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Evidence-Based Patient Education in Diabetes and Beyond – Application to Other Chronic Diseases

From Obedience Training to Informed Decision Making

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Abstract

Diabetes education is a model to illustrate milestones in the evolution of patient education from obedience training to participation in medical decision making. The present article focuses some new developments in diabetes education and its evaluation, application to other chronic diseases, and patient and consumer participation in medical decision making. Traditionally, patient education has mainly aimed at increasing patient compliance to physician defined therapeutic goals and treatment strategies. Diabetes self-management programmes have been most effective and have served as models for other chronic conditions such as asthma bronchiale, hypertension and anticoagulation therapy. To further strengthen their rights and their autonomy, patients need to become involved in medical decision making with respect to their individual therapeutic goals as well as concerning their therapeutic options to pursue these goals. The need to have the patients participate in these decisions becomes particularly obvious when long-term therapeutic efforts, even if carried out by the patients with perfection, do not lead to the elimination of the complications attributed to the disease, but much rather to a quantitative change of the risk to develop them. Examples are presented such as anticoagulation therapy in atrial fibrillation, treatment of persons with multiple sclerosis and screening for breast or colorectal cancer. Information as a basis for informed decision making has to be evidence based and presented in an unbiased format. This includes information of the benefits, lack of benefits and unwanted effects as well as burdens of various interventions. Regarding diagnostic procedures consequences of false-positive and false-negative results have to be communicated. Outcome data have to be presented as natural frequencies rather than relative differences. In order to avoid framing of data equal emphasis has to be put on the proportion of persons who are likely to benefit and those who are unlikely to benefit or likely to be harmed. The concept of patient participation in medical decision making represents a fundamental challenge for the future development particularly of the care of patients with chronic diseases.

Diabetes Education as a Model

Diabetes education may serve as a good example illustrating milestones in the evolution of patient education and patient participation in medical decision making. In addition, evaluation of diabetes education programmes may serve as a model for compiling evidence on complex interventions. The present article focuses some new developments in diabetes education and its evaluation, application to other chronic diseases, and patient and consumer participation in medical decision making. The article reports on personal experience by referring to recent projects of the author as a member of the diabetes and education research groups at the diabetes center of the University of Düsseldorf and the Unit of Health Sciences and Education at the University of Hamburg, Germany.

Diabetes Education – From Obedience Training to Self-Management

Traditionally, treatment and patient information were expert-based rather than evidence-based as reflected by a variety of non-evidence based dogmas [1]. Prohibition of sugar consumption ('Zuckerverbot') is just one example. The Zuckerverbot was based on misinterpretation of animal experiments carried out by Dr. Allen early last century [1]. Hence, 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. Figure 1 displays a typical example for the material used in patient education. The poor patients were not only forbidden to consume sweets or cakes, but they were also not allowed to talk. Diabetes education was reduced to obedience training [2]. Systematic assessment of the outcome of this approach was missing, but acute and late complications appeared to be frequent.

Towards the end of the 1970s, the increasing acceptance of a causal relationship between glycemic control and microangiopathy led to the formulation of near-normalization of metabolic control as a primary therapeutic goal. The introduction of glycosylated hemoglobin (HbA_{1c}) measurements confronted physicians and patients with their ill success to achieve this ambitious objective. In 1979, the Diabetes Education Study Group (DESG) of the European Diabetes Association (EASD) was founded. 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. A main

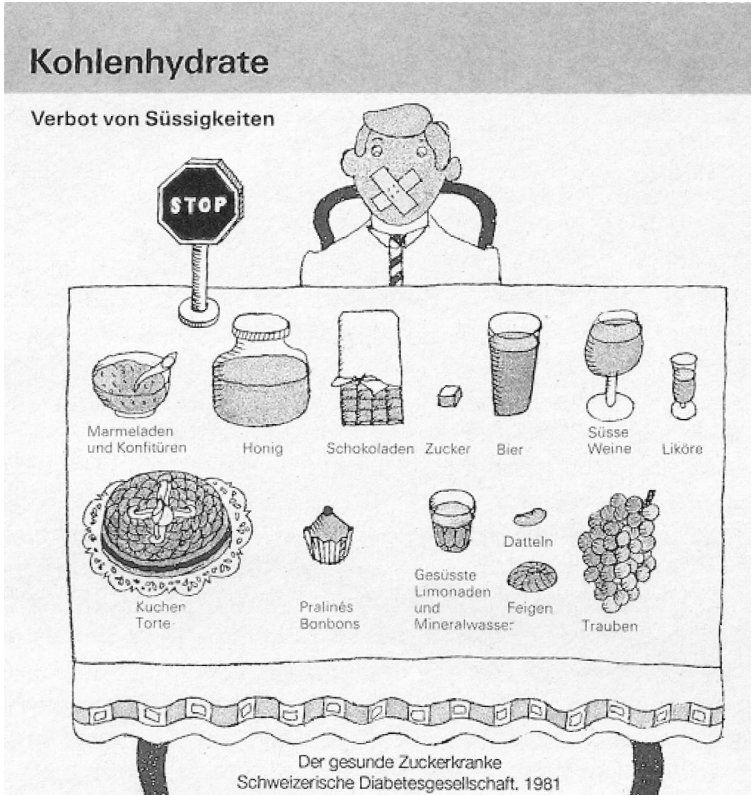


Fig. 1. A typical example for the material used in patient education. (Original drawing taken from a paper published by the Swiss Diabetes Association, 1981.)

objective of diabetes education was the training of the patients in self-adaptation of insulin dosages to variable amounts and timing of carbohydrate intake. Sugar consumption was not prohibited. Meals could be skipped altogether. No snacks were prescribed. The success of this treatment and teaching approach has been documented in a large number of controlled trials carried out by a variety of research groups all over the world [3, 4].

Framework for Evaluation of Education Programmes

The particular problems related to the evaluation of diabetes treatment and teaching programmes including systematic reviews on self-management

programmes have been discussed recently [4]. Diabetes education programmes are complex interventions. Their evaluation is difficult because of problems in identifying and separately assessing the effect of the various components of the intervention. A phased approach defining the sequential stages of a continuum of increasing evidence has been proposed as a framework for the design and evaluation of such complex interventions [5]: pre-clinical or theoretical phase, modelling of the components of the intervention, exploratory trials, randomized controlled trials, and phase of implementation including replication and transfer to different settings. At present it is not possible to readily extract the information on such a continuum of evidence for diabetes programmes from databases such as Medline or The Cochrane Library. Replication, transferability and implementation trials might have been carried out by different authors than the core (randomized) controlled trials. In addition, the identity of the intervention can become apparent only by scrutinizing the original articles. Hence such publications usually can not be identified by conventional methods of searching databases and screening abstracts. Systematic reviews on the effectiveness of patient education and self-management training programmes typically attempt to dissect the programmes into single components and to evaluate them separately [6–8]. Studies using complex interventions are usually excluded or included only if the reviewers feel they can isolate the educational component to examine it separately. In addition, problems with respect to the definition of outcome measures have become apparent. Definition of one common outcome measure for different programmes disregarding the complexity of effectiveness parameters of the original studies will lead to misinterpretations; for example, the use of HbA_{1c} as an isolated outcome variable without considering treatment goals, intended changes in medication or weight or inseparable effects on hypoglycemia. The methodology used in these systematic reviews are not suitable to evaluate complex interventions [4]. Improvement of methodology is urgently needed.

Education and Self-Management Application to Other Chronic Disease

Hip Fracture Prevention by Hip Protectors

Traditional adherence increasing educational interventions may still be very effective. Recently, we have evaluated a programme to increase adherence to the use external hip protection [9–12]. Hip fractures are a major cause of disability among the elderly. External hip protectors can effectively reduce the impact of falls and thereby the risk of the hip fracturing. However, acceptance

of hip protectors is poor. We have developed a two-part intervention, consisting of a structured theory-based single education session and provision of free equipment, directed at nursing staff and residents to encourage the use of hip protectors. The intervention was evaluated in a randomized controlled trial showing a reduction of hip fractures by about 40% [10, 11].

Arterial Hypertension

Hypertension as a model for patient education is comparable to type 2 diabetes. Care for patients with hypertension is characterized by under- and overdiagnosis and under- and overtreatment. Similar to diabetes, hypertension is often asymptomatic and its optimal control needs daily and lifelong adherence to a medical regimen that entails possible side effects. Patient compliance is poor. Providing patients with sufficient information about the disease and its treatment in combination with blood pressure self-monitoring increases patient adherence to dietary and drug treatment and improves control of hypertension. Based on the experiences gained during the development of the diabetes treatment and teaching programme for non-insulin-dependent diabetes [13] the development and evaluation of a hypertension treatment and teaching programme was initiated in the mid-1980s [4]. Components of the programme and conditions for long-term success are comparable for type 2 diabetes and hypertension. Thus, the hypertension programme is similar in design and organization: education for small groups of patients comprising four weekly sessions, delivered by paramedics in out-patient clinics or in the physician's office, written curriculum and teaching materials; structured preparatory course for physician and staff. Important components of the programme are correct blood pressure measurements, a validated diagnosis of hypertension and systematic blood pressure self-monitoring by the patients, active involvement of patients in decision making and adaptation of drug therapy. The programme was evaluated according to the phased approach of a continuum of increasing evidence for complex interventions [4]. The intervention leads to improvement of blood pressure control and at the same time to reductions of prescriptions and changes of antihypertensive medication indicating better adherence to prescribed treatment [4]. In combination with intensified care the programme led to a significant reduction in morbidity and mortality in type 1 diabetes [14, 15].

Asthma Bronchiale

Patients with bronchial asthma are confronted with comparable problems as patients with type 1 diabetes. The disease is characterized by unpredictable fluctuations with acute and sometimes life threatening asthma attacks. Patients with severe asthma face frequent hospital admissions and impairment of quality

of life. Self-monitoring by measuring peak flow may inform the patient in advance about deterioration of the disease. Effective symptomatic treatment is available including the administration of short courses of cortisone during exacerbations. We have developed a treatment and teaching programme following the model of the 5-day inpatient programme for patients with type 1 diabetes. Patients trained in self-management including peak-flow self-monitoring and self-adaptation of medication can substantially reduce severe asthma attacks and numbers of hospital admissions [16, 17]. At present, the programme is used at various centers in Germany and has been adopted to be carried out as an outpatient programme as well [18].

Oral Anticoagulation

Control of oral anticoagulation therapy is often inadequate. A structured treatment and teaching programme based on self-monitoring of blood coagulation (international normalized ratio) and self-adjustment of oral anticoagulation has been shown to result in improved accuracy of anticoagulation therapy results and in treatment-related quality-of-life measures [19].

Medical Decision Making by Patients and Consumers

At present, diabetes education programmes to train and motivate patients to therapeutic autonomy are regarded as crucial to increase both the patients' quality of care and independence. However, almost invariably the patients remain excluded from medical decision processes, i.e. to define their individual therapeutic objectives and to select a certain treatment strategy. Thus, it is generally assumed to be in the diabetic patient's interest that HbA_{1c} levels are (near-) normalized and that body weight, LDL-cholesterol levels and blood pressure should be aggressively treated until ideal standards are reached.

With the patients becoming more and more knowledgeable and independent through the successful implementation of patient education in diabetes, their right to actively participate or eventually even to assume responsibility in these medical decision processes is becoming obvious. Clearly, most of the therapeutic efforts the patients are asked to make will, even if diligently carried out, not lead to the elimination of the vascular complications attributed to their diabetes, but much rather serve to decrease the likelihood/risks for the occurrence of such complications over time. It is in this context that the patients should be involved in the decision making processes themselves balancing the risks they are prepared to take against the efforts they are prepared to make – rather than having the physicians or other parties making these decisions on their part [20].

The active involvement of patients and consumers in decision making about preventive, therapeutic or diagnostic interventions is increasingly advocated [21]. Evidence-based medicine (EBM) explicitly integrates patients' values and preferences in treatment decisions. The basis for informed patient/consumer decision making is the communication of evidence-based scientific data in a format that can be understood by non-medically trained persons [22]. In the UK, the General Medical Council has produced ethical guidelines for the procedures necessary to obtain patients' informed consent prior to undergoing any medical intervention, i.e. investigation or treatment [23]. These guidelines are quite specific in stating that patients must be given sufficient information in order to enable them to exercise their right to make informed decisions about their care. Ideally, 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; finally, advice as to whether a proposed treatment is experimental and a reminder that patients have a right to seek a second opinion need to be given. With regard to diagnostic procedures, including screening tests, a doctor or other party should explain the purpose of the investigation, the likelihood of positive and negative findings, including false negative and false positive results; uncertainties and risks, important medical, social or financial consequences, follow-up plans, including counseling and support services [23]. In general, the physician should abstain from making assumptions about patients' views; and information must not be withheld because of the possibility that the patient or consumer might become upset or decide to refuse a suggested investigation or treatment. Furthermore, the physician has to declare any potential conflicts of interest due to financial benefits, and the patients should be allowed sufficient time to reflect before and after they make a decision [23].

Traditionally, in medical decision making patients or consumers rely on experts' opinions. Decisions are being made by intuitively evaluating the credibility of information sources and based upon own preferences. Expert opinions are usually presented as simplified statements such as 'this treatment is better than another treatment' or 'this treatment saves lives'. Under such conditions individual judgment of potential benefits or harm is not possible. Traditionally, health education has been aimed at persuading the public to adopt a specific recommendation or behavior, e.g. increasing the consumption of fruits and vegetables, decreasing the consumption of saturated fats or eggs, or participating in

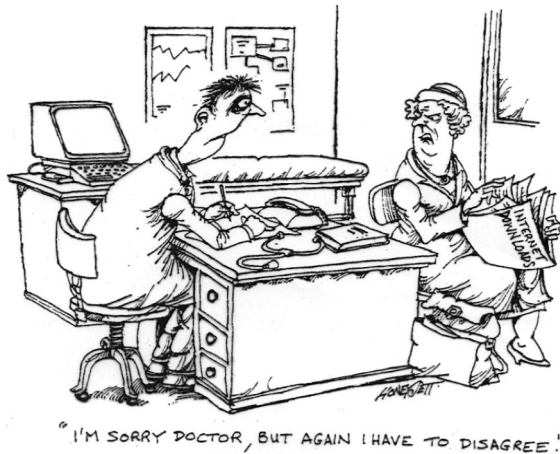


Fig. 2. Cartoon depicting a patient presenting information picked up on the internet during a consultation [from ref. 21, with permission].

screening programmes. This approach contrasts with the communication of evidence based information on objective pros and cons of such general recommendations enabling persons to make informed decisions concerning health related behavior or respective life style changes [20].

The question is not whether patients should or should not participate in medical decision making. Patients and lay people cannot be ‘protected’ any longer from disquieting and worrying information. Free access to almost all medical information via the internet is used and appreciated by the public. Physicians are challenged by patients who present their internet downloads during consultations (fig. 2). Patients have always made medical decisions, for example, by adhering to prescriptions or not. But, such decision making is usually done without availability of necessary information. Thus, active support of this new development of patient involvement in medical decision making could result in high quality information and real informed decision making.

Presenting Evidence-Based Patient Information

Currently available information materials for patients/consumers do not fulfil the quality criteria required for unbiased evidence-based patient information [24]. A well-known problem in communicating scientific data is

represented by the phenomenon of framing-of-data [25]. The particular way study results are presented exerts a substantial influence upon decisions by patients, health care providers and health policy makers alike. Thus, the impact of framing of outcome data as either relative or absolute differences is substantial [26, 27]. Furthermore, outcome data can be framed by either emphasizing achievable benefits or the lack of such benefits. So far, studies evaluating the communication of treatment results usually focus on the patients who might benefit from the respective interventions. In order to objectively communicate outcome data the entire spectrum of data presentation must be given, i.e. the proportion of persons who are likely to benefit as well as the proportion of persons who are unlikely to benefit or likely to be harmed as a result of the intervention should be presented with equal emphasis irrespective of whether results are communicated by illustrations or numbers [20].

Examples of Evidence-Based Information in Diabetes

Table 1 presents a possible scenario of evidence-based information for patients with type 2 diabetes on the basis of recent data provided by the UKPDS [28]. A detailed description of the extraction and presentation of the data from the UKPDS has been published previously [20]. In short, the UKPDS reported a 12% (95% CI 1–21%, $p < 0.03$) reduction of the primary combined outcome ‘any diabetes related endpoint’ between the ‘intensified therapy’ group with a median HbA_{1c} value of 7.0% and the ‘conventional therapy’ group with a median HbA_{1c} value of 7.9% over 10 years.

A comprehensive estimation of the potential benefit-harm relation would have to include information on secondary effects and quality of life aspects. In this context, the patient would have to be informed what his personal extra contribution/effort would have to be over a period of 10 years. This effort would include sustained extra efforts concerning drug/insulin therapy, blood glucose self-monitoring (not quantified in the UKPDS) and the therapeutic side effects, such as an increased incidence of hypoglycemia and weight gain. On the other hand, avoidance of hospitalizations and of diagnostic and therapeutic procedures (e.g. laser therapy for retinopathy) attributed to diabetes related complications should be presented [20].

Framing of data is even more important for primary prevention studies. Recent primary diabetes prevention studies have reported 25–60% reductions in diabetes by lifestyle or drug therapy interventions. Table 2 displays the data of one of those studies. Relative risk reduction for the risk of diabetes was 51% corresponding to an absolute risk reduction of 15%. However, related to fasting

Table 1. To what extent can intensified therapy prevent ‘any diabetes related endpoint’? [20]

With conventional therapy of 100 newly diagnosed patients 46 have at least one endpoint over the next 10 years

With intensified therapy of 100 newly diagnosed patients 41 have at least one endpoint over the next 10 years

With conventional therapy of 100 newly diagnosed patients 54 do not have an endpoint over the next 10 years

With intensified therapy of 100 newly diagnosed patients 59 do not have an endpoint over the next 10 years

Out of 100 newly diagnosed patients with intensified therapy 5 have a benefit over the next 10 years as they do not have an endpoint as a result of intensified therapy

Out of 100 newly diagnosed patients with intensified therapy 95 have no benefit over the next 10 years since they would not have had an endpoint with conventional therapy (54 patients) or they will have an endpoint despite intensified therapy (41 patients)

Table 2. Framing of data in diabetes prevention studies [Diabetes Prevention Program Research Group. NEJM 2002;346:393–403]

	Risk of diabetes over 3 years			
	Control group	Intervention group	Relative risk reduction	Absolute risk reduction
Risk of diabetes	29%	14%	51%	15%
Fasting BG, mmol/l	6.2	5.9		Difference 0.3
HbA _{1c} , %	6.1	6.0		Difference 0.1

blood glucose levels or HbA_{1c} levels these findings relate to minimal changes of negligible clinical relevance. More details with respect to this example have been published recently [29]. The public will have to be informed about relevant outcome data by presentation of natural frequencies rather than relative risk reductions.

Framing of data will also lead to different decisions in hypertension care [30, 31]. Many patients may prefer not to take treatment for mild hypertension if the risks were fully explained. In one study, almost all patients would have accepted treatment using a relative risk reduction model whereas less than

half would have accepted treatment with a personal probability of benefit model [30].

Informed Decision Making – Application to Other Diseases

Anticoagulation in Atrial Fibrillation

Anticoagulation in atrial fibrillation has been used frequently as an example of sharing decisions with patients [32, 33]. Effectiveness of oral anticoagulation is well documented by randomized controlled trials and meta-analyses. In high-risk subjects warfarin may reduce stroke incidence by as much as 70%. However, there are unwanted effects by minor and major bleeding and treatment may interfere with patients' quality of life. Protheroe et al. [33] have investigated the impact of patients' preferences for the treatment of atrial fibrillation, by using individualized decision analysis combining probability and utility assessments into a decision tree. They found that a vast majority of their on average 77-year-old participants stated a preference to be involved in shared decision making about their medical care. Taking patients' preferences into account would have resulted in substantially fewer prescriptions of warfarin than under published guideline recommendations. In addition, there was marked disagreement between the decision analysis and guideline recommendations. Thus, even very old patients may opt for informed decision making. However, simple tools to present the necessary information to the patients are still lacking.

Multiple Sclerosis

Multiple sclerosis is a chronic recurrent disorder. Etiology and pathogenesis have still not been clarified. The course of the disease is variable and hardly predictable. Relapses are of great importance for most patients. There is a high level of anxiety and uncertainty associated with the unpredictable occurrence and the possible long-term effects of relapses. In addition, treatment is an area of uncertainty both for treatment of acute relapses with high-dose corticosteroids and long-term preventive treatment with immune therapy. This makes multiple sclerosis a field where informed shared decision making could be of advantage for the patients [34]. We are currently developing information and education programmes for patients with multiple sclerosis [34, 35]. Most patients indicated that they preferred an autonomous role in treatment decisions giving the shared decision and the informed choice model the highest priority [35]. However, the information patients with multiple sclerosis would need to make informed decisions is complex. Thus, information models are urgently needed to offer these patients participation in decision making.

Screening Programmes

Providing the public evidence-based, unbiased and understandable information is particularly relevant for population based screening programmes, such as breast cancer, colorectal cancer, cervix cancer or prostate cancer screening. Evidence from randomized controlled trials is available for breast cancer and colorectal cancer screening whereas such studies are not yet available for cervix cancer and prostate cancer screening. It has been repeatedly shown that the quality of the information provided to the public is poor, biased and market driven [36, 37]. Information usually emphasizes benefits without mentioning lack of benefit, uncertainties and harm of screening. The benefit is usually presented as relative percent rather than absolute percent or natural frequencies. Such approaches have led to misconceptions and irrational enthusiasm for screening programmes [38].

At the University of Hamburg we have developed evidence-based information for breast and colorectal cancer screening following the criteria for the development of such information [39–41]. However, in people not used to this kind of information, presentation of evidence-based data may lead to cognitive dissonance and paradox reactions of consumers [42]. This is an area which needs further research on educational approaches.

Training Courses in Clinical Research Competencies for Patients' and Consumers' Representatives

Consumer involvement in health care issues has increasingly been promoted [43]. However, until now patients rarely participate in the planning, conduct or interpretation of medical research. Consumers have skills that complement those of researchers and they argue for research that addresses issues of clinical relevance [44]. Therefore, their participation could increase the quality of clinical trials. Motivated and highly educated consumers could play an important role as negotiators for change and improvement in medical research. This is particularly relevant for chronic diseases. In Germany, like in other countries, no structures exist for consumers to play an active part in research. So far, patients are invited to work in guideline-development or to comment on physician prepared patient-information such as consent sheets.

During the last two years we have performed basic training courses on evidence-based medicine (EBM) for consumers to enhance consumer and patient involvement in the planning and appraisal of research and the development of patient-information material [45]. The development, evaluation and implementation of curricula for EBM training courses for different target

groups has been a major part of our research [46]. So far, about 150 patients and consumers have accomplished our basic courses [45].

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