The nature of medical evidence and its inherent uncertainty for the clinical consultation: the example of midlife women

Frances Griffiths
Senior Clinical Lecturer
Centre for Primary Health Care Studies
University of Warwick
Coventry
CV4 7AL UK
Tel 02476 573957
Fax 02476 528375
Email f.e.griffiths@warwick.ac.uk

Eileen Green
Professor
Centre for Social and Policy Research
University of Teesside
Middlesbrough
TS1 3BA
Email e.e.green.@tees.ac.uk

Maria Tsouroufli
Research Fellow
Institute for Society, Health and Ethics
University of Cardiff
Cardiff
CF10 3AT
Email: **TSOUROUFLIM@cf.ac.uk**

All authors declare that the answer to the questions on your competing interest form [http://bmj.com/cgi/content/full/317/7154/291/DC1] are all No and therefore have nothing to declare

Abstract

Objectives: to describe how clinicians deal with the uncertainty inherent in medical evidence in clinical consultations

Design: recording and qualitative comparative analysis of clinical consultations related to hormone replacement therapy, bone densitometry and breast screening

Setting: UK National Health Service 6 general practices and 3 secondary care clinics

Participants: All women aged 45-64 attending the clinic/surgery session invited to participate. 109 relevant consultations were recorded.

Results: 45 consultations included sufficient discussion for analysis of how uncertainty inherent in medical evidence was dealt with. The consultations could be categorised into three groups to aid understanding and reflection:

- Focus on certainty 'for now' and 'this test' with slippage into general reassurance
- Weaving a coherent account of the medical evidence for risks and benefits but with blurring of the uncertainty inherent in the evidence and giving an impression of certainty
- Acknowledging the inherent uncertainty of the medical evidence and negotiating a provisional decision

Conclusions: There is a dilemma in applying medical evidence to individual patients. There are dangers of creating a myth of certainty around what is inherently uncertain. Negotiating provisional decisions may avoid this danger. The dilemma needs to be remembered when developing and teaching skills for communicating about medical evidence in consultations.

Introduction

Clinicians have access to a growing body of good clinical research evidence informing them about the effectiveness of many medical interventions. However robust the research there is a dilemma for the clinician when applying this research evidence to individual patients [1]. This is the uncertainty inherent in the nature of medical evidence. For example, epidemiology tells us that smoking is a risk factor for heart attack but does not tell us which individuals will be affected[2]. Randomised controlled trials of hormone replacement therapy (HRT) [3] tell us the number of extra breast cancers identified in a large number of women on HRT compared to those not on HRT but this cannot tell us which individual women will develop the extra cancers. This dilemma between the nature of medical evidence and individual patient care is central to medicine's history and will not disappear as they are essential to each other. Diseases always manifest themselves in the bodies and minds of individual patients and in seeking to understand, treat and predict the outcome of disease, clinicans need to move their focus from the individual to more generalised research[4].

Clinicians recognise this dilemma and have reflected on this in relation to their clinical practice [2] and the need for research methods that give more attention to the 'particular' rather than the general [5]. Its importance is discussed within related disciplines including medical philosophy[6], ethics[7], and health policy[8 9]. However, few studies[10] have examined what clinicans actually say to patients. Studies have considered how clinicians communicate clinical evidence to the patient, taking account of their preferences [11] and maintaining the clinician-patient relationship[12]. Studies acknowledge the difficulty of communicating about risk and benefit of

interventions[13]. However, these studies do not examine the communication in relation to the inherent uncertainty in the evidence. This paper examines how clinicians talk to patients about this uncertainty, and provides a framework for reflecting on how they handle this dilemma of applying clinical evidence to the particular patient.

Method

This paper examines health care consultations with clinicians in both primary and secondary care, doctors, nurses and radiographers, dealing with diagnosis, prevention and symptom relief. The patients were all women at midlife and the consultations were those where there was discussion of one or more of the following interventions: hormone replacement therapy (HRT), bone densitometry and breast screening.

Consultations of women aged 45-64 years were recorded in the UK National Health Service in 6 general practices and 3 specialist clinics. The study included contrasting socio-economic contexts in the Midlands and North East England. This data collection was part of a larger study which included interviews with health professionals and with women, and is reported elsewhere[14 15] .

All women aged 45-64 attending the clinic/surgery session, were invited to participate. All recorded consultations were reviewed for their relevance to the study. Those with no mention of any of the interventions at the focus of the study, were discarded. All other consultations, even with only a passing mention of one of the interventions were retained for transcription and analysis. The clinics/surgeries and relevant consultations recorded are detailed in table 1 and the research process including analysis is detailed in box 1.

There were 109 relevant consultations, 72 from general practice and 37 from specialist clinics. In specialist clinics most women agreed to recording; in general practice the consent rate was lower, in some surgeries as low as 20%. This may have been because women assumed the consultation would not be relevant to the study.

During analysis, a key theme that emerged was uncertainty and how it is discussed between health professionals and women, particularly the uncertainty inherent in medical evidence when it is applied to particular individuals. This paper reports the subsequent analysis of the consultations in relation to this theme.

The data included 64 consultations with only a brief mention of the interventions. For example:

- A woman with symptoms she thinks are due to the menopause, discusses with Practice Nurse: HRT mentioned only briefly
- A woman on Tamoxifen suffers vaginal dryness: HRT mentioned by GP as something the woman cannot have
- In an appointment for a cervical smear, taking the smear was not possible due to vaginal soreness. This was the main topic of discussion with the Practice Nurse: HRT mentioned as something tried in the past with no benefit
- Brief discussion of how the mammography service is organised -in a GP consultation about other issues
- Before a bone scan the Radiographer briefly explains to the woman why she is having the scan

- In a consultation about diabetes, GP checks if woman is happy with her HRT while issuing a repeat prescription

These consultations were not included in subsequent analysis as they contained insufficient data to indicate how uncertainty was dealt with. Through a process of discussion and constant comparison of the data, a categorisation was developed of how the uncertainty was dealt with in the remaining 45 consultations. These 45 consultations had been recorded from 25 different health professionals. Nine health professionals had more than one consultation in this data set and of these three had more than two. The consultation categories were developed as a tool for understanding and reflecting on what is taking place in the consultations. The results of the analysis were presented to three University based focus groups, two of doctors and one of patients, which provided feedback on the validity of the categories form their own experience. Further comparative analysis explored links between how uncertainty was dealt with and the health care issues and context.

Results

Uncertainty and medical evidence

The focus of the analysis was on how uncertainty due to the nature of medical evidence was managed within the consultations. The extract in Box 2 provides an example of this; the doctor knows what should make a difference to bone density based on medical research but he does not know what has made a difference for this particular woman.

Three categories were developed of the approach taken within the consultations to the uncertainty inherent in medical evidence.

Certainty for now

The health professionals talked about certainty for now, or for this test, for example a an ultrasound result at the time of the ultrasound. However they also slipped into general reassurance.

Coherent story of certainty

The health professionals wove a coherent account of the medical evidence for risks and benefits, for example taking HRT for osteoporosis, that included a great deal of detail including estimates of the size of risk. However, the way in which the health professional delivered this detail gave an impression of certainty, even though the health professional may have used words implying uncertainty.

Acknowledging uncertainty

In these consultations the uncertainty of outcome from using an intervention was acknowledged. This included acknowledgement of the inherent uncertainty of the medical evidence when it is applied to the individual. Negotiating a provisional decision was a strategy used to cope with this uncertainty.

Most consultations included elements of each of the three categories. However it was possible to identify a dominant approach to the inherent uncertainty of medical evidence in all but four consultations. The latter involved strict use of a protocol or were administrative. Of the nine health professionals for whom there was more than

one consultation, all except one (a specialist registrar) used more than one approach to epistemological uncertainty. The approaches to uncertainty are described below.

Certainty for now

Health professionals talked of certainty in relation to the results of the test they had performed or were planning. Reassurance was given before test results were available, but with the proviso that the test results were needed to be absolutely sure. For example, in two consultations women told the GPs about changes they had noted in their breasts. The GPs examine and reassure the women that their breasts seem 'normal' and refer the women to the breast clinic for further certainty from the tests they would have (see Box 3 extract 1). A doctor in the breast assessment clinic emphasised the need for certainty by saying 'obviously we need to know for sure' and arranged a biopsy to try and achieve that. He follows this up saying 'often we biopsy things to prove that they're nothing … we get so many surprises, we're sort of duty bound to offer you the .. chance of biopsy' (Consultation032). The type of certainty being talked about is a test result for the here and now – a particular piece of tissue at this time. The mention of 'surprises' indicates uncertainty but only until the certain results of the biopsy.

In Box 3, extract 2 the doctor talks about certainty provided by the ultrasound result for the breast tissue at this time and then goes on to explain to the woman the limited nature of this certainty. However, other consultations in this category did not include such explanation. The health professionals took care to tell the women that the particular tissue examined was 'normal' but followed it up with a reassuring phrase which was rather general, for example 'it's perfectly normal, you're alright' (Consultation031).

Coherent story of certainty

In these consultations the health professional wove together an account or explanation for the woman that was coherent, almost as a story. The intention of the health professionals seemed to be to provide information and explanation so the woman could make her own decisions, although the overall tenor of the consultations was in favour of the intervention. In some of the consultations the health professional provided a great deal of detailed information including numerical estimates of risk and explanation of uncertainty. However, from the way women responded, it seemed that for them this formed an unfocused backdrop for their decisions.

In Box 4, extract 1, both the doctor and the woman seem to struggle with epistemological uncertainty. The doctor actually contradicts himself in the process of trying to provide a coherent account of the risk of osteoporosis. The woman also struggles to understand how the evidence applies to her. At one point the doctor links his explanation to the woman's mother's experience, a reality they both know about. However, most of what the doctor says is drawn from evidence based on populations (much of this detail has been removed from the extract for brevity). The impression this creates is one of certainty about how the evidence applies to this particular woman despite the doctor using words and phrases that includes uncertainty and

probability. The doctor creates a myth about the certainty of the evidence for this woman.

Consultations in general practice tended to be shorter than in specialist clinics, with less detail given of the risk and benefits. Some GPs expressed certainty about the effect of HRT. For example, in discussing HRT a patient says ‘I don’t really want to come off it, if it’s not doing any harm.’ To which the GP replies ‘Not, not any harm at all…..’ (Consultation008). In Box 4 extract 2 a different GP gives quite a lot of information about the risks and benefits of HRT and the different factors to be weighed up for different individuals. However, the tenor of the consultation is of weaving a coherent account that indicates that it is possible for each individual to work out what is best for them with some certainty.

Acknowledging uncertainty

In Box 5 extract 1, the woman is concerned about the new evidence about HRT. The woman has concluded for herself that the risks are small. The doctor backs up the woman’s assessment of the risk being small and also explains the difficulty of applying population evidence to an individual ‘it’s very difficult to know whether if something happens to you whether it’s this or more likely whether it would have happened anyway’ (Consultation072). It then becomes clear that for the woman having energy for her ‘young lad’ is important to her and given priority over the medical risk. A provisional plan is made where by HRT will be used for now but then reviewed. It is through this provisional approach that the woman and doctor have achieved some integration of future risk from the intervention including the uncertainty inherent in the medical evidence, with how things are for the woman in the current time and place.

In another consultation (Box 5 extract 2) there is agreement of a provisional plan for a reduction in the dosage of HRT, a suggestion that came from the woman. This plan integrates the concern about future risk from the HRT with the woman’s experience of symptoms, so linking across the gap between the medical evidence and the woman’s individual experience.

In a consultation with a practice nurse (Box 5 extract 3) the risks of HRT are discussed and the woman describes feeling well. The nurse explaines the risk of breast cancer in a manner similar to that described above, weaving a coherent story of the risks and benefits. The woman introduces the provisional decision making ‘by then I might be okay we'll just have to wait and see’. They agree on continuing the HRT for now, aware of the potential risk and of the good quality of life for the woman.

In another consultation (Consultation005) the doctor tells the woman (who has been on HRT 6 years for symptom relief, has a family history of breast cancer and has annual mammography) that her risk of breast cancer is going up: it is about ‘weighing the two up’, ‘it becomes personal choice’. The woman says ‘Will anybody sort of say “hey” at a certain point? Or will that be up to me?’. The doctor says ‘I think what you’ll find is that there’ll be conversations like this once in a while’, indicating that the decision is a provisional one.

Usage of the different approaches to uncertainty inherent in the nature of medical evidence

Analysis of the consultations by role of the health professional and type of health care setting (table 2) indicates a link between the approach to epistemological uncertainty used and the health care site. 'Certainty for now' was found in the breast assessement clinic. Weaving a 'coherent story of certainty' predominated in the HRT/bone clinic setting. General practice used all three approaches. The pattern of approach used became clearer when explored in relation to the health concern discussed in the consultations (see table 3). In all consultations where there was concern about a breast problem health professionals used the approach of 'certainty for now' with slippage into general reassurance. Where the result of bone densitometry and subsequent management was discussed, which in some consultations included use of HRT, nearly all the consultations used 'a coherent story of certainty'. In the one consultation on this health issue that did not use this approach, further test results were awaited. 'A coherent story of certainty' was also used for consultations where HRT was initiated for other reasons. The above health issues were discussed in specialist clinics and in general practice and by both doctors and nurses.

When reviewing HRT usage or restarting it after a break, 'acknowledging uncertainty' predominated. However, some health professionals wove a 'coherent story of certainty' (see table 3). All the consultations on this health issue were recorded in general practice. There was no apparent pattern linking the category of the consultation and whether the review was initiated by the patient or the health professional.

Discussion

For good communication between health professional and patient, health professionals need strategies for coping with the dilemma of applying medical evidence to individual patients, as it cannot be avoided. These strategies could include using provisional decisions that allow for changing priorities and circumstances over time, avoiding slippage into general reassurance from a particular test result and avoiding the creation of a myth of certainty.

This paper illustrates how health professionals and women have been dealing with the dilemma of uncertainty inherent to medical evidence in relation to medical interventions focused on midlife women. These interventions offer prevention, screening and symptom relief so the results may inform other areas of medicine where the type of evidence base is similar, such as prevention and treatment of chronic disease. Further research may be needed to examine consultations about acute illness. The recorded consultations include examples where the doctor was attempting to communicate risk in ways that are known to be unhelpful to patients[16], particularly when weaving a 'coherent story of certainty'. Training in clinical communication, including how to communicate risk is important. There are many successful models for such training. This research is not suggesting a new model but highlights the importance of including, in existing training models, an awareness of the dilemma involved in applying medical evidence to individual patients and strategies to cope with this.

In the data the health professionals expressed an understanding of the evidence about the risks and benefits of the interventions more or less in line with the prevailing medical consensus at the time. However, during data collection new evidence on the risks of HRT was published [3] so the content of some of the consultations would now be different with less positive accounts of HRT [17] . However, it is the way the accounts of the medical evidence are woven together that produces the impression of certainty rather than the detail.

The data reveal a danger of creating a myth of certainty around what is inherently uncertain through the way the medical evidence is presented and discussed. This seems to be particularly so when there is a test result, such as bone densitometry, or where an intervention such as HRT is being initiated. This way of presenting evidence about a medical intervention reinforces the idea of medicine as a precise science independent of context and persons with the ability to predict outcome, which has become incorporated into lay models of illness [18]. Apparent certainty can be persuasive and can lead to the health professional changing their understanding of the evidence to fit the story they are presenting to the patient. Part of learning to communicate well about risks and benefits of health interventions, and so truly include patients in decision making, may be to fully recognise the uncertainties inherent in our clinical evidence and not to hide this from patients. Health professionals would then stop reinforcing the myth of medicine as a science of certainty and prediction and could work creatively with its uncertainties alongside patients.

In consultations where HRT was being reviewed or restarted, a provisional decision was often agreed. This avoided the danger of further reinforcing the myth of certainty. The women interpreted the medical evidence for their current situation [19] including their physical symptoms, their hopes and fears, their social situation and priorities[14]. They may have been more able to do this at a review appointment as by then they had some personal experience of taking HRT. They may also have sought information themselves about the medical evidence, and through this process developed their ability to assess the evidence[20].

Time is an important dimension in this analysis. The clinicians in the breast clinic struggled to stay with the here and now in their desire to reassure the woman. Consultations at Bone/HRT specialist clinics included mention of review of treatment in three, four or five years. Mention of this length of time added to the impression of certainty rather than implying something provisional. In contrast to the other categories the use of time by making provisional plans was the striking feature of the third category ‘acknowledging the uncertainty’. This fits with the lived reality for women, as their context and experience changes over time, as does their level of risk. The consultations in our third category ‘acknowledging the uncertainty’ may provide useful examples of using time in decisions related to health [1] for use in the teaching of communication skills as they demonstrate how a conditional decision can be reached and be a satisfactory outcome for a consultation.

Reassurance is appropriate where there are high levels of anxiety such as in a breast clinic, however, as demonstrated by the extract 1 in Box 3, it is also possible to be

[1] All data from this study is available for bona fide use via the Economic and Social Data Service Qualidata: http://www.esds.ac.uk/qualidata/ (accessed 07.05.04)

clear about the temporary and tissue specific nature of the test result. Patients may seek certainty from health professionals because they feel vulnerable at that time or because they believe the myth of medical certainty. Health professionals are in a position of influence with patients, so in responding to a desire for certainty, they should critically reflect on the impact this may have on their patient now and in the future, such as building an expectation of certainty of outcome from medical interventions. The assessment of how much to emphasise certainty or not for each individual patient should be explicit in medical communication skills training.

Negotiation between the health professional and woman was present in the consultations where a provisional decision was made. How much it was guided by the woman and how much by the health professional varied, as illustrated in Box 5. Data from the overall study indicates that women vary in their preference for involvement in decision making with health professionals this varies according to their individual circumstances[15]. It is the provisional nature of the decision, rather than the woman's involvement in the decision, that seems to allow the decision to sit comfortably with acknowledging the uncertainty inherent in medical evidence.

General practice in the UK is organised so that it is possible to make provisional decisions with patients and review them. It provides continuity of care for individuals[21] of which this decision-making process is one aspect. In contrast, specialists may see a patient only once or review their treatment at infrequent intervals making it more difficult to negotiate provisional decisions. The challenge for all health professionals is to develop the skills to acknowledge uncertainty and negotiate provisional decisions including when considering test results or initiating a new intervention.

The major types of evidence used in clinical medicine cannot be directly applied to an individual. The dilemma this creates is one that will remain even with further developments in our research methods. Through the teaching of training communication skills and the design of health care systems it is important to enable health professionals to make provisional decisions with individual patients. This approach to decision making has the most potential for a continuing acknowledgement of the inherent uncertainty in medical evidence, an uncertainty which will remain even with the progress in basing medical intervention on robust research evidence.

References

1. Fox RC. Medical Uncertainty Revisited. Bendelow G, Carpenter M, Vautier C, Williams S, Editor. Gender, Health and Healing: The public / private divide. London: Routledge, 2002: 236-53.

2. Willis J. The Paradox of Progress. Oxford: Radcliffe Medical Press, 1995.

3. Writing Group for the Women's Health Initiative Investigators. Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women. JAMA 2002; 288:321-33.

4. Rosenberger NR. The Process of Discourse: Usages of a Japanese Medical Term. Social Science & Medicine 1992; 34(3):237-47.

5. McWhinney IR. An Acquaintance with Particulars... Family Medicine 1989; 21(4):296-8.

6. Gorovitz S, MacIntyre A. Toward a Theory of Medical Fallibility. The Journal of Medicine and Philosophy 1976; 1:51-71.

7. Beresford E. Uncertainty and the shaping of medical decisions. Hastings Centre Report 1991; 21:6-11.

8. Tanenbaum S. What physicians know. The New England Journal of Medicine 1993; 329:1268-71.

9. Tanenbaum S. Evidence and expertise: the challenge of the coutcomes movement to medical professionalism. Academic Medicine 1999; 74:757-63.

10. Tanenbaum SJ. Knowing and Acting in Medical Practice: The Epistemological Politics of Outcomes Research. Journal of Health Politics, Policy and Law 1994; 19:27-44.

11. Haynes RB, Devereaux PJ, Guyatt GH. Physicians' and patients' choices in evidence based practice. British Medical Journal 2002; 324:1350.

12. Summerskill, William SM, Pope C. "I saw the panic rise in her eyes and evidence-based medicine went out of the door." An exploratory qualitative study of the barriers to secondary prevention in the management of coronary heart disease. Family Practice 2002; 19:6:605-8.

13. Lewis D, Robinson J, Wilkinson E. Factors involved in deciding to start preventive treatment: qualitative study of clinicians' and lay people's attitudes. British Medical Journal 2003; 327:841-7.

14. Green E, Thompson D, Griffiths FE. Narratives of Risk: women at midlife, medical "experts" and health technologies. Health Risk and Society 2002; 4:243-86.

15. Griffiths FE, Green EE, Bendelow G, Backett-Milburn K. Innovative Health Technologies at Women's Midlife; Theory and Diversity among women and Experts (L218252038). ESRC, 2003.

16. Edwards A, Elwyn G, Mulley A. Explaining risks; turning numerical data into meaningful pictures. British Medical Journal 2002; 324:827-30.

17. Minelli CAK, Sutton A, Cooper N. Benefits and harms associated with hormone replacement therapy: clinical decision analysis. BMJ 2004; 328.

18. Griffiths F., Green E. A normal biological process? Brittle bones, HRT and the patient-doctor encounter. Williams S.J., Birke L., Bendelow G.A., editors. Debating Biology: Sociological reflections on health medicine and society. London: Routledge, 2003: 210-22.

19. Massé R, Légaré F. The limitations of a negotiation model for perimenopausal women. Sociology of Health and Illness 2001; 23(1):44-64.

20. Bond M, Bywaters P. Working it out for ourselves: women learning about hormone replacement therapy. Women's Studies International Forum 1998; 21(1):65-76.

21. WONCA Europe. The European Definition of General Practice/Family Medicine [Web Page]. 2002; Available at http://www.euract.org/pap041.html. (Accessed 12 July 2004).

Table 1 Health care consultations recorded

Health care site	Health professionals recording consultations	Number of relevant consultations recorded with each type of health professional
General practice	3 GPs 2 practice nurses	6 GP 3 practice nurse
General practice	3 GPs	9 GP
General practice	4 GPs 1 practice nurse	6 GP 2 practice nurse
General practice	3 practice nurses 1 GP	3 GP 3 practice nurse
General practice	4 GPs 1practice nurse	8 practice nurse
General practice	2 GPs 2 practice nurses	13 practice nurse
HRT clinic	1 consultant 1 specialist registrar	2 consultant 3 specialist registrar
Breast clinic	1 associate specialist 1 consultant 2 specialist nurses	2 nurse 4 consultant 2 associate specialist
Bone clinic	2 consultants 1 specialist nurse 1 radiographer	11 radiographer 12 consultant 1 specialist nurse

Table 2 Categories of approaches to uncertainty inherent in the nature of medical evidence by role of the health professional and type of health care setting

Health professional	Focus on certainty 'for now' and 'this test' with slippage into general reassurance	Weaving a coherent account of the medical evidence for risks and benefits but with blurring of the uncertainty inherent in the evidence and an impression of certainty	Acknowledging the uncertainty of outcome from using an intervention including the inherent uncertainty of the medical evidence, and coping with this uncertainty through negotiated a provisional decision.	Not categorised	Total
Breast assessment clinic doctor	4				4
Breast assessment clinic nurse	1				1
HRT/Bone clinic doctor		8	1		9
Radiographer		1		1	2
GP	2	7	8		17
General practice nurse		3	6	3	12
	7	19	15	4	45

Table 3 Categories of approaches to uncertainty inherent in the nature of medical evidence by health issue

Health issue discussed in consultation	Focus on certainty 'for now' and 'this test' with slippage into general reassurance	Weaving a coherent account of the medical evidence for risks and benefits but with blurring of the uncertainty inherent in the evidence and an impression of certainty	Acknowledging the uncertainty of outcome from using an intervention including the inherent uncertainty of the medical evidence, and coping with this uncertainty through negotiated a provisional decision.	Total
Concern about breast lump/positive screening result	7	0	0	7
Bone densitometry result and subsequent management	0	9	1	10
Initiation of HRT	0	4	0	4
Review of HRT usage or restarting after a break	0	5	13	18
Requesting information or referral for screening (mammography/bone densitometry	0	1	1	2
Total				41

The four consultations not categorised are excluded from this table.

Box 1

Research process detail

The study
This paper reports on data collected as part of a study funded by the ESRC Innovative Health Technology Programme which aims to understand the interaction between health technology and society. This project focused on how individual women and health professionals interact with the health technologies.

Recruitment
Recruitment and consent was undertaken by researchers (MT and DT) in each clinic/surgery waiting room over 2-4 days. The health professional started the audio-recorder on receipt of the consent form from the woman.

Analysis
The transcripts were checked for accuracy by the researchers (MT and DT) and then analysed in stages. As part of the wider study, FG and EG initially read 20% of the consultations, identified major themes and discussed them, drawing on their different disciplinary backgrounds (medicine and sociology). The theme at the focus of this paper emerged as a key issue in the interaction of women and health professionals with technological health interventions. Six members of the research team (FG, EG, MT, DT, KMB and GB) then read three different consultations (plus interview transcripts from the wider study) and these were discussed. From this an initial categorisation was developed of how the uncertainty was dealt with in consultations. This categorisation was used for structuring further analysis on this issue. MT and DT read all the consultations, FG read 80% and PL read 20%. The content of the consultations with only a brief mention of the health interventions were summarised. Relevant part(s) of the other consultations were extracted (sometimes this was the whole consultation). The remaining 45 were categorised and the analytical categories were developed and refined through constant comparison of the extracts. All the consultation extracts were then reviewed by FG/PL to check their categorisation. The consultations were finally reviewed to categorise the health concerns discussed in the consultations (AL/FG). Further comparative analysis (AL/FG) explored links between the role of the health professional, the type of health care setting, the health concern discussed, and how uncertainty was dealt with.

Focus groups
The results of the analysis was presented by FG to three focus groups formed from existing groupings at the University of Warwick, one of GP Lecturers, one of GP registrars and one of patients. A limitation of this process was the lack of representation of clinical specialists and nurses. The groups were audio-recorded or detailed notes taken. All three groups recognised the dilemma of uncertainty and with minor refinements, affirmed the validity of the categories of consultations from their own experience. Their feedback was used in developing the discussion section of the paper.

Box 2 The uncertainty of medical evidence

This extract is from a consultation in a Bone/HRT specialist clinic and follows a follow up bone density reading which showed that the woman was was ‘holding her own’ (bone density not decreasing).

W: I'm still on the Didronel, should I continue with it, I, I thought possibly that you might have said come off it now, because I understood that my level was sort of normal for my age now
D: For your age, that's correct
W: Umm, so I wondered possibly if that's why I was coming to see you today, you'd maybe say I had to come off it but if you feel that I should continue with it, I'm quite happy to do that.
D: Umm, as long as there's no problems with it
W: If necessary, I don't have any problems whatsoever
D: Umm, okay. My view would be take a belts and braces approach. By that I mean you've changed your diet, you're doing more exercise, those two things are good for you. Err, taking the Didronel we know now is allowed on a long term basis
W: Yes
D: Err and I am a little uncertain as to which of these three strands, the diet, the exercise or the medication, is making the difference, but something is.
(Consultation054)

(D-Doctor; W-Woman)

Box 3 Focus on certainty ‘for now’ and ‘this test’ with slippage into general reassurance

Extract 1: GP consultation - women has told the GPs about changes in her breast

P: …. I just kept putting it to the back of my mind and then it was just, I thought well its not, it doesn’t feel right you know it was like pulling and I thought hmmm.
D: I'll sort you out a review at the breast clinic and then they'll be able to reassure you fully I'm, I'm sure “ (Consultation094)

Extract 2: in a breast assessment clinic

While doing breast ultrasound:

D: here it is looking very clear that it is an innocent kind of, er, thing. That’s why we don’t need to do any biopsy.

After the ultrasound:

D: the thing is, it doesn’t exclude you to getting something else some other place…. that’s the thing. I can tell about what—what is happening today, and about these ones, which look innocent. (Consultation003).

Box 4 Weaving a coherent account of the medical evidence for risks and benefits but with blurring of the uncertainty inherent in the evidence and an impression of certainty

Extract 1: A Bone/HRT clinic consultation (Consultation001) following bone densitometry

D: …your bone mineral density is following the course you would, we would Expect.
P: Right
D: It is going down, you would expect that at this point in the menopause
P: So it's not abnormal then or anything?
D: It's not abnormal..
(The woman's mother has osteoporosis. The doctor explains:)
D: ..a women with a close female relative has 30% chance of having osteoporosis just 'cos you know they're related…
(He then suggests she considers taking calcium and vitamin D and taking HRT. The woman says 'I've never really been very keen on HRT'. The doctor then examines her and then continues:)
D: With the constant, bone loss starts just round the very beginning that the hormones start to change, what we call the peri-menopause and then you're likely to lose bone well totally predictably to lose bone for about 10 years after the menopause so it will start to gradually come down. At the moment the results are normal, you have normal bone mineral density but err after about 10 years it's going to drop into the below normal range, you can't be certain, but it's predictable, err, and it's obviously what's happened to your Mum….
(There followed further very detailed explanation of the role of HRT, its benefits and risks including numerical expressions of risk with the woman saying very little until the doctor says:)
D: ..effectively the choice is yours.
P: Right
D: Err, it doesn't suit everybody, really the only way to know if it's going to suit you is to try for a time
P: Mmmh, do you really think that I need to be on it then?
D: Err
P: Do you think that if I don't go on it I'm going to end up more with osteoporosis
D: I think you'll continue, you will continue to lose bone, it's quite a difficult decision to take because you're decision now, really you're trying to take a decision now to improve your health when your in your 70s and 80s with osteoporosis
(The doctor continues with further explanation. The consultation ends with the doctor saying:)
D: Anyway the choice is yours
P: All right thank you for your time.

Extract 2: GP consultation with a woman who complains of tiredness.

(The GP enquires about menopausal symptoms and after some discussion the woman asks:)
W: With HRT, can't you only go on that for so long, and then they take you off? Am I wrong?

D: What happens with HRT is…
W: (laughs)
D: …right HRT…whilst you've got your own hormone you don't need HRT, so your bones are being protected by your natural hormone. Um, and HRT you get benefit from for your bones, for your heart point of view, from lots of different points of view. Now the longer you're on HRT from the bones point of view, the better. The problem is the longer you're on it from your breast point of view, people worry about the increase in breast cancer.
W: Mmm.
D: And so what they try…it's a balance of risks. So you take everybody individually. So somebody who has, a, a, wor…a concern about breasts, maybe family history of breast cancer or something like that, you may be a bit more cautious on that side, but if somebody's got a dreadful history of thinning of the bones, and osteoporosis you sort of have to weigh that up, don't you. So you'd say 'oh well perhaps you…' you know. So everybody's individual, you weigh it up individually. The basic thing is that if you're on HRT for, say, ten years, say, there is definitely an increase in risk of breast cancer. At five years, less so. Seven-and-a-half, it…what…up to five years is thought to be fairly safe. So what…that, that's where this business about 'you can only be on it a certain length of time.'
W: Mmm.
D: I've actually got ladies that have been on it fifteen years. And are very very happy with it. I mean they wouldn't stop it because it makes…it keeps them well.
W: Mmm.
D: So you, what you do is you balance up that good you're getting from it, with the downside.
(The consultation continues, returning to consideration of the woman's tiredness. HRT is not prescribed but the woman is asked to think about it as a possibility for the future.) Consultation025

Box 5 Acknowledging the inherent uncertainty of the medical evidence and negotiating a provisional decision

Extract 1: General practice consultation with woman concerned about taking HRT

W: I've been having 'em, HRT patches and in the middle of the year there was a new finding.
D: Right, the scare
W: Right, so when they've finished I thought, I'd try to do without them.
D: Right
W: And I've been considering it and considering it - what I want to know is do you think - what's your opinion on it - when we talked about – when we talked about it earlier we weighed up all the pros and cons,
D: Yes.Yes
W: Is there a history of cancer, is there a history of heart problems - no history of cancer - but a history of heart problems so we decided it offered some a sort of protection to - but it seems to have taken a change - and then when I sort of thought about it later the percentage is quite small really isn't it ..
D: Yes.
W: When we, sort out how many people we're talking about it isn't large so I think that, I think that I'll go ahead with some more. Is that what, is that what you would advise, do you think it isn't - it isn't a big risk
D: No. - It's certainly not a big risk - how long were you been on HRT for
W: Oh not long - less than a year
D: OK, that's important because there's also risks associated with time that you're on HRT, so basically the longer you're on, the risk goes up, particularly if you're looking at breast cancer, but having said that you're absolutely right, the risk is still very small so any risk that there is only affects a very tiny minority of women and of course its very difficult to know whether if something happens to you whether its this or more likely whether it would have happened anyway.
W: And I was thinking of the quality of my life as well - my young lad I really need a bit more energy
D: Well that's important too.(laughing)
(discussion continues, blood pressure is checked – towards the end of the consultation the doctor says:)
D: so I'll just give you some more now - and then what we do .. if you're happy with them you can either come and see one of us or see (practice nurse) in six months for the next lot…… (consultation072)

Extract 2 General practice consultation to review HRT

W: Err my Estraderm patches, I'm getting a new prescription today, now the last time I saw the nurse, she said this would be my last prescription and I wouldn't be able to have any more.
D: Did she mean because..
W: Because of my age or something - and I thought well I'll come and see you, because I did funnily enough try to come off patches myself, and I still got very flushed, so I thought I better just pop in and see you while I'm here anyway.
D: Yes, I mean you're 62 and therefore, sort of ten years beyond a natural menopause but you had a pretty dramatic menopause - you've had your ovaries taken out

W: Oh I've had all sorts
D: I guess, she may have been thinking in terms of osteoporosis prevention, in that ten years would be adequate for that and also as you also will know, a longer term use of HRT is associated with breast cancer, however, if you feel that you'd rather carry on, bearing in mind you know the increased risk of breast cancer.
W: Yes
D: You know the big one, then I don't have any particular problem with this.
W: What about after this six months I mean obviously it's - would it -if I only say tried one a week instead of two how would that -or don't you do that with HRT.
D: Well, or else what you could well, - I'm just looking to see if they come in 25's - if you put one a week on, you'd be fine for the first half of the week and then ...
W: Sure enough.
D: Yes, they come in 25's so one option might be to draw three months of the 25's to see how you get on.
W: Yes, yes
D: You might find that when you decide to stop you have no hot flushes or you know whatever you got when you last decided to stop. But I think she probably just felt that that she would flag it up about breast cancer, (Consultation002).

Extract 3: consultation with Nurse in general practice
The woman and nurse have discussed the increase in breast cancer risk with taking HRT longterm shown by the US study as reported in the media. The woman is feeling very well on HRT.

N: ...but there is still a risk of breast cancer - but there again there is a risk of breast cancer in this age group anyway, but it is increased with long term use of
W: Well when you say long term use of ...
N: Long term - 10 years plus
W: Oh, I'm getting up to that one now aren't I - 8 years isn't it.
N: Yes, that's right - they advise five years, fine, up to ten years is okay and then to re-think about it.
W: Well I mean by then I might be okay we'll just have to wait and see.
N: That's right - blood pressure's fine - but it is something that you've got to be aware of.
W: Oh yes, I realize that - yes. (N) Consultation083
(N – Nurse)

Contributors
Dr Frances Griffiths was principal investigator for the study. Professor Eileen Green was co-applicant on the study funding proposal, managed a study field site and contributed to every stage of the study development, process, analysis and reporting. Dr Gillian Bendelow, Dr Kathryn Backett Milburn were co-applicants on the study funding proposal, contributed to the design of the study, advised on the conduct of the study and contributed to analysis and reporting. Dr Di Thompson and Dr Maria Tsouroufli undertook all the data collection and contributed to analysis and reporting. Dr Pamela Lowe and Dr Antje Lindenmeyer contributed to analysis.

Acknowledgements:
We thank all the health professionals and women participating in the data collection for the research project for their time and interest. We thank the Leicester Warwick Medical School GP Lecturer Group, the University of Warwick Academic GP Registrar Group and the University of Warwick Primary Care Research User Group for their contribution to the study. We thank the reviewers for their very helpful suggestions for improvements to the paper.

Funding
This study was funded by an Economic and Social Research Council project grant Innovative Health Technologies at Women's Midlife; Theory and Diversity among women and Experts (L218252038); part of the Innovative Health Technology Programme (http://www.york.ac.uk/res/iht/ accessed 14.02.04). The funder approved the study design but had no further input to the research process

What this paper adds
Intrinsic to the nature of medical evidence is uncertainty about outcome for an individual patient. This creates a dilemma that will always be present. Communicating evidence to patients is a key part of clinical consultations with a growing evidence base of how it is best achieved.

This study focuses on how the uncertainty inherent in medical evidence is dealt with in consultations. It identifies the danger of creating a myth of certainty around what is inherently uncertain and suggests that negotiating provisional decisions may avoid this danger. The dilemma created when applying medical evidence to an individual needs to be remembered when developing and teaching skills for communicating about medical evidence in consultations.

Information sheet used to obtain informed consent:

INFORMATION FOR RESEARCH PARTICIPANTS

Research Project Title: Innovative Health Technology at Women's Midlife

You are being invited to take part in a research study. Before you decide to participate it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully. If anything is not clear or you would like more information please contact a member of the research team by asking the person handing you this information sheet. Take time to decide whether or not you wish to take part. Thank you for reading this.

Purpose of the Research

As women reach midlife they are offered the use of health technology such as screening for breast cancer using 'breast awareness' advice and mammography (X-ray of breast), checking for a high risk of osteoporosis (brittle bones) using bone densitometry, and the use of hormone replacement therapy (HRT) for the prevention of osteoporosis and cardiovascular disease.

This research project aims to find out from women (aged 45-64) and from health care professionals (doctors and nurses) what they think about these health technologies, how they approach the decision to use them or not, and what they do when facing these decisions. The research aims to include women and health care professionals with a wide variety of life experiences. The research will be used to inform how health technologies are developed and offered in the future. With many new technologies being developed it is important that the views of the people using health technology are included in the debates on their development and use.

Why have you been chosen?

You have been chosen to be invited to take part in this research as you are between the age of 45 and 64 and are attending the general practice surgery/clinic during the week that the research team are present in the practice/clinic. The practice/clinic has agreed to be part of the study and will be contributing their views to the study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You will be given a copy of the signed consent form to keep. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive.

What does the study involve?

The research project involves interviews with women and health care professionals. Some of these individuals will also be asked to record their consultations about HRT, breast screening or osteoporosis, with their doctor/nurse/patient. All the interviews

and consultations will be tape recorded. The recordings will then be typed up by a research secretary. The typed version will omit names and any other identifying factors so the transcript will be anonymous. Only the research team will know who gave which interview or consultation and this information will remain confidential to the research team.

The interviews and consultations will be analysed and a research report written by the research team. The research may be published in professional and academic journals/books to inform others of the research findings and may be discussed and written about more generally. Any quotes taken from the interviews/consultations will be anonymous.

To ensure future researchers do not do unnecessary data collection on similar issues the ESRC maintains an archive of research data. The anonymised transcripts from this research project will be placed in an archive by the ESRC Qualitative Data Archival Resource Centre (Qualidata). Access to the data in the future would be monitored by Qualidata and restricted to bona fide researchers only.

What we are asking from you

The research team is asking you to allow your consultation with the doctor or nurse to be tape recorded. The main reason for you attending the clinic/surgery need not be connected to the topic of the research for the recording of the consultation to be of use for the research project.

We are also asking you to agree to being approached for an interview at a later date. If you are not asked for an interview the tape recording of your consultation will still be valuable data. If you are asked for an interview the researcher will endeavour to find a time and place convenient for you. The interview will last approximately one hour. The interview will be tape-recorded.

Who is organising and funding the research?

This research project is funded by the Economic and Social Research Council of the UK (ESRC) and is being conducted by researchers from the Universities of Teesside, Warwick and Edinburgh.

The Research team:

Project Leader:
Dr. Frances Griffiths, Centre for Primary Health Care Studies, University of Warwick

Project Supervisors:
Professor Eileen Green, Director of the Centre for Social Policy Studies, University of Teesside
Dr Kathryn Backett-Milburn, Senior Research Fellow, Research Unit in Health & Behavioural Change, University of Edinburgh
Dr Gillian Bendelow, Lecturer, Sociology Department, University of Warwick

Researchers: Dr Maria Tsouroufli and Dr Di Thompson

The ESRC is funding the salaries of the researchers. Your doctor or nurse is not receiving any payment for participating in the study.

Who has reviewed the study?

This study has been approved by the Economic and Social Research Council and by the NHS Research Ethics Committee in your locality. (North Tees/South Tees/Warwickshire).

Contact for further information

If you have any questions about this research project please contact the research project office nearest you.

Centre for Primary Health Care Studies
University of Warwick
Coventry
CV4 7AL

Tel: 024 765 72950
Fax: 024 765 28375
e-mail: f.e.griffiths@warwick.ac.uk

Centre for Social & Policy Research
University of Teesside
Middlesborough
TS1 3BA

Tel: 01642 342346
Fax: 01642 342396
e-mail: e.e.green@tees.ac.uk

PLEASE RETAIN THIS INFORMATION SHEET FOR YOUR FUTURE REFERENCE. THANK YOU FOR TAKING TIME TO READ THIS.