How the Women's Health Initiative (WHI) Influenced Physicians' Practice and Attitudes

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BACKGROUND: The landmark Women's Health Initiative (WHI) Postmenopausal Hormone Therapy Trial published in 2002 showed that the health risks of combination hormone therapy (HT) with estrogen and progestin outweighed the benefits in healthy postmenopausal women. Dissemination of results had a major impact on prescriptions for, and physician beliefs about HT. No study has fully examined the influence of the widely publicized WHI on physicians' practice and attitudes or their opinions of the scientific evidence regarding HT; in addition, little is known about how physicians assist women in their decisions regarding HT.

DESIGN AND PARTICIPANTS: We conducted in-depth telephone interviews with family practitioners, internists, and gynecologists from integrated health care delivery systems in Washington State (n=10 physicians) and Massachusetts (n=12 physicians). Our objectives were to obtain qualitative information from these physicians to understand their perspectives on use of HT, the scientific evidence regarding its risks and benefits, and counseling strategies around HT use and discontinuation.

APPROACH: We used Template Analysis to code transcribed telephone interviews and identify themes.

RESULTS: Physicians were conflicted about the WHI results and its implications. Seven themes identified from in-depth interviews suggested that the WHI (1) was a ground-breaking study that changed clinical practice, including counseling; (2) was not applicable to the full range of patients seen in clinical practice; (3) raised concerns over the impact of publicized health information on women; (4) created uncertainty about the risks and benefits of HT; (5) called for the use of decision aids; (6) influenced discontinuation strategies; and (7) provided an opportunity to discuss healthy lifestyle options with patients. As a result of the WHI, physicians reported they no longer prescribe HT for prevention and were more likely to suggest discontinuation, although many felt women should be in charge of the HT decision.

CONCLUSIONS: Physicians varied in their opinions of HT and the scientific evidence (positive and negative). Whereas the WHI delineated the risks and benefits of HT, physicians reported that decision aids are needed to guide discussions with women about menopause and HT. Better guidance at the time of WHI study publication might have been valuable to ensure best practices.

KEY WORDS: practice patterns; attitudes; postmenopausal hormone therapy.
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BACKGROUND

In July 2002, results of the Women's Health Initiative (WHI) Estrogen-Plus-Progestin study were published, indicating that the overall health risks of long-term combination hormone therapy (HT) with estrogen and progestin exceed the benefits in healthy postmenopausal women.[1] These findings were widely publicized in the popular press, producing immediate and major impacts on women and physicians.[2,3] Prescriptions for conjugated equine estrogen/medroxyprogesterone acetate tablets (Prempro™, the medication used in the study)—and of conjugated equine estrogens (Premarin™)—plummeted. Women who were using HT were advised to discuss the pros and cons of continuation with their physicians.[4,5] Recent publications have criticized the release and interpretation of the WHI findings and questioned the generalizability of findings, given the population studied and medications selected.[6–8] Variability in physicians' attitudes and beliefs about HT after WHI has been reported in numerous studies. For example, physicians were less favorable toward using HT for prevention[9,10] and gynecologists indicated they would continue to prescribe HT despite the WHI results[11,12] and that they were more likely to hold positive views of HT than were general internists.[10,13,14] Although there are growing data about physician attitudes since the release of the WHI,[9–11,13–18] these studies provide little insight into physicians' thoughts regarding the scientific evidence about HT—nor the impact of the WHI on day-to-day clinical practice. No studies have collected data on the

strategies physicians use when counseling women about the use of HT, especially regarding discontinuation.

Qualitative methods are ideally suited to gathering in-depth information about attitudes and experiences of research subjects. The goals of the present study were to obtain detailed qualitative information from physicians to (1) understand their perspectives on use of HT and the scientific evidence regarding the risks and benefits of HT; (2) understand the impact of the WHI on physicians' attitudes and clinical practice, including their practices and counseling strategies around HT discontinuation; and (3) inform development of a survey for a larger quantitative study.

Design

We used semistructured, in-depth telephone interviews to elicit physician attitudes and beliefs and Template Analysis to group phrases and identify common themes.[19] The study team developed an interview guide consisting of a priori open-ended questions to address (1) physicians' attitudes about using HT, (2) strategies they use to help women make informed decisions about HT, (3) opinions of the WHI, (4) discontinuation efforts, and (5) perceptions of the scientific evidence. These predetermined topics were based on expert opinions of the study team and external sources, prior research, and goals of the overall study. Research team members have epidemiological (AB, LN, SR, AL, KN) and clinical expertise (LN, SR, MC, KN, EL) in menopause-related studies and other major health issues affecting women across the life span as well as experience in qualitative analysis (AB, EL, LN, MC, TB).

One author (TB) conducted all of the telephone interviews with physicians at two integrated health care delivery sites. The interviewer began with a general question about HT: "What are your thoughts about hormone therapy?" Specific probes were used to explore other aspects of HT, such as "What strategies do you use to help women make informed decisions about hormone therapy?" and "What are your views of the Women's Health Initiative?"

Participants

Participants included physicians from Group Health and Harvard Vanguard Medical Associates. Group Health is a large integrated health plan that serves over 500,000 enrollees in Washington State. Family practice physicians deliver most primary care, although some women receive care from internists and specialists in obstetrics/gynecology. Clinical practice guidelines are available on Group Health's website to assist physicians with menopause counseling. Harvard Vanguard Medical Associates is a group multispecialty medical practice consisting of 14 health centers serving approximately 300,000 members in the greater metropolitan Boston area. Primary care is provided in the departments of internal medicine and/or obstetrics/gynecology. A specialized menopause practice serves approximately 400 referred women per year.

Data Collection

We used purposive sampling with a goal of collecting narrative data from 20 physicians (10/site); approximately 16 women and 4 men; 10 from family practice/internal medicine and 10 from obstetrics/gynecology. We purposely oversampled female physicians because of the uneven distribution of female patients in their practices. Based on qualitative methods and previous studies, we estimated that 20 interviews would suffice to identify salient themes and reach data saturation—the point at which no new themes or information emerge. We mailed invitation letters to 44 physicians in batches of 4–10 (depending on completion rate within groups); 27 from family practice/internal medicine and 17 from obstetrics/gynecology. The advance letter informed physicians about the study and invited their participation in a telephone interview for which they would receive $100. The letter explained that an e-mail would follow within 3 weeks to arrange a time for the interview, and gave a telephone number to call if a physician wished to decline. If we received no reply after two e-mail attempts and leaving two voicemail messages, we stopped trying to contact that physician. We obtained verbal informed consent at the beginning of the telephone interviews, which were conducted between January 2005 and May 2005. The Institutional Review Boards of Group Health and Harvard Vanguard Medical Associates approved all study procedures.

Analysis

A professional service transcribed the tape-recorded interviews, and the study manager checked a sample of typed transcripts against the tapes to verify transcription accuracy. To code and summarize the narratives, we used "Template Analysis,"[20] a qualitative research method for "thematic coding" of text data, whereby coders produce lists of codes to represent themes identified in the interview data. Others have used Template Analysis to code similar types of qualitative data.[19,21–23] In Template Analysis, thematic categories are predetermined a priori according to the researchers' study goals (e.g., physicians' opinions of WHI and their counseling strategies around HT discontinuation). Categories are usually organized in a hierarchical fashion, with more global overarching themes encompassing more specific categories.[19]

Multiple readings and coding of transcripts and modifications to the coding template proceed in an iterative fashion. Initial coding templates are modified based on coding the transcripts and comparing revised templates with other coders; new codes are added when data do not fit conceptually within the predetermined categories. The iterative coding development process permits conceptual refinement and organization of the topic under study. Two authors (TB and AB) coded the interviews, created, compared, and modified initial coding templates, recoded several interviews and then compared subsequent templates. Modifications to coding templates involved adding, deleting, or merging codes and themes. Differences were resolved by consensus and the mutually agreed upon final template was then applied to all of the interviews.[19,24] Two coders (EL and TB) verified interim and final templates with 5 interviews. Coders were trained and/or had prior experience in qualitative research methods.

RESULTS

Of the 44 contacted physicians, 25 agreed to participate and 22 completed the interviews; 10 from Group Health (2 men and 8 women; 5 in family practice/internal medicine and 5 obstetrics/gynecology) and 12 from Harvard Vanguard Medical

Table 1. Emergent Themes from Qualitative Interviews with Physicians at Two Health Care Organizations

No.	Theme	Quotes
1a	WHI was an important groundbreaking study that changed clinical practice	"A good study that really changed the way everybody practiced." "Prior to WHI my colleagues were pressuring me to write more prescriptions for HT. I was always cautious about using HT. So, after WHI, I felt relief to be able to practice closer to what I believe." "I'm eternally grateful to it [the WHI]. I think being a large prospective study that carries statistical weight makes it easier to say, 'Based upon what we know now, this is the information that you need to use to make your decision. Then you can go ahead and make it.'" "It [the WHI] has made my life much simpler and much more straightforward. I have no troubles with it at all." "Publicity [from WHI] helped more than harmed, because I think people became more aware of osteoporosis risks, and just became more aware about the quality-of-life issues surrounding menopause."
1b	WHI influenced how physicians counsel women about HT	"Women are in control. It is their decision." "I am happy when they [women patients] don't bring it up. I felt better 10 years ago being ignorant and saying 'HT will even cure heart disease.'" "There's no longer a treatment for women with menopausal symptoms; there's calcium and vitamin D for bones, but other than that, there is nothing else." "It's a woman's choice. After describing the risk factors, if in 10 years she gets breast cancer, will she look back at her decision to take HT?" "Some women want doctors to tell them what to do. I start from where a woman is at. I can't make the decision for her. There are no right or wrong answers: There are risks of taking and not taking."
2	WHI is not applicable to the women I see	"WHI does not represent all women, I mean the population in that study was a little bit older, the majority were anywhere from 5 to 10 years remote from menopause." "WHI applies only to older [women], 5–10 years remote from menopause. They do not have severe symptoms, and they may have started it for prevention." "WHI published risks for heart disease are very minimal; there's maybe an increased risk of cardiovascular disease, but it's very minimal." "The study applied to a particular group of patients. It doesn't apply to most of the patients I'm talking to." "The other problem with the study of course is that most of the women I treat are starting their HT early because they're symptomatic. They're not starting it from the age of 65 and I don't know if that's a different route than the women who are not symptomatic and being started on it for the WHI. So I'm not sure I'm comparing my group of patients to the group that was in the study."
3	WHI raised concerns about the impact of health information on women	"Too much misinformation leads to confusion." "[WHI] was blown out of perspective; the risks have been vastly overplayed in the public mind even in the mind of medical professionals." "The media has not been helpful... It's all scare–scare–scare–scare... I've never seen a television presentation that talked about the gray areas. They never give the absolute numbers. It's always, '[HT] raises risks.' They use inflammatory language." "The people who are on it [HT] want to try to go off of it certainly more readily because of everything they've read and the fear factor with it." "Women are ill-informed; I think the best way for women to get the information is from a health care provider in both verbal and printed form." "Some women have seen so many studies that they don't believe anything—and the HT helps them, so they don't really want to change."
4	WHI created uncertainty in the scientific evidence	"It raised more questions than it answered." "Everybody is different in what symptoms they might perceive from a sudden loss of estrogen, and how they might respond to various compounds." "Knowing how things have gone in medicine, I don't want to say it [the WHI] is the final word." "I am not convinced of the data." "One study does not usually erase all prior research." "We need another study that follows women from the perimenopausal transition through after menopause." "There are still a zillion unanswered questions. There are still uncertainties." "Neither of us is satisfied with our current treatment or explanations at this point." "Science changes, and that's a lesson I try to also talk to my patients about. I say [to my patients], 'Bring this up every time you have a well visit, because there may be new science in two or three years, and I may be telling you something different, and the story does change.'" "I'm not at all sure that the net effect of it [WHI] is going to do more good than harm. If you look at all of the ramifications and effects on women's health that this study has produced [the sum], it could easily be negative."

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Table 1. (continued)

No.	Theme	Quotes
5	Physicians lack information and decision aids	"It's hard to keep up with the literature." "Researchers at the WHI released results before preparing physicians. We were not adequately armed with information. This continues to be a problem as more papers are coming out of the WHI." "Things have changed so much, and there's really not any current information on what to do." "I am looking for some sort of statement of what to do. I haven't seen anything in print from any national organization that really tells you what to do." "I'd like to know how to counsel women: how directive to be, whether to recommend [HT] versus let a woman decide versus individualize." "If somebody would think through the decision-making tree in a careful way and work out an algorithm that a clinician could use—or even one that the patient could use based on real evidence—that would be a very useful thing."
6	Physicians are using various discontinuation strategies	"That's the art, not the science, of medicine." "If they have a significant risk of heart disease, I tell them to come off. I gave everyone a year to think about it." "Every other day unless on high dose, for two weeks to one month; then take every third day, then two times per week." "I ask them how long they've been on HT and if they're aware of the new information suggesting risk for breast cancer and dementia. I ask, 'Are you interested in working with me to taper you off?' and I try to make it, I guess the buzzwords are a shared decision about the benefits and risks of staying on, and then work with trying to taper them off if they're willing."
7	The silver lining in WHI is a chance for discussion	"An opportunity to discuss important issues of lifestyle, health habits, and aging in general." "It is a doorway for discussing other issues: lifestyle, quality of life, aging, planning for the next 50 years. It's more important than the HT [to] plant those seeds regarding lifestyle and aging." "Some women are in denial about being overweight or diabetic. So I use the estrogen discussion to get to the importance of lifestyle. 'Are you exercising? This [exercise] is good for everything.' The biggest challenge for women is to learn how to start 'taking care of me' [themselves]." "Everyone is hemming and hawing over an odds ratio of 1.2; and yet, if they exercised and got their weight appropriate, they could make huge differences in many other things." "The physical part of menopausal symptoms is less of an issue for women than the changes in lifestyle, social, and environmental stresses." "I think that it's important for physicians to know enough about their patient and have an understanding of their patients' lifestyle so that they can have that kind of discussion with them."

Associates (3 men and 9 women; 6 in family practice/internal medicine and 6 in obstetrics/gynecology). Three agreed to participate but were unavailable during the times interviews were scheduled. Of the other 19, 8 refused participation and 11 were out of town, unavailable by email, or unresponsive to emails. Although our goal was to interview 20 physicians, we enrolled 22 by including 2 physicians who replied late to our invitation. The interviewer (TB) and coders (AB, EL) confirmed that 22 interviews sufficiently captured the main topics of interest and that additional interviews were unlikely to reveal new themes. Participants ranged in age from 37 to 63 and reported a range of 8 to 35 years in practice. Interviews lasted from 20 to 60 minutes (average=34.5). Qualitative analyses of coded transcripts revealed important issues that we grouped into seven themes (Table 1).

Theme 1. WHI was an important groundbreaking study that changed clinical practice. Physicians we interviewed described the WHI as a well-designed study that contributed greatly to the scientific evidence that influenced clinical practice. As a result of the WHI, physicians said they stopped using HT for prevention of heart disease and osteoporosis and many were reluctant to prescribe it for relief of uncomfortable menopausal symptoms (hot flashes, night sweats, sleep, and mood).

Theme 2. WHI is not applicable to the women I see. Interviewees noted that the WHI focused on older postmenopausal women and did not inform them regarding the younger age profile of many women seen in their clinical practice. Some physicians expressed disappointment that the WHI tested only one hormone regimen and wanted more scientific evidence on the effectiveness of other estrogen formulations and alternatives (e.g., herbals), especially for perimenopausal women.

Theme 3. WHI raised concerns about the impact of health information on women. Some interviewees reported that the media presentation of the WHI was detrimental because it frightened women away from medicines that worked to relieve uncomfortable symptoms. Physicians reported that the barrage of information and sound bytes "could prevent some women who need HT from taking it." They suggested that "too much information" (available from the media) can be a source of confusion for women and physicians around HT decisions.

Theme 4. WHI created uncertainty in the scientific evidence regarding HT. Whereas most who were interviewed had strong opinions regarding WHI, whether positive or negative, others were less confident in their understanding of the results. Some were not satisfied with the current state of the science around menopausal management and treatment. They discussed gaps that still remained in the evidence and said that, as with many health conditions, "there isn't an all woman model that works for everybody."

Theme 5. Physicians lack information and decision aids. Some interviewees were overwhelmed by new studies that are constantly coming out and wondered how to sort through all of the data to determine how it applies to their patients. These physicians discussed the need for decision aids to help in their discussions with women about menopause and alternatives to HT. Some called for a statement from a respected national organization on best practices.

Theme 6. Physicians are using various discontinuation strategies. Discontinuation methods of those interviewed were "not set in stone" but generally involved gradual tapering as opposed to stopping "cold turkey." Rather than talk about discontinuation, some physicians explained why they continued to support use of HT; "some of them [women] want to take the hormones despite other risks because they feel that in their family history, osteoporosis is a greater risk."

Theme 7. The silver lining in WHI is a chance to discuss healthy lifestyle options. Changes in physician attitudes and beliefs after WHI led many to use the clinical encounter with women of menopausal age as an opening to discuss ways of achieving healthy lifestyles, including stress reduction and behavior changes to reduce menopausal symptoms and prevent osteoporosis. For example, interviewees indicated that they now spend time discussing lifestyle choices such as using fans, layering clothes, increasing exercise.

DISCUSSION

To our knowledge, this is the first in-depth qualitative study of family practice/internal medicine physicians and gynecologists opinions of the WHI trial, as well as physician counseling strategies and opinions about HT discontinuation. As a whole, the physicians interviewed in our study indicated that the WHI was a ground-breaking study that changed clinical practice, but we observed considerable variability in physician attitudes and beliefs about HT and the findings of the WHI. Unanticipated themes that emerged included the effect of the media after the release of the WHI, and the effect of the WHI on enhancing physician discussion with patients about healthy lifestyles to manage symptoms and prevent disease. Our qualitative analysis revealed that physicians have conflicting beliefs about the WHI and HT use. The tension between the themes "WHI was a well designed study that changed practice" and "WHI created uncertainty" may reflect an appreciation of the quality of the WHI and the frustration that it ultimately raised more questions than answers for many physicians.

The themes "WHI was a well designed study" and "was not applicable" appear contradictory and reflect the beliefs of some physicians that WHI participants were older postmenopausal women and thus not representative of the younger perimenopausal women in their practice. This is consistent with critical reviews of the WHI[6] and survey findings of obstetrician–gynecologists suggesting that physicians were skeptical of the WHI findings.[12] The themes "discontinuation strategies" and "was not applicable" reflect a similar set of contrasting beliefs. A possible reason for the latter is that these themes arose out of discussions initiated by women wanting to stop HT. Inconsistent views between and within physicians about HT may indicate a state of ambivalence around the safety of HT as well as the effectiveness and safety of alternatives for symptom relief ("don't know if topicals are any less harmful;" "there is no evidence"). The variability in physician attitudes and beliefs that we observed is consistent with other studies.[9–11,13] For example, two thirds of physicians overestimated the risks reported in WHI[10] and gynecologists were more favorable toward HT than internal medicine physicians.[9–11,13] Also consistent with prior research,[14] we found that physicians in our study no longer used HT for prevention of heart disease and osteoporosis. With the availability of suitable, effective alternatives for prevention and treatment of these conditions, this transition appeared not to be difficult for study physicians. However, some felt challenged by their discussions with women seeking relief of menopausal symptoms, partly because physicians did not view alternative treatments as viable evidence-based options. Some interviewees felt the WHI empowered them, whereas others felt they lacked the tools to assist their patients. These findings are consistent with prior studies that found that women[25] and physicians[26,27] were dissatisfied with shared decision making and had counseling needs that published guidelines did not address. In either case, in the face of uncertainty and inadequate information, interviewees felt the final choice regarding HT use comes down to a woman's preference. Although it was not an a priori goal of our study to evaluate the effect of the media on HT counseling, this theme emerged in review/analysis of transcripts. Concern about the impact of publicity of the WHI on women is warranted. In a recent study, researchers reviewed newspaper coverage of HT before and after two large clinical trials, the WHI,[1] and the Heart and Estrogen/Progestin Replacement study (HERS),[28] and reported a dramatic increase in news coverage about HT and a subsequent drop in HT prescriptions after publication of the WHI study, but not after the HERS.[29]

Our study has several limitations. First, we acknowledge there are many ways to conduct qualitative studies and different analytic tools. It is possible that other experts in the area may have identified additional themes as new interpretations of the data may be possible depending on each new frame of reference that is introduced. This is a potential limitation of all qualitative studies. We limited this risk by using established qualitative design and analytic methods,[20] including a large sample of physicians (n=22) to ensure data saturation and utilizing a comprehensive coding and analysis scheme, which involved multiple codings and coders and reconciliation of coding differences. Two coders developed coding templates and a third verified and tested the coding templates and reviewed the final themes and selected quotes. Interim and final results were then evaluated by our research team, all of whom have expertise in this methodology.

Our findings have potential implications for clinical practice, research, and policy change. Different beliefs about the safety of HT may contribute to variability in prescribing practices and counseling strategies. For example, a physician who believes the benefits of HT outweigh the risks is likely to convey a different message to women than a physician who either believes HT is harmful or finds it difficult to counsel women about HT or menopause. These findings are consistent with a pre-WHI study showing that physicians who have positive attitudes toward HT are more likely to prescribe it.[26] Physicians in our study indicated that more sophisticated decision aids and discussion guides are needed, especially because the lay media often publish and present research summaries, anecdotal stories, and recommendations of uncertain quality. Communication with patients might benefit from physician education and preparation of clinical decision aids that include key aspects of research findings that the media seldom portray adequately. Wider circulation of position statements such as that published by the North American Menopause Society[30] may be needed to ensure best practices. Future research should examine the safety and effectiveness of other HT applications and alternative nonmedicinal treatments.

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