

## Research paper

# Speaking of risk, managing uncertainty: decision-making about cholesterol-reducing treatment in general practice

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## ABSTRACT

**Background** Decision making regarding treatment options and risk communication between health professionals and patients have become key areas of research and quality improvement. Decisions are directed towards applying evidence, exploring individual patient concerns, and addressing medical uncertainty. Compared with research on health professionals' views on higher stakes decisions, relatively little attention has been paid to improving decision making and risk communication for lifestyle-related risk conditions involving lower stakes or longer term treatment options, such as medication to reduce risk of future disease.

**Aim** To examine general practitioners (GPs) who experienced difficulties with decision making regarding treatment options and risk communication with asymptomatic patients with high cholesterol and risk of cardiovascular disease.

**Methods** An exploratory qualitative and ethnographically informed approach was used. Danish GPs (six male, six female, average age 48 years), were

interviewed in three groups. Interviews were transcribed and coded, while analytical concepts about medical uncertainty were identified.

**Results** The study identified two modalities of medical uncertainty: epistemological uncertainty about scientific knowledge and evidence-based medicine; and situational uncertainty produced in the one-to-one relationship between the GP and the patient during the consultation. The study also stressed that the decision making about cholesterol-reducing treatment is interpreted by the GPs as reversible and provisional.

**Conclusion** These modalities of medical uncertainty can be addressed proactively when developing concepts, tools and training interventions to optimise communication about treatment options in primary care.

**Keywords:** cardiovascular disease, decision making, general practitioner, preventive treatment, primary care, risk, uncertainty

## How this fits in with quality in primary care

### What do we know?

Medical uncertainty constitutes a challenge for general practitioners (GPs) in decision making about cholesterol-reducing treatment for asymptomatic patients with high cholesterol and risk of cardiovascular disease. Shared decision making has been promoted as a useful concept to facilitate discussion about knowledge, support, values and treatment choices between GPs and patients. Shared decision making and the use of decision aids may help GPs and patients in dealing with medical uncertainty.

### What does this paper add?

This paper presents two main findings: (1) uncertainty regarding high cholesterol and risk of cardiovascular disease is not only derived from questions that are epistemological in nature, but also produced in the consultation between the GP and the patient. This finding may be used to make decision aids that can help the GP and the patient verbalise uncertainty about cholesterol-reducing medication. (2) Uncertainty about cholesterol-reducing medication produces a particular type of decision making; cholesterol-reducing medication is interpreted by the GPs as reversible and provisional in nature. Development of decision aids for cholesterol-reducing medication to reduce risk of cardiovascular disease needs to take this into consideration.

## Introduction

Decision making around preventing future disease is embedded in significant medical uncertainty about benefits and risks.<sup>1</sup> For some treatment options, the benefits are marginal, or the risks of side-effects are significant. In these situations, there is often no single best option.<sup>2</sup>

General practitioners (GPs) try to tailor treatment options and care to individual patients. This has been recognised as a key competence for GPs, to be able to clarify the unique situation of the individual patient drawing on a range of medical guidelines about suitable treatment options.<sup>3</sup> Evidence-based medicine emerged in the early 1990s as a counter-measure to scientific uncertainty and practice variation, in order to standardise quality of care and enhance patient safety.<sup>4</sup> The patient was seen as a competent actor to be invited to take part in the decision making about treatment and care. Patients expressed personal preferences and opinions alongside or in the context of the evidence, supported by their healthcare professional. For many, these are the core features of shared decision making.<sup>5–8</sup>

Uncertainty is, however, an increasing part of medical work.<sup>9–13</sup> It has been recognised that uncertainty plays a prominent part in the field of general practice, and tools have been developed to measure the degree of this uncertainty.<sup>12,14–19</sup> To counter and deal with uncertainty, decision making and risk communication have become areas of research and quality improvement, directed towards applying evidence, exploring individual concerns, and addressing medical uncertainty.<sup>20,21</sup> A particular area of development concerns decision aids: tools to structure information

provision and aid patients to consider the best choice for them in line with their personal values.<sup>22</sup> Although some have been shown to be effective technologies,<sup>23</sup> this area has tended to focus primarily on patients genetically disposed to high risk of future disease, e.g. familial risk of breast cancer,<sup>24,25</sup> or patients facing irreversible treatment options with potentially severe outcomes, e.g. surgery for prostatism.<sup>26,27</sup> Compared with research on health professionals' views on higher stakes decisions, relatively little attention has been paid to improving decision making and risk communication regarding lifestyle-related risk conditions involving lower stakes or longer term treatment options, such as medication to reduce risk of future disease. This paper describes results from the development of shared decision making and risk communication tools in the 'The RISAP Study'.<sup>28</sup> The aim of the study presented in the current paper was to explore GPs' experienced difficulties with decision making and risk communication with patients with high cholesterol and risk of cardiovascular disease.

## Method and analytic approach

### Participants

All GPs in Kolding, Denmark, 61 in total, were contacted by telephone and invitations were sent directly to each GP in practice with a reply slip and self-addressed envelope to indicate willingness to participate. Participation was reimbursed with a fee of 1400 DKK (€190). Thirty GPs returned the note, and 12 GPs agreed to participate, six male and six female. Their average age was 48 years, ranging from 41 to 56

years. By comparison, the mean age of Danish GPs is 52 years.<sup>29</sup>

## Focus group discussions

An exploratory qualitative and ethnographically informed approach was chosen.<sup>30</sup> Focus group discussions with GPs were conducted to bring different views on decision making and risk communication into the discussion, drawing on the dynamics of different viewpoints on how to use new communication tools.

Three focus groups were formed among the 12 GPs, and each GP participated once. Each focus group discussion lasted two hours.

An interview guide was used. The questions addressed GPs' experiences with risk communication in order to produce data on their daily practice, interpretations of daily practice, and ideals for risk communication. The questions in the first part of the interview addressed both specific risk communication situations and attitudes to risk communication in general.

The second part of the interview explored participants' reactions to paper-based drafts of decision making and risk communication tools. The drafts were based on a literature review; they worked as 'interventions' or 'questions' and prompted the GPs to discuss the relevance and feasibility of communicating risk with asymptomatic patients with high cholesterol. After the first focus group discussion, the drafts were revised and discussed in the next focus groups, in correspondence with the exploratory, ethnographic approach.<sup>31,32</sup>

## Analytic approach and data analysis

Ethnographic analysis is a continuing process from project formulation to publication of data.<sup>33</sup> The research process is iterative, alternating between data production, analysis and theory, testing analytical ideas, concepts or patterns.<sup>34</sup> A prominent theme in the data became clear in the first focus group discussion: the GPs' experienced difficulties with 'uncertainty' in and outside the medical encounter with patients. This theme is not derived from directly formulated statements, but is a result of a conceptual and contextual analysis of the empirical material. The interviews were transcribed verbatim after each interview and read carefully, discussed among the researchers and analysed. Two researchers (PK and AGJ) each conducted coding which was then discussed and analysed. The purpose of the coding and analysis in between focus group discussions was to support the iterative process in which analytical concepts were tested.

## Results

Two modalities of medical uncertainty emerged as prominent concepts in the theoretical analysis: (1) epistemological uncertainty about scientific knowledge and evidence-based medicine; and (2) situational uncertainty produced in the one-to-one relationship between the GP and the patient during the consultation. These are presented below.

### Epistemological uncertainty

Epistemological uncertainty in medicine is uncertainty that stems from the gaps in medical knowledge and understanding.<sup>35,36</sup> It raises the question of the reliability and adequacy of medical knowledge produced by science and accumulated experience.<sup>37</sup>

The GPs in the study disagreed strongly on whether to recommend cholesterol-reducing medication to patients with high cholesterol but without manifest morbidity. Some relied on the 'newest evidence' produced by scientific trials and stressed the importance of commanding knowledge and skills of continually advancing modern medicine in order to optimise and standardise patient care. Others, however, argued that too little is known about the effect of cholesterol reduction in otherwise healthy patients. When they discussed the role of scientific knowledge and evidence-based medicine, they agreed that science and evidence should form the basis of medical practice, but also felt that it is impossible 'to know all' (Box 1).

The GPs felt uncertain about scientific knowledge and evidence-based medicine for two reasons: (1) a lack of sufficient studies on relevant subpopulations (e.g. 'people with a cholesterol level bordering on a normal level'); and (2) a perception of scientific knowledge and evidence-based medicine as evolving, i.e. the knowledge of yesterday is disputed and replaced by new knowledge of today. However, in some instances, 'yesterday's knowledge' was taken into account during the assessment of risk (Box 2).

#### Box 1

'You should take evidence as the point of departure, right. You should be up-to-date on what's going on, and there are always lots of research studies in the pipeline. You can always go to a cardiological congress to see one study lined up after another. One study reports one thing, the next study reports another. But, as [GP2] says, if people have a cholesterol level bordering on a normal level without any other morbidity, we don't really know what happens to them. Well, actually we don't know.' (GP5)

**Box 2**

‘When I look at a patient who I assess to be a healthy 60-year old woman with a normal blood pressure and a cholesterol level of 7, I bear in mind that 7 was a perfectly normal cholesterol level when I was a young doctor. A level of 7 was not to be treated, it was OK. Thus, if I think this woman has a reasonable lifestyle, I say to her: you have this cholesterol level, and you are 60, and if you had this cholesterol level at 50, it would mean nothing, but age does matter. And at 70, the expected life time left is 13 years if you die at 83 – how much can we do about that?’ (GP1)

It is not possible to tell from this quote whether the GP would advise the ‘healthy 60-year old woman’ to start preventive treatment if the clinical guideline recommended it. ‘Yesterdays’s knowledge’ (‘when I was a young doctor’) and the ‘today’s knowledge’ (the clinical guideline) alike imply no-treatment of a patient with the above-mentioned profile, assuming non-smoking status.

Uncertainty about the predictive value of a risk number for the individual patient was a very prominent concern for these GPs. The GPs considered the need and challenge to ‘translate’ group-based, epidemiological knowledge into an individual patient’s situation (Box 3). In this way, GPs expressed a tension between collective-oriented medicine and individual-oriented medicine. They found this tension to reconcile and integrate the individual patient characteristics with scientific knowledge and evidence-based medicine reasoning and recommended interventions to be one of the most important challenges.

**Situational uncertainty**

Situational uncertainty is produced in a specific situation with situated actors. The consultation (as a social situation) produces uncertainty about the intentions and actions of the actors, as well as uncertainty about conditions (temporal/social/biological, etc) in which the consultation is embedded.<sup>38</sup> The one-to-one relationship between the GP and the patient during the consultation includes uncertainty about

**Box 3**

‘Even if we could reduce your cholesterol level from 7 to 6, we don’t know [if it helps]. We know nothing. We can measure that a number is reduced. But we don’t know how it affects your life.’ (GP6)

the interpretation of risk profiling and communication to convey the interpretation. For example, the GPs felt they should seek sufficient knowledge about the individual patient to convey the risk of disease in a way that addressed the values, wishes and concerns of the particular patient. However, they also stressed that it was impossible to know everything about a patient; patients may omit significant details in their narratives about their lifestyle, or the GP may not be able to get a clear picture of the patient’s ‘true state of health’, or their values (e.g. about health) or preferences (e.g. about treatments). This calls for GPs’ skills in interpreting the patient’s problem. This was discussed by the GPs as a major concern, especially when several factors pointed in different directions (Box 4).

In all, the trusting relationship between the GP and the patient was valued as the cornerstone of general practice (Box 5). In this kind of relationship, the GPs saw trust as a means to overcome both epistemological and situational uncertainties, by sharing their value judgements regarding cholesterol-reducing medication with patients. This sharing of value judgements was supported by the fact that a decision about cholesterol-reducing treatment is reversible in nature and, as such, provisional, because the patient can start

**Box 4**

‘If I have a patient with high cholesterol without manifest CVD or diabetes, I think about the potential risk reduction [of medication] but I don’t know how much it is. I don’t know if it reduces your risk or the risk of 9,000 others [with high cholesterol]. [...] I had an old patient today – 80 years or more – with a cholesterol level of 7, and she complained about side-effects. I took it from her and said to her that I didn’t think it was a good idea [to continue with medication]. In fact, it worried her a bit.’ (GP10)

**Box 5**

‘They come to me because I am their consultant. They have questions, and I am supposed to help them solve a problem. And if I can direct them in a direction where I use my professional knowledge to their satisfaction, it is a success for me. And I am not afraid to say to them ‘If I were you, I would do this’. In this way they understand it and it doesn’t get too technical. They don’t need it to be too technical when they come to me. It is really about talking with them, as a private person to a private person – down to earth. I think this is our major strength.’ (GP9)

and stop treatment without known or visible consequences (Box 6). Cholesterol-reducing medications were viewed as relatively cheap and side-effects were rarely severe, and hence it was not seen as a 'tough decision' to recommend medication. When patients reported side-effects, the decisions would be reconsidered. Thus, preventive treatment with cholesterol-reducing medication in primary prevention is different from other preventive treatment that implies irreversible procedures, e.g. removal of breast tissue to lower the risk of breast cancer. The GPs reported that the potential reversibility of treatment decisions (lack of identifiable short-term consequences) made room for changes of strategy with individual patients.

The GPs' verbalised demands for risk communication and risk communication tools were: (1) easy access and handling (a piece of laminated paper was preferred), (2) conspicuous colouring (signal colours, intuitively easy to understand), and (3) options and risk explanations in simple and precise wording. The data from this study were used to make a training programme for GPs in shared decision making and risk communication. The data were also used to make three paper-based tools to be used during training and the following consultations.

- Four folders with multi-factorial risk profiles for male/smoker, male non-smoker, female/smoker and female/non-smoker. Besides smoking, the risk factors in the profiles were cholesterol level (6, 7, 8 mmol/l) and blood pressure level (140, 150, 160, 170, 180 mmHg). Risk reduction was calculated in proportion to non-smoking status, cholesterol level 5 and blood pressure 140 mmHg. The risk reduction was shown on a bar chart and a smiley faces diagram, and the relative distribution of risk factors was shown on a pie chart. The purpose of these folders was to address the epistemological uncertainty.
- A patient pamphlet with balanced information about cardiovascular disease and the benefits and risks of cholesterol-reducing treatment. This pamphlet included a four-question decision aid to fill out at home and return to the GP for discussion.

### Box 6

'When discussing preventive treatment with statins that are cheap and free of side-effects. I may assert myself saying this is a good idea, I think you should try it [preventive treatment]. But if the patients experience side-effects I tell them that it has to be without side-effects, as it is about a risk reduction. [...] You should not tolerate side-effects caused by a risk reduction.' (GP6)

The purpose of this pamphlet was to facilitate discussion between the GP and the patient and in this way to enable verbalisation about situational uncertainty.

- A one-page decision aid to be discussed during the consultation, addressing the patient's knowledge, support, values and choices. As with the patient pamphlet, this decision aid was aimed to enable communication about the situational uncertainty produced in the medical encounter.

## Discussion

This study explored GPs' experienced difficulties about communicating risk of cardiovascular disease with asymptomatic patients with high cholesterol. The study revealed two modalities of medical uncertainty that should be addressed in the process of developing tools to support shared decision making and risk communication: epistemological and situational uncertainties. Medical uncertainty has been described elsewhere in the literature, and distinctions have been proposed: Fox distinguishes between epistemological 'collective-oriented' uncertainty, derived from the limitation in current medical knowledge; epistemological 'individual-oriented' uncertainty, derived from the individual doctor's inability to know all; and epistemological uncertainty, derived from the individual doctor's inability to distinguish between the two.<sup>37</sup> Beresford distinguishes between 'technical' uncertainty, derived from limitations in current medical knowledge, 'personal' uncertainty derived from the doctor's inability to know the patient's wishes, and 'conceptual' uncertainty, which derives from the application of abstract knowledge to concrete situations.<sup>39</sup> Edwards *et al* distinguish between 'collective professional uncertainty' (similar to Fox's collective-oriented uncertainty and Beresford's technical uncertainty), 'individual professional uncertainty' (similar to Fox's individual-oriented uncertainty) and stochastic uncertainty.<sup>40</sup> All these definitions and distinctions seem to presuppose that medical uncertainty is 'out there' in a collective memory about indeterminacy, either in the shape of medical knowledge inadequacy or in the shape of mathematical principles of chance, or 'inside' the doctor as a personal feeling of inadequacy. In our study, however, we propose a different distinction: that between epistemological uncertainty as proposed by Fox and Edwards, and situational uncertainty that is produced 'between' the doctor and the patient; the latter demands the GP's ability to interpret the unique patient's 'true state-of-health', resources and preferences for treatment. The two modalities of uncertainty exist side-by-side, without being mutually exclusive.

The situational uncertainty, produced in the one-to-one encounter between the GP and the patient, seems particularly important here. Preventive treatment with cholesterol-reducing medication in primary prevention is different from preventive treatment that involves irreversible procedures, such as removal of breast tissue to lower the risk of (recurring) breast cancer. The potential reversibility of the treatment decision (lack of consequences) allowed provisional decisions about preventive treatment. These types of uncertainty may not be present in the same way in secondary prevention of future disease, not to mention in the acute medical sector and the secondary medical sector. Studies in decision making and risk communication have primarily focused on 'tough' decision with high risk of less serious outcomes, or 'tough' decision with small risk of serious adverse outcomes.<sup>23</sup> The results of the study here show that primary prevention of cardiovascular disease with cholesterol-reducing medication is interpreted and practised by GPs as a provisional and reversible decision. This may indicate patient-centred care at a most efficient state: the GP tailors treatment to the individual patient and is open to negotiation about treatment in order to satisfy the patient's needs and personal values. The actual difference, however, between the number of written prescriptions and the number of actually redeemed prescriptions indicates that GPs and patients do not always have common understanding of risk and whether it is 'worth' reducing with medication.<sup>41,42</sup>

Thus, the results provide insights into modalities of medical uncertainty regarding reversible treatment decisions. These insights may provide guidance to help professionals develop interventions to support shared decision making and risk communication in primary prevention of disease. Interventions should embrace epistemological uncertainty by acknowledging for both GP and patient that this modality of medical uncertainty is inevitable, but offers flexibility to match decisions to the individual situation. They should also address situational uncertainty by providing a space for communication about patients' thoughts, opinions, preferences, reactions to information and deliberation about risk taking. The reversibility of treatment decisions (initiate/continue cholesterol-reducing medication or stop) gives rise to provisional decisions such as those found elsewhere in the literature.<sup>43</sup> This is problematic in treatment with cholesterol-reducing medication, as no effect of short-term treatment with cholesterol-reducing medication has been documented except in the treatment of manifest cardiovascular disease.<sup>44,45</sup> It is well-known that cholesterol-reducing medication as a preventive treatment for cardiovascular disease in asymptomatic patients without other comorbidity has a low compliance rate.<sup>41,42</sup>

Other studies have shown that doctors tend to recommend treatment in cases of medical uncertainty, especially if the outcome is reversible.<sup>46,47</sup> This subverts the ideal of shared decision making and risk communication as patients have been shown to prefer watchful waiting over treatment when faced with medical uncertainty.<sup>23</sup> Further studies are needed to investigate the tension between doctors' and patients' preferences when faced with medical uncertainty regarding potentially reversible and provisional treatment decisions in medical encounters.

## Conclusion

This study explored GPs' experience of difficulties when communicating about risk of cardiovascular disease with asymptomatic patients with high cholesterol.

Two modalities of medical uncertainty emerged in the data: epistemological uncertainty about scientific knowledge and evidence-based medicine, and situational uncertainty produced in the one-to-one relationship between the GP and the patient during the consultation. The results provide an understanding of the challenges faced by GPs when dealing with decision making and risk communication in medical encounters with patients facing potentially reversible and provisional treatment decisions. The identification of modalities of medical uncertainty might be used proactively when developing concepts, tools and training interventions to optimise communication about preventive treatment.

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## ETHICAL APPROVAL

The study was notified to the Danish Data Protection Agency and collection of data was handled according to their guidelines (journal no 2007–41–1,446). The study was exempted from obligation of notification for the Danish Scientific-Ethical Committee but followed the ethical code of American Anthropological Association.<sup>48</sup> The study was nested in the RISAP study which was registered at ClinicalTrials.gov: NCT01187056.

## PEER REVIEW

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## CONFLICTS OF INTEREST

None.

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