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Women's Decisions and Decisional Conflict
Regarding Long Term Hormone Replacement Therapy

By

Elizabeth Anne Wood

Submitted to the School of Graduate Studies in

Partial Fulfilment of the Requirements

for the Degree

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Abstract

Long term preventive hormone replacement therapy (LTP-HRT) is attracting considerable attention for its potential in reducing the incidence of coronary heart disease and osteoporosis associated fractures in post-menopausal women. Recently, the American College of Physicians and the Society of Obstetricians and Gynaecologists of Canada (SOGC) issued guidelines suggesting that all women consider LTP-HRT at menopause. The acceptability of LTP-HRT to women after they have had the opportunity to consider the benefits and risks has not been well studied.

The study objectives were: 1) to describe women's decisions and decisional conflict regarding LTP-HRT after being presented with the evidence of benefits and risks and clarifying values; 2) to describe the difference between those who accept or decline LTP-HRT in terms of: a) expectations of LTP-HRT benefits and risks, and b) the importance women attach to the benefits and the risks; and 3) to describe the factors women identify as contributing to their decision to take or not take LTP-HRT or being unsure about taking LTP-HRT.

A secondary analysis from an existing data base was conducted. The variables in the data base included women's expectations, importance ratings, decisions and decisional conflict about LTP-HRT after they had been exposed to a decision aid explaining benefits and risks and clarifying

personal values. Hypotheses derived from a Consumer Health Decision Model asserted that women choosing LTP-HRT would: have higher expectations of the LTP-HRT benefits; lower expectations of the risks; place higher importance on the benefits and lower importance on the risks. Inclusion sampling criteria of the 100 women providing responses were: aged 50-60; attending a family practice; current users or never users of HRT; at least two years postmenopausal or perimenopausal, but on HRT for at least two years; and English speaking. Sampling exclusion criteria included those women who: had previously discontinued HRT due to intolerance of side effects; were currently on HRT for less than two years; had a personal cancer history; or had recurrent thrombophlebitis. Descriptive statistics were used to analyze demographic characteristics, decisions and decisional conflict. Differences in expectations and importance ratings between those accepting and declining LTP-HRT were analyzed using the Mann-Whitney U test. Reasons underlying the women's decisions were analyzed using content analysis.

The typical woman who participated in the study was 57 years of age; had some post secondary education; and was currently using HRT. Over half the women had at least one CHD risk factor and had a hysterectomy. Less than 15% of the respondents reported having osteoporosis or a first degree relative with breast cancer.

Women's decisions to take LTP-HRT were distributed as follows: 56% yes; 26% no; and 18% unsure. Decisional conflict was generally low: 66% of the women expressed certainty about their choice; 80% felt knowledgeable about LTP-HRT benefits and risks; and 75% felt they had made an effective decision. However, less than half felt they had enough advice/support and were sure about the relative importance of the benefits compared to risks.

Women who accepted or declined LTP-HRT did not have statistically significant differences in expectations of risk of CHD, osteoporosis, and breast cancer with and without hormone therapy. However, meaningful differences were noted with higher expectations of CHD without HRT in those accepting LTP-HRT and higher expectations of breast cancer with HRT in those declining LTP-HRT.

In contrast, women's importance ratings of LTP-HRT benefits and side effects did differ significantly between those accepting and declining LTP-HRT. Women who chose LTP-HRT had higher expectations of benefits and lower expectations of risks. Differences in importance ratings attached to breast cancer were meaningful but not statistically significant.

The reasons most often identified by women who chose LTP-HRT were prevention of CHD and osteoporosis (61%) and relief of hot flashes (54%). Those who chose not to take LTP-HRT

gave reasons such as dislike of taking pills (47%), and risk of cancer (11%).

The study demonstrates that decisional conflict is low in the information and values domain after using a decision aid but some still need to obtain support and advice from others to complete the decision making process. The differences in importance of benefits and risks expressed by women making different decisions, highlight the salience of women's values in decision making.

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Chapter 1

Introduction

Long-term hormone replacement therapy (LTP-HRT) is receiving considerable attention for its potential in reducing coronary heart disease (CHD) and osteoporosis in postmenopausal women (10). CHD is a major cause of mortality and morbidity among women past menopause. Over 75% of CHD in women occurs after menopause (2). Low CHD rates in premenopausal women suggest that estrogen protects women from heart disease (2,3).

Osteoporosis, an important disorder associated with aging (4-6), is largely responsible for the growing incidence of fractures in the older population (7,8). It is due to decreased bone density associated with the decrease of estrogen after menopause (10). In Canada, it is estimated that 850,000 Canadians suffer from osteoporosis, costing the health care system from \$100 million to \$300 million annually (6,9). Fifteen out of every 100 women sustain an osteoporosis-associated fracture during their postmenopausal years (8).

Recently, the American College of Physicians (20) published practice guidelines urging that all postmenopausal women consider LTP-HRT to prevent osteoporosis and heart disease after learning of the benefits and risks, and considering the personal importance of the benefits and risks.

The Society of Obstetricians and Gynaecologists of Canada (SOGC) also issued a statement recommending that every woman be given the opportunity to make an informed choice regarding her physical and mental health (21). Specifically mentioned, was the importance for women to understand LTP-HRT and the associated benefits and risks.

Little is known about women's acceptance of LTP-HRT . The overall purpose of this study was to describe decisions and decisional conflict for women after they have reviewed the evidence of LTP-HRT benefits and risks, and considered their personal importance.

This information is important to nurses who counsel women on choices of therapy in any primary or tertiary setting. Nurses can support women's decision making by providing information and helping them to balance the benefits and risks so an informed choice can be made consistent with their personal values.

Research Objectives

1. To describe women's decisions and decisional conflict regarding LTP-HRT.
2. To describe the differences between those women who accept or decline LTP-HRT in terms of: a) expectations of LTP-HRT benefits and risks; and b) the importance women attach to the benefits and to the risks.

3. To describe the factors women identify as contributing to their decision to take or not take LTP-HRT or being unsure about their decision regarding LTP-HRT.

Review of Previous Research

Benefits of LTP-HRT

The recommendation for LTP-HRT as preventive therapy for CHD (38) is based on clinical studies demonstrating beneficial effects (40-44). There have been extensive prospective and case control data indicating up to a 50% reduction in the age-specific incidence of CHD in women taking HRT. There has been a more substantial benefit in women with documented CHD (10,44,45). The benefits of LTP-HRT are evident within two years of treatment and are much greater for current users, compared with women who have taken HRT but stopped (46,47).

There has been increasing evidence that the risk of a fracture is causally associated with low bone mineral density (BMD) (4,5,7,8), a condition associated with the decrease of estrogen in postmenopausal women (10). BMD, although not equal to bone strength, has been highly correlated with it (11-13). LTP-HRT has been a recommended preventive measure for women at risk for osteoporosis. Estrogen therapy acts as an antiresorptive drug inhibiting osteoclastic bone resorption, thereby, reducing osteoporotic fractures (4,14,44). Several studies have demonstrated the benefits of

estrogen in preventing bone loss (77-87) and reducing the incidence of fractures (13).

Risks of LTP-HRT

Unopposed estrogen increases the risk of endometrial cancer (10,16,21,22,26,27). When progestin is added there is no extra risk of cancer of the uterus (10,88-90). However, there is a potential increase in breast cancer with long term use (10,16,17). Other factors which must be considered when taking LTP-HRT are the side effects associated with the resumption of a woman's menses including menstrual bleeding, tenderness of the breasts, weight gain, and pre-menstrual syndrome (16).

Acceptance of LTP-HRT

It is estimated that only 10 to 15% of Canadian women who take HRT, will continue using LTP-HRT despite the evidence supporting the beneficial effects for women's health. Women have used HRT for various reasons ranging from alleviation of menopausal symptoms after a total hysterectomy (ovaries and uterus), to prevention of osteoporosis and heart disease (47,49). Several factors are correlated with HRT use. (See Appendix A Table 1. 42, 49, 50-53, 71-76, 78). Studies indicate, a woman on HRT is more likely to be younger, thinner, to have a higher education, to have had a hysterectomy and to be more active. There has been some discussion in the literature as to why the aforementioned

correlates have been noted. Younger women aged 50-59 may be experiencing more menopausal symptoms and be already taking HRT to alleviate symptoms. Women with more education may have greater exposure to information on current health care issues and be better able to utilize the knowledge (50) available to them to make health care decisions. An Australian study (49) noted most LTP-HRT information packages in Australia were geared towards the higher educated white population and did not address the educational needs of aboriginal women and those from other cultures. Most studies in Canada and the United States have not reported the type of educational material available to postmenopausal women, but may have geared health information to the higher educated white population like the Australian studies.

One study suggested that a major determinant of continued use was the diagnosis of osteoporosis (51); however, only 24% of women with osteoporosis used LTP-HRT. Concern over side effects is the most important deciding factor in the non-use of HRT (47,48). Many women discontinue HRT because of side effects such as withdrawal bleeding and weight gain (49). Non-use is also attributed to misinformation regarding the long term benefits (47,49). One survey showed only 27% of women not on HRT knew that lack of estrogen was a significant factor in osteoporosis compared with 89% of users (50).

With the American College of Physicians guidelines (20)

urging that all postmenopausal women consider the use of LTP-HRT and the recommendations of SOGC (21), it is anticipated the use of LTP-HRT will increase as the population ages. This anticipated trend raises important issues about the acceptability of LTP-HRT to women when they are presented with the evidence of benefits and risks. Women's decisions in such circumstances and potential associated decisional conflict are not known. Previous studies of HRT decision making do not adequately address this issue because the focus has been predominantly on short term therapy for menopausal symptom relief and dated prior to current practice guidelines and therapies. It is important therefore, to study the acceptability of LTP-HRT in the prevention of CHD and osteoporosis when women are informed consumers.

Conceptual Framework: Consumer Health Decision Model

Overview

The conceptual framework of the study is a Consumer Health Decision Model (CHDM) (see Figure 1) developed by O'Connor (53). The following section draws heavily from her writings about the model.

Consumer Health Decision Model

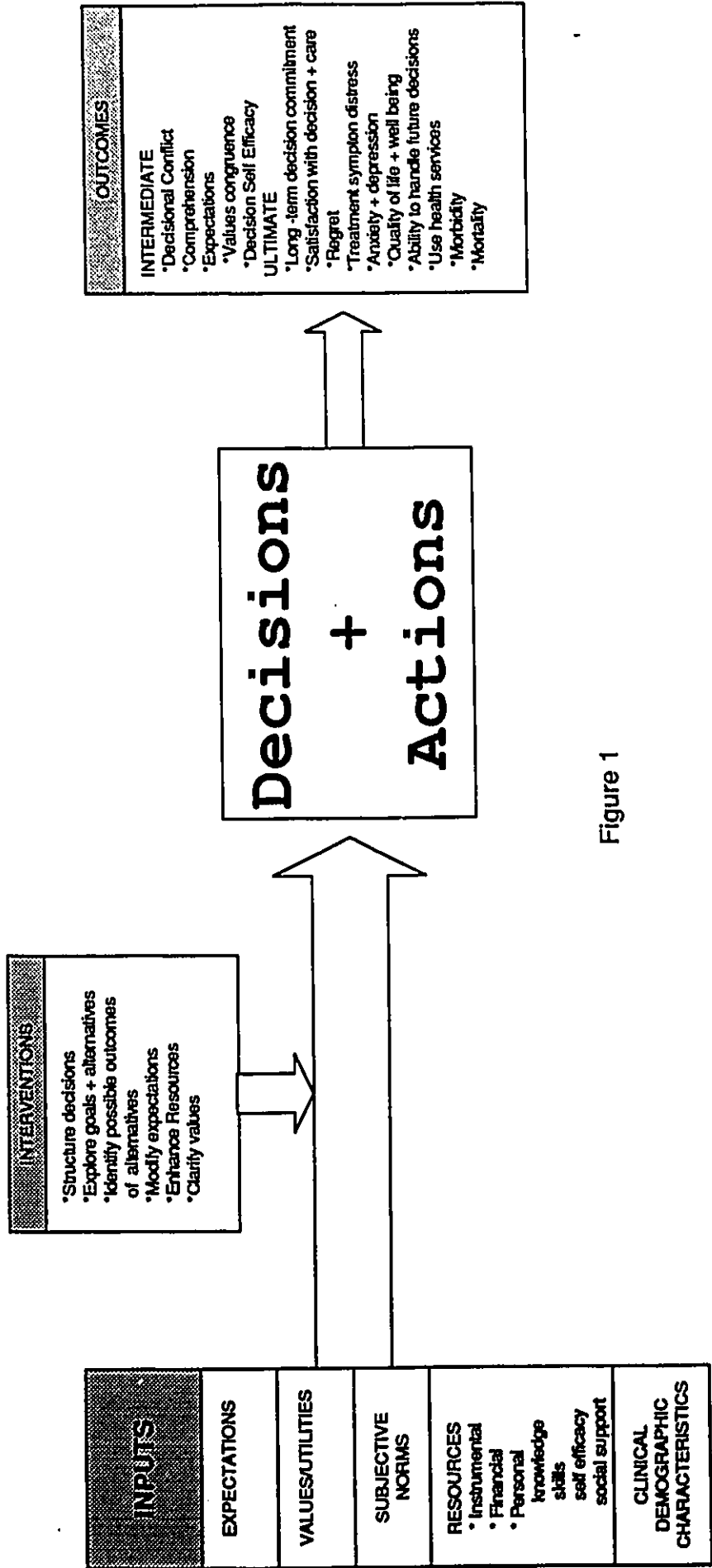


Figure 1

The model is located within the theoretical constructs of expectancy value decision theories in economics (55), psychology (56) and social psychology (59) and the construct of decisional conflict described by Janis (54) and the North American Nursing Diagnosis Association (58). As summarized in Figure 1, the four key concepts are: 1) the inputs into the decisions; 2) the decisions and actions taken; 3) their subsequent impact on outcomes; and 4) the interventions, which can modify the inputs and consequently affect the decisions and outcomes. The decision model is interactive, characterized by feedback and feed-forward loops among the four concepts. The CHDM summarizes the variables that discriminate between or predict decisions and actions.

Inputs

The inputs into decisions include expectations, values or utilities, subjective norms, resources, and clinical and demographic characteristics. These are defined by O'Connor as follows:

Expectations. The perceived likelihood of the consequences or outcomes of each option (53).

Values. The desirability or importance of these consequences; in uncertain or risky decisions, values become utilities, which then incorporate not only desirability but also attitude toward risk (53).

Subjective norms. Personal beliefs about what significant others think is the right decision. Subjective norms are modified by the consumer's motivation to comply with significant others (53).

Resources. The resources that consumers have to make and implement the decision. Resources include: instrumental; financial; and personal such as knowledge, skills and self-efficacy (confidence in one's decision making ability) (53).

Clinical and demographic characteristics. These include such variables as age, gender, ethnicity, education, diagnosis, duration and severity of illness, and psychosocial functioning (53).

Decisions and Actions

Decision making involves making choices in response to identified problems, needs or goals. Orem (60) has labelled two phases of decision making as deliberative (making the choice) and operational (implementing the choice). The relationship between decisions and action is not always straight forward. Actions often follow deliberation about choices but not all decisions are followed by action. Moreover, actions may occur spontaneously in response to problems, needs and goals without extensive deliberation.

According to the model, the relationship between inputs and the decision to take LTP-HRT are as follows. A woman may decide to take LTP-HRT because: 1) the woman expects it will lead to outcomes she most values; 2) others whose opinion she values (e.g. her physician, her spouse) also think it is a desirable option and, she is motivated to comply with their opinions; and 3) she has the necessary personal, financial, and instrumental resources to make the decision and implement

the choice. Women with different demographic and clinical characteristics make different decisions.

Outcomes

Outcomes of the decisions and actions can be classified as intermediate and ultimate. The CHDM defines intermediate outcomes as indicators of "effective" (61) decision making. These are difficult to define for value-laden choices cannot be classified as "right" or "wrong". O'Connor (53) has defined an effective decision as one in which consumer decisional conflict is reduced. A consumer makes a choice that is informed, consistent with personal values and acted upon using resources previously on hand or acquired during the process of deliberation and implementation. Indicators of effective decision making include: reduced decisional conflict; improved comprehension of alternatives, benefits, and risks; more realistic expectations of consequences; value congruence with the decision; and improved self-efficacy in making the decision.

The key outcomes to be examined in this study are decisional conflict, expectations, and values following the administration of the decision aid. Expectations and values have been defined previously. According to O'Connor (53,58,69) decisional conflict occurs when there is a state of uncertainty about a course of action to be taken when choice among competing actions involves risk, loss, regret, or

a challenge to personal life values. Factors hypothesized to contribute to decisional conflict include: lack of knowledge about alternatives and the consequences; unclear values; skill deficits in making or implementing decisions; emotional distress; and perceived pressures from significant others (69). In the case of LTP-HRT, women have to balance the tradeoffs between the benefits and the risks.

Ultimate outcomes are the longer term consequences of the decision including: long-term commitment to the decision; satisfaction with the decision and care; quality of life and well-being; ability to handle future decisions; use of health services; regret and disappointment; distress from treatment side effects; anxiety and depression; and in some cases, morbidity and mortality.

Interventions

Interventions range from unstructured counselling to structured decision aids. Currently decision aids are being evaluated (70,92,93) as a tool for presenting treatment benefits and risks to consumers and clarifying personal values. Methods currently being evaluated are: 1) Wennberg's videodiscs (92); 2) Rothert's group intervention (94); 3) Levine and Gafni's decision board (93); 4) Llewellyn-Thomas' treatment trade off approach using index cards (95); and 5) O'Connor's audio-booklet (96).

Health care providers/researchers have addressed the

variables identified in the CHDM, concluding they do affect a person's decision making process. Eraker et al. (63) identified that client preferences could have an effect on therapeutic decisions and that "comprehensive" knowledge of benefits and risks is essential to make a decision. Dennis (64) studied the perceived need for control and the importance of relevant information in decreasing stress in the client decision making process. Wilberding (65) identified client values clarification as a focus of nursing intervention to aid in health care choices that are congruent with their beliefs. Llewellyn-Thomas et al. (66) and Sackett and Torrance (67) stressed the need to quantify the values of clients and to incorporate these into health care decisions. The Health Care Research Group (68) concluded further studies of consumers' knowledge, beliefs and preferences is needed, with particular emphasis on the process of decision making.

The CHDM provides a framework that pulls together the identified factors affecting consumer decision making when making treatment choices. The model has been utilized in two studies (68,70), however, consumer decision models are in the early stages of development and study. Empirical evidence supporting the potential relationships between knowledge, expectations, values and their effect on intermediate and long term outcomes remains limited. The changing dynamics of our health care system, which supports the concept of informed

choice (91) for the health care consumer, necessitates further study of decision making when making choices about treatments which involve benefits and risks. The acceptability of LTP-HRT for the prevention of CHD and osteoporosis in postmenopausal women provides an opportunity to use a model that considers the factors that affect decision making.

For the present study, the variables investigated included: 1) inputs such as expectations of benefits and risks, the values/importance attached to the benefits and risks, and demographic characteristics, 2) the decision to use LTP-HRT, and 3) the intermediate outcome of decisional conflict. Health care choices were examined following the administration of a structured decision aid which presented the evidence of benefits and risks and clarified their personal importance.

Hypotheses

1. Women who choose to take LTP-HRT will have greater expectations of benefits and fewer expectations of risks compared with women who choose not to take LTP-HRT.
2. Women who choose to take LTP-HRT will place greater importance on protection from heart disease and osteoporosis and less importance on the risk of breast cancer and side effects compared with women who choose not to take LTP-HRT.

Chapter 2

Design

A secondary analysis from an existing data base was conducted. The data were derived from a study using a before and after design of 100 women exposed to a decision aid about LTP-HRT. Once recruited to the study, women completed a baseline questionnaire to elicit demographic characteristics, knowledge, expectations, importance ratings, decisions and decisional conflict about LTP-HRT (See Appendix B). In a follow up appointment, women were exposed to a self-administered decision aid delivered via an audio-booklet (see Appendix C) and then completed a post-questionnaire to ascertain possible changes in their knowledge, expectations, importance ratings, decisions, reasons for their decision, and decisional conflict (see Appendix D). The data relevant to this study included: the demographic characteristics of the sample elicited at baseline; and the women's post-questionnaire responses related to: expectations; importance ratings; decisions; reasons underlying decisions; and decisional conflict.

Sample Selection

A convenience sample of 100 women attending one of six medical practices at the Elisabeth Bruyere Family Practice Centre in Ottawa from July 1994 to December 1994, were

recruited to participate in the study. The computer flagged all age appropriate candidates who were screened by the family practice nurse in the clinic using the Family Nurse Screening Form (See Appendix E). One of two Research Assistants (RA) approached potential candidates, briefly explained the study and further screened (See Appendix F) the women according to the inclusion/exclusion criteria. Inclusion criteria were English speaking women: aged 50-60; attending a family practice centre; current users or never users of HRT; and at least two years postmenopause or menstruating and on HRT for two years. Women who were current users of HRT were included as it was assumed they were taking HRT for relief of menopausal symptoms, given the age categories studied, and may not be aware of the recent recommendations regarding LTP-HRT. Women on HRT did not have to be post-menopausal because their menses may have continued with HRT use; however they needed to have taken HRT for at least two years to consider LTP-HRT. Exclusion criteria were women who: had previously discontinued HRT due to intolerance of side effects; were currently on HRT less than two years; had a personal cancer history; or had recurrent thrombophlebitis. Written consent was obtained.

Decision Aid

A self administered decision aid using an audio-booklet medium was presented (See Appendix C) to all participants.

The structured decision aid consisted of the following components: 1) a screen for the contra-indications to LTP-HRT; 2) information on CHD, osteoporosis and prevention strategies including LTP-HRT; 3) an algorithm for choosing LTP-HRT benefits and risks according to personal risk of CHD, osteoporosis and breast cancer; and 4) a values clarification exercise to indicate the importance of each benefit and risk on a "weigh scale".

Measurement

A baseline questionnaire elicited data such as: age; highest education level; and HRT use. Data about presence of risk factors (CHD, osteoporosis, breast cancer, hysterectomy status) and importance ratings using the weigh scale values clarification exercise were obtained from the women's responses to the decision aid. A post-test questionnaire, completed after the decision aid intervention, elicited women's expectations, importance ratings, decision and rationale, and decisional conflict.

Expectations of risk of heart disease, osteoporosis and breast cancer without LTP-HRT, were measured by asking women to identify one of eight possible risk levels for each disease: 95%, 71%, 46%, 36%, 19%, 15%, 10% and 1%. These levels corresponded to the risks of disease outcomes presented in the decision aid. The numbers were accompanied by an icon

representing the proportion of 100 women who would be affected. Each woman was asked to indicate her own opinion of having heart disease, osteoporosis or breast cancer sometime in her life by circling the box that best indicated her personal risk for the specific disease.

Expectations of benefits and of risks with LTP-HRT were also measured. Women were asked to check how many women out of 100 just like her, may be protected from CHD and osteoporosis and may get breast cancer from taking LTP-HRT. There were nine categories: 100%, 76-99%, 51-75%, 26-50%, 16-25%, 7-5%, 3-6%, 1-2% and 0%. The measures of expectation had content validity in that they were derived from the educational material (10) in the decision aid.

Women's importance ratings were elicited in two ways for the following: protection from heart disease; protection from osteoporosis; side effects of therapy; and risk of breast cancer. First, in the decision aid, women were asked to indicate how important each of the benefits and risks of LTP-HRT were in their decision by colouring 30 millimetre (mm) boxes situated on a weigh scale, to the height that best represented their opinion (30 mm = extremely important; 0 mm = not at all important). The boxes were identified as: Protection from Heart Disease; Protection from Osteoporosis; Other Positives; Risk of Breast Cancer; Side Effects; and Other Negatives. Second, the post-questionnaire used an 11

point rating scale ranging from of 0 (not at all important to me), to 10 (extremely important to me in this decision). In a pilot study (95) the test-retest validity coefficient of each rating ranged from $r = 0.79$ to 0.89 (67). When the importance ratings were compared to the women's decision, there was 95% accuracy in discrimination indicating excellent congruence between the values women held for each benefit and risk and the women's decision.

The women's decisions regarding use of LTP-HRT were elicited using three categories: taking HRT; not taking HRT; and unsure. In a pilot study (96); the test-retest reliability coefficient for the question was 0.91.

Decisional Conflict was assessed using a 16 item, 5-point Likert scale eliciting: uncertainty about choosing among alternatives; factors contributing to uncertainty; and perceived effective decision making. Perceived effective decision making was elicited by assessing the degree to which women believed they had made an informed decision, that was consistent with personal values, that they anticipated implementing, and for which they expressed satisfaction. The scale had satisfactory reliability and validity in other preventive decisions involving women over 50 (66) with test-retest and internal consistency coefficients exceeding 0.80. The scale discriminated between those who: 1) delayed; and 2) made a decision either for or against a preventive health

action such as influenza immunization (68) or breast screening (70). In a previous pilot study (96) of women considering LTP-HRT, the internal consistency alpha was 0.89 and the test-retest coefficient was 0.81 (68).

Data Management and Analysis

The data were analyzed using SSPS-Windows 6.0. The following analyses was conducted.

Objective 1. Descriptive statistics were used to describe the demographic characteristics of the sample and women's decisions and decisional conflict regarding LTP-HRT. Percentages were used to describe the demographic profile including age category, education category, and previous use of hormones. Presence of risk factors were recorded in percents per category. Distributions of responses to the decision question and to each item in the decisional conflict scale were recorded in percents.

Objective 2. The statistical approach used to test the hypothesized differences in the expectations and importance ratings between those who chose to take LTP-HRT and those who chose not to take HRT-LTP was a Mann-Whitney U test. To correct for multiple testing, Bonferroni's approach was used to preserve the overall alpha of 0.05. A meaningful or clinically significant difference was defined as one category difference in the expectations or importance ratings between the women who chose to take LTP-HRT and those who chose not to

take LTP-HRT.

Objective 3. The reasons women identified as contributing to their LTP-HRT decision were examined using a content analysis of the women's: 1) responses elicited in the decision aid in the boxes labelled "other positives" and "other negatives" found in the weigh scale values clarification exercise; 2) reasons for their decision (yes, no, unsure) elicited in the post-questionnaire; and 3) comments recorded by the research assistant as the women were responding to the decision aid. The responses were clustered into themes and percentages of women identifying each theme were presented according to their decision. The coding of themes was verified by a second coder, who was a graduate student with expertise in women's health and reproductive cancers. Coding of themes was conducted separately and disagreements were discussed until a consensus was reached.

Protection of Human Rights

The study was approved by the Research Ethics Board of Elisabeth Bruyere Health Centre. Participation in the study was entirely voluntary. Each participant was informed of her rights, signed a consent form, and received a carbon copy (See Appendix G). The investigator obtained permission from the research team to conduct a secondary analysis of the data. All data collection sheets were masked; identifying information about the respondents had been removed.

Chapter 3

Results

Sample Characteristics

A total of 245 women, aged 50-60, were screened for the LTP-HRT study. Of these, 124 women met the eligibility requirements. Of the eligible women, 100 agreed to participate and 24 (19%) declined. The demographic profile of the participants and their HRT use are presented in Table 1. The typical woman in the sample was 57 years of age, had some post-secondary education and was currently using HRT.

Table 2 indicates women's responses to questions posed in the decision aid about risk factors for CHD, osteoporosis, breast cancer and hysterectomy status. Over half the respondents reported having at least one CHD risk factor, and having a hysterectomy. Less than 15 percent of women reported having osteoporosis or a first degree relative with breast cancer.

Table 1. Baseline Demographic Characteristics and HRT Use of the Sample (n=100)

Variable	%	Mean
Age		
50-55	51%	57 yr
56-60	49%	(SD=10.2)
Highest Education		
grade school or less	6%	
some high school	14%	
high school diploma	17%	
some college	12%	
college diploma	11%	
some university	9%	
university degree	31%	
HRT Use		
never	37%	
previous	16%	
current	47%	

Table 2. Percentage of Women Reporting the Presence of a Risk Factor in the Decision Aid (n=95)

Risk Factor	% Indicating Presence of Risk Factor
CHD	
Smoker	17%
High Cholesterol	14%
Diabetes	11%
High Blood Pressure	25%
Family History	39%
At least 1 CHD risk factor listed above.	54%
Hysterectomy	54%
Osteoporosis/ Low Bone Density	7%
Family History of Breast Cancer (mother, sister)	14%
Breast Cancer	1%
Blood Clots	5%

Women's Decisions and Decisional Conflict After Administration of Decision Aid

Following administration of the decision aid, women's decisions to take LTP-HRT were as follows: 56% yes; 26% no; and 18% unsure. Table 3 presents their responses to each item in the 16 item decisional conflict scale when reflecting on their decision. The five-point Likert scale was reduced to three categories for the purpose of presentation: 1) strongly agree/agree; 2) neither agree/disagree; 3) Disagree/Strongly disagree. Approximately two thirds of the respondents expressed certainty about their choice. Over 80% felt knowledgeable about LTP-HRT benefits and risks and their personal importance. However, only one third believed they had enough advice in making the choice and one half had enough support or were sure about the relative importance of the benefits compared to the risks. Three quarters felt they had made an "effective" decision.

Table 3. Distribution of Responses to Each Item in 16 Item Decisional Conflict Scale
(n's vary for each item n=93-100)

Scale Item	Response Scale		
	% Agree/ Strongly Agree	%Neutral	%Disagree/ Strongly Disagree
<u>Certainty Making Decision</u>			
decision is easy	55	12	33
sure about what to do	68	11	22
clear what choice is best	65	18	17
<u>Informed About Options/Risks/Benefits</u>			
aware of choices	89	8	3
know LTP-HRT benefits	85	14	1
know LTP-HRT risks	83	15	2
have enough info/advice	35	16	49
<u>Clear About Importance Benefits/Risks</u>			
clear about importance of benefits	89	10	1
clear about importance of risks	92	7	1
sure which are more important	49	12	38
<u>Social Support</u>			
no pressure from others	83	7	4
right amount of support	50	32	18
<u>Perceived Effective Decision Making</u>			
informed choice	78	16	6
shows what is important to me	87	10	3
expect to stick to decision	70	27	3
satisfied with decision	78	18	4

Differences In Decisions, Expectations and Importance Ratings
Between Women Who Accept or Decline LTP-HRT

Differences in expectations and importance ratings between those 53 women who chose to take LTP-HRT and the 24 who chose not to take LTP-HRT are summarized in Tables 4 to 7. Data from 23 women who were unsure are not included because the hypotheses focused only on those who made a definite decision to accept or decline LTP-HRT. The CHDM does not predict what the nature of expectations and values were for those who were unsure about what to do.

In Table 4, the women's post-intervention expectations of CHD, osteoporosis and breast cancer without LTP-HRT are summarized by the decision according to whether they accept or decline LTP-HRT. Mean rank differences between the groups were not found to be statistically significant at the 0.016 p level although a meaningful difference was found between acceptors and decliners for CHD. Those women who chose to take LTP-HRT consistently rated themselves at higher risk for all diseases than the women who chose not to take LTP-HRT. The p values for CHD and osteoporosis were close to the corrected 0.05 level.

Table 5 presents the women's perceived effect of hormone therapy on their risk of disease. There were no statistically significant differences in expectations between those who chose LTP-HRT and those who did not. However, meaningful

differences were noted for two outcomes with women accepting LTP-HRT expecting a greater benefit in protection from osteoporosis and a lower risk in getting breast cancer.

Table 4. Women's Post-Intervention Expectations of Disease Without LTP-HRT (n=77)^c

Disease Outcome	Decision		Z ^a	P [*]
	Yes LTP-HRT Median Category (n=53)	No LTP-HRT Median Category (n=24)		
CHD	46%	19%	-2.2	0.03
Osteoporosis	36%	19%	-1.9	0.06
Breast Cancer	36%	19%	-0.7	0.50

a = Mann-Whitney U, Z scores.

b Categories: number of women just like you at risk; 95%; 71%; 46%; 36%; 19%; 15%; 10%; 1%.

c Unsure group (n = 23) not included.

* Statistically significant defined as $p < 0.016$ using the Bonferroni correction for the 3 statistical tests.

Table 5. Median Expectations of Benefits and Risks with LTP-HRT by Decision to Accept or Decline LTP-HRT ^c

Disease Outcome	Decision		Z ^a	p *
	Yes LTP-HRT Median Category (n=53)	No LTP-HRT Median Category (n=24)		
# of Extra Women Protected from CHD	7-15	7-15	0.8	0.44
# of Extra Women Protected from Osteoporosis	16-25	7-15	1.0	0.33
# of Extra Women Getting Breast Cancer	3-6	7-15	1.2	0.50

a = Mann-Whitney U, Z scores.

b Categories: number of women just like you, effects of LTP-HRT, 100; 76-99; 51-75; 26-50; 16-25; 7-15; 3-6; 1-2; 0.

c Unsure group (n = 23) not included.

* Statistically significant defined as $p < 0.016$ using the Bonferroni correction for the 3 statistical tests.

The group differences in importance ratings, as measured by the 0-10 importance rating scale, are presented in Table 6.

Table 6. Median Importance Ratings Given to Benefits and Risks of LTP-HRT Using a Rating Scale^a as a Function of Decision Group^c

Outcome	Decision Regarding LTP-HRT		Z ^b	p*
	Yes LTP-HRT Median (n=53)	No LTP-HRT Median (n=24)		
Protection from CHD median	10	8	-2.9	0.00*
Protection from Osteoporosis median	10	8	-1.7	0.09
Risk of Breast Cancer median	8	10	-1.8	0.08
Risk of LTP-HRT Side Effects median	4	7	1.91	0.06

a = Mann-Whitney U, Z scores.

b Importance rating scores range from 0 (not at all important) to 10 (extremely important).

c Unsure group (n = 23) not included.

* Statistically significant was defined as $p < 0.012$ using the Bonferoni correction for four statistical tests.

Those who chose to take LTP-HRT placed a significantly higher importance on protection from CHD than those choosing not to take LTP-HRT ($p < 0.012$). There were no statistically significant differences in importance ratings between groups for other benefits and risks at the $p = 0.012$ level. However, the women choosing LTP-HRT consistently rated the importance of benefits higher and the importance of risks lower and the differences were clinically important.

The women's importance ratings of the LTP-HRT benefits and risks as measured by the "weigh scale" values clarification exercise are presented in Table 7. There were statistically significant differences in the importance ratings for: protection from CHD; protection from osteoporosis; "other positive" factors associated with their decision; and "other negative" factors. ($p < 0.008$). The women who chose LTP-HRT rated the importance of the benefits significantly higher than those women who chose not to take LTP-HRT. The women who chose LTP-HRT also rated the importance of risk of side effects significantly lower than the women who chose not to take LTP-HRT. The importance ratings between the two groups for breast cancer risk were not found to be statistically significant. Figure 2 shows the differences in weigh scale pictures between the women who accepted or declined LTP-HRT.

Table 7. Median Importance Ratings of LTP-HRT and Benefits Risks as Measured by the Values Clarification Exercise^a as a Function of Decision Group^c

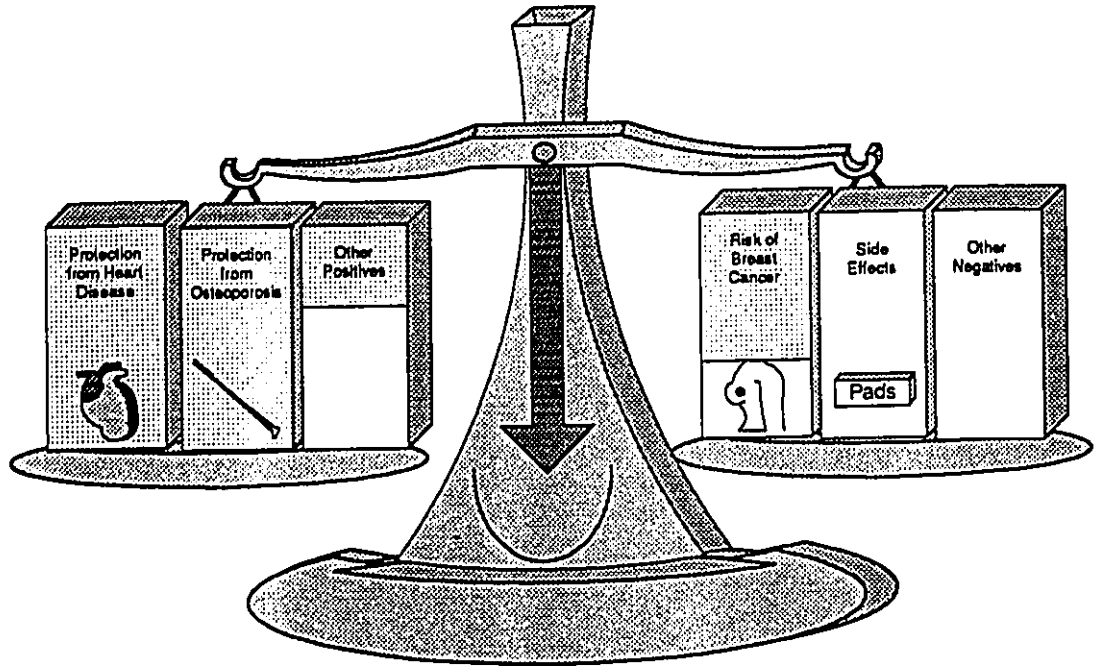
Benefit/Risk	Decision		Z ^a	p =*
	Yes LTP-HRT Median (n=53)	No LTP-HRT Median (n=24)		
Protection from CHD median	30	15	-5.2	0.0000*
Protection from Osteoporosis median	30	14	-4.24	0.0000*
Other Positives median	11	0.	-3.69	0.0002*
Risks of Breast Cancer median	20	30	-1.86	0.0630
Risk of LTP-HRT Side Effects median	0.	9	-3.52	0.0004*
Other Negatives median	0.	20	-4.12	0.0000*

a = Mann-Whitney U, Z scores.

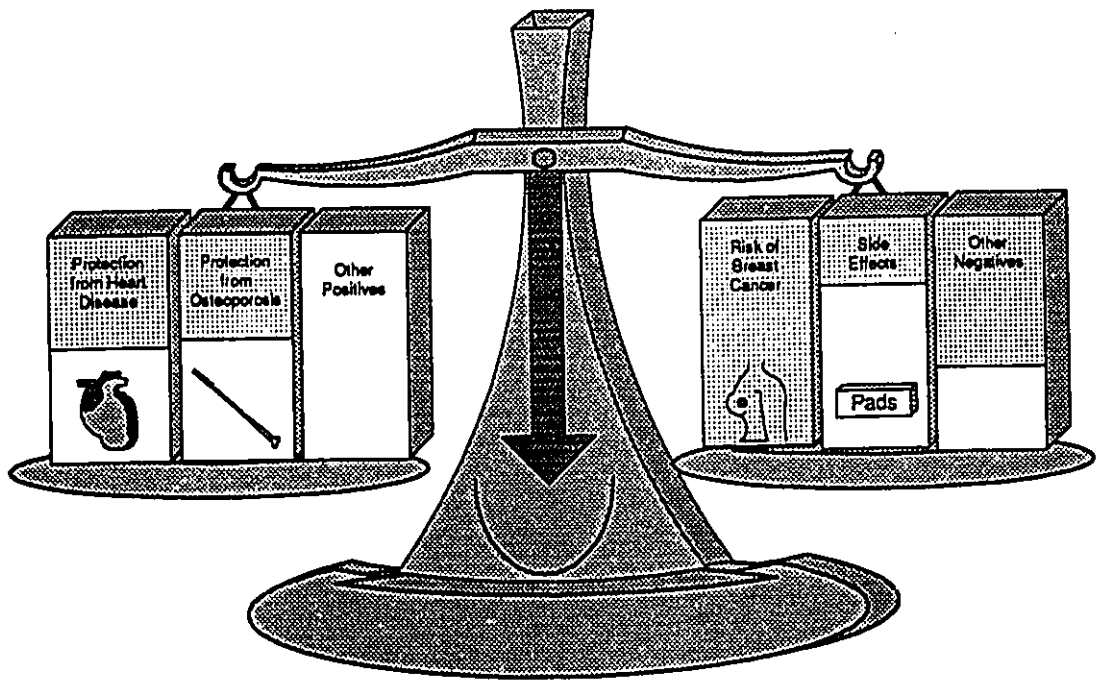
b importance ratings ranged from 0 (not at all important) to 30 (extremely important).

c Unsure group (n = 23) not included.

* statistically significant was defined as $p < 0.008$ using the Bonferroni correction for six statistical tests.



Decision = Yes LTP-HRT



Decision = No LTP-HRT

Figure 2. Median Importance Ratings of the LTP-HRT Benefits and Risks as Elicited in the Values Clarification Exercise Between Those Choosing to Take or Not Take LTP-HRT



Importance ratings in mm

Reasons for Taking/Not Taking or Being Unsure
About Taking LTP-HRT

Out of 100 respondents, 80 commented on the reasons behind their decision, from at least one of three sources: 1) the "other positives" and "other negatives" boxes identified by the women during the values clarification exercise component of the decision aid; 2) reasons elicited directly from the questionnaire after women were asked to make a choice; and 3) comments women made as they were responding to the decision aid, which were recorded by the research assistant.

Of the 80 women who provided reasons for their decision: 58% chose LTP-HRT; 24% declined; and 18% were unsure. One person (1%) did not check any category (Yes/No/Unsure LTP-HRT). This group of 80 commentators had comparable distributions of decisions compared to the complete sample of 100 women (56% "yes; 26% "No"; and 18% "unsure"). The group of women who were unsure were included in the content analysis as the objective was to identify factors that contributed to the women's decisions, not predict their decision.

The author conducted a content analysis of responses by pooling and clustering them into themes. Ten themes were initially defined, with an eleventh added when the content analysis was verified by the second reviewer (see Table 8). The two reviewers agreed in the classification of all cases

once the prevention category was added and when it was agreed to put alleviation of menopausal symptoms under relief/prevention of menopausal symptoms, even if the woman used the word prevention e.g. "prevention of hot flashes".

Table 8. Themes for Reasons Women Identified for Their Decision About LTP-HRT (n=80)

Menopausal Symptom Relief

relief/prevention of recognized menopausal symptoms (98-99) including: hot flashes; insomnia; irritability; depression; night sweats; mood swings; urinary problems (e.g. stress incontinence); and vaginal dryness.

Other Problem Relief

relief of other health problems/symptoms (e.g. "I feel better.")

HRT Side Effects

side effects of HRT (the expression "side effects" was used or women identified a recognized side effect such as weight gain).

Taking Pills

respondents identified they did not like taking pills.

Information Request

requesting more information/education (e.g. ways of taking hormones)

Inadequate Research

not enough "research"/what does "research say"

Non Medical Prevention

prefer alternative preventions to LTP-HRT (e.g. calcium, exercise)

HRT Contraindications

health status precludes LTP-HRT (thrombosis, history of breast cancer in mother/sister)

Other

other (confusing statements, information shared)

Cancer Fear

fear of cancer

CHD/Osteoporosis Prevention

prevention of osteoporosis and CHD

Table 9 represents the specific comments women who chose LTP-HRT inserted in the boxes "other positives" and "other negatives" in the values clarification component of the decision aid. As the table indicates, "other positives" largely related to the relief of menopausal symptoms. The symptom most frequently mentioned was the relief of hot flashes (57%). The most frequent response in the "other negatives" category was weight gain (11%). "Other positives", were mentioned more frequently than "other negatives" by half the women.

Table 10 summarizes the comments found under "other positives" and "other negatives" in the values clarification component for the women who chose not to take LTP-HRT. Negatives themes were more frequently reported than positive themes. The most commonly cited other negative factor was, taking pills (47%) and the most frequently reported other positive factor was relief of hot flashes (16%).

Table 11 summarizes the reasons women, who were unsure, identified as "Other Positives" and "Other negatives" in the values clarification exercise. The most frequently identified "other positives" were relief of hot flashes (14%) and help with sleep disturbance (14%). Weight gain (29%) was the most frequently identified "other negative".

Table 9. "Other Positives^a" and "Other Negatives^a" Added in the Values Clarification Exercise by Women Who Chose LTP-HRT (n=46)

"Other Positives"	%	"Other Negatives"	%
Menopausal Symptom Relief		HRT Side Effects	
-relief of hot flashes	54	-weight gain	11
-better mood/less tired	17	-the effects of medication	2
-sleep disturbance	7	-migraine	2
-staying younger	2	-period every month	2
-better skin texture	4		
-concentration	2	Taking Pills	
-helps stress incontinence	2	-more pills	7
		-not to forget pills	7
-relieves vaginal dryness	4	-don't like to take pills	4
-less dry skin	4		
-migraines	2	Inadequate Research	
-bad nerves	2	-? long term usage problems	2
-stronger morale	2	-don't know enough	2
Other Problem Relief		Other	
-easier breathing	2	-rise in blood pressure	2
-with aldactone keeps hair growth down	2	-masking on my arms	2
-helps with arthritis symptoms	2	-I would prefer shots to O.D. pills	2
-general health	2	-anxiety	2
Other		-expense	2
-believe in it	2		
CHD/Osteoporosis Prevention		HRT Contraindications	
-family history of heart attacks	2	-taking medication that may be incompatible	2

a: comments are direct quotes from the women

Table 10. "Other Positives^a" and "Other Negatives^a" Added in the Values Clarification Exercise by Women Who Declined LTP-HRT (n=19)

"Other Positives"	%	"Other Negatives"	%
Menopausal Symptom Relief		Taking Pills	
-hot flashes	16	-pills to take	47
-skin	5	HRT	
Other Problem Relief		Contraindications	
-dizziness	5	-blood clots in legs, not recommended	11
Other		-medication for thrombosis	5
-no family history on mother's side of family	5	HRT Side Effects	
		-always some side effects	5
		-weight gain	5
		-headaches	5
		-monthly periods	5
		Information Request	
		-(?) risk of osteoporosis and cancer if I take hormones	5
		Cancer Fear	
		-mother has cancer	5
		Inadequate Research	
		-uncertain data	5

a: comments are direct quotes from the women

**Table 11. "Other Positives"^a and "Other Negatives"^a Added
in the Values Clarification Exercise by
Women Who Where Unsure About LTP-HRT (n= 14)**

"Other Positives"	%	"Other Negatives"	%
Relief of Menopausal Symptoms		HRT Side Effects	
-helps with hot flashes	14	-weight gain	29
-helps with sleep	14	-effects on endometriosis	7
-alters mood swings	7	-irritability a concern	7
-increases energy	7	-taking pills	7
-maintenance of skin integrity	7	-back to menstrual period	7
-helps with wetting	7		
Other Problem Relief		Cancer Fear	
-weight control	7	-cancer a concern	14
Other		Inadequate Research	
-hormones are a normal part of body	7	-fear of the unknown	7
		-results of LTP-HRT	7
		HRT	
		Contraindications	
		-idiopathic oedema syndrome	7
		-must have doctor's OK due to health	7
		Other	
		-hemorrhage	7

a: comments are direct quotes from the women.

Table 12 summarizes responses to the second and third sources of information about women's reasoning behind their decision. The data in Table 12 came from comments recorded by the research assistant as women were responding to the decision aid and from reasons elicited directly after women were asked to make a choice on the questionnaire. Women who chose LTP-HRT, identified the benefits more frequently than the risks. In particular, women identified the importance of prevention of CHD and osteoporosis (61%). The reverse was true for the women who chose not to take LTP-HRT. The risks were identified more frequently than the benefits, most notably taking pills, cancer, side effects and the preference for non-medical prevention measures. The women who were unsure also identified more risks than benefits such as side effects, HRT contraindications and cancer.

Other issues identified by women differed by decision. For the women who chose LTP-HRT, requests for more information/education were focused on questions pertaining to the effects of hormone replacement therapy and ways of taking HRT. Typical questions included: "Is it OK to take hormones for a trial period and then assess side effects? Do hormones really prevent vaginal dryness? Is it OK to take calcium if I am taking hormones?" Other questions related to various tests such as endometrial biopsy and bone density measurement.

**Table 12. Reasons Identified by Women for Decision
About LTP-HRT As Elicited in the
Questionnaire (n=79)**

Reason	Yes (n=46)	No (n=19)	Unsure (n=14)
Benefits			
Prevention of CHD/Osteoporosis	61%	-	-
Menopausal Symptom Relief	13%	-	-
Other Problem Relief	17%	5%	-
Other	17%	37%	7%
Risks			
Fear of Cancer	13%	42%	21%
HRT Side Effects	2%	21%	14%
Taking Pills	-	21%	-
HRT Contraindications	-	11%	21%
Non-Medical Preference	-	42%	7%
Other Themes			
Information Request	35%	21%	50%
Other	32%	-	7%
Inadequate Research	4%	5%	14%

"Other" comments by women choosing LTP-HRT elaborated on the women's medical history or provided a general comment about HRT e.g. "I need it." One statement credited LTP-HRT with preventing breast cancer.

The group choosing LTP-HRT had research questions pertaining to why there was a 10-20 year recommendation to take LTP-HRT and what happened after the time period. One woman wanted to do some personal research for herself in relation to the risk of breast cancer. There were no responses under the category "Prefer Non Medical Intervention", although women asked if they should take calcium as well as hormones.

For the women who chose not to take LTP-HRT, the requests for more information/education focused on how to obtain information about their physical condition by having bone scans done or requesting information on alternative interventions. "Other" comments were related to family and personal medical history which would support their choice of not taking LTP-HRT. (e.g. no family history of CHD or osteoporosis). The women's research comments reflected their views that the current data supporting LTP-HRT was uncertain.

For the women who were unsure about LTP-HRT, requests for more information/education focused on personal health issues not addressed in the decision aid that might be exacerbated by hormone replacement therapy (e.g. endometriosis) and more

information about the risks of hormones before making a decision. The women also wanted to consult with their doctor/or defer to their doctor's decision more often than the women who made a clear yes or no decision. Research questions focused on the need to know the long-term effects of LTP-HRT.

Chapter 4

Discussion

In this study of 100 women from six family medical practices who were exposed to a decision aid, 56% chose LTP-HRT, 26% declined, and 18% remained unsure about their choice. Although only half of the women found the decision easy, most believed they were informed, clear about values and had made an effective decision. The hypotheses about the differences in expectations and importance ratings between those accepting or declining LTP-HRT were partially supported. Expectations of LTP-HRT benefit and risks did not differ significantly between the acceptors and the decliners but importance ratings did. Women choosing LTP-HRT placed greater importance on the benefits and lower importance on the risks. This observation was confirmed by the reasons women gave for their decisions.

Decisions and Decisional Conflict

The high proportion of women choosing LTP-HRT is not surprising given 47% of the women in the sample were currently using HRT and thus had already made a decision in favour of HRT. Although, only half the sample of women found the decision easy, most expressed few problems with factors contributing to decision difficulty such as lack of information about the benefits and risks, unclear values, and pressure from others. Notable exceptions were: 1) having enough information or advice; 2) having the right amount of

support; and 3) being sure whether the benefits outweigh the risks.

The belief that they were informed about benefits/risks and clear about values could be associated with the fact the women had been exposed to the decision aid. The decision aid provided benefit/risk information about LTP-HRT, thereby increasing women's knowledge. The decision aid also included a values clarification exercise that gave women the opportunity to visually weigh the personal importance of the benefits and risks of LTP-HRT, enabling the women to consolidate their decision. This interpretation is supported by the significant improvement in knowledge and reduction in decisional conflict compared to baseline reported in the primary analysis of the data base (102).

However, only a third of the women believed they had enough information. Perhaps they had enough benefit/risk information, but needed other types of information. For example, the women who chose to take LTP-HRT requested information about how to take LTP-HRT, which was information beyond the scope and purpose of the decision aid. Another plausible explanation is that women needed some advice from their physician now that they were informed about the issue.

The high proportion of women who were unsure whether the benefits outweighed the risks (50%) corresponds to the high proportion of women who found the decision difficult (45%).

Women may have been responding to the conflicted nature of the choice which is characterized by competing benefits and risks. Even after exposure to the decision aid, and after making the decision, this problem still remains. An alternative explanation of the women's responses may be methodological. The research assistants noted that women had greater difficulty in responding to the scale item which incorporated the concepts of benefits/risks in the same question; therefore, it may have reduced their agreement with the item.

The high proportion of women feeling they did not have the right amount of support (50%) may also reflect a response problem to that item on the scale. The research assistants reported that some of the women who felt it was their independent decision to make thought the right amount of support was a non-issue. Therefore they may have disagreed with the item for that reason. On the other hand, other women said they needed to talk with their doctor prior to a decision, confirming that they needed further support before deciding.

The implications of the decisional conflict results for the health practitioner underscores the practitioner's need to be aware that a decision aid cannot be used in isolation. It is important for nurses and other clinicians to meet with women after the utilization of the decision aid to clarify consumer concerns. The decision aid gives needed information

about the benefits and risks of treatment options to the client. A follow-up office visit can then focus on further information needed by the client, to seek opinions, and to finalize the choice, and to follow through on the decision made (e.g. What are the different ways of taking LTP-HRT).

In future research, decisional conflict needs to be measured again once clients have seen their practitioners to examine: 1) improvement in responses to items such as advice and social support; and 2) reductions in uncertainty among those who were expressing decisional conflict after administration of the decision aid. Such a study would also serve to validate the model used in the study.

The items in the decisional conflict scale, which created response problems (e.g. have the right amount of support; unsure if the benefits outweigh risks) need to be reviewed and revised. Respondents also expressed difficulty with the five point Likert scale (1 = strongly agree to 5 = strongly disagree), particularly when switches were made between positively and negatively worded items. Perhaps all the items should be worded positively.

The Decisions, Expectations and Importance Ratings

There are several plausible explanations for the lack of difference in expectations between women choosing to accept or decline LTP-HRT. First, there was not enough power to detect a clinically important difference, thus resulting in a Type II

error. There was only sufficient power to detect an effect size of .66 which Welkowitz et al (103) defines as just above a medium effect size of .50 for Z scores when testing the significance of the difference between independent means for parametric measures. Seigal (104) states the power-efficiency of the Mann-Whitney U is close to 95.5% for large samples ($n > 20$). The power to detect a statistically significance difference therefore was only moderate. The differences in expectations for most of the benefits and risks were in the hypothesized direction and the p values for expectation of CHD and osteoporosis without LTP-HRT, approached significance.

A second explanation for the lack of a statistically significant difference is that expectations were elicited after the decision aid intervention had taken place and may have resulted in equalizing the groups. Following the decision aid, both groups had more realistic expectations of benefits and risks as was reported in the primary analysis of the data (102).

Thirdly, the presentation of risk information and measurement of expectations could have been a problem. In the decision aid, women found the presentation of risk information and the effect of LTP-HRT on those risks, to be the least comprehensible component. The research assistants reported that women tended to express more negative comments about how the material was presented in this section.

Moreover, in the questionnaire women frequently expressed the thought that they might get the "wrong answer" when completing that section. Also, the measurement of expectations had only eight or nine response levels; a more sensitive measure ranging from 0-100% with more response levels may have increased the sensitivity of the measures to detect differences.

The results of the analysis of expectations indicates a trend that women who accept/decline LTP-HRT have differences in expectations of disease outcome. Women who had a higher expectation of getting the disease outcome of CHD and osteoporosis were more likely to choose LTP-HRT. It is important for nurse practitioners to know the expectations clients have of a disease outcome as it influences their decision and to identify the degree to which it is realistic, given the client's risk profile.

In future research, more sensitive measures for eliciting expectations should be used to elicit differences between groups and the sample size should be increased to improve power. It would also be important to investigate exactly what was uncomfortable for women in the presentation of the material and to develop a more user-friendly way of presenting the information. Perhaps women are uncomfortable with the algorithm approach. In addition, it would be important to explore perceptions of risk in order to establish if women

tend to overestimate or underestimate their personal risk of disease and, if they do, identify the confounding factors in this phenomena.

Women's importance ratings did discriminate between decisions, as hypothesized. The importance ratings derived from the weigh scale exercise were better at detecting differences than the 0-10 rating scale. The former measurement approach was more sensitive possibly due to a finer level of measurement (0-30 mm). The 0-10 importance rating scale did detect a significant difference in protection from CHD but not in protection from osteoporosis, risk of breast cancer and risk of side effects. However, the differences were in the hypothesized direction and were clinically important.

The women's importance ratings of LTP-HRT as measured by the 30 mm weigh scale discriminated acceptors and decliners for all benefits/risks except for the risk of breast cancer. The p value was, however, nearing significance and the difference was in the hypothesized direction.

When one examines importance of the benefits and risks together, the women who chose to take LTP-HRT rated the importance of benefits as outweighing the risks. The women who chose not to take LTP-HRT rated the risks as outweighing the benefits. This is congruent with the CHDM, and the strong result highlights the salience of values in the model. This

is supported by Rothert et al. (105) who also concluded that women's values influence their choice in accepting or declining LTP-HRT and recommended (106) development of decision models such as the CHDM that recognize the importance of consumers' values.

Knowing the importance women place on the benefits and risks of a treatment option is important to clinical practice. Every treatment involves both benefits and risks. The value that clients place on a benefit or a risk will affect their behaviour. If clients place greater importance on the risks they are not likely to follow through with the treatment under discussion. It is then important to clarify these values in relation to the suggested treatment, to explore alternative treatment options with clients, and support clients in their choice.

Further research in the role values play in decision making is important if decision aids are to be developed to help consumers become more collaborative in the decision making process. Strategies, such as the values clarification exercise, need to be tested with differing populations such as senior citizens, aboriginal women and women from other cultures. It is important to establish what is valued by different populations and cultures so that members of each aggregate can be helped to make choices appropriately. Also the independent contributions of the values clarification

exercise should be assessed on decisional conflict and long term decision commitment. For example, how would responses vary if the decision aid did not contain a values clarification component? Several decision aids do not have explicit values clarification exercises and it would be important to know the relative contributions they make.

Reasons Behind Decisions

The quantitative data is supported by the qualitative comments made by the women and provides clinically interesting information. The factors women identified as the rationale for their decisions further supports the hypotheses. The women choosing LTP-HRT identified twice as many benefits as risks; those declining LTP-HRT identified risks three times more often than benefits. Benefits identified by women who chose LTP-HRT were frequently related to an improved quality of life after menopausal symptoms were relieved. Conversely the women who chose not to take LTP-HRT saw the risks (e.g. side effects) decreasing their quality of life. Quality of life is defined by what an individual values and individuals have different value profiles which result in different health care decisions (107).

Study Limitations

The secondary analysis was limited to the data collected. The sample data was limited to healthy English speaking women of the age cohort sampled. In order to be generalizable to the population of postmenopausal women, a more representative sample of women in multiple settings with an increased number of age cohorts would have to be recruited. It would be important to address women who have difficulty accessing family physicians (e.g. house bound women) and women from different cultures and different socioeconomic backgrounds (e.g. immigrant and First Nation women). Half of the women in the sample were current users of hormone therapy. Current users may already have increased acceptance and have a more favourable attitude toward LTP-HRT. In future studies there would need to be an increased proportion of never users (50% ever users, 50% never users).

Conclusion

Despite the limitations, the study has demonstrated partial support for the CHDM and provided useful insights into the values women hold and the underlying rationale for women's decisions. Specifically, the results support the assumption of the model that the importance or value women place on the benefits and risks of a treatment is related to their decisions. By utilizing a decision aid generated by the

model, women increased their knowledge about the benefits and risks of LTP-HRT and most importantly, clarified the personal importance of the benefits and risks. The women were then able to make informed treatment choices with decreased decisional conflict. The information on values obtained using the quantitative and qualitative methods indicates women do make different decisions based on personal values, related to a perceived improvement in their quality of life.

The study also identifies implications for nursing practice as Nursing holds the belief that clients have the right to be informed and to be active participants in their health care. To this end nursing has identified health education as an important nursing intervention, teaching consumers the benefits and risks of treatment choices and life style choices. Inherent in making choices is making decisions. It is important therefore, for nurses, to explore the variables that influence decisions , such as the variables identified in the CDHM.

In order to recognize such key factors affecting a woman's decision regarding LTP-HRT, nurses could benefit from using decision aids that assist women to: identify their expectations of treatment; inform them of the benefits and risks; and clarify the personal importance of the benefits and of the risks. By utilizing interventions such as the decision aid which identify these key factors nurse clinicians could

then direct health care information to the specific needs of the client. Employing a decision aid that is generated by the CHDM which incorporates empirical evidence of decision process is congruent with today's changing health care system with the focus on prevention of illness, promotion of wellness and the informed consumer. Decision aids that inform consumers about personal disease risk and health care choices to manage disease risk that may prevent chronic illnesses like CHD and osteoporosis, may promote healthy behaviours in clients that could result in a healthier life.

Attention to these factors may improve the involvement of women in decision making and result in reduced decisional conflict. Also, as women feel more informed about benefits and risks, they are more likely to make decisions consistent with expectations and personal values. The ultimate outcome would hopefully be a commitment to a decision resulting in a choice that is perceived by the woman as improving or maintaining her quality of life.

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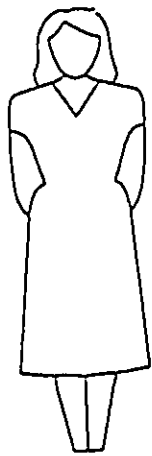
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Appendix A

Table 1

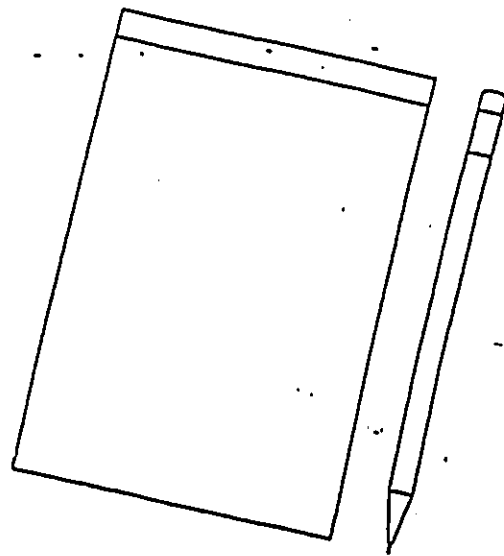
Correlates of Hormone Replacement Therapy

Factor	Positive Correlation	Negative Correlation	No Correlation
Age		51, 52, 74	
Hysterectomy	42, 49, 71, 72, 78		
Income	49, 74, 75, 76, 77		
Exercise	74, 78		
Education	50, 53, 73, 78		75



**Women's Opinion Survey
About the Use of
Hormone Therapy**

Baseline Questionnaire



A. What I know about hormone therapy now



We would like to know how familiar you are with hormone therapy before you use the tape and booklet.

Below are listed some statements about hormone therapy taken after menopause (when menstrual periods stop for good). Please show whether you think they are true, false, or you are not sure by circling the word beside each statement.

1. Hormone therapy can be given:

early in menopause	True	False	Unsure
well past the menopause	True	False	Unsure
for 10-20 years	True	False	Unsure

2. Benefits of using hormone therapy are:

protection from breast cancer	True	False	Unsure
protection from osteoporosis (weak, easily broken bones)	True	False	Unsure
protection from diabetes	True	False	Unsure
protection from heart disease	True	False	Unsure

3. Risks of using hormone therapy are:

increases risk of breast cancer	True	False	Unsure
increases risk of osteoporosis (weak, easily broken bones)	True	False	Unsure
increases risk of diabetes	True	False	Unsure
increases risk of heart disease	True	False	Unsure

✓

4. Some side effects of hormone therapy are:



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morning sickness	True	False	Unsure
breast tenderness	True	False	Unsure
irritability	True	False	Unsure
fainting	True	False	Unsure
bloating	True	False	Unsure
hot flashes	True	False	Unsure
headache	True	False	Unsure
allergy	True	False	Unsure
menstrual bleeding	True	False	Unsure
weight gain	True	False	Unsure

✓

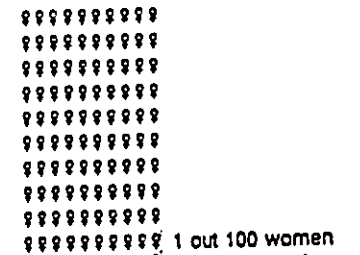
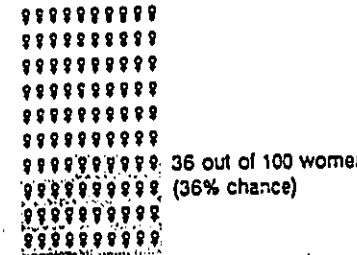
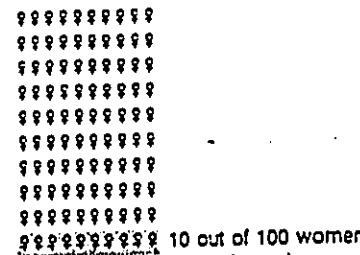
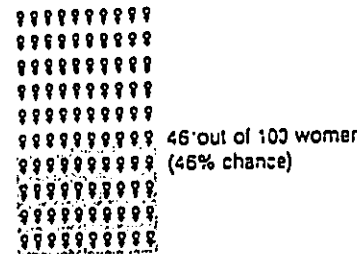
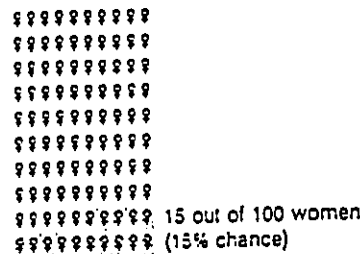
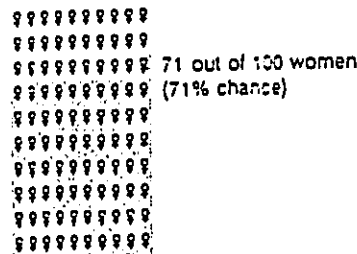
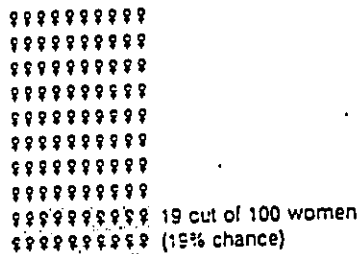
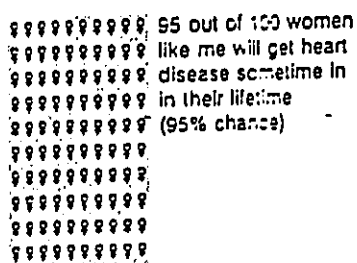


B. My risk of heart disease

Again, we are interested in your opinions before you use the booklet and tape.

Below we show different women's lifetime risk of heart disease from high to low. Each box contains 100 symbols representing 100 women. The women who are coloured grey will get heart disease. Therefore boxes showing more grey mean a woman's risk, or chance of heart disease is greater.

Please show your opinion of your risk of having heart disease sometime in your life by circling the box that best shows your risk.

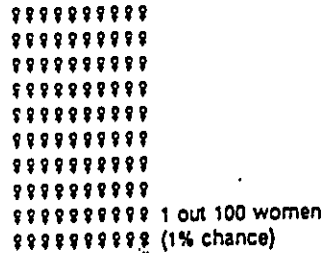
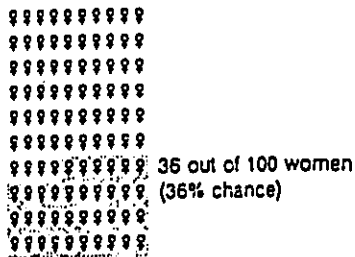
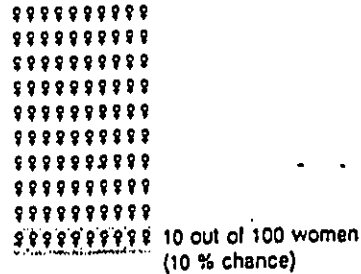
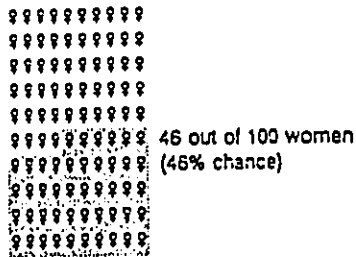
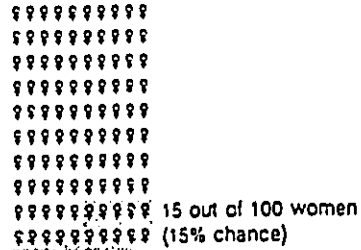
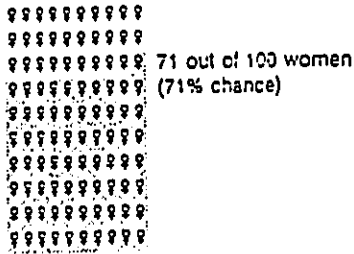
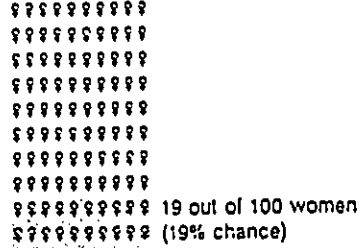
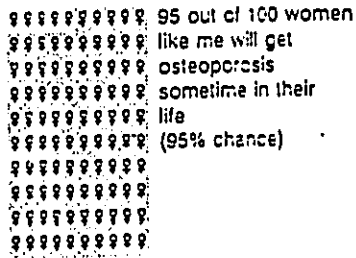




My risk of osteoporosis

Below we show different women's lifetime risk of osteoporosis from high to low. Each box contains 100 symbols representing 100 women. The women who are coloured grey will get osteoporosis. Therefore boxes showing more grey mean a woman's risk, or chance of osteoporosis is greater.

Please show your opinion of your risk of having osteoporosis sometime in your life by circling the box that best shows your risk.



611

My risk of breast cancer

Below we show different women's lifetime risk of breast cancer from high to low. Each box contains 100 symbols representing 100 women. The women who are coloured grey will get breast cancer. Therefore boxes showing more grey mean a woman's risk, or chance of breast cancer is greater.

Please show your opinion of your risk of having breast cancer sometime in your life by circling the box that best shows your risk.

95 out of 100 women
 like me will get
 breast cancer
 sometime in their
 life
 (95% chance)

19 out of 100 women
 (19% chance)

71 out of 100 women
 (71% chance)

15 out of 100 women
 (15% chance)

46 out of 100 women
 (46% chance)

10 out of 100 women
 (10% chance)

36 out of 100 women
 (36% chance)

1 out 100 women
 (1% chance)

✓

C. The effects of hormone therapy on my risks



Now we are interested in your opinion on how much hormone therapy will affect your risk of heart disease, osteoporosis and breast cancer. Please check the box that best show how much you think hormones will affect your chances of heart disease, osteoporosis and breast cancer:

Heart Disease

If 100 women like me were to take hormone therapy, how many women would be protected from heart disease?

100

76 to 99

51 to 75

26 to 50

16 to 25



7 to 15

3 to 6

1 to 2

0

Osteoporosis

If 100 women like me were to take hormone therapy, how many women would be protected from osteoporosis?

100

76 to 99

51 to 75

26 to 50

16 to 25



7 to 15

3 to 6

1 to 2

0

Breast Cancer

If 100 women like me were to take hormone therapy, how many extra women would get breast cancer?

100

76 to 99

51 to 75

26 to 50

16 to 25

6/11

7 to 15

3 to 6

1 to 2

0

D. The things that are important to me when making a decision about hormone therapy

Below are listed some things women consider when making a decision about hormone therapy. Please show how important these are to you by circling a number from:

0 (not at all important to me)
to
10 (extremely important to me).

How important would these things be to you when making a decision about hormone therapy?

Protection from heart disease



0 1 2 3 4 5 6 7 8 9 10
not at all important to me extremely important to me in this decision

Protection from osteoporosis (weak easily broken bones)



0 1 2 3 4 5 6 7 8 9 10
not at all important to me extremely important to me in this decision

Side effects of therapy



0 1 2 3 4 5 6 7 8 9 10
not at all important to me extremely important to me in this decision

Risk of breast cancer

6/11

0 1 2 3 4 5 6 7 8 9 10
not at all important to me extremely important to me in this decision

E. My opinion of hormone therapy



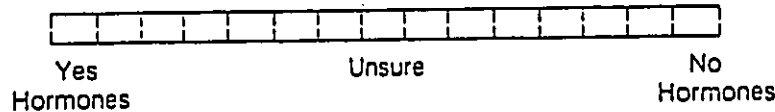
We want to know what your opinion is of hormones before you review the booklet and tape.

If your doctor asked you right now to make a choice about using hormone therapy, please show where you would be on the scale below by placing a check in the box .

If you wanted to take hormones, you would check far to the left.

If you did not want to take hormones, you would check far to the right.

If you were not sure, you would check in the middle.



F. My difficulty making this choice

Now, thinking about the choice you just made, please look at the following comments made by some women when deciding about hormone therapy.

Please show how strongly you agree or disagree with these statements by circling the number from 1 (strongly agree) to 5 (strongly disagree) which best shows how you feel about the choice you just made.

This decision is <i>hard</i> for me to make	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
I'm <i>unsure</i> what to do in this decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
<u>It's clear</u> what choice is best for me	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
I'm aware of the choices I have to reduce my risk of heart disease and osteoporosis	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree

I feel I know the benefits of hormone therapy	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
I feel I know the risks and side effects of hormone therapy	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
I need more advice and information about the choices	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
I know how important the <u>benefits</u> are to me in this decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
I know how important the <u>risks</u> and <u>side effects</u> are to me in this decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
It's <i>hard to decide</i> if the benefits are more important to me than the risks, or if the risks are more important to me than the benefits	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
I feel <i>pressure</i> from others in making this decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
I have the right amount of support from others in making this choice	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree

G. Other

So that we know we have tested the program with women with different levels of education, please check your highest completed education.

79

- grade school or less
- some high school
- high school diploma
- some college
- college diploma
- some university
- university degree

✓

Program developed by researchers at the University of
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E. R. Drake BA
Health Care Research

Information based on scientific research and recommendations from
American College of Physicians. Guidelines for counseling
postmenopausal women about preventive hormone therapy. *Annals of
Internal Medicine*. 1992, 117(12):1038-1040.

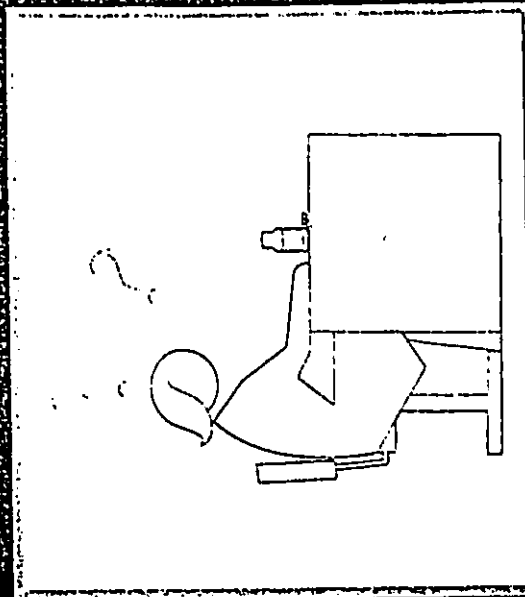
Grady et al. Hormone therapy to prevent disease and prolong life in
postmenopausal women. *Annals of Internal Medicine*. 1992,
117(12):1016-1037.

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Canada



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Making Choices About Hormone Therapy To Prevent Osteoporosis and Heart Disease



Is it for me?

Printed with permission
from
A. O'Connor and P. Tugwell

Welcome!

This booklet gives the facts you need to make a decision about hormone therapy. It's designed for you.

The booklet comes with a cassette and pencils.

The cassette guides you through the booklet.

The pencils are used to answer questions about your opinions.

Instructions

Take aside 25 minutes.

Put the cassette in a tape recorder.

Press the play button.

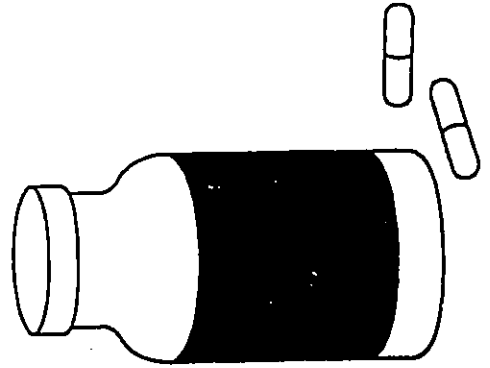
Turn on this page until you are asked to turn to the next page.

Question list...

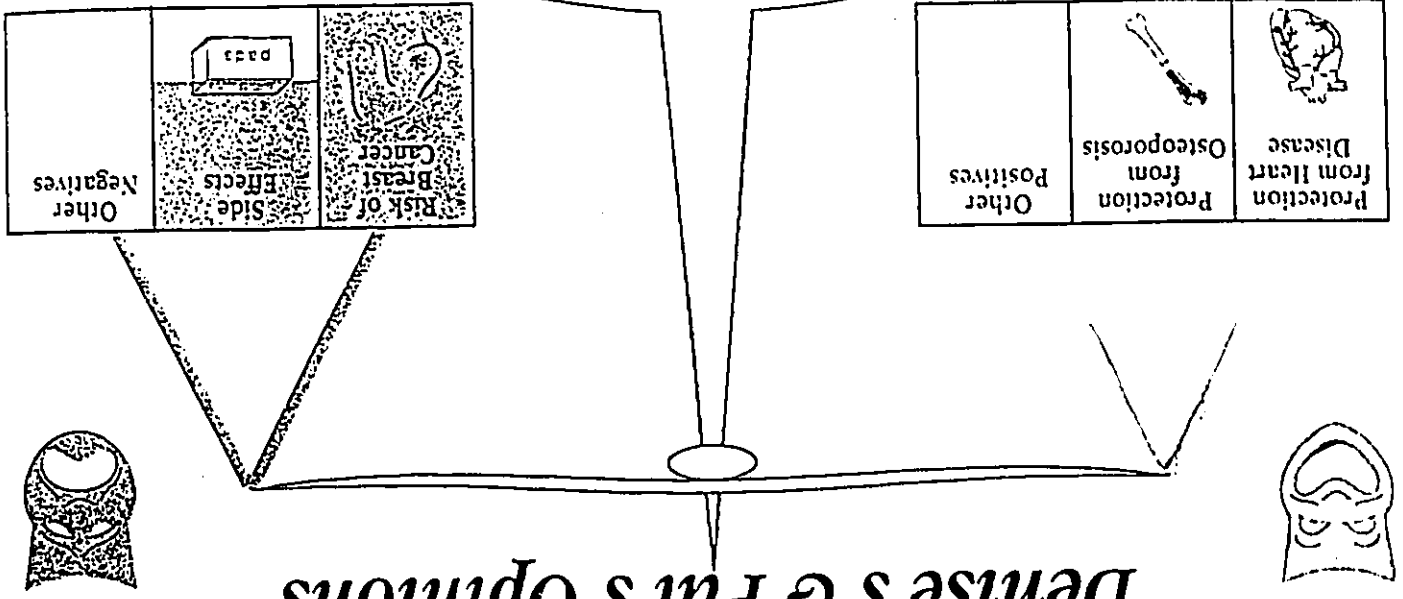
A new use for hormone therapy ...

Long term preventive treatment

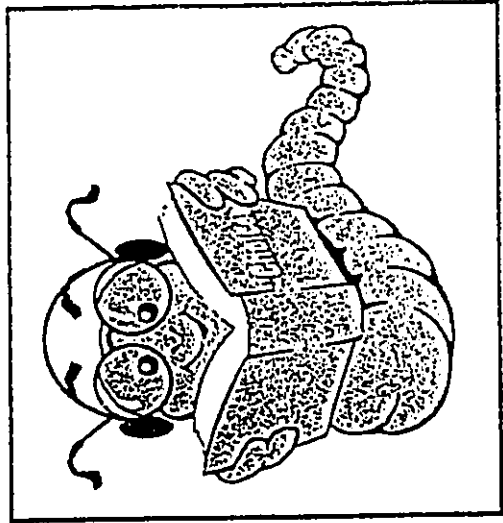
- For women well past menopause.
- For women with no problems at menopause
- Taken for 10 - 20 years



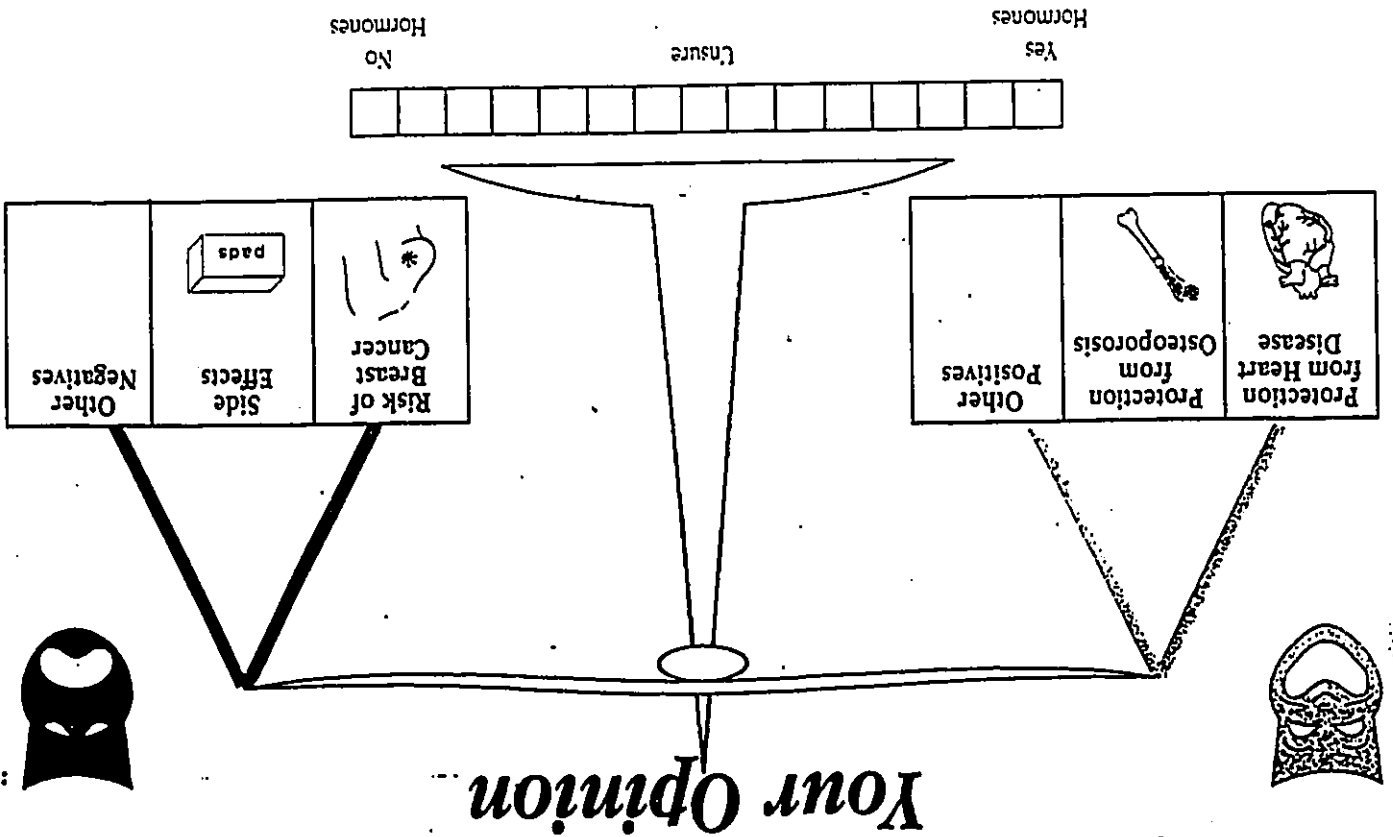
Denise's & Pat's Opinions



Facts about hormone therapy for women in their 50's...

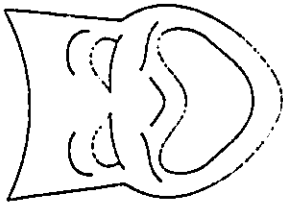


Note:
If you *already* have heart disease or osteoporosis, your doctor will advise you about treatment. This booklet talks about *preventing* these problems.



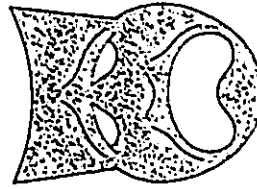
Benefits...

- Increased protection from heart disease and osteoporosis

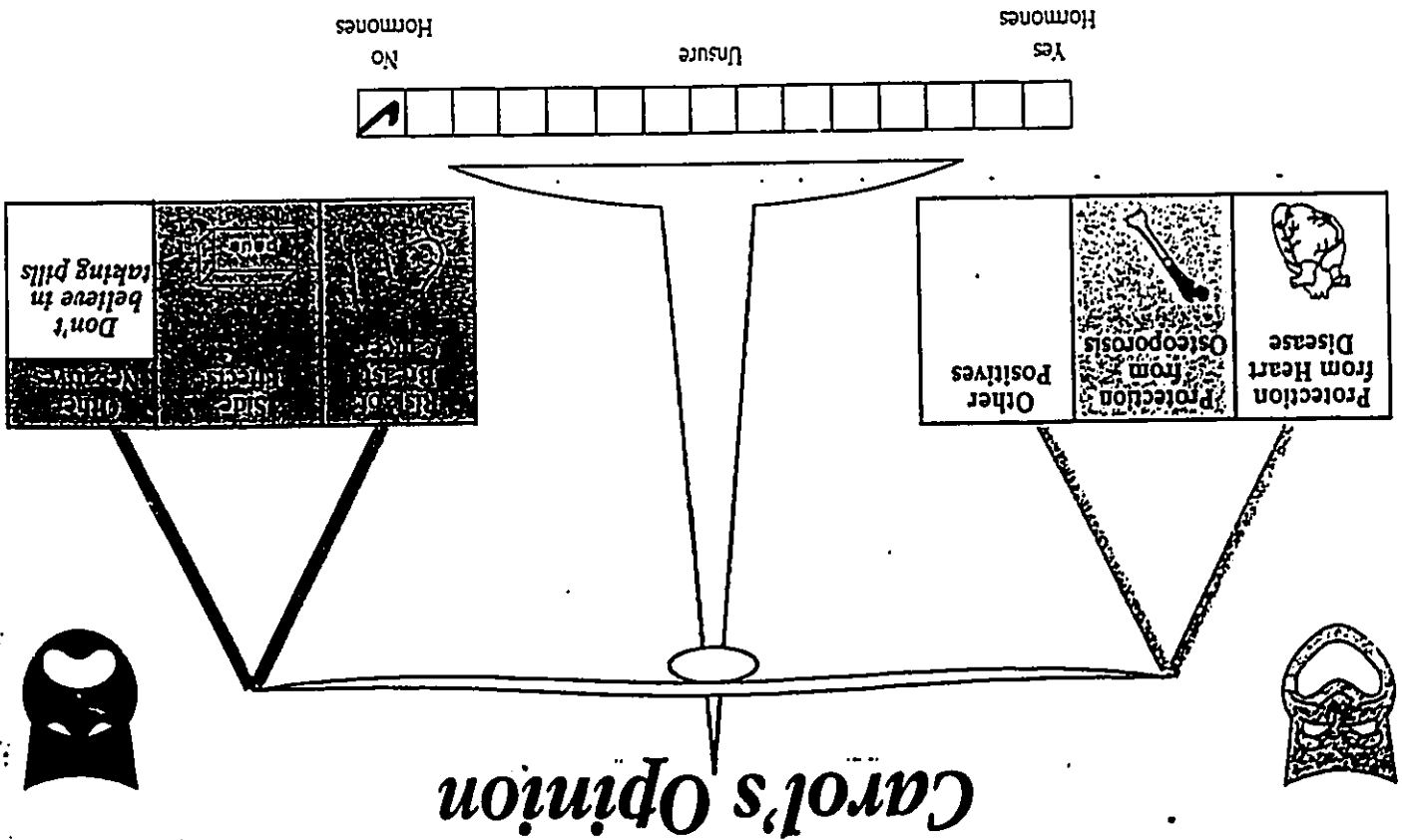


Risks...

- Possible risk of cancer and unpleasant side effects



Is hormone therapy right for me?



YES _____
 NO _____

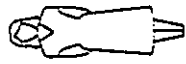
Other Negatives	Side Effects	Risk of Breast Cancer	Other Positives	Protection from Osteoporosis	Relief of hot Flashes
--------------------	-----------------	-----------------------------	--------------------	------------------------------------	-----------------------------

Mary's Opinion

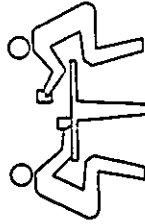


Who Do You Think Should Decide?

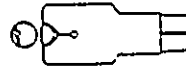
check one box



I should decide after getting opinions from others



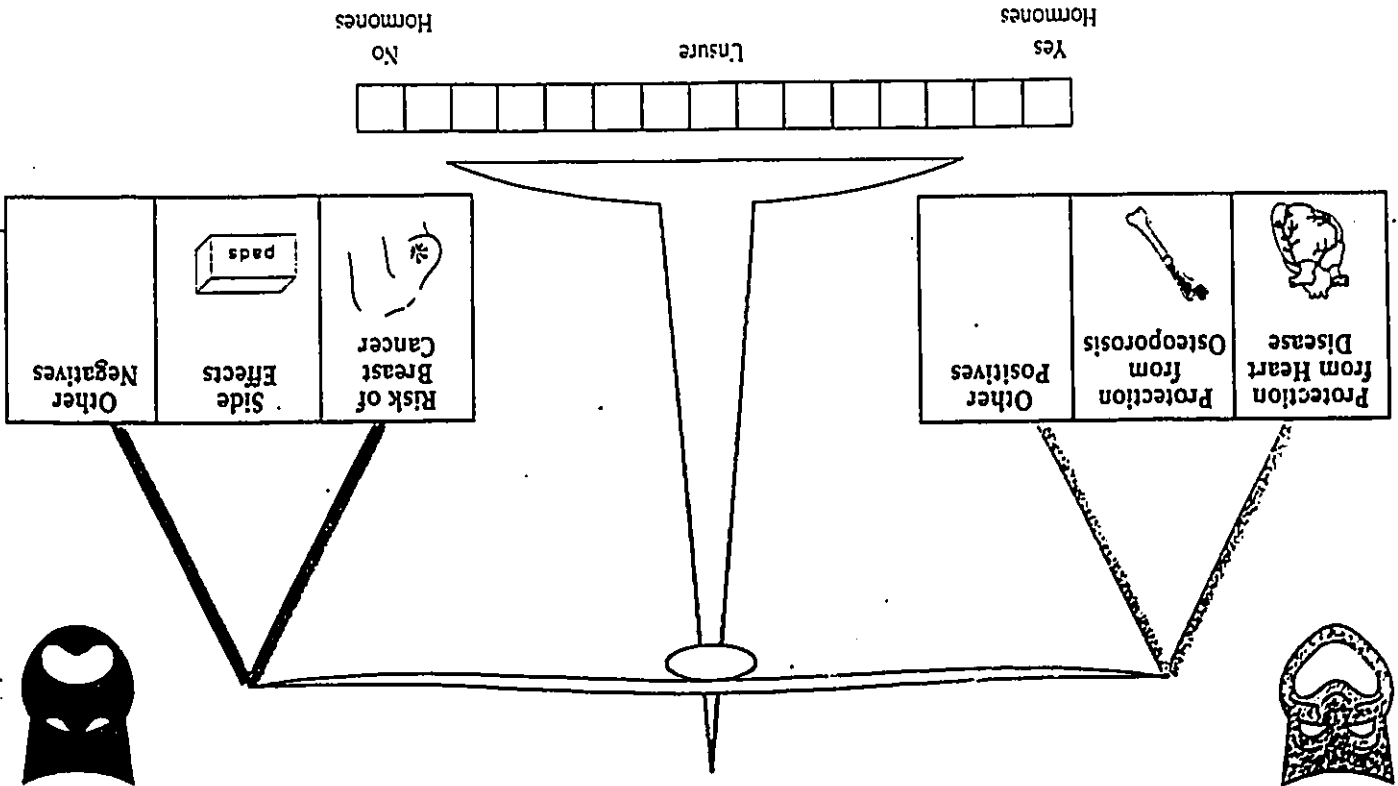
My doctor and I should decide together



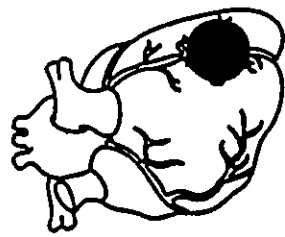
My doctor should decide



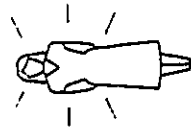
I'm not sure yet



You will learn about:

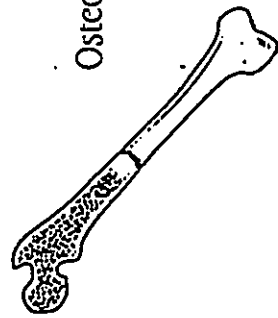


Heart disease



- Weight gain
- Irritability
- Bloating
- Headache

- Breast Tenderness

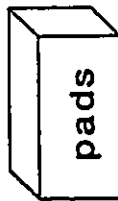


Osteoporosis

These symptoms are usually mild, and improve if prescription adjusted.



Side effects of hormone therapy...



Women with a uterus will have light menstrual bleeding requiring a pantyliner...

- For women using daily estrogen and progestin...

the bleeding is irregular, but it stops completely in 95% of women after 8 to 12 months

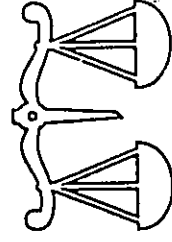
Month						
1	8			14		20
						26

- For women using estrogen and progestin on a monthly schedule...

the bleeding happens regularly on the last few days of the month, but it lessens over time and stops completely in 35% of women after 10 years



Risks & benefits of hormone therapy

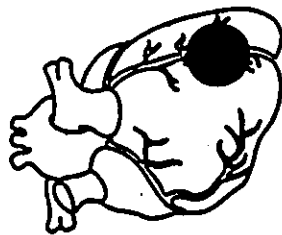


What is important to you?

Heart disease...

Narrowing of arteries that feed the heart muscle

- Angina (chest pain)
- Heart attack
- Heart failure

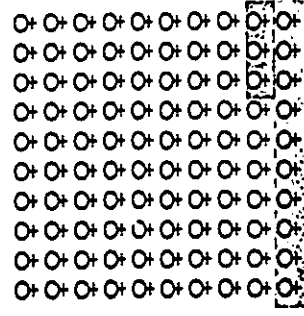
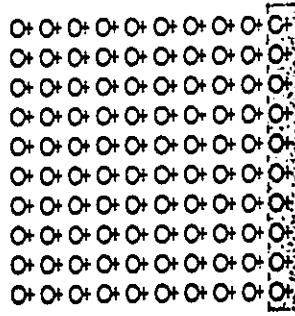


R_x Treatment

to widen narrow arteries and to strengthen the heart muscle

- Medication
- Surgery

The "Average" 50 year old woman:



Hormones may increase length of life by 1 to 1.5 months.

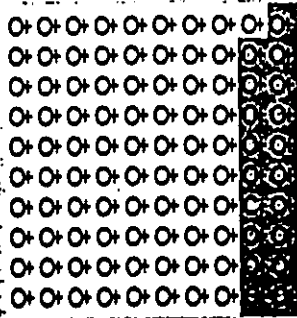
Possible breast cancer risk...

(estrogen for more than 7 years)

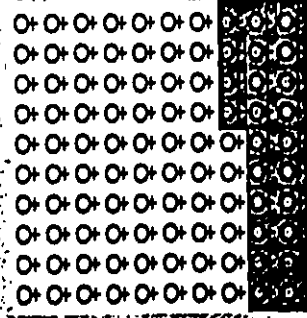
The "High Risk" 50 year old woman:

Check if it applies to you

I have a sister or mother with breast cancer.



19 out of 100 women will get breast cancer in their lifetime



with hormones, 29 extra women may get breast cancer

Hormones may increase length of life by 9 months or decrease it by 6 months.

Effects of heart disease...

Physical

- Chest pain
- Shortness of breath
- Feeling tired



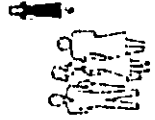
Emotional

- Feeling afraid or unsure
- Feeling discouraged or frustrated



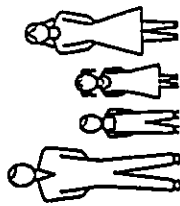
Social

- Limited activities



Heart disease

risk factors...



Family history

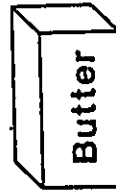
- father or brother before 55 years
- mother or sister before 65 years



Diabetes



High blood pressure



High cholesterol



Smoking

Breast cancer

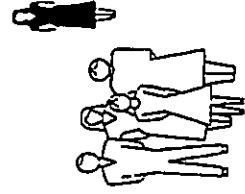
effects...



- Pain from surgery
- Disfigurement from surgery
- Side effects of chemotherapy:
 - nausea, vomiting, fatigue,
 - temporary hair loss, prone to
 - infection or bleeding



- Anxiety
- Depression
- Afraid cancer will return or spread



- Feeling of being alone



Breast cancer...

Uncontrolled growth of abnormal cells in the breast

- Can spread to the bones, liver, lungs and brain

Rx Treatment

- Surgery to remove lump or breast
- Radiation to breast if surgery just removed lump
- Sometimes chemotherapy pills or intravenous for 6 months



Lowering your risk of heart disease...



Control cholesterol



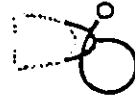
Exercise regularly



Not smoking



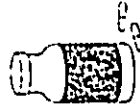
Lessen stress in your life



Control blood pressure



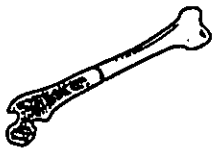
Control weight



Hormone pills

Osteoporosis...

Weak brittle bones



- Break very easily

-Hip

-Wrist

-Spine

- Stooped, round shouldered
"dowager's hump"



- Loss of height of up to 6 inches

Rx Treatment

- Medication
- Surgery—to fix broken bones

Breast Cancer

Risk of breast cancer unclear

...some studies say no
...a few say yes



breast
cancer

All women 50 years and older should have:

- Mammogram every 2 years
- Physical breast exam every year
- Breast self-exam every month

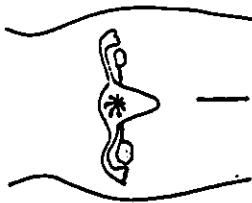
Cancer risk with hormone therapy...

Cancer of the uterus

Taking estrogen by itself increases risk of cancer of the uterus

...if progestin added to estrogen, *no* extra risk of cancer of uterus

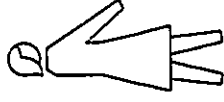
- if unable to tolerate progestin and take estrogen alone, you should have a yearly test to check for cancer known as "endometrial monitoring or biopsy"
- women with hysterectomy can take estrogen alone



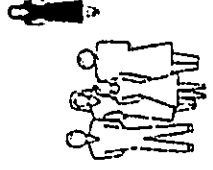
cancer of the uterus

Effects of broken bones from osteoporosis...

- Pain standing, carrying, sitting
- Difficulty walking, lifting, bending
- Difficulty shopping and doing housework



- Afraid of falling, doing things
- Frustration
- Anger
- Self-conscious about appearance

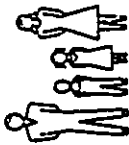


- Limited travel, social activity

Osteoporosis risk factors...



Low bone density



Family history

Race - white or asian

Small physical build



Pills such as cortisone



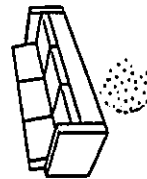
Too much caffeine & alcohol



Smoking

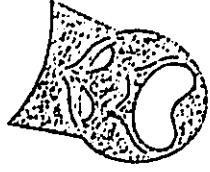


Low calcium & vitamin D in diet

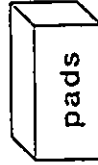


Lack of exercise

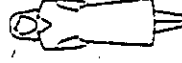
Risks...



Cancer risk?



Side effects



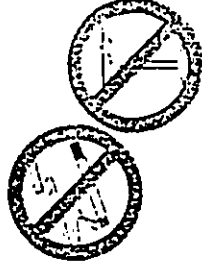
Who should not use hormone therapy...

check ✓ if it applies to you

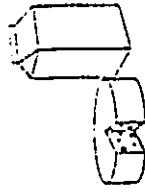
- I have breast cancer
- I now have blood clots in my legs

Your doctor will check whether you have other problems where hormones should not be taken.

Lowering your risk of osteoporosis...



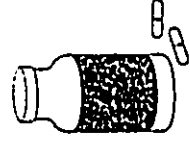
Avoid smoking, excess alcohol and caffeine



Eat foods high in calcium or take calcium tablets



Exercise regularly



Use hormone therapy

Hormone therapy...

- Replace hormones you lose naturally after menopause
- Taken for 10 to 20 years

Ways of taking hormones depends...

check ✓ one box

if you have no uterus or womb (hysterectomy)

daily estrogen pill

if you have a uterus (no hysterectomy)

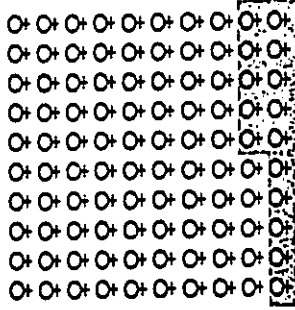
daily estrogen and progestin pills

OR

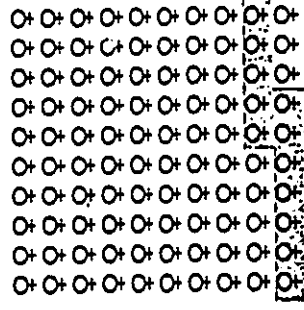
monthly schedule

- estrogen pill for part or all of the month, and
- progestin pill added for part of the month

The "Average" 50 year old woman:



15 out of 100 women will have broken hips in their lifetime



with hormones, 3 women may be protected

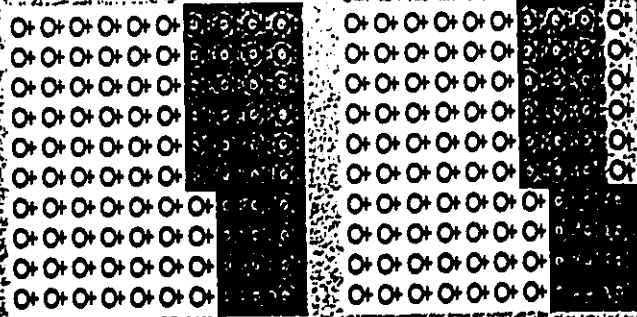
Hormones may increase length of life by 1 to 13 months.

Protection from broken hips from osteoporosis...

The "High Risk" 50-year old woman who:

check ✓ if it applies to you

I had a test showing my bones are not very dense (low bone density):



36 out of 100 women will have broken hips in their lifetime

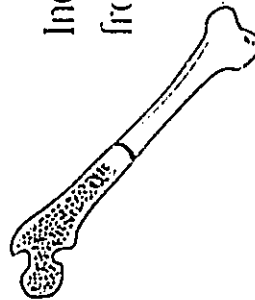
with hormones, 4 to 6 women may be protected

Hormones may increase length of life by 2 to 13 months.

Benefits...



Increased protection from heart disease



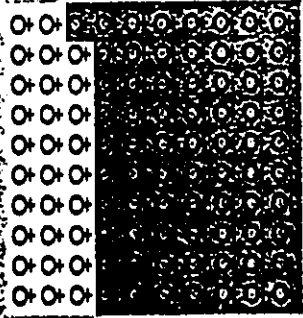
Increased protection from osteoporosis

Protection from heart disease...

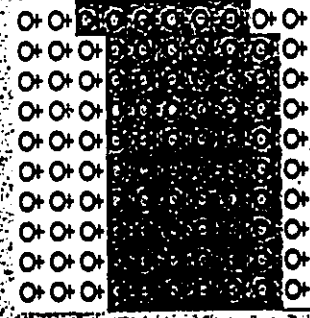
The "High Risk" 50 year old woman having at least one of these factors:

check all that apply

- smoker
- high cholesterol
- family history
- high blood pressure
- diabetes



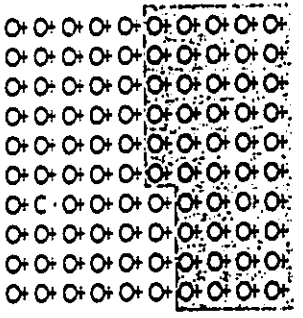
71 out of 100 women will have heart disease in their lifetime



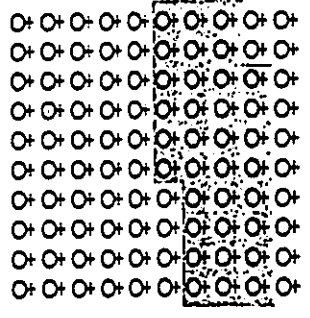
with hormones, 7 to 11 women may be protected

Hormones may increase length of life by 7 to 19 months.

The "Average" 50 year old woman:

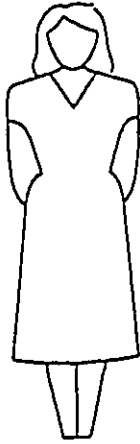


46 out of 100 women will have heart disease in their lifetime



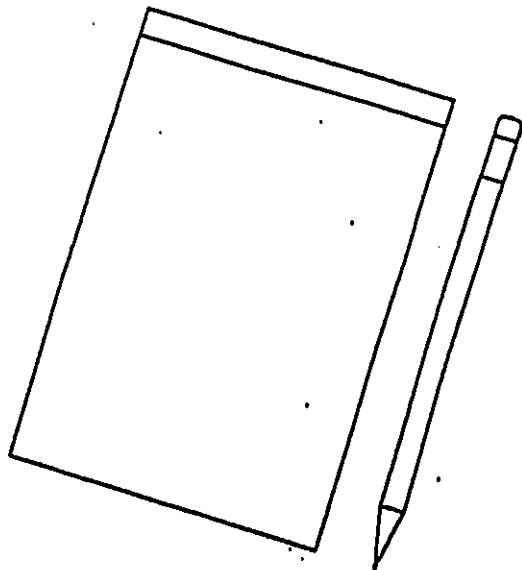
with hormones, 7 to 12 women may be protected

Hormones may increase length of life by 1 to 13 months.



Women's Opinion Survey
About the Use of
Hormone Therapy

Post-test Questionnaire





A. What I know about hormone therapy

We would like to ask the same questions again ... don't worry if you can't remember everything ... we did not expect you to memorize the presentation for a test! But it would help us to learn what things impressed you enough that you can recall them without having had to study them very hard.

Below are listed some statements about hormones taken after menopause (when menstrual periods stop for good). Please show whether you think they are true, false, or you are not sure by circling the word beside each statement.

1. Hormone therapy can be given:

early in menopause	True	False	Unsure
well past the menopause	True	False	Unsure
for 10-20 years	True	False	Unsure

2. Benefits of taking hormones are:

protection from breast cancer	True	False	Unsure
protection from osteoporosis (weak easily broken bones)	True	False	Unsure
protection from diabetes	True	False	Unsure
protection from heart disease	True	False	Unsure

3. Risks of using hormone therapy are:

Increases risk of breast cancer	True	False	Unsure
Increases risk of osteoporosis (weak, easily broken bones)	True	False	Unsure
Increases risk of diabetes	True	False	Unsure
Increases risk of heart disease	True	False	Unsure



4. Some side effects of hormones are:

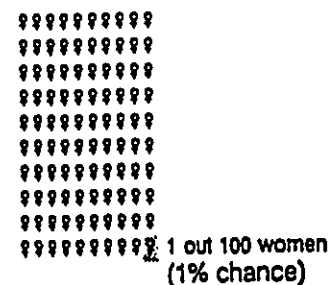
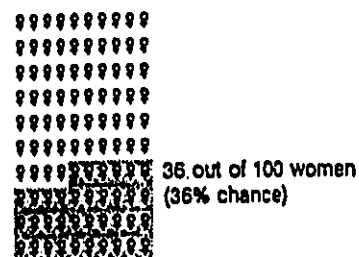
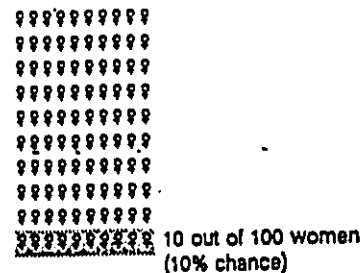
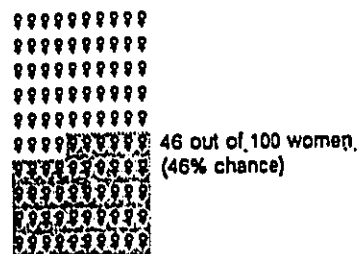
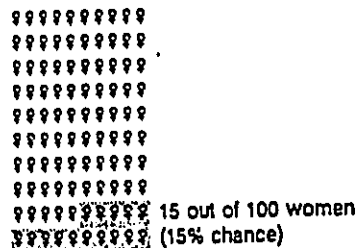
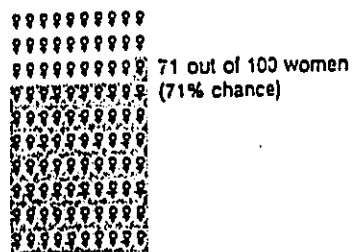
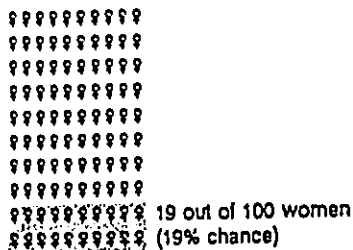
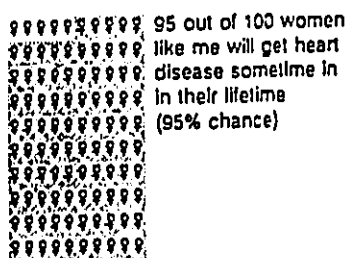
morning sickness	True	False	Unsure
breast tenderness	True	False	Unsure
fainting	True	False	Unsure
irritability	True	False	Unsure
bloating	True	False	Unsure
hot flashes	True	False	Unsure
headache	True	False	Unsure
allergy	True	False	Unsure
menstrual bleeding	True	False	Unsure
weight gain	True	False	Unsure



B. My risk of heart disease

Below we show different women's lifetime risk of heart disease from high to low. Each box contains 100 symbols representing 100 women. The women who are coloured grey will get heart disease. Therefore boxes showing more grey mean a woman's risk or chance of heart disease is greater.

Please show your opinion of your risk of having heart disease sometime in your life by Circling the box that best shows your risk. We are interested in your risk without the use of hormone therapy.

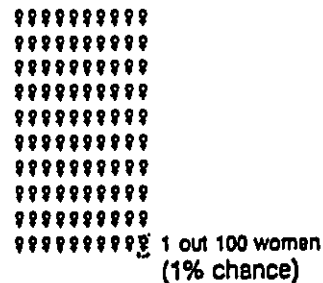
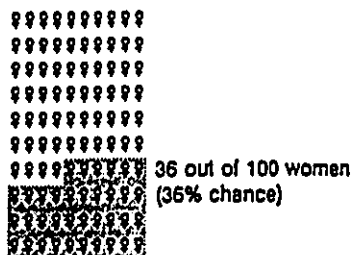
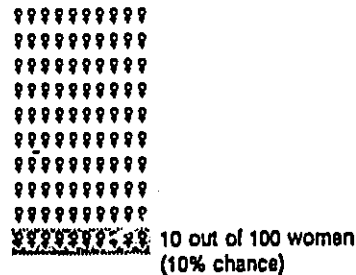
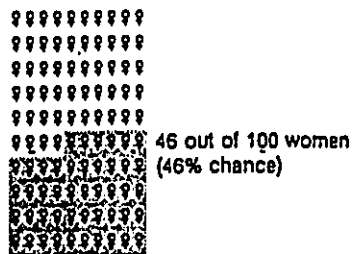
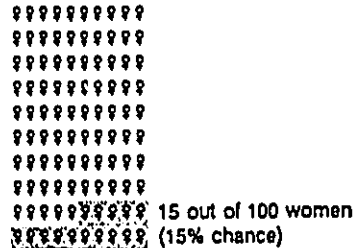
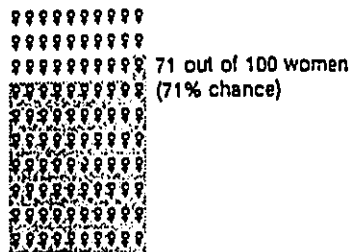
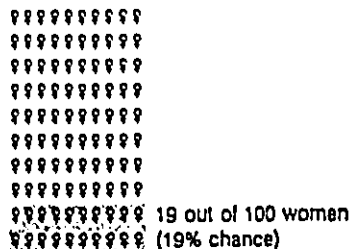
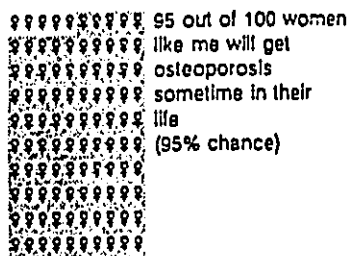




My risk of osteoporosis

Below we show different women's lifetime risk of osteoporosis from high to low. Each box contains 100 symbols representing 100 women. The women who are coloured grey will get osteoporosis. Therefore boxes showing more grey mean a woman's risk, or chance of osteoporosis is greater.

Please show your opinion of your risk of having osteoporosis sometime in your life by circling the box that best shows your risk. We are interested in your risk without hormone therapy.

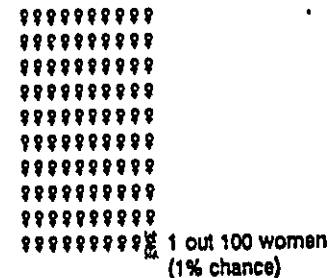
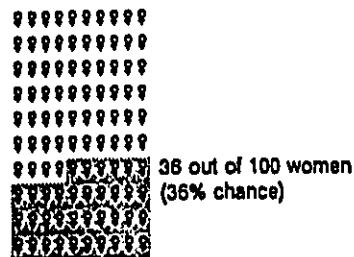
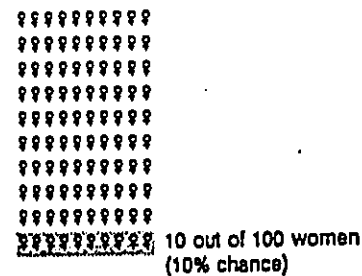
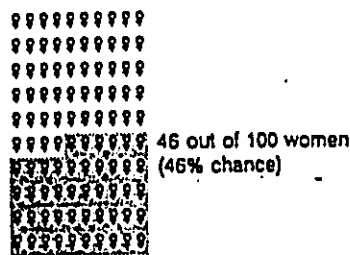
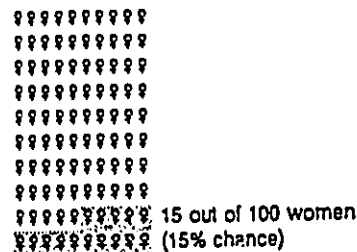
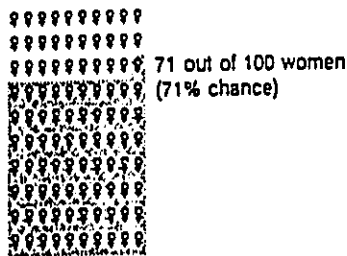
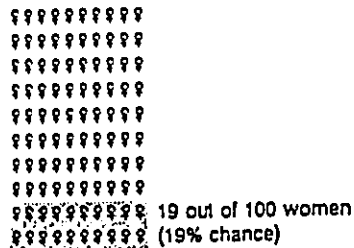
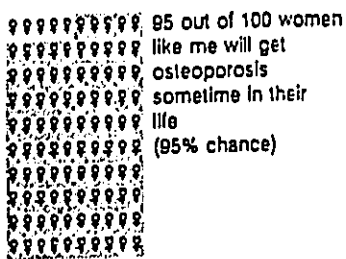


411

My risk of breast cancer

Below we show different women's lifetime risk of breast cancer from high to low. Each box contains 100 symbols representing 100 women. The women who are coloured grey will get breast cancer. Therefore boxes showing more grey mean a woman's risk, or chance of breast cancer is greater.

Please show your opinion of your risk of having breast cancer sometime in your life by circling the box that best shows your risk. We are interested in your risk without the use of hormone therapy.



C. The effects of hormone therapy on my risks



Now we are interested in your opinion on how much hormone therapy will affect your risk of heart disease, osteoporosis and breast cancer. Please check the box that best show how much you think hormones will affect your chances of heart disease, osteoporosis and breast cancer:

Heart Disease

If 100 women like me were to take hormone therapy, how many women would be protected from heart disease?

- | | |
|-----------------------------------|----------------------------------|
| <input type="checkbox"/> 100 | <input type="checkbox"/> 7 to 15 |
| <input type="checkbox"/> 76 to 99 | <input type="checkbox"/> 3 to 6 |
| <input type="checkbox"/> 51 to 75 | <input type="checkbox"/> 1 to 2 |
| <input type="checkbox"/> 26 to 50 | <input type="checkbox"/> 0 |
| <input type="checkbox"/> 16 to 25 | |



Osteoporosis

If 100 women like me were to take hormone therapy, how many would be protected from osteoporosis?

- | | |
|-----------------------------------|----------------------------------|
| <input type="checkbox"/> 100 | <input type="checkbox"/> 7 to 15 |
| <input type="checkbox"/> 76 to 99 | <input type="checkbox"/> 3 to 6 |
| <input type="checkbox"/> 51 to 75 | <input type="checkbox"/> 1 to 2 |
| <input type="checkbox"/> 26 to 50 | <input type="checkbox"/> 0 |
| <input type="checkbox"/> 16 to 25 | |



Breast Cancer

If 100 women like me were to take hormone therapy, how many extra women would get breast cancer?

- | | |
|-----------------------------------|----------------------------------|
| <input type="checkbox"/> 100 | <input type="checkbox"/> 7 to 15 |
| <input type="checkbox"/> 76 to 99 | <input type="checkbox"/> 3 to 6 |
| <input type="checkbox"/> 51 to 75 | <input type="checkbox"/> 1 to 2 |
| <input type="checkbox"/> 26 to 50 | <input type="checkbox"/> 0 |
| <input type="checkbox"/> 16 to 25 | |



D. The things that are important to me when making a decision about hormone therapy.

Below are listed some things women consider when making a decision about hormone therapy. Please show how important these are to you by circling a number from:

0 (not at all important to me)
to
10 (extremely important to me).

How important would these things be to you when making a decision about hormone therapy?

Protection from heart disease



0 1 2 3 4 5 6 7 8 9 10
not at all important to me extremely important to me in this decision

Protection from osteoporosis (weak easily broken bones)



0 1 2 3 4 5 6 7 8 9 10
not at all important to me extremely important to me in this decision

Side effects of therapy



0 1 2 3 4 5 6 7 8 9 10
not at all important to me extremely important to me in this decision

Risk of breast cancer



0 1 2 3 4 5 6 7 8 9 10
not at all important to me extremely important to me in this decision

E. My thoughts on the best choice for me

If your doctor asked you to make a choice about using hormone therapy with the information you now have, which choice | | looks the best for you:

| | Not using hormone therapy

reason/comments



| | Using hormone therapy

reason/comments



| | I'm not sure

reason/comments



F. My difficulty making this choice



Now, thinking about the choice you just made, please look at the following comments made by some women when deciding about hormone therapy.

Please show how strongly you agree or disagree with these statements by circling the number from 1 (strongly agree) to 5 (strongly disagree) which best shows how you feel about the choice you just made.

This decision is <i>hard</i> for me to make	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
I'm <i>unsure</i> what to do in this decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
<u>It's clear</u> what choice is best for me	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
I'm aware of the choices I have to reduce my risk of heart disease and osteoporosis	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
I feel I know the benefits of hormone therapy Disagree	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly
I feel I know the risks and side effects of hormone therapy	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
I <i>need more advice</i> and information about the choices	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
I know how important the <u>benefits</u> are to me in this decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree

I know how important the <u>risks and side effects</u> are to me in this decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
It's <i>hard to decide</i> if the benefits are more important to me than the risks or if the risks are more important to me than the benefits	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
I feel <i>pressure</i> from others in making this decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
I have the right amount of support from others in making this choice	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
I feel I have made an informed choice	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
My decision shows what is important to me	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
I expect to stick with my decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
I am satisfied with my decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree



G. My thoughts on the tape and booklet

Please show what you thought about the presentation by placing a mark across the line _____ which goes from poor to excellent for each of the things listed below:

1. The way the information was presented to help you understand:

what heart disease is like poor _____ excellent

what osteoporosis is like poor _____ excellent

what breast cancer is like poor _____ excellent

hormone side effects poor _____ excellent

using the block of 100 women
to show me my risks of
disease with and without
hormone therapy poor _____ excellent

using the weigh scale to
show my opinions of the
risks and benefits of
hormones poor _____ excellent

2. The speed of presentation (check one)

fast

slow

just right

3. The length of presentation

- long
- short
- just right

4. The amount of information

- too much information
- too little information
- just right

5. The woman's voice on the tape

- irritating
- boring
- pleasant

6. I found the presentation

- slanted toward taking hormone therapy
- slanted against taking hormone therapy
- balanced

What I liked:

Suggestions for improvement:

THANK YOU FOR YOUR HELP!

Appendix E.

Hormone Replacement
Therapy Study

ID |_|_|_|_|_|_|_|_|

|_|_|_|_|_| 103 |_|_|
da mo yr

Family Nurse Screening Form

TEAM |_|_|

Nurse's Assessment:

Is there any reason
why we should not
approach this patient
to participate in the
HRT study?

|_|_| No

|_|_| Yes (SPECIFY)

Does the patient
communicate well in
English?

|_|_| Yes

|_|_| No (SPECIFY)



IF BOTH CHECK MARKS ARE IN THE FIRST COLUMN, PLEASE INFORM THE WOMEN:

Researchers at the University of Ottawa are conducting a study of
women's OPINIONS about hormone replacement therapy.
We are helping them to identify women for the study.
Would it be OK if a nurse from the study met with you to explain more
about it so you can decide whether to participate?

PLEASE INSTRUCT WOMEN WHO ARE ELIGIBLE - TO BRING THEIR BLUE SHEET TO THE TEAM
#1 DESK AFTER THEIR APPOINTMENT WITH THE PHYSICIAN.

FORMS FOR WOMEN WHO ARE INELIGIBLE SHOULD BE LEFT ON THEIR CHART.

THANK YOU!

Hormone Replacement Therapy Study
Screening Form

ID [][][][][][] [][][] [][][] 104 [][]
yr mo ua

Are you still menstruating?

- Yes
- No
- Hysterectomy

How long ago did you have your
last menstrual period?
(SPECIFY)

- _____
- 2 years or more
 - Less than 2 years

Are you currently using hormone
replacement therapy? (Premarin,
Provera, estrogen pills, estrogen
patch, progestin)

- No
- Yes, 2 years or more
- Yes, less than 2 years

Tell me about any previous use of
hormone replacement therapy?

- Never used
- Used and stopped

Reason for stopping:

- Symptoms under control
 - Discontinued due to side effects
 - No longer necessary
 - Other (SPECIFY)
- _____

**Hormone Replacement Therapy Study
Recruitment form**

Your answers to these questions show that you might be eligible to participate in the study on women's opinions about hormone replacement therapy.

There isn't much information about women's opinions and the type of information they need before making a choice that best suits them.

Your participation would take:

15-20 minutes sometime during this visit to:

- complete a questionnaire

45 minutes at a later time to:

- review a booklet and audiotape about the risks and benefits of hormone replacement therapy
- complete another questionnaire

YOU ARE FREE TO PARTICIPATE OR NOT AND YOUR DECISION WILL NOT AFFECT THE CARE YOU WILL RECEIVE.

No

Yes——> Specify patient's name and telephone numbers:

Name: _____

Telephone Home: _____

Office: _____

