

A Patchwork of Life: One Woman's Story

For Women Making Breast Cancer Treatment Decisions

TECHNICAL REPORT

PROGRAM OVERVIEW

Patients who have been diagnosed with early stage breast cancer are able to participate in making more informed decisions about their surgical treatment options, if they can learn about the options in ways that are understandable. The patient decision aid, "A Patchwork of Life—One Woman's Story" (www.bcm.edu/patchworkoflife), is an online tool that prepares women for making this important breast cancer surgery decision. This program may also assist patients diagnosed with breast cancer with no surgical options learn about medical, anti-estrogen, and biologic treatments. The treatments discussed in this program are:

- Breast-conserving surgery (lumpectomy) with radiation
- Mastectomy (with or without breast reconstruction)
- Medical, anti-estrogen, and biologic therapies

Patient decision-aid programs, such as "A Patchwork of Life," have been developed as adjuncts to counseling and are designed to support decision making and patient involvement when making complex decisions. "A Patchwork of Life" includes a combination of soap-opera video segments and interactive learning modules with factual information to deliver the content.

EDUCATIONAL OBJECTIVES

"A Patchwork of Life" was designed to walk women through the steps involved in making a decision about breast cancer surgery. Following the learning modules sequentially (1 through 4) will best inform women and prepare them to make their surgery decision. Also, this program may assist breast cancer patients with no surgical options learn about medical, anti-estrogen, and biologic treatments.

Module 1: About Breast Cancer

This module explains with vivid graphics what cancer is and the misconceptions women generally have about having a diagnosis of breast cancer.

Module 2: Breast Cancer Diagnosis

In this module, viewers get information about how doctors (radiologists, surgeons, and pathologists) make a breast cancer diagnosis. This module also presents some common misconceptions women have about getting breast cancer treatment.

Module 3: Making a Surgery Decision

In this module, viewers are walked through the process of making a breast cancer surgery decision and can explore their surgical treatment choices: breast-conserving surgery (lumpectomy) with radiation and mastectomy (with or without reconstruction). Viewers also have the option of learning of other therapies (hormonal therapy, chemotherapy, and biologic therapy) that may be recommended for their breast cancer before their breast surgery. An interactive jewelry box is available throughout this module to assist viewers in storing information (i.e., the short- and long-term effects of treatments) that might be of concern to them personally. A print function allows viewers to get a print out of the stored informational items for later discussion with their family members, significant others, and/or health-care providers. The print function is an optional feature.

Module 4: Medical, Anti-Estrogen, and Biologic Treatments

This module presents possible treatments (radiation therapy, anti-estrogen therapy, chemotherapy, and biologic therapy) that health-care providers may recommend after breast surgery as part of a personalized medical treatment.

At the conclusion of the program, the viewer/participant facing a surgery decision for early stage breast cancer should:

- Know that a decision needs to be made and that there are two options.
- Understand the impact of having breast-conserving surgery with radiation or a mastectomy for treating her early stage breast cancer.
- Be more certain about which surgery may be best for her.
- Feel more comfortable in discussing surgery options with her doctor, family, and significant others.
- Understand that there are other treatments for late stage of breast cancer

TARGET AUDIENCE

"A Patchwork of Life" is designed to meet the educational needs of English- and Spanish-speaking women who have been diagnosed with early stage breast cancer and are facing an initial surgery decision, as well as for breast cancer patients with no surgical options who want to become informed of breast cancer treatments. The program was designed to meet the needs of novice computer users and uses video clips and full voice-over narration to meet the needs of individuals with limited reading skills.

METHOD OF VIEWING

The content of "A Patchwork of Life" is presented as a combination of audio (video voice-over narration) and visual (graphics, animations, video, picture stills, and text) formats. Content and instructions are fully narrated so on-screen text is minimal. Following the learning modules sequentially (1 through 4) is the best way to inform and prepare women for making their decision about breast cancer surgery. Breast cancer patients who do not have surgical options may skip/ jump viewing of the program modules via the navigation menu panel. At the end of module 3, "Making a Surgery Decision," the user can print out information she selected while using the program. The printout may then be used by the patient to share her concerns about the treatment options with her doctor, family, and/or significant others. Other than this printout, the program content cannot be printed because it is not text or graphic-based. Web-based (www.bcm.edu/patchworkoflife) and CD-ROM versions of "A Patchwork of Life" are currently available to the public and health professionals upon request.

APPRAISAL USING THE INTERNATIONAL PATIENT DECISION AID STANDARDS INSTRUMENT (IPDASI)

The IPDAS Collaboration¹ has identified a set of standards (the IPDAS checklist) and instruments² (the IPDASi and the IPDASi-SF [short form]) to assist developers, researchers, and users in judging the quality of a patient decision aid (as a decision-support technology). In this report, the IPDASi-SF was used to appraise whether "A Patchwork of Life" meets or does not meet the criteria specified for a patient decision aid. We chose the shorter version of the IPDASi instrument because it can demonstrate the quality of patient decision aids while focusing on fewer items.² The table presented in the following pages includes dimensions of the 16 core-set items of the IPDASi-SF for decision-support technologies that do not involve tests or screening.

"A Patchwork of Life" meets most (13 of 16) of the IPDASi-SF quality criteria for patient decision aids: in providing information on treatment options, in offering explicit ways to clarify personal values, in being produced from a systematic development process, in providing citations of scientific evidence, in having had a source of development funding, and giving evidence that it helps women make quality decisions about breast cancer surgery. The IPDASi-SF dimension that was not met is the presentation of probabilities. Survival probabilities for each early breast cancer stage (I, IIA, and IIB) are not included in the decision aid. Content experts determined that because of the complexities of counseling women about survival probabilities before their initial surgery, it was best to present a broader message about survival. The message presented

is that women who choose breast conserving surgery followed by radiation are likely to live as long as women who have a mastectomy.⁶⁻¹⁵ Furthermore, given that our intent is to reach individuals with various levels of health literacy, including populations of women with low health literacy, we have concerns about being able to adequately present probabilities such that they be correctly understood so they can be correctly understood by the viewers. (See Appendix A for more details.)

REVIEW PROCESS

The review process for updating "A Patchwork of Life" included several in-person meetings and e-mail exchanges with members of the Expert Content Panel to review the Patchwork of Life Reference Document. The purpose was to provide feedback on areas of the program that needed revisions. Panel members were asked to provide suitable revisions to the electronic Reference Document (in digital form), as well as references in support of the content presented or revised. Once revisions were received from the panel members, changes or revisions were made to a "revised" master reference document. This comprehensive document was then distributed for final review and approval to the panel members.

EXPERT CONTENT PANEL

The content for "A Patchwork of Life" was developed under the guidance of a content panel who are experts in breast cancer treatment and medical decision-making. Between November 2012 and April 2013, the patient decision aid was reviewed by the following panel members:

Rodger Hamilton Brown, M.D., Plastic Surgeon and Assistant Professor, Plastic Surgery Division, Department of Surgery, Baylor College of Medicine

Hsin H. Lu, M.D., Radiation Oncologist and Associate Professor, Department of Radiology, Baylor College of Medicine

Julie Rani Nangia, M.D., Medical Oncologist and Assistant Professor, Lester and Smith Breast Center, Baylor College of Medicine

Mari B. Rude, R.N.C., Nurse Practitioner, Lester and Sue Smith Breast Center, Baylor College of Medicine

Eric J. Silberfein, M.D., Surgical Oncologist and Assistant Professor of Surgery, Division of Surgical Oncology, Baylor College of Medicine

Maria L. Jibaja-Weiss, Ed.D., Associate Professor, School of Allied Health Sciences, Director of the Office of Outreach and Health Disparities, Dan L. Duncan Cancer Center, Baylor College of Medicine

PUBLICATION DATE

August 2013

UPDATE POLICY

To ensure the continued scientific and medical relevance of "A Patchwork of Life", it will be reviewed again in August 2015, with a plan for subsequent reviews every 2 years.

ACKNOWLEDGEMENT OF SUPPORT

Original funding for the development of "A Patchwork of Life" was provided by the U.S. Department of Defense (DAMD 17-2-98-8022). Funding for the first update and the packaging and dissemination of the decision aid was provided by Susan G. Komen for the Cure, Dallas, Texas. The latest update was funded by the Dan L. Duncan Cancer Center, Houston, Texas.

DEVELOPERS' CREDENTIALS

Appendices B and C (Credits) provide credentials for the developers of the latest update (August 2013), as well as individuals who participated in the original development of the product.

DISCLOSURE

Baylor College of Medicine has a policy of assuring balance, independence, objectivity, and scientific rigor in all of its sponsored educational activities. Thus, all individuals who participate in sponsored activities, including members of expert content committees, are expected to disclose any significant relationships that may pose a conflict with the principles of

balance and independence. For this update of the “A Patchwork of Life” application, we received no disclosure reports from individuals involved in the content review of financial or other relationship with commercial entities whose products/services may relate to the educational content of this activity.

READABILITY LEVEL

The “A Patchwork of Life” patient decision aid provides ways to help viewers understand information other than by simply reading. The program is fully narrated; illustrations, animations, and minimal headline-type text are used throughout the program. The readability level of the optional printout available at the end of Module 3 (Making a Surgery Decision) will vary, depending on the content selected by the viewer but generally will be at a grade-10 reading level (Flesch-Kincaid) because it includes medical treatment terminology (i.e., lumpectomy, chemotherapy). As mentioned earlier, to facilitate understanding, complex concepts and medical terminology are explained in the patient decision aid by using multimedia (voice-over narration and synchronized visual graphics) throughout the interactive version of the program.

REFERENCES

A. References to Inform Evaluation of the Patient Decision Aid

1. Elwyn G, O'Connor A, Stacey D, et al, for the International Patient Decision Aids Standards (IPDAS) Collaboration. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ* 2006;333(7565):417.
2. Elwyn G, O'Connor AM, Bennett C, et al. Assessing the quality of decision support technologies using the International Patient Decision Aid Standards instrument (IPDASi). *PLoS One* 2009;4(3):e4705.

B. References to Inform Content (with assigned Levels of Evidence: Level 1, 2, 3)*

*1 most valid; 2 mid-level; 3 not based on scientific analysis

3. Jibaja-Weiss ML, Volk RJ, Granchi TS, et al. Entertainment education for informed breast cancer treatment decisions in low-literate women: development and initial evaluation of a patient decision aid. *J Cancer Educ* 2006;21(3):133-9. (1)
4. Jibaja-Weiss ML, Volk RJ, Friedman LC, et al. Preliminary testing of a just-in-time, user-defined values clarification exercise to aid lower literate women in making informed breast cancer treatment decisions. *Health Expect* 2006;9(3):218-31. (1)
5. Jibaja-Weiss ML, Volk RJ, Granchi TS, et al. Entertainment education for breast cancer surgery decisions: a randomized trial among patients with low literacy. *Patient Educ Couns* 2010 Jul 5. [Epub ahead of print] (1)
6. Fisher B, Anderson S, Bryan J, et al. Twenty-Year Follow-up of a Randomized Trial Comparing Total Mastectomy, Lumpectomy, and Lumpectomy plus Irradiation for the Treatment of Invasive Breast Cancer. *N Engl J Med* 2002; 347:1233. (1)
7. Jatoi I, Proschan MA. Randomized trials of breast-conserving therapy versus mastectomy for primary breast cancer: a pooled analysis of updated results. *Am J Clin Oncol* 2005;28(3):289-94. (1)
8. American College of Radiology. Practice guideline for the breast conservation therapy in the management of invasive breast carcinoma. *J Am Coll Surg*. 2007 Aug;205(2):362-376.
9. White JR, Halberg FE, Rabinovitch R, Green S, Haffty BG, Solin LJ, Strom EA, Taylor ME, Edge SB. American College of Radiology appropriateness criteria on conservative surgery and radiation: stages I and II breast carcinoma. *J Am Coll Radiol*. 2008 Jun;5(6):701-13.

10. Clarke M, Collins R, Darby S, et al. Effects of radiotherapy and differences in the extent of surgery for early breast cancer on local recurrence and 15-year survival: an overview of the randomised trials. *Lancet* 2005;366(9503):2087-106. (1)
11. Vinh-Hung V, Verschraegen C. Breast-conserving surgery with or without radiotherapy: pooled-analysis for risks of ipsilateral breast tumor recurrence and mortality. *J Natl Cancer Inst* 2004;96(2):115-21. (1)
12. Holli K, Hietanen P, Saaristo R, et al. Radiotherapy after segmental resection of breast cancer with favorable prognostic features: 12-year follow-up results of a randomized trial. *J Clin Oncol* 2009;27(6):927-32. (1)
13. Malmstrom P, Holmberg L, Anderson H, et al. Breast conservation surgery, with and without radiotherapy, in women with lymph node-negative breast cancer: a randomized clinical trial in a population with access to public mammography screening. *Eur J Cancer* 2003;39(12):1690-7. (1)
14. Beitsch PD, Shaitelman SF, Vicini FA. Accelerated partial breast irradiation. *J Surg Oncol*. 2011 Mar 15;103(4):362-8. doi: 10.1002/jso.21785.
15. Truong PT, Olivetto IA, Whelan TJ, et al. Steering Committee on Clinical Practice. Clinical practice guidelines for the care and treatment of breast cancer: 16. Locoregional post-mastectomy radiotherapy. BC Cancer Agency-Vancouver Island Centre. *CMAJ*. 2004 Apr 13;170(8):1263-73.
16. Sanghani M, Balk EM, Cady B. Impact of axillary lymph node dissection on breast cancer outcome in clinically node negative patients: a systematic review and meta-analysis. *Cancer* 2009;115(8):1613-20. (1)
17. Fisher B, Bryant J, Dignam JJ, et al. Tamoxifen, radiation therapy, or both for prevention of ipsilateral breast tumor recurrence after lumpectomy in women with invasive breast cancers of one centimeter or less. *J Clin Oncol* 2002;20(20):4141-9. (1)
18. Fyles AW, MMcCready DR, Manchul LA, et al. Tamoxifen with or without breast irradiation in women 50 years of age or older with early breast cancer. *N Engl J Med* 2004;351(10):963-70. (1)
19. Hughes KS, Schnaper LA, Berry D, et al. Lumpectomy plus tamoxifen with or without irradiation in women 70 years of age or older with early breast cancer. *N Engl J Med* 2004;351(10):971-7. (1)
20. Killander F, Anderson H, Ryden S, et al. Radiotherapy and tamoxifen after mastectomy in postmenopausal women – 20 year follow-up of the South Sweden Breast Cancer Group randomised trial SSBCG II:I. *Eur J Cancer* 2007;43(14):2100-8. (1)
21. Jakesz R, Gnant M, Schmid M, et al. Extended adjuvant therapy with anastrozole among postmenopausal breast cancer patients: results from the randomized Austrian Breast and Colorectal Cancer Study Group Trial 6a. *J Natl Cancer Inst* 2007;99(24):1845-53. (1)
22. Winer E, Hudis C, Burstein HJ, et al. American Society of Clinical Oncology technology assessment on the use of aromatase inhibitors as adjuvant therapy for postmenopausal women with hormone receptor-positive breast cancer: status report 2004. *J Clin Oncol* 2005; 23:619-629. (1)
23. Moss LS, Starbuck MF, Mayer DK, Harwood EB, Glotzer J. Trastuzumab-induced cardiotoxicity. *Onc Nur Forum* 2009;36: 676-685. (2)
24. Herceptin [package insert]. South San Francisco, CA: Genentech, Inc. 2010.

APPENDIX A: IPDASi-SF QUALITY CRITERIA FOR PATIENT DECISION AIDS

IPDASi Checklist Dimension	No	Yes	N/A	Comments to support criteria	Module/ Document
INFORMATION					
Providing information about options in sufficient detail for making a specific decision					
The decision-support technology...					
1. Describes the options available for the index decision		X		Breast-conserving surgery and mastectomy options are presented	3
2. Describes the positive features (benefits or advantages) of each option		X		Positive features are fully described	3
3. Describes negative features (harms, side effects, or disadvantages) of each option		X		Negative features are fully described	3
4. Makes it possible to compare the positive and negative features of available options.		X		A special section provides a comparison of both treatment options	3.8
PROBABILITIES					
Presenting outcome probabilities					
The decision-support technology...					
1. Specifies the defined group (reference class) of patients for which the outcome probabilities apply	X			Survival probabilities for each early breast cancer stage (I, IIA, and IIB) are not included in the decision aid. Content experts determined that because of the complexities of counseling women about survival probabilities before their initial surgery, it was best to present a broader message about survival. The message presented is that women who choose breast-conserving surgery followed by radiation are likely to live as long as women who have a mastectomy. The section, Consequences of Not Receiving Radiation (3.9), includes probabilities of cancer recurrence in the breast (stated as a percentage) if one does not get radiation; however, these probabilities do not affect the outcomes of the surgical treatment decision. ⁶⁻¹⁵	TR
2. Specifies the event rates for the outcome probabilities (in natural frequencies)	X				
3. Allows the user to compare outcome probabilities across options by using the same denominator and time period		X			

IPDASi Checklist Dimension	No	Yes	N/A	Comments to support criteria	Module/ Document
VALUES					
Clarifying and expressing values					
The decision-support technology...					
1. Asks patients to think about which positive and negative features of the options matter most to them		X		This module (Making a Surgery Decision) allows the viewer to reflect and to select issues of personal concern by saving information in an <i>Interactive Jewelry Box</i>	3
DEVELOPMENT					
Using a systematic development process					
The development process included...					
1. Finding out what clients or patients need to prepare them to discuss a specific question		X		Obtained input from 50 English- and Spanish-speaking patients from the General Medicine Clinic at an urban public hospital	1-4
2. Expert review by clients/patients not involved in producing the decision-support technology		X		Obtained feedback about its acceptability from women who participated in the evaluation ³⁻⁵	1-4
The decision support technology was...					
3. Field tested with patients who are facing the decision		X		It was evaluated with 51 newly diagnosed women at the point of decision making ³⁻⁵	TR
EVIDENCE					
Using evidence					
The decision-support technology (or associated documentation)...					
1. Provides citations to the studies selected		X		References are provided (Sections A and B)	TR
2. Provides a production or publication date		X		Decision aid was last updated in August 2013	Home page; TR
DISCLOSURE					
Disclosure and transparency					
The decision-support technology (or associated documentation)...					
1. Provides information about the funding used for development		X		Latest update was funded by the Dan L. Duncan Cancer Center	TR
EVALUATION					
There is evidence that the decision-support technology...					
1. Improves the match between the features that matter most to the informed patient and the option that is chosen		X		In an RCT, women who viewed the patient decision aid were better informed and clearer about their surgical choice than women assigned to a control group ⁵	TR
2. Helps patients improve their knowledge about the options' features		X		In an RCT, women who viewed the program showed a significant improvement in knowledge compared to the women in the control group ⁵	TR
RCT = randomized controlled trial					

APPENDIX B: CREDITS FOR UPDATE (AUGUST 2013)

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Animation and Graphics

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Narration

Smilex, Inc.
Programming Design

SPECIAL THANKS TO:

Harris Health System

Smith Clinic

APPENDIX C: CREDITS FOR ORIGINAL PRODUCTION (1998–2000)

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Brenda Congdon
Concept Developer, Script Writer, Video Producer

Doris Georgiou, Ph.D.
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Jessica Couderc, B.A.
Research Assistant

Loga Interactive Communication
Program Design

Brian White
Illustrations

Chris and Larry Clifton
Video Production

Accessible Sound, Inc.
Sound Production

Lidia Porto
Narration, Spanish Translation

Michelle Schmidt
Make-up

CAST OF ACTRESSES

Standardized Patient Program

Betty Barrett.....trying on head wraps
Eugenia GreenfieldHispanic in clinic shots
Sue Hibbetts.....radiation therapy shot
Gena Miller.....younger Caucasian
Gladys ShermanAfrican-American in clinical shots
Kathi WhiteChemotherapy shot

Older Caucasian Track

Dell Aldrichfriend
Michea Carterfriend at party
Jessica Couderc.....hairdresser
Nita Elliott.....woman at salon
Grace Givenswoman sewing
Terri Harreldaughter
Barbara Jenkins.....woman with cancer

Younger Caucasian Track

Dell Aldrichmother
Elena Coateswoman with cancer
Jessica Couderc.....hairdresser
Nita Elliott.....woman at salon
Grace Givenswoman sewing
Terri Harrelfriend
Sylvia Rawleyfriend at party

Older African-American Track

Edna Auguillardwoman with cancer
Michea Cartergranddaughter
Jessica Couderc.....hairdresser
Terri Harrelfriend at party
Cassandra White.....woman at salon
Shirley Whitmorefriend
Bebe Wilsonwoman sewing

Younger African-American Track

Jessica Couderc.....hairdresser
Rachel Hemphilldoctor
Ann James.....friend
Barbara Jenkins.....friend at party
Eileen Morriswoman with cancer
Nancy E. Neff.....doctor
Cassandra White.....woman at salon
Shirley Whitmoremother
Bebe Wilsonwoman sewing

Older Hispanic Track

Jessica Couderc..... hairdresser
Ann James.....friend at party
Neila Portofriend, woman sewing
Sylvia Rawleywoman with cancer
Rosa M. San Miguel..... woman at salon
Josefina Villa.....god daughter

Younger Hispanic Track

Jessica Couderc..... hairdresser
Maria Grillodoctor
Lidia Portofriend
Neila Portofriend at party; woman sewing
Sylvia Rawleygodmother
Rosa M. San Miguel.....woman with cancer
Melissa Webb woman at salon

SPECIAL THANKS TO:

Baylor College of Medicine
Standardized Patient Program
Karen Lewis

Harris County Hospital District
Ben Taub General Hospital
Breast Pathology Clinic

Ben Taub General Hospital
Chemotherapy Clinic
Rose Guidry, R.N.

Radiation Therapy
Drs. Chiu and Ms. Mattox

T. Carolyn Fashions

Ofelia's Hair Design
Leticia Greiwe (location for videotape sessions)

The Rose
Amy Rigsby (set up for videotape session)

La Rosa Breast Cancer Support Group
Rosebuds Breast Cancer Support Group
Sisters Breast Cancer Support Group

Women's Health Boutique

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