Abstract
Patients have the right to make informed decisions on treatment goals and treatment regimens and also to be provided with reliable information necessary for decision-making. Evidence-based medicine explicitly integrates patients’ values and preferences in treatment decisions. Both are regarded as crucial to increase both the patients’ quality of care and independence. Education programmes or patient decision aids are complex interventions, typically comprising separate components acting interdependently (e.g. content, structure, and media of an education programme). They are heterogeneous in their goals, methods and target populations. Development and evaluation of complex interventions are sophisticated processes requiring both qualitative and quantitative methods. In a previous review we showed that common methodologies used in systematic reviews do not allow adequate appraisal of complex interventions. Patient education programmes were used as an example. The present review outlines present developments in patient education and shared decision making in diabetes care. It also comprises an update of the previous review. Methodological challenges of the development and evaluation of complex interventions are discussed. Methods of current systematic reviews do still not meet the challenges to appraise patient education and self-management programmes. Since these are complex and heterogeneous interventions, consideration of aggregated evidence is necessary. Information necessary for the evaluation of such programmes is difficult or impossible to identify. In conclusion we propose to establish a scientific network and database, which supports scientific exchange and systematic tagging of self-management programmes, patient education programmes and patient decision aids.

Keywords: self-management, education, diabetes, hypertension, systematic reviews.

Introduction
Patients have the right to self-determination, to make free decisions regarding themselves. Patients have the right to make informed decisions on treatment goals and treatment regimens and to reliable information necessary for decision-making. Evidence-based medicine explicitly integrates patients’ values and preferences in treatment decisions. The successful implementation of patient education in diabetes has resulted in knowledgeable and independent patients. Recent approaches such as evidence based patient information and patient decision aids can support people to participate in decision making about health care options.

Traditionally, diabetes patient education was expert-based rather than evidence-based as reflected by a variety of non-evidence based dogmas. Diabetes education was restricted to dietary training. Regular self-monitoring (of urine glucose) was not an obligatory part of treatment, and patients with type 1 diabetes were not allowed to change insulin dosages themselves. The primary educational goal was to increase patient compliance to strict dietary regimens. Towards the end of the 1970s, the increasing acceptance of a causal relationship between glycemic control and microangiopathy led to an agreement for the primary therapeutic goal, i.e. near-normalization of metabolic control. Education, encouragement, and training of the patient to actively take over increasing parts of his/her therapy in order to stepwise render him/her more independent from physicians and medical institutions became primary objectives of patient education. The success of this approach has been documented in a large number of controlled trials carried out by a variety of research groups all over the world.

The present review outlines present developments in patient education and shared decision making in diabetes...
Evidence-based patient choice and shared decision making in diabetes care

The successful implementation of patient education in diabetes has resulted in knowledgeable and independent patients. Their right to actively participate or eventually even to assume responsibility in medical decision-making processes is becoming obvious. The basis for informed patient choice is an unbiased communication of evidence-based scientific data in a format that can be understood by non-medically trained persons. The British General Medical Council published ethical guidelines for the procedures necessary to obtain patients’ informed consent prior to undergoing any medical intervention. These are quite specific in stating that patients must be given sufficient information to enable them to exercise their right to make informed decisions about their care. For instance, this information needs to include details of the diagnosis, and the likely prognosis if the condition is left untreated; potential uncertainties about the diagnosis and options for further investigation prior to treatment; options for treatment or management of the condition, including the option not to treat. For each therapeutic option, the probabilities of success, the risks of failure, or harm as well as any lifestyle changes which may be caused by or necessitated by the treatment need to be explained using accurate data. The patient should be given time to reflect before and after making a decision, especially where the information is complex. The physician should abstain from making assumptions about patients’ views; and information must not be withheld because of the possibility that the patient might become upset or decide to refuse a suggested investigation or treatment.

The active involvement of patients in decision making about medical interventions has been increasingly advocated. In particular, in the chronic care setting, decision making requires an active patient role. Previous systematic reviews found that interventions targeting patient autonomy (such as empowering group education) can result in measurable improvements in quality of life and in physiological markers of disease control. In 1997 medical sociologists introduced the concept of shared decision making (SDM). SDM can be defined as the involvement of patients with their providers in making health care decisions that are informed by the best available evidence about treatment/screening/illness management options, potential benefits, and harms, and that consider patient preferences. The physician and patient together go through all phases of the decision-making process, share treatment preferences, and reach an agreement on treatment choice.

However, diabetes is usually not considered a typical disease for SDM even by protagonists of SDM. The belief is still widely held that control of blood glucose and other cardiovascular risk factors are beyond any doubt beneficial and therefore, supporting patients in adherence increasing behaviour rather than SDM has been standard procedure in diabetes care. By contrast, the large variety of available treatment options to improve prognosis on one hand and the poor adherence to long-term treatment on the other hand, urge SDM in diabetes care. Patients should be supported to define a hierarchy of individual goals and to triage interventions. This might facilitate long-term adherence to albeit a few but individually acceptable and possibly the most effective treatment interventions. From this point of view diabetes might even be prototypic for SDM.

Decision aids for people with diabetes

Patient decision aids are tools designed to help people participate in decision making about health care options. They typically provide information on the health problem and available treatment options. They are designed to help patients clarify and communicate the personal value they associate with different features of the options. Decision aids may include an estimate of probable treatment effects based on a patient’s risk factors, exercises to help patients clarify their preferences, and proposed strategies for making informed decisions. Decision aids are supposed to be used when there is no single “best” choice among equally effective options or when the best choice depends on how patients balance benefits versus harms.
Patient decision aids typically consist of various elements (related to different topics, e.g. glucose control, blood pressure treatment), address a variety of health decisions (e.g. on preventative or curative treatment or diagnostic procedures), use various formats (e.g. decision boards, booklets, interactive software and videos), and aim to achieve various goals (e.g. to enhance knowledge, to generate realistic expectations and satisfaction with the decisions, and to strengthen patient autonomy). A decision aid can also be part of a decision-making programme, which additionally comprises a strategy for patient counselling or an introductory educational module. Effectiveness of decision aids has not been shown in general. Different tools developed to facilitate critical appraisal of decision aids include other important quality criteria (e.g. ethical aspects and theoretical basis). The International Patient Decision Aids Standards (IPDAS) Collaboration established internationally consented quality criteria (table 1). Our research group developed MATRIX, a guide designed to structure a systematic development and evaluation of decision aids (for key criteria of MATRIX see table 1).

Transparency is an important quality criterion for the development of a decision aid. Authors should state whether and in which way a decision aid includes patient-relevant evidence-based information (including the strength of available evidence), and whether and in which way users are supported to deliberate about positive and negative features of options.

We have browsed the Internet perpetually and undertook systematic literature searches in October 2008 using the “Ottawa Inventory”, PubMed, EMBASE, CINAHL, PsycINFO, and PSYNDEXplus. Three evidence based decision aids specifically designed for people with diabetes were identified. One additional decision aid was identified by personal contact. One publication about a diabetes decision aid was identified, which is still under evaluation and currently not available. Our research group has developed an evidence based decision aid for coronary prevention in type 2 diabetes, which has been pilot-tested but is not yet available.

Characteristics of the four currently available diabetes-specific decision aids and related quality criteria according to IPDAS and MATRIX are summarised in table 1. One of the identified decision aids refers to the use of an insulin pump in type 1 diabetes. Patients are asked to deliberate about positive and negative features of options. Scientific references are cited. However, probabilities of benefits and harms are lacking. The second decision aid was designed for women with type 1 diabetes deliberating about getting pregnant. The contents rely on expert recommendations. Evidence-based risk information that could help to deliberate about options is not provided. Sources of information are not transparently reported. The Health Dialog decision aid for patients with type 2 diabetes promotes modification of health behaviour in addressing smoking, diet and physical activity. A hierarchy of targets is suggested with emphasis on control of blood pressure and cholesterol rather than on blood glucose. Risk information on benefits and harms of options is not provided. Rather, patients are referred to their physicians. References are not listed. The “Statin Choice” decision aid targets treatment with statins in patients with type 2 diabetes. This decision aid meets nearly all IPDAS-criteria (table 1). One limitation is that the external validity of the included risk calculator is unclear and problems with reliability of risk prognosis are not discussed.

Evidence about the implementation of these decision aids in clinical practice is lacking. Background information on development and evaluation was identified for one decision aid only. Weymiller et al. randomly assigned 98 patients to the decision aid or a standard educational pamphlet. The decision aid was rated to be more helpful, enhanced knowledge, improved the estimation of the cardiovascular risk, reduced decisional conflict and also led to potential risk reduction with statin drugs. The follow-up was 3 months so long-term effects are unknown.

Development and evaluation of complex interventions

In diabetes care, single interventions (e.g. a single drug) coexist with complex interventions (e.g. treatment regimens, patient education and patient decision aids). Complex interventions typically comprise a number of components that may act interdependently and seem essential to their proper functioning. A self-management programme for type 1 diabetes may illustrate the complexity. Decisive components are the insulin regimen used and the quality of the teaching process to empower pa-
Patients to carry it out effectively and safely. Empowerment of patients to set individual treatment goals and to balance favourable blood glucose targets and an acceptable risk of hypoglycaemia by self-adaptation of insulin dosages to adjust to lifestyle may be more effective than defining normoglycaemia as the primary treatment goal and asking patients to adapt their lifestyle to match prescribed doses of insulin. Liberalisation of the diet may be important for motivation of patients to carry out an intensified insulin therapy regimen in the long-term. Though indispensable, knowledge by itself may not improve outcomes. The information and how it is transmitted is decisive. Blood glucose self-monitoring may be at best useless unless patients have learned to interpret results and to react by adjusting insulin dosages. In addition, the success of a diabetes self-management programme depends on the motivation and competence of the health care team and structural, organisational and financial conditions.

The U.K. Medical Research Council (UKMRC) proposed guidance on the development, evaluation and implementation of complex interventions. Four stages of the development and evaluation process were defined (in the following “stages of evidence”, figure 1). Stage one comprises the “development” of the complex intervention. Before conducting substantial evaluation, the intervention should be developed to the point where it can reasonably be expected to have a worthwhile effect. It includes identifying the evidence base (e.g. systematic review), identifying or developing appropriate theory about what changes are expected and how these changes can be achieved, and the modelling of process and outcomes. The latter includes prior evaluation to a full-scale evaluation to achieve information about the design of both the intervention and further evaluation (i.e. design and outcomes). Stage two (“feasibility and piloting”) includes testing procedures for their acceptability, estimating the likely rates of recruitment and retention of subjects, and the calculation of appropriate sample sizes for the full-scale evaluation. A mixture of qualitative and quantitative methods is likely to be needed. Stage three and four comprise quantitative methods: Core of stage three (“evaluation”) is the (randomised) controlled trial to assess the effectiveness. Stage four comprises the implementation of the complex intervention and long-term surveillance. Figure 1 summarises the key activities of each stage. The authors underline that the process would not follow a linear or even a cyclical sequence, which is indicated by the arrows between the “stages of evidence”.

**Evaluation of complex interventions in systematic reviews**

A high quality randomised controlled trial (RCT) is considered the most valid method to evaluate a medical intervention and a systematic review of high quality RCTs the most powerful evidence available. A systematic review may, but need not, include meta-analysis as a statistical method for combining the results of individual studies. If used appropriately, meta-analysis is a powerful tool for investigating overall effects. However, if studies are clinically or methodologically heterogeneous, data-pooling may be meaningless and genuine differences in effects may be obscured.

Complex interventions are heterogeneous in their goals, methods and target populations. Thus, using meta-analysis to evaluate complex interventions may disregard the complexity of efficacy measures of the original studies. For example, GHb should not be used as a single outcome variable without considering individual treatment goals, and effects on hypoglycaemia, body weight or quality of life. Similarly, blood pressure values should not be used in isolation without taking into account intended changes in drug and non-drug therapy. Lowering of blood pressure may be associated with more or less drug prescriptions and linked adverse effects.
In a previous methodological review we described and critically appraised available methodologies of systematic reviews on complex interventions. Three patient education programmes of diabetes and hypertension self-management were used as an example (table 2). We had access to the bulk of publications on these programmes. Evidence for almost all phases of development had been generated; relevant components and outcome measures had been defined previously. The available evidence of these programmes was used as a reference to assess whether the included reviews consider the complexity of the programmes. Detailed information about the search strategies and methods of data collection and synthesis have been reported in the previous review. We updated the systematic searches and data analysis in October 2008. A total of 18 reviews were finally appraised (table 3). We identified several methodological problems.

**Systematic searches**
The majority of reviews report their (mostly comprehensive) search strategies transparently. In nine reviews the excluded studies were not reported. It was therefore not traceable whether or why particular programmes were not identified or not included. Experts in the field to identify additional publications were contacted in eight reviews. Reference tracking or hand searching was performed in 13 reviews. Only, one review reported that authors of the included publications were contacted to identify additional publications or unpublished material. A systematic contact including all authors has not been reported in any review.

**Stages of evidence**
The selection criteria used in most of the reviews excluded study types other than RCTs; other important types of publications concerning the “stages of evidence” were rarely included (table 3). In some reviews limitations to publication year and/or publication type prevented the detection of publications referring to pilot or implementation studies of our three reference programmes, since some of these were published more than 20 years ago and do not always fulfill all quality criteria of nowadays standards. Nevertheless, all studies are part of the “stages of evidence” and could have been considered when evaluating the overall evidence.

No review differentiates between the core controlled trials and the controlled replication trials referring to the same programme. Those trials may differ in their methodology, which depends on their specific research question. However, the “stages of evidence” are closely related to each other and should be considered as parts of the same evaluation process.

**Theoretical basis**
The importance to consider the theoretical basis of a patient education programme was widely discussed but we could not identify any approach to systematically assess the theoretical basis and its influence on judging the quality of an education programme. Without considering the underpinning theory it is not possible to identify which components of the programmes are the most important ones, which goals are aimed at being achieved, and which outcome measures are appropriate to show efficacy. There might be only few authors of efficacy trials who report on all “stages of evidence” of their intervention. We have to acknowledge that the problems of considering theoretical funding may also be due to space limitations in printed journals.

**Active components**
All included reviews reported at least some features of the assessed interventions, which were either active components (e.g. setting, duration, interventionist, formal syllabus) or study characteristics (e.g. follow-up, age of participants, study quality). The investigated features were heterogeneous. Six reviews used regression or subgroup analysis in order to analyse the impact of single active components. The majority of reviews reported that the included programmes had been “multifaceted” or “multidimensional” or “consist of multiple active components”. In two reviews the authors considered “multi-component interventions” only if the effects of the educational component could be examined separately. However, the separate analysis of the impact of certain single active components is problematic since the components can be closely interrelated. For example, within our reference programme for patients with type 2 diabetes the primary patient-oriented educational part may be as important as the preparatory course for the physicians and their assistants. Both are interdependent parts of the same complex intervention.
Categories of interventions

In 15 reviews the included programmes were allocated into categories of interventions. Those were defined according to the active components of the included interventions (e.g. setting, duration, interventionist, formal syllabus), to the type of the interventions (e.g. type of disease, type of activity, organisational interventions) targeted on patients or health professionals, or to the study characteristics (e.g. follow-up, age of participants, study quality). The applied categories varied and often seemed to be arbitrary. Each review used different categories; none of them explained the rational of their categorization.

Allocation of complex interventions into categories can be problematic, even if categories are derived from core components of programmes (e.g. education directed to the patient). If the categories refer to single but interdependent components, the compartmentalization of efficacy is not possible. Regression and subgroup analyses were performed in eight reviews. Those tools are best used to explore heterogeneity. However, these techniques should not be misused to identify the contribution of the various active components (e.g. intensity or duration of the program) on the overall effect (e.g. knowledge of the target group or the importance perceived by the provider).

Outcome assessment

We compared the outcome measures explored in the included reviews with the outcomes of our reference studies. The analysed reviews did not consider all patient relevant outcome parameters. Components of complex outcome measures were singled out, especially if they used meta-analysis. The complex interdependency between individual treatment goals and outcomes (e.g. changes in medication and metabolic or blood pressure control) remained unexplored.

Implications for research

Methodological challenges of evaluating complex interventions especially in systematic reviews have been increasingly discussed. The first version of the UKMRC approach of the evaluation of complex interventions was published in 2000, which has recently been updated. In our previous review on complex interventions in systematic reviews we identified and described several methodological problems. The present update has shown that the same problems still exist.

Therefore, we again propose to take the following criteria into account when undertaking a systematic review on complex interventions:

- All studies referring to the development, evaluation and implementation should be considered. The reviewers should differentiate between “stages of evidence”. A comprehensive analysis of the underpinning theory should be performed.
- Information necessary for the evaluation of complex interventions is difficult or impossible to identify. Therefore, specific search strategies need to be developed and validated that aim at identifying publications concerning all “stages of evidence”. Literature searches should not be limited by criteria such as certain types of studies, specific target groups and publication dates. Reference tracking should be performed and authors should be contacted systematically.
- Interdependencies between the active components should be taken into account. Components should be identified, described and assessed, but only be examined separately if they are independent and should not be disassembled if they work interdependently. Complex interventions should not be allocated into categories referring to interdependent components.
- All relevant patient orientated outcome parameters should be included. Pooling of outcome measures across different complex interventions is usually inappropriate. Instead, the relative importance of outcomes and the complex interdependency between treatment goals and outcomes should be described in detail.

In addition, we propose to establish an international scientific network to resolve the methodological problems related to the development and evaluation of education programmes and patient decision aids. The network should include a database, which supports scientific exchange and systematic tagging of self-management programmes, patient education programmes, and patient decision aids. In particular, the structure of the database should allow systematic identification of components that appear indispensable for best practice approaches for such programmes’ development, evaluation, and implementation. The database should be structured according to the UKMRC framework. Re-
searchers/authors should be asked to provide publications and materials in whatever language, which can be continuously supplemented and updated. Materials and publications could be translated in agreement with copyright regulations. The system should be opened to critical exchange between users (WIKI-approach). Distinct scientific rules for reporting and critical appraisal should be implemented.

Conclusions
Various different approaches in patient education exist, varying across diseases and health care systems. Despite the availability of various evaluation strategies, development, systematic identification and appraisal of educational remain challenging. A web-based international scientific network and database of self-management programmes for chronic diseases could facilitate further research.

Declaration of potential conflicts of interest
None of the authors have a duality of interest with regard to this work.

Practical considerations

- Patients have the right to make informed decisions on treatment goals and treatment regimens and also to be provided with reliable information necessary for decision-making.
- Methods of current systematic reviews do still not meet the challenges to appraise patient education and self-management programmes.
- A scientific network and database, which supports scientific exchange and systematic tagging of self-management programmes, patient education programmes and patient decision aids, is currently needed.

References


