Risk Talk
– On Communicating Benefits and Harms in Health Care
Atomreaktorn i Ågesta har börjat läcka. Enligt samtliga statliga utredningar i frågan är det ytterst osannlikt att detta kan ha hänt. Sannolikheten har i ett slag sprungit upp från någon miljarddels promille till inte mindre än 100 procent, vilket får anses som mycket ovanligt. Ett stort antal personer har ådragit sig så oerhört osannolika strålskador att man knappast tror sina ögon. Man får dock se optimistiskt på det hela, framhåller man från experthåll, eftersom de skadade rent statistiskt sett faktiskt är helt friska.

Och en annan blad sak i sammanhanget: när nu detta tydligen trots allt har hänt en gång, så är sannolikheten för att det ska hända en gång till så fruktansvärt fabulöst otroligt liten att de strålskadade knappast alls behöver befara att det hela upprepas. I varje fall inte inom de närmaste dagarna. Denna bedömning gäller dock givetvis enbart en upprepning i Ågesta. Beträffande andra kärnkraftverk är sannolikheten för olyckor av det här slaget oförändrad, dvs. så oerhört liten att man lugnt kan bortse från risken för en olycka av den typ som alltså egentligen inte har inträffat i Ågesta heller, i statistisk mening.

Tage Danielsson
Tankar från Roten
Wahlström & Widstrand 1974

To Yvonne, Fredrik and Katrina with love.

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Mikael Hoffmann, 2005
Printed by LTAB, Linköping, Sweden, 2006.981
ISBN: 91-85497-68-1
ISSN: 0345-0082
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Abstract

One of the most critical elements in empowering the patient, and ensuring concordance, is communication of the possible benefits and harms of different actions in health care. Risk assessment is a complex task due both to the different interpretations of the concept of risk, and the common lack of hard facts.

Hormone therapy (HT) is used by many women in, and after, the menopause. The benefits and possible harms associated with short and long term treatment with HT have been extensively discussed. During the last few years several randomized clinical trials of HT have found that there are no long-term benefits with HT on cognition and cardiovascular diseases, and that the beneficial effect on osteoporosis and colon cancer cannot balance the increased risk of venous thromboembolism, cardiovascular diseases and breast-cancer in long-term treatment. These findings have been widely reported in the media, and have probably influenced the attitudes of the women. During the same period of time the use of HT has decreased dramatically internationally.

The aims of this thesis were to study the interaction between patient and physician when discussing risks and benefits of different treatment alternatives, and to suggest strategies to improve risk communication in clinical practice. The studies have focused on how risks and benefits with HT were communicated between women and physicians during first-time consultations in 1999-2000 on this subject (20 women, 5 gynaecologists), and through questionnaires how attitudes towards HT have changed between 1999 (n=1,760) and 2003 (n=1,733) among women entering the menopause (53-54 years).

Through a qualitative analysis of the risk communication in the consultations a system was constructed to classify how risk is communicated in relation to benefits. This was used to assess and present differences in risk communication in the consultations. Different rhetorical strategies by the physicians were identified and the dominating tendency was a move from the woman’s current problems to the long-term effects of HT.

The questionnaires showed a marked difference in attitudes towards HT between the years. In 2003 women perceived HT to be associated with higher risk and less benefits than in 1999. This correlated to a drastic reduction in the use of HT over the same period. Media was the most frequent source of
information about HT during the last twelve months before the questionnaire in 2003.

Possible explanations for the different attitudes towards HT between women entering the menopause and gynaecologist; how this difference might have influenced the results; and how the results may have implications for future communication strategies are discussed. This thesis illustrates the importance of a deeper understanding in health care of the concept of risk in order to achieve an adequate communication of risk. This is important both in consultations and in campaigns to educate and inform the public.
Populärvetenskaplig sammanfattning (Swedish)

Alla åtgärder i vården medför både nytta och risker för patienten. Att diskutera de möjliga fördelarna och nackdelarna med skilda behandlingar i vården är en av de viktigaste förutsättningarna för patientens möjlighet att fatta beslut om den egna behandlingen. Att värdera risk och nytta är en svår uppgift, inte bara för att underlaget för beslutet ofta är ofullständigt utan även på grund av att begreppet risk kan tolkas på många olika sätt.

Hormonbehandling mot besvär i klimakteriet är en vanlig behandling. Nytta och riskerna med detta vid kort respektive lång tids behandling har diskuterats utförligt i såväl den vetenskapliga litteraturen som i massmedia. Under de senaste åren har resultaten från flera stora kliniska prövningar där hormonbehandling jämförts med placebo presenterats. I dessa studier har man, i motsats till vad man tidigare antagit, inte kunnat påvisa att långvarig hormonbehandling kan förebygga utveckling av demens eller hjärt-kärlsjukdomar. Vidare har man funnit att den positiva effekten mot benskörhet och grovtarmscancer inte kan balansera den ökade risken för komplikationer till följd av blodproppar, hjärt-kärlsjukdomar och bröstcancer vid långtidsbehandling. Dessa fynd har fått stor uppmärksamhet i media och har sannolikt påverkat hur kvinnor ser på hormonbehandling i klimakteriet.

Syftet med denna avhandling var att studera hur patienter och läkare diskuterar risk och nytta med olika behandlingsalternativ. Studierna I-III handlar om hur risk och nytta med hormonbehandling mot besvär i klimakteriet diskuteras mellan kvinnor och läkare i första-gängsbesök kring detta (20 kvinnor, 5 läkare). I studie IV redovisas två enkätundersökningar kring hur uppfattningar om hormonbehandling skiljer sig åt mellan åren 1999 (1 760 kvinnor) och 2003 (1 733 kvinnor) hos kvinnor som närmar sig eller är i klimakteriet (53-54 år).

Risk kan diskuteras isolerat eller i direkt samband med nytta av behandlingen; respektive för ett eller flera skilda behandlingsalternativ samtidigt. En analys av samtalen mellan kvinnor och läkare visade att risk diskuteras på flera olika sätt. Detta kunde användas för att klassificera samtalen. Vid samtal om hormonbehandling använde läkarna flera olika strategier för att beskriva
denna behandling. Den dominerande tendensen i samtalen var att gå från kvinnans nuvarande problem till att diskutera effekterna på lång sikt av hormonbehandling mot besvär i klimakteriet.


I avhandlingen diskuteras möjliga förklaringar för de skilda uppfattningarna om hormonebehandling mellan kvinnor som närmar sig eller är i klimakteriet å ena sidan och gynekologer å andra sidan; hur denna skillnad kan ha påverkat resultaten från undersökningarna; och hur detta kan ha betydelse för framtida strategier för att diskutera olika behandlingsalternativ i vården. Denna avhandling illustrerar betydelsen av en djupare förståelse av begreppet risk för att kunna åstadkomma en god dialog kring risk och nytta med skilda behandlingsalternativ. Detta är betydelsefullt både i möten mellan patient och vårdpersonal och i samband med kampanjer för att informera och utbilda allmänheten.
Papers in the present thesis

I
Mikael Hoffmann, Lotta Lindh-Åstrand, Johan Ahlner, Mats Hammar, Karin I Kjellgren.
Hormone replacement therapy in the menopause - structure and content of risk talk.
Maturitas 2005;50:8–18.

II
Mikael Hoffmann, Mats Hammar, Karin I Kjellgren, Lotta Lindh-Åstrand, Johan Ahlner.
Risk communication in consultations about hormone therapy – concordance in risk assessment and framing due to the context
Submitted to Climacteric.

III
Mikael Hoffmann, Per Linell, Lotta Lindh-Åstrand, Karin I Kjellgren.
Risk talk: rhetorical strategies in consultations on hormone replacement therapy.

IV
Mikael Hoffmann, Mats Hammar, Karin I Kjellgren, Lotta Lindh-Åstrand, Jan Brynhildsen.
Changes in women’s attitudes towards and use of hormone therapy after HERS and WHI.
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARR</td>
<td>absolute risk reduction</td>
</tr>
<tr>
<td>ATC</td>
<td>anatomical therapeutic chemical classification</td>
</tr>
<tr>
<td>BRFSS</td>
<td>behavioral risk factor surveillance system (see CDC)</td>
</tr>
<tr>
<td>CCEPT</td>
<td>combined continuous estrogen (oestrogen) and progestogen (progestagen) therapy</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
</tr>
<tr>
<td>CONSORT</td>
<td>consolidated standards for reporting trials</td>
</tr>
<tr>
<td>CSEPT</td>
<td>combined sequential estrogen (oestrogen) and progestogen (progestagen) therapy</td>
</tr>
<tr>
<td>CVD</td>
<td>cardiovascular disease</td>
</tr>
<tr>
<td>DDD</td>
<td>defined daily dose</td>
</tr>
<tr>
<td>EPT</td>
<td>estrogen (oestrogen) and progestogen (progestagen) therapy</td>
</tr>
<tr>
<td>ET</td>
<td>estrogen (oestrogen) therapy</td>
</tr>
<tr>
<td>FDA</td>
<td>US Food and Drug Administration</td>
</tr>
<tr>
<td>HERS</td>
<td>heart and estrogen/progestin replacement study</td>
</tr>
<tr>
<td>HRT</td>
<td>hormone replacement therapy</td>
</tr>
<tr>
<td>HT</td>
<td>hormone treatment</td>
</tr>
<tr>
<td>MeSH</td>
<td>medical subject heading</td>
</tr>
<tr>
<td>MHT</td>
<td>menopausal hormone treatment</td>
</tr>
<tr>
<td>NNH</td>
<td>numbers needed to harm</td>
</tr>
<tr>
<td>NNT</td>
<td>numbers needed to treat</td>
</tr>
<tr>
<td>OPTION</td>
<td>observing patient involvement in decision making (scale)</td>
</tr>
<tr>
<td>PDD</td>
<td>prescribed daily dose</td>
</tr>
<tr>
<td>PIL</td>
<td>patient information leaflet</td>
</tr>
<tr>
<td>RCT</td>
<td>randomized clinical trial</td>
</tr>
<tr>
<td>RRR</td>
<td>relative risk reduction</td>
</tr>
<tr>
<td>SARF</td>
<td>social amplification of risk framework (model)</td>
</tr>
<tr>
<td>VAS</td>
<td>visual analogue scale</td>
</tr>
<tr>
<td>WHI</td>
<td>women’s health initiative study</td>
</tr>
<tr>
<td>QoL</td>
<td>quality of life</td>
</tr>
</tbody>
</table>
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5. Socio-demographic characteristics of the women
6. Rhetorical strategies used by the physicians in the consultations
7. Reported sources of information during the last twelve months
8. Number of reported sources per category HT-user

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6. Characteristics of two main factors used to describe different types of risks
7. Printout from Visual Rx
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9. Use of symptom relieving therapy in relation to HT use and menopausal status
10. Classification of risk according to the context
11. Benefits and risks with HT as reported in 1999 and 2003
Introduction

Risk is a daunting concept. Every person can claim to be an expert of estimating and valuing different risks in daily life. Every situation leading to a decision - whether it results in an action or not, and whether or not the need for a decision is acknowledged - ultimately leads to an outcome. The outcome can either be positive or negative, i.e., leading to a benefit or a cost - a gain or a loss. The chance of gaining a benefit has to be weighed against the possible losses incurred by the decision or action. Risk describes the possible losses either by focusing on the possibility of one or several negative outcomes, or by focusing on the possible consequences, or by taking both aspects into consideration in a compound estimation. Beck defines risk as a *systematic way of dealing with hazards and insecurities induced and introduced by modernization itself* and characterizes our society as a *risk society* where risks are deliberately introduced in the society as a consequence of our technological progress.

In all decisions in health care, whether or not they are made by the patient and/or the health care professional, the opinion about risks and benefits associated with different treatment alternatives are pivotal. One of the great challenges in the consultation for the health care professional, most often a physician, is to understand the patient’s attitudes and preferences and communicate risk assessments accordingly. The estimations of risks and benefits with a certain treatment might differ substantially between patients and physicians.

This thesis describes the underlying theories and constructs of why patient participation in health care matters, and how risks (and benefits) can be understood and communicated. The thesis focuses on one particular situation, hormone treatment of women in the menopausal transition and/or the climacteric period, HT.

The reasons for choosing HT as an example were several. First of all, this is an area with well-informed parties receiving information from several different sources, thus constituting the basis for a risk discussion which otherwise often is absent, even in long-term therapy such as treatment of hypertension. Secondly, women in the climacteric period are in general healthy women with a high degree of autonomy, thus making it easier to handle ethical considerations about studying interactions with health care.
This thesis consists of the following parts.
1. Background with description of key concepts in patient participation in health care, risk communication, and hormone treatment in the menopausal transition.
2. Aims.
4. Results from the four included studies.
5. A discussion of the results, and the validity and reliability of the findings.
6. Conclusions.
7. General reflections about the situations studied and the methods used, and a short discussion about possible future research within the area.
Background

Patient participation in health care

The relationship between patients and health care professionals is changing into a more active partnership involving the close social network, like family members, when appropriate. The change from a paternalistic view of the patient towards regarding the patient as an active and cooperative consumer of health-care is not only a consequence of ethical considerations but also a legal prerequisite in many countries. According to the Swedish National Board of Health and Welfare the care of patients should emphasize concordance, and the patient should receive individualized information about his state of health and opportunities for treatment.

It has been shown that patients want to be informed of treatment alternatives, and be involved in treatment decisions when there is more than one treatment alternative. Thus, a patient-centred approach is increasingly regarded as crucial for care of a high quality. Patient-centred care has been described in many ways – understanding the patient as a unique human being; a style of consulting where the physician uses the patient’s knowledge and experience to guide the interaction, and where the physician tries to enter the patient’s world, to see the illness through the patient’s eyes. Five key dimensions of patient-centredness have been described:

- A biopsychosocial perspective, including also the illnesses presented that cannot adequately be assigned to conventional disease taxonomies.
- The patient-as-person, or understanding the personal meaning of the illness for the patient.
- Sharing power and responsibility, promoting the ideal of an egalitarian patient-professional relationship.
- The therapeutic alliance, acknowledging the importance of aspects of the patient-professional relationship.
- The physician-as-person, where the physician cannot be seen as an exchangeable person only applying diagnostic and therapeutic techniques, and acknowledging that the physician and the patient are influencing each other.

A clear correlation has not been established between patient-centredness in the consultation and patients’ post-consultation satisfaction and enablement, possibly due to methodological shortcomings.
Informed consent and shared decision making are sometimes used interchangeably but the relationship between them can be described as in Figure 1. The relationship between informed consent and shared decision making, in relation to level of risk and number of treatment alternatives are shown in Figure 2. A framework for teaching and learning informed and shared decision making has been developed.

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**Figure 1. Models of decision making about treatment.** Charles C, Whelan T, Gafni A. What do we mean by partnership in making decisions about treatment? BMJ 1999;319(7212):780-2. Reproduced with permission.

<table>
<thead>
<tr>
<th>Analytical stages</th>
<th>Paternalistic model</th>
<th>Intermediate approaches</th>
<th>Shared model</th>
<th>Intermediate approaches</th>
<th>Informed model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flow</td>
<td>One way (largely)</td>
<td>Two way</td>
<td>One way (largely)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Direction</td>
<td>Doctor ↓ patient</td>
<td>Doctor ↓↑ patient</td>
<td>Doctor ↓ patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type</td>
<td>Medical</td>
<td>Medical and personal</td>
<td>Medical</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minimum amount</td>
<td>Legal requirement</td>
<td>Anything relevant for decision making</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deliberation</td>
<td>Doctor alone or with other doctors</td>
<td>Doctor and patient (plus potential others)</td>
<td>Patient (plus potential others)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Who decides what treatment to implement?</td>
<td>Doctors</td>
<td>Doctor and patient</td>
<td>Patient</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Informed consent and shared decision making are sometimes used interchangeably but the relationship between them can be described as in Figure 1. The relationship between informed consent and shared decision making, in relation to level of risk and number of treatment alternatives are shown in Figure 2. A framework for teaching and learning informed and shared decision making has been developed.
The concept of shared decision making has developed in close connection with concepts such as patient empowerment and patient-centred care. Shared decision making describes a situation where both partners contribute to decisions about the health care\textsuperscript{14, 17}. The concept can be interpreted in different ways depending on

- the role of the patient and the health care professional – whether they contribute equally or not,
• the sequence in which they interact – for instance who is the first to propose a certain action and thus is in a position of decisional priority, and
• what they share during the interaction – information about risks and benefits only and/or attitudes.
The term informed consent has a background in legal doctrines and ethical considerations.
• Legal – a formal process that care-givers are required to adhere to before permitting certain procedures and aimed at reducing the health care professional’s liability.
• Ethical - an individual’s autonomous authorization of a medical decision or intervention.

A strict interpretation of informed consent is that the transfer of information is the key responsibility and the only contribution by the physician to the decision making while deliberation and decision making are the sole prerogatives of the patient. Or in other words, the patient has full control over the decision making while the health care professional, most often a physician, has the role of an informer and interpreter.

Instruments for assessing patient involvement
Several different instruments for assessing patient involvement in treatment and management decisions have been developed. A systematic review in 2001, focusing on instruments assessing patient involvement by direct or indirect observation of the consultation found eight instruments. The instruments found were designed neither to measure the broader concept patient-centredness, nor to specifically measure the concept of patient involvement. One of the most cited instruments, elements of informed decision making by Braddock et al was described as although it requires validation, (it) has the benefit of having a firm theoretical stance and mirrors sequences that professionals suggest are needed in order to involve patients in decision-making.

A specific scale for measuring patient involvement – the OPTION scale (observing patient involvement in decision making) – has been developed and validated after this review. Table 1 shows the relation between the factors assessed in elements of informed decision making and in the OPTION scale.
### The OPTION scale for measuring patient involvement

<table>
<thead>
<tr>
<th>Element of Informed Decision Making</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>The clinician identifies a problem(s) needing a decision making process</td>
<td>Discussion of the clinical issue or nature of the decision</td>
</tr>
<tr>
<td>The clinician states that there is more than one way to deal with an identified problem (“equipoise”)</td>
<td>Discussion of the alternatives</td>
</tr>
<tr>
<td>The clinician lists “options” including the choice of “no action” if feasible</td>
<td></td>
</tr>
<tr>
<td>The clinician explains the pros and cons of options to the patient (taking “no action” is an option)</td>
<td>Discussion of the pros (potential benefits) and cons (risks) of the alternatives</td>
</tr>
<tr>
<td>The clinician checks the patient’s preferred information format (words/numbers/visual display)</td>
<td>Discussion of uncertainties associated with the decision</td>
</tr>
<tr>
<td>The clinician explores the patient’s expectations (or ideas) about how the problem(s) are to be managed</td>
<td>Exploration of patient preference</td>
</tr>
<tr>
<td>The clinician explores the patient’s concerns (fears) about how problem(s) are to be managed</td>
<td></td>
</tr>
<tr>
<td>The clinician checks that the patient has understood the information</td>
<td>Assessment of the patient’s understanding</td>
</tr>
<tr>
<td>The clinician provides opportunities for the patient to ask questions</td>
<td></td>
</tr>
<tr>
<td>The clinician asks for the patient’s preferred level of involvement in decision making</td>
<td>Discussion of the patient’s role in decision making</td>
</tr>
<tr>
<td>An opportunity for deferring a decision is provided</td>
<td></td>
</tr>
<tr>
<td>Arrangements are made to review the decision (or the deferment)</td>
<td></td>
</tr>
</tbody>
</table>

Another way of measuring patient involvement instead of observing the consultation would be to ask the patients. Several instruments have been developed in order to evaluate the patients’ satisfaction with the consultation, and to assess the effectiveness of risk communication and treatment decision making in consultations.²⁵
Risk

The concept of risk takes on qualitatively different meanings within epidemiology, clinical medicine and lay-persons’ experiences of health and illnesses. For the epidemiologist with a societal perspective, risk is an objective, quantifiable, scientific concept. For a patient it is more of a qualitative description of a future state of health. The physicians’ task is to try to reconcile the perspectives: quantitative vs. qualitative and societal vs. individual.

Risk factor vs. disease

The identification of risk factors for specific diseases, often as targets for treatment to prevent future diseases or complications, has expanded rapidly. This has been especially pronounced for cardiovascular diseases. Treatment of hypertension and/or elevated blood lipids have become some of the most frequent prescribed pharmaceutical interventions in modern health care. By defining, searching for, and informing the patient about the existence of a certain risk factor for disease the physician might influence the patients’ conceptions of health, or as Gifford describes it: Being at risk can be seen as a state somewhere between health and illness.

Applying the 2003 European guidelines on cardiovascular disease prevention to a Norwegian population would give a point prevalence of individuals with serum cholesterol and/or blood pressure levels above the recommended cut-off points of 50 % by the age of 24 years, and 90 % by 49 years. According to the guidelines three out of four of the adults (20-79 years) in one of the healthiest populations in the world would be candidates for at least life-style advice and medical follow-up because of their serum cholesterol and/or blood pressure. This raises not only practical and economical issues, but also the

"Erst wägen, dann wagen!"

Count Helmuth von Moltke

Løvborg: Og dette her handler om fremtiden.
Tesman: Om fremtiden! Men, Herregud, den véd vi jo slet ingen ting om!
Løvborg: Nej. Men der er et og andet at sige om den alligevel.

From the play Hedda Gabler by Henrik Ibsen
ethical dilemmas of informing a majority of the population that they have an increased risk for cardiovascular disease.

**Risk as a probability**

Risk is most often defined as the possibility of a loss or an injury. It can also be defined as the potential for realization of unwanted, negative, consequences of an event. Often risk is seen as the inverse of safety. An alternative, and more conservative interpretation of safe is to see it as a level of risk judged to be insignificant. Probability is a description either of the expected frequency of random outcome, or the degree of reliability of an estimation, in a situation without enough information to be certain. Another way of discussing this is the way chance has been defined:

- judgements of a priori probability – *the chance of throwing double-six with a pair of true dice is one in 36*;
- estimates of actual frequency - or to forecast the future from experiences in the past such as *there is a slightly better than even chance that any given unborn infant will be a boy*; and
- judgements of credibility - such as to state that *there is a fair chance that I will not become a member of the parliament* which is essentially a person’s degree of belief or subjective probability that something will occur.

In clinical decisions in health care the majority of probability estimates will be projections based on earlier experience. Exactly the same situation will however never be repeated a large number of times, so even objective probabilities are in one way always depending on someone’s subjective probability estimate. Decision-making in the clinical setting will, even when there is ample objective probability estimates from clinical trials and/or epidemiological surveys, typically rely on subjective probability estimates by the clinician who has to adapt to his patient’s unique situation. The major problem lies in small probabilities. Most people, even trained experts, run into trouble when the probability for a given event is very low, such as $<10^{-4}$. The absolute difference between $10^{-3}$ and $10^{-6}$ is for instance very small but the relative difference is the same as between $10^{-2}$ and $10^{-3}$. In such situations people may find discrepancies between their perception and the mathematical model. The very small absolute difference between zero and a very small probability can on the other hand be perceived as a very important difference between *absolute safety* and the possibility that an adverse event may take place at all.
Uncertainty in risk estimation
Risk and uncertainty are often used as synonyms since both concepts are results of lack of information about the future. An early distinction between the two states that risks are future outcomes to which it is possible to attach probabilities, whereas uncertainty is a situation where the individual cannot attach probabilities to the future. Uncertainty is closely linked to the concept of risk. Without uncertainty the gains and losses would be known beforehand and the concept of risk as we know it would not be applicable to the situation.

Uncertainty is however not restricted to discussions of probability. There are other kinds of uncertainty such as the uncertainty associated with dependency on others, especially other experts, on demarcation of the problem discussed and in defining the set of values used in assessing the situation.

Risk as a function of probability and consequence
The term risk is often used as a synonym for the probability of an adverse event in encyclopaedias and in daily conversation. The consequence, or the magnitude of the consequence, is however also an important dimension of risk and has to be taken into consideration. In 1983 Britain’s Royal Society made a detailed report on risk where it was stated that the Study Group viewed risk as the probability that a particular adverse event occurs during a stated period of time, or results from a particular challenge.

The report did also discuss the compound measurement of risk described as a numerical measure of the expected harm or loss associated with an adverse event … it is generally the integrated product of risk and harm including both probability and the unwanted consequence (harm). According to this, risk can be described as a function of probability of an adverse event and the magnitude of the consequences of the event.

Risk = F (probability, consequence)

As a consequence in any measurement of or mathematical expression of risk one has to:

• have knowledge about the structure of this function, not only in the specific situation, but also among all involved parties,
• be able to estimate probabilities,
• describe the consequences,
• value the consequences, and finally
• put this into the social and cultural context of all interest groups.
A variant is to describe the function as:

\[
\text{Risk} = \text{Detriment} = \text{probability} \times F(\text{consequence})
\]

This way of describing risk as the product of probability and the weighted magnitude of consequence is called detriment. Detriment is sometimes used in the scientific literature as a more unambiguous term. 42

**Objective vs. perceived risk**

One frequent problem with risk estimation is the often quite different estimates made by experts and lay persons. 43, 44 This has been attributed to the different weighting of probability versus magnitude of consequences. The experts are thought to adhere more strictly to a more “scientific” interpretation (at least within their field of expertise) by using detriment, while lay persons are thought to pay more attention to the consequences, especially in situations with low probabilities and dire consequences. The report from the Royal Society in 1983 explicitly distinguished between objective and perceived risk. Objective risk would be what experts would say about a given situation, often in the form of a function of probability and magnitude of adverse effect, while perceived risk would be the lay person’s anticipation of future events. A similar conclusion was the result of a report from the National Research Council in U.S.A. stressing the distinction between the scientific basis and the policy basis of decisions about risks.

In 1992 a new report from the Royal Society acknowledged that risk is culturally constructed and stated that *the view that a separation can be maintained between objective risk and subjective or perceived risk has come under increasing attack, to the extent that it is no longer a mainstream position*. The classical conflict in risk estimation between lay persons and experts could be described as a conflict between the individual’s and the society’s perspective. This difference might also explain the observed discrepancy between medical decisions made by physicians for individual patients and for groups. 47, 48 To teach physicians to make better judgments about probabilities may however not alter their decisions. 49 Another difference between the individual and the societal perspective is the risk target bias. People tend to rate the risk for themselves, to their family, and to the people in general differently. In general, the personal risk is considered lower than the risk to the general population. 50, 51 Ballard showed that even though women tend to associate the menopause with an increased risk of disease, they do not generally consider themselves to be at personal risk, and therefore do not take HT primarily for prevention. 52
Are there any rational explanations why the individual risk estimates differ? It’s first of all important to realise that it is hard to separate risk assessment from risk aversion. It is rational to have a risk aversion strategy based on something else than detriment for every-day decisions since information about probabilities and consequences very often is not readily accessible. Decision making and risk aversion would become much simpler and quicker if for instance one would immediately avoid alternatives where one possible consequence, even with a very low probability, would be unacceptable in the light of possible gains; or avoid all alternatives where the probability of an unwanted consequence is very high, no matter the consequences. Based on different factors such as the amount of knowledge and the risk propensity or personality, either, or a combination of both strategies, might be chosen.

**Risk assessment and communication**
Assessing the risk or risks in a given situation consists of more than just estimating probabilities and valuing the consequences. It is also a question of evaluating whether or not the risk is acceptable, see Figure 3 for an overview of risk assessment terminology according to Rowe.

![Figure 3. A hierarchy of risk assessment terminology. Rowe, WD. An anatomy of risk. John Wiley & Sons 1977, page 45. Redrawn and reproduced with permission.](image-url)
**Risk determination**

Risk determination consists of risk identification and risk estimation. While risk identification can be described as reducing descriptive uncertainty, risk estimation might be thought of as the identification of consequences of a decision and the subsequent estimation of the probability for and magnitude of consequences of adverse events.

When estimating risk the identified risks can be divided into three basic categories depending on the level and type of uncertainty:

1. Risks for which statistics of identified casualties are available.
2. Risks for which there may be some evidence, but where the connection between suspected cause and injury to any one individual cannot be traced (for instance cancer long after exposure to radiation or a chemical).
3. Experts’ best estimates of probabilities of events that have not yet happened.

**Risk evaluation**

Risk evaluation incorporates both risk acceptance and risk aversion. Risk acceptance follows either from a process where the possible gain or benefit of a certain action is balanced against the risk; or from a situation where there is no or few alternatives for action leading to resignation. The net result is an acceptance level for risks, and thus the ground for the term acceptable risk. If a risk is deemed higher than the acceptable risk, this will lead to an action to reduce the risk.

Since risk evaluation is done in a specific context where the different alternatives for action are associated not only with risks, but also with benefits, it is obvious that the perceived net benefits of a certain action will be a stronger deciding factor than the risk itself. Since it probably is very difficult for one specific individual to evaluate the risk of a certain action without being influenced by the net benefits of that action, the evaluated risk might be biased by framing.

Every individual is subjected to various risks throughout their daily life. In order to make quick and effective decisions involving risks, several simple algorithms and strategies are developed. These are a result of the individual’s propensity of risk-taking and the socio-cultural context in which he or she has grown up.

According to Adams the response to risk - risk compensation - can be described through a conceptual model, the so called *risk thermostat*, Figure 4. In this model:

- Everyone has a propensity to take risks.
• The propensity to take risks varies from one individual to another.
• The propensity to take risks is influenced by the potential rewards of risk-taking.
• Perceptions of risk are influenced by experience of accident losses – one’s own and others’.
• Individual risk-taking decisions represent a balancing act in which perceptions of risk are weighed against the propensity to take risks.
• Accident losses are, by definition, a consequence of risk-taking; the more risks an individual takes, the greater, on average, will be both the rewards and losses he or she incurs.

Risk assessment doesn’t occur in a social vacuum according to the model. This is also true for risk communication. Publicly available information about hazards is subjected to normal social influences. Current examples are the debates over bovine spongiform encephalitis, food containing genetically modified organisms, and the health hazards associated first with traditional
non-steroid anti-inflammatory drugs and then with rofecoxib (Vioxx) and other related drugs. The SARF model (social amplification of risk framework) has been developed in order to provide a systematic approach to analyse how psychological, social, institutional, and cultural processes interact with risk perception and communication\textsuperscript{59,60}, Figure 5.

Redrawn and reproduced with permission

In the SARF model a risk event becomes known either through direct experience, or by communication via different types of formal or informal information providers. These sources create a risk representation by enhancing, filtering, and reconfiguring the information. This representation will be further refined, re-interpreted, and elaborated. This will take place both at the individ-
dual level (through psychological filters), as well as the societal level (through societal filters). These processes interact and stimulate responses both among individuals and in the society. These responses in turn influence the filters. They may also lead to secondary impacts, or ripple effects, throughout the society that change the way risks are represented, but may also lead to changes in the society leading to a modified frequency or nature of the risk event.

**Gender perspective**

The possibility of a gender difference in risk assessment is widely acknowledged, but there are few research reports focusing on this question, especially in health care.

In psychometric studies, a number of different risks have been investigated, mainly through questionnaires. In these studies a consistent pattern emerges in the western world. Men tend to express less concern for the risks studied than women, while their ranking of risks differs very little. In North America Flynn et al showed that the gender difference was very clear in the studied Caucasian group, but non-significant among non-Caucasians. The conclusion from this study was that gender (and ethnic) differences in risk perception may depend on socio-political factors such as power, status, alienation, and trust. Women also seem to perceive most food hazards, especially technological hazards such as genetic modification, as posing a greater risk than men perceive them to be.

Studies using open-ended questions, and especially qualitative studies, have shown other types of gender differences. Women mentioned environmental risks and risks threatening their home and family, whereas men were more concerned about health and safety risks, and risks relating to their working life.

**Risk perception – heuristics and biases**

People’s choices are assumed to be rational and to satisfy some elementary requirements of consistency and coherence. However, sometimes basic psychological principles can lead to systematic violation of what seems to be rational. Heuristics is a term that stems from the Greek word *heuriskein*, meaning to find out, to discover. Within a psychological context heuristics can be interpreted as simple or more complex rules of thumb simplifying the everyday decision-making process. The term is also used within computer technology where it implies use of intuition instead of formal techniques, and stands for the opposite of a precisely defined and structured algorithmic approach.

There are several cognitive processes that lead to systematic biases in how the
risk is perceived. A landmark summary of heuristics and biases is a review by Tversky and Kahneman69 followed some years later by an article of framing55. According to Tversky and Kahneman the most important biases are problems with representativeness, with availability, and with adjustment and anchoring.

The representativeness heuristic can lead to the estimated probability being influenced by the degree by which A is representative of, or resembles B. This can lead to several problems such as insensitivity to prior probability of outcomes and to sample size; misconceptions of chance (i.e. that people expect that even a short random sequence of events will represent the essential characteristics of that process); insensitivity to predictability; illusion of validity; and misconceptions of regression to the mean.

Assessment of the frequency of a class or probability of an event by the ease with which instances or occurrences can be brought to mind, is called availability heuristic. These can be further divided into biases due to the retrievability of instances, and to the effectiveness of a search set; biases of imaginability and illusory correlations (i.e. that likely occurrences are recalled better). Different starting points will yield different estimates biased towards the initial values. Common problems are insufficient adjustment from an initial estimate; overestimating the probability of conjunctive events; and expressing more certainty in the estimation than is justified.

The decision-maker’s conception of the acts, outcomes and contingencies associated with a particular choice can be called the decision frame and is controlled by the problem definition, but also by the norms and personal characteristics of the decision-maker. By framing a given decision problem in different ways, different - and sometimes opposing - answers can be elicited even in questions pertaining to the loss of human lives55,70. This is shown in the following result from a questionnaire to students at the university level:

Problem 1 (n=155)
Imagine that the U.S. is preparing for the outbreak of an unusual Asian disease, which is expected to kill 600 people. Two alternative programs to combat the disease have been proposed. Assume that the exact scientific estimate of the consequences of the programs are as follows:

If program A is adopted, 200 people will be saved.
If program B is adopted, there is $\frac{1}{3}$ probability that 600 people will be saved, and $\frac{2}{3}$ probability that no people will be saved.
Which of the two programs would you favour?
Problem 2 (n=155)
If program A is adopted 400 people will die.
If program B is adopted, there is 1/3 probability that nobody will die, and 2/3 probability that 600 people will die.
Which of the two programs would you favour?
A 22%  B 78%

All decision-makers are affected by framing. Some types of action may however affect separate categories of decision-makers differently. A variant of this effect of framing shown to be valid for the judgment of physicians is the char-grin factor, or the reluctance to accept action alternatives where the action itself may lead to a negative outcome for the patient. When faced with two alternative actions where one may harm the patient through the action and the other through inaction, most physicians prefers the latter in accordance with the principle of doing no harm, *primum est non nocere*. A variant of this desire not to harm is the appeal to zero risk, i.e. that the elimination of a risk is more attractive than a reduction, even if the reduction is of the same magnitude as the elimination. Closely related to this is our inherent incapability to distinguish between very small risks.

**Different dimensions of risk**
The psychometric paradigm uses psychophysical scaling and multivariate analysis to develop a taxonomy for hazards that can be used to understand risks. Through these techniques quantitative representations or *cognitive maps* of risk attitudes and perceptions are constructed. The work is based on Starr’s studies of the question: *How safe is safe enough?* His approach assumed that society, through trial and error, had arrived at a more or less optimal balance between risks and benefits associated with any activity. Even though Starr’s conclusions have been questioned, further studies of expressed preferences have shown that perceived risk is quantifiable and predictable and that the concept of risk means different things to different people. In several studies with lay persons and experts judging diverse sets of hazards, factor analysis has condensed a number of characteristics into two main factors:

- dread risk with perceived lack of control, dread, catastrophic potential, fatal consequences and inequitable distribution of risks and benefits, and
- unknown risk with unobservable, unknown, new hazards with often delayed manifestation of harm.
While nuclear weapons and nuclear power scores high on dread risk, chemical technologies scores high on unknown risk. Oral contraceptives, diazepam, aspirin, antibiotics, vaccines and X-rays all show up in the upper left (low dread risk - high unknown risk) quadrant, Figure 6.

Lay person’s risk perception is influenced strongest by the dread risk. Experts’ perception of risk is not closely correlated with these factors but seems to be associated with expected annual mortality. The explanatory power of the model has been questioned, and additional relevant factors such as unnatural risk and immoral risk have been found to be valid in certain settings.

Language
Risk, or more often the probability that a hazard will lead to harm, is often presented as a verbal estimate. However, studies (mostly performed in English) have shown that words and/or phrases could be open to a high degree of variability in interpretation. There are differences between groups, but also within well-defined groups of professionals such as in consultations between physicians. There might even be an increased variability when the probability expressions are presented in a context instead as an isolated expression. Beyth-Marom showed that the study subjects seemed able to discriminate between seven levels of subjective confidence, which is in agreement with earlier studies on discriminatory capacity. The choice of, and interpretation of, a verbal phrase is based not only on the level of probability but also on situational and linguistic cues. For instance, terms used to describe the likelihood of unpleasant events were interpreted as denoting a lower probability, when applied to the subject’s own future, as opposed to in someone else’s future.

Adelswärd and Sachs studied how mathematically expressed test results or statistical probabilities were understood in two data sets (a voluntary health survey aimed at men, and in a consultation service for genetic assessment of risk of hereditary cancer). The interpretation of numerical risk depended on whether the subjects believed that the risk was relevant to them, and on whether or not they could influence their future health. Both patient groups had difficulties in interpreting decontextualized numerical expressions.

The European Commission Directive on the labelling of medicinal drugs states that they have to be accompanied by a comprehensive patient information leaflet (PIL), meeting identical criteria (including a list of all recognised side effects) and using some standardized language. Berry et al have shown that consumers significantly overestimated the risk of side effects occurring when interpreting the verbal descriptor common. Only one participant out of 188 interpreted common as defined in the directive (i.e. between 1 % and 10 %).
Numbers

Presenting risk, or probability, as a number is simple enough when the risk is known, or when it's possible to estimate a plausible interval. But in order to communicate a risk level with success the information has to be interpreted in the same way by the recipients and the sender. Due to several human fallacies, including varying degrees of innumeracy and different preconceived conceptions, this is however a difficult task\textsuperscript{87-90}. Grimes et al studied 633 women in a gynaecological outpatient clinic in California. Risk expressed as rates per 1000 women were generally better understood than proportions with one as the numerator. However, the women showed poor understanding of both formats. Only 56\% were able to correctly identify that 1 in 112 was a higher risk than 1 in 384, while 73\% correctly identified the higher risk when expressed as a 8.9 per 1000 as opposed to 2.6 per 1000\textsuperscript{91}.

One way of handling the wide range of probabilities between different risks is to use a logarithmic scale for risk. Calman\textsuperscript{88} has proposed a compound scale, a \textit{community risk scale} incorporating several different elements including a logarithmic risk scale (risk magnitude), Table 2, where the magnitudes are compared with other risks. An alternative presentation of risk magnitude is the Urquahart-Heilmann safety degree scale\textsuperscript{92} where the risk magnitude 10 is equivalent with the safety degree of zero, and vice versa.

<table>
<thead>
<tr>
<th>Risk magnitude</th>
<th>Risk</th>
<th>Risk description (unit in which one adverse event would be expected)</th>
<th>Example (based on N:o of deaths in Britain per year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>1 in 1</td>
<td>Individual</td>
<td>Lightning</td>
</tr>
<tr>
<td>9</td>
<td>1 in 10</td>
<td>Family</td>
<td>Measles</td>
</tr>
<tr>
<td>8</td>
<td>1 in 100</td>
<td>Street</td>
<td>Oral contraceptives</td>
</tr>
<tr>
<td>7</td>
<td>1 in 1,000</td>
<td>Village</td>
<td>Any cause, age 40</td>
</tr>
<tr>
<td>6</td>
<td>1 in 10,000</td>
<td>Small town</td>
<td>Road accident</td>
</tr>
<tr>
<td>5</td>
<td>1 in 100,000</td>
<td>Large town</td>
<td>Murder</td>
</tr>
<tr>
<td>4</td>
<td>1 in 1,000,000</td>
<td>City</td>
<td>Any cause</td>
</tr>
<tr>
<td>3</td>
<td>1 in 10,000,000</td>
<td>Province or country</td>
<td>Lightning</td>
</tr>
<tr>
<td>2</td>
<td>1 in 100,000,000</td>
<td>Large country</td>
<td>Measles</td>
</tr>
<tr>
<td>1</td>
<td>1 in 1,000,000,000</td>
<td>Continent</td>
<td>Lightning</td>
</tr>
<tr>
<td>0</td>
<td>1 in 10,000,000,000</td>
<td>World</td>
<td>Lightning</td>
</tr>
</tbody>
</table>

Another way to present risk is to anchor the levels through either verbal expressions, or well-known outcomes; or by visualizing the differences in order to help the respondent to appreciate how large the differences between different magnitudes really are. There are commercial solutions as well as free web resources such as Visual Rx for this, see Figure 7.

Figure 7. This picture illustrates an output from a Cochrane Review of the use of antibiotics in acute otitis media (middle ear infection) in children. The picture represents 100 children who are all given antibiotics for ear infections. The 86 happy grey faces are children who would have been free from pain at 2 to 7 days even if they had not received an antibiotic. The nine sad faces are children who are still in pain even with antibiotics. The five happy light-grey faces are the only children who show a benefit; they would have been in pain without the antibiotic but are not when they receive one. Since it is not possible to identify which children will benefit, all 100 need to be given the antibiotic for five to benefit. This represents the number needed to treat (NNT) of 20 for a single child to benefit. Printout from Visual Rx, a web-resource at www.nntonline.net. Reproduced with permission.
**Risk reduction**

Often the result of a clinical study, and thus also the expected benefit of a specific treatment alternative versus other alternatives (including inaction), is presented as difference, or a risk reduction. Such a reduction in risk can be expressed in different ways, either as an absolute reduction or as a reduction relative to the alternative, *relative risk reduction* (RRR). *Absolute risk reductions*, ARR, can be further transformed into *numbers needed to treat* (NNT) in order to gain one defined beneficial outcome. NNT is the inverse of the absolute benefit of the intervention\(^94, 95\) and is often presented only as a point estimate, even though it is easy to calculate a confidence interval for NNT\(^96\).

When presenting negative outcomes the terms *numbers needed to harm* (NNH) can be used\(^97, 98\). In the late nineties very few clinical trials presented NNT\(^99\). In a revised version of the CONSORT statement on improving the quality of reporting the results of clinical trials encouraged reporting of absolute values and NNT\(^100\).

Reporting the risk reduction as an absolute or a relative risk reduction can influence the perception of the possible treatment gains by both physicians\(^101-105\) and patients\(^106\). When the positive result was presented as RRR, the physicians were more likely to accept the treatment compared with when ARR or NNT were presented. Teaching physicians basic principles about different ways of presenting risk reductions can have an impact on their perception of treatment effects, but will in itself not suffice to change their clinical practice\(^107\). Sheridan et al studied how patients interpret the benefits of treatment when given in different formats. The best understanding was achieved when relative risk reduction was used together with a given baseline risk of disease. ARR, as well as NNT, were both easily misunderstood by the patients\(^108\). This is contrary to the perceived clinical immediacy of NNT by physicians. The recommendation to use NNT in presenting results from clinical trials for physicians\(^109\) thus cannot automatically be extended to the physician-patient-interaction.

The conclusion that can be drawn is that risks have to be described in several ways in a consultation, and in different ways in different situations, i.e. physicians have to learn to speak *both the language of populations and the language of individuals*\(^110, 111\). Tools for risk communication have been shown in qualitative studies to be well received by physicians\(^112\). Edwards et al showed that health care professionals perceived a standardized language potentially helpful for communication between professionals. For communication with patients the views differed\(^113\).
Other ways of presenting risk and risk reduction

A Swedish computerized system for assessing the risk for cardiovascular disease for an individual had as an option to present the result as risk age (Swedish riskålder). Risk age was defined as the age at which a person would have the same risk to develop cardiovascular disease as without the present risk factors. The possible reduction of risk by modulating one or more of the risk factors was described in the program as reduction of risk age, not to be confused with life-years gained. The theoretical background to the concept of risk age and the related reduction of risk age, and to which degree they were understood or misunderstood by the patients, were not reported.

The European Society of Cardiology has developed a risk score system (SCORE) using data from 12 European cohort studies (n=205,178) covering a wide geographic spread of countries at different levels of cardiovascular risks. A further development of this system is the web based program HeartScore®. Heartscore has been selected as the new standard in European prediction and management of risk for cardiovascular disease (CVD) by the Third Joint European Societies Task Force on CVD Prevention in Clinical Practice.

Decision aids

In a Cochrane review over 200 decision aids were identified, most of them intended for use before, and not during counselling. Few included description of uncertainty and only 38 were evaluated in clinical trials. The conclusion of the review was that decision aids can help people take an active role in informed decision making through improving knowledge, enhancing participation, lowering decisional conflict, and improving agreement between values and choices. There were too few studies to determine effects of decision aids on persistence with the chosen therapy, costs, resource use, or efficacy of dissemination strategies. Seven studies of decision aids for hormone therapy were included in the Cochrane review. In five of the studies different interventions were compared with each other, and in the remaining two studies the intervention was compared with usual care.

Murray et al showed that an interactive multimedia programme with booklet and printed summary lead to significantly lower scores for decisional conflict in the intervention group, compared with usual care. A higher proportion of general practitioners perceived that patients in the intervention group had been more active in treatment decisions. At three months fewer of the women
in the intervention group were undecided about treatment, and a higher proportion had decided against hormone replacement therapy. After nine months there were no differences. In the study by McBride et al. women who received a trifold decision aid (facts about HT; worksheet to record preferences; vignettes of women at decision points and a checklist of questions) were compared with women receiving usual care. Women in the intervention group were more likely to be confident about making a decision; more likely to accurately perceive their level of risk for breast cancer; and to be very satisfied with their HRT decision. For the first two outcomes the effect persisted after nine months. Detailed decision aids for decisions about hormone treatment reduced preference for HT significantly, compared with simple decision aids (relative risk 0.68, 95% confidence interval: 0.48, 0.97).
The menopausal transition

The International Menopause Society adopted the following definitions in 1999:

- The menopause is the time in life when permanent cessation of menstruation occurs due to loss of ovarian follicular activity. The time point can only be established when one year has elapsed since the last bleeding. Menopause is derived from the Greek words men (month) and pauses (cessation).
- The perimenopause covers the period of endocrinological and clinical changes, prior to the menopause and until 12 months after the menopause. The years prior to the menopause encompasses the change from normal ovulatory cycles to cessation of menses.
- The climacteric is a more general term and it is the transition from the reproductive phase to the non-reproductive state. This phase incorporates the perimenopause, by extending for a longer variable period before and after the perimenopause. Climacteric is a Greek word and means ladder.

In ongoing clinical trials several different menopausal staging definitions are used. Comparison between some of these staging systems with biochemical changes suggests that early changes in bleeding pattern, in particular cycle length changes, reflect significant underlying hormonal changes among women already in the early transition of menopause.

In Sweden the median age of menopause is between 50 and 52 years. Every year more than 50,000 Swedish women will reach the menopause. A number of symptoms associated with oestrogen deficiency have been described in women around menopause. The most common symptoms, beside menstrual irregularities are hot flushes and sweats. They might interfere with night sleep and lead to a decrease in the general well-being. Around 75% of peri- and post-menopausal women are afflicted, with the highest prevalence during the first five years after the menopause.

Hormone treatment in the menopausal transition

The term hormone replacement therapy (HRT) is usually used to describe treatment with medium-potency oestrogens, with or without progestagens, in symptomatic menopausal women. Sequential therapy with oestrogen/progestagen can also be used to treat irregular, anovulatory cycles, which are common the last years before menopause.
According to the International Menopause Society in 2004\textsuperscript{134}, administration of hormones to symptomatic, estrogen-deficient women such as those in the observational studies is referred to as hormone replacement therapy (HRT). Administration of hormones to asymptomatic women such as those in the recent RCTs is referred to as hormone therapy (HT). The term HRT has been criticized since the combinations of oestrogens and progestagens used are not a physiological replacement. Instead the term hormone treatment (HT) has been suggested by amongst other the US Food and Drug Administration, FDA\textsuperscript{135}. In order to be more specific the terms estrogen therapy (ET), estrogen and progestogen therapy (EPT), combined sequential estrogen and progestogen therapy (CSEPT), and combined continuous estrogen and progestogen therapy (CCEPT) have been suggested by the North American Menopause Society\textsuperscript{135, 136}. See Appendix 2 for an outline of different alternatives for HT in Sweden during the studied period.

Substitution with oestrogen, usually combined with progestagens, is a well-documented therapy for vasomotor symptoms\textsuperscript{137}. Several studies have showed improvement in quality of life (QoL) after hormone treatment but whether hormone treatment improves QoL not only through relief of climacteric symptoms, but also by a direct effect on well-being is uncertain\textsuperscript{138}.

Oestrogen substitution has been recommended as a first-line therapy to prevent osteoporosis on the basis of earlier clinical trials. This has been challenged by recent publications. In 2002 the Swedish Council on Technology Assessment in Health Care presented an evidence based review over HT\textsuperscript{131}. This review concluded that there was a higher risk for thromboembolic complication, particularly during the early years of treatment. Short-term treatment could not be shown to increase the cancer risk. Long-term treatment was associated with an increased risk for breast cancer and the risk increased with time. More research was needed to assess the effects on ovarian and colon cancer and malignant melanoma. No conclusions could be drawn about the effect of oestrogen on cognition, nor whether it could prevent osteoporosis or fracture except in certain risk groups. A preventive effect on cardiovascular diseases could not be confirmed.

The Heart and Estrogen/progestin Replacement Study (HERS)\textsuperscript{139} and the follow-up study (HERS II)\textsuperscript{140} showed no differences in hip fractures or any fractures. The Women’s Health Initiative (WHI) showed an increase in bone mineral density and found a significant reduction in the risk for hip, vertebral, and all fractures (RR 0.66, 0.66 and 0.76). The effect appeared to be present in all subgroups of women studied. However, considering every important
disease outcome there was no net benefit for the women. The conclusion was that oestrogen and progestagen should not be recommended as first line therapy for prevention or treatment of osteoporosis for women without vasomotor symptoms\textsuperscript{141, 142}.

Epidemiological data have indicated that HT prevents cardiovascular disease\textsuperscript{143, 144}. Recent prospective, placebo-controlled studies have been unable to confirm these cardiovascular advantages\textsuperscript{141, 145}. A preventive effect on Alzheimer’s disease and cognition has been suggested and three meta-analyses\textsuperscript{146-148} showed an effect but also concluded that there were major methodological problems. The WHI, on the other hand, showed an increased risk for dementia among women given HT\textsuperscript{149}.

A recent Cochrane review\textsuperscript{150} concluded that combined continuous HT in relatively healthy women significantly increased the risk of venous thromboembolism or coronary event (after one year’s use), stroke (after 3 years), breast cancer (after 5 years) and gallbladder disease. Long-term oestrogen-only HT also significantly increased the risk of stroke and gallbladder disease. Overall, the only statistically significant benefit of HT was a decreased incidence of fractures and colon cancer with long-term use. Among relatively healthy women over 65 years taking continuous combined HT, there was a statistically significant increase in the incidence of dementia.

**Pharmacoepidemiology**

The use of HT increased rapidly during the eighties and nineties\textsuperscript{151, 152}. In Sweden, only 7% of women (53-55 years) used HT in the early 1980s\textsuperscript{129}. The use of HT among women in Gothenburg was highest among women 54 years of age and increased from 25% in 1992 to 42% in 1998 (average reported use by women aged 52 and 56 years)\textsuperscript{153}.

The reported sale of oestrogen and oestrogen-progestagen in Sweden increased from 40 million defined daily doses annually 1985 to a peak of almost 180 million doses in 1999. After the Heart and Estrogen/progestin Replacement Study (HERS)\textsuperscript{139} in 1998 had questioned the secondary preventive effect of HT against coronary heart disease, the discussion about the net balance between risks and benefits with HT intensified. From 2000 the use of HT started to decline and after the publication of the studies HERS II\textsuperscript{140}, \textsuperscript{154} and WHI\textsuperscript{141} in 2002 the prescription of HT declined rapidly in Sweden, Figure 8, as well as in the U.S.,\textsuperscript{152, 155, 156}.
Determined of women’s decision to use HT
A current review over women’s perceptions of risks and benefits with HT showed that use and discontinuation of HT are influenced more by short-term symptom relief than by considerations of long-term benefits, and that many women who refuse HT believe that the menopause is a natural event that doesn’t warrant drug treatment. Primary sources of information appeared to be women’s magazines and newspapers rather than health care professionals.

A theoretical model using structured interviews to identify decision factors, together with a telephone survey, showed that among HT-users concerns...
about heart disease, osteoporosis, and symptom of menopause were the main factors supporting use of HT\textsuperscript{158}. Side effects and concern for breast cancer were the main factors against HT among former users and never users, respectively.

Many women make decisions about HT (such as deciding to consult a physician; whether or not to fill a prescription at the pharmacy; to take the medicine at home; and if and when to quit) on their own without contact with the health care. Through telephone interviews in the mid-nineties (1,082 women, aged 50-80, 42 % current users of HT) Newton et al\textsuperscript{159} showed that the most frequently cited reasons by current users to initiate HT were menopausal symptoms, osteoporosis prevention, and physician advice. The most frequently cited reasons for quitting were side effects, physician’s advice, fear of cancer, and not wanting bleedings. More than half of the past users reported that they had stopped HT on their own. The most commonly cited reasons by never users for not initiating HT were that hormones were not needed and that menopause is a natural event. One out of every 20 never-users reported having received an HT prescription they did not use.

In a questionnaire study in California in 1991 (126 women, 45-55 years, had attended an outpatient clinic) a majority of women were aware of increased risk of osteoporosis and cardiovascular disease after the menopause\textsuperscript{160}. Sixty-nine percent of the women knew that HT decreased the risk of osteoporosis, and 48 % reported an effect on the risk for cardiovascular disease. The factors most important in predicting HT use were recommendation from the health care, and concern for developing osteoporosis. No aspects of heart disease were associated with the decision to use, or not to use HT.
Bardel et al showed that among Swedish women in 1995 (2991 women 35-64 years), users of HT more often used symptom relieving therapy (defined as tranquillisers, hypnotics, antidepressants and pain killers) than never users and previous users, irrespective of menstrual status, Figure 9. The authors interpreted both the high frequency of use of symptom relieving therapy, and the reported general symptoms and symptoms associated with menopause, among HT-users and previous users, as a consequence of confounding by indication (i. e. that women more affected by menopausal symptoms seek medical care and receive HT to a higher degree). In addition, lack of effect and/or fear of long-term side effects may explain the relative higher degree of reported symptoms and use of symptom relieving therapy among previous users compared with both users and never users.

In 1996 a telephone survey was performed in Quebec (644 women, 45-54 year, premenopausal and not hysterectomized). Women with a strong inten-
tion to adopt HT represented 25% of the sample. These women were more likely to believe that adopting HT would have positive consequences such as an improvement in general well-being and prevention of health problems. They were also more likely to believe in negative side-effects such as increased risk of cancer and weight gain\textsuperscript{161}. In a questionnaire study in Canada in 1998 (205 women from the mid-forties to the mid sixties, 22% current users) women who intended to utilise or continue to utilise HT, compared with woman who did not, perceived more advantages of HT and more social support for utilising HT. Their opinions about the negative side effects of HT did not differ from the other women\textsuperscript{162}.

In 2000 Li et al reported the result from a questionnaire (1,415 women, 48% ever users and 32% current users)\textsuperscript{163}. The most common reasons for use of HT were menopausal symptoms (72%), prevention of bone loss (50%) and/or cardiovascular disease (31%). The most common reasons for quitting HT were weight gain, anxiety of cancer, bleeding, breast tenderness, and emotional problems. In this study HT-users were more educated, and worked full-time to a higher degree than the other women. In 2003 Scheid found in the U.S. that HT-users, compared to non-users (387 women, 45 year and older), reported a greater perceived risk reduction for osteoporosis (-35% vs. -18%) and myocardial infarction (-21% vs. -8%), and a lower risk increase for breast cancer (3% vs. 16%) and endometrial cancer (1% vs. 9%). HT-users also associated osteoporosis with a greater reduction of quality of life than non-users. Regardless of HT-use women in this study overestimated their risk for all four diseases studied\textsuperscript{164}.

A nation-wide telephone survey in U.S.A. in 2002 (819 women, 40-79 year) showed that 64% of the women had heard something about the findings from WHI\textsuperscript{165}. Three out of four women (74%) were confused about HT use. When hearing about the study findings 13% stopped taking HT.

In California a telephone survey (670 women, 50-69 year, HT-user in the year before the survey) in 2003 showed that most women (93%) were aware of the findings from the Women's Health Initiative. More than half of the women (56%) reported having attempted to discontinue HT during the 6-8 months after the publication\textsuperscript{166}. Similar findings were reported from New Zealand where 58% of the women responding to a questionnaire (881 women, screened for WHI but ineligible or unwilling to participate, HT-users) reported having stopped taking HT during the six months after the
study. Of these nearly one-fifth had resumed taking HT at the time of the 
survey. Of all women 83 % reported having discussed HT with a health pro-
professional. An interview-survey among Australian women (907 women, >40 
year) showed that HT-use among women over 50 year dropped from 28 % in 
2000 to 10 % in 2002. By October 2003 the use of HT had increased to 19 %. 
The most common information source was media reporting and 40 % of the 
women over 50 year stated that they had been influenced by media. In 
Minnesota a survey among current users of HT showed that almost a third of 
the women with an intact uterus discontinued HT during the first six months 
after WHI. The majority had consulted their physician about whether or not 
to discontinue HT. Other studies have reached similar results. A study 
in Chile in 2002 (500 women, 40-64 year) showed that HT-users perceived 
themselves to healthier and to have a smaller risk for cardiovascular disease 
than non-users did.

A review focusing on qualitative studies about women’s decision making about 
HT showed that there were major gaps in the care of midlife women, espe-
cially considering information about the menopause. The studies included did 
not discuss the role of other health care professionals, such as the role of the 
nurses, in informing women about the menopause and HT. Marmoreo et al 
described four major spheres of influence as important in the women’s deci-
sion making about HT: The woman’s internal influence (opinions about, fee-
lings and symptoms of menopause, the benefits of HT, and the experiences of 
side effects); interpersonal relationships (including the patient-physician rela-
tionship); external influences (ageism, sexism); and consequences of the treat-
ment decision chosen.

Other qualitative studies have shown that users of HT had more knowledge 
than non-users about the menopause and osteoporosis. Women wanted 
more information especially about the risks and benefits with HT. Barriers to optimal risk communication and decision making included lack of 
time, attitudes of general practitioners and poor communication in the prima-
ry care consultation. To understand risk and to make a personal interpreta-
tion, the women used their own knowledge, the presentation and context of 
that risk, together with their individual belief system particularly relating to 
representations of womanhood, lay beliefs and fatalism, control and choice.
Three main themes could be identified in the women's accounts of their decisions about HT:

1. the presence or absence of troublesome vasomotor symptoms,
2. physicians' views and advice, and
3. views towards menopause and medication.

Menopause was seen as a natural process unless severe symptoms were present. Women seemed to handle risk of menopause-related diseases on both a collective and an individual level. They did not generally consider themselves to be at personal risk of disease even when an increased risk of osteoporosis and cardiovascular disease was acknowledged on a collective level. Since decisions to use, or not to use, HT were largely based on an assessment of the personal risk, the perceived value with HT was limited for most women. Among HT-users the overwhelming reason for continuation seemed to be the improved quality of life.
Aims of the Study

The general aim of this thesis is to study the interaction between patient and physician when discussing risks and benefits of different treatment alternatives, and to suggest strategies to improve risk communication in clinical practice.

Specific aims:
• to investigate how, and to which extent, risks and benefits of hormone therapy in the menopausal transition are communicated between women and physicians in first-time visits on this subject (paper I), and to which degree a shared understanding of the risks and benefits associated with hormone replacement therapy is achieved (II),
• to develop a system for classification of risk framing, and to validate its usefulness in analysing the interaction between the physician and the patient when discussing risk (I & II),
• to analyse both social-communicative aspects of framing (of the activity) and types of cognitive framings (parties’ understanding of problems discussed) with a particular focus on physicians’ rhetorical strategies (III), and
• to assess changes in women’s perception of risks and benefits from hormone therapy in the menopausal transition, as well as use of hormone therapy and alternative treatment strategies, as a consequence of new knowledge and revised guidelines for health care personnel between 1999 and 2003 (IV).
Materials and Methods

Data corpus and methods
The four studies are based on two different data sets analyzed with different methods, Tables 3 & 4. The studies were reviewed and approved by the local Ethics Review Board at the Faculty of Health Sciences, Linköping University (98-323; 99-247, addendum 020529). The main ethic consideration for papers I-III was the possible infringements on the patients’ personal, and the physicians’ personal and professional integrity. In order to reduce these concerns both parties were informed about the nature and objectives of the investigation and were assured that the analysis and presentation of the findings would be performed without the investigators (with the exception of the interviewer, LLÅ) knowing the identity of the participants. The written information given included the following statement: *To which degree the knowledge about different kind of treatment alternatives of climacteric discomfort is discussed between physicians and patients, and how this influences the decision to treat, is largely unknown. The aim of our research project is to gather knowledge about how you as a patient understand the information given to you by the physician; whether you can make yourself understood; and how easy it is for you to raise questions during the consultation.*
| **Participants/respondents** | Women aged 45–59 years with a scheduled consultation for a first-time visit for discussion of climacteric discomfort and/or HT. | Specialists in gynaecology at out-patient clinics of gynaecology. One clinic at a large teaching hospital and two community-based clinics. | Women 53-54 years of age living in the community of Linköping at the time of the questionnaires. |
|**Sampling procedure** | Consecutively identified through a manual search of the appointment lists for the participating physicians. | Convenience sampling | All women eligible according to the public census. |
|**Material** | Audio-taped consultations | Audio-taped consultations | Questionnaires |
| | Pairs of audio-taped consultations and semi-structured interviews consisting of open-ended questions conducted immediately after the consultations | | |
|**Number of eligible participants/respondents** | 26 | 5 (two male, three female) | Number of women and respondents after one reminder 1999: 1,760 / 1,298 2003: 1,733 / 1,339 |
|**Included** | 20 consultations | Not applicable | Respondents with conclusive answers for menopause-status: 1999: 1,180 (67% of 1,760) 2003: 1,263 (73% of 1,733) |
| | 19 pairs of consultation and interview | | |
|**Reasons for exclusion** | Denied to participate: 1 | Not applicable | No response after one reminder 1999: 462 2003: 394 |
| | Suitable time for the consultation and interview could not be arranged: 4 | Inconclusive answers for menopause-status 1999: 118 2003: 76 |
| | Technical failure: 1 consultation, 1 patient interview | | |
|**More information about participants/respondents** | Table 5 in the thesis | | Table 1, Paper IV |

Table 3. Data sets in the thesis.
Table 4. Methods.

**Papers I, II & III**

**Selection of the participants**

Twenty-one women, aged 45-59 years, were recruited from three clinics of gynaecology in 1999-2000. One clinic was an out-patient clinic of gynaecology at a university hospital; the other two clinics were community-based. All three clinics provided health care to the general public without requiring a physician referral.

The women were consecutively identified through a manual search of the appointment lists for 5 gynaecologists (2 male, 3 female) who agreed to participate in the study. The physicians were selected through convenience sampling and were informed about the objective of studying risk discussions but were asked to use their usual consulting strategy. Women, who had a scheduled consultation for a first-time visit for discussion of climacteric discomfort and/or HT, were identified consecutively and invited by letter to participate in a study about risk communication. The women had to be non-users of HT,
be able to understand and speak Swedish, and be able to give their informed consent to participate in the study. The criteria for participation were deliberately wide in order to ensure participation of women with different reasons for scheduling a consultation.

<table>
<thead>
<tr>
<th>Age group</th>
<th>N</th>
<th>Civil status</th>
<th>Employment</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Single</td>
<td>Married/cohabiting</td>
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<td>- 45</td>
<td>1</td>
<td>1</td>
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<tr>
<td>46-50</td>
<td>9</td>
<td>1</td>
<td>8</td>
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<tr>
<td>51-55</td>
<td>6</td>
<td>1</td>
<td>5</td>
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<tr>
<td>56-60</td>
<td>4</td>
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<td>4</td>
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<tr>
<td>Total</td>
<td>20</td>
<td>3</td>
<td>17</td>
</tr>
</tbody>
</table>

Table 5. Socio-demographic characteristics of the women (n=20).

All women were native Swedes, except one woman born in Asia. For socio-demographic characteristics see Table 5. Six women were postmenopausal (more than 12 months since last menstrual bleeding), four women were perimenopausal (between 6-12 months since last bleeding), seven women had irregular bleedings during the last six months (premenopausal) and four women had undergone a hysterectomy. The most common reason why women asked for medical advice and for an appointment was hot flushes and sweating. This was reported by 16 out of the 20 women. Sleep disturbances (n = 6), mood disturbances (n = 6), palpitations (n = 4), pain in joints and muscles (n = 3), headache (n = 2) and urogenital symptoms (n = 1) were other reasons why women sought medical advice. One woman had no symptoms and wanted primarily to discuss prevention of osteoporosis. Before the consultation, each woman met one of the investigators who explained the study and asked for and received the patient’s informed consent.

**Data collection and validation**

The consultations and interviews were audio-taped, except during the gynaecological examination. The audio-tapes were transcribed in a broad transcription format capturing pauses and verbal support. The transcriptions were then compared and validated against the tape-recordings by three of the authors (LLÅ, MiH and KK) independently.
Twenty-six women were contacted. Out of these four were willing to participate but a suitable time for the consultation, including audio-taping and interview, could not be arranged. One woman refused to participate. One consultation and one interview could not be analyzed due to technical reasons. In total, twenty consultations, and nineteen pairs of consultations and interviews, were analyzed. One of the women included had tried HT for a short period during a blinded clinical trial three years before the consultation. None of the other woman had previous personal experience of HT.

This study was primarily designed to understand the variations of conceptions of menopause, as well as risk communication during a consultation. The consultations were studied and analysed consecutively. During the latter part of the analysis, few new structures in risk communication emerged and thus the sample was considered saturated at 20 women for the purpose of analysing risk communication.

A good interviewer is a person with good knowledge in the field, and with skills and experience from interpersonal communication\textsuperscript{181}. The semi-structured interviews were performed immediately after the consultation in a quiet room at the outpatient clinic by one of the investigators (LLÅ), a nurse with extensive experience in menopause medicine. An interview guide with open-ended questions was used throughout the interviews to minimize the influence of the interviewer. Several differently formulated open-ended questions exploring the women’s perception of risks and benefits associated with the menopause and HT were used. Three pilot interviews were performed with women who met the inclusion criteria in order to test the questions in relation to the aim of the study. These pilot interviews showed the questions to be understandable and deemed relevant by the participating women. The pilot interviews were not included in the study.

Rhetorical strategies were defined as recurrent patterns of argumentation, largely controlled by the physicians, which constituted solutions to the communicative tasks and dilemmas involved in dealing with risks and in advising women to take HT.

**Data analysis**

The consultations and interviews were analyzed using QSR NUD\textsuperscript{*}IST VIVO\textsuperscript{®} (version 1.3.146, Qualitative Solutions & Research Pty. Ltd.). Data were classified by two of the investigators (MiH and KK), working together. The women’s involvement in the decision making was assessed through an
instrument - Elements of informed decision making\textsuperscript{21, 22} – chosen in 2000 after an extensive literature search, and before the publication of the systematic review\textsuperscript{20} and the subsequent development of the OPTION scale\textsuperscript{24}, see Table 1.

The data sets from the consultations and interviews were repeatedly organized in a conceptual framework in order to identify and describe:

1. the defining properties of the consultations, including different strategies by the women and the physician,
2. rhetorical strategies employed by the physicians
3. risk communication in general, and
4. different types of risk communication depending on the relationship to discussion about benefits.

Discussions about the risks and benefits associated with HT, or alternatives to HT, either by the woman or the physician, were coded as risk discussion. Discussions of risk in the same context as benefits were operationally defined as co-occurrence if they occurred in the same logical train of thought and not further apart than two turns of talk. For classification of comparison between alternatives, at least one alternative treatment/strategy to HT had to be mentioned in the risk discussion. The first mention of HT in every consultation, and whether it was positive, neutral or negative, was identified. In addition, the first statement by either the physician or the woman acknowledging the decision to treat or not to treat with HT was identified. The actual decision to treat was then classified as preceding, co-occurring, or as a sequel to the risk discussion.

During this iterative process several new concepts of how to describe the risk discussion were discussed and tested. New concepts and definitions were discussed between at least two of the investigators. These discussions yielded a risk classification according to the context, i.e. whether or not risks were discussed in the same context as benefits and/or alternative treatments in a 2x2 table, Figure 10.
 Assigned risk, risk_A describes the simplest way of communicating a risk. This is when the risks associated with a specific alternative are presented without reference to other alternatives, including inaction. It is called assigned risk since it is a personal choice whether the risk is seen as probability only, or as a function of probability and consequence.

Risk_B, or balanced risk, is when the assigned risk, risk_A, is discussed in the same context as the possible benefits of one alternative in isolation. When the assigned risk is discussed for more than one alternative at once, the risks are compared to each other and classified as compared risk, risk_C. A discussion of balanced risks, the risks and benefits associated with more than one alternative, is named risk difference, risk_D.

**Paper IV**

**Selection of the participants**
All women who reached the age of 53 or 54 years during the study year and lived in the community of Linköping (number of inhabitants 136,000) according to the national census in 1999 (n=1,760) and in 2003 (n= 1,733). The age-group was selected on basis of a documented high frequency of current users of HT.^[31]

**Data collection and validation**
Questionnaires focusing on benefits and risks with HT and use of HT, were
mailed to the participants’ postal addresses according to the national census late in 1999, and in the second quarter of 2003 (8 or 9-step adjectival ordinal scale, see Appendix III). One reminder was mailed after two months to the women who hadn’t answered.

The questionnaire in 1999 was validated in three steps.
1. Three middle-aged women with appointments to one of the outpatient gynaecological clinics answered the questionnaire and were interviewed by one of the investigators immediately after this. The objective of this was to ensure that the questions were correctly understood, and the answering alternatives were considered valid by the respondents. Some adjustments were made as a consequence of this.
2. Ten middle-aged women selected by convenience sampling were tested. Seven of them answered a re-test two weeks later.
3. The face validity of the questionnaire was tested by means of a structured personal interview with the seven women who had answered the questionnaire twice.

In two separate questions the women were asked for how large the risks for inconveniences (adverse drug reactions) (Swedish besvär (biverkningar)), and the benefits (Swedish nytta) with HT were for a woman in general in the menopause. Since risk in many cases is a more complex dimension than probability the use of the word probability was avoided. The test-re-test stability for the questions on risks and benefits showed a good stability with a Cohen’s kappa of 0.75 (linear weights). The median difference between first and second answer was 0 out of 8 steps. A questionnaire with identical questions about risks and benefits with HT was used in 2003.

Data were optically scanned and exported to SPSS for Windows (release 10.1.0). The agreement between optical and manual reading was checked for the first ten complete questionnaires and the optical reading was continued only after the manual and the optical reading agreed totally.

Data on number of dispensed Defined Daily Doses (DDD) of oral and transdermal oestrogen, and oestrogen-progestin combinations with a registered indication of supplemental treatment during menopause were obtained from the National Corporation of Swedish Pharmacies for the period of 2000 through 2004. This database covers all prescriptions dispensed to inhabitants of Sweden (identified through their social security number) at all Swedish pharmacies.
Statistical analysis
Data were analysed with SPSS for Windows (release 10.1.0). The data was collected with a discrete ordinal scale and therefore non-parametric statistical methods (chi-square test and Mann-Whitney U test / Wilcoxon rank sum test) were used for the main analyses, Table 4. One-way ANOVA was used for comparison of number of information sources reported.
Results

Structure and content of risk discussion in the consultations (papers I, II & III)

The total audio taped speaking time varied between 15 and 25 min, with two exceptions lasting 32 and 43 min respectively. Five different phases could be identified in the consultations:

- Gynaecological history-taking.
- Introduction of HT.
- Discussion of risks and benefits of HT and other treatment options.
- Gynaecological examination.
- Closing (in which each patient was prescribed HT).

Discussion of risks and benefits could be identified in 18 of 20 consultations. In some consultations the discussion of risks and benefits of HT continued after the examination, and sometimes constituted a part of the end of the consultation.

Word count showed that the discussion of risks and benefits with HT comprised on average 21% of the consultations (excluding the gynaecological examination). The risk discussion was asymmetrical, with the physician dominating with a 4:1 ratio of spoken words. No decision aids such as printed material or multimedia presentations were used actively, neither before, during, nor in direct connection with any of the risk discussions and prescriptions.

HT was introduced by the physician in 19 of the consultations, in 15 cases in a positive mode. In one of the consultations HT was introduced by the woman.

Patient participation in the decision making (paper I)

The average number of identifiable criteria for informed consent, according to Braddock\textsuperscript{21, 22}, for the decision to use HT was 4.0 out of 7 (range 2-6), Table 1, Paper I. The clinical decision was specified in all consultations. In 13 cases the woman’s preferences were explored, but in only 2 of the cases the woman’s role in decision making was addressed.

In 10 of the 18 consultations with risk discussion, the decision to prescribe HT came after the risk discussion, in five cases before the risk discussion was
finished, and in three consultations preceded the risk discussion, Table 3, Paper I. In six cases the risk discussion continued after HT had been prescribed and the prescription had been handed over to the woman.

**Risk classification (papers I & II)**

The information given by all the gynaecologists but one was about HT without any comparison with other treatment strategies. Quantification in numerical terms was used in five risk discussions, and only when discussing breast cancer. Absolute risk rates and absolute risk reduction were used.

The asymmetrical risk discussion with the physician dominating the conversation showed similarities in structure and content in consultations with the same physician, thus making it possible to assume that the different physicians had different strategies for this part of the consultation. During the analysis phase different strategies for risk discussion were identified depending on the context, i.e. depending on whether or not the risk associated with treatment was discussed together with the possible benefits, and whether or not one or several treatment alternatives were discussed. As a result of these findings a separate risk classification according to the context was developed as presented in Methods, Figure 10.

The application of this classification made it possible to illustrate the major differences between the consultations, and thus between the physicians, see Table 3, Paper I. The physician C used both risk subscripts B and D in the majority of the consultations, physicians B and D used both risk subscripts A and B, physician E used only risk subscripts B, and physician A used risk subscripts B in most but not all consultations.

**Rhetorical strategies (paper III)**

In paper III, the rhetorical strategies of the physicians were further explored. The word risk was avoided to a considerable extent and the term *drawback* was used instead. Eight different rhetorical strategies were identified within the consultations, Table 6.
Recontextualising risks in terms of drawbacks and benefits

By placing ideas and concepts in a new concept their meaning will be modified. The professional/institutional framing of the discussion leads to a dispreference for “risk talk” and a preference for simplified drawback-benefit calculation.

Simplifying calculations

Instead of discussing risks and benefits in terms of their relative weights and probabilities, a simple calculation of the number of benefits and risks is used.

Embedding drawbacks in positive environments

A positive bias to HT is given by either introducing it in a positive way, and/or not mentioning drawbacks without discussing possible benefits.

Asking for the patient’s perspective first

By first topicalising one (or several) worries by the woman, the physician talks him/herself into a position where (s)he can give a positive message after the negative aspects have been dealt with.

Ending with positive aspects

Always end with positive aspects – “Pollyanna strategy”

Warding off objections

If the patient mentions worries, there is often a cascade of mitigations from the physician, combined with a massive enumeration of benefits.

Selling the option of HT

A selling strategy: don’t force anything on the woman, but invite her strongly to try HT.

Moving from menopausal problems to long-term medical risks

There is a move from the woman’s (current) problems to prevention issues. The climacteric is reframed from a period of inconveniences to the starting-point of a period of increased medical risks.

Table 6. Rhetorical strategies used by the physicians in the consultations. See Paper III.

Changes in women’s attitudes towards HT (paper IV)
The perceived level of risk with HT was significantly higher, and the perceived level of benefit was lower in 2003 than in 1999, according to the answers in the two questionnaires (both p<0.001, chi-2-test and Mann-Whitney U test). See Figure 11 and Table 3, Paper IV.

Even though the median for the risks with HT differed only one out of eight steps (from pretty low in 1999 to average in 2003), and the median for benefits of HT did not change at all (pretty high in both 1999 and 2003), there
still was a major differ in the extremes. In 1999 every eighth woman (12.8 %) perceived the risk with HT as pretty high or higher. In 2003 this had increased to every fourth woman (24.8 %). In 1999 four out of five women (79.5 %) saw the benefit of HT as pretty high or higher, but in 2003 this fraction had decreased to two out of three (68.6 %).

Figure 11. Benefits and risks with HT as reported in 1999 (n=1,180) and 2003 (n=1,263). See also Table 3, Paper IV.
Changes in women’s use of HT and alternative treatment strategies for climacteric discomfort (paper IV)

The number of dispensed Defined Daily Doses, DDD, of HT (as defined in Material and Methods) per 1000 women aged 53-54 years and day in Sweden decreased from 384 in the first quarter of 2000 to 216 in the third quarter of 2003 when the second questionnaire was answered (-44 %). In Linköping the amount dispensed decreased from 397 to 199 DDD per 1000 women aged 53-54 years (-50 %), Paper IV, Figure 2.

The fraction of women aged 53 to 54 years in Linköping who reported current use of HT decreased from 40.5 % to 25.3 % (a relative decrease of 38 %). The decrease in reported use was a combination of both fewer women starting, and more women discontinuing HT. Both effects contributed to a similar extent (7.5 vs. 7.8 %) to the reported decrease in current use of HT in 2003. At the same time the fraction of women that either used, or had used, natural remedies against climacteric discomfort increased from 11.2 % to 24.1 %, Table 2, Paper IV.

Sources of information about HT (paper IV)

Nearly two thirds of the women who answered the questionnaire in 2003 (799 out of 1,263 or 63 %) reported that they had received new information about HT during the last year, Table 4, Paper IV. The main sources of new information about HT during the last year among all women were newspapers or magazines (reported as being a source by 43.8 % of the women) and television or radio (31.7 %). The third most common information source was health care personnel (18.3 %). The differences between media sources (newspaper/magazines or television/radio) and health care personnel were significant (p<0.001, chi-2-test). Few women had received new information through the Internet (4.5 %). Many women reported having received information from more than one source, Table 7.
Table 7. Reported sources of information during the last twelve months (2003, n=1,263). Out of the 485 women reporting having received information through newspapers or magazines, 310 also reported having received information through TV or radio. 155 did not answer that specific question.

Current and previous users of HT reported receiving information from more sources than never users (average number of sources 1.44, 1.43 and 1.11 respectively), Table 8. Of the 203 women who had received information from health care personnel 111 were current users of HT. Women with current use of HT had received information from health care personnel significantly more often than women with previous use, Table 5, Paper IV.

Table 8. Average number of reported information sources per respondent, depending on their HT-use. The three groups are not equal (p<0.001, one-way ANOVA). Never users reported significantly fewer sources than both current users and previous users.
Discussion

The communication of the possible benefits and harms of different actions in health care is one of the most critical elements in empowering the patient and ensuring concordance. Communication is a two-way process and consists of much more than presenting fact about different actions (such as for instance drug treatment), and the expected outcomes of these actions. Communication in health care is about understanding each other; acknowledging each others opinions and beliefs; discussing expected outcomes and evidence for different options; and for the health care professional to explore not only the patients understanding but also the patients preferences for his/hers role in the decision making, and for different alternatives.

Risk can be interpreted as a probability of an adverse event, or a function of the probability and the magnitude of the consequences. Risk can also be described, and be differently perceived, from different perspectives, i. e. from a personal or a societal perspective. This makes it difficult both to assess and to discuss risk. The way probabilities and possible consequences are presented does influence the understanding and interpretation. The different ways of presenting risk, such as absolute or relative risk reduction, number needed to treat etc. is sometimes interpreted differently by health care professionals, patients, and citizens. Communication is further complicated by cultural filters and different rules-of-thumbs employed in decision making. It is thus not surprising that it is hard within the limited time available in a consultation to establish a concordance between the physician and the patient about the benefits and harms associated with different treatment alternatives.

Easier access to information through patient organizations, traditional media, and new information sources, including the Internet, have helped to empower the patient. The interaction between the physician and the patient is influenced not only by patients that have already formed an opinion before the consultation, but also when the physician expects that to be the case, whether it is true or not.

This was one of the reasons for choosing hormone treatment as an example when studying communication of benefits and harms with different treatment alternatives in health care. Decisions about hormone treatment against climacteric discomfort (HT) are made by women competent to make decisions, i. e. with a high autonomy. They are most often healthy, relatively well-informed
from different sources, and most often in their fifties. This made it probable that benefits and harms actually were discussed within the consultations. In addition, the ethical conflict of studying the consultations was easier to resolve when studying individuals competent to make decisions discussing questions that were not immediately life-threatening, as opposed to cancer treatment.

During the last few years the long-term benefits and risks with HT have been documented through large randomized controlled studies with long duration. These studies showed less benefits and higher risks than expected from the earlier studies and theoretical considerations. The results are summarized in a Cochrane review\textsuperscript{150} and have contributed to the major decrease in the use of HT internationally\textsuperscript{152, 155, 156}. After receiving information about the two pivotal studies HERS II\textsuperscript{140, 154} and WHI\textsuperscript{141} in 2002, many women either stopped, or did not start treatment with HT\textsuperscript{166-171}. Media reports have consistently been the most frequently reported source of information, although the relative importance (and thus impact) of different sources has not been well studied\textsuperscript{157}. The study results have confused many women\textsuperscript{165}, and many women have expressed a wish for more information about the risks and benefits with HT\textsuperscript{176, 177}. In 2005 a study calculating the population attributable risk based on the results from WHI estimated that 3,440 cases of breast cancer in Sweden during the nineties were caused by HT\textsuperscript{182}. This study was widely reported in the media. An accompanying editorial from the Medicinal Products Agency discussed some methodological problems with the study, but concluded that HT should only be used within the defined indications and during the shortest possible time\textsuperscript{183}.

In this thesis women in their early fifties and their conceptions of HT are studied. In the questionnaires the women were 53-54 years, and in the studied consultations the median age was 50.5 year (range 45-59). The two pivotal studies in 2002 did however not study the risks and benefits for these women. The study HERS II\textsuperscript{140, 154} included postmenopausal women younger than 80 years with established coronary disease who had not had a hysterectomy. The average age at inclusion was 67 years (range 44-79), and the mean follow-up time was 6.8 years. In WHI\textsuperscript{141} postmenopausal women 50-79 years were included. The average age at screening was 63 years and the mean follow-up time was 5.2 years. The study was stopped early by the safety monitoring board because the evidence for breast cancer harm, along with evidence for some increase in coronary heart disease, stroke, and pulmonary embolism out-
weighed the evidence of benefit for fractures, and possible benefit for colon cancer over the average 5.2-year follow-up period. Thus the reported increase in absolute risk for breast cancer, and for other side effects, were findings among women significantly older than most women entering the menopause.

There was a marked discrepancy between the low use of HT among women in general, and the high use among female gynaecologists, and female partners to gynaecologists, in Sweden, both in 1996 and 2003\(^\text{184}\). This makes it probable that the deciding factor whether or not to use HT is the woman’s attitude towards HT. This attitude will influence both her willingness to discuss treatment with HT, to accept a prescription, and to have that prescription dispensed at the pharmacy; not to mention to actually take the drug as prescribed. The knowledge of the existence of such a difference in attitudes towards HT, with many women sceptical against HT, might very well influence the interaction between women and physicians.

**Papers I, II & III**
The first three papers of this thesis focus on the interaction between twenty otherwise healthy women with their five physicians during consultations with the specific aim of discussing climacteric discomfort and/or HT. These consultations took place before the results from HERS II\(^\text{140, 154}\) and WHI\(^\text{141}\) were known. They can be described as best-case scenarios. The participating women were healthy, had initiated the consultation with the specific aim to discuss a specific issue, and thus probably were relatively well-informed beforehand. The way of recruiting the women, by scanning for appointments for discussion of treatment of climacteric discomfort, probably biased the sample towards active women actively searching for information, and perhaps already planning to use HT. The women might also have received information about HT in earlier consultations with the same or another physician.

The women and the physicians had volunteered to participate and were informed about the nature and objectives of the investigation (see Methods, page 51). This might have biased the findings in two ways. First of all, knowledge of the objectives of the study might have made the physicians and/or the women more focused on the process of communicating the risks and benefits with HT. As a consequence more time might have been used to discuss both HT and the alternatives. This knowledge might also have made the physicians abandon their usual strategies. In addition, the studying of the interaction between the women and the physicians could have influenced the consulta-
tions in a positive way by the attention given to the participants and their roles – a Hawthorne effect.\(^\text{185}\)

The field observation considered of a non-participatory observation. The consultations were audio-taped, except during the gynaecological examination. The physician had been instructed to refrain from discussing risks and benefits during this phase of the consultation. Thus all risk discussion ought to have been captured, but the discussion might have been biased by the fact that the physicians and the women could not interact freely during the whole consultation. The presence of a tape-recorder in the consultation room might have influenced the interaction. The use of a tape-recorder also means that other types of interaction, such as visual cues were overlooked. The use of a broad transcription format (as described in the Methods section), and comparison with the audio-tapes individually by all of the three authors directly involved with the analytical process, minimized the risk of missing vital parts of the spoken communication.

The purpose of sampling in a quantitative study is usually to study a randomly selected, and thus representative, subsection of a precisely defined population in order to make inferences about the whole population. In a qualitative study the aim is not to have a statistically representative sampling since it would lead to a vast data set with an obvious risk of the analysis becoming superficial instead.\(^\text{186}\) Instead, the exploratory nature of qualitative research requires a sampling to cover a range of participants or situations with different views and reactions. A common method is to continue the sampling and analysis until no new structures emerges in the analysis, i.e. until the dataset is saturated. The question of whether or not it is possible to infer the findings from one isolated study to a larger population is referred to as generalizability (or external validity). In quantitative research this is handled mainly by statistical methods. Findings from qualitative studies might need to be further analysed through different techniques such as combining qualitative research with quantitative studies, and/or different sampling procedures such as purposive sampling.\(^\text{187}\)

The term validity in qualitative research stands for truth, or to which extent an account accurately represents the social phenomena to which it refers.\(^\text{187-189}\) In other words, whether the researchers have based their findings on a critical investigation of all available data, or presented anecdotes that do not describe or fit the complete dataset. There are different techniques to handle the
question of validity, or trustworthiness, in qualitative research. Lincoln & Guba have listed four specific criteria that ought to be addressed: credibility, transferability, dependability, and conformability. The main focus on the different techniques are to try as convincingly as possible to refute the findings described, either through the studied dataset or through triangulation where different kinds of data and different methods are compared in order to corroborate each other. This is however not always achievable, due to lack of time and resources. A variant of this technique is the constant comparative method where the researcher always should attempt to find another case through which a provisional hypothesis could be tested, and if rejected reformulated. While a small number of cases support the hypothesis, one negative case disproves it and the cycle of examination of cases, redefinition of the phenomenon, and reformulation of hypotheses is then repeated until the final hypothesis is accepted within the total dataset studied. The constant comparative method stresses the use of the total dataset, i.e. a comprehensive data treatment. Within quantitative studies the researcher search for statistically and clinically significant, non-spurious correlations and is satisfied if most or nearly all of the data support (doesn't reject) the hypothesis. In qualitative research on the other hand, the findings ought to be relevant to all data collected. This means that deviant-case analysis is an important tool in order to prove the validity of the findings.

An important distinction when considering the validity of the research is the difference between the analytical study results and the description of the dataset. The latter, is by nature often qualitative – number of participants, word count, phases in the consultation, time sequence for different discussions and decisions, number of different types of risk communication etc. These data are presented in order to give a description of the dataset, not to infer conclusion about how these dimensions are present in the health care, nor to draw any conclusions about statistically significant differences within the dataset. Traditional statistical techniques are not relevant since the sampling technique doesn't strive neither to achieve statistical power, nor to have a statistically random subset of the situations studied, but rather to find a dataset where many important different situations are represented.

Another technique used to validate qualitative studies is respondent validation where the tentative results are presented to the participants in order to be further refined by the participants’ reactions. Respondents can of course describe
In this study five physicians (two male, three female), all specialist-trained gynaecologists, participated. The analysis showed distinctive differences between the physicians in how risk was communicated, especially in relation to benefits and alternative treatments. The five physicians could be divided into four different groups, see Results/Risk classification, page 62. Physicians often dominate consultations and this was the case in these consultations also. Thus one could argue that the study covers not twenty consultations, but four or five types of consultations when considering risk communication. The number of physicians, and not the number of consultations (or participating women), should therefore be considered the main limiting factor in this analysis. Even though few new structures emerged in the latter consultations this probably would not have been true with more participating physicians and/or other types of consultations included. First of all, it is reasonably to assume that there are other types of strategies present in the real world since we detected at least four different strategies when classifying risk communication according to the context among the five participating physicians. Secondly, not all HT treatments are initiated by specialist-trained gynaecologists. Thirdly, not all physicians working at gynaecological policlinics are specialist-trained. Fourthly, most decisions to start treatment with HT are probably not made in consultations with this as the sole purpose for the consultation.

The physicians’ tendency to avoid the term risk and instead use other terms such as drawback is in agreement with earlier findings. It is also in accordance with Hollnagel who recommends avoiding value laden words as risk and chance in exchange for absolute estimates of the risk reduction. The variation between the women’s description of the benefits and risks with HT after the consultations was high. This is not surprising since the women had different social and cultural backgrounds, had different symptoms, and probably had different preconceived conceptions of HT, of drugs in general, and of the menopause.

There was ample time during the consultations to address the issue of the menopause, disorders related to the menopause, and different treatment alternatives. The consultations also scored high on identifiable criteria for informed consent with in average 4.0 out of 7 elements identified. In Braddock’s original study fifty decisions about new medication were identified, and for
these decisions the mean number of elements discussed was 1.4. The validity of Braddock’s result has however been questioned since Braddock’s strategy for data collection might have made physicians with previous malpractice claims over-represented\textsuperscript{195}.

In several of the consultations the risk discussion either preceded or continued after the decision to treat had been made and expressed by either the physician or the woman. The consultations were few and thus chance alone could explain this finding. The finding does support the interpretation of the rhetorical strategies of the physicians as a selling strategy trying to overcome either a lack of knowledge and/or different attitudes among the women towards HT. This is in accordance with the finding that the use of HT was much more widespread among female gynaecologists (71\%), and partners to male gynaecologists (68\%) with climacteric discomfort, than among Swedish women in general with climacteric discomfort\textsuperscript{156}. There are however other equally possible, and perhaps concurrent, explanations for this finding. The decision to treat could have been interpreted by the physicians and/or the women as a proposition to treat, open to rejection later in the consultation, and not an actual decision. The women could also have been seeking reassurance in a decision already made by them by taking initiative, either through direct questions or other cues perhaps not captured by the audio-recording, later in the consultation, thereby starting a new discussion about possible benefits and harms. Likewise, the physicians could initiate a new discussion as a strategy to forestall the need for such reassurance, or to inform the women more thoroughly.

The classification of risk into four different groups depending on the context (risk\textsubscript{A} through risk\textsubscript{D}, see Paper II) was easy to accomplish and showed a good inter-observer reliability. The inter-observer agreement was good (Cohen’s kappa 0.78) for the most critical concept, classification of different benefits and risks associated with HT mentioned and agreed upon in the consultations, and expressed by the women in the interviews. This has to be seen only as a description of the inter-rater reliability within the current research project. The intra-rater, as well as the inter-rater reliability, ought to be tested in different data sets in order to be considered evaluated. The classification helped to describe the structure of the consultations, especially when identifying the physicians’ different strategies for risk discussion.
An essential question when assessing a questionnaire study is whether the respondents understood the questions posed and the response alternatives given. The questions used to study the women’s estimation about risks and benefits with HT were part of a questionnaire validated in three consecutive steps (see Material and Methods), and with a good test-re-test stability with Cohen’s kappa.

Risk is a different variable to handle in surveys. First of all, it is not well defined in the ordinary vocabulary and therefore the respondent might misinterpret the question posed. Secondly, risk can be either subjective or objective, i.e. referring to your own risk or your perception of the average person’s risk. Thirdly, risk is either a simple variable equal to the probability, or a compound variable which is a function of both probability for and the magnitude of the consequences of different outcomes. Finally, words describing different levels of likelihood or risk might mean something quite different for another person. Careful wording and validation of both the question and the anchor-points or alternatives is thus of utmost importance. Otherwise the survey may measure something else than it is supposed to measure.

There are principally three different alternatives when recording the respondents answer in quantitative studies of risk estimation.

1. Direct estimation of the magnitude, such as for instance visual analogue scale and adjectival scales (Likert, semantic differential scale).
2. Comparative methods where the respondent choose among different alternatives representing different levels of risk.
3. Econometric methods such as standard gamble and time tradeoff, where the respondent anchor their preference to extreme states, for instance perfect health – death.

The alternatives have different pros and cons. While direct estimation techniques are simple and quick ways of constructing, validating and administering a survey, the ordinal nature of the scale is often obvious and undesirable. With a comparative method the ordinal nature might be obscured, but such questionnaires are more time-consuming to construct and validate. Econometric methods assume that under conditions of uncertainty people will act rationally and make rational choices. There are however several problems, including framing, with using the state of death as an anchor-point.

In this study the respondents were asked to estimate the risk directly by using
a discrete ordinal scale with adjectival descriptions. The choice of not only the method but also scales, not to mention different wordings of anchor points and discrete alternatives, might influence the level and accuracy of the answers. So does the statistical method when analyzing the result. In this study the data was collected with a discrete ordinal scale and therefore non-parametric statistical methods were used for the main analyses.

A postal questionnaire in Swedish will lead to an under-representation of women from other cultures and other mother-tongues, as well as analphabetic women and women with dyslexia. The questionnaire was a follow-up of an earlier study on symptoms associated with the menopause. It included all eligible women in Linköping community and the response rates were high (74% and 77%) after only one reminder.

In the questionnaire of 1999 menopause status was assessed through several compounded questions in congruence with an earlier questionnaire. This lead to a relatively high degree of incongruent answers from women who subsequently were excluded (n=118). In 2003 the question about menopause status was changed in order to make it easier to answer correctly. This probably explains the statistically significant difference in menopause status (79.2% vs. 75.7% postmenopausal), Table 1, Paper IV. The way of selecting the women (all women in the age group in a defined community); the high response rate with only one reminder; the high concordance between reported use of HT and dispensed prescriptions of HT to the sampled group of women all support our assumption that the groups in 1999 and 2003 were representative samples of the population, and that the difference in menopause-status was an artefact. In addition, the concordance between the reported use of HT in 1999 and 2003 and the levels and profound change in dispensed prescriptions for the same age group of women in Sweden supports the assumption that the sample was representative for Swedish women in the same age group, and the difference in menopause-status an artefact.

For the studied time period the available data in the national prescription database at the National Corporation of Swedish Pharmacies could not identify the number of individuals treated. The number of treated individuals had to be estimated by using the unit Defined Daily Dose, DDD, as defined in 2005.
Two assumptions were made:

1. that the defined daily dose equalled the average consumed daily dose
2. that women who filled their prescriptions also took their dispensed HT

The first assumption was deemed valid since most products within HT (as defined in appendix II) has only one recommended daily dose which coincides with the DDD. The second one could be questioned. However, even though there is lot of evidence that dispensed prescriptions not always are consumed, in this case with long-term treatment it is reasonable to assume that a woman who stops taking HT will not fill her next prescription. Since the maximum time for which a prescription is dispensed within the Pharmaceutical Benefit Scheme is three months, and the recommended duration of treatment with HT is three to five years, this assumption would lead to an overestimation of in the worst case less than 10%.

The DDD is the assumed average maintenance dose per day for a drug used for its main indication in adults. It is a unit of measurement and does not necessarily reflect the recommended or the prescribed daily dose, PDD. HT can be prescribed in different doses and therefore it is possible that fear of oestrogen and its side effect might have led to reduced doses and a decrease in dispensed DDD. In addition, different products might have a different ratio between PDD and DDD and thus a switch between products might influence the number of DDD. Between first quarter 2000 and the third quarter 2003 the average DDD per dispensed prescription for women 53-54 years in Linköping decreased with 18 % (from 78 to 63 DDD/dispensed prescription) while the decrease in DDD per 1000 women was 50 %. Thus, a reduction in dose of HT could explain part of the reduction in DDD.

The decrease in use of HT in both the women answering the questionnaire, and women of the same age group living in Linköping, follows the national and international trend for the time period. Among the respondents opinion about risks and benefits associated with HT differed significantly between the questionnaires, with HT seen as a less beneficial and associated with a higher risk for complications in 2003 compared with 1999. These findings are consistent with another Swedish study of attitudes towards HT in the last decade among women 45-60 years of age. The reported use of natural remedies in 2003 was 6 %, an increase from 1 % in 1999. The number of previous users had also increased from 9.6 to 18 %. Whether this is a true increase in the use of natural remedies or a time-dependent factor in interpreting the term,
and/or a different attitude to the use of natural remedies in the society could be debated. The definition of natural remedies in Sweden changed in 1993, and as a consequence the use of the term by lay persons has changed slowly during the last decade.

The reported current or previous use of natural remedies against climacteric discomfort was higher in 2003 than in 1999. When interpreting the reliability of this result one has to consider that in 1999 the number of women who did not answer the question of natural remedies was higher than the number that used, or had used it (218 vs. 107). In 2003 the drop-out for this question was lower (92 vs. 282 current or previous users). The change doesn't have to be a result from a change in opinion about natural remedies since it may, at least in part, reflect the fact that fewer women had an effective treatment of their menopausal symptoms in 2003 (25.3 % current users vs. 40.5 %). Few women used, or had used acupuncture against climacteric discomfort both in 1999 and 2003.

News media reports about drugs have been shown to include inadequate or incomplete information about the benefits, risks, and costs of the drugs and about financial ties between cited experts and pharmaceutical manufacturers. A majority of the women had received information through media in the last twelve months before the questionnaire in 2003. Mass media such as newspapers, magazines, television or radio were the most common reported sources. Women with current use of HT reported having received information from health care personnel more often than women with previous use. The most plausible explanation for this is more opportunities for women under current treatment with HT to discuss their treatment with caregivers. Another explanation could be that women with HT are more active in seeking information about their treatment than women without HT.

The results are congruent with the results from review of women's opinions about HT and from a current survey with telephone interviews in Germany where women were more likely to continue HT (60.4 %) when they had received information about WHI only from physicians, compared with when mass media was the source of information (46.1 %).

Even though women with previous use of HT had received information from the Internet more often (8.0 %) than either current (3.4 %) or never users (3.8 %) the result is neither statistically, nor clinically, clearly significant. The actual number of women answering the question with yes were low (45 out of
1263) and 12 analysis were performed (table 5, paper IV). After a Bonferroni-correction for multiple analysis the achieved p-values would be too high for a strict interpretation of statistical significance\textsuperscript{208, 209}.

The questions about sources of information about HT were prone to recall bias. The women had to remember what kind of information they had received, when they had received it, and through which media channel. It was probably easier for women who had recently stopped or started taking HT, to remember when and where they received their information especially if that information had influenced their decision in either direction. It is also plausible to assume that information sources that the women deemed more relevant or easier to understand, were easier to remember and thus reported to a higher degree.
Conclusions

The conclusions from the studies included in this dissertation are:

1. A system for classifying how risk is communicated in relation to the benefits, and for different treatment alternatives, is possible to construct and could be used to describe different types of communication patterns in the consultations studied.
2. The validity and reliability of this system of classifying risk communication ought to be validated in another dataset.
3. Within the studied consultations the perspective of the physicians was mainly on prevention while the women were more focused on symptom alleviation.
4. Eight different rhetorical strategies by the physicians could be identified within the studied consultations.
5. Between 1999 and 2003 the use of HT in women decreased dramatically. This was in accordance with international trends.
6. The decreased use of HT correlated with pronounced changes in the opinion about risks and benefits with HT. Between 1999 and 2003, the opinion about benefits and risks of HT among Swedish women 53-54 years of age, changed significantly to HT being associated with both a higher risk and less benefits.
7. Media were a more frequent source of information about HT than health care personnel among women 53-54 years of age. The relative impact of different information sources was not studied.

Whether or not to use HT is a complex question that cannot easily be answered either by the woman, or the physician, or the woman and the physician in cooperation, without taking into consideration several issues:

- The woman’s and the physician’s knowledge, attitudes towards and beliefs about the menopause and HT.
- The slowly changing concept of patient-physician interaction into a more active partnership.
- The multitude of, and easy access to, information sources, and the media interest in questions relevant to a large audience.
- The changing evidence about short- and long-term effects of HT.
- How the menopause is perceived in the society.
• Basic theoretical concepts in the field of communication, especially within risk communication.
• Marketing and communication strategies of the manufacturers of HT, and other parties with vested interests in HT.
Reflections & future research

The consultations showed a high degree of patient involvement as measured by a specific instrument – elements of informed decision making. The interviews showed (even though this is not reported in the papers included in this thesis) that most of the women in the interviews expressed confidence in their treatment, satisfaction with the discussion, and that the physician had listened to their agenda. During the consultations several women raised other issues, not related to HT and thus not included in the analysis, which they hadn’t discussed earlier with health care professionals. My subjective and professional interpretation as a physician is that these consultations in fact were very good consultations.

Why then does the result from the studies show a gap between the ideal situation and the these consultations? First of all, when studying only the part of the consultations where the benefits and harms with different treatment alternatives are discussed, a lot of information about how the physician and the woman interact is lost. Secondly, there are alternative explanations to some of the findings, such as the order between the actual discussion to treat and the risk discussion. Thirdly, the different steps in an interaction cannot be completely separated from each other since they depend on each other. But the

Science is a grand thing when you can get it; in its real sense one of the grandest words in the world. But what do these men mean, nine times out of ten, when they use it nowadays? … They mean getting outside a man and studying him as if he were a gigantic insect: in what they would call a dry impartial light, in what I should call a dead and dehumanized light. … I don’t deny the dry light may sometimes do good; though in one sense it’s the very reverse of science. So far from being knowledge, it’s actually suppression of what we know. It’s treating a friend as a stranger, and pretending that something familiar is really remote and mysterious. … Well, what you call ‘the secret’ is exactly the opposite. I don’t try to get outside the man. I try to get inside …

From The Secret of Father Brown by G. K. Chesterton

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main explanation might very well be that the ideal communication is hard to achieve within the limited time available in a consultation, and that the woman (or patient) doesn’t expect something even close to that. Both patients and physicians have earlier experiences about what to expect of the health care, and this probably influence their satisfaction with the consultation. This probably is the case with me as a subjective observer too.

If we accept that shared decision making is not only a legal requisite but also a tool to ensure concordance, and thus a successful treatment – and if we assume that a thorough communication of benefits and harms of different treatment alternatives are necessary to achieve shared decision making – then we have to search for a solution that is possible to achieve in daily practice. A first step would to be to discuss solutions to decisions about short-term and long-term (or several years of) treatment separately. When the treatment continues for a long period, perhaps even for the rest of the life, then it is extra important to find time to discuss the different treatment alternatives in detail. One way to achieve this is to see risk communication as a process that starts before, and continues after the consultation. Another option is better collaboration between different groups of health care professionals.

The finding that these consultations to a high degree were driven by the physicians’ agenda is not surprising considering that the physician is supposed to dominate the information exchange. If physicians can acknowledge that they already are agenda-driven to a high degree, then it might be easier for them to accept to use a decision aid in the consultation. Such a strategy might indeed give the physician more freedom to respond to concerns voiced by the patient. A structured agenda for the main issue would probably be easier to deviate from than a personal and informal one, since there would be less risk of forgetting important part of the information with a such a decision aid.

The change in the women’s opinion about HT was pronounced and seems to have influenced the use in the population to a higher degree than the relative small revisions of guidelines, or the small change in the attitudes among gynaecologists. One explanation for this discrepancy might be that the scientific studies included women on average 10-15 years older at inclusion, than women entering the menopause. The long-term effects among the women in the studies are not easily transferred to the current Swedish guide-lines recommending short-term (less than five years) treatment of symptoms in women entering the menopause. Physicians’ knowledge about this difference in opinions about, and attitudes towards HT, might very well influence the
The introduction of an electronic version of the SCORE risk charts, the HeartScore®, by the European Society of Cardiology raises new possibilities but also new concerns. The vision expressed by the Society that at the end of the consultation, the clinician may print an individual’s health advice based on their actual risk profile raises the questions about how the patient will perceive the information given, and how this tool will influence the consultations and thus concordance.

In conclusion, a deeper understanding of the concept of risk is needed in order to achieve an effective communication of risk, both in consultations and in campaigns to educate and inform the public about health care.
I wish to express my sincere gratitude to all those who generously have contributed to this thesis. I particularly want to express my thanks to:

The 2637 women in Linköping answering the questionnaires, and the 21 women and 5 doctors who generously agreed to have their interaction studied, and in addition took the time to be interviewed afterwards.

My supervisor, Karin Kjellgren, for your unfailing enthusiasm, your wide knowledge in the field of communication, and your ability to help me stay focused on the patient.

My associate supervisor professor, Johan Ahlner, for recruiting me to the department of clinical pharmacology, thereby not only introducing me into the world of pharmacology and critical assessment but also giving me time to reflect on issues important for me, such as the subject of this thesis.

My associate supervisor professor, Mats Hammar, for introducing me into the field of menopause and HT and for supporting me in all conceivable ways, including recruiting Alexander, Andreas, August, Martin and Olle who handled the questionnaires.

Lotta Lindh-Åstrand, my co-author, and brilliant research nurse who recruited, informed and interviewed the women. I wish you the very best luck with your own studies about the conceptions of menopause.

Professor Per Linell for your expertise and your analytical skills.

Dr Jan Brynhildsen, co-author and colleague, who helped devise the questionnaire study. Thank you for your skilled reflections and assistance with the writing. Dr Susanne Johansson for all assistance with the first questionnaire.

Professor emeritus Edgar Borgenhammar, Nordic School of Public Health, Gothenburg, for being there and giving the right impetus at the right time.

Professor Lennart Sjöberg, Center for Risk Research, Stockholm School of Economics, for generously assisting me several times in my early attempts to grasp the wide research area of risk.

Professor Curt Peterson and all my colleagues at the Department of Clinical Pharmacology for keeping up with me and my ideas and for supporting me.
through the years, and especially professor emerita Elisabeth Hamrin for all your support during this time.

Associate professor Peter Nilsson, Department of Clinical Sciences, Malmö, for constructive criticism and encouragement.

Johnny Dahlgren for assistance with the mysteries of printing a thesis, and Per Norberg for actually reading (most of) it.

Elinor Sviberg Carlberg for professional transcriptions of consultations and interviews.

Agnetha, Göran, Jonatan, Kjell and Micke at Läkemedelsgruppen for taking care of all the workload while I’ve been reading and writing.

My late father Witold for inspiring me. I’m sorry you couldn’t be here today. Thank you mother, Kristina and Anna-Maria, for being there all the time. Well, in the case of Anna-Maria, not for the first three years of my life.

All other relatives and friends who haven’t seen much of me lately.

Thank you Fredrik and Katrina for all the huggings and distractions. And first and finally all my love to Yvonne for minimizing the risks, and maximizing the benefits of love.

This thesis was supported by the Research Council of South-East Sweden (FORSS) and the County Council of Östergötland.
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Appendices

Appendix I
– Risk in MeSH (Medical Subjects Heading)

Medical subjects heading (MeSH) is National Library of Medicine’s controlled vocabulary used for indexing articles for MEDLINE / PubMed. In Medical Subjects Heading the term risk is defined as “the probability that an event will occur. It encompasses a variety of measures of the probability of a generally unfavorable outcome.” New terms within the area of risk have been introduced in the MeSH-structure during the last three decades.

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<thead>
<tr>
<th>Mesh term</th>
<th>Definition</th>
<th>Year first introduced</th>
<th>Revised year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk</td>
<td>The probability that an event will occur. It encompasses a variety of measures of the probability of a generally unfavorable outcome.</td>
<td>1975</td>
<td>1988</td>
</tr>
<tr>
<td>Risk-Taking</td>
<td>Undertaking a task involving a challenge for achievement or a desirable goal in which there is a lack of certainty or a fear of failure. It may also include the exhibiting of certain behaviors whose outcomes may present a risk to the individual or to those associated with him or her.</td>
<td>1975</td>
<td>1979</td>
</tr>
<tr>
<td>Risk Management</td>
<td>The process of minimizing risk to an organization by developing systems to identify and analyze potential hazards to prevent accidents, injuries, and other adverse occurrences, and by attempting to handle events and incidents which do occur in such a manner that their effect and cost are minimized. Effective risk management has its greatest benefits in application to insurance in order to avert or minimize financial liability. (From Slee &amp; Sleeve Health care terms, 2d ed)</td>
<td>1980</td>
<td>1990</td>
</tr>
<tr>
<td>Risk Factors</td>
<td>An aspect of personal behavior or lifestyle, environmental exposure, or inborn or inherited characteristic, which, on the basis of epidemiologic evidence, is known to be associated with a health-related condition considered important to prevent.</td>
<td>1988</td>
<td></td>
</tr>
<tr>
<td>Mesh term</td>
<td>Definition</td>
<td>Year first introduced</td>
<td>Revised year</td>
</tr>
<tr>
<td>---------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Risk/Logistic Models</td>
<td>Statistical models which describe the relationship between a qualitative dependent variable (that is, one which can take only certain discrete values, such as the presence or absence of a disease) and an independent variable. A common application is in epidemiology for estimating an individual's risk (probability of a disease) as a function of a given risk factor.</td>
<td>1990</td>
<td></td>
</tr>
<tr>
<td>Risk Assessment</td>
<td>The qualitative or quantitative estimation of the likelihood of adverse effects that may result from exposure to specified health hazards or from the absence of beneficial influences. (Last, Dictionary of Epidemiology, 1988)</td>
<td>1995</td>
<td></td>
</tr>
<tr>
<td>Pregnancy, High-Risk</td>
<td>Pregnancy in which the mother and/or fetus are at greater than normal risk of morbidity or mortality. Causes include inadequate prenatal care, previous obstetrical history (abortion, spontaneous), pre-existing maternal disease, pregnancy-induced disease (gestational hypertension), and multiple pregnancy, as well as advanced maternal age above 35.</td>
<td>1995</td>
<td></td>
</tr>
<tr>
<td>Risk Sharing, Financial</td>
<td>Any system which allows payors to share some of the financial risk associated with a particular patient population with providers. Providers agree to adhere to fixed fee schedules in exchange for an increase in their payor base and a chance to benefit from cost containment measures. Common risk-sharing methods are prospective payment schedules (prospective payment system), capitation (capitation fees), diagnosis-related fees (diagnosis-related groups), and pre-negotiated fees.</td>
<td>1999</td>
<td></td>
</tr>
</tbody>
</table>
Risk as a MeSH-term is indexed within four categories, see figure. There are three direct underheadings to the term “Risk”: “Logistic models”, “Risk factors” and “Risk assessment”. Within the “Health Care Category” the term “Risk assessment” is further indexed into “Risk adjustment”.

<table>
<thead>
<tr>
<th>Mesh term</th>
<th>Definition</th>
<th>Year first introduced</th>
<th>Revised year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk</td>
<td>The use of severity-of-illness measures, such as age, to estimate the risk (measurable or predictable chance of loss, injury or death) to which a patient is subject before receiving some health care intervention. This adjustment allows comparison of performance and quality across organizations, practitioners, and communities. (from JCAHO, Lexikon, 1994)</td>
<td>1999</td>
<td></td>
</tr>
<tr>
<td>Risk Adjustment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk Reduction</td>
<td>Reduction of high-risk choices and adoption of low-risk quantity and frequency alternatives.</td>
<td>2003</td>
<td></td>
</tr>
<tr>
<td>Behavior</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Behavioral Risk Factor</td>
<td>Telephone surveys are conducted to monitor prevalence of the major behavioral risks among adults associated with premature morbidity and mortality. The data collected is in regard to actual behaviors, rather than on attitudes or knowledge. The Centers for Disease Control and Prevention (CDC) established the Behavioral Risk Factor Surveillance System (BRFSS) in 1984.</td>
<td>2003</td>
<td></td>
</tr>
<tr>
<td>Surveillance System</td>
<td></td>
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</tbody>
</table>

Risk: The use of severity-of-illness measures, such as age, to estimate the risk (measurable or predictable chance of loss, injury or death) to which a patient is subject before receiving some health care intervention. This adjustment allows comparison of performance and quality across organizations, practitioners, and communities. (from JCAHO, Lexikon, 1994)
Analytical, diagnostic & therapeutic techniques & equipment category

Investigative techniques

Biological sciences category

Environment and public health

Natural sciences category

Public health

Natural sciences

Biological sciences category

Epidemiological methods

Physical sciences category

Statistics

Health care category

Probability

Health care quality, access & evaluation

Risk

Natural sciences

Logistic models

Mathematics

Risk factors

Risk assessment

Risk adjustment
### Appendix II

– Hormone therapy in the menopausal transition in Sweden

Hormone therapy in the menopausal transition in Sweden in 2004 according to the Medical Products Agency

**Oestrogens**

<table>
<thead>
<tr>
<th>Name</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>oestradiol</td>
<td>G03 A03</td>
<td>Climara® transdermal system</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Divigel® transdermal gel</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Estraderm®/Estraderm® Matrix transdermal system</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Estradot® transdermal system</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Evorel® transdermal system</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Femane® tablets</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Femseven® transdermal system</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Menorest® transdermal system</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Oesclim® transdermal system</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Progynon® tablets</td>
</tr>
<tr>
<td>oestriol †</td>
<td>G03 A04</td>
<td>Premaria® tablets</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Oestro® tablets</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ovesterin tablets</td>
</tr>
<tr>
<td>oestradiol †</td>
<td>G03 A03</td>
<td>Oestring® vaginal ring</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Vagifem® vaginal tablets</td>
</tr>
<tr>
<td>(low dose for local urogenital symptoms)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>conjugated estrogens</td>
<td>G03 A57</td>
<td>Gestapuran® tablets</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Provera® tablets</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Livial® tablets</td>
</tr>
<tr>
<td>medroxyprogesteron</td>
<td>G03 A02</td>
<td>Activelle® tablets</td>
</tr>
<tr>
<td>tibolon*</td>
<td>G03 C05</td>
<td>Estalis® transdermal system</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Femane® tablets</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Kliogest® tablets</td>
</tr>
<tr>
<td>noretisteron + oestradiol</td>
<td>G03 F01</td>
<td>Cliniom® tablets</td>
</tr>
<tr>
<td>dienogest + oestradiol</td>
<td>G03 F15</td>
<td>Indivina® tablets</td>
</tr>
<tr>
<td>medroxyprogesteron + oestradiol</td>
<td>G03 F12</td>
<td>Premelle® tablets</td>
</tr>
<tr>
<td>oestrogens</td>
<td></td>
<td></td>
</tr>
<tr>
<td>trimegeston + oestradiol</td>
<td>G03 F11</td>
<td></td>
</tr>
</tbody>
</table>

*Note: † indicates low dose for local urogenital symptoms.*
<table>
<thead>
<tr>
<th>Progestagen + oestrogen in combination, sequential administration</th>
<th>ATC code</th>
<th>Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>noretisteron + oestradiol</td>
<td>G03F B05</td>
<td>Estalis® Sekvens transdermal system</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Estracomb® transdermal system</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Femasekvens® tablets</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Novofem® tablets</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Trisekvens® tablets</td>
</tr>
<tr>
<td></td>
<td></td>
<td>G03F A01</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Evorel® Micronor transdermal system + tablets</td>
</tr>
<tr>
<td>levonorgestrel + oestradiol</td>
<td>G03F B09</td>
<td>Cyclabil tablets</td>
</tr>
<tr>
<td>medroxyprogesteron + oestradiol</td>
<td>G03F B06</td>
<td>Divina®/Divina® Plus tablets</td>
</tr>
<tr>
<td>medroxyprogesteron + conjugated oestrogens</td>
<td>G03F B06</td>
<td>Trivina® tablets</td>
</tr>
<tr>
<td>trimegeston + oestradiol</td>
<td>G03F B11</td>
<td>Premelle® Sekvens tablets</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Totelle® Sekvens/Totelle® Sekvens Mite tablets</td>
</tr>
</tbody>
</table>

* tibolon is classified as progestagen according to the ATC-classification, but has also oestrogen effects and is used on the same indication as progestagens + oestrogens in combination.
† products are not included in oral and transdermal oestrogen, and oestrogen-progestin combinations with a registered indication of supplemental treatment during menopause as defined in paper IV
Appendix III – Questionnaire 2003

Enkät kring övergångsåldern och östrogenbehandling.

Vi är mycket tacksamma om Du fyller i nedanstående frågor så noga du kan. Använd kulspetsspenna och markera med ett tydligt kryss i rutan. Om Du ändrar Dig, fyll då i hela rutan med färg och sätt ett tydligt kryss i den ruta som är den rätta.

Frågeformuläret består av 3 delar. Först kommer några frågor om Dig och Din bakgrund. Sedan följer några kunskapsfrågor om övergångsåldern och slutligen kommer frågor om kunskaper om hormonbehandling mot övergångsbesvär.

Din bakgrund

1. Vilken skolutbildning har Du?
   Ange den högsta helt genomförda utbildning?
   - Grundskola, folkskola
   - Gymnasieutbildning
   - Universitets- eller högskoleutbildning

2. Vilket är Ditt modersmål?
   - Svenska
   - Annat nordiskt språk
   - Annat språk

3. Röker Du varje dag?
   - Ja
   - Nej

4. Var bor Du?
   - I tätort/stad
   - På landsbygd

5. Vilket är Ditt civilstånd
   - Gift/sambo
   - Lever ensam utan partner
   - Särbo

6. Är Du för närvarande?
   - Förvärvsarbetande, hel- eller deltids
   - Hemarbetande
   - Sjukskriven/sjukpensionär
   - Studerar/arbetssökande

165
7. Har Du opererat bort Din livmoder?

☐ Ja
☐ Nej
☐ Vet ej

8. Har Du opererat bort båda äggstockarna?

☐ Ja
☐ Nej
☐ Vet ej

9. Har Du mensblödningar?

☐ Ja, jag har regelbunden “naturlig” mens (= blödning ungefär varje månad) eller blödningar p.g.a. östrogenbehandling
☐ Ja, jag har gles eller oregelbunden mens och senaste blödningen hade jag för mindre än 12 månader sedan.
☐ Nej, jag har inte haft någon blödning de senaste 12 månaderna och mensen slutade ”naturligt”.
☐ Nej, jag har inte haft någon blödning de senaste 12 månaderna eftersom jag opererat bort livmodern.
☐ Nej, jag har inte haft någon blödning de senaste 12 månaderna eftersom jag använder hormonspiral eller annat preventivmedel som tar bort mensen.

10. Använder Du eller har Du använt östrogen i samband med övergångsåldern?

Med östrogen avses östrogenbehandling med tabletter, plåster eller gel men INTE lokalbehandling i slidan eller behandling med Ovesterintabletter. OBS, ange endast ett alternativ!

☐ Nej, jag har aldrig använt östrogen i samband med övergångsåldern.
☐ Ja, jag använder eller har använt östrogen huvudsakligen pga. vallningar och svettningar
☐ Ja, jag använder eller har använt östrogen huvudsakligen pga. nedstämdhet.
☐ Ja, jag använder eller har använt östrogen huvudsakligen pga. sömnproblem.
☐ Ja, jag använder eller har använt östrogen huvudsakligen för att förebygga benskörhet.
☐ Ja, jag använder eller har använt östrogen huvudsakligen pga. annan orsak.
11. Behandlas Du för närvarande med östrogen?

Med östrogen avses östrogenbehandling med tabletter, plåster eller gel men INTE lokalbehandling i slidan eller behandling med Österintabletter.

☐ Ja – gå vidare till fråga 18 men ange först namnet på Ditt Östrogenpreparat:

☐ Nej

Om Du svarade NEJ på ovanstående fråga:

12. Har Du behandlats tidigare med östrogen?

☐ Ja

☒ Nej – gå vidare till fråga 18

Om Du svarade JA på ovanstående fråga:

13. När slutade Du med östrogen?

☐ <12 månader sedan

☐ 12-24 månader sedan

☐ >24 månader sedan

14. Under hur många år använde Du östrogen?

Under ☐ år.

15. Hade Du övergångsbesvär i form av svettningar/värmevallningar innan Du började med östrogen?

☐ Ja

☒ Nej – gå vidare till fråga 17

Om Du svarade JA på ovanstående fråga:

16. Återkom svettningar/värmevallningar när Du slutade med östrogen?

☐ Ja, men mindre besvär än när jag började med östrogen.

☐ Ja, lika mycket besvär som när jag började med östrogen.

☐ Ja, mer besvär än i när jag började med östrogen.

☐ Nej, besvären med svettningar/värmevallningar kom inte tillbaka.
17. Varför slutade Du med östrogenbehandling?

Ange ditt **viktigaste** skäl att sluta! Sätt kryss i EN ruta.

- Fick rådet av min läkare att sluta behandlingen
- Fick rådet av annan person än min läkare att sluta behandlingen
- Provade själv att sluta med östrogen och fick inte tillbaka besvär
- Blev orolig för risken att få biverkningar och slutade
- Fick biverkningar och slutade
- Fick inte tag i läkare att få nytt recept från och slutade därför med östrogen
- Annan orsak gjorde att jag slutade

**OBS, denna fråga skall besvaras av alla!**

18. Har Du haft biverkning som Du kopplat till att Du använt östrogen? **OBS: Kryssa för de biverkningar du haft (Du kan kryssa i flera rutor)!**

- Har aldrig använt östrogen.
- Inte haft biverkningar av östrogen.
- Oönskade blödningar
- Bröstspänningar
- Viktökning
- Svullnadskänsla
- Påverkan på humöret
- Blodpropp
- Bröstcancer
- Kärlkram eller hjärtinfarkt
- Annan biverkan, i så fall vad?

**OBS, denna fråga skall besvaras av alla!**


- Inte oroat mig för biverkningar av östrogen.
- Oönskade blödningar
- Bröstspänningar
- Viktökning
- Svullnadskänsla
- Påverkan på humöret
- Blodpropp
- Bröstcancer
- Kärlkram eller hjärtinfarkt
- Annan biverkan, i så fall vad?


- Aldrig
- Provat men slutat
- Använder idag
- Effekt
- Ej effekt

Naturläkemedel
- Vagitorier/kräm (Vagifem, Dienoestrol, Ovesterin, Estring)
- Ovesterin tabletter
- Akupunktur

Del 2- Kunskaper om övergångsåldern. Här ber vi Dig ange vad Du tycker eller tror.

21. Hur stor är sannolikheten för en kvinna i övergångsåldern att uppleva värmevallningar eller svettningar?

Sätt ett kryss i den ruta som bäst överensstämmer med din åsikt

- Ingen
- Mycket liten
- Liten
- Ganska liten
- Måttlig
- Ganska stor
- Stor
- Mycket stor
- Alla drabbas

22. Hur stor är sannolikheten för en kvinna i övergångsåldern att få blodpropp?

Sätt ett kryss i den ruta som bäst överensstämmer med din åsikt

- Ingen
- Mycket liten
- Liten
- Ganska liten
- Måttlig
- Ganska stor
- Stor
- Mycket stor
- Alla drabbas

23. Kvinnor i övergångsåldern upplever ofta värmevallningar och/eller svettningar

- Ja
- Nej
- Vet ej

<table>
<thead>
<tr>
<th></th>
<th>Aldrig provat</th>
<th>Provat men slutat</th>
<th>Använder idag</th>
<th>Effekt</th>
<th>Ej effekt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naturläkemedel</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vagitorier/kräm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Vagifem, Dienoestrol, Ovesterin, Estring)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ovesterintabletter</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Akupunktur</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Del 2- Kunskaper om övergångsåldern. Här ber vi Dig ange vad Du tycker eller tror.

21. Hur stor är sannolikheten för en kvinna i övergångsåldern att uppleva värmevallningar eller svettningar?

Sätt ett kryss i den ruta som bäst överensstämmer med din åsikt

<table>
<thead>
<tr>
<th></th>
<th>Ingen drabbas</th>
<th>Mycket liten</th>
<th>Liten</th>
<th>Ganska liten</th>
<th>Måttlig</th>
<th>Ganska stor</th>
<th>Stor</th>
<th>Mycket stor</th>
<th>Alla drabbas</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

22. Hur stor är sannolikheten för en kvinna i övergångsåldern att få blodpropp?

Sätt ett kryss i den ruta som bäst överensstämmer med din åsikt

<table>
<thead>
<tr>
<th></th>
<th>Ingen drabbas</th>
<th>Mycket liten</th>
<th>Liten</th>
<th>Ganska liten</th>
<th>Måttlig</th>
<th>Ganska stor</th>
<th>Stor</th>
<th>Mycket stor</th>
<th>Alla drabbas</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

23. Kvinnor i övergångsåldern upplever ofta värmevallningar och/eller svettningar

☐ Ja
☐ Nej
☐ Vet ej
24. Vad händer vanligen med kvinnors vikt i övergångsåldern?
- □ Vikten ökar
- □ Vikten minskar
- □ Vikten ändras inte
- □ Vet ej

25. Övergångsåldern beror på minskad östrogenproduktion.
- □ Ja
- □ Nej
- □ Vet ej

26. Östrogen – det viktigaste kvinnliga könshormonet, bildas framför allt i?
- □ Äggstockarna
- □ Livmodern
- □ Vet ej

27. Menstruationsblödningar slutar i övergångsåldern eftersom?
- □ Äggstockarna slutat att fungera
- □ Livmodern åldras
- □ Vet ej
Del 3 – Kunskaper om östrogenbehandling i övergångsåldern

28. Östrogen har både positiva effekter och biverkningar. Hur ser Du på östrogenbehandling hos en kvinna i övergångsåldern?

Sätt ett kryss i den ruta som bäst överensstämmer med din åsikt

<table>
<thead>
<tr>
<th>I huvudsak</th>
<th>Nackdelar</th>
<th>Varken bra eller dåligt</th>
<th>I huvudsak fördelar</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

29. Vid östrogenbehandling i övergångsåldern – hur stor är NYTTAN för kvinnor i allmänhet?

Sätt ett kryss i den ruta som bäst överensstämmer med din åsikt

<table>
<thead>
<tr>
<th>Obefintlig nytta</th>
<th>Mycket liten</th>
<th>Liten</th>
<th>Ganska liten</th>
<th>Måttlig</th>
<th>Ganska stor</th>
<th>Stor</th>
<th>Mycket stor nytta</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

30. Vid östrogenbehandling i övergångsåldern – hur stor är RISKEN för besvär (biverkningar)?

Sätt ett kryss i den ruta som bäst överensstämmer med din åsikt

<table>
<thead>
<tr>
<th>Obefintlig risk</th>
<th>Mycket liten</th>
<th>Liten</th>
<th>Ganska liten</th>
<th>Måttlig</th>
<th>Ganska stor</th>
<th>Stor</th>
<th>Mycket stor risk</th>
</tr>
</thead>
<tbody>
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</tr>
</tbody>
</table>

31. Hur bedömer Du att risken är för en kvinna i övergångsåldern, som använder östrogenbehandling, att drabbas av bröstcancer jämfört med en kvinna utan östrogenbehandling?

☐ Ökad risk
☐ Oförändrad risk
☐ Minskad risk
☐ Vet ej
32. Hur bedömer Du att risken är för en kvinna i övergångsåldern, som använder östrogenbehandling, att drabbas av blodpropp jämfört med en kvinna utan östrogenbehandling?

☐ Ökad risk
☐ Oförändrad risk
☐ Minskad risk
☐ Vet ej

33. Hur bedömer Du att risken är för en kvinna i övergångsåldern, som använder östrogenbehandling, att drabbas av hjärtinfarkt jämfört med en kvinna utan östrogenbehandling?

☐ Ökad risk
☐ Oförändrad risk
☐ Minskad risk
☐ Vet ej

34. Hur bedömer Du att risken är för en kvinna i övergångsåldern, som använder östrogenbehandling, att drabbas av benskörhet jämfört med en kvinna utan östrogenbehandling?

☐ Ökad risk
☐ Oförändrad risk
☐ Minskad risk
☐ Vet ej

35. Om en kvinnas mensblödningar har upphört MEN återkommer vid behandling med östrogen i övergångsåldern – kan hon då bli gravid?

☐ Ja
☐ Nej
☐ Vet ej

36. Östrogenbehandling i övergångsåldern fungerar som ett preventivmedel- dvs. en kvinna med östrogenbehandling behöver inte oroa sig för att bli gravid även om hon aldrig slutat menstruera då hon började med östrogenbehandling?

☐ Ja
☐ Nej
☐ Vet ej
37. Gulkroppshormoner används tillsammans med östrogenbehandling i övergångsåldern för att förstärka östrogenets effekt på värmevallningar och svettningar.

☐ Ja

☐ Nej

☐ Vet ej

38. Gulkroppshormoner används tillsammans med östrogenbehandling för att motverka att östrogenet stimulerar livmoderslemhinnan för kraftigt.

☐ Ja

☐ Nej

☐ Vet ej

39. Östrogenbehandling rekommenderas idag till alla kvinnor över 50 års ålder.

☐ Ja

☐ Nej

☐ Vet ej

40. Östrogenbehandling rekommenderas idag i huvudsak till kvinnor med övergångsbesvär.

☐ Ja

☐ Nej

☐ Vet ej

Har Du det senaste året fått ny kunskap om östrogenbehandling i övergångsåldern?

41. Har fått nya kunskaper från vårdpersonal t.ex. läkare, sköterska

42. Har fått nya kunskaper från anhöriga eller vänner.

43. Har fått nya kunskaper från TV eller radio.

44. Har fått nya kunskaper från dags eller veckotidningar.

45. Har fått nya kunskaper från Internet.

46. Har fått ny kunskap från annat informationsmaterial t.ex. på apotek, i böcker mm.
47. Hur uppfattar Du att massmedia beskriver östrogenbehandling i övergångsåldern?

Sätt ett kryss i den ruta som bäst överensstämmer med hur du uppfattade rapporteringen

<table>
<thead>
<tr>
<th>I huvudsak</th>
<th>Varken bra eller dåligt</th>
<th>I huvudsak</th>
<th>Ingen uppfattning</th>
</tr>
</thead>
<tbody>
<tr>
<td>nackdelar</td>
<td></td>
<td>fördelar</td>
<td></td>
</tr>
</tbody>
</table>

48. Har rapportering i massmedia kring östrogenbehandlingen det senaste året påverkat Din syn på östrogenbehandling i övergångsåldern?

Sätt ett kryss i den ruta som bäst beskriver hur din uppfattning förändrats.

- Ja, till det sämre
- Nej, inte alls påverkat mig
- Ja, till det bättre

- Ej sett någon rapportering i massmedia

49. Har rapportering i massmedia kring östrogenbehandling i övergångsåldern det senaste året gjort att Du

- valt att börja med östrogenbehandling.
- övervägt att börja med östrogenbehandling.
- ej påverkat mitt beslut om östrogenbehandling
- övervägt att sluta med östrogenbehandling
- slutat med östrogenbehandling

- Ej sett någon rapportering i massmedia
Det finns många olika tankar och åsikter om övergångsåldern.

50. Hur ställer Du Dig till följande påståenden?

<table>
<thead>
<tr>
<th>Övergångsåldern är ett naturligt tillstånd</th>
<th>instämmer helt</th>
<th>instämmer delvis</th>
<th>varken delvis eller</th>
<th>tar delvis avstånd</th>
<th>tar helt avstånd</th>
</tr>
</thead>
<tbody>
<tr>
<td>I övergångsåldern har man brist på hormoner</td>
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<tr>
<td>Övergångsåldern är ett tecken på att man börjar bli gammal</td>
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<tr>
<td>Kvinnor med besvärliga symtom i övergångsåldern bör använda hormonbehandling</td>
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<tr>
<td>Övergångsåldern innebär mer frihet för kvinnan</td>
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<tr>
<td>Eftersom övergångsåldern innebär sjunkande östrogennivåer bör alla kvinnor använda hormonbehandling</td>
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<tr>
<td>Manliga partners till kvinnor i övergångsåldern ser dem som mindre tilldragande</td>
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<tr>
<td>Det är skönt att inte längre kunna bli gravid</td>
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<tr>
<td>En kvinna känner sig mindre kvinnlig efter att mannen upphört att tänka på preventivmedel</td>
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<td></td>
</tr>
<tr>
<td>Det är skönt att inte längre behöva tänka på preventivmedel</td>
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<td></td>
</tr>
<tr>
<td>När man använder hormonbehandling kan man få tillbaka sina blödningar</td>
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<tr>
<td>Psykologiska besvär i övergångsåldern beror mer på livsförändringar (t ex barn flyttar hemifrån) än på hormonförändringar</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Tack för Din medverkan!

Skicka in formuläret i det bifogade svarskuvertet till avdelningen för Obstetrik & Gynekologi, Hälsouniversitetet, Universitetssjukhuset, 581 85 Linköping.