THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 13, Number 7, 2007, pp. 741–749

DOI: 10.1089/acm.2006.6398

Women's Decision Making About the Use of Natural Health Products at Menopause: A Needs Assessment and Patient Decision Aid

FRANCE LÉGARÉ, M.D., Ph.D.,[1] DAWN STACEY, R.N., Ph.D.,[2] SYLVIE DODIN, M.D., M.Sc.,[1]
ANNETTE O'CONNOR, R.N., Ph.D.,[2] MONIQUE RICHER, Ph.D.,[3]
FRANCES GRIFFITHS, M.D., Ph.D.,[4] ANNIE LeBLANC, M.Sc.,[1] JEAN L.C. ROUSSEAU, Ph.D.,[1]
and SYLVIE TAPP, B.Sc.[1]

ABSTRACT

Objective: To identify the decision-making needs of women about the use of natural health products (NHP) at menopause and to develop a decision aid responsive to their needs.

Design: A qualitative study using focus groups, key informant interviews and group consultation. Content analysis was guided by the Ottawa Decision Support Framework.

Methods: Six focus groups with menopausal women aged 45 to 64 (n = 40) and key informant interviews (n = 15; physicians, nurses, women's advocacy group, NHP stores owners, pharmacists, policy makers) were conducted in two Canadian cities. Two groups of menopausal women (n = 11) were consulted to obtain feedback on the acceptability of the new patient decision aid.

Results: The most common difficult decisions identified by women were: whether or not to take NHP; which NHP to choose; and whether or not to take anything for menopausal symptoms. In addition, key informants identified the challenge of choosing between hormone therapy and NHP for menopausal symptoms. The main sources of difficulty in making these decisions were the following: (1) inadequate knowledge and unrealistic expectations associated with NHP; (2) closed mindedness of physicians to discussion about NHP; (3) conflicting opinions of others; (4) inadequate resources to support NHP decision-making (e.g., information, finances, time); and (5) menopausal symptoms interfering with decision-making (e.g., lack of sleep due to hot flashes). To facilitate decision making, participants suggested the need for information about available choices, tighter regulation of NHP by the government, and access to health professionals conversant in NHP and medical options. The patient decision aid was developed according to the International Patient Decision Aid Standards and based on women's identified needs. Women described the aid as easy to understand and useful for considering the decisions about NHP.

Conclusions: Middle-age women reported difficulty when facing decisions about the use of NHP. Many sources of difficulty could be addressed in the patient decision aid. Subsequent studies should evaluate the effect of this decision aid on the decision-making process of women.

[1]Centre de Recherche du Centre Hospitalier Universitaire de Québec, Hôpital Saint-François d'Assise, Québec, Canada.
[2]School of Nursing, University of Ottawa, Ontario, Canada.
[3]Faculté de Pharmacie, Université Laval, Québec, Canada.
[4]Health Science Research Institute, University of Warwick, UK.

INTRODUCTION

In the last decade, the interest of individuals toward the use of natural health products (NHP) has grown considerably,[1] and middle-aged women who are living through menopause are no exception.[2] Many women exhibiting menopausal symptoms such as hot flashes, mood swings, or insomnia may consider using one or more NHP.[3,4] Although estrogen therapy remains the most effective treatment for relieving menopausal hot flashes, there is a growing interest in nonhormonal therapies.[5] Consequently, more than 100 new NHP aimed at women in menopause appeared in the American market between 1998 and 2000.[6]

Decision making about the use of NHP to manage menopausal symptoms is rife with uncertainty.[7] A recent systematic review concluded that data were insufficient to support the effectiveness of any complementary and alternative therapy for the management of menopausal symptoms.[5] Decision making in the context of scientific uncertainty (i.e., when convincing data are in conflict or nonexistent) is influenced by other factors such as realistic expectations, values associated with potential risks and benefits, undue pressure from others, as well as the desired role in decision-making.[8] Thus, in the face of uncertainty, decision support often requires (1) evidence-based information about options, benefits, risks, and the degree of scientific uncertainty so as to promote informed decision making based on realistic expectations; (2) values clarification to determine which option has outcomes that are more consistent with an individual's preferences; and (3) guidance to facilitate patient participation in decision making.

Consequently, new interventions that address gaps in mutual understanding of facts and values between patients and health professionals have been developed.[9,10] One such intervention is a "patient decision aid" that aims to prepare patients for discussing health decisions with their practitioner by helping patients understand the facts (e.g., options, benefits, harms) and clarifying their values associated with their options.[10] The goal is to arrive at a decision that is informed by the best evidence and consistent with the patient's values. Patient decision aids increase individuals' knowledge of the options, promote the active participation of individuals in the decision to be made, lead to more realistic expectations, improve the match between the choice that is made and the individual's values, and reduce decisional conflict. The individual's values refer to the importance this individual place on benefits and harms that are associated with the options. However, the Cochrane Inventory of more than 500 patient decision aids and literature review conducted for this study found no decision aids focused on the use of NHP by menopausal women. Consequently, the aims of this study were to identify the decision-making needs of women regarding the use of NHP at menopause, to develop a decision aid to address their needs, and to determine its acceptability.

MATERIALS AND METHODS

In health services research and most specifically in studies that aim at improving our understanding of how individuals make health-related decisions, there is a growing body of literature that emphasizes the lack of theory.[11] In turn, this lack of theory is said to be hampering our interpretation of change as well as the development of effective interventions.[12] Therefore, guided by the Ottawa Decision Support Framework (ODSF),[8] this study used (1) qualitative methods to identify the decision-making needs of women facing decisions about using NHP; (2) a process of decision aid development that followed the recent guidelines established by the International Patient Decision Aid Standards (IPDAS) Collaboration[13]; and (3) group consultation for assessing the acceptability of the decision aid. The ODSF is a 3-step process that comprises (1) assessing determinants of decision making (e.g., perception of the decision, perception of others, resources needed to make the decision, characteristics of the individual); (2) addressing identified decisional needs; and (3) evaluating the decision quality and progress in decision making.

Data collection involved focus groups, individual interviews, and a group consultation. The semistructured interview guide used in the focus groups and individual interviews consisted of a standardized set of questions for conducting decision-making needs assessments based on the ODSF.[14] Focus groups were conducted in 2 Canadian cities with peri- or postmenopausal women ages 45 to 64 years who were considering the use of NHP for menopausal reasons. Women were recruited using bulletin boards in health organizations, local newspapers, radio stations, and word of mouth. A purposeful sampling strategy sought to recruit 15 key informants representing groups of individuals who may advise and/or guide women on use of NHP (e.g., physicians, nurses, pharmacists, NHP store owners, representatives of women's advocacy groups, and policymakers). Previous studies have documented the potential influence of these individuals on the decision-making process of women regarding complementary and alternative therapies at menopause.[15] In order to locate these key informants, we used a snowball approach, which means that we asked "well-situated people" in each group to identify potential individuals.[16] We contacted identified individuals until we obtained a minimum of 2 individuals per targeted group. Given the lack of homogeneity among these key informants, the decision was made to conduct individual interviews. These interviews were conducted in French or English, depending on the preference of the interviewee.

According to IPDAS collaboration, quality decision aids are developed based on the decisional needs as perceived by the target audiences, review by individuals who have made the decision, and pilot testing at the time of decision making.[13] Higher-quality decision aids include information on the options and their outcomes (benefits and harms), prob-

abilities of outcomes, help with clarifying values associated with outcomes, and explicit guidance in the process of decision making. Additional IPDAS criteria focus on balanced presentation of options, use of scientific evidence, disclosure of potential conflicts of interest, and plain language. Finally, quality decision aids are evaluated to determine their effect on decision quality (informed and values based) and the decision-making process.

Focus groups and individual interviews were tape-recorded and transcribed verbatim. Content analysis of each transcript was guided by the ODSF. The unit of analysis was the individual focus group or key informant interview. In this qualitative study, our intention was to maximize the potential for triangulation of views from the women themselves and key informants in the field.[17] Participants were sent the transcript with a summary of the identified themes and were asked to verify their accuracy (response rate: 65% of women, 73% of key informants). Based on the identified themes, a prototype of a first decision aid was produced. Menopausal women were recruited from 2 community groups to participate in group consultation sessions aimed at assessing the acceptability of the first prototype of the patient decision aid. In addition to an open discussion that provided feedback on the decision aid, they were asked to complete a standardized acceptability survey.[18] This survey elicits feedback on the amount, length, clarity, balanced presentation, and usefulness of the information for decision making. The acceptability survey and participant demographics were analyzed descriptively using SAS v9.1 (Cary, NC). Approval was received from the ethics review committees at the Ottawa Hospital in Ottawa and at Hôpital St-François d'Assise in Québec City, Canada.

RESULTS

Characteristics of participants

Of the 49 women who agreed to participate, 40 attended 1 of 6 focus groups offered in French (n = 3) or English (n = 3). The typical woman participant was 56 years old, married, with postsecondary education, and in good health (Table 1). On the Menopause-Specific Quality of Life Questionnaire (MENQOL),[19] the mean scores were as follows: vasomotor symptoms 2.54 ± 1.76, psychosocial symptoms 2.67 ± 1.37, physical symptoms 3.30 ± 1.18, and sexual symptoms 3.14 ± 1.83. The MENQOL is a validated instrument that tests physical, vasomotor, psychosexual, and sexual domains of quality of life. For each domain, a minimum score of 0 corresponds to no symptoms and a maximum score of 7 corresponds to extremely bothersome symptoms.

Of 19 key informants invited to participate, 15 were interviewed: 3 representatives from women's advocacy groups, and a francophone and anglophone participant for each of the following groups: nurses, gynecologists, family physicians, pharmacists, NHP store owners, and policymakers. Most key informants were female (n = 13) with a median age of 53 (range 30–68). Two group consultation sessions were conducted with 11 women from community-

Table 1. Characteristics of the Women in the Focus Groups

Characteristics	*6 Focus groups (n = 40)*
Median age in years (range)[a]	56 (44–67)
Married or living with a partner, %	82.5
Living alone, separated or widowed, %	17.5
Secondary education or less, %	12.5
Postsecondary education, %	87.5
Employed full time, %	32.5
Employed part time, %	32.5
Not employed (includes retired), %	32.5
No response	2.5
Annual income $45,000 or more, %	77.5
Annual income less than $45,000, %	20
No response	2.5
Good to excellent health, %	87.5
Fair to poor health, %	10
No response	2.5
Preferred role in decision	
Women prefer to make the decision alone, %	12.5
Women make decision with advice from physician, %	55
Decision is shared between women and their physician, %	25
Physicians make the decision with advice from the women, %	5
Physicians makes decision alone, %	0

[a]($N = 37$).

Table 2. Difficult Decisions About the Use of Natural Health Products (NHPs) at Menopause that were Identified

	Focus groups (n = 6)	*Key informants (n = 15)*
Difficult decisions	N *(%)*	N *(%)*
What to take? Which product?	4 (67)	10 (67)
Whether or not to take NHPs?	4 (67)	6 (40)
Take nothing at all?	4 (67)	2 (13)
Hormone therapy or NHPs?	2 (33)	7 (47)
NHPs with hormone therapy	2 (33)	1 (17)
Who to consults?	1 (17)	2 (13)
NHPs to replace hormone therapy?	1 (17)	1 (7)

based groups, ages 45–64, who provided comments on the acceptability of the first prototype of the patient decision aid.

Types of decisions and sources of difficulty regarding the use of NHP at menopause

Table 2 shows frequency of difficult decisions about the use of NHP at menopause that were identified, and Table 3, the sources of difficulty in making these decisions. Consistent with the ODSF, participants identified that unrealistic expectations of risks associated with NHP and poor understanding of information influenced women's perception of the decision. Difficulties related to having adequate support and advice from others were due to close-mindedness of physicians in the discussion of NHP, conflicting opinions from others, societal pressures to look young and healthy, and lack of a credible person for advice. Limited resources that negatively influenced the decision making included lack of scientific evidence, questionable quality of information, costs associated with purchasing NHP as well as consultation with NHP practitioners, and inadequate time for deliberating on the decision. Finally, menopausal symptoms such as memory problems or being sleep deprived were described by key informants as interfering with being able to make decisions.

The role of others in NHP decision making

In all focus groups, women expressed that they wanted to play an active role in making decisions about the use of NHP at menopause. One woman shared, "It's because if your doctor says to you 'don't touch that' and you wanted to try something, I know what I would do because I'm capable of taking my own health in hand." However, in 3 focus groups, women also reported wanting to share decision-making with their physician. For example, one woman said, "I prefer to do it in conjunction with my doctor, but with my doctor being informed and having the information there so I can get the information I want."

When the women were asked who else was involved in making their decisions about the use of NHP, they identified equally their partner, female friends, and physician (n = 3/6 focus groups), then the nurse, their families, and their

Table 3. Sources of Difficulty with Natural Health Products (NHPs) Decision Making (Part 1)

ODSF concepts	*Sources of difficulty*	*Exemplars from participants*
Perception of the decision	Unrealistic perception of risk with NHP	"I feel that the medical world is safer in some ways." (FG #3)[a]
	Poor understanding of information about NHP	"We are in lower town here and sometimes there are women who are not rich and their level of education is very low…They might have received the explanation from the physician and they might have all the information but they do not understand." (KI #4[a])
		"The power of the Internet makes so much information available at the fingertips and the woman doesn't know what is scientific and what is marketing. And they're trying to make a decision based on things they've read without really knowing how to assess the validity of the information they're reading (KI #9)

[a]Literal translation of French quotes from focus groups (FG) or key informant interviews (KI).
ODSF, Ottawa Decision Support Framework.

Table 3. Sources of Difficulty with Natural Health Products (NHPs) Decision Making (Part 2)

ODSF concepts	*Sources of difficulty*	*Exemplars from participants*
Support/advice from others	Closed-mindedness of physicians to discuss NHPs	"I have gone to the doctor and I don't necessarily want to be put on pills at age 44… Every time I bridge [sic] the fact of, can we try something else, I was told no, that's not the route that we want to go. I don't like that answer. I have been to 2 doctors now and both of them have sort of said, that sort of stuff doesn't work and no, I want you to take these pills." (FG #5)
	Conflicting opinions from others	"There are so many diverse opinions. In the last 3 months I have probably been to 6 or 7 different health food stores and they all ask: Have you tried evening primrose, have you tried soy, more vitamin B? They all have different opinions. It is overwhelming. I have to go home and try to absorb what 1 person said and then I go to the next person and I get a whole different story. It is all just very confusing." (FG #5)
		"On one side of the family they are all for natural health products. But this is a split family. On the other side, they only swear by regular medication. When they all meet together they keep arguing and when I hear them arguing I wonder: for God's sake, what will I do for myself when it is the time to decide?" (Fig #2[a])
	Pressure from society	"They are very intrigued by more of an approach like what [Susan] Sommers says which is one that speaks to women's need to be sexually attractive, to stay as young looking as possible. This is caused by a society pressure I think. We, women, must stay young and pretty and… all our [lives]. Yes. It's absolutely true that this is something that our culture teaches us. And I often have a difficult time having my patients realize what the real issues are in terms of health." (KI #12)
	Lack of credible person to provide decision support	"They [women] don't have many credible persons they can trust. This is why it is so difficult to make a decision. (KI #3[a])
		"Those who are responsible for selling natural health products, wherever they are, have a personal interest and I don't want be part of that. As I said, I tend to back away from that. I am afraid of being taken advantage of and I tell myself that one day or another I will be taken advantage of, so I don't buy that product." (FG #3[a])

[a]Literal translation of French quotes from focus groups (FG) or key informant interviews (KI).
ODSF, Ottawa Decision Support Framework.

Table 3. Sources of Difficulty with Natural Health Products (NHPs) Decision Making (Part 3)

ODSF concepts	*Sources of difficulty*	*Exemplars from participants*
Resources: information	Lack of scientific evidence	"Somehow there needs to be more research done on the natural health products and just more information about what they really can do." (FG #4)
	Too much information	"I think it's probably the amount of information that's available. There is so much information that women have. And everything sounds good." (KI #11)
	Sources of information are not reliable	"When you walk into one of those places, all of the signs around the various products appeal to what most middle-aged women are really interested in: weight loss, joint pain, lack of sleep, miracle creams. They list one or two symptoms and it is all labeled for weight loss. Lose 10 lbs in 10 days. You tend to gravitate to the sign." (FG #6)
Resources: financial	Cost of purchasing NHP and of accessing advice from NHPs practitionrs	"Then there is the financial thing.…" (FG #6)
		"You can't go perhaps to a naturopath because it's not covered." (KI #11)
Resources: time	Lack of time for women and health professionals	"So when I do get in to see her with all of those things I checked off, how much time is she going to have now? I think the time spent consulting the family physicians is going to diminish hugely for our age group and people behind us. They do not have time." (FG #6)
		"Many women are in the sandwich situation and the last thing that they put ahead of everything else, is themselves. And this is part of self-care, looking at these issues. So time is a problem." (KI #12)
Characteristics of women	Menopausal symptoms interfere	"The symptoms that they're suffering from make it difficult for them to make decisions. Because they're sleep deprived or they think they got memory problems, they're forgetting things." (KI #9)

ODSF, Ottawa Decision Support Framework.

pharmacists (n = 2/6 focus groups), followed by the naturopath and NHP store owners (n = 1/6). Key informants cited the same individuals or groups of individuals as the women and the most frequently identified were family (n = 11/15) followed by physicians (n = 10/15).

Resources for NHP decision making

In the focus groups and interviews, resources currently used by women to make a decision about NHP at menopause were (from most to least frequent): magazines, Internet, pharmacies, women's groups, physicians, family/friends, and naturopaths. When asked what was needed to better support these types of decisions, the resources most frequently identified by women were (1) more support from physicians; (2) better information (objective, reliable, and credible); and (3) individuals they perceived as being adequately qualified in the area (Table 4). Women also expressed their desire for tighter government regulations regarding the use of NHP at menopause and their lack of confidence resulting from the fact that these products are not regulated. Key informants identified similar resources needed to support NHP decision making as did the women (Table 4).

Patient decision aid

The results from the needs assessment were used to design a patient decision aid focused on the decision "whether or not to take NHP" for menopausal symptoms. The paper-based prototype decision aid provided (1) information on the available options for menopausal women, including the probabilities of outcomes when available, lack of scientific evidence for many NHP, and possible interaction effects between medications and NHP; (2) a balance scale to clarify values associated with outcomes of options; (3) a structured process to follow when making the decision; and (4) questions to self-assess the severity of menopause-related health issues.[20]

Of the 11 women who provided feedback on the acceptability of the first prototype of the patient decision aid, 9 rated the presentation of the information and usefulness of the decision aid as good to excellent. Seven women said that the sections presenting NHP and menopause were complete and useful. During the consultations, participants suggested removing the section aimed at educating women about the concept of probabilities and requested more information about specific products, even if the evidence was not conclusive. The decision aid was modified according to their suggestions and included a list of the most commonly used NHP at menopause with the level of evidence that is available for each one of them (Fig. 1).[21–23]

DISCUSSION

This study is the first focused specifically on the decision-making needs of women regarding the use of NHP at menopause and the difficulties associated with making this decision. Overall, results from this study suggest that women are actively involved in decisions regarding the use of NHP at menopause and that these decisions are perceived as difficult by women and those who provide advice and/or guidance to them. Many of the factors interfering with decision making (e.g., inadequate information, unclear values, and conflicting opinions of others) could be addressed by the development of a patient decision aid that would guide women in the process of decision making. Menopausal women clearly identified that the information to support decision making, including patient decision aids, should be made available through the Internet, women's magazines, and directly from health care professionals.

Although the decision aid addresses some factors causing menopausal women difficulty in making decisions about NHP, it does not address financial issues or directly address inadequate time for decision making. The current prototype

Table 4. Resources Needed to Support Natural Health Products (NHPs) Decision-Making

	Focus groups (n = 6)	*Key informants (n = 15)*
Resources	N *(%)*	N *(%)*
More support from physicians	6 (100)	1 (7)
Information (objective, reliable, credible)	6 (100)	7 (47)
Adequately qualified individuals	5 (83)	4 (27)
Tighter government regulations	4 (67)	5 (33)
Integrated care approach	4 (67)	1 (7)
Education sessions	3 (50)	3 (20)
Telephone information line	3 (50)	0 (0)
More time with physician	3 (50)	0 (0)
Trustworthy website	2 (33)	2 (13)
Insurance coverage	2 (33)	2 (13)
NHP requiring a medical prescription	2 (33)	1 (7)
More research	1 (17)	4 (27)

Step 2. Getting the facts

When learning about the benefits and risks of natural health products that have been used by women during menopause. It is important to know that the quality of the information varies. This quality depends on the number and types of research studies that have been done.

A: Very good level of evidence that there are benefits related to menopause (No product in this class)

B: Good quality evidence showing that there are benefits related to menopause

Common name *(latin)*

Black cohosh *(cimicifiga racemosa, Actaea racemosa)*

Active chemical
27-deoxyactein

Dose
1 to 2 mg of 27-deoxyactein per day taken by mouth

Tablets
1 or 2 tablets (20 mg tablet=1 mg 27-deoxyactein)

Liquid
20 to 40 drops of a 60% ethanol tincture daily (1:10) (20 drops=1 mg 27-deoxyactein)

Dried root powder
40 to 200 mg of dried rhizome divided in several doses (40 mg=1 mg 27-deoxyactein)

Dried root infusion
1 to 2 g boiled in 150 ml of water, filtered and cooled

(doses recommended by The British Herbal Compendium)

Possible benefits
Decreases general menopause symptoms such as migraine headaches, sleep disturbances, hot flashes, mood problems, perspiration, heart palpitations, and vaginal dryness for up to 6 months.

Possible risks
No study has reported risks and benefits when taken longer than 6 months.
If an overdose is taken, it may cause nausea, vomiting, bradycardia (low heart rate), headache, fainting, sweating and vision problems.

Restrictions or warnings
Consult your physician before use if you:

- have or have had breast or uterine cancer
- have an allergy to aspirin or to the *ranunculaceae* family
- suffer from endometriosis
- are using a hormone replacement therapy for menopause (hormones)
- suffer from epilepsy
- are taking medication for hypertension
- have heart or liver problems

It may be confused with blue cohosh *(caulophyllum thalictroides)* that can have harmful effects on the heart.

*Please check with Health Canada Advisory regarding possible link between black cohosh and liver damage *http://www.hc-scgcca/dhp-mps/advisories-avis/indes_e.html*

Soya *(Soja hispida, Glycine max)*

Dose
50 to 75 mg of isoflavones per day taken by mouth
Isolated protein (powder)
60 g (25 g=60 mg of isoflavones)
Soy flour
45 g (50 g=60 mg of isoflavones)

Possible benefits
Decreases hot flashes due to menopause.

Possible risks
Soya does not have any known long-term toxic effects.

Side-effects may include nausea, constipation, and bloating.

Restrictions or warning
Some people can have or develop an allergy to soya. Consult your physician if you:

- have or have had breast, ovarian or uterine cancer
- are taking estrogen
- are taking medication for the treatment of cancer
- are taking a blood thinner such as warfarin

C: Uncertain or contradictory evidence related to menopause

Common name *(latin)*		
Ginseng *(Panax ginseng)*	**Red clover** *(Trifolium pratense)*	It is not possible to identify the benefits or risks associated with the use of these products. Research studies are needed.
Wild yam *(Dioscoreaceae villosa)*	**St Johns wort** *(Hypericum perforatum)*	
Green tea *(Camellia sinensis)*	**Vitamin E or** *alpha-tocopherol*	

D: Good level of evidence showing that there are NO benefits related to menopause

Common name *(latin)*	
Evening primrose oil *(Oenothera biennis)*	Studies show that evening primrose oil does not decrease hot flashes.

E: Very good level of evidence showing that there are NO benefits related to menopause (No product in this class)

F: No available scientific evidence related to menopause

Common name *(latin)*	
Garlic *(Alium sativum)* **Chamomille** *(Matricaria recutita, Anthemis nobilis)* **Dong quai** *(Angelica sinensis)* **Echinacea** *(Echinacea)* **Ginkgo** *(Ginkgo biloba)* **Common valerian** *(Valeriana officinalis)*	The benefits and the risks related to these products are not known. Research studies are needed.

Withdrawn from the market by Health Canada

Common name *(latin)*	
Kava *(Piper methysticum)*	Health Canada and similar agencies in other countries have reports that kava may cause serious liver dysfunction and as a result have withdrawn it from the market.

These tables are based on the information available on *http://www.naturalstandard.com.*

Given that NHPs may have adverse events and interactions,
please discuss with your healthcare provider if you are considering taking any natural health product.

FIG. 1. Most commonly used natural health products at menopause with the level of evidence that is available for each one of them. From Légaré F, Stacy D, Dodin S, Tapp S. A Decision Aid for Women Considering Natural Health Products for Menopause Symptoms© expiring November 28, 2007. Excerpted with permission from the authors.

of the patient decision aid has the potential to enhance support from practitioners, given that it has an interactive worksheet that can be used to facilitate communication between practitioners and patients. Previous evaluation of patient-practitioner dialogue, when patients were prepared using a similar decision-making worksheet for discussing decisions about using hormone replacement therapy, found that compared to controls, the dialogue was more 2-way and the key factors influencing the decision (e.g., patients' knowledge, clarity of their values, and adequate support from others) were more likely to be discussed.[24] Therefore, if women share their NHP worksheet with their practitioner, there is the potential for more discussion about the decision being stimulated. However, strategies are also required to enhance practitioner skills[25,26] in addressing the decision-making needs of menopausal women. Such strategies include counseling and/or referring these women to patient decision aids such as the one developed in this study.

The vast majority of women we met in the focus groups said they wanted to play an active role in making the decision to take NHP during menopause. This is congruent with previous research in this field.[27] However, women also expressed the need to be supported in their decision-making process by their physician or by their immediate circle (female friends, family). Unfortunately, they do not perceive that physicians are open to discussing this subject. This observation has been noted in other studies.[28] Therefore, it would be important to plan interventions with physicians to provide them with the tools and abilities to facilitate open discussion on the subject.[29] It is possible that a greater open-mindedness or ability to tackle patients' expectations toward NHP on the part of physicians might decrease the risk of undesirable interactions between NHP and medications.[30,31]

In this study, women expressed their desire for tighter government regulation regarding the use of NHP at menopause and their lack of confidence resulting from the fact that these products are not currently regulated. These findings suggest that women who participated in this study were favorable toward regulation; however, they also suggest that these women had not learned of the new regulations by Health Canada concerning NHP, which came into effect in January 2004. Therefore, information about NHP regulations needs to be communicated to the public, and patient decision aids provide a medium for doing so. For example, in the patient decision aid that was developed, the section on kava highlights the Health Canada stop-sale order for all products containing kava and provides the URL for access to more detailed information.

Limitations and strengths of the study

This is a qualitative study in which the women were recruited using a "snowball" strategy and publicity in various media. As a result, we had a fairly homogeneous group of women who were married, educated, in the middle-income range, and in good-to-excellent health. Unfortunately, we did not assess other potentially important characteristics of women such as race and religion. Therefore, we cannot assume that our results are transferable to other populations. However, this study followed a rigorous process that has proven useful and effective for producing decision aids that were shown to improve the decision-making process of individuals facing difficult decisions. Also, this study was focused on the decisional needs of women regarding NHP. Therefore, it cannot inform us as to the decisional needs of physicians themselves regarding NHP. More specifically, the strengths of our study are (1) guidance based on a conceptual framework focused on decisional conflict; (2) member checking by participants of the results; and (3) feedback on the prototype decision aid developed, based on identified needs of women facing this decision. Consequently, we believe that the decision aid about NHP during menopause, produced in French and in English, has the potential to fill a growing need among women who are considering the use of NHP.

CONCLUSIONS

Menopausal women describe decisions about the use of NHP as difficult and express the need for support with decision making. In particular, they are looking for written information as well as someone well informed on both medical and NHP options with whom they can discuss the decision. Patient decision aids, such as the one developed in this study, are effective for improving knowledge, expectations, and engaging women in a stepped process of decision making. However, given the limited evidence on the effectiveness of NHP at menopause, this decision is likely to continue to be a challenging one. Furthermore, women are mentioning that, in addition to the need for resources such as the decision aid, they prefer to have individuals who can discuss both medical and NHP options for managing menopausal-related symptoms. Future studies are needed to evaluate the decision aid with women facing the decision regarding the use of NHP at menopause, including its effect on the patient/practitioner discussion.

ACKNOWLEDGMENTS

We thank all participants in this study. This study was supported by a grant from Health Canada–Natural Health Products Directorate. France Légaré is Tier 2 Canada Research Chair in Implementation of Shared Decision Making in Primary Care. Sylvie Dodin is Lucie and André Chagnon Chair in Alternative and Complementary Medicine. Annette O'Connor is Tier 1 Canada Research Chair in Health Care Consumer Decision Support.

REFERENCES

1. Eisenberg DM, Davis RB, Ettner SL, et al. Trends in alternative medicine use in the United States, 1990–1997: Results of a follow-up national survey. JAMA 1998;280:1569–1575.
2. Brown JB, Carroll J, Boon H, Marmoreo J. Women's decision-making about their health care: Views over the life cycle. Patient Educ Couns 2002;48:225–231.
3. Singh B, Liu XD, Der-Martirosian C, et al. Menopausal issues: A national probability sample of US women. Altern Ther Health Med 2007;13:24–29.
4. Dennerstein L, Dudley EC, Hopper JL, et al. A prospective population-based study of menopausal symptoms. Obstet Gynecol 2000;96:351–358.
5. Nelson HD, Vesco KK, Haney E, et al. Nonhormonal therapies for menopausal hot flashes: Systematic review and meta-analysis. JAMA 2006;295:2057–2071.
6. Kass-Annese B. Alternative therapies for menopause. Clin Obstet Gynecol 2000;43:162–183.
7. Taylor M. Alternatives to HRT: An evidence-based review. Int J Fertil Womens Med 2003;48:64–68.
8. O'Connor AM, Tugwell P, Wells GA, et al. A decision aid for women considering hormone therapy after menopause: Decision support framework and evaluation. Patient Educ Couns. 1998;33:267–279.
9. Towle A, Godolphin W. Framework for teaching and learning informed shared decision-making. BMJ 1999;319:766–771.
10. O'Connor AM, Stacey D, Entwistle V, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev 2003;1:CD001431.
11. Grol R, Grimshaw J. From best evidence to best practice: Effective implementation of change in patients' care. Lancet. 2003;362:1225–1230.
12. Mullen PD, Allen JD, Glanz K, Fernandez ME, et al. Measures used in studies of informed decision-making about cancer screening: A systematic review. Ann Behav Med 2006; 32:188–201.
13. Elwyn G, O'Connor A, Stacey D, et al. Developing a quality criteria framework for patient decision aids: Online international Delphi consensus process. BMJ 2006;333:417.
14. Cranney A, O'Connor AM, Jacobsen MJ, Tugwell P, et al. Development and pilot testing of a decision aid for postmenopausal women with osteoporosis. Patient Educ Couns 2002;47:245–255.
15. Suter E, Verhoef M, Bockmuehl C, et al. Inquiring minds: Women's approaches to evaluating complementary and alternatives therapies for menopausal symptoms. Can Fam Physician 2007;53:84–90.
16. Patton MQ. Qualitative Evaluation and Research Methods. 2nd ed. London: Sage, 1990.
17. Creswell J. Research Design: Qualitative, Quantitative and Mixed Methods Approaches. 2nd ed. London: Sage, 2003.
18. Barry MJ, Fowler FJ Jr, Mulley AG Jr, et al. Patient reactions to a program designed to facilitate patient participation in treatment decisions for benign prostatic hyperplasia. Med Care 1995;33:771–782.
19. Hilditch JR, Lewis J, Peter A, et al. A menopause-specific quality of life questionnaire: Development and psychometric properties. Maturitas 1996;24:161–175.
20. Heinemann K, Ruebig A, Potthoff P, et al. The Menopause Rating Scale (MRS) scale: A methodological review. Health Qual Life Outcomes 2004;2:45.
21. Mahady GB, Parrot J, Lee C, et al. Botanical dietary supplement use in peri- and postmenopausal women. Menopause 2003;10:65–72.
22. Newton KM, Reed SD, Grothaus L, et al. The Herbal Alternatives for Menopause (HALT) Study: Background and study design. Maturitas 2005;52:134–146.
23. Natural Standard Collaboration. Natural Standard. The Authority on Integrative Medicine. Online document at: http://www.naturalstandard.com Accessed June 15, 2007.
24. Guimond P, Bunn H, O'Connor AM, et al. Validation of a tool to assess health practitioners' decision support and communication skills. Patient Educ Couns 2003;50:235–245.
25. Légaré F, O'Connor A, Graham I, et al. Supporting patients facing difficult health care decisions: Use of the Ottawa Decision Support Framework. Can Fam Physician 2006;52: 476–477.
26. Stacey D, Pomey MP, O'Connor AM, Graham ID. Adoption and sustainability of decision support for patients facing health decisions: An implementation case study in nursing. Implement Sci 2006;1:17.
27. Alfred A, Esterman A, Farmer E, et al. Women's decision-making at menopause: A focus group study. Aust Fam Physician 2006;35:270–272.
28. Barnett R. A Preliminary Framework for Understanding Women's Use of Natural Health Products (NHP) and Complementary and Alternative Health Care (CAHC) [in French]. Health Canada: Natural Health Products Directorate. Health Products and Food Branch, and Women's Health Bureau. Health Policy and Communications Branch, Ottawa, Canada. 2004.
29. Kemper KJ, Gardiner P, Gobble J, Woods C. Expertise about herbs and dietary supplements among diverse health professionals. BMC Complement Altern Med 2006;6:15.
30. Seidl MM, Stewart DE. Alternative treatments for menopausal symptoms: Qualitative study of women's experiences. Can Fam Physician 1998;44:1271–1276.
31. Richter DL, Corwin SJ, Rheaume CE, McKeown RE. Perceptions of alternative therapies available for women facing hysterectomy or menopause. J Women Aging 2001;13: 21–37.

Address reprint requests to:
France Légaré, M.D., Ph.D.
Department of Family Medicine
Université Laval
Centre de Recherche du Centre Hospitalier
Universitaire de Québec
Hôpital St-François d'Assise
10 rue de l'Espinay
Québec, Québec G1L 3L5
Canada

E-mail: france.legare@mfa.ulaval.ca