AHRQ Grant Final Progress Report
Title Page

Title of Project: Incorporating Temporary Health States into Decision Support

Final Report submitted by:
Maine Medical Center
22 Bramhall Street
Portland, ME 04102

Principal Investigator: Nananda Col, MD, MPH, MPP, FACP (9/30/02-11/12/10)

Key Team Members:
Nancy Avis, PhD
Mark Eckman, MD
Long Ngo, PhD
Annette O'Connor, PhD
Beverly Rockhill, PhD
Anne Stiggelbout, PhD
Griffin Weber, MD, PhD
Valerie Reyna, PhD

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Federal Project Officer: Judith Sangl

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1. Structured Abstract

Purpose: Hormone therapy (HT) use has declined because of associated increases in risks of cardiovascular disease (CVD) and breast cancer; however alternate treatments are less effective for menopause symptom management and also carry risks. We previously developed a Web-based decision aid, the Women's Interactive System for Decisions on Menopause (WISDOM), to help menopausal women and their clinicians make informed decisions about menopause. We aimed to measure the effects of incorporating utilities into WISDOM.
Scope: We sought to develop a tool to measure and embed temporary health states into a Web-based decision aid by testing two prototypes of the Website.
Methods: Menopausal women were asked to give feedback on the paper prototype of the two versions of the Website. Structured one-on-one interviews were conducted. These were audio-taped. The feedback was used to improve the decision aid.
Results: Most of the women liked the more detailed version of the Website. They also found the treatment cards very useful.
Key Words: decision making, menopause symptom management, utilities

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Administrative Note: Hereafter, all citations referenced by Roman Numerals (i, ii, iii, etc. refer to "References" citation list on page 15.) Other publications (referenced by author) refer to the "List of Publications and Products" supported by the grant on pages 8-10.

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2. **Purpose**: The purpose of the study was to measure the effects of incorporating utilities into the previously developed decision aid, the Women's Interactive System for Decisions on Menopause (WISDOM), and to measure its impact on patients and clinicians. The original specific aims of the study were:

Aim #1: Develop and optimize the Practical Approaches to Temporary Health States (PATHS) tool:
- 1.1. Adapt a previously developed web-based utility assessment tool (Lenert's instrument) to measure the utility of both short-term vasomotor and progressive urogenital menopausal symptoms
- 1.2. Conduct usability testing among patients and clinicians to guide its development

Aim #2: Assess the construct validity and reliability of utility values elicited by PATHS on a sample of 64 women

Aim #3: Evaluate the impact of WISDOM+PATHS on:
- 3.1 Decisional conflict and patient satisfaction with decision-making
- 3.2 Treatment decisions and adherence, focusing on HT
- 3.3 The quality of menopausal counseling

Specific Aim #2 was modified and this modification was reported to AHRQ in the progress report submitted in June 2009. All others remained the same as funded.

Modified Aim #2: Assess risk communication and preference elicitation strategies through a comparison of alternative communication approaches using a simplified version of the Website (hereafter termed the "gist" version)

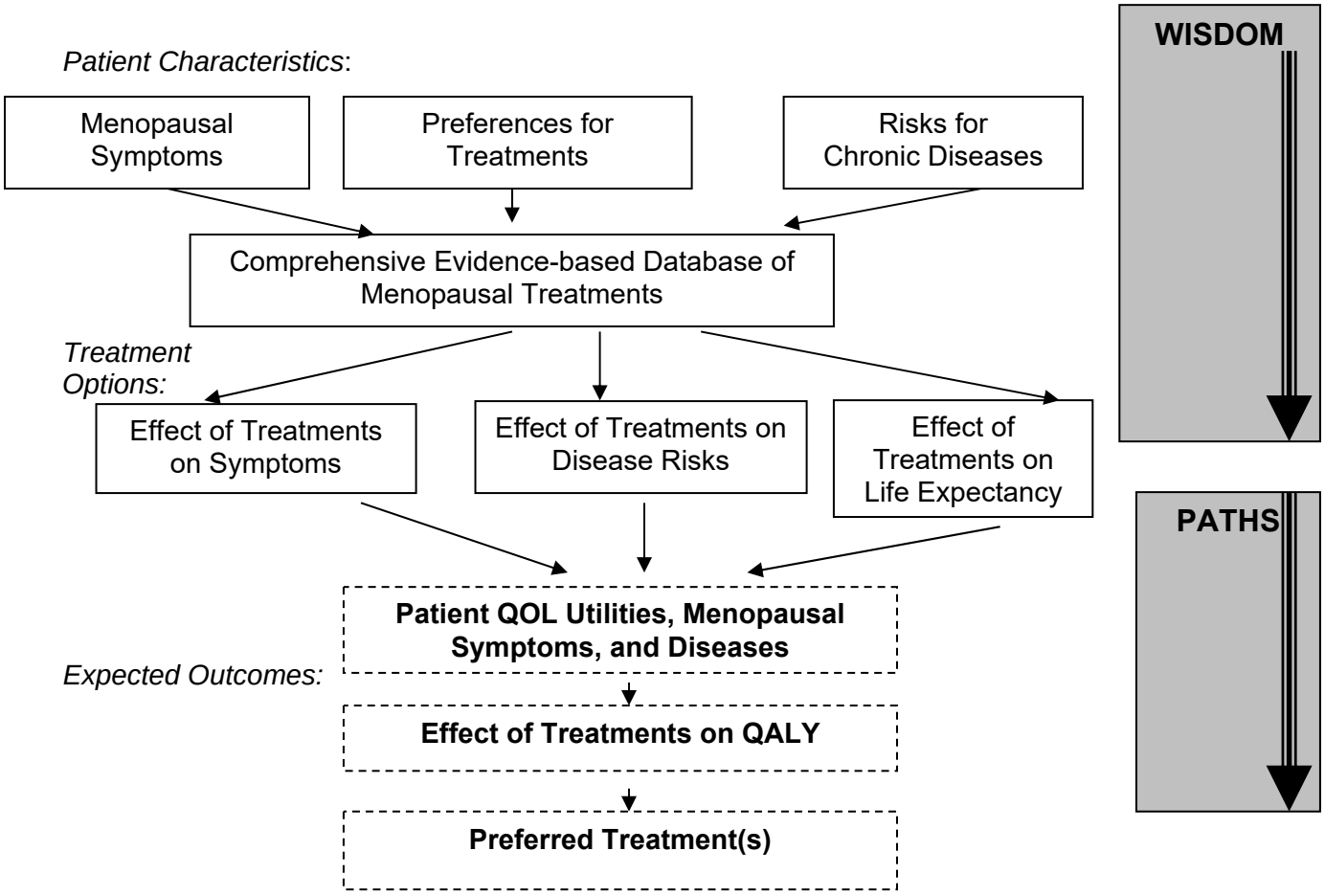
Rationale for change: During the course of this project the field of decision science had continued its shift from using complex utility solicitation instruments to the use of more simplified instruments, such as Visual Analog Scale (VAS). For example, two studies had reported evidence that when utility instruments that measure the quality of life (QOL) are too complicated, people do not necessarily understand the task they are asked to perform [i, ii] . Thus, emerging evidence suggested that a more effective approach is the use of simplified approaches[iii]. We therefore changed Specific Aim #2 to reflect these findings. In the modified aim, instead of testing the validity and reliability of the Website on a cohort of 64 women, we planned to conduct a smaller pilot test of 10-25 women to compare two versions of decision aids that varied in their degrees of complexity as a means of informing the final Website design.

3. Scope

The number of North American women transitioning into menopause will increase in the years to come. Women who experience hot flashes are much more likely to seek medical care than those who do not (50% vs. 33%); the longer the menopause transition, the more medical consults.[iv] Hormone therapy is decreasing in popularity due to its known risks of CVD, breast cancer, and venous thrombotic events (VTE).[v] However, alternate menopausal treatments are less effective (e.g., Selective Serotonin Reuptake Inhibitors), less well studied (e.g., black cohosh), and carry other risks.[vi] Deciding which treatment, if any, is appropriate for an individual requires careful assessment of the woman's symptoms, risks for CVD, osteoporosis, breast cancer, VTE, and treatment goals.[vii,viii] Any short-term benefits of a treatment need to be carefully balanced against long-term risks to ensure that the benefits outweigh the harms. Because of the plethora of menopausal treatments available, with many treatments affecting several conditions, counseling a woman about her treatment choices can be cognitively challenging and time-consuming.[ix] However, because some treatments have severe side effects (e.g., stroke, coronary heart disease (CHD), VTE), failure to adequately evaluate and counsel patients can have serious consequences. Patients need to factor in their symptoms and preferences for outcomes that are potentially affected by treatment. The ability to provide prognostic information about the expected duration and severity of menopausal symptoms according to a woman's age, current symptoms, and possibly other characteristics such as body mass index (BMI) and smoking could help her balance the risks of a treatment against the expected benefit. The current project aimed to synthesize and incorporate available longitudinal data in a novel decision aid to help women deciding upon treatment better understand the expected time-course of their symptoms and the impact of treatment on their symptoms and risks. As the field of decision science changed, we added a revised version of the decision aid based on the 'gist' model and intended to test the acceptability and performance of this shortened and simplified version against the original tool.

This project improved upon previous decision tools in several ways. We began with our previously developed decision aid for menopausal women called WISDOM (Women's Interactive System for Decisions on Menopause) and improved it as follows. By incorporating women's personal utilities into the decision aid, the PATHS (Practical Approach to Temporary Health States) module aimed to help women make better decisions; decisions that are more consistent with their own preferences and values. Rather than use a decision aid to tell patients what treatment decision is "best" for them based on absolute risk estimates and expected utilities, we intended to use the decision aid to inform patients and their clinicians of the many complex tradeoffs involved and to make these trade-offs explicit and personal by basing them on women's personal risks and quality of life (QOL) preferences. WISDOM+PATHS clarifies the trade-offs between QOL (symptom improvement), morbidity, and length of life, to help women make decisions that are consistent with their expectations and values. To bridge a potential gap between patient preferences and clinical recommendations, our decision aid aimed to target both the patient and her primary care provider (PCP), incorporating patient preferences and risks into an evidence-based decision model. In the past, there has been an implicit trade-off between the efficacy of the health intervention versus its 'reach' (with individual counseling being most effective but the most difficult to disseminate). WISDOM+PATHS was designed to maximize both 'reach' and impact by being easily accessed on the web ("reach"), and by providing highly personalized information to the user ("impact"). In addition, we intended to make WISDOM+PATHS available in PCP offices.

Figure 1. Schematic Overview of Conceptual Design of WISDOM+PATHS



4. Methods

We initially conducted a literature search on the duration of vasomotor symptoms of menopause. We found that the data were not robust enough to use in our Web tool, and therefore we embarked on a formal systematic quantitative meta-analysis of data collected from the initial review. In addition, we analyzed primary data from a longitudinal study by the Melbourne Women's Midlife Health Project – the longest follow up of menopausal women to date and the most informative on the topic. These studies revealed that the length of vasomotor symptoms is longer than previously thought. (see section 6, pg. 8, Col, Guthrie, Politi et al and pg. 9, Politi, Schleinitz, Col.) Previous estimates were 1-2 years, while these studies show it is 4-5 years in duration.

The results of these analyses had substantial implications for our study. Instead of facing a 1-2 year duration of treatment, most women actually face 4-5 years of lingering symptoms. Long term use of the menopausal treatments in consideration can substantially affect the risk of various chronic diseases (osteoporosis and breast cancer). We needed to update and expand sections of the Website that address these long term risks and that weigh the risks against their impact on quality of life. Additionally, we found that there are few consistent predictors of menopause duration or severity.

We also found there were changes in the field of decision science, which had been shifting from using complex utility solicitation instruments to the use of more simplified instruments, such as the Visual Analog Scale (VAS).

The results of both of these findings affected our study methodology in two ways:

a) We revised Specific Aim #2 in response to our findings about the trend toward simpler decision aids. Instead of testing 64 women, we aimed to test a smaller number of women (10-25) for a pilot project on a comparison of the simplified "gist" version and a more detailed shared decision-making tool (the full version of the PATHS Website).
b) We had to re-write the initial draft content of the Website to incorporate the new findings on the length of menopause symptoms and the impact on risk factors and treatments, causing a delay in the development of the website.

By mid- 2009, we had revised the Website content, updated information on the risk and benefits of menopause treatment, and developed a comprehensive usability testing guide to elicit feedback on the intervention from eligible women in our target age group, with a particular focus on comparing the "gist" version with a more detailed shared decision-making version (as per revised Aim #2). We conducted a first round of paper prototype testing, as detailed below.

Paper Prototype Usability Testing (2009-2010)

During **paper prototype testing**, done under the revised Specific Aim #2, women participated in one research interview. In the interview, they worked through two paper simulations of the PATHS design. One version contained detailed information of topics related to menopause and treatment choices (the full version) and the other contained related abbreviated and simplified information augmented by eight menopause decision treatment cards that were developed by the research team (the *gist* version). These cards contained information on areas of interest to women experiencing menopausal symptoms. Some examples of topics covered on the cards are "relieving hot flashes," "relieving vaginal dryness," and "cost per month." Copies of these cards are on pages 11-14 and the full and gist paper prototypes of the Website are in appendices A (21 Powerpoint slides) and B (8 Powerpoint slides) and part of the AHRQ official grant file.

Each woman was asked to review scenarios about menopause symptoms and completed QOL measures. A structured questionnaire was used to elicit feedback on appearance, content, readability, and comprehensibility. Interviews were audio-taped. Participants received $40. The women were asked for permission to recontact them in order to obtain feedback on revisions to PATHS. An abbreviated set of inclusion and exclusion criteria were developed to identify participants for this phase of the study.

Inclusion criteria:
- English-speaking
- Between 45 and 65 years of age (the group most likely to be going through the menopause transition)
- Experiencing symptoms perceived as being related to menopause

Exclusion criteria:
- Inability to give informed consent
- Age under 45 or over 65 years (The mean age of menopause is 51 with the menopause transition typically occuring between the ages of 45 and 55)

Recruitment and Informed Consent:
Paper Prototype: Recruitment was done through flyers placed throughout the community. Interested women called and were screened for eligibility, offered the opportunity to ask any questions, and (if eligible) invited to participate in the study. A brief demographic questionnaire was then completed. Each eligible woman gave informed consent prior to participation in research activities.

5. Results

Although the project supported by this grant did not achieve all of its original aims, the work accomplished did advance the goal of measuring the effectiveness of decision-making tools for treatment of menopausal symptoms in a Web-based tool. Progress was achieved on several levels: our data analysis led to important discoveries in the field of menopause symptoms and related treatment strategies; our review of decision science led to a modification of the study to ensure we would use the most current knowledge in the field; and

our work on paper prototype and initial pilot testing has laid a strong foundation for getting a novel tool on the Web. Results from completing the comparison testing of two versions of the decision tool could provide important information for refining decision tools in medicine in the future.

Improving Knowledge of Menopause and its clinical treatment:
Our review and analysis of the length of vasomotor symptoms during menopause resulted in the publication of two peer reviewed articles (pg. 8-9, section 6, Col, Guthrie, et al and Politi, Schleinitz, Col). The information garnered from this work is highly relevant, as it has important implications for how women are counseled about treatment of their menopausal symptoms and their risk/benefit profiles. To further advance knowledge of menopausal symptoms and treatments, we published "In the Clinic: Menopause" (pg. 8, Section 6, Col, Fairfield, Ewan Whyte, et al) which provides an overview for clinicians and patients of the latest evidence-based knowledge about menopause and its symptoms, the benefits and risks of a variety of clinical treatments, including lifestyle changes to improve vasomotor symptoms, non-pharmacological treatments and alternative therapies, and side effects and risks of hormonal treatments. Additionally, we published a paper (Col, Chlebowski, pg. 8, sec. 6) in which we proposed an approach for identifying and managing menopausal women at high risk for breast cancer that can be readily implemented in clinical practice. A simple algorithm is presented in this paper to streamline identification and management of menopausal women at high risk for breast cancer.

Expanding Knowledge of Decision-making Tools:
Two articles were published during the grant period that advance knowledge in the field of decision science. O'Connor, Bennett, Stacey et al (pg. 9, Section 6) reported on a systematic review of randomized controlled trials (RCTs) evaluating the efficacy of decision aids for people facing difficult treatment or screening decisions. The findings demonstrated that decision aids increased patient's involvement and were more likely to lead to informed values-based decisions; however, the size of the effect varies across studies. Decision aids reduced the use of discretionary surgery without apparent adverse effects on health outcomes or satisfaction. Elwyn, O'Connor, Bennett et al (pg. 9, sec. 6) describes the development, validation and inter-rater reliability of an instrument to measure the quality of patient decision aids. It was found that the instrument has the ability to assess the quality of decision support technologies.

Results of Paper Prototype Development and Testing
We tested the paper prototype of the two versions of the decision aids on a first round of seven women, thereby achieving a large portion of Specific Aim #2. The prototype was designed to compare the effectiveness of a simplified 'gist" version with the more complex version of the decision aid tool.

We used descriptive statistics to examine the characteristics of the women. These results are below:

A total of seven participants were interviewed for the first round of this phase of the study. The average age was 53.9 years, ranging from 45-65 years of age. Most of the participants had college level education or above. Professions varied and included a licensed practical nurse, a registered nurse, a graphic designer, and a financial planner. Most of the participants (71%) had experienced either hot flashes or night sweats, and 86% found these menopausal symptoms to be "somewhat bothersome." The table below shows the demographic and relevant medical characteristics of the participants.

Demographic and medical characteristics of the participants

Number of participants	7
Average age (yrs, range)	53.9 (45-65%)
Race (n, %)	
White	6 (86%)
African American	1 (14%)
Highest grade of school completed (n, %)	
Some College	1 (14%)
College	3 (43%)
Postgraduate	3 (43%)
Chronic Illness (n, %)	
Hypertension	2 (29%)
Seizures	1 (14%)
None	4 (57%)
Hormone Therapy Use (n, %)	
Current	3 (43%)
Past	1 (14%)
Never	3 (43%)
Hysterectomy (n, %)	
Yes	3 (43%)
No	4 (57%)
Last Menstrual Period (n, %)	
1-2 yrs ago	2 (29%)
>5 yrs ago	1 (14%)
>10 yrs ago	2 (29%)
never missed	2 (29%)
Hot Flashes experienced (n, %)	
Yes	5 (71%)
No	2 (29%)
Night Sweats experienced (n, %)	
Yes	4 (57%)
No	3 (43%)
Preferred Version (n, %)	
Full	7 (100%)
GIST	0 (0%)
Preferred Risk Report Format (n, %)	
Graph	4 (57%)
Pictograph	3 (43%)

All but one of the participants found the two versions of the Website to be informative and useful, and all preferred the “full” version because of the level of information contained and its ability to give personalized feedback to the user. Thus, for trying to make an informed decision, all participants found the “full” version to be more useful than the shortened “gist” version. Participants felt that the gist version was too short and lacked information that would be vital if trying to make a treatment choice for their menopausal symptoms (even though being short was also its most often cited strength). The gist version was often cited as a good basic overview of menopause that would be useful for someone wishing to understand what menopause is and what to expect.

Additional findings were that the layout of the Website was easy to follow, the tone was very well liked (neutral and friendly) and so were the colors and images. The Website was thought to be well written and the content was easy to understand and the language did not come across as “medical.” Participants appreciated the lack

of use of medical jargon throughout the Website. Many commented that this was the first time that any of the participants had seen this amount of information together in one place and they thought that PATHS was an excellent idea.

A few participants (3/7) found the "rating your symptoms" exercise challenging - - they were not quite sure where to put the mark if the symptoms were worse (higher/lower). Some also found interpreting the graphs somewhat challenging. While most preferred the bar graph as a better format for displaying the risk report than the pictograph (due to it being the format they were more familiar with), they all thought that both formats should be kept since they are both very interesting. The limitation most often cited was the need for detailed medical information to be entered in order to receive the personalized feedback. Another limitation was the fact that some pages had too much text, suggesting that the information needs to be broken into smaller sections or that bullets need to be added for emphasis.

The Values Clarification (VC) exercise that asked participants to rate a number of values on a scale of 1-5, with 5 being the highest, was well received. Participants liked that it made them think carefully about what is more important if they were making a decision about the best treatment for their menopausal symptoms. We tested another VC exercise that asked participants to distribute 100 stars among the same values, placing more stars on the value that was deemed to be more important. We discontinued this VC exercise after it was found to be too time-consuming and could not be done effectively on paper.

Menopause Decision Treatment Cards. A series of eight cards were developed and tested in preparation for the implementation of the gist version of the PATHS Website. Each of these cards addressed specific major topics that are related to menopause: example relieving hot flashes, relieving vaginal dryness, cost of treatment, mood and sleep. The participants were allowed to choose as many cards as they liked and in whatever order they preferred and were asked some comprehension questions. All participants liked the cards, understood the concept, and would be willing to either use them with their doctors on a one-on-one basis or to use them prior to an office visit and then take the information to the visit and use to start a conversation (see pages 11-14).

All suggestions from the first round of testing conducted as part of the modified Specific Aim #2 were carefully documented and the contents of the paper prototypes of both versions of the Website modified to reflect these changes. These changes were incorporated into the material provided to the Web programmer to be programmed into the PATHS Website but not completed.

6. List of Publications and Products

Directly Relevant Publications * indicates abstract of this publication appears in Appendix C which is part of the AHRQ official grant file.

a) Journal Articles, Reviews and Editorials

***Col, NF**. Using Internet technologies to improve and simplify counseling about menopause: the WISDOM website. *Maturitas* 2007; 57(1):95-9. Epub 2007 Mar 26

***Col NF**, Chlebowski RT. Risks and benefits of therapy with menopausal hormones versus selective estrogen-receptor modulators in peri- and postmenopausal women at increased breast cancer risk. *Menopause* 2008; 15(4 Suppl):804-9.

Col NF, Fairfield KM, Ewan Whyte C, Miller H. In the Clinic. Menopause. *Ann Intern Med*. 2009 Apr 7;150(7):ITC4-1-15; quiz ITC4-16.

***Col NF**, Fortin J, Ngo L, O'Connor AM, Goldberg RG. Can Computerized Decision Support Help Patients Make Complex Treatment Decisions? A Randomized Controlled Trial of an Individualized Menopause Decision Aid. *Med Decis Making* 2007; 27:585-598.

***Col NF**, Guthrie JR, Politi M, Dennerstein L. Duration of vasomotor symptoms in middle-aged women: a longitudinal study. *Menopause*. 2009; 16(3):453-7.

Col NF, Haskins AE, Ewan-Whyte CJ. Measuring the impact of menopausal symptoms on quality of life: methodological considerations. *Menopause*. 2009;16:860-869.

Col NF, Weber G, Stiggelbout A, Chuo J, D'Agostino R, Corso P. Short-term menopausal hormone therapy for symptom relief: An updated decision model. *Arch Int Med*, 2004; 164:1634-1640

*Elwyn G, O'Connor AM, Bennett C, Newcombe RG, Politi M, Durand MA, Drake E, Joseph N, Khangura S, Saarimaki A, Sivell S, Stiel M, Bernstein SJ, **Col N**, Coulter A, Eden K, Harter M, Holmes Rovner M, Moumjid N, Perestelo Perez L, Stacey D, Thomson R, Whelan T, van der Weijden T, Edwards A. Assessing the quality of decision support technologies using the International Patient Decision Aid Standards Instrument (IPDASi). *PLoS ONE* 2009 4(3):e4705 http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0004705

O'Connor AM, Bennett C, Stacey D, Barry MJ, **Col NF**, Eden **K**, Entwistle V, Fiset V, Holmes-Rovner M, Khangura S, Llewellyn-Thomas H, Rovner D, TetroeJ. Patient Decision Aids for People Facing Health Screening or Treatment Decisions: A Systematic Review and Meta-analysis. *Med Decis Making* 2007; 27: 554-574.

*O'Connor AM, Bennett CL, Stacey D, Barry M, **Col NF**, Eden KB, Entwistle VA, Fiset V, Holmes-Rovner M, Khangura S, Llewellyn-Thomas H, Rovner D. Decision aids for people facing health treatment or screening decisions. *Cochrane Database of Systematic Reviews* 2009;(3):CD001431.

*Politi MC, Schleinitz MD, **Col NF.** Revisiting the Duration of Vasomotor Symptoms of Menopause: A Meta-Analysis. *J Gen Intern* Med. 2008; 9:1507-13. Epub 2008 Jun 3.

Visvanathan K, Chlebowski R, Hurley P, **Col NF**, Ropka M, Collyar D, Morrow M, RunowiczC, Pritchard K, Hagerty K, Arun B, Garber J, Vogel V, Wade JL, Brown P, Cuzick J, Kramer BS, Lippman SM. American Society of Clinical Oncology Clinical Practice Guideline Update on the Use of Pharmacologic Interventions Including Tamoxifen, Raloxifene, and Aromatase Inhibition for Breast Cancer Risk Reduction. *J Clin Onc* 2009, May 26

b) Abstracts

Col N, Anderson B, Weber G, Cyr M, Landau C, O'Connor A. Impact of an individualized, web-based menopause decision support on decisional conflict. *Med Decis Making* 2007: 27(4):E81.

Col N, Anderson B, Weber G, Cyr M, Landau C, O'Connor A. Impact of individualized web-based decision support on medication use. *Med Decis Making* 2007: 27(4):E27-28.

Col NF, Cyr MG, Fortin JM, Landau C, Snyder D, Goldberg R. Helping primary care physicians counsel menopausal women: The Menopause Interactive Decision Aid System. *J Gen Intern Med* 2004; 19(S1):105.

Col NF, Fortin JM, Ngo L, O'Connor AM, Goldberg R. Integrating personalized decision support into primary care: Impact on decisional conflict. *J Gen Intern Med* 2004; 19(S1):169.

Col NF, Fortin JM, Ngo L, O'Connor AM, Goldberg R. Computer-generated decision support can promote behavioral change and preventive screening. *J Gen Intern Med* 2004; 19(S1):132.

Col NF, Weber G. Corso P, Chlebowski R, Chuo J, D'Agostino R, Wong JB, Sonnenberg F, Stiggelbout A. Short-term Menopausal Hormone Therapy for Symptom Relief: An Updated Decision Model. *J Gen Intern Med* 2003;(S1).

*Hansen MH, Goldstein G, **Col N.** The cost implications of shared decision making using decision aids: a meta-analysis and critical appraisal of the literature. *Soc of Medical Decis Making* 2010 Oct 25 Toronto.

Weber G, Fortin JM, Landau C, Cyr M, **Col NF**. Measuring How Patients use Internet-based Decision Aids. *Society for Med Decis Making* 2004.

Other (Related) Publications

Chlebowski RC, **Col N**. Menopausal hormone therapy after breast cancer. Lancet 2004; 363(9407): 410-411.

Col NF. Editorial: Decision making at the fringe of evidence: take what you can get. Arch Intern Med 2006; 166(4):389-90.

Col NF, Duffy C, Landau C. Commentary--Surgical decisions after breast cancer: Can patients be too involved in decision making? Health Services Research 2005; 40(3):769-779. PMCID: 1361167

Col NF, Duffy C, Cyr MG. The Pitfalls of Non-Evidence Based Guidelines. Menopause: The Journal of the North American Menopause Society 2006; 13(3):334-337.

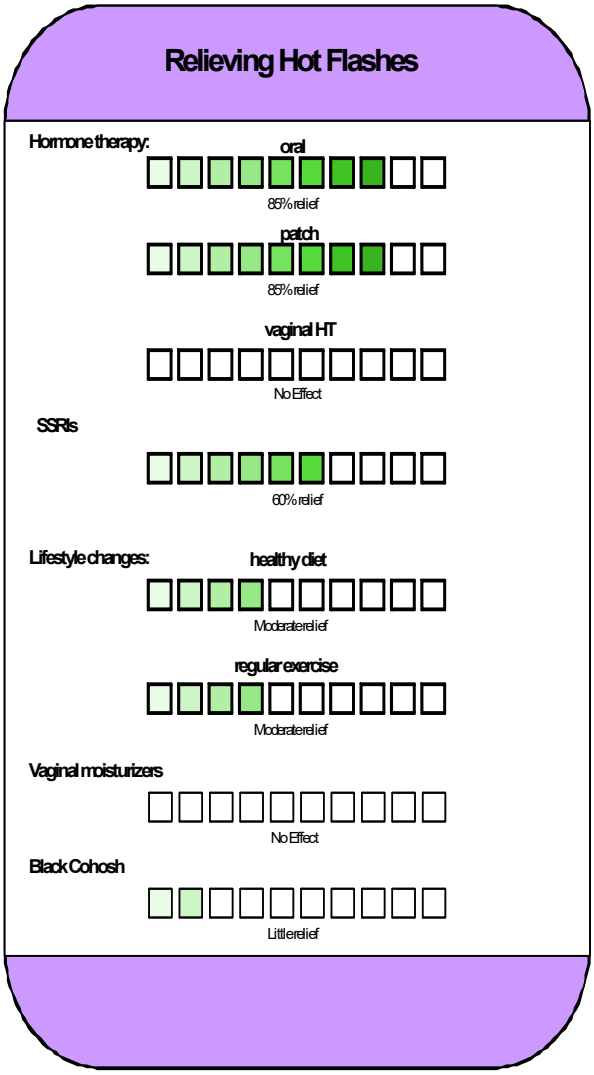
Col NF, Kim JA, Chlebowski RT. Menopausal hormone therapy after breast cancer: A Meta-analysis and critical appraisal of the evidence. Breast Cancer Research 2005; 7:R535-R540 (http://breast –cancer-research.com/ content/7/4/R535). PMCID 1175064

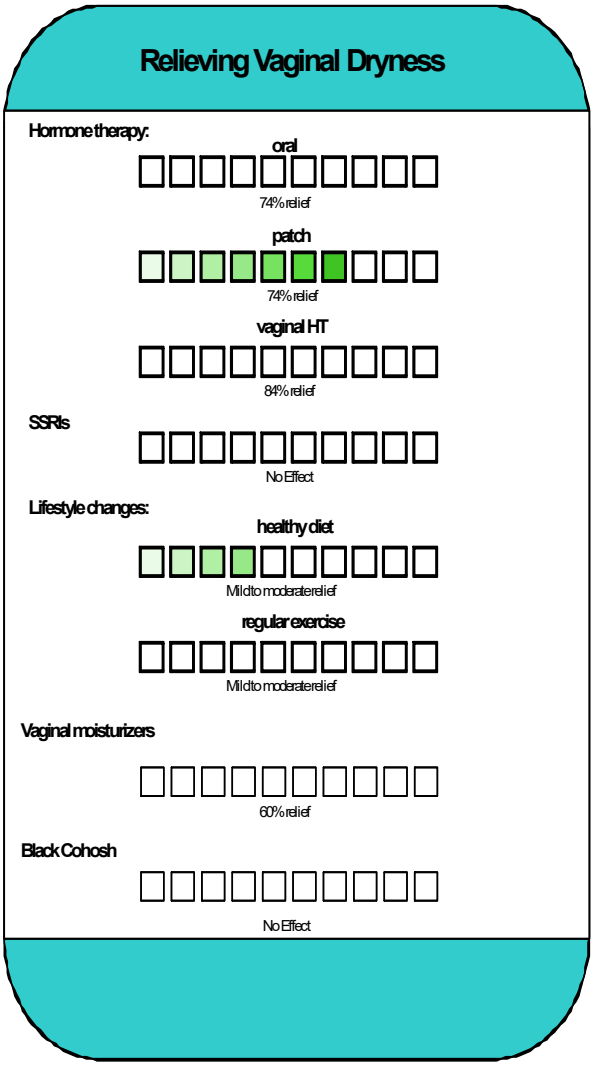
Matloff ET, Moyer A, Shannon KM, Niendorf, KB, **Col NF**. Healthy Women with a Family History of Breast Cancer: Impact of a Tailored Genetic Counseling Intervention on Risk Perception, Knowledge, and Menopausal Therapy Decision-Making. J Women's Health, 2006; 15(7):843-56.

Matloff ET, Shannon KM, Moyer A, **Col NF.** Should Menopausal Women at Increased Risk for Breast Cancer Use Tamoxifen, Raloxifene, or Hormone Therapy? A Framework for Personalized Risk Assessment and Counseling. Journal of Cancer Education 2007; 22(1):10-14.

Politi MC, Han PKJ, **Col NF**. Communicating the Uncertainty of Harms and Benefits of Medical Interventions; White Paper Series, Eisenberg Center. Med Decis Making 2007; 27:681-695

Menopause Decision Treatment Cards – Used in testing the "Gist" version of the Website (Paper Prototype)





Side Effects

Hormone therapy:

oral and patch

Increased risk of breast cancer (93 out of 100,000 women), blood clots such as pulmonary embolism (45 out of 100,000 women), coronary heart disease (26 out of 100,000 women), stroke (20 out of 100,000 women), gallbladder disease, breast tenderness, irregular vaginal bleeding.

vaginal HT

Minimal risks.

SSRIs

Dry mouth, decreased appetite, nausea, constipation.

Lifestyle changes

Healthy diet No side effects.

Regular exercise No side effects.

Vaginal moisturizers

Mild vaginal discharge when first starting treatment.

Black Cohosh

Gastrointestinal pains, nausea, headaches, weight gain, constipation, liver toxicity.

Mood

Hormone therapy:

oral and patch

May improve mood.

vaginal HT

No effect on mood.

SSRIs

May improve mood.

Lifestyle changes:

Healthy diet

A healthy, balanced diet may help improve mood.

Regular exercise

Increased physical activity helps improve mood.

Vaginal moisturizers

No effect.

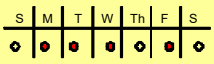
Black Cohosh

No effect.

Daily Routine

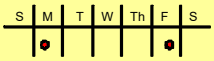
Hormone therapy:

oral



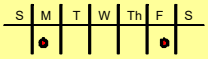
Pill taken once daily

patch



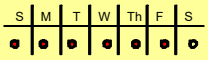
Patch applied once or twice per week

vaginal HT



Applied twice per week

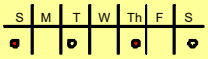
SSRIs



Pill taken once daily

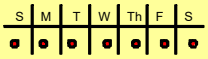
Lifestyle changes:

regular exercise



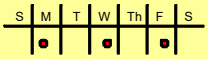
30 minutes four times a week

healthy diet



Daily modifications. Avoid caffeine, spicy foods, hot drinks and excessive alcohol.

Vaginal moisturizers



Applied every three days

Black Cohosh

Tablet twice -daily (or drops daily)

Sleep

Hormone therapy:

oral and patch
May improve sleep if sleep disturbances are due to night sweats.

vaginal HT
No effect.

SSRIs
May improve sleep if sleep disturbances are due to night sweats.

Lifestyle changes

Healthy diet
May improve sleep.

Regular exercise
May improve sleep.

Vaginal moisturizers
No effect.

Black Cohosh
No effect.

Cost per month

Cost estimates are given in ranges and are based on national pharmacy prices for generic medications (when available) with no insurance.

Hormone therapy:		
oral	**$$$$**	**$60-$71**
vaginal HT	**$$$$$**	**$142-$156**
patch	**$$$**	**$32-$40**
Lifestyle changes (depends on changes made)		
healthy diet		**No Cost**
regular exercise		**No Cost**
SSRIs	**$$$$**	**$59-$64**
Vaginal moisturizers	**$**	**$13-$18**
Black Cohosh (depends on strength and dose)	**$$**	**$4-$35**

Additional Benefits

Hormone therapy:

oral and patch

Decrease the risk of developing a hip fracture if taken for many years.

vaginal HT

Relieves discomfort during sexual intercourse.

SSRIs

May improve mood.

Lifestyle changes

Healthy diet helps maintain a healthy weight and reduce risk of stroke, heart disease, diabetes and some cancers.

Regular exercise lowers stress, improves mood and body image. It reduces risk of obesity, heart disease, stroke and diabetes. Weight -bearing exercise helps maintain bone density.

Vaginal moisturizers relieve discomfort during sexual intercourse.

Black Cohosh: No known additional benefits.

References

[i] Murtagh, MJ, Thomson RG, May CR, Rapley T, Heaven BR, Graham RH, Kaner EF, Stobbart L, Eccles MP. Qualitative methods in a randomized controlled trial: the role of an integrated qualitative process evaluation in providing evidence to discontinue the intervention in one arm of a trial of a decision support tool. Qual Saf Health Care. 2007; 16(3):224-9

[ii] Wakker PP. Lessons learned by an economist working in medical decision making. Med Decis Making. 2008 28(5):690-698.

[iii] Reyna V. A theory of medical decision making and health: fuzzy trace theory. Med Decis Making. 2008; 28(6):850-65.

[iv] McKinlay SM, Brambilla DJ, Posner JG. The normal menopause transition. Maturitas. 1992; 14(2):103-15.

[v] Hersh AL, Stefanick ML, Stafford RS. National use of postmenopausal hormone therapy. Annual trends and response to recent evidence. JAMA. 2004; 291:47-53.

[vi] Chlebowski RC, Kim JA, Col NF. Estrogen deficiency symptom management in breast cancer survivors in the changing context of menopausal hormone therapy. Semin Oncol. 2003; 30(6):776-88.

[vii] Col NF, Moulton AW, Cyr MG. Weighing the risks and benefits of hormone replacement therapy on an individual basis-- A clinical framework. Infertility and Reproductive Medicine Clinics of North America 1999; 10:229-242.

[viii] Chlebowski R, Col NF, Weiner E, Collyar D, Cummings S, Vogel V, Eisen A, Lipkus I, Pfister D for the ASCO Breast Cancer Technology Assessment Working Group. American Society of Clinical Oncology Technology Assessment of Pharmacologic Interventions for Breast Cancer Risk Reduction Including Tamoxifen, Raloxifene, and Aromatase Inhibition. J Clin Onc. 2002; 20(15):3328-43.

[ix] Crawford F, Langhorne P. Time to review all the evidence for hormone replacement therapy. BMJ 2005; 330:345.

Remaining Steps Needed to Complete the Project

A. Programming of the PATHS Website. As described in the results section, the paper prototype is now ready to be made available on the Web through programming; this task still needs to be done.

B. Usability Testing of Programmed Website

This phase would test the applicability, relevance and ease of use of the PATHS Website once it became available. The plan called for participants to be recruited through the use of flyers placed in the community and healthcare facilities. Clinicians also were to be recruited to obtain their feedback. Each participant would be screened for eligibility and brief demographic information collected. Each participant would be asked to interact with the Website by logging into the Website and going through twice. First, without interruption from the tester and while thinking aloud, then a second time to answer specific questions about each Web page. These sessions would be audio-taped. If any significant deficiencies are noted at this stage, they would be sent to the programmer for final changes to be made to the Websites. All participants were to be be compensated for their time.

C. Randomized Clinical Trial (RCT)

This phase would be conducted in clinical settings and involve both patient and clinician participation. During the RCT, participants with upcoming standard care clinic appointments would be randomized to either the complete PATHS Website or a comparison group shown the "*GIST"* version. All women would complete a baseline survey and access the Website before their clinic appointment. Assistance would be provided to those without computers or Internet access and those uncomfortable with computers. After they interact with the Website, their doctors would receive a summary report (if approved by the patient). Each participant would be asked to complete two follow-up surveys after their appointment. Participants would be paid for each completed survey returned. Clinicians at each participating clinic would also be invited to participate in this phase of the study. Participating clinicians would complete a baseline survey on demographics, menopausal counseling practices, and prescribing practices concerning menopausal therapies. Following each menopausal counseling session, clinicians would complete a one-page survey that asks how the interaction with the Website affected their counseling, efficiency, and patient interaction.

Proposed criteria for selection of participants for a future RCT are as follows:

Inclusion criteria:

- English-speaking
- Between 45 and 65 years of age (the group most likely to be going through the menopause transition)
- Patient at participating clinics
- Experiencing symptoms that the patient perceives as being related to menopause OR
- Being 6 months or more past their last menstrual period
- Have an upcoming appointment for menopausal counseling or annual physical exam

Exclusion criteria:

- Inability to give informed consent
- Cognitive impairment (using a 6-item screening tool)
- Age under 45 and over 65 years (The mean age of menopause is 51 with the menopause transition typically occuring between the ages of 45 and 55.)
- Personal history of cardiovascular disease, breast cancer, or pre-existing terminal illness that limits life expectancy to less than 2 years (the predictive models used in WISDOM, the basis for PATHS, are not valid for this population)
- Either currently taking hormone replacement therapy (HRT) or selective serotonin reuptake inhibitor (SSRI), OR intending to start taking either HRT or SSRI in the next month.

D. Analysis and Report of Data

Analysis of covariance is proposed for the assessment of ***differences in decision conflict and satisfaction*** between groups, statistically adjusting for any baseline differences. Covariates would include baseline health status, knowledge and satisfaction scores, depression, Internet use, and baseline physician characteristics. Mixed Linear Models would be used for repeated measures such as 2-week and 6-month satisfaction. Patient-level and physician-level factors would be controlled for by including them as covariates.

To determine whether the intervention was associated with a ***change in treatment decisions***, a comparison of the percentage of women who changed treatment decisions from baseline at each measurement time point according to treatment group would be done. Independent variables would include symptom severity (using summary MenQOL score), utility score from PATHS, socio-demographics, time spent in each module (e.g., risk assessment vs PATHS), 10-year risk for CVD, breast cancer, and hip fracture, and physician baseline preferences.

Additionally, we would evaluate patients' overall satisfaction with menopause counseling. ***Satisfaction*** would be evaluated based on the total score for the items included. Analysis of two-way contingency tables of categorical variables (study arm vs. satisfaction category) would be used for each questionnaire item, sub-score, and overall score, based on published guidelines. The independence of these variables would be tested to assess for differences in opinion between the two study arms. The mean overall scores would then be compared using a two-sample nonparametric or parametric test, also stratified by site. The mean difference in satisfaction would be compared using clustered analysis, with the recruiting site as a cluster, with such differences compared among sites. In addition, regression analysis would be performed using a mixed-effects model to differentiate the effect of study group on the level of satisfaction, adjusted for other patient and clinical-center covariates.

APPENDICES (in separate documents as part of AHRQ official grant file)

Appendix A: FULL PAPER PROTOTYPE
Appendix B: GIST PAPER PROTOTYPE
Appendix C: SELECTED ABSTRACTS FROM DIRECTLY RELATED PUBLICATIONS
Appendix D: TIMELINE OF MAJOR EVENTS SURROUNDING GRANT