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Published in:
Journal of Medical Ethics

DOI:
10.1136/jme.2008.025031

Citation for published version (APA):

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Clinical ethics

Under what conditions do patients want to be informed about their risk of a complication? A vignette study

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ABSTRACT

Background: Discussing treatment risks has become increasingly important in medical communication. Still, despite regulations, physicians must decide how much and what kind of information to present.

Objective: To investigate patients’ preference for information about a small risk of a complication of colonoscopy, and whether medical and personal factors contribute to such preference. To propose a disclosure policy related to our results.

Design: Vignettes study.

Setting: Department of Gastroenterology, Academic Medical Centre, the Netherlands.

Patients: 810 consecutive colonoscopy patients.

Intervention: A home-sent questionnaire containing three vignettes. Vignettes varied in the indication for colonoscopy, complication severity and level of risk. Patients were invited to indicate their wish to be informed and the importance of such information. In addition, sociodemographic, illness-related and psychological characteristics were assessed.

Main outcome measurements: Wish to be informed and importance of information.

Results: Of 810 questionnaires, 68% were returned. Patients generally wished to be informed about low-risk complications, regardless of the indication for colonoscopy or the severity of the complication. The level of risk did matter, though (OR = 2.48, SE = 0.28, p = 0.001). The information was considered less important if done for population screening purposes or diagnosis of colorectal cancer, if the complication was less severe (bleeding) and if the risk was smaller (0.01% and 0.1%). Patients’ information preference was also related to age, mood and coping style.

Limitations: Difficulty of vignettes.

Conclusions: Patients generally wish to be informed about all possible risks. However, this might become uninformative. A stepwise approach is suggested.

Patients’ right to receive information from physicians and to discuss the benefits, risks, and costs of appropriate treatment alternatives is generally accepted. Consequently, discussing treatment risks has become increasingly important in medical communication.3 Such risks concern the likelihood of an adverse event such as future illness, possible side effects or complications of treatments and tests and the severity of the consequence of such an event. The certainty of the risk, the level of risk and the effect of the risk on the individual or population determine its importance.2

Patients should be informed about these risks, for psychological, ethical and legal reasons. Psychologically, information may help patients to anticipate future events and thus reduce uncertainty,7 and to take control by engaging in appropriate action at an early stage in case adverse events occur. It also allows patients to make informed decisions.4

The (moral) obligation for health professionals to disclose information also reflects several ethical principles, such as honesty, trustworthiness and respect for patient autonomy. The patient–physician relationship has changed from a paternalistic one to one in which decision-making is shared where appropriate.5 6 Patients have the right to have maximal control over anything done to their bodies. This principle has been translated into an obligation for informed consent. Such obligation has been laid down in legal standards throughout the Western world.7

Following these developments, risk communication is now considered an integral part of clinical communication. However, despite regulations, healthcare professionals still must decide how much and what kind of information to present and how to frame the discussion of risk.8 9 10 They may find this difficult, because communicating risks has a downside also, in particular when small risks are involved.9

Patients may want to avoid information in order to prevent mental discomfort.2 3 Second, patients experience difficulty in understanding risks,3 11 12 resulting in cognitive burden. Third, physicians may fear that patients will overestimate risks and renounce diagnostic procedures and treatments on that basis. Finally, providing information is time-consuming. The more complex the information and the more detailed the level of information, the more attention should be paid to the information-giving process.

As a result of these contradictory arguments, practising physicians may find it difficult, during busy clinics, to find a balance between their wish to inform the patient, to ensure that the patient understands the information, and, at the same time, to avoid giving information that is either not wanted or considered unimportant. The law is not univocal in this respect. In the UK, the law would state that the doctor should tell “what a reasonable and careful doctor would disclose”.7 In both the USA and the Netherlands, the law describes the physician’s duty in terms of “what a reasonable patient would need to know”.7

Much research focused on how risk information is conveyed.4 11 Many models, however, do not even consider that patients might not want to seek
information. As a result, it is relatively unknown to what extent patients actually wish to know about their risks, especially when these risks are small.

Also, what conditions lead patients to want more or less information is largely unknown. Medical factors, such as the level of risk, may play a role. For example, Hagerty and colleagues asked patients with metastatic cancer about their wish to know side effects of treatment. As it turned out, almost all wanted to know common ones, whereas about 10% did not want to know uncommon ones. Similarly, patients with a worse prognosis were less likely to want to be informed. Also, patient characteristics may be relevant. Kaplowitz and colleagues, for example, found that patients with a higher need to avoid thoughts about death, greater anxiety and more fear of cancer were less likely to desire, request and receive information.

This paper discusses the need to inform from a patient perspective. It addresses the patients’ preference for information regarding complications with a low probability: those related to colonoscopy. Colonoscopy is a large-bowel examination that provides information to diagnose various colon conditions in patients or to screen for bowel cancer in asymptomatic men and women. It is a visual examination of the large intestine using a video endoscope. The patient is mildly sedated, after which the endoscope is inserted through the rectum into the colon. Patients generally experience emotional distress and mild cramping or abdominal pressure during and/or shortly after the examination. While undergoing a colonoscopy, patients have a low risk of colon perforation. Several retrospective studies have reported the incidence of a small perforation after colonoscopy to be in the range of 0.052% (1 in 1981) to 0.9% (1 in 111). The implications of this complication are severe. However, if the perforation is detected early, effective treatment—surgical intervention—is available. Also, a colonic tear may result from the intervention, though this complication occurs more rarely. If it does, however, its consequences are even more severe.

The research question addressed in this study therefore is: “Do patients wish to be informed about their risk of a complication of colonoscopy and, if so, under what conditions?” Conditions assumed to be relevant include:

- medical factors, such as the medical indication for the procedure, the severity of the complication and the level of risk;
- personal factors, such as the demographic and psychological characteristics of the patients.

PATIENTS AND METHODS

Sample and procedure

The sample comprised consecutive patients selected from the patient database of the gastroenterology department of our hospital. Eligible patients had undergone a colonoscopy in the previous 9 months and were aged 18 years or older. They were sent a questionnaire at their home address with a letter explaining the aim of the study. If necessary, a reminder was sent after 3 to 4 weeks.

Instruments

Vignettes

We used vignettes to study patients’ preferences for information about small risks. A vignette is a paper case description in which case characteristics are systematically varied. The selection of relevant factors and the wording of the vignettes were based on in-depth interviews with eight colonoscopy patients and a first, pilot version of the vignettes. The pilot revealed a low power of discernment: patients did not differentiate between the vignettes. As a result, the vignettes were rephrased and simplified. An example of a vignette is presented in appendix A.

The following medical factors were varied in the vignettes:
- the indication for colonoscopy (ie, population screening, Crohn’s disease or suspected colon cancer)
- the level of severity of the complication (ie, in increasing order, bleeding followed by a blood transfusion, small perforation of the colon followed by surgical intervention, or a colonic tear also followed by surgical intervention)
- the level of risk of the complication—ie, 1 in 10,000 (0.01%), 1 in 1000 (0.1%) or 1 in 100 (1%)

Systematic variation of these characteristics produces a total of 27 vignettes. Since it was deemed impossible to have individual patients rate all vignettes, each patient received three randomly selected vignettes about one indication for colonoscopy (either population screening or Crohn’s disease or colon cancer). Hence, an incomplete design was used. The sequence of “severity of the complication” and “the level of risk” was presented in three random ways to control for a possible order effect. This resulted in 27 questionnaire versions, each including three vignettes.

Patient characteristics

The questionnaire included patients’ sociodemographic characteristics such as gender, age, educational level, ethnicity and marital status. We investigated the patients’ medical history by asking how many colonoscopies they had undergone earlier, the time since their last colonoscopy, and whether or not they were receiving treatment.

Various psychological characteristics were included. Information-related experience and attitudes were measured as follows. The information received preceding the colonoscopy was measured with two questions, using a 5-point rating scale:
- “The health professional did not tell me anything about possible complications and side effects/procedure” (1)
- “The health professional told me everything there is to know” (5)

The patients’ satisfaction with the amount of information received was measured with one question, using a 5-point rating scale:
- “I wanted much more information” (1)
- “I wanted much less information” (5)

The patients’ general preference for information was measured with a 10-point rating scale:
- “I prefer as little information as possible” (1)
- “I prefer all the information there is” (10)

Patients’ preferred level of participation in decision-making was measured with a scale of two questions covering desired participation in deciding about treatment and diagnostic examinations, using a 5-point rating scale:
- “I give the health professional full responsibility for decision-making” (1)
- “I want full responsibility for decision-making” (5)

To determine the patients’ tendency to actively search for information about aversive events, the monitoring scale of the Threatening Medical Situations Inventory (TMSI) questionnaire was used. This scale pertains to three different items:
- (a) looking for information within a threatening situation,
- (b) going deeply into the situation by reading about it and
- (c) getting information about the situation from other
doctors, patients or an organisation. For practical reasons, patients were offered two of the original four hypothetical situations (vague suspicious headache complaints and choosing uncertain heart surgery). For these situations, they had to answer three questions on a 5-point rating scale (‘‘not at all applicable to me’’ = 1; ‘‘strongly applicable to me’’ = 5). An overall monitoring score was calculated (range 6–30, Cronbach’s α = 0.74).

Patients’ mood states were measured using the Dutch short version of the Profile of Mood States,\(^{22,23}\) containing five subscales: depression (eight items, α = 0.92), anger (seven items, α = 0.91), fatigue (six items, α = 0.94), vigor (five items, α = 0.81), and tension (six items, α = 0.89). Participants indicate to what extent adjectives describe their moods over the previous days on a 5-point rating scale (‘‘not at all’’ = 1, ‘‘extremely’’ = 5).

Finally, the degree to which the presentation of vignettes in the questionnaire caused worries was measured with one ad hoc question, using a 5-point rating scale (‘‘not at all alarming’’ = 1, ‘‘very alarming’’ = 5).

Patients’ information preferences
First, after each vignette we asked whether patients wish to know their risks (‘‘Do you want to be informed about the possibility of this complication?’’ (yes/no)). Second, their perceived level of importance of such information was addressed (‘‘How important is this information for you?’’ (‘‘not important’’ = 1, ‘‘very important’’ = 5) (see appendix A).

Statistical analyses
The effects of medical factors (reason for colonoscopy, severity of the complication, and risk) and patient characteristics on patients’ information preferences were investigated through regression analyses. As each patient responded to three vignettes, with varying levels of complication severity and risk, multilevel regression analysis was used to account for within-person correlations. Multilevel logistic regression analysis was used to test the effects on the dichotomous variable ‘‘wish to be informed’’, and multilevel linear regression analysis was used to test the effects on the variable ‘‘importance of information’’. With both dependent variables, we first included the three medical factors and all patient characteristics as possible predictors in the regression analysis. Subsequently, we removed patient characteristics with non-significant effects one by one from the regression analysis, in a step-by-step backward procedure (α = 0.05). As the primary research question is about medical factors, the medical factors were always retained in the regression analysis, even if their effects were not significant.

The multilevel analyses allowed for the testing of interactions and order effects. Only two of many tests were significant. We considered these to be chance findings. The analyses were carried out with the computer program MLwiN.\(^{24}\)

RESULTS
Sample
Of the 810 questionnaires sent out, 585 (72%) were returned. Of those, 22 had not been delivered to the address, seven indicated that the patients refused participation and four patients were unable to participate. Thus, 552 (68%) questionnaires could be used for analysis. Sample characteristics are presented in table 1. No differences in sex, age, or predictor variables were found between the 27 conditions.

Patient preference for information
The large majority (range 91%–96%) of patients wished to be informed about low risks for complications. They most often considered receiving such information very important (65%–74%) or important (16%–19%) (fig 1).

The role of medical factors
Patients’ wish to be informed
Patients wanted to be informed irrespective of the reason for the colonoscopy and the severity of the complication (table 2). The level of risk turned out to be of relevance though (p = 0.001). If the risk was 1% rather than 0.01%, patients were more likely to want to be informed. Whether the risk was 0.1% or 0.01% did almost make a difference (p = 0.055).

Importance of the information
The reason a colonoscopy was performed did affect the perceived importance of information about low complication risks (fig 1A, table 2). If a colonoscopy was performed for Crohn’s disease, patients found risk information more important (p = 0.019). Likewise, the severity of the complication played a role (fig 1B). Patients considered the information about internal bleeding to be less important than the information about a small perforation or a colonic tear (p<0.001). The level of risk also affected the perceived importance of information: the percentage of patients considering such information as ‘‘very important’’ declined from 74% with a risk of 1% to 65% with a risk of 0.01% (p<0.001; fig 1C).

No effects were found for the order in which the severity and risk of complications were presented.

Table 1 Characteristics of population sample (n = 552)*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No or %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (%)</td>
<td></td>
</tr>
<tr>
<td>Male (n = 255)</td>
<td>47</td>
</tr>
<tr>
<td>Female (n = 291)</td>
<td>53</td>
</tr>
<tr>
<td>Age (years) (n = 547)</td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>56 (15)</td>
</tr>
<tr>
<td>Range</td>
<td>18–89</td>
</tr>
<tr>
<td>Education level (%)</td>
<td></td>
</tr>
<tr>
<td>Primary school (n = 62)</td>
<td>11%</td>
</tr>
<tr>
<td>Lower-level high school (n = 176)</td>
<td>32%</td>
</tr>
<tr>
<td>Middle-level high school (n = 99)</td>
<td>18</td>
</tr>
<tr>
<td>Advanced vocational/university (n = 169)</td>
<td>31</td>
</tr>
<tr>
<td>Other (n = 39)</td>
<td>7</td>
</tr>
<tr>
<td>Ethnicity (%)</td>
<td></td>
</tr>
<tr>
<td>Dutch (n = 515)</td>
<td>94</td>
</tr>
<tr>
<td>Surinamese (n = 14)</td>
<td>3</td>
</tr>
<tr>
<td>Dutch Caribbean (n = 2)</td>
<td>0.4</td>
</tr>
<tr>
<td>Other (n = 16)</td>
<td>2.9</td>
</tr>
<tr>
<td>Marital status (%)</td>
<td></td>
</tr>
<tr>
<td>Married/living with partner (n = 391)</td>
<td>71.2</td>
</tr>
<tr>
<td>Living with someone else (n = 28)</td>
<td>5.1</td>
</tr>
<tr>
<td>Single (n = 119)</td>
<td>2.7</td>
</tr>
<tr>
<td>Other (n = 11)</td>
<td>2.0</td>
</tr>
<tr>
<td>Number of colonoscopies undergone (n = 533)</td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>4.6 (5.3)</td>
</tr>
<tr>
<td>Range</td>
<td>1–50</td>
</tr>
<tr>
<td>Time since last colonoscopy (weeks) (n = 517)</td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>27.3 (13.6)</td>
</tr>
<tr>
<td>Range</td>
<td>1–100</td>
</tr>
</tbody>
</table>

*Because of missing values, the numbers and percentages do not always add up to 552 or 100%.
The role of patient characteristics

Wish to be informed

The patients’ wish to be informed was higher when in general they wanted more detailed information and had a tendency to actively search for information (monitoring) (table 2). More angry patients (p = 0.023) as well as more vigorous patients (p = 0.001) were less likely to want information on complications.

Importance of the information

Elderly patients found information on low-risk complications more important (p = 0.001). Patients more satisfied with the information given in the past found such information more important (p = 0.024). Similarly, patients who in general had a stronger preference for detailed information (p < 0.001) and participation in decision-making (p = 0.004) found information about low risks more important.

The more angry patients were less likely to find information important (p < 0.001). Patients indicating that they became worried by the vignettes pointed out that information about low risk of complications was very important to them.

DISCUSSION

Information giving has become highly important in everyday clinical practice, but physicians face the question of how much and what kind of information they should provide to patients. We asked patients' preference for information about low-risk complications resulting from colonoscopy. The vast majority of these patients wished to receive such information and found it important, which is consistent with other reported findings.

Patients generally wanted to know high risks, and our results suggest this also to be the case with low risks. As expected, the smaller the risk, the less likely the patients were to find it very important to be informed. It should be noted, however, that most patients considered the information important even when the risk was as low as 0.01%.

Unlike most other studies, we also addressed antecedents and consequences. We expected that a person who undergoes a colonoscopy for population screening purposes might be less likely to want to take a risk and, therefore, more likely to want to be informed. We found no such effect. Patients may not realise that the cost—benefit ratio is less evident in such case. This lack of awareness may result from most of the respondents having symptoms or a probable diagnosis as the primary reason for attending the department of gastroenterology. In fact, when the indication was Crohn’s disease, a chronic illness, patients found the information most important. Patients may want to avoid risks more strongly because this condition is already burdensome. They therefore require more information to inform the decision to undergo a colonoscopy. Patients may, on the other hand, consider such information about risk less important in case of a life-threatening disease such as cancer, because the results of the procedure, whether cancer is diagnosed or metastases are found, has overwhelming consequences.

It is also important that patients understand the possible negative consequences of invasive procedures, and more so if these are more severe. In this study, patients indeed found information regarding internal bleeding least important. The other two complications presented—a small perforation or a colonic tear—were of equal importance to them. Patients might have had difficulty understanding the difference between the complications. On the other hand, Coleman and colleagues...
found that women considering elective treatment generally wanted much information about complication risks, even if the seriousness of the complication was relatively minor.25

Is information-giving equally important for every patient with the same medical condition? Our results indicate it isn’t. Patients do differ in information preference for low-risk complications.

Elderly patients found the information more important than younger ones. This concurs with older women more often desiring maximum information about small risks of adverse medication effects. Other studies found either no relation with age26 27 or older patients to want less information.28 29 30 Perhaps younger patients more easily understand and, as a result, differentiate between low risks of complications such as 0.1 and 0.01%. This may allow them to consider some information to be less important, even if the seriousness of the complication was relatively minor.25

Some study limitations should be mentioned. First, the literature describes pros and cons of using vignettes.23 Advantages are the ability to collect information simultaneously from many subjects and the possibility of manipulating a number of variables at once. Disadvantages include the problems of establishing reliability and validity. However, studies have shown the clinical validity of vignettes.31 Additionally, our vignettes seemed relevant for colonoscopy patients, as is suggested by the high response rate. In fact, our finding that answers to preference for information about small risks are correlated with general information preference supports the validity of such an approach. However, respondents may have had difficulty differentiating between complications such as a colon perforation and a colonic tear. Second, future research should incorporate both patients and non-patients. It is plausible that naïve respondents, non-patients, would react differently to the vignettes. Some of them may eventually be the patients to be informed.

What is the ethical relevance of these results? First, they fill an empirical gap in the existing ethical literature about disclosure or non-disclosure. Second, they show the complexity of the issue. Where physicians, on grounds of beneficence and attitudes to good care, may consider complete disclosure of even smallest risks both infeasible and ethically wrong, patients seem to have different views (which may be related to a greater difficulty on their part in interpreting risks, especially small risks—or at least to a completely different interpretation from that of physicians).

Given our results, our conclusion could then be that patients should always be informed about small risks. This does not seem to be common practice yet. Only 19% of patients who consented to sigmoidoscopy could mention bleeding and perforation as possible complications.32 Clearly, an additional explanation is that some of the patients could not recall this information.

However, the ethical problem cannot be solved by our data alone: the fact that patients seem to want to know each and

### Table 2  Effects of medical factors and patient characteristics on the patients’ wish to be informed and the perceived importance of information

<table>
<thead>
<tr>
<th>Factor or patient characteristic</th>
<th>Wish to be informed</th>
<th></th>
<th>Importance of information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Odds ratio</td>
<td>SE</td>
<td>p Value</td>
<td>B</td>
</tr>
<tr>
<td>Reason for colonoscopy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suspected colon cancer vs population screening</td>
<td>1.31</td>
<td>0.27</td>
<td>0.38</td>
<td>0.472</td>
</tr>
<tr>
<td>Crohn’s disease vs population screening</td>
<td>1.82</td>
<td>0.60</td>
<td>0.40</td>
<td>0.137</td>
</tr>
<tr>
<td>Level of severity of the complication</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colon perforation vs internal bleeding</td>
<td>1.43</td>
<td>0.36</td>
<td>0.27</td>
<td>0.183</td>
</tr>
<tr>
<td>Colonic tear vs internal bleeding</td>
<td>1.17</td>
<td>0.16</td>
<td>0.26</td>
<td>0.529</td>
</tr>
<tr>
<td>Level of risk</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.1% vs 0.01%</td>
<td>1.62</td>
<td>0.48</td>
<td>0.25</td>
<td>0.055</td>
</tr>
<tr>
<td>1% vs 0.01%</td>
<td>2.48</td>
<td>0.91</td>
<td>0.28</td>
<td>0.001</td>
</tr>
<tr>
<td>Age†</td>
<td>0.13</td>
<td>0.03</td>
<td>–0.001</td>
<td></td>
</tr>
<tr>
<td>Satisfaction with amount of information†</td>
<td>0.08</td>
<td>0.03</td>
<td>0.023</td>
<td></td>
</tr>
<tr>
<td>General preference for detailed information†</td>
<td>1.93</td>
<td>0.66</td>
<td>0.15</td>
<td>–0.001</td>
</tr>
<tr>
<td>Preference for participation in decision-making†</td>
<td>0.09</td>
<td>0.04</td>
<td>0.007</td>
<td></td>
</tr>
<tr>
<td>Monitoring coping style†</td>
<td>1.45</td>
<td>0.37</td>
<td>0.17</td>
<td>0.030</td>
</tr>
<tr>
<td>Tension†</td>
<td>0.67</td>
<td>–0.40</td>
<td>0.17</td>
<td>0.021</td>
</tr>
<tr>
<td>Vigor†</td>
<td>0.54</td>
<td>–0.61</td>
<td>0.19</td>
<td>0.001</td>
</tr>
<tr>
<td>Concern by vignettes†</td>
<td>0.17</td>
<td>0.04</td>
<td>–0.001</td>
<td></td>
</tr>
</tbody>
</table>

Separate analyses with other reference categories for Reason for colonoscopy, Level of severity, and Level of risk show that the difference in effects on Importance of information between Suspected colon cancer and Crohn’s disease is not significant at the 5% level (p = 0.077), that the difference between Colon perforation and Colonic tear is not significant either (p = 0.695), but that the difference between 0.1% risk and 1% risk is significant (p = 0.001). With respect to Wish to be informed, the odds ratio between Suspected colon cancer and Crohn’s disease, between Colon perforation and Colonic tear and between 0.1% risk and 1% risk are not significant (respective p values are 0.425, 0.486 and 0.144).

*The regression coefficient in logistic regression analysis equals the log odds ratio.

†Standardised scores with zero mean and unity variance.
every risk, however small and medically insignificant, does not imply that such risks should always be mentioned. Other considerations, such as the need for routine care, may ‘over-rule’ such general patient preferences. Good care relationships imply a prudent approach to disclosure of risks.

We therefore suggest a different, stepwise approach. As Lankton and colleagues proposed in 1977, in a first phase, physicians can tell patients, in broad terms, what the most likely complications of the intervention might be. In this phase they can also underline that medicine is not without risk anyway. In a second step, they should try to ascertain to what extent the patient wants to be informed. Based on such elicitation of patients’ information preferences, a tailored approach to discussing risks can be chosen. Good communication in this phase will help the physician to avoid being legalistic and remain, at the same time, respectful of patients’ wishes. In the third phase, if judged appropriate during the second, the physician can present additional information using written or multimedia support. In a recent study, a large majority of patients (88%) appreciated written information regarding complications of endoscopy. Thus, disclosure of information will be balanced. Physicians will provide all relevant information either verbally or in writing and will surmount legal problems without having, painstakingly, to discuss every imaginable small risk of their work.

Acknowledgements: This research was undertaken with a grant from the Netherlands Organization for Scientific Research (Grant # EB-01-01/2).

Competing interests: None declared.

Provenance and peer review: Not commissioned; externally peer reviewed.

REFERENCES
Scenario A
Imagine the following scenario:
The physician reports that for population screening, people of your age are offered bowel examination. He wants to examine your bowel for possible bowel deviations.

As a consequence of a bowel examination you can get internal bleeding. When this happens to you, you will get a blood transfusion. The risk that this can happen to you is 1 in 100 (1%).

How important is this information for you? 1 2 3 4 5*

Do you want to be informed about the occurrence of this complication? Yes/No

*1 = not important, 2 = a little bit important, 3 = rather important, 4 = important, 5 = very important