Breast Cancer Surgery
Decision Quality Instrument User Guide

I. Purpose:
To measure the extent to which patients are informed, involved in the decision making process and receive treatments that match their goals and preferences.

II. Versions:
- Breast Cancer Surgery Decision Quality Instrument v2.0, ©2010 [updated 2012].
- Decision Quality Worksheet: For Breast Cancer Surgery v2.0, ©2010 [updated 2012].
- Hoja de Trabajo Sobre La Calidad de Decision en La Cirugia Para el Cancer de Mama v.2.0 ©2012 [Spanish version of Breast Cancer Surgery worksheet].

III. Timing
The decision quality instrument version is designed to be administered <u>after</u> a decision has been made. Modifications are required (e.g. to instructions and tenses of items) if it is to be used before a decision has been made.

The shorter worksheet version is worded to be used <u>during</u> the decision making process. The knowledge items and goals can be administered at any time, e.g. before or after a visit, before or after a decision aid. The decision process items need to be administered <u>after</u> a provider consult.

IV. Scoring:
The survey contains three sets of items and results in three scores, a total knowledge score, a concordance score and a decision process score.

1. Knowledge Score: The items are located in "Section 2: Facts About Breast Cancer Surgery." For each fact, a correct response receives one point (see Table 1). Questions with multiple parts (e.g. item 9 in Table 1) are scaled to total 1 point per item. Missing responses receive 0 points. A total score is calculated for all patients who complete at least half of the items. Total scores are scaled from 0-100%.

Table 1: Facts (# indicates items in the worksheet version)

Question	Correct response
#1. For most women with early breast cancer, how much would waiting a few weeks to make a treatment decision affect their chances of survival?	A little or not at all
#2. <u>With treatment</u>, about how many women diagnosed with early breast cancer will eventually die of breast cancer?	Most will die of something else
#3. After which treatment is it more likely that women will need to have another operation to remove more tumor cells?	Lumpectomy
4. How many women are <u>satisfied</u> with the way their breast looks after lumpectomy and radiation?	Most

Question	Correct response
#5. On average, which women with early breast cancer live longer?	There is no difference
#6. On average, which women have a higher chance of having cancer come back in the breast that has been treated?	Women who have a lumpectomy and radiation
7. After a lumpectomy, what is the usual schedule for traditional radiation treatment?	5 days a week for 5 to 6 weeks
8. Out of 100 women who have radiation after lumpectomy, how many will have a <u>serious</u> side effect, such as another cancer, heart or lung problem?	Fewer than 5
9. For each of the following, mark whether or not some women have this <u>side effect from radiation after lumpectomy</u>.	
9a. Is fatigue a side effect from radiation after lumpectomy?	Yes
9b. Is the breast skin looks darker a side effect from radiation after lumpectomy?	Yes
9c. Is the breast feels harder and thicker a side effect from radiation after lumpectomy?	Yes
9d. Are migraines a side effect from radiation after lumpectomy?	No
10. If cancer comes back in the treated breast after lumpectomy and radiation, how is it usually treated?	Mastectomy
11. If 100 women with early breast cancer have a <u>mastectomy,</u> about how many will have <u>breast cancer come back</u> in the treated breast area in the ten years after treatment?	2-10
12. If 100 women with early breast cancer have a <u>lumpectomy and radiation</u>, about how many will have <u>breast cancer come back</u> in the treated breast in the ten years after treatment?	5-15

2. Concordance score: In "Section 1: What Matters Most To You," patients rate their goals and concerns on an 11-point importance scale from 0 (not important at all) to 10 (extremely important). These questions and one question about patient's treatment preference can be used to calculate a concordance score. There are multiple approaches to calculate a concordance score, we describe two below. Note: for those who use the worksheet version, there must be some way to track the treatment that patients received to complete this calculation.

The first is a simple match, and in this direct approach, we use patients' preferred treatment (assessed with a single item, "Which treatment did you want to do to treat your early stage breast cancer?") and then compare with treatment received to determine whether they match. Patients who are unsure are not considered to have treatment that matches. A summary score (0-100%) indicating the percentage of patients who received treatment that matched their stated preference can be generated.

The second approach uses patients' ratings of the importance of salient goals and concerns on a 0 to 10 scale in a multiple logistic regression model to generate a predicted probability of surgery. The dependent variable is binary: Mastectomy versus Lumpectomy and the independent variables that remained significant in multivariable analysis were: three goals (keep breast, remove breast for peace of mind, and avoid radiation). Table 2 presents the parameter estimates for the model published in Sepucha et al 2012. Patients with a predicted probability ≥ 0.5 and who had a mastectomy and those with a predicted probability < 0.5 and who had lumpectomy, were classified as having treatments matching their goals. A summary score (0-100%) can be generated to reflect the percentage of patients in the sample who received treatments that matched their goals.

Table 2: Concordance model: analysis of maximum likelihood estimates

Parameter		DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept		1	-5.2726	0.7872	44.8633	<.0001
Stage	II	1	0.5926	0.3618	2.6828	0.1014
Keep breast		1	-0.2408	0.0563	18.3039	<.0001
Remove breast for peace of mind		1	0.6294	0.0810	60.4372	<.0001
Avoid radiation		1	0.2078	0.0525	15.6378	<.0001

3. Decision Process Score: These questions are located in the Decision Quality Instrument in "Section 3: Talking with your Health Care Providers" and in the Decision Quality Worksheet in "Section 3: Making Choices." Patients are asked about whether they were offered a choice, how much the pros and cons were discussed, and whether the health care provider asked for their preferences. Participants receive 1 point for a response of "yes" or "a lot/some." The total points are summed and then divided by the total number of items to result in scores from 0-100%, with higher scores indicated a more shared decision making process.

V. Development Process:
This has been described in detail in Sepucha et al (2008), briefly to generate the survey we:
- Conducted a review of the clinical evidence & of focus groups and interviews with patients to generate a candidate set of facts and goals salient to the decision
- Surveyed a convenience sample of patients (n=14) and a multidisciplinary group of clinical experts (n=15) to rate the facts and goals for importance, completeness, and accuracy.
- Drafted the instrument and then conducted cognitive interviews with patients who had breast cancer (n=6) to evaluate items for acceptability and comprehension
- Conducted field test to evaluate the instruments

Three field tests were used to evaluate psychometric properties:
- A cross-sectional retrospective study with 440 adult females diagnosed with early stage (Stage 1 or 2) breast cancer in the U.S.
- A survey of 88 primary care providers and specialists in the U.S.
- A longitudinal study with 267 adult females diagnosed with early stage (Stages 1-3) breast cancer in the U.S. surveyed shortly after the decision and again one year later

VI. Psychometric Properties:

These data are taken from Sepucha et al (2012).

Feasibility: The survey was feasible and had very low missing data. Note: "I am not sure" was a response category for the knowledge items in the field test. We took it out of these versions as we felt that it was better to force respondents to guess; however, removing this response may increase missing items.

Acceptability: The survey was acceptable with high response rates when administered by mail and by phone, and took about 6 minutes to complete.

Reliability:
- Knowledge score short term (~4 week) retest reliability ICC=0.70
- The short term (~4 week) retest reliability for the goals were ICC > 0.72 for all except "avoid cancer coming back in the breast" (ICC=0.66), "avoid serious side effects of radiation" (ICC=0.64), and "avoid hassle of radiation" (ICC=0.61).
- Decision Process score: Not available because not all interaction questions were asked in the retest survey.

Note: We did not calculate the internal consistency of the knowledge score because the items do not draw from a single underlying construct.

Validity
- Discriminant validity:
  - The total knowledge score discriminated between patients and providers (52.7% vs. 87.7%, p<0.001)
  - The total knowledge score did not discriminate significantly between patients and healthy controls (52.7% vs. 49.3%, P=0.28).
  - The concordance model was able to discriminate among patients who stated a preference for mastectomy, those who were unsure and those who stated a preference for lumpectomy (model predicted probabilities of 0.70 vs. 0.30 vs. 0.08, respectively, p<0.0001 for all comparisons).
- Content validity was confirmed through the extensive feedback from patients and providers in the development process as well as in the field test.
- Predictive validity: For the retrospective sample, patients who had concordant care had similar levels of confidence and regret compared to those who did not have concordant care. Confidence was generally very high and regret was very low in this sample.

Knowledge score: Worksheet version (5 items):

Reliability: Short term (~4 week) retest reliability ICC=0.60

Validity: The short knowledge score discriminated between patients and providers (60.7% vs. 93.6% p<0.001) and between patients and healthy controls (60.7% vs. 57.7% p<0.001)

<u>Reproducibility</u>: The short knowledge score was highly correlated with the total knowledge score R=0.80 p<0.001.

VII. Appropriate Use
The DQIs are protected by copyright. They are available to use at no cost, provided that you:
- Cite the reference in any questionnaires or publications
- Do not charge for or profit from them
- Do not alter them except for customization for a specific condition and reformatting

Suggested Citations for the DQIs:
Sepucha KR. Breast Cancer Surgery Decision Quality Instrument v.2.0. ©Massachusetts General Hospital, 2010 [updated 2012].

Sepucha KR. Decision Quality Worksheet: Breast Cancer Surgery. v.2.0. ©Massachusetts General Hospital, 2010 [updated 2012]. Downloaded from:
http://www.massgeneral.org/decisionsciences/research/DQ_Instrument_List.aspx.

Suggested Citation of the User Guide:
Sepucha KR and Feibelmann S. Breast Cancer Surgery Decision Quality Instrument User Guide. © 2013. Available from: http://www.massgeneral.org/decisionsciences/research/

VIII. Selected References
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IX. Questions or comments? Please contact us at decisions@partners.org or visit our website at http://www.massgeneral.org/decisionsciences/research/.