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Doctor's views on disclosing or withholding information on low risks of complication

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Background: More and more quantitative information is becoming available about the risks of complications arising from medical treatment. In everyday practice, this raises the question whether each and every risk, however low, should be disclosed to patients. What could be good reasons for doing or not doing so? This will increasingly become a dilemma for practitioners.
Objective: To report doctors' views on whether to disclose or withhold information on low risks of complications.
Methods: In a qualitative study design, 37 respondents (gastroenterologists and gynaecologists or obstetricians) were included. Focus group interviews were held with 22 respondents and individual in-depth interviews with 15.
Results: Doctors have doubts about disclosing or withholding information on complication risk, especially in a risk range of 1 in 200 to 1 in 10 000. Their considerations on whether to disclose or to withhold information depend on a complicated mix of patient and doctor-associated reasons; on medical and personal considerations; and on the kind and purpose of intervention.
Discussion: Even though the degree of a risk is important in a doctor's considerations, the severity of the possible complications and patients' wishes and competencies have an important role as well. Respondents said that low risks should always be communicated when there are alternatives for the intervention or when the patient may prevent or mitigate the risk. When the appropriateness of disclosing risks is doubtful, doctors should always tell their patients that no intervention is without risk, give them the opportunity to gather all the information they need or want, and enable them to detect a complication at an early stage.

The concept of risk has become an important guiding concept in medicine. The ''risk epidemic'', as some call it,[1] confronts doctors with new questions about what risks they should discuss with their patients.

There are large differences in legal standards for what should be disclosed to patients. For instance, UK and German law take as a standard ''what a reasonable doctor would disclose''. Both the USA and The Netherlands (Medical Treatment Agreement Act (Wet op de geneeskundige behandelingovereenkomst)) describe the doctor's duty to inform in terms of what Beauchamp and Childress[2] call a ''reasonable patient'' standard: what a reasonable patient would need or want to know to be able to give informed consent.

When the complication risk is high and consequences may be severe, it is obvious that doctors have to inform their patients. But in cases of low or negligible risk, doctors have doubts about disclosing information because it is not clear what a reasonable patient would need or want to know. There may also be a danger of information overkill, threatening instead of strengthening patient autonomy. The ethical question here is, What should doctors do when it is unclear whether a reasonable patient would want to have particular risk information?

A large amount of literature is available on how to disclose both low and high risks; for instance, the *BMJ* issue of September 2003 contains a highly informative special section on this problem.[3] Risks, when disclosed, may be improperly and incorrectly perceived by both patients and doctors[4–7] and patients may have only a poor memory of what is disclosed by the doctor.[4 7–9] Nevertheless, patients generally seem to appreciate communication on the risks involved.[10]

We will not deal with the issue of how to communicate. Instead, we will take up the problem raised by the philosopher Onora O'Neill,[11] who argued that the preoccupation with informed consent has led us to disregard forms of shaping autonomy that rely less heavily on giving exhaustive information, and that the question is not only how we should inform about risk but also to what extent.

We explored the views, motives and practices of doctors on the question of what complication risks doctors should inform their patients about.

METHODS

As our study aimed to explore views, motives and practices, a qualitative interview design seemed most appropriate. For two reasons, we decided to use both focus groups and individual interviews. Firstly, using different methods of data collection provides an opportunity for triangulation, and secondly, in focus groups, we could use the discussion among respondents to elicit more data and to refine our understanding of the arguments used by respondents either for disclosing or withholding information on low risks.

Sample

We interviewed 37 respondents in

- 5 focus group interviews with 22 respondents: 9 gastroenterologists, 6 gynaecologists and 7 obstetricians;
- 15 open in-depth interviews, taking between 1 and 2 h, with 8 gastroenterologists, 5 gynaecologists and 2 obstetricians.

The interview guide was constructed on the basis of observations of consultations and insights from semistructured interviews with patients (n = 8), ethicists (n = 9), health lawyers (n = 6) and different risk experts (mountaineer, parachute jumper and actuary).

The gastroenterologists and respondents for the focus group interviews were approached after consulting the participating medical experts in the research group. Gynaecologists (n = 5) and obstetricians (n = 2) were selected by asking the respondent at the end of each interview which colleague the researcher had to approach to hear a different idea on disclosing information on low risks.[12]

Procedure and interview content

The researcher (GGP) asked respondents to reflect on low complication risk and what arguments and doubts they had regarding disclosing or withholding information. In interviews with gastroenterologists and gynaecologists, we presented the risk of a perforation of the large intestine due to a colonoscopy as an example of a low complication risk. Several retrospective studies[13–15] have reported the incidence of perforation after colonoscopy to be in the range of 0.032% (1 in 3115) to 0.9% (1 in 111). The gynaecologists and obstetricians were asked to think about and reflect on similar types of low complication risks in their own discipline.

Analysis

All interviews were recorded on Minidisk and transcribed ad verbatim. A summary of the interview in edited quotations was presented to the respondent for member check. Occasionally, this resulted in a subtle modification of or minor supplement to the summary. To ensure intersubjectivity, most ad verbatim interviews were assessed by, and discussed with, members of the research group, to exclude blind spots and doubtful interpretations.

The analysis was carried out with analysing software (MAXqda2) using open coding approaches, followed by reorganising the code tree.[16] Codes and categories were made inductively. Categories are mentioned here as section headings: Reasons to withhold information on low risks; Reasons to disclose information on low risks when in doubt; and Considerations influencing the doctor's decision to disclose or not.

RESULTS

Reasons to withhold information on low risks

The reasons our respondents gave for withholding information on low risks can be divided into patient-related and doctor-related reasons. Respondents were not convinced that informing about low risk serves a useful purpose, because many patients do not understand the concept of risk and because patients have a poor memory of the disclosed information. Some respondents reported on their experience with patients getting upset by (low) risk disclosure. In the following quote, a respondent says that patients tend to over-react to information on low risks:

> By disclosing the risk of perforation, the risk will be remembered. The rest will be forgotten. Thus it will be enlarged and it will lead a life of its own. Especially when you have informed patients about certain risks, they are terrified for a certain intervention.[…] So these people are in cold sweat (gastroenterologist VIII).

Some doctors related the disclosure question to their own risk of getting sued. According to some of our respondents, proper documentation is pivotal, but at the same time, the sheer number of different types of low risk makes it unfeasible to register in detail what has been disclosed. For this reason, they said they disclose risks of an intervention only in broad terms, realising that they will not escape the risk of getting sued anyway.

> The sort of notes I make about risks are not conclusive at all. It is always possible for a patient to say: ''I didn't hear anything about risks'' and nothing is documented about risks! (gynaecologist V).

Just as patients have difficulties with understanding risk properly, doctors face these difficulties, too. In particular, practitioners find it difficult to translate the epidemiological origin of risk knowledge to the individual situation of a patient. A gynaecologist stated that a chance of 2% in the actual case of the individual patient would eventually not be 2%, but 0% or 100%. However, then it is not a risk any more, but the outcome of the procedure.

Reasons to disclose information on low risks when in doubt

The primary reason for disclosing risk information is that a patient is entitled to full information. However, respondents mentioned specific reasons for disclosing information on low risk when they had doubts about the appropriateness of disclosure.

Other than for legal back-up, doctors disclose risk to enable the patient to detect a complication as soon as possible. Risk disclosure in this sense is less related to informed consent than to giving advice to act properly in case a complication materialises.

> I think it is very important – not only to escape suing – that a patient knows what can happen, so he is able to alarm when something goes wrong. In that case we can intervene in time (gastroenterologist V).

Another argument in favour of disclosing (low) risks that some of our respondents mentioned is that it enables the doctor to educate the patient, to discourage medical consumerism and encourage patients to be more aware of the limits and risks of medical treatment.

> You have to communicate risks. Medical consumerism will be stimulated when you pretend there are no risks. So, it is extremely important to do so (obstetrician II).

Doctors also disclose low risk because doing this makes it easier to maintain a relationship with the patient in case a complication arises.

> When something has gone awry [and you have communicated the risk], it is easier to keep up a good relationship with the patient. If you haven't informed the patient, it feels like you have caused something the patient did not have the slightest idea of (gastroenterologist VI).

> I will mention—at least briefly—all things I don't want to happen to my patients. So in case the complication has occurred, you can say: ''Madam, how terrible this has happened, but you know, we have considered it and weighed the pros and cons.'' As an attitude and as a motive to inform about complications, this is somewhat chickenhearted. You can refer to them after they have occurred and so you avoid comments like: ''This outcome is very disappointing and I wasn't aware it could happen'' (gynaecologist III).

Conditions influencing the doctor's decision to disclose or withhold information

What exactly constitutes a ''low risk'' was an important topic in all interviews. Doctors expressed doubts about communicating

risk information within a wide range—from about 1 in 200 (0.5%) to 1 in 10 000 (0.01%). They mentioned three variables influencing the decision to disclose in this "grey" range: (a) the assumed probability and severity; (b) patient characteristics; and (c) characteristics of the intervention.

Firstly, respondents distinguished a quantitative and a qualitative pole of the concept of risk: probability and severity. In assessing which risk to disclose and which to withhold, the combining of these two poles was seen as difficult, especially when there is a very low risk of a very serious complication—for instance, a <0.01% risk of an intestinal perforation. There was a case in which a gastroenterologist had not disclosed a considerable risk, after an oesophageal operation, that the patient would be unable to belch and would be increasingly flatulent, because she considered this to be a low-severity risk. The other two combinations (high risk/high severity and low risk/low severity) posed no real problems to our respondents, because it was either obvious that information should be given, or indifferent.

Secondly, doctors said patients have many different reasons and wishes for being informed about (low) risks and also different intellectual capacities to cope with information on low risks. Independently of these personal patient characteristics, one doctor emphasised that patients also differ medically: the physical condition of the patient influences the severity of a risk. Thus, for (very) fragile patients, the consequences of a complication can be more severe (and should therefore be disclosed) than in otherwise healthy patients.

Not only do patient characteristics differ but interventions can also have different purposes and circumstances. Some gastroenterologists disclose the risk of a perforation only after the colonoscopy has taken place and after they have performed an intervention that has increased the normal risk (for instance, removing polyps in the coecum area—what the respondent in the next quote calls "doing tricky things").

> If I think I have done some tricky things, I tell the patient explicitly: "If you get increasing abdominal pains, you have to check in directly to the hospital emergency ward. Don't go to your family doctor first. Go to the hospital directly and mention you have undergone a colonoscopy, so they can consult the gastroenterologist on duty" (gastroenterologist VIII).

When polyps are removed, the purpose of the intervention changes from diagnostic to therapeutic, or at least preventive. Doctors know that removing polyps increases the perforation risk of a colonoscopy from 1 in 1000 to 1 in 100. According to most of our respondents, 60–80% of all colonoscopies were only diagnostic and were associated with a low risk of perforation. However, it is impossible to predict which colonoscopies will shift, while being performed, from diagnosis to treatment. Therefore, gastroenterologists tend to always disclose the risk of a perforation, even if, theoretically, it is low.

Yet another variable doctors take into consideration when deciding whether to disclose complication risk is the degree of inevitability of the intervention and the existence of alternatives:

> The more doubts you have about the indication, the more explicit you have to be about complication risks. And soft indications we have in abundance. The less hard the indication, the more strictly I will investigate the pros and cons of a colonoscopy, and the more I am inclined to give patients the opportunity to decide together with me [about disclosing the low risk information – authors' note] (gastroenterologist III).

In this context, one respondent contrasted medically necessary caesareans with medically unnecessary ones:

> If a woman has to undergo a Caesarean section because it is the only way to give birth to her child, I will not mention all probabilities of risks.[…] You don't mention probabilities, because there are no other possible interventions (gynaecologist II).

DISCUSSION

We interviewed doctors about their judgements and considerations on disclosing or withholding information on low complication risks to patients. Doubts about communicating low risks centred on risks between 1 in 200 (0.5%) and 1 in 10 000 (0.01%). Within this range the doctor's judgement on whether or not to communicate information on risk depended on their views on the following issues:

- the assessment of probability and severity;
- the personal preferences and physical and cognitive condition of the patient; and
- the purpose and indication of the proposed intervention.

Some doctors said they withheld information on low risks because of doubts about the possibilities of a patient's informed consent, as both patients and doctors have difficulties in understanding the risk concept properly. For patients this has been mentioned in the literature,[4–6] but less so for doctors. Translating the epidemiological origin of risk knowledge to the individual situation of a patient proves to be especially difficult for practitioners.[7 9] In conformity with the largely non-empirical literature,[4 7–9] our respondents emphasised the patients' poor memory of the disclosed information. This could lead to a patient giving his or her disinformed consent even after being given extensive information by the doctor.[7]

An important argument for disclosing low risks is that it is important for doctors and patients to be aware of them to create, and comply with, safer procedures. Better understanding may enhance the safety of the procedure and further diminish risks: in quality management terms, "working blame-free". Disclosing low complication risk to enable the patient to detect a complication at an early stage is a part of increasing safety and working blame-free,[17] because it allows for advice on acting properly in case of a complication.

Our results are consonant with the ideas put forward by O'Neill[11] in *Autonomy and trust in bioethics*. According to O'Neill, a focus on exhaustive information, even about low to very low future health risks, may sometimes harm instead of benefit patients. The decision to disclose a particular low risk should therefore be based not on a general rule, but on the individual aspects of the situation of the patient. It should include judgement about the relevance of such information for a patient's well-being. This may imply that, in many cases, opting for trust may be a more promising way of ensuring this than full information about low risks.

Our study has some limitations. We selected doctors largely using a snowball method; we tried to compensate for this disadvantage by purposely searching for counterexamples. The way we did this (by asking respondents to suggest further interviewees with a different view), even though an accepted recruitment method in qualitative studies, may not guarantee that we found the extremes of the opinion spectrum. However, we think the explorative character of the study warrants that

potential drawback. A strength of our study is that we interviewed doctors from different specialties and that we were able to construct our topic list on the basis of several quite varied interview sources.

It may be objected that terms like ''severity'', which we used in this study following the terminology of our respondents, may be too imprecise and could be replaced, for instance, by ''utility''. We decided not to use that term in our analysis, because our respondents did not use it even once, and because severity, for our aims, is distinctive enough. Our data imply that there are at least two situations in which low complication risks should be communicated explicitly: (a) in case the intervention is elective or there are reasonable alternatives with lower risks; and (b) when relevant advice may be given to the patient on how to act in the event that complication materialises.

However, our data also show that there will always be uncertainty about the appropriateness of disclosure, especially in the area between 0.5% and 0.01%. Doctors will have to learn to live with this ''grey area''.

We think a procedure of informing the patient in three phases could represent a balanced way of disclosing:

- Doctors should tell patients in broad terms that no medical intervention is without risk.
- They should try to ascertain to what extent the patient wants to be informed, partly by asking the patient, and partly on the basis of circumstantial or previous knowledge of that patient. In this second phase the communication skills of the doctor as well as the social skills and preferences of the patient will be a major influence on what is being communicated.[8 18]
- If judged appropriate during the second phase—the doctor can present additional information via multimedia (written; the internet; and CD-ROMS).

Creating a culture of balanced information disclosure, in which doctors give patients access—either orally or in writing—to relevant information will surmount most legal problems without forcing doctors to painstakingly discuss each and every risk, however minute.

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