



## Patient Decision Aids



**Research Advocacy Network**

*Advancing Patient-Focused Research*

[www.researchadvocacy.org](http://www.researchadvocacy.org)

# Patient Decision Aids

Healthcare decisions can be confusing for patients, particularly when dealing with a serious disease such as cancer. Patients are not only faced with a deluge of new terms and facts about their condition and its treatment, but are also typically dealing with emotions (their own and their families') and thoughts of the future. As advocates, one way that we can help improve patients' experience is through the promotion of decision aids.

As we will see, decision aids are a form of patient education, but not all patient education material can be formally considered a decision aid. In the following text, we will discuss the definition of patient decision aids and present some examples of internet-based decision aids for cancer patients. We then outline the specific guidelines set out for the development of patient decision aids and consider the evidence for their utility based on randomized controlled trials. We conclude with some information about a specific decision aid that is being developed as part of the Komen Promise Grant. [pending]

## What are patient decision aids?

According to the International Patient Decision Aid Standards (IPDAS), decision aids are tools designed to help people participate in decision making about healthcare options. Decision aids do not tell people which treatment option they should choose, but rather lay out the pros and cons of each so that patients can weigh the benefits and drawbacks in relation to their values and, if relevant, individual factors such as age or disease characteristics. For instance, patients with early-stage prostate cancer may need to decide between several treatment options that all have a good likelihood of success. Their choices may then be influenced by the expected side effects, duration, and convenience of the treatment, and each patient may weigh these factors differently.

One view on patient decision aids is provided by IPDAS:

Patient decision aids are meant to support informed values-based decision making. They are usually developed when there is more than one reasonable option and there is considerable variation in how patients value the features of different options. Practitioners and patients may find it challenging to arrive at a good decision without advance preparation using a patient decision aid that helps patients understand the options and clarify the personal value of their different features.

Decision aids may take a variety of forms. Printed brochures have historically been a popular format because patients can take them home and consider the information at their leisure, free from the distractions and stress that may accompany a visit to their physician. Many decision aids incorporate questions for patients to answer that can help them sort out their priorities as they relate to treatment. These information pieces and questionnaires are increasingly available on the internet where patients can print the information they want or return to the Web site as needed.

Decision aids can also take the form of videos that may include an overview of treatment options or an exploration of a single treatment such as chemotherapy. Videos may incorporate interviews with healthcare experts or explanations by patients who have undergone the treatment in question. Patients often describe their personal experiences with the treatment, including its effects on daily activities, emotions, and family members. Videos are frequently available on the internet and may be embedded in an article.

## Examples of patient decision aids on the web

### *WebMD®*

An example of a decision aid on the use of chemotherapy for early-stage breast cancer can be found at <http://www.webmd.com/breast-cancer/should-i-use-chemotherapy-for-early-stage-breast-cancer>. This decision aid provides background information on breast cancer and chemotherapy, a table listing reasons to use or not to use chemotherapy, and a questionnaire/worksheet designed to help patients determine whether they are a good match for chemotherapy.

### *NCCN® Patient Guidelines*

The National Comprehensive Cancer Network® (NCCN®) has developed a series of guidelines for cancer patients that are available on the Web at <http://www.nccn.com/cancer-guidelines.html>. These patient materials are based on the NCCN Clinical Practice Guidelines, which are targeted to healthcare providers.



NCCN Patient Guidelines are available for breast cancer, chronic myelogenous leukemia, non-small cell lung cancer, malignant pleural mesothelioma, melanoma, multiple myeloma, prostate cancer, and ovarian cancer, and guidelines for additional cancer types are currently in development. The booklets provide general information about each type of cancer and the organ it affects (eg, breast, blood, etc.), as well as the types of tests that may be done to screen for, diagnose, and characterize the cancer. Cancer treatments are explained, along with a step-by-step treatment guide. The booklets also contain a series of tools for patients such as questions to ask about treatments and clinical trials, in addition to a section on definitions.

### *Adjuvant! Online*

Adjuvant! Online is an Web site designed to help healthcare providers and patients with early cancer discuss the risks and benefits of getting additional therapy after cancer surgery. This type of therapy, known as adjuvant therapy, usually involves chemotherapy, hormone therapy, or both. Adjuvant! Online is available at <http://www.adjuvantonline.com/index.jsp>.

Adjuvant! Online must be accessed by a medical professional, and each user must register to access the site. Adjuvant! Online was designed to help healthcare providers evaluate the consequences of using or not using adjuvant therapy for a given patient. Information is provided on the risk of negative outcomes such as relapse or mortality without systemic adjuvant therapy, estimates of the reduction of these risks if treated with adjuvant therapy, and risks of side effects of with adjuvant therapy. Estimates are based on each patient's demographic characteristics such as age and specific features of his or her tumor such as its size and histological grade. Because this information is somewhat technical, it should be entered by a healthcare provider and hence the site is designed for access only by healthcare providers with some expertise in cancer.

### Are patient decision aids beneficial?

Although patient decision aids have high face value—that is, they appear to be useful—it is important to verify this assumption. A number of scientific studies have attempted to determine whether or not decision aids help patients make decisions and, if so, in what ways. Here we consider only the results of randomized, controlled trials—studies with strong experimental designs that minimize the risk of biasing the results.

A recent evidence-based review found that decision aids have a variety of different effects on patients and their choices. These effects include improving patient knowledge and involvement, improving choices based on values, and reducing the number of times patients choose to receive discretionary surgery (ie, surgery that is not mandatory, but is up to the patient). These effects are summarized in the following table. The authors also concluded that little is known about the degree of detail that decision aids must incorporate in order to have positive effects on attributes of the decision or decision-making process.

Documented Effects of Patient Decision Aids
• Increase patient involvement
• Improve patient knowledge
• Increase realistic perception of outcomes
• Improve informed values-based choices (pertains to decision aids with explicit values-clarification exercises)
• Positively affect patient-practitioner communication
• Have a variable effect on length of consultation with healthcare providers
• Reduce the choice of discretionary surgery
• Have no apparent adverse effects on health outcomes or satisfaction
From Stacey et al, 2011. <i>Cochrane Database Syst Rev.</i> Oct 5;(10):CD001431.

Following is an abbreviated list of selected studies in oncology that have recently evaluated the utility of patient decision aids. These references may be useful for you, as advocates, when participating in the development of decision aids, studies evaluating decision aids, or other activities.

- Belkora JK, Hutton DW, Moore DH, Siminoff LA. Does use of the adjuvant! model influence use of adjuvant therapy through better risk communication? *J Natl Compr Canc Netw.* 2011 Jul 1;9(7):707-12.
- Fagerlin A, Dillard AJ, Smith DM, et al. Women’s interest in taking tamoxifen and raloxifene for breast cancer prevention: response to a tailored decision aid. *Breast Cancer Res Treat.* 2011 Jun;127(3):681-8.
- Oostendorp LJ, Ottevanger PB, van der Graaf WT, Stalmeier PF. Assessing the information desire of patients with advanced cancer by providing information with a decision aid, which is evaluated in a randomized trial: a study protocol. *BMC Med Inform Decis Mak.* 2011 Feb 14;11:9.
- Vodermaier A, Caspari C, Wang L, Koehm J, Ditsch N, Untch M. How and for whom are decision aids effective? Long-term psychological outcome of a randomized controlled trial in women with newly diagnosed breast cancer. *Health Psychol.* 2011 Jan;30(1):12-9.

### Who uses decision aids?

Decision aids are not only important to patients. Groups that use decision aids include:

- Patients or other individuals who are making health decisions
- Practitioners guiding patients in making health decisions
- Developers of new decision aids for patients
- Researchers or evaluators of patient decision aids
- Policy makers or payers of patient decision aids

### How are decision aids developed?

Given the large number of treatable diseases and the many screening and treatment options available in medicine today, one would predict that the number of decision aids might multiply rapidly and perhaps uncontrollably. It has been estimated that there are more than 500 patient decision aids currently available or in development by various individuals and groups worldwide. The importance of medical decisions suggests that the process of developing decision aids not be undertaken haphazardly, but rather should proceed via a systematic process.

The International Patient Decision Aid Standards (IPDAS) group was founded to promote the development of quality decision aids via the establishment of an internationally approved set of criteria. These criteria have been published in the British Medical Journal and are available on the internet at: <http://www.bmj.com/cgi/content/full/333/7565/417>.

The checklist of criteria for decision aids includes the three broad areas of content, development process, and effectiveness. Each of these areas is broken down into sub-categories of checklist items, some of which are outlined below.

Example Items from the International Patient Decision Aid Standards Collaboration Criteria Checklist	
<b>Content</b>	
• Provide information about options in sufficient detail for decision making?	Does the patient decision aid describe the health condition?
	Does the patient decision aid list the options?
	Does the patient decision aid list the options of doing nothing?
• Present probabilities of outcomes in an unbiased and understandable way?	Does the patient decision aid use event rates specifying the population and time period?
	Does the patient decision aid compare outcome probabilities using the same denominator?
<b>Development Process</b>	
• Present information in a balanced manner?	Is the patient decision aid able to compare positive / negative features of options?
	Does the patient decision aid show negative / positive features with equal detail [fonts, order, display if statistics]?
• Have a systematic development process?	Does the patient decision aid include developers' credentials / qualifications?
	Does the patient decision aid find out what users [patients, practitioners] need to discuss options?
<b>Effectiveness: Does the patient decision aid ensure decision making is informed and values based?</b>	
• Decision process leading to decision quality...	The patient decision aid helps patients to recognize a decision needs to be made?
	The patient decision aid helps patients to know options and their features?
From Elwyn et al. BMJ. 2006;333(7565):417. <a href="http://www.bmj.com/cgi/content/full/333/7565/417">http://www.bmj.com/cgi/content/full/333/7565/417</a>	

### Updating decision aids

Advances in medicine necessitate updates of patient decision aids. These advances may include results from clinical trials evaluating a new therapy, new safety information about a given treatment or its effects in a certain population, availability of biomarker tests, or updated treatment recommendations. The frequency with which decision aids need to be updated will be determined by the state of the science, as well as commercial availability of tests and FDA approval of new medications or other therapies.

### Patient decision aid in Komen Promise Grant

While investigators have not yet identified the sub-population which would gain the most benefit and the least toxicity with bevacizumab, prior evidence suggests that biomarkers may help to determine this and these issues are being explored in the study titled “A Double-Blind Phase III Trial of Doxorubicin and Cyclophosphamide followed by Paclitaxel with Bevacizumab or Placebo in Patients with Lymph Node Positive and High Risk Lymph Node Negative Breast Cancer (E5103).” With findings from this clinical trial regarding the biomarker associations with both risks and benefits of therapy, as well as patient and provider information gleaned from surveys of both the patients and providers, we will develop a decision aid to educate patients and providers about biomarker tests and their use in selecting adjuvant systemic treatments. To further inform the decision aid, we will run focus groups and individual interviews with patients at select high volume sites (6-10 groups across the US with 8-10 patients each). The booklet will provide information about the treatment choices, including likelihood of the benefits and harms.

### Summary

Patient decision aids are designed to help individuals participate in healthcare decisions that involve weighing the pros and cons of various treatment options in relation to their values. Examples of internet-based patient decision aids in cancer include the WebMD® site on treating early breast cancer with chemotherapy, the NCCN® Patient Guidelines, and Adjuvant! Online.

Randomized, controlled studies have found that patient decision aids improve patient knowledge, involvement, and choices made based on values. They also decrease patient selection of discretionary surgery in favor of less invasive options.

Although patient decision aids are typically educational, not all patient education pieces qualify as decision aids. Given the importance of quality decision aids to individual patients and medicine as a whole, the International Patient Decision Aid Standards (IPDAS) group has developed an internationally approved set of criteria by which to judge the quality of patient decision aids. It is important to apply these standards to existing patient decision aids, as well as those in development, in order to promote consistency and quality in these important tools.

## References

Adjuvant, Inc. Adjuvant! Online. Available at: <http://www.adjuvantonline.com/index.jsp>. Accessed January 3, 2012.

Elwyn G, O'Connor A, Stacey D, Volk R, Edwards A, Coulter A, Thomson R, Barratt A, Barry M, Bernstein S, Butow P, Clarke A, Entwistle V, Feldman-Stewart D, Holmes-Rovner M, Llewellyn-Thomas H, Moumjid N, Mulley A, Ruland C, Sepucha K, Sykes A, Whelan T; International Patient Decision Aids Standards (IPDAS) Collaboration. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *Brit Med J*. 2006;333(7565):417.

Foundation for Informed Medical Decision Making. Evidence base. Available at: [http://informedmedicaldecisions.org/evidence\\_base.html](http://informedmedicaldecisions.org/evidence_base.html). Accessed December 12, 2011.

International Patient Decision Aids Standards (IPDAS) Collaboration. Available at: <http://ipdas.ohri.ca/>. Accessed November 23, 2011.

National Comprehensive Cancer Network. About the NCCN Guidelines for Patients™. Available at: <http://www.nccn.com/cancer-guidelines.html>. Accessed January 3, 2012.

Stacey D, Bennett CL, Barry MJ, Col NF, Eden KB, Holmes-Rovner M, Llewellyn-Thomas H, Lyddiatt A, Légaré F, Thomson R. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev*. 2011 Oct 5;(10):CD001431.

WebMD®. Should I use chemotherapy for early-stage breast cancer? Available at: <http://www.webmd.com/breast-cancer/should-i-use-chemotherapy-for-early-stage-breast-cancer>. Accessed January 3, 2012.

## Why was this guide developed?

As advocates try to work within the system to advance research it is important to understand the basic tenets of the science. By gaining a better understanding, advocates can identify and illustrate the issues and problem-solve to support solutions. The emerging science and issues in research involving biomarkers and genome wide association studies were the motivation for developing this document. We hope that this information will be helpful to advocates and others interested in advancing the science and improving care for cancer patients.

## About Research Advocacy Network

Research Advocacy Network is committed to improving patient care through research. Our goals are to get results of research studies for new treatments and improved methods of detection of cancer to patients more quickly, to give those touched by the disease an opportunity to give back and to help the medical community improve the design of its research to be more attractive to potential participants. Because research holds the hope for improvements in treatment, diagnostics and prevention, we are dedicated to patient focused research. We believe dissemination of research results to the medical community and patients can have a major impact on clinical practice.

The Research Advocacy Network (RAN) is a not for profit (501 c 3 tax exempt) organization that was formed in 2003 to bring together participants in the research process with the focus on educating, supporting, and connecting patient advocates with the medical research community. While there are many organizations addressing the needs of patients with specific diseases, political advocacy, cancer education and fundraising, no organization has focused on advancing research through advocacy. RAN works with advocates and organizations to effectively integrate advocates into research activities. Please learn more about us at our website at [www.researchadvocacy.org](http://www.researchadvocacy.org) or contact us about our work by e-mailing us at [info@researchadvocacy.org](mailto:info@researchadvocacy.org) or by phone 877-276-2187 or FAX at 888-466-8803.

## Funding

Funding for the development and printing of this material is part of the Patient Advocacy and Care Translation (PACT) Core of the Komen Promise Grant “Comprehensive Biomarker Discovery Project for Bevacizumab in Breast Cancer” at Indiana University Melvin and Bren Simon Cancer Center, Bryan Schneider, M.D. Principal Investigator

## Reviewers

- Bryan P. Schneider M.D.  
Assistant Professor  
Departments of Medicine & Medical and Molecular Genetics Divisions of  
Hematology/Oncology & Clinical Pharmacology  
Indiana University School of Medicine

## *Development Staff and Contributors*

- Nancy Biddle, Graphic Designer
- Mary Ann Chapman, Ph.D., Medical Writer
- Mary Lou Smith, Co-Founder, Research Advocacy Network, PACT Core Advocate
- Elda Railey, Co-Founder, Research Advocacy Network, PACT Core Advocate