

# Evidence-based patient information in diabetes

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## Abstract

Patient education in diabetes has been successful in training and motivating patients to assume a more active and independent role in monitoring and treating their disease resulting in an improvement of patient-orientated outcomes. Traditionally, diabetes education has mainly aimed at increasing patient compliance to physician-defined therapeutic goals and treatment strategies. To strengthen their rights and autonomy, patients need to become more involved in medical decision making with respect to their individual therapeutic goals, such as HbA<sub>1c</sub> and blood pressure, body weight, etc., as well as choosing whether they pursue these goals. The importance of patient participation is particularly relevant to Type 2 diabetes. Even perfect, long-term therapeutic co-operation will not eliminate diabetic complications, only reduce the risk of developing them. The benefits, lack of benefits and unwanted effects of various interventions need to be communicated to the patient in an unbiased manner, so that he/she can make an informed choice with regard to different therapeutic goals and strategies. In diabetes, ways of presenting patients with unbiased information to enable them to make such informed decisions are not yet available. We present ways of how this might be achieved using data provided by the UKPDS. The concept of patient participation in medical decision making represents a fundamental challenge for the future development of diabetes care.

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**Keywords** decision-making, evidence-based medicine, health education, risk communication, Type 2 diabetes mellitus, UKPDS

**Abbreviations** ADREP, 'any diabetes-related endpoint'; NNT, number of patients needed to treat; UKPDS, UK Prospective Diabetes Study

## Patient education in diabetes

In 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 [1,2]. 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<sub>1c</sub> levels are (near-) normalized and that body weight, LDL-cholesterol

levels and blood pressure should be aggressively treated until ideal standards are reached.

As patients become more knowledgeable and independent through the successful implementation of patient education, their right to participate or even to take responsibility for these medical decisions is becoming obvious. Clearly, most of the therapeutic efforts patients are asked to make will not eliminate diabetic vascular complications. At best, their full co-operation will decrease the likelihood/risks of such complications. It is in this light that patients should be involved in the decision making processes. It is for them to balance the risks they are prepared to take against the efforts they are prepared to make – rather than physicians or other parties making these choices.

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## Medical decision making by patients and consumers

The active involvement of patients and consumers in decisions about preventive, therapeutic or diagnostic interventions is increasingly advocated [3]. Evidence-based medicine (EBM) explicitly integrates patients' values and preferences in treatment decisions [4,5]. The basis for informed patient/consumer choice is the communication of evidence-based scientific data in a format that can be understood by non-medically trained persons [3,6]. 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 [7]. 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. 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. When discussing 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 counselling and support services [7]. 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 as a result of financial benefit; and patients should be allowed sufficient time to reflect before and after they make a decision [7].

Clearly, evidence-based patient or consumer choice as outlined by the General Medical Council goes far beyond that conventionally understood by patient information or what is currently felt to represent the utmost possible under day-to-day care, i.e. merely obtaining the patient's consenting signature on a form.

Traditionally, in medical decision-making, patients or consumers rely on experts' opinions. Decisions are made by intuitively evaluating the quality of

information, based upon physicians' 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 judgement of potential benefits or harm is not possible. Furthermore, many diagnostic or screening tests, such as measuring blood glucose or cholesterol values in healthy subjects, or screening for microalbuminuria in patients with Type 2 diabetes, are performed even without seeking the person's informed consent. According to the ethical guidelines of the General Medical Council, this is clearly unacceptable even if one could argue that the benefits of such practices to society outweigh the rights of the individual. In contrast, evidence-based patient choice rests upon providing people with research-based information about the effectiveness of healthcare options.

This new approach is clearly different from what we conventionally understand by health education of the public or patient education in chronic diseases. Traditionally, *health education* has been aimed at persuading the public to adopt a specific recommendation or behaviour, e.g. increasing the consumption of fruits and vegetables, decreasing the consumption of saturated fats or eggs, or participating in 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 behaviour or respective life style changes. *Patient education* has also rarely been based on informed choice by the patient, but is often used to produce patients who comply with treatments, assumed to be in their best interest.

In contrast to these traditional approaches, there is clear evidence, particularly in chronic diseases, for the readiness and desire of patients to take on decision making responsibilities [8–10], even if the effort of such a strategy is substantial and there are major limitations in providing evidence-based information, useful to them.

## Available methodologies of evidence-based patient information

Currently available information and materials for patients/consumers do not fulfil the quality criteria required for unbiased evidence-based patient information [11]. A well-known problem in communicating scientific data is represented by the phenomenon of framing-of-data. The particular way study results are presented exerts a substantial influence upon decisions by patients, healthcare providers and health policy makers alike [12–16]. Thus, the impact of framing-of-outcome-data as either relative or absolute differences is substantial [6,12–14,16]. Furthermore, outcome data can be framed by either emphasizing achievable benefits or the lack of such benefits

[16]. So far, studies evaluating the communication of treatment results usually focus on the patients who might benefit from the respective interventions [15,17]. Such an approach is incompatible with unbiased informed decision making by the patient or consumer. To communicate outcome data objectively, 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 those who are unlikely to benefit or could be harmed as a result of the intervention should be presented with equal emphasis [18].

Recently, there have been special theme issues on patient/consumer participation in decision making by the *British Medical Journal* on 'Embracing Patient Partnership' [19] and by the National Cancer Institute entitled 'Cancer Risk Communication: What We Know and What We Need to Learn' [20]. In the field of diabetes, however, no studies are available on evidence-based patient information methodology or its application in patient care. A modified search strategy of the Cochrane Consumers and Communication Group (The Cochrane Library – 1999 issue 4) for electronic MEDLINE searching, years 1/1990–12/1999 did not reveal any relevant information (appendix). Therefore, we present a possible scenario of evidence-based information for patients with Type 2 diabetes on the basis of recent data provided by the UKPDS.

## Presentation of outcome data of the UKPDS

We have used a selection of clinical outcomes generated by the UKPDS to demonstrate the problems of framing-of-data.

Table 1 summarizes different ways of presenting the results of the UKPDS [21,22] on the effects of alternative treatments aiming at different therapeutic objectives on the clinically relevant aggregate target endpoint 'any diabetes-related endpoint' (ADREP). Data are either presented as absolute estimates, relative risks or absolute risks. In addition, data are presented by emphasizing either the proportion of subjects who benefit from the intervention (intensified therapy) or the positive effects of the intervention on the target outcome; or by emphasizing the proportion of subjects who do not benefit or experience no positive effect. Reporting results as relative rather than absolute risk reductions is still favoured by clinical investigators and by the media. Other ways of presentation are only rarely used [10,23–25] or not used at all, such as reporting the percentage increase of the proportion of persons who remain free of ADREP as the result of the intervention (as relative or absolute increase); or the percentage of subjects with ADREP despite the intervention. Alternative ways of presenting the outcome data are the number of patients needed to treat [4] to prevent the

**Table 1** Various ways of presenting identical data on the effects of intensified vs. conventional therapy on 'any diabetes-related endpoint' (data based on [21])

	Intensified therapy 100 patients over 10 years median HbA <sub>1c</sub> 7%	Conventional therapy 100 patients over 10 years median HbA <sub>1c</sub> 7.9%
Patients with at least one endpoint No. of patients (%)	41 (41%)	46 (46%)
Patients without any endpoint No. of patients (%)	59 (59%)	54 (54%)
		<b>Differences</b>
<b>Benefit of intensified vs. conventional therapy</b>		
Decrease in patients with endpoint		
No. of patients		5
Absolute risk reduction		5%
Relative risk reduction		11%
Increase in patients without endpoint		
No. of patients		5
Absolute increase		5%
Relative increase		9%
<b>Lack of benefit of intensified vs. conventional therapy</b>		
Patients with endpoint despite intensified therapy		
No. of patients		41
Absolute per cent		41%
Relative per cent (41 of 46)		89%
All patients who do not benefit		
No. of patients (%)		95 (95%)

**Table 2** To what extent can intensified therapy prevent 'any diabetes-related endpoint'?

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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).

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**Table 3** Benefit chart for a newly diagnosed patient with Type 2 diabetes, 54-years-old, for the prevention of the primary aggregate endpoint 'any diabetes related endpoint' by intensified glycaemic control and intensified blood pressure control, respectively, over the next 10 years (based upon data from the UKPDS [21,22])

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Imagine 100 persons your age, over the next 10 years will experience a primary endpoint if they

lower their HbA <sub>1c</sub> from approx 8% to 7%			lower their blood pressure from approx 155/85 mmHg to 145/80 mmHg		
no	yes	patients with endpoint prevented	no	yes	Patients with endpoint prevented
46	41	5 (0–10)	67	51	16 (1–38)

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occurrence of an ADREP in one patient,  $NNT_{(10\text{ years})} = 20$  [21]; or the mean prolongation of life free of an ADREP over time, reported in the UKPDS as time to when 50% of patients had at least one ADREP, 14.0 years under intensified therapy vs. 12.7 years on conventional therapy [21,22].

To enable the patient or consumer to evaluate the efficacy of an intervention in an unbiased manner both aspects – i.e. the proportion of patients who benefit and those who do not – should be presented. An example for a quantitative presentation of outcome data of blood glucose lowering on the occurrence of ADREP is presented in Table 2. Such a presentation should also include data on total mortality. Since the differences in mortality were not significant [21] the information could be presented as follows.

- During the first 10 years after the diagnosis of diabetes a comparable number of persons die irrespective of whether diabetes therapy is conventional or intensified.
- Under conventional therapy, out of 100 persons who die, 58 die of diabetes-related causes and 42 die of causes unrelated to diabetes.
- Under intensified therapy, out of 100 persons who die, 55 die of diabetes-related causes and 45 die of causes unrelated to diabetes.

The precision or lack of precision, respectively, of the numbers presented should be made clear. For this purpose confidence intervals for the NNT have to be made available. For the aggregate endpoint ADREP, the  $NNT_{(10\text{ years})}$  was reported as 20 with 95% confidence intervals of 10–500 [21]. This means that the number of patients who might benefit from the intervention during

the first 10 years after diagnosis of diabetes could be estimated to be as high as 10 out of 100 but also as low as 2 out of 1000.

In addition, a comprehensive estimate of the potential benefit–harm relationship would have to include information on secondary effects and quality of life aspects. In this context, the patient should be informed what his personal extra contribution/effort would have to be, for example, to maintain a median HbA<sub>1c</sub> value of 7.0% (corresponding to the UKPDS 'intensified therapy') vs. a median value of 7.9% 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 hypoglycaemia 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.

Furthermore, the patients should be presented with information on the possibilities of risk reduction by other therapies, including the comparison of the actual size of preventive effects achievable by different interventions, e.g. in the format of a benefit chart (Table 3). When presented with such information, individual patients often assume that they themselves will be the ones who have the benefit. Skolbekken has outlined that this popular misbelief has to be addressed specifically [18].

Finally, it needs to be explained to what extent the results as based upon scientific evidence are applicable to the target individual in a given healthcare system.

This example, as based upon recent evidence from the UKPDS, underlines that future studies evaluating different formats of communicating outcome data of preventive or therapeutic interventions should include the presentation of results both by emphasizing the benefits and the lack of benefits. Otherwise patients or consumers cannot make informed choices free from framing-of-data.

### Making information available

Unbiased presentation of evidence-based scientific data must be made available to all patients and to the public. Initiatives have been started in various countries, such as the National Electronic Library for Health in Oxford [26] or the internet information for patients provided by the Agency for Quality in Health Care of the German Chamber of Physicians [27]. Even in the era of electronic media, however, the quality of sources of information remains heterogenous [28,29]. Instruments to rate the quality of health information are offered to the public [30].

The amount of additional and validated information which needs to be made available to involve patients in medical decision making is substantial. However, even if medical decision making were to remain in the hands of physicians, this extra information is still needed to improve the process of medical care.

### Challenges for the future

Enabling patients and the public to make informed choices requires several prerequisites.

1 A systematic work up and presentation of scientific data that can be readily used by physicians and the public. The Cochrane database represents a useful source of information; rigorous data presentation is urgently needed in other areas, such as risk assessment of individual patients under certain healthcare conditions or concerning the evidence base of diagnostic/screening processes.

2 Selecting the best format of presenting the information to patients and public, be it by numbers, verbal or visual displays. Innovative research is still required in this field. To our knowledge, there are no materials currently available in diabetes care that fulfil the quality criteria for an unbiased presentation.

3 The effects of communicating scientific data in an unbiased way to the consumer, and in particular to the person with diabetes, need further study.

4 There must be easy and affordable access to evidence-based high quality information to support decision making by patients and consumers.

5 Instruments for the evaluation of the quality of the information must be developed and made available.

6 Providers of diabetes care need specific training to communicate this information.

The eventual objective of these efforts is to provide the individual patient with a database on which he/she can decide on the effort he/she is prepared to make (lifestyle changes, nutrition, metabolic self control, drug/insulin treatment) and on the risks he/she is prepared to take (concerning diabetes related endpoints) [2]. Ideally, the patient will then be able to make his/her own decisions concerning his/her individual therapeutic goals and choice of treatment. The person with Type 2 diabetes would thus be able to choose individual target ranges of HbA<sub>1c</sub> values, blood pressure control, blood lipids, and body weight, etc., as to their (sequential) priorities, and to what extent he/she wants to employ various self-monitoring strategies and non-drug or drug treatments to reach these objectives.

As a consequence, the quality of diabetes care will not be exclusively measured by comparing actual surrogate outcome data of patients with yardstick levels as agreed upon by consensus guidelines. There will need to be a demonstration that patients have been provided with appropriate information to make informed choices on their therapies; and, the extent to which the patient reaches his/her individual treatment objective has been taken into account.

This picture appears futuristic in many ways, in particular the efforts to establish effective methods to generate and communicate the necessary information in diabetes, and their implementation in routine care. There is no question, however, that these developments will take place in the framework of the ongoing general development of our societies. Evidence-based information of patients in diabetes will overcome the attempts of *traditional patient education* which has mainly served as a means to increase the patients' compliance to physician-defined treatment goals and prescribed therapies – in that patients will become more independent partners, not only by executing prescribed treatment strategies, but by choosing their own diagnostic and therapeutic goals and strategies. These goals may often differ from those the physician or consensus guideline would have recommended. The responsible physician will then have to support the patient to strive for the implementation of his/her *informed medical choices*. The practicability and efficacy of these approaches on the part of the patients, the physician and the healthcare system need to be rigorously studied by clinical research.

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## Appendix

### Search strategy

A modified search strategy of the Cochrane Consumers and Communication Group (The Cochrane Library – 1999 issue 4) for electronic MEDLINE searching, years 1/1990–12/1999 was used. The following MeSH terms with all subheadings were exploded:

1. 'DIABETES-MELLITUS'
2. 'CONSUMER-ORGANIZATIONS'
3. 'SELF-HELP-GROUPS'
4. 'CONSUMER-PARTICIPATION'
5. 'INFORMED-CONSENT'
6. 'COMMUNITY-INSTITUTIONAL-RELATIONS'
7. 'CONSUMER-ADVOCACY'
8. 'PROFESSIONAL-PATIENT-RELATIONS'
9. 'PHYSICIAN-PATIENT-RELATIONS'
10. 'NURSE-PATIENT-RELATIONS'
11. 'DENTIST-PATIENT-RELATIONS'
12. 'PROFESSIONAL-FAMILY-RELATIONS'
13. 'INFORMED-CONSENT'
14. 'TRUTH-DISCLOSURE'
15. 'PATIENT-PARTICIPATION'
16. 'PATIENT-ADVOCACY'
17. 'PATIENT-EDUCATION'
18. 'COMMUNICATION-AIDS-FOR-DISABLED'
19. 'CONTINUITY-OF-PATIENT-CARE'
20. 'PERSUASIVE-COMMUNICATION'
21. 'PATIENT-ACCEPTANCE-OF-HEALTH-CARE'
22. 'TREATMENT-REFUSAL'
23. 'PATIENT-COMPLIANCE'
24. 'PATIENT-SATISFACTION'
25. 'CONSUMER-SATISFACTION'
26. #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25
27. #1 and #26
28. explode 'DECISION-MAKING' /all subheadings
29. explode 'HEALTH-EDUCATION' /all subheadings

30. #28 or #29
31. #1 and #30
32. #27 or #31
33. explode 'EVIDENCE-BASED-MEDICINE' /all sub-headings
34. #1 and #33

A total of 2373 records were identified, 232 were clinical trials. However, no publication specifically addressed the topic of 'evidence-based patient information in diabetes'.