening for women 75 years or older [17]. Women who score less than ten points on the mortality index are categorized as being in "good" health while those who score fifteen or more points are categorized as being in "poor" health [27]. While scores on this index are associated with life expectancy (e.g., women who score ten or more are estimated to have less than ten year life expectancy), the DA does not inform women of their estimated life expectancy so as not to increase anxiety. The DA also includes a value clarification exercise (e.g., please answer from one to ten how important is it to you to avoid radiation treatment) since such exercises have been shown to help elicit patient preferences and encourage communication [24,28]. The DA also asks users their treatment preferences and includes eight question prompts (i.e., example questions to ask one's doctor).

2.2. Evaluation

Initially, the investigative team presented the DA to four multidisciplinary breast cancer groups in the Boston area (one academic medical center, one comprehensive cancer center, and two community hospitals) that included surgeons, radiation and medical oncologists, nurses, and social workers. The investigative team also sent a draft of the DA to ten experts in diverse and relevant fields to review early drafts of the DA including two experts in geriatric oncology, two patient advocates, two experts in medical decision making, a prominent breast surgical oncologist, a community based oncologist, a nurse oncologist, and an expert in health literacy. Changes to the wording and/or content of the DA were recommended by each expert and by clinicians at each presentation. The DA was revised based on their feedback. Women aged 70 years or older without dementia, able to read and write in English, who were diagnosed with a first primary ER positive, HER2 negative, clinically and/or pathologically lymph node negative, breast cancer smaller than three centimeters in the past six to twenty-four months were then recruited between September 2016 and July 2017 from the Dana-Farber Cancer Institute and Beth Israel Deaconess Medical Center (both members of the Dana-Farber-Harvard Cancer Center in Boston) to provide feedback on the DA and its acceptability. Women who scored >9 on the Orientation-Memory-Concentration Test (indicative of dementia) were also excluded [29]. The study was approved by the institutional review board of the Dana-Farber Harvard Cancer Center and the research met the requirements for protection of human subjects. Once a potentially eligible woman was identified, a research assistant emailed her physician to obtain permission to contact the patient and to confirm eligibility. Women approved for contact were sent an informational letter about the study and a number to call to opt-out. Women who did not opt-out were called to confirm eligibility and assess their willingness to participate. A research assistant met women who were interested in participating in person to obtain feedback on the DA. If a family member was involved in the participant's care, s/he was also invited to participate. After confirming women's capacity to participate and obtaining written informed consent the research assistant began the interview. All interviews were audio-recorded. The interview guide (see Appendix) included closed-ended questions about the DA's length, balance, clarity, usefulness, preparation for decision making (ten item scale scored from one [Not at all] to five [A great deal]) [30], and whether it was anxiety provoking. It also asked participants about their sociodemographic characteristics, numeracy [31], and health. The interview guide also included open ended questions about what participants liked and disliked about the DA and how they would improve it. The DA was iteratively revised by the investigative team based on participant feedback.

2.3. Analyses

SAS statistical software (version 9.4) was used for descriptive analyses. Interview audio recordings were transcribed verbatim and analyzed using NVivo 11 (QSR international) qualitative software. The investigative team conducted a thematic analysis to identify themes in the data related to the usability and acceptability of the DA [32,33]. Three investigators independently reviewed six of the initial transcripts to develop a codebook. Codes were generated inductively (i.e., they emerged from the text). After the open coding process, the investigative team met to organize codes into larger categories to reflect major themes in the data. Disagreement about the meaning of themes or codes were discussed by the research team and resolved by consensus. Once a codebook was established, subsequent interviews were coded in detail by at least one investigator. As new themes emerged, new codes were developed and previously coded interviews were recoded. Participants were interviewed until no new themes emerged from interviews and thematic saturation was reached [32]. Direct quotes from the data are used below to illustrate the themes that emerged.

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3. Results

Thirty-five of 48 women (73%) contacted, who met eligibility criteria, agreed to participate. Of the thirteen women who chose not to participate, seven reported that they were too busy, four were not interested, one became flustered completing the Orientation-Memory-Concentration test used to assess cognition and stopped answering eligibility questions, and one had a negative experience with treatment and did not want to share. Table 1 presents the sample characteristics. The mean age was 74.3 years (standard deviation, 3.3 years). Thirty-three (94%) were non-Hispanic white, twenty-four (69%) were college graduates, and three (9%) had an estimated life expectancy of less than ten years. Only three patients (9%) had cancers larger than two centimeters; and twenty-one (83%) were grade 1 or 2. All but one were treated with BCS, twenty (59%) of whom also had RT. Thirty women (86%) had a sentinel lymph node biopsy. Thirty women (86%) received ET. Two patients received chemotherapy in addition to BCS, RT, and ET. Two patients (6%) were treated with BCS alone. Four family members participated; their comments about the DA were included in qualitative analyses.

Table 1
Sample characteristics ($n = 35$)[a].

Characteristics	
Mean age	74.3 years (+/− 3.3)
Non-Hispanic white, n (%)	33 (94%)
Education	
Completed high school, n (%)	2 (6%)
Some college, n (%)	9 (26%)
Completed college, n (%)	10 (29%)
Beyond college, n (%)	14 (40%)
Currently married, n (%)	22 (63%)
Lives alone, n(%)	8 (23%)
Health	
Excellent/Very good, n (%)	27 (77%)
Good, n (%)	6 (17%)
Fair/poor, n (%)	2 (6%)
<10 year life expectancy, n (%)[b]	3 (9%)
Recruited from	
Cancer center, n (%)	11 (31%)
Academic hospital, n (%)	24 (69%)
Mean subjective numeracy (1–7)	3.96 (±1.2)
MacArthur socioeconomic scale ladder (1 [worst off] to 10 [best off])	7.2 (+/− 1.3)
Confidence completing medical forms by yourself:	
Extremely confident, n (%)	31 (89%)
Quite a bit confident, n (%)	2 (6%)
Somewhat confident, n (%)	2 (6%)
Treatment[c]	n (%)
Mastectomy+ET	1 (3%)
BCS + RT + ET + chemotherapy	2 (6%)
BCS + RT + ET	16 (46%)
BCS + RT	2 (6%)
BCS + ET	12 (34%)
BCS	2 (6%)
Sentinel node biopsy	30 (86%)
Tumor characteristics	n (%)
How breast cancer was detected:	$N = 25$ responded
Found on screening mammogram	21 (84%)
Patient felt a lump	4 (16%)
Size	
0–0.5 cm	6 (17%)
>0.5–1 cm	12 (34%)
>1–2 cm	14 (40%)
>2–3 cm	3 (9%)
Grade	
1	14 (40%)
2	15 (43%)
3	6 (17%)

[a] Not all proportions add to 100% due to rounding.
[b] Calculated using the Schonberg mortality index. Scores of 10 or more suggest >50% mortality in <10 years.
[c] Abbreviations: ET = Endocrine Therapy; BCS=Breast Conserving Surgery; RT = Radiotherapy.

Table 2
Acceptability of the decision aid ($n = 35$).

Measure of acceptability	
Length	
Just right, n (%)	26 (74%)
Too long, n (%)	7 (20%)
Too short, n (%)	2 (6%)
Information	
Just right, n (%)	22 (63%)
More than needed, n (%)	7 (20%)
Less than needed, n (%)	6 (17%)
All information in DA clear, n (%)	15 (43%)
Most information in DA clear, n (%)	14 (40%)
Some information in DA clear, n (%)	3 (9%)
Information in DA unclear, n (%)	3 (9%)
Balanced, n (%)	28 (80%)
Slated towards radiation, n (%)	4 (11%)
Slated against radiation, n (%)	2 (6%)
Don't know, n (%)	1 (3%)
Understood all of the information, n (%)	25 (71%)
Understood most of the information, n (%)	10 (29%)
At least a little helpful, n (%)	32 (91%)[a]
Would recommend it, n (%)	33 (94%)
Reading DA made me	
A little anxious, n (%)	7 (20%)
Not at all anxious, n (%)	28 (80%)
Prepared me for decision making (mean, +/− SD)	4.0 (±1.0)
Preferred format	
Paper, n (%)	21 (60%)
Computer internet, n (%)	2 (6%)
No preference, n (%)	10 (29%)
Other, n (%)	2 (6%)
When would you like to receive DA:	
Mailed ahead of visit, n (%)	15 (43%)
In waiting room before visit, n (%)	5 (14%)
Doctor give during the visit, n (%)	7 (20%)
Staff give after a visit, n (%)	4 (11%)
At time of diagnosis (from PCP), n (%)	3 (9%)
No preference, n (%)	1 (3%)

Table 2 presents information on the DA's acceptability. Overall, 26 (74%) women thought the length of the DA was just right, while seven (20%) thought it was too long, and two (6%) thought it was too short. Twenty-two (63%) thought the amount of information in the DA was just right while seven (20%) thought it had more information than needed and six (17%) felt more information would be helpful. Twenty-nine (83%) thought all/most of the information in the DA was clear. Thirty-two women (91%) found the DA helpful, and thirty-three (94%) would recommend it. On average women thought it would help them prepare for decision-making with their doctors quite a bit (mean of 4.0 [range 1–5] on preparation for decision-making scale). Twenty-eight (80%) felt that reading the DA did not make them anxious, while seven (20%) felt that it made them a little anxious. Twenty-three (66%) felt that women should receive the DA before seeing their surgeon, including three who would prefer to receive it from their primary care physician, while eleven (31%) felt that women should receive the DA during or after their first surgical encounter (one woman had no preference). Twenty-one women (60%) preferred a paper DA, while two women preferred that the DA be on the internet (6%); ten women (29%) had no preference.

Table 3 presents themes related to older women's and their family members' comments about the DA and treatment decision-making. Participants felt it was important that treatment for older women be individualized and that women's overall health be considered. Many felt that their treatment decisions were made by their doctors (especially with regards to surgical treatment) and several noted that decision-making around RT after BCS was challenging ("the biggest decision in the whole process, everything else was simple").

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Table 3
Themes related to treatment decision making and thoughts on the decision aid.

Themes	Example quotes
Themes related to treatment decision making in general	
Doctor makes the decision	"I would have done whatever my doctor tells me, doesn't matter what the data says." "I don't think I was even given a choice, they just told me."
Family members involved	"Especially for a woman over age 70 to have a family member there to gather this information. It's important to have another set of ears." "Some women don't decide, the family does."
Perceptions of mortality	"I don't think about what's going to happen in 15–20 years, I live for today." "You want to live and it's all based on that."
Individualized treatment	"For a woman over 70, I think that would be such an individual thing. There are some who are a young 70 and some who are an old 70." "Not everyone will be recommended the same thing. It's not one-size fits all."
Aging/health	"The other thing is when you look at a 10-year window, for women over 70, they do die from other causes. The aging thing plays a role." "It's important to think about our health when we are diagnosed with breast cancer."
Themes related to the decision aid	
Helpful	"I would have loved to have something handed to me like this." "I thought this was excellent. It gives you a feel that there are options."
An adjunct to a visit	"I would use it in conjunction with the live doctor's appointment that I had." "Helpful as a kind of summary after you have spoken to the doctor."
May review on your own	"I would want time to study it without the pressure that the doctor will call me in a few minutes." "Having something to read at your own pace and absorb is helpful."
Learned something new	"Oh, boy, I never knew a lot of these thing." "This is a nice little booklet, I am learning things."
Increases patient engagement	"You're giving people the license to tell this to the doctor, to say I don't want this." "After the person has this they can be more involved with decision making."
Increases family member engagement	"It's a good way [the DA] for the patient to tell the family members I don't want to do any of this. I just want to live the rest of my life without damage." "There is enough to help the woman decide, but to also help her family decide."
Mastectomy vs. lumpectomy helpful information	"This is excellent when it comes to choosing which breast cancer surgery you should have." "I like the comparison between lumpectomy and mastectomy."
Lymph node testing helpful information	"I learned more about lymph nodes than I ever had before going through this." "This is interesting. They took mine out I don't think I had an option, I am learning something."
Radiotherapy helpful information	"This was the biggest decision in the whole process, everything else was simple." "I believe that you would use this to decide whether or not to have radiation. Until I read this, I never considered not having radiation."
Endocrine therapy helpful information	"I would find the difference between the tamoxifen and estrogen-inhibiting drugs very useful and interesting." "This section on medication and hormones was exceptionally well done, perhaps the best part of all."
Question prompts helpful	"You don't know what even to ask so these help you think about what to even ask." "Those are all excellent questions, excellent."
Varying views of the amount of information	"It's just right, you are covering it all without it being so heavy." "I think there are a lot of woman who would read this and just be overwhelmed by the amount of information."
Clear	"It was clear and concise and easy to read." "It was easy to understand and right to the point.
Well organized	"You communicated a lot of information effectively, with power points and bullets, it was just fine." "I like the fact that it is big print and the colors."
Varying views on pictographs	"I am not too sure about these graphs. It is convoluted and I would rather see something in writing." "I am more visual. You actually picture the number of people in each category down here."
Literacy	"It was very organized and basic looking so you can use it for a variety of [education] levels." "I thought it was just right and clearly presented. You don't need a college degree to figure it out."
Psychological effect varies	"Reading that pamphlet before would cause me to feel very anxious, so maybe at the doctor's office." "It answered questions and to me would relieve anxiety."
Varying views regarding timing of the DA	"If I got it before I saw the doctor, I would have thought it would be helpful. I would have been a lot more knowledgeable, and wouldn't have had to take as much time with her [the doctor]." "After talking with the surgeon, it would have been fine. It might have been overwhelming to get it beforehand."
Other sources of information	"Because I got all my info from ACS I had to go through this mass of information and condense it and you have done all that." "I like information so it would have been helpful, otherwise I would go on the internet and try to find it all."

When reflecting on the DA, most felt it was very helpful ("I wish I had this"), clear, and organized. They thought it would be a useful summary that they could review on their own and/or with family. Several noted that they learned something new reading the DA and felt that it would help women "be more involved with decision-making." They also felt that it would be appropriate for women regardless of educational attainment. They found the information on BCS versus mastectomy, RT after BCS, side effects of tamoxifen versus aromatase inhibitors, and the question prompts particularly helpful. While many participants commented that it would be useful to receive the DA before their initial surgical encounter to prepare for the visit, others felt that it would be too overwhelming until after their surgeon had introduced the concepts.

The investigative team made many changes to the DA based on participants' comments, as detailed in the Appendix Table 2. To improve clarity, the DA was revised to be used for women with Stage I breast cancer only (tumors two centimeters or smaller). Also, the DA was divided into two parts to reduce the amount of information that a woman would need to read at any one time. Part one focuses on locoregional therapy, and Part two focuses on ET. While the DA initially compared outcomes between mastectomy and BCS in a table, women found the table overwhelming and confusing. Instead, the DA now summarizes the differences between mastectomy and BCS using text. The cover page and introduction to the DA were also revised to be more comforting to women.

Participants had mixed feelings about the use of pictographs in the DA. Some felt strongly that the pictographs helped them, while others felt strongly that they were confusing. To meet the needs of diverse users, both text and pictographs were retained in the DA to explain the likely outcomes of RT after BCS and of ET. In addition, the DA originally included information on what women age 70 years or older generally choose for treatment, but women found this information prescriptive. As the DA was revised, feedback on its acceptability became increasingly more positive.

4. Discussion

A 2016 systematic review identified twenty-three individual DAs on breast cancer treatment and another web-based DA regarding local-regional therapy appeared subsequently [34,35]. None of these DAs were designed to help women age 70 years or older weigh the benefits

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and risks of treatment options based on their health and preferences. Only a few of these DAs are currently being used, either because they are not accessible, are no longer current, take too long to complete, require access to a computer, and/or are written at a high literacy level [36]. The current DA was designed to overcome these barriers. However, to learn the effects of this DA and to inform its implementation, it will need to be tested in a large randomized controlled trial with diverse older women seen at diverse medical centers. If the DA is efficacious, the investigative team will make it easy to print from the web (e.g., at the ePrognosis website) and will keep it up to date. The paper format allows for revisions to be made easily and inexpensively. Reassuringly, there are increasing examples of breast cancer treatment DAs successfully being implemented even in practices with few resources [37,38]. Also, national policy is becoming increasingly supportive of shared decision making and the National Academy of Medicine (formerly known as the Institute of Medicine) supports the development of DAs for facilitating high-quality cancer care [39,40].

Undertreatment of breast cancer in older women has been a longtime concern, but there is increasing recognition that overtreatment is also an issue for the population to whom our DA is directed [41]. Recognizing that it can take more effort to advise a patient that they do not need a treatment than it does to recommend it [42], numerous experts have called for decision support to help older women make informed and individualized decisions [12,43,44]. However, no such decision support exists. As a result older women are often poorly prepared to participate in breast cancer treatment decisions and/or to communicate their preferences and needs to their physicians and as a result may be overtreated [45]. The investigative team has designed a promising DA to help older women and involved family members weigh the benefits and risks of their treatment options based on their health and preferences.

While many older women in this study noted that the major decision they faced was whether or not to have RT after BCS, the DA includes information on surgical and endocrine treatment options since treatment decisions for older women are interconnected. Also, a Canadian study of a DA on RT after BCS for women age 65 years or older found that most women had already decided whether or not to have RT by the time they saw their radiation oncologist [46]. Therefore, a DA that helps inform decision-making about RT after BCS needs to get to women earlier in the decision-making process and as a result needs to also include information on surgical options. Also, many older women with low-risk breast cancers continue to undergo lymph node surgery despite the fact that the results of testing rarely change treatment decisions or survival outcomes and is considered low value care by the Choosing Wisely Campaign [8,9,47]. Therefore, it was important that the DA also include information on lymph node surgery. Since some women decide to have RT after BCS instead of taking endocrine therapy for five years, participants also felt it was important for the DA to include information on both treatments.

Based on participant feedback, the DA was divided into two parts to prevent information overload. The second part focuses on endocrine therapy and can be read after surgical treatment; however, interested women can always read both parts before surgical treatment if preferred. For women contemplating whether or not to undergo surgical treatment, the section on primary endocrine therapy in part one of the DA refers users to the pages in part two of the DA that discuss the benefits and risks of endocrine therapy.

While pictographs have been shown to be an effective method of presenting frequencies, especially to patients with low health literacy, several women in this study preferred to read text rather than review a pictograph [24,25,48]. Others felt that the pictographs were very helpful. Prior research suggests that graphical formats assist in the perception, understanding and interpretation of quantitative information, even among older adults with low numeracy [24,49]. Therefore, the DA uses both pictographs and text to explain the outcomes of RT after BCS and of ET since these are two of the major treatment decisions older women with low-risk breast cancers face.

Participants had varying views on when women should receive the DA. While many thought it would be helpful to have the information before their first surgical encounter; others thought it would be too overwhelming and anxiety-provoking before meeting with their surgeon. Some participants thought it would be helpful to have the information to discuss their treatment choices with their primary care physician (PCP). This finding is consistent with other studies that have found that the majority of women prefer PCP involvement in their breast cancer care especially older women and those with comorbidities [50]. Future work should explore timing of delivering the DA and whether the DA helps facilitate communication between older women, their family members, and their care providers including PCPs.

This study had important limitations. Generalizability is limited because it was a small study conducted in one geographic area and the DA was tested in English only. Most participants were highly educated and non-Hispanic white which may partly be due to the fact that 90% of US women aged 70 or older diagnosed with early stage, ER+, HER2- breast cancers are non-Hispanic white [2]. Also, participants had already completed treatment decision making when they reviewed the DA, so their thoughts on how the DA would have affected them at the time of diagnosis were hypothetical and retrospective in nature. Therefore, a trial testing the DA among diverse older women newly diagnosed with breast cancer, including those who are Spanish speaking, is needed. The trial will also need to test whether the DA can be used by patients themselves and/or whether some patients (e.g., those with low health literacy) may need the help of family, a navigator, and/or other allied health professional to use the DA. The DA may need to be further revised based on the expressed needs of older women from diverse backgrounds and with lower health literacy levels.

In summary, there is a critical need for a DA to help older women, especially those with competing health issues, better understand their breast cancer treatment options and engage in treatment decisions. The investigative team has developed a promising DA that is acceptable to older women with a history of breast cancer. The DA now needs to be tested in a randomized clinical trial with a diverse population to inform broad implementation and integration of the DA into practice.

Conflicts of Interest

MAS declares that she has no conflicts of interest. RAF declares that she has no conflicts of interest. AR serves on medical advisory board EviCore and US Oncology's Ask the Expert panel. ARJ declares that she has no conflicts of interest. GMA declares that she has no conflicts of interest. MK declares that she has no conflicts of interest. FN declares that she has no conflicts of interest. EPM declares that she has no conflicts of interest. SEP declares that she has no conflicts of interest. RS declares that she has no conflicts of interest. LD declares that she has no conflicts of interest.

Authors' Contributions

MAS conceived and designed the study, interpreted the data, and drafted the initial manuscript. RAF, LSD, and FN made substantial contributions to the conception, design of the study, acquisition and interpretation of the data and read and substantively revised the manuscript. ARJ, GMA, and MK, made substantial contributions to acquisition and analysis of the data and read and revised the manuscript. EPM made substantial contributions to design of the study and read and substantively revised the manuscript. SEP and RS, made substantial contributions to the design of the study and acquisition of the data and read and substantively revised the manuscript. All authors read and approved the final manuscript.

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Availability of Data and Material

Data were entered as it was collected into REDCap (Research Electronic Data Capture), secure, web-based, data collection software. The datasets generated and/or analyzed during the current study are not publicly available to maintain participant confidentiality but are available from the corresponding author on reasonable request.

Declarations

The work described in this manuscript has not been published previously, is not under consideration for publication elsewhere, has been approved by all authors, and it will not be published elsewhere in the same form in English or in any other language, including electronically without the written consent of the copyright-holder. The study was approved by the institutional review board of the Dana-Farber Harvard Cancer Center. Informed consent was obtained from all individual participants included in the study.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jgo.2019.05.004.

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