Development and Evaluation of a Decision Aid on Mammography Screening for Women 75 Years and Older

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**IMPORTANCE** Guidelines recommend that women 75 years and older should be informed of the benefits and risks of mammography before being screened. However, few are adequately informed.

**OBJECTIVES** To develop and evaluate a mammography screening decision aid (DA) for women 75 years and older.

**DESIGN** We designed the DA using international standards. Between July 14, 2010, and April 10, 2012, participants completed a pretest survey and read the DA before an appointment with their primary care physician. They completed a posttest survey after their appointment. Medical records were reviewed for follow-up information.

**SETTING AND PARTICIPANTS** Boston, Massachusetts, academic primary care practice. Eligible women were aged 75 to 89 years, English speaking, had not had a mammogram in 9 months but had been screened within the past 3 years, and did not have a history of dementia or invasive or noninvasive breast cancer. Of 84 women approached, 27 declined to participate, 12 were unable to complete the study for logistical reasons, and 45 participated.

**INTERVENTIONS** The DA includes information on breast cancer risk, life expectancy, competing mortality risks, possible outcomes of screening, and a values clarification exercise.

**MAIN OUTCOMES AND MEASURES** Knowledge of the benefits and risks of screening, decisional conflict, and screening intentions; documentation in the medical record of a discussion of the risks and benefits of mammography with a primary care physician within 6 months; and the receipt of screening within 15 months. We used the Wilcoxon signed rank test and McNemar test to compare pretest-posttest information.

**RESULTS** The median age of participants was 79 years, 69% (31 of 45) were of non-Hispanic white race/ethnicity, and 60% (27 of 45) had attended at least some college. Comparison of posttest results with pretest results demonstrated 2 findings. First, knowledge of the benefits and risks of screening improved ($P < .001$). Second, fewer participants intended to be screened (56% [25 of 45] afterward compared with 82% [37 of 45] before, $P = .03$). Decisional conflict declined but not significantly ($P = .10$). In the following 6 months, 53% (24 of 45) of participants had a primary care physician note that documented the discussion of the risks and benefits of screening compared with 11% (5 of 45) in the previous 5 years ($P < .001$). While 84% (36 of 43) had been screened within 2 years of participating, 60% (26 of 43) were screened within 15 months after participating (≈2 years since their last mammogram) ($P = .01$). Overall, 93% (42 of 45) found the DA helpful.

**CONCLUSIONS AND RELEVANCE** A DA may improve older women's decision making about mammography screening.
n the US approximately 11.4 million women are 75 years and older, and this number is projected to almost double by 2030.1 Meanwhile, breast cancer incidence increases with age.2 While mammography screening has been shown to reduce breast cancer mortality by 15% to 25% for women aged 50 to 74 years,3-4 no mammography screening trial has included women 75 years and older.4 Screening may benefit some older women by detecting breast cancers early that otherwise would have resulted in major morbidity or mortality had treatment been delayed. However, screening may also cause immediate harm, including pain, anxiety, complications from follow-up tests (eg, breast biopsy), and overdagnosis (detecting tumors that are of no threat).5 Overdiagnosis is particularly concerning because complications from breast cancer treatment increase with age.6-7

Because of an estimated 10-year lag time to experiencing a mortality benefit but due to important risks of mammography that occur immediately,8 the American Cancer Society9 and the American Geriatrics Society10 recommend not screening older women in poor health and with short life expectancies. The US Preventive Services Task Force11 states that there is insufficient evidence to recommend mammography to women 75 years and older. The guidelines recommend that older women should be informed of the risks and benefits of mammography.9-11 However, few older women are adequately informed in practice.12 In many cases, the benefits of screening are overestimated, and the harms of screening are underestimated.13-14

Despite the need, no decision support is available to help women 75 years and older decide whether to continue undergoing mammography screening. Decision aids (DAs) are designed to help patients learn more about a medical intervention, clarify their values, and be more involved in decision making.15,16 The DAs may be designed in various formats (eg, booklets and web pages) and differ from the usual health educational materials because of their detailed focus on the options and outcomes of a decision.17 The use of DAs has been shown to improve medical decision making,15,16 and they are especially recommended when the ratio of benefits to risks of an intervention is uncertain,17 as is the case for mammography screening among women 75 years and older.

We developed a comprehensive, easy-to-read DA for women 75 years and older who are contemplating mammography that informs users of the risks and benefits of mammography and includes tailored information about health and life expectancy. We evaluated the DA in a pilot pretest-posttest trial to examine its effect on older women’s knowledge about mammography, decisional conflict, and screening decisions. In addition, we examined whether providing patients with the DA before a clinic visit leads to a more balanced discussion with their primary care physician (PCP) about mammography.

**Methods**

We developed a DA to help women 75 years and older with mammography screening decisions. We evaluated this DA in a pretest-posttest trial. Beth Israel Deaconess Medical Center’s Committee on Clinical Investigations approved this study. Once potentially eligible women were identified and PCPs gave their approval, we contacted women to inform them of the study and to obtain verbal informed consent for participation.

**Description of the DA**

We developed our DA in concordance with international standards.18,19 It used the Ottawa Decision Support Framework20 and considered older adults’ decision-making processes.21 To better understand older women’s decision-making and informational needs concerning mammography, our group had previously conducted a qualitative study.22 Because the current cohort of women 75 years and older tends to have low computer literacy,22 we chose a pamphlet format for the DA.

Our DA provides information on the entire screening process, including follow-up tests and treatment.17 It begins by explaining what its purpose is and who should read it (eg, it is not for women with a history of breast cancer). The eTable in the Supplement gives the justification and references for the content of the DA. Briefly, the information presented was collected by a literature review and includes data on the following: (1) breast cancer risk factors for women 75 years and older, (2) health and life expectancy, (3) likely outcomes if screened and not screened with mammography, (4) competing mortality risks, (5) breast cancer treatments, and (6) a values clarification exercise. The last page asks users their intentions of being screened on a 15-point validated scale and invites users to share this information with their doctor.23

To enhance clarity, we used at least a 14-point font, brief sentences, and a neutral tone.24 We described outcomes using words and frequencies. We presented frequencies using pictographs (icon arrays), in which there is a picture of 1000 circles, where each circle represents one woman, and we shaded in the number likely to experience an outcome.25 To maximize comprehension, we used the same denominator of 1000 (allowing us to show events as whole numbers) and time frame (5 years) for every outcome.24 We used positive framing (eg, 975 are screened but not diagnosed as having breast cancer) and negative framing (eg, 25 are diagnosed as having breast cancer).24

As recommended for the development of DAs,19 we assembled a 10-member expert panel (internists, geriatricians, health services researchers, and a psychologist) to review iterative versions. Once the expert panel approved a final version, we tested the comprehensibility of the DA among 5 older women who had recently decided whether to be screened. The DA was revised based on their feedback. We then tested the DA among 15 older women who were contemplating mammography and 5 of their PCPs recruited from a large academic primary care practice in Boston, Massachusetts. Additional edits were made based on their feedback. Throughout the pretest-posttest trial, we also made small, nonsubstantive changes to the DA to improve its clarity. The final version is 11 pages, filled with pictures, and written at a sixth-grade reading level (available in eAppendix 1 in the Supplement and by request from the author).
**Pretest-Posttest Trial**

**Study Sample**

Women were eligible for the pretest-posttest trial if they met the following inclusion criteria: (1) they were aged 75 to 89 years; (2) they did not have dementia (determined by the problem list, PCP communication, or a score exceeding 19 [indicative of severe impairment] on the Short-Blessed Test,26 which was administered before enrollment); (3) they had no history of invasive or noninvasive breast cancer; (4) they received care at a large general internal medicine or primary care geriatrics practice in Boston; and (5) they were scheduled for a visit with their PCP between July 14, 2010, and April 10, 2012. To target women contemplating screening, we further excluded women who had not been screened in 3 years, women who had been screened in the past 9 months, and women with documentation that they had declined future mammograms. While data increasingly suggest that it is appropriate to screen women biennially,27 many women undergo mammography annually, and we aimed to include women before their next mammogram.28

**Recruitment**

We identified women by reviewing PCP appointment logs. A research assistant (M.C.G.) administered the pretest survey. We then asked women to come to a routine appointment with their PCP early to read the DA. After reading the DA, which takes approximately 5 to 10 minutes, participants attended their scheduled visit. The PCPs were not required to discuss mammography. They were informed that their patients had received the DA and were sent the DA to review if preferred. After the visit, the research assistant administered the posttest survey. The PCPs were sent a separate survey, asking about their perceptions of the DA.

**Data Collection**

At baseline, we assessed participants’ race/ethnicity, educational attainment, health insurance, marital status, subjective numeracy,29 medical literacy (measured by the Rapid Estimate of Adult Literacy in Medicine7 [score range, 0-7, with higher scores indicating greater literacy]),30 and estimated life expectancy (measured using the index by Schonberg et al26,31 [a score of ≥8 indicates life expectancy of ≤9 years]). We assessed the outcomes in the pretest and posttest surveys (the instruments are available in Appendix 2 in the Supplement). All measures used are recommended to assess whether a DA improves decision making.16,18,32

**Outcomes**

**Knowledge About Mammography** | Knowledge about mammography was assessed by 10 questions (2 multiple choice and 8 true or false); 7 questions were adapted from other studies.33-36 Three questions were developed based on material in our DA and were cognitively tested with 10 older women before use. We summed the number of correct responses.

**Decisional Conflict Scale** | A validated 16-item scale was used to measure whether one perceives herself to be informed, certain and supported in her decision making, and clear about her values (eg, “I am clear about whether the benefits or risks of mammography are more important to me”).37,38 We calculated the total score and 5 subscale scores (uncertainty, informed, values clarity, support, and effective decision). Scores on each scale range from 0 to 100, with lower scores indicating higher-quality decision making.

**Screening Intentions** | A 15-point validated scale was used to assess one’s propensity to being screened. We categorized scores as 1 to 5 (yes), 6 to 10 (unsure), or 11 to 15 (no).25

**Decision-Making Role** | We assessed older women’s preferred role in decision making about mammography. Answers were categorized as shared, passive (deferring to the physician), or active (the patient makes the final decision).39

**Acceptability** | In the posttest survey only, we asked about the DA’s length, clarity, and balance and about whether it is anxiety provoking and whether participants would recommend it to a friend.40 We also recorded additional comments that participants made about the DA.

**Screening Discussions** | All participants’ PCP notes 5 years before participating and 6 months afterward were reviewed to identify any documented discussions about mammography. A 6-month follow-up period was chosen because we hypothesized that some women would ask their PCP about mammography at the next visit. We defined a balanced discussion as documentation beyond the typical notation endorsing mammography (eg, “mammogram recommended”). We categorized a woman as having received a balanced discussion about mammography if her PCP (1) documented a discussion of a limitation of screening (eg, “no data on benefit for this age”) or (2) documented that mammography was discussed and whether the patient chose to continue with screening. Authors (M.A.S., M.B.H., and E.R.M.) coded whether or not a balanced discussion had occurred. Two authors (M.B.H. and E.R.M.) were masked as to whether the relevant note was in the pretest or posttest period. The authors’ coding agreed on the first review except in 2 cases, and these were reconciled by consensus among the 3 authors.

**Screening** | Medical record abstraction was performed to examine the receipt of mammography screening at 15 months after participation. Medical record abstraction is considered the gold standard for assessing the receipt of mammography.41 We chose a 15-month follow-up period because it provided at least 2 years of data since the participants’ last mammogram (9 months [eligibility criteria] plus 15 months [follow-up data] equals 24 months since the last mammogram). Two years is the upper bound of the recommended screening interval for women among whom mammography is appropriate.11 We also captured any diagnostic mammograms performed. Screening performed outside of the health system is captured in preventive health sheets or PCP notes. All medical records were reviewed twice by one of us (M.A.S.), with the second time at least 20 months after patients had participated to capture mam-
mammograms completed during the 15-month follow-up period but entered later in the medical record.

**Statistical Analysis**

The Wilcoxon signed rank test and McNemar test were used to compare pretest-posttest information. We further examined the effect of the DA on screening decisions among older women stratified by life expectancy (≤9 vs >9 years). 31 We examined whether the acceptability of the DA differed by educational attainment using bivariate statistics. We aimed to recruit 42 participants to detect a moderate effect size (0.6 times the estimated SD) of the DA on patient knowledge and decisional conflict, assuming a within-patient correlation of 0.1. A complete case analysis was performed. All analyses were completed using SAS statistical software, version 9.3 (SAS Institute Inc).

**Results**

We reviewed 326 patient records, of which 84 met the eligibility criteria (Figure). Among these 84 women, 27 declined participation, and 12 were unable to complete the study because of scheduling conflicts or hospital admission. Women who did not participate did not differ in age from those who participated (P = .20), and the 12 women who were unable to complete the study also did not differ from those who participated in educational attainment (P = .71). Table 1 summarizes the characteristics of the 45 participants.

Table 2 gives changes in outcomes after exposure to the DA relative to baseline. The posttest survey was administered immediately after the visit in 82% (37 of 45) of patients and was administered a median of 9.5 days (interquartile range, 4.5-14.5) after the pretest. Participants’ knowledge of the risks and benefits of mammography improved: women answered on average 1 (interquartile range, 0-2) more questions correctly on the 10-item index. After reading the DA, fewer participants intended to be screened. Among women with a 9-year life expectancy or less, a significantly lower proportion intended to pursue screening after reading the DA compared with before. In contrast, we found no difference in screening intentions among women with more than a 9-year life expectancy. Decisional conflict declined after reading the DA but not significantly. We also did not observe a significant change in the number of women preferring an active role in decision making after reading the DA.

Overall, 93% (42 of 45) found the DA helpful, 96% (43 of 45) would recommend the DA, 71% (32 of 45) said the length was just right (29% [13 of 45] said it was too long), and while 76% (34 of 45) found the amount of information just right, 22% (10 of 45) thought there was too much information. Forty-two percent (18 of 43) found the information balanced, 42% (18 of 43) found it slanted toward not getting a mammogram, and 16% (7 of 43) found it slanted toward getting a mammogram. All but 1 patient (98%) said they would prefer the DA to be on paper rather than a computer. Perceptions of the DA did not differ by educational attainment except that 44% (8 of 18) of women who had a high school education or less compared with 19% (5 of 27) of women who had attended at least some
college education reported anxiety after reading the DA (P = .07).

Among 25 PCPs of the 45 participants, 15 PCPs (60%) completed a survey about using the DA, 2 of whom completed the survey for 2 different patients (we used the first survey completed). Overall, 73% (11 of 15) of PCPs agreed that using the DA would allow their patients to make more informed decisions, 80% (12 of 15) agreed that the DA would help their patients make more value-laden decisions, and 93% (14 of 15) thought it would be helpful to patients. Sixty-seven percent (10 of 15) thought using the DA was better than their usual approach to mammography. While 87% (13 of 15) thought the amount of information in the DA was just right, 67% (10 of 15) reported it was too long. In addition, 67% (10 of 15) found the DA balanced, while 33% (5 of 15) found it slanted toward not getting a mammogram.

Table 3 summarizes the effect of exposure to the DA on PCP documentation of balanced discussions about mammography and on the receipt of screening. Fifty-three percent (24 of 45) of participants had a PCP note documenting a discussion of the risks and benefits of screening within 6 months of participating compared with 11% (5 of 45) in the previous 5 years (P < .001). Two women underwent diagnostic mammograms as their first follow-up test and were excluded from analyses that examined the receipt of screening. One of these women had a negative diagnostic mammogram, and the other was diagnosed as having stage I ductal carcinoma. Among the 43 remaining women, 84% (n = 36) were screened within 2 years before participating and 60% (n = 26) by the 15-month follow-up date (P = .01).

Discussion

Findings from this pilot study suggest that we have developed a promising DA that may improve older women’s mammography screening decisions. In a small sample of older women, our DA improved their knowledge of the risks and benefits of mammography, led to fewer older women intending to be screened (particularly those with a short life expectancy), and possibly resulted in fewer women with a short life expectancy being screened. Providing the DA before a visit with a PCP may also have led to improved patient-physician communication about screening.
Allowing older women to make an informed mammography screening decision is essential for high-quality care. Our DA may improve this process. To date, only one other study has examined the effect of a mammography screening DA among older women. The DA used in that study was designed to help women aged 70 years decide whether to continue screening. In Australia, although women aged 70 years and older may choose to be screened, only women aged 50 to 69 years are invited for screening; therefore, age 70 years is a decision point. The large trial demonstrated that the use of a DA increased older women’s knowledge about mammography but did not change their participation in screening, even among women in poor health. The DA used was also limited by its length and high literacy requirement. Unlike our DA, the DA used in that study did not discuss the influence of life expectancy, did not mention which breast cancer treatments may be offered to older women, and did not inform users about the uncertainty of a mortality benefit of mammography for older women. The inclusion of these features may be why exposure to our DA resulted in fewer older women, particularly those with a short life expectancy, choosing to be screened. Developing and testing a DA in the United States is particularly important because enthusiasm is high for cancer screening in this country.

Although most older women and their PCPs found our DA balanced, a substantial minority found it slanted toward not getting a mammogram. This may be due to years of public health messages and physicians emphasizing the benefits of mammography. In this setting, an educational tool that presents the risks and benefits of mammography may be perceived by some as biased against mammography. Also, there is some evidence that users of DAs perceive balance in the direction of the choice that they have made. In our study, 56% (9 of 16) of women who were not screened found the DA slanted toward not getting a mammogram compared with 36% (9 of 25) of women who were screened (P = .20). Some women who chose not to be screened said the DA provided them this option. They had privately wondered if they could stop being screened but assumed they needed to continue. Furthermore, perfect balance may not be achievable in a DA if the body of evidence surrounding a test tends to favor not getting the test, which may be true in the case of mammography screening for women 75 years and older. However, based on our findings, we will make changes to the DA to improve balance. We will add that most older women treated with lumpectomy do well. Also, based on an updated literature review, we may have overestimated the rate of overdiagnosis and will reduce our estimate (see the eTable in the Supplement for the justification). Despite perceptions by some that the DA was biased against screening, 63% (27 of 43) of women in our study chose to be screened after reading the DA, particularly those in good health.

Overall, we found a small, nonsignificant decline in decisional conflict after the participants read the DA. While reducing decisional conflict has traditionally been an important goal of DAs, some researchers argue that decisional conflict may promote appropriate deliberation. In the case of mammography, it is feasible that older women who were previously unaware of the limitations of mammography may be more conflicted about screening after reviewing the DA. Our results tended to show that after using the DA women perceived themselves to be more informed, clearer in their values, and more supported in their decision making; however, there was no change in the certainty about one’s choice. In line with these findings, 30% (13 of 44) of women found the DA to be anxiety provoking, particularly women with lower educational attainment. These women reported being anxious that if they chose not to get screened they would be disappointing their PCPs or deviating from societal norms. Our findings suggest that older women with lower educational attainment may need more support when using the DA or when engaging their PCP in shared decision making about mammography.

While most patients said the length of the DA was just right, 67% (10 of 15) of PCPs thought it was too long. An interactive web-based DA would allow users to focus on aspects of the DA that are helpful to them. Because we anticipate that future cohorts of older women will likely be more computer literate, we plan to develop and test a web-based version of the DA as a next step.

There are logistical challenges to using DAs in primary care, including inconsistent delivery by PCPs, limited time during clinic visits, and difficulty in identifying appropriate patients for use. To overcome these challenges, we had a research assistant (M.C.G.) act as a panel manager and identify appropriate patients for inclusion and provide patients with the DA before their PCP visit. Ideally for implementation, health systems

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<th>Table 3. Decision Aid Pretest and Posttest Data Obtained From Medical Record Abstraction</th>
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<td>Documented discussion of benefits and risks of mammography*</td>
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<td>Screened with mammography</td>
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<td>Overall (n = 43)</td>
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<td>≤9-y Life expectancy (n = 25)</td>
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<td>&gt;9-y Life expectancy (n = 18)</td>
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*We reviewed medical records from the 5 years before participating and up to 6 months after participating to see if there was a primary care physician note documenting a discussion of the benefit and risks of mammography.

In this table, we examined screening 15 months after participating because this follow-up time allowed for information at least 2 years since the participant’s last screening mammogram.

*We excluded 2 women whose first follow-up test was a diagnostic mammogram.
would have the infrastructure to identify eligible patients to read the DA before a visit. However, this is often not the case, and more work is needed to identify the best ways to implement decision support across a range of practices, especially for older adults. This is particularly important because the Patient Protection and Affordable Care Act explicitly promotes shared decision making and the use of decision support interventions.\textsuperscript{50} This study has important limitations. The generalizability is limited because it was a small, single-site study and because many of the participants were highly educated. We used a quasi-experimental design; therefore, changes in PCP discussions about mammography and decreases in screening rates could be due to secular changes. Moreover, 5 participants were aged 75 years, and a discussion about stopping mammography in the 5 years before participation may not have been appropriate. Knowledge may have improved because the post-test survey was the second exposure to the knowledge test. In addition, we cannot separate the effect of PCP knowledge of the DA from the effect of the DA itself; however, DAs are intended to supplement rather than replace physician-patient interaction.\textsuperscript{15,16} Finally, our power to adjust our analyses for multiple comparisons was limited in this pilot study.

Conclusions

We designed a novel DA to help older women with decision making about mammography screening. We next plan to test the efficacy of the DA in a large randomized clinical trial. The DA may lead to improved decision making regarding mammography, especially among older women with a short life expectancy who are least likely to benefit and are at greater risk of being harmed from screening.

REFERENCES

16. O’Connor AM, Stacey D, Entwistle V, et al. Decision aids for people facing health treatment or...


