

Development of a patient decision aid for prevention of myocardial infarction in type 2 diabetes – rationale, design and pilot testing

Entwicklung einer Entscheidungshilfe zur Herzinfarktprävention für Patienten mit Typ 2 Diabetes – Grundlagen, Design und Pilotierung

Abstract

Aims: Development and testing of a decision aid about prevention of myocardial infarction for persons with type 2 diabetes.

Methods: Development and testing were guided by the *UK Medical Research Council's* guidance for the development and evaluation of complex interventions. This comprised a systematic literature review, a focus group of 9 potential providers, modelling a prototype, interviews to qualitatively explore understanding and additional information needs, and revision of the decision aid.

Results: The decision aid includes evidence-based information, a tool for individual risk-assessment, worksheets, and an action plan. Five diabetes educators and 15 patients underwent two 60-minutes face-to-face interviews, firstly browsing the decision aid for the first time and then after using it. Both groups differed in their ratings. Overall, the decision aid was rated to present essential information in a complex but understandable and unbiased manner. Difficulties involved understanding of terminology and risk interpretation. "Social status as a risk factor" was the most challenged content by educators but considered as highly important by patients. The risk assessment tool was used inadequately. 5 patients allocated themselves into false risk categories. After revision of the tool, all 12 patients who were recruited for reassessment used the tool correctly.

Conclusion: The decision aid was evaluated with diabetes educators and patients. Qualitative data analysis revealed aspects for revision. The decision aid is planned to be part of a shared decision making programme, comprising a strategy for patient counselling and educational modules addressed to providers. Quantitative evaluation is required to assess its effectiveness.

Keywords: diabetes mellitus type 2, acute coronary syndrome, cardiovascular diseases, decision support techniques, patient education, patient participation

Zusammenfassung

Zielsetzung: Entwicklung und Evaluation einer Entscheidungshilfe zur Herzinfarktprävention für Patienten mit Typ 2 Diabetes.

Methodik: Entwicklung und Evaluation der Entscheidungshilfe folgten der Leitlinie des *UK Medical Research Councils* zur Entwicklung und Evaluation komplexer Interventionen. Dies beinhaltete eine systematische Literaturanalyse, einen Fokusgruppenworkshop mit 9 potentiellen Anbietern, Erstellung eines Prototyps der Entscheidungshilfe, Interviews zur qualitativen Erfassung von Verständnis und zusätzlichem Informationsbedarf und Revision der Entscheidungshilfe.

Ergebnisse: Die Entscheidungshilfe beinhaltet evidenzbasierte Informationen, ein Instrument zur Herzinfarkttrisikoprognose, Arbeitsblätter,

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sowie einen Aktionsplan. Fünf Diabetesberater und 15 Patienten wurden zweimal 60 Minuten einzeln interviewt, zuerst während des erstmaligen Durchsehens und dann nach Verwendung der Entscheidungshilfe. Beide Gruppen kamen zu unterschiedlichen Einschätzungen. Insgesamt wurden die Inhalte als wichtig, deren Darstellung als komplex aber verständlich und unverzerrt bewertet. Schwierig waren das Verstehen der verwendeten Fachterminologie sowie die Interpretation von Risiken. Die Diabetesberater stellten insbesondere das Thema „Sozialstatus als Risikofaktor“ infrage, während es von den Patienten als sehr wichtig gewertet wurde. Das Risikoprognoseinstrument wurde nicht richtig verwendet, 5 Patienten ordneten sich falschen Risikokategorien zu. Nach Überarbeitung wurde es von allen 12 Patienten, die zur wiederholten Evaluation rekrutiert worden waren, richtig verwendet.

Fazit: Die Entscheidungshilfe wurde mit Diabetesberatern und Patienten evaluiert. Die qualitative Datenanalyse ergab Aspekte für die Revision. Die Entscheidungshilfe ist als Teil eines Entscheidungshilfeprogramms (*shared decision making programme*) geplant. Dies beinhaltet eine Strategie zur Patientenberatung sowie ein Schulungsmodul für potentielle Anbieter. Für die Evaluation der Effektivität der Entscheidungshilfe sind quantitative Methoden notwendig.

Introduction

People with type 2 diabetes are at increased risk of coronary heart disease (CHD). An array of behavioural directives is imposed on them such as quitting smoking, increasing exercise, normalising weight, and adhering to monitoring, dietary and medication prescriptions. However, evidence on effectiveness of many of these measures is limited and some of these measures do more harm than good [1]. Compliance to long term treatment is poor, even with the most promising interventions such as blood pressure control and statin use [2], [3], [4].

Lack of patient involvement in decision making has been suggested as one reason for limited treatment success [5], [6]. Involving patients with diabetes in decision making may improve knowledge and enhance discussions between patients and their doctors about CHD prevention [5], [6].

A “good decision” can be characterised by the extent to which it is informed and consistent with the patient’s personal values [7]. Patient decision aids (DAs) are designed to help people make specific and deliberative choices among options by providing information about the options and outcomes that is relevant to a person’s health status [8]. DAs may include estimates of probable treatment effects, exercises, and strategies for decision-making. DAs could be part of regular patient education curricula, specific decision-making programmes or could be offered during patient counselling. Educating and informing patients are already key components of diabetes care. Diabetes educators are increasingly asked to communicate research results to patients. The use of DAs may facilitate patient counselling.

In November 2008 we updated former systematic literature searches [9] using the *Cochrane Inventory*, *PubMed*, *Embase*, *CINAHL*, *PsycINFO*, and *PSYDEXplus* [1]. Fourteen publicly available DAs about cardiovascular prevention were identified [6], [10], [11] [12], [13], [14],

[15], [16], [17], [18], [19], [20], [21], [22], [23], [24], [25], [26]. One of them, *Statin Choice*, was specifically designed for people with type 2 diabetes [22], [23], [24], [25], [26]. One additional diabetes DA was identified by personal contact [27] (for characteristics and quality aspects see Table 1). *Statin Choice* [24] focuses on statin treatment. It meets nearly all quality criteria established by the International Patient Decision Aid Standards (IPDAS) Collaboration [8]. We identified three publications on development and evaluation of this DA [24], [25], [26]. One reported a randomised controlled trial (RCT) in which the DA was rated more helpful than a standard educational pamphlet. It was found effective concerning knowledge, improving patients’ estimation of their cardiovascular risk and of potential risk reductions with statin drugs, and it decreased decisional conflict [25].

The Health Dialog DA [27] promotes modification of health behaviour suggesting a hierarchy of targets with emphasis on control of blood pressure and cholesterol. Risk information on benefits and harms is not provided. Data sources are not listed. Evidence about the implementation of this DA in clinical practice was not identified.

The present article describes development and pilot testing of a DA about prevention of myocardial infarction for patients with type 2 diabetes (http://www.chemie.uni-hamburg.de/igtw/Gesundheit/images/pdf/Decision_Aid_HerzinfarktpraeventionDM2.pdf).

Methods

DAs are *complex interventions* comprising a number of interactive components [28]. Therefore, the *UK Medical Research Council’s* guidance [29] was used to structure modelling and evaluation of this DA. This widely accepted guidance was developed to support transparent development and evaluation of complex interventions [30], [31]. The local ethics committee approved the study protocol.

Table 1: Decision aids for cardiovascular prevention in type 2 diabetes

Title	Living with diabetes. Making life style changes to last a life time	Statin Choice
Publisher	Health Dialog, Foundation for Medical Informed Decision Making, US	Mayo Foundation, US
Scientific background publication(s)	Unknown	Available [24-26]
Type of diabetes	Type 2 diabetes	Type 2 diabetes
Topics	Losing weight, physical activity, healthy eating quitting smoking, controlling blood pressure, controlling cholesterol, controlling blood sugar	Statin use
Last update	2007	2008
Format	Video, booklet, diabetes management worksheet, and "Questions to Ask My Doctor About my Diabetes"-form	Booklet, Coronary Heart Disease Calculator; decision sheets (average, elevated, and high coronary risk)
Language	English	English, Spanish
Availability	The DA can be requested from the Foundation for Medical Informed Decision Making	Publicly available for free from http://mayoresearch.mayo.edu

Rationale and design of the decision aid

The DA is designed for people with type 2 diabetes without history or clinical signs of coronary disease, major other cardiovascular disease or diabetic late complications. It is aimed to be used by patients to prepare them for consultations with their diabetes educator and/or their general practitioner. Patients should have participated in a structured diabetes education programme previously. The DA targets lifestyle changes or drug interventions recommended for primary coronary prevention. Objective is to improve the quality of decision-making. This means that patients understand and clarify personal importance of outcomes and probabilities of their occurrence, and participate in decision-making actively. This approach is ethically justified and implicated by action control theories such as the theory of planned behaviour [32]. According to this model, behaviour is influenced by *attitudes to the behaviour*, *subjective norm* (e.g. perceived physician's attitudes), and *perceived and actual behaviour control*. The DA provides evidence-based information to resolve knowledge deficits in order to strengthen *behaviour control*. Information about probabilities of outcomes tailored to the individual risk is aimed at realigning unrealistic expectations. Worksheets are designed to help deliberating about individually important information. The DA is in German language.

The project was designed and executed by the three authors covering three research areas (education and health sciences, diabetology and internal medicine, psychology). The protocol has been based on MATRIX, a guide for systematic development and evaluation of DAs [33]. The IPDAS quality criteria [34] were considered.

Evidence was gathered and "translated" into simple language suitable for patients. Selection and presentation of research data followed recent criteria for evidence based patient information and shared decision making

[35]. We used a background paper of the German diabetes disease management programme [36] and the *consent guidance* by the British General Medical Council [37]. Updates were performed by systematically searching the *Cochrane database of systematic reviews*, *Medline*, and *Embase*. Articles were selected according to validity, patient relevance and clinical importance. References are listed in the DA.

Information on risk factors and available treatment options (Table 2) is provided on a simple level. 100-stick figure pictograms and bar graphs visualise the risk of having a heart attack and treatment effect probabilities (examples in Figure 1 and Figure 2). An appendix provides additional information (e.g. reliability of individual risk prognosis). A glossary explains important technical and medical terms.

Users are guided to estimate individual risk of having a myocardial infarction in the next ten years and to find tailored information about statin treatment effects. The PROCAM risk score [38] and data of the German Federal Health Monitoring [39] were used to calculate the risk in rough categories (Figure 3). Risk estimates do not contradict with current recommendations [36], [40].

Component modelling

A draft version was evaluated in a focus-group of potential providers during a two-hour workshop held at the 16th Forum of Quality in Health Care in Munich 2006. Three physicians, two psychologists and four patient counsellors were invited to reflect and criticise the concept. Comments were clustered according to topics. We revised the DA based on qualitative data synthesis.

Table 2: Components of the decision aid

1.	General information about the role of the patient in informed decision making and objectives and structure of the DA
2.	Summary of information about myocardial infarction, symptoms and complications
3.	Detailed information on "coronary risk" <ul style="list-style-type: none"> ○ The definition of the terms "risk" and "coronary risk" ○ "Risk factors" and their relevance (age, gender, family predisposition, overweight, deficit of motor activity, poor nutrition, poor education, poor-employment- or poor-financial conditions, lacking social support, lipid levels, type 2 diabetes, and high blood pressure) ○ Coronary risk prognosis and individual applicability
4.	Primary coronary prevention in type 2 diabetes <ul style="list-style-type: none"> ○ Benefit, lack of benefit, and possible harm of non-drug, behavioural preventive interventions (smoking cessation, exercise, stress management, nutrition and vitamins) ○ Benefit, lack of benefit, and possible harm of preventive drugs (for glucose control and treatment of high blood pressure, use of statins and aspirin)
5.	Personal worksheets to encourage the user to summarise individual relevant information in order to deliberate between preventive options
6.	Action plan to facilitate decision making together with the physician
7.	Appendix that contains a glossary of technical and medical terms, additional information for users who want to learn more about coronary risk, and references

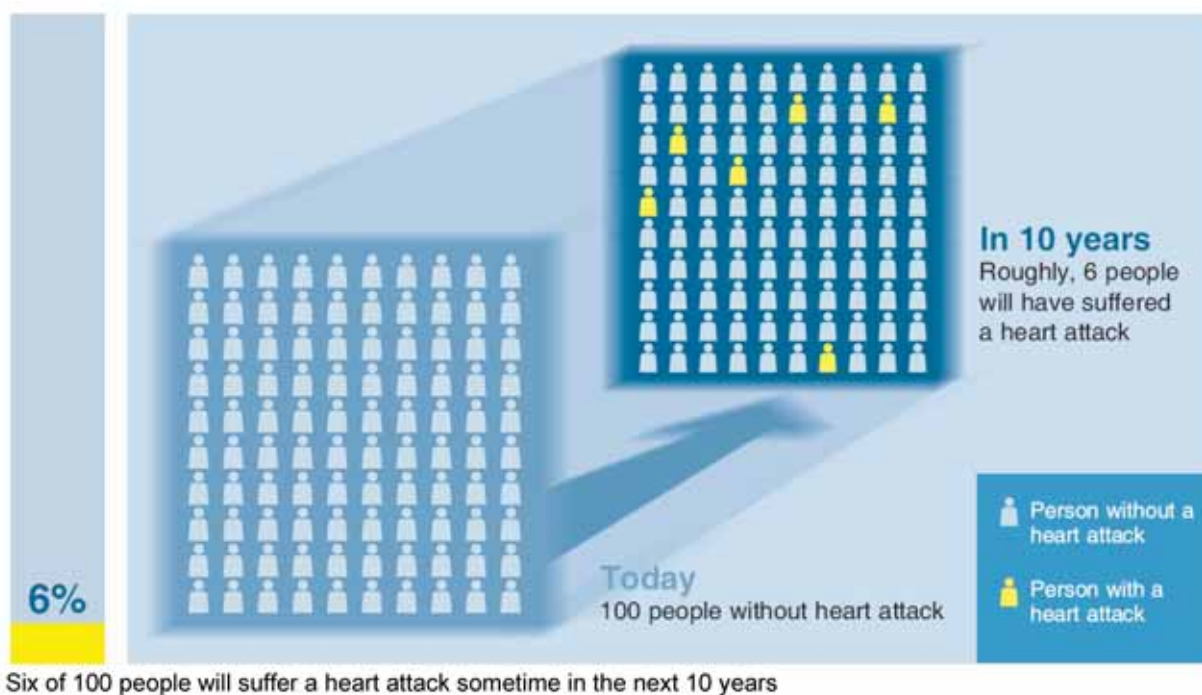


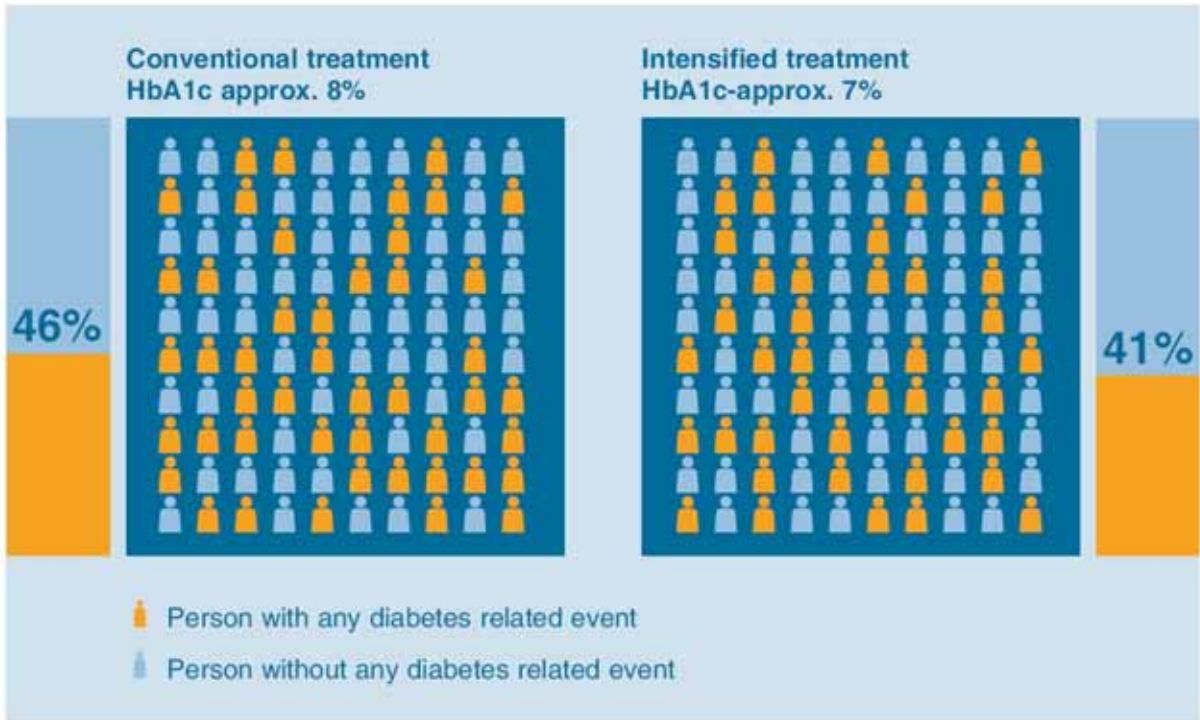
Figure 1: Heart attack risk of 6%

Pilot testing among providers

Qualitative methods were used to gather insight into 1) difficulties of understanding the contents of the DA, 2) appropriateness of complexity, 3) completeness, and 4) expected applicability.

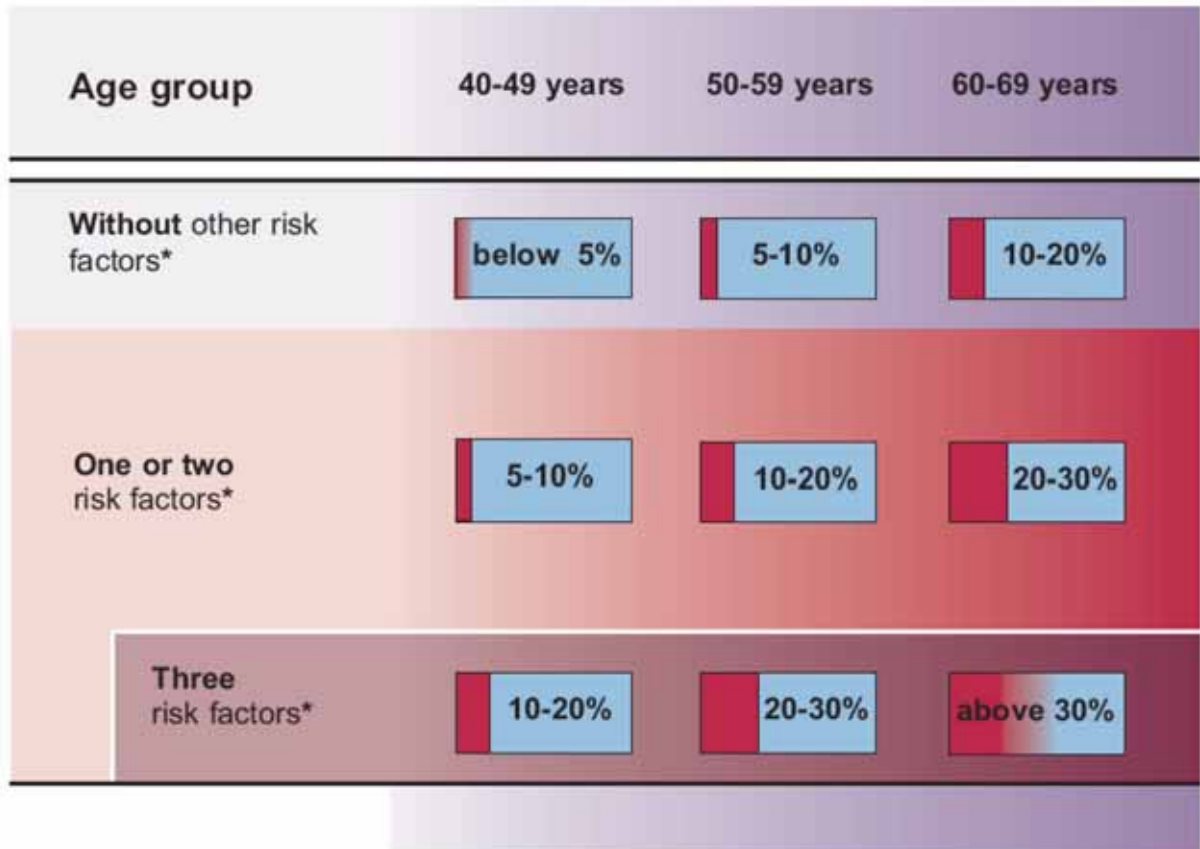
Five diabetes educators were recruited from diabetes clinics in Hamburg. Each underwent two semi-structured face-to-face interviews conducted by two researchers. All participants gave written informed consent. All interviews were documented in written form. At the beginning of the

first interview, we explored the spontaneous orientation within the DA. Using the concurrent "think-aloud" technique [41], [42], each educator was encouraged to express thoughts and associations loudly while browsing the contents. Subsequently, we explored detailed understanding of passages about risk prognosis. Each educator was asked to shortly summarise the content. Difficulties of understanding were intensively discussed. Each educator received a short evaluation guide for homework. The guide comprised three tasks: 1) "please mark passages (texts and figures) that you do not understand";



Estimated probability of benefit of intensified treatment on the outcome "any diabetes related event"

Figure 2: Treatment effect



* As risk factors count smoking, high blood pressure, and high LDL-cholesterol

Figure 3: Tool as used in the decision aid for the assessment of a 10-year risk of having a heart attack for people with type 2 diabetes

2) “do you feel that your patients would be sufficiently informed and supported in decision making?” 3) “Please reflect on passages or topics, which you think that more information is necessary”.

The second interviews were conducted two weeks later. The tasks were intensively discussed.

Data analysis

Data analysis passed four steps: identifying units of analysis in the transcripts, allocating the statements into categories, interpreting the data, and extracting needs of revision of the DA. Categories were 1) content, 2) complexity, 3) structure/orientation, 4) media and layout (colours, illustrations etc.), and 5) patient centeredness (Table 3, Table 4). Comments that could not be allocated into a category were documented separately. Two raters (ML, JK) discussed and interpreted each statement until consensus about the allocation was achieved. Inter-rater-agreement was not assessed. Decisions on revision were made in a discourse by an expanded research group (IM, ML, JK, MB).

Pilot testing among patients

Evaluation among patients comprised two studies. We explored 1) difficulties of understanding the contents of the DA, 2) appropriateness of complexity, and 3) additional information needs (completeness). Participants were recruited by screening the registers of a diabetes outpatient clinic in Hamburg.

For the first study, 15 women and men at the age between 40 and 69 years with type 2 diabetes and without history of CHD were included selected according to age, gender, blood pressure, and status of smoking (Table 5). Study procedures were identical to the educator’s interviews. In addition, passages according to specific risk factors were allocated according to individual risk profiles (Table 5). Patients were asked to summarise those contents. Difficulties were intensively discussed. Each participant received a short evaluation guide for homework comprising two tasks: 1) “please mark passages (texts and figures) that you do not understand”; 2) “Do you feel sufficiently informed? Please, reflect on passages or topics, which you are interested to learn more”.

The second interviews were conducted two weeks later. The tasks were intensively discussed. Both interviews were analysed analogous to those among the educators. The second study was conducted after revision of the DA. The coronary risk assessment tool was reassessed, which had shown insufficient performance in the first study. Twelve women and men (40–70 years) with type 2 diabetes were recruited by screening the registers of the diabetes clinic again. Face-to-face interviews were undertaken to explore how the participants use the revised coronary risk assessment tool for an imaginary patient. Each hypothetical patient varied across coronary risk categories. Using concurrent “think-aloud” [41], [42], the

participants were encouraged to express their thoughts loudly while using the tool.

Results

Pilot testing among providers

Five educators were enrolled; one of them was male, four of them female. All had a minimum of 10 years working experience in diabetes education and counselling.

Each interview lasted 60 minutes. Typical statements are displayed in Table 3. The DA was anticipated helping patients to understand the concept of risk prognosis and the role of type 2 diabetes. A general understanding of coronary risk was found necessary to reflect benefits and risks of preventive options. It was also mentioned that the “multiple risk factor approach” might be too difficult to understand.

The complexity of the DA was considered as very high emphasising that the target group is highly heterogeneous related to social status and level of literacy. It was proposed to delete passages that are “too statistical” and to develop versions providing different levels of information.

The DA was found to guide patients through the decision making process in an acceptable and logical way and that it would help them to prepare for and reach a decision.

The media used were considered appropriate. The educators proposed to rearrange the layout (e.g. code of colours in terms of a recurrent theme) and to include an initial “quick guide” facilitating orientation. Providing the included illustrations (risk, benefits and harms) as leaflets supporting patient education and counselling was also proposed.

The educators perceived the DA mainly as patient centred. However, they challenged the technical style of language, which was chosen to provide information in an unbiased way. They suggested “talking” to patients in a “more personal and non-technical” manner and to include some kind of case reports for illustration purposes. The invitation to decide on preventive options in an “autonomous” or “shared” manner was anticipated to overstrain most patients.

The most controversial content related to “social status as a risk factor”. Inconvenience was expressed to communicate a factor, “which can not be modified or exactly quantified”, “whose causes are difficult or impossible to explain”, or “which might discriminate patients with a low social status”. It was also suggested to lay emphasis on social support in order to motivate people to become actively involved in their social environment.

In preparation for the second interviews, all educators had reviewed the DA intensively. It was found to have an appropriate format. All educators mentioned that communicating the “multiple risk factor approach” is necessary to support decision-making. Difficulties were expected concerning the understanding of the term risk and indi-

Table 3: A sample of statements* from the first and second interviews with diabetes educators in categories

1) Content/Information
'Is this [refers to the whole DA] what patients get to work through? Patients are not capable and motivated enough to deal with this amount of information.'
'I understood this passage [refers to the passage about global coronary risk] though it is difficult; I could not explain this term [global coronary risk] spontaneously. It is however necessary to understand this term to be able to understand benefits and risks [refers to preventive measures].'
'It gives the impression that we might not know what exactly contributes to the heart attack risk and that there is a lot of uncertainty about the effectiveness of preventive measures. I guess this could discourage patients from doing something.'
'Bearing in mind the pure amount of information, these contents [relating to social factors] should be shortened or deleted. Socially disadvantaged people cannot influence their situation anyway.'
2) Complexity
'I could hardly follow the structure; this decision aid is far too complex for the patients I know.'
'Good structure: it is made to learn it from scratch.'
'There is not <i>the diabetes patient</i> . These patients are different in knowledge, literacy, and motivation. Maybe different versions [providing different levels of information] should be provided.'
3) Structure/Orientation
'A quick guide <i>how to use this decision aid</i> at the beginning of the decision aid would be good.'
'More structuring elements would help with orientation.' [This was mentioned several times and specified after requests: pictures with individuals concerned, pictograms, accentuated headlines and key messages, and loud and contrasting colours]
'More information about <i>what do I learn reading this passage</i> should be included.' [refers to the table of contents]
4) Media/Layout (colours, illustrations etc.)
'You always find the same kind of risk visualisation [refers to the 100 stick figure pictograms]. You get used to it, which makes it easier to understand. I would use these graphics for education and counselling as well.'
'This table [refers to the risk assessment tool] is helpful to guide the individual to the relevant information about statin treatment.'
'Maybe it [refers to the passage about the term risk] is helpful to tell the patients that the heart attack risk is not an individual risk. Though, applying this information to the individual situation might be challenging.'
5) Patient centeredness
'The brochure seems somewhat uninspiring.' [after request:] 'It would be nice to display some concern for instance <i>we care about you or it is not only about statistics, it is about humans</i> .'
'A problematic social situation cannot be improved by an individual. It is rather stigmatising; it is like <i>look at yourself in the mirror, you are disadvantaged</i> . But those people feel disadvantaged anyway.'
'I like that patients have their own choice about the measures, they are not forced to do something.'

*The style of language used in these comments has been slightly modified; authors comments in square brackets

vidual risk perception. Worksheet and action plan were expected to structure decision making and to define a preventive strategy. The chapter "social status as a coronary risk factor" was challenged again by expressing concerns to implement this topic into patient education and counselling.

All educators would support the implementation of this DA. Conditions of implementation were considered as optimal within education curricula and patient counselling. The DA was expected to facilitate discussions between patients, educators and doctors and to support shared decision making.

Pilot testing among patients

Fifteen patients were enrolled in the first qualitative study (Table 5). Median age was 57 years; all finished a minimum of 8 years elementary school; five were of higher educational level. Both interviews lasted approx. 60 minutes. Typical statements are displayed in Table 4. Spontaneous orientation was rated as good. All participants could describe the main topics of the DA. The contents about risk prognosis were mainly reproduced correctly but differed in completeness and profoundness. The overall complexity was considered as high. Some passages were found "too statistical". However, no participant felt overstrained.

Table 4: A sample of statements* from the first and second interviews with patients in categories

1) Content/Information
'I have always said that social status is important. I suggest even smoking is probably a social factor.'
'Everything is related to it [refers to social problems], even smoking and high blood pressure. Social factors are the most important issue.'
'Hard to believe that living among those people [refers to socially disadvantaged people] causes high risks.'
'I have understood that heart attack risk is caused by various factors. But it is all about chance; it is not certain even if you have all those risk factors.'
'I am not interested in how many people out of a group will have an event. When will I get a heart attack? – That is what concerns me.'
'How can I be sure if this information is complete? Still, I trust the people who provide this information. [specification after request:] 'The reference section at the end makes it trustworthy.'
'It is partly too superficial, too short, with too little explanation. That makes it sometimes difficult to understand. I would prefer to learn more about other complications.' [specification after request: 'What about my eyes? How do all these drugs work?]
'Something practical is missing, an advice, a recommendation.'
2) Complexity
'Repetition of information in some passages helps to memorise important aspects.'
'There are too many repetitions, which makes the whole text too long and rather confusing.' [specification after request:] 'It is clear from the beginning that it is about a ten-year-risk; this does not need to be repeated all over.'
3) Structure/orientation
'I had to read some passages several times before I got the message.'
'Pros and cons can not be easily identified within this amount of information. Short summaries could help.'
'More pictures and illustrations and less text would make it more attractive to read.'
4) Media and layout (colours, illustrations etc.)
'Who am I among all those figures in the graphs?' [refers to the 100-stick figure pictograms]
'I like this random illustration, it refers to reality [refers to the 100-stick figure pictograms visualising the ten-year-risk]. Everybody could be affected.'
'If my risk is 20%, I certainly will have a heart attack; I am surely one out of those 20 yellow figures [refers to the 100-stick figure pictograms visualising the ten-year-risk]. This is the reason why this book is given to people like me.'
'Although I understand that heart attack risk is nothing individual, my concern is, who of them am I? Am I a lucky white one or one of the yellow figures who will get the attack?' [refers to the 100-stick figure pictograms]
'These graphics do not help to understand the risks, they are too abstract. [refers to the 100-stick figure pictograms]. For me, tables that include percentages of all risks would be helpful to get an overview.'
'There are too many pictograms. It is boring and impossible to recognise any proportions; you have to count the figures. I would prefer bar graphs or similar.'
5) Patient centeredness
'There is so much information I definitely do not need. However, I have picked the information I needed.'
'It is not possible to transfer study results to my individual situation.'
'I have lived in a smoking friendly environment. To quit smoking is not a matter of being well informed about its risks.'
'These scales are meaningless [refers to the worksheet about quitting smoking]; to quit smoking is not a matter of being well informed. It is an addiction. I have been trying to quit for 10 years and there is nothing I can do.'
'The passages about statin treatment seem to be advertisements from a pharmaceutical company: <i>take statins, this is the miracle cure.</i> '
'I tried to use these scales [refers to the worksheet relating to the preventive measures]. However, I always felt I needed more information to distinguish between all pros and cons.'
'If I had to make a decision on one of these measures, based on the information in this book, I would have been sure that my decision was the right one.'

*The style of language used in these comments has been slightly modified; authors comments in square brackets

Table 5: Patients' allocation according to moderating variables

Nr.	Age	Gender	Hypertension	Smoking	Evaluated passage
1.	44	m	yes	no	„High blood pressure“
2.	45	f	yes	yes	“Smoking”
3.	46	m	no	no	“Use of Statins”
4.	49	m	no	yes	“Social factors”
5.	52	f	yes	no	“High blood pressure “
6.	55	m	no	yes	“Smoking”
7.	58	m	no	yes	“Use of Statins”
8.	59	m	yes	no	“Glucose control”
9.	60	f	no	no	“Glucose control”
10.	60	f	yes	no	“Social factors”
11.	61	f	no	no	“Social factors”
12.	64	m	no	yes	“Smoking”
13.	65	f	no	yes	“Glucose control”
14.	67	m	yes	no	“High blood pressure “
15.	70	f	no	no	“Use of Statins”

f = female; m = male

Graphical illustrations were mainly considered as helpful. Most participants correctly interpreted the probabilities presented using 100 stick figure pictograms. The risk assessment tool was not used correctly by five participants as they allocated themselves to false risk categories.

Each passage specific for a risk factor was evaluated by 3 participants. The passage about glucose control was rated as easy to understand. One participant expressed difficulties in transferring the findings of study results to his individual situation. Similar results were found for the passages about “high blood pressure” and “use of statins”. The risk specific information about statin use was correctly identified by all participants. The information about the “social factor” was considered as highly important and proposed to be communicated even more extensively. Patients also expressed concerns that this might discriminate patients with a low social status.

The chapter about smoking was easily understood. However, it was challenged that the information contributes to “quitting smoking”, since smoking was not a matter of lacking knowledge about risk.

In preparation for the second interviews, all participants had reviewed the DA intensively. The DA was rated as helpful; the amount of information was mostly rated as “just right”; some asked for additional information (e.g. about stress and smoking as social factors and brands of statins available on the German market).

Several passages were rated as difficult to understand. Some participants reported that they had to read some passages several times until they understood the message. Most participants reproduced the term coronary risk and the “multiple risk factor approach” correctly. It

was mentioned that too many statistics could be confusing. Some expressed problems in understanding technical terms such as “any diabetes related endpoint”, “intensified treatment”.

The overall structure could easily be followed. Some participants felt confused by the amount of information and claimed more structuring elements such as pictograms and accentuated key messages. The 100 stick figure pictograms were rated helpful to reflect on benefits and harms. Some participants proposed to add bar graphs to simplify the comparison of proportions.

The DA was felt to provide good decision support. The worksheet about quitting smoking was felt needless. Some participants stated that they learned to ask “the right questions” to the doctor.

All participants were very interested to use a validated and revised version. Similar to the educators, conditions of implementation were considered being optimal within diabetes patient education curricula and counselling.

Twelve patients were enrolled in the second study to reassess a revised version of the risk assessment tool (Figure 3). Seven participants were women; median age was 56 years. All finished a minimum of 8 years elementary school. The revised coronary risk assessment tool showed optimal performance. No participant expressed difficulties in using it and all were able to correctly allocate risk profiles.

Revision of the decision aid

Data analysis revealed several aspects, which contributed to the revision of the DA. E.g. technical terms were explained more intensively; the layout (headlines, colours,

and type style) was clarified; textual passages were simplified; 100 stick figure pictograms illustrating benefits and harms were supplemented by bar graphs to facilitate the comparison of proportions; the coronary risk assessment tool was simplified and explained in more detail. Despite patients concerns, the chapter about smoking cessation remained. Quitting smoking is highly important compared to other preventive options. The chapter about glucose control was updated because of new evidence from the recent ACCORD trial. The current version of the DA (http://www.chemie.uni-hamburg.de/igtw/Gesundheit/images/pdf/Decision_Aid_Herzinfarkt_praeventionDM2.pdf) contains 65 pages comprising seven components (Table 2).

Discussion

Following the *UK Medical Research Council's* guidance for the development and evaluation of complex interventions [29], we described the theoretical concept, component modelling and preliminary qualitative evaluation of this DA (http://www.chemie.uni-hamburg.de/igtw/Gesundheit/images/pdf/Decision_Aid_Herzinfarkt_praeventionDM2.pdf) in detail. At this stage of development, qualitative studies were necessary to gather an in-depth understanding of how providers and users understand the DA's objectives, content and structure, how they anticipate its applicability, and which additional information needs may exist. Representativeness and transferability of these studies are limited, due to their qualitative design. Further evaluation needs to include quantitative methods to assess the DA's effectiveness. The DA was evaluated within its particular decision making context including German speaking patients. An English translation is under development. The evaluation suggested that most parts of the DA were understandable and that information needs were mainly satisfied. Interestingly, we found discrepancies between the patients' understanding and the patients' understanding anticipated by the diabetes educators. E.g. while educators expected that many patients could be overstrained, most patients could easily follow contents and structure. Educators' anticipations that contents related to the social status as a risk factor could be misunderstood or discriminate, were not confirmed by patients' comments. We plan to develop additional components that are necessary for a successful implementation. E.g. an *evidence table* is going to be implemented, which includes an overview of available preventive options and probabilities of benefits and harms. Graphical illustrations are going to be combined in a handbook to support risk communication in patient education curricula and counselling. Finally, the DA is planned to be the core of a shared decision making programme, which comprises a strategy for patient counselling and an introductory educational module that addresses providers (diabetes educators and specialised nurses). Effectiveness of this programme

will be evaluated over 12 months within a RCT. Long term implementation will be surveyed in observational studies.

Notes

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Declaration of competing interests

Nothing to declare.

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