Diabetologia (2010) 53:2285–2288
DOI 10.1007/s00125-010-1891-9

COMMENTARY

From authority recommendations to fact-sheets—a future for guidelines

I. Mühlhauser

Received: 21 July 2010 / Accepted: 30 July 2010 / Published online: 29 August 2010

Abstract ADA/EASD recommendations and diabetes expert consensus statements are not evidence-based. Reform of guideline development is urgently needed. Overriding governance and composition of the guideline committee is a key problem. Methodologists without important conflicts of interest should lead the development process and have primary responsibility. The rating of the quality of evidence should be separated from making the recommendations, transparency has to be increased and conflicts of interest must be tackled. Patient needs are not yet met in guidelines. Patients increasingly demand concise, easy-to-read summaries of the benefits and risks of medicines together with more comprehensive scientific data. However, patient participation in individual decision making is not considered in guidelines. Guidelines do not provide the information necessary for informed or shared decision making. Study fact-sheets and drug facts boxes should be included in practice guidelines. It is timely to consider patient needs from the outset of the development of future guidelines.

Keywords Conflict of interest · Consumer health information · Diabetes · Disclosure · Ethics · Evidence-based medicine · Informed consent · Practice guidelines as topic/standards

Abbreviations

AHRQ	US Agency for Healthcare Research and Quality
IQWiG	German Institute for Quality and Efficiency in Health Care

I. Mühlhauser (✉)
Unit of Health Sciences and Education, University of Hamburg,
Martin-Luther-King Platz 6,
20146 Hamburg, Germany
e-mail: Ingrid_Muehlhauser@uni-hamburg.de

Lack of evidence in consensus statements

The dispute is timely. The fighters are opinion leaders on both sides. Schernthaner and combatants [1] accuse Nathan and allies [2] of a lack of evidence for their ADA/EASD consensus statements on the medical management of hyperglycaemia in type 2 diabetes. They oppose several recommendations. Yet such a battle of contradicting statements cannot be won, but is rather turning into ‘a manifestation of the territorial imperative’ [3]. Neither party applies evidence-based methodology to support their claims [4]. Evidence-based medicine is on the label but not in the box. The quarrel flags the dilemma that is inevitably inherent in the authority-opinion approach, even when applied by prestigious institutions such as the WHO [5].

In the commentary accompanying the paper by Schernthaner et al. [1], J. Nolan tries to reconcile the differences between the two groups [6]. He suggests avoiding the quandary by not taking guidelines too seriously. Instead, physicians should make up their own minds and make personalised treatment decisions founded on evidence. This appears to be an intriguing solution as it conforms to the original concept of practising evidence-based medicine [4]. However, most physicians still lack the competencies necessary to apply the methodology of evidence-based medicine. In addition, in face of an ever increasing body of knowledge it has become impossible for an individual to continuously survey the entire literature on a field, even within a specialty such as diabetes care. Complete, reliable and ready-to-use information on the necessary evidence base is neither available nor generally accessible to the practising doctor. Guidelines are intended to assist healthcare providers to make better decisions and are increasingly used as a standard reference for quality assurance. They are needed and should not be abandoned, but, rather, should be further developed.

Appraisal of research is frequently not straightforward. Only rarely is there unanimity on the validity of a clinical study or the implications thereof. Reasons for dissent are diverse. On the one hand different physicians understand research and research data to varying degrees [7]. On the other hand, personal values, attitudes, beliefs and conflicts of interest have an impact on reasoning [8]. Different stakeholders have different agendas. Even if a study is of the highest possible quality with results of statistical significance, patients, professionals and healthcare managers often disagree about the implications of this in terms of, for example, treatment, reimbursement strategies or changes in healthcare structure. Hence, it is not surprising that different expert statements or guidelines on the same topic may have divergent conclusions even if based on the same research material [9].

Concepts for reform of guideline development

The limitations of traditional consensus recommendations and health technology assessment are well acknowledged [3, 9, 10]. Various international working groups and national institutions have been formed to improve the methodologies for the assessment and use of clinical research data based on contemporary principles of evidence-based medicine. Examples include the Grades of Recommendation Assessment, Development and Evaluation Working Group (GRADE) [10], the US Agency for Healthcare Research and Quality (AHRQ) and the German Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen [IQWiG]).

Essential elements of enhanced guideline development are: (1) the separation of rating the quality of evidence from making the recommendations [10]; (2) an increase in transparency; and (3) tackling conflicts of interest. Schünemann and colleagues have defined ten key visions on guideline development using chronic obstructive pulmonary disease as an example [11]. Their template for drawing up guidelines could assist other guideline developers. Guyatt et al. have outlined possible solutions for the worrying problem of conflicts of interest, proposing the following strategies [12]:

1. Place equal emphasis on intellectual and financial conflicts and provide explicit criteria for both.
2. A methodologist without important conflicts of interest should have primary responsibility for each chapter.
3. Experts with important financial or intellectual conflicts of interest can collect and interpret evidence, but only panel members without important conflicts can be involved in developing the recommendation for a specific question.

These strategies should help to achieve the benefit of expert input without conflicts of interest influencing recommendations. In line with these proposals, Kahn and Gale suggest that guidelines should be divorced from organisational infighting, and that guidelines should be posted online so that they act as the focus of ongoing discussion and modification [3]. Sniderman and Furberg are also concerned about the overriding problem of governance and composition of the guideline committee. They suggest that the majority of the members of the guideline group, and in particular the leaders, should be changed from one edition to the next [9]. In addition, they demand that reports are not issued unanimously as consensus statements unless all members fully agree to all sections. Rather, disagreement should be documented and reported [9].

Study fact-sheets are urgently needed

Worldwide researchers and healthcare providers devote their valuable time to developing guidelines and health technology assessments, and compiling systematic reviews or meta-analyses. They spend weeks and months identifying and critically appraising the evidence base. A large part of this time is spent repeating work already done by colleagues. Institutions such as the Cochrane Collaboration, AHRQ and IQWiG have accumulated an enormous amount of knowledge on individual studies. However, the information is not systematically documented and is not accessible to the public or even to other researchers. What a waste! Short summaries of single studies, as usually provided in reviews, are not sufficient.

What is needed is a detailed description of the specific features of a study according to the standards of evidence, focusing on the strengths and limitations of the trial protocol, performance of the study and reporting of results. Discrepancies between protocol and reporting, as well as other apparent or emerging biases, should be documented and emphasised. Information hidden by intention but uncovered by later users and findings not originally published owing to space limitations should complement the study profile. Finally, study results would have to be transformed into an easy-to-understand, unbiased format that could be used in communications between healthcare providers and patients. The product would be a study fact-sheet covering the life of a study and including its specific attributes.

I suggest that an international internet-based scientific network should be developed with the aim of designing a database that provides fact-sheets for clinical studies. The database could be continuously updated, increased and improved by authors and users applying distinct scientific rules for reporting the study information. Schünemann et al. have already initiated a standardised database of existing

evidence and gaps in evidence for the management of chronic obstructive pulmonary disease and its related comorbidities, to serve as a shared resource for participating organisations [11]. A comparable project providing fact-sheets on studies relevant for diabetes care would be well received.

Patient needs are not yet met

Patient participation in decision making is a core element of evidence-based medicine. '[Evidence-based medicine] is the integration of best research evidence with clinical expertise and patient values' [13], where clinical expertise is defined as 'the ability to integrate research evidence and patients' circumstances and preferences to help patients arrive at optimal decisions' [14]. The implementation of guideline recommendations would require the adaptation of decisions to specific values [12].

Diabetes management still relies on strong traditional physician roles as reflected by consensus guidelines. Patients are not explicitly targeted to be involved in defining treatment goals or in the selection of therapeutic regimens. Rather, an array of behavioural directives are imposed on patients, such as increasing exercise, decreasing weight, stopping smoking and following monitoring, dietary and medication schedules. However, patients express a strong desire for information and increasingly want to be involved in decisions related to their health [15]. They demand concise, easy-to-read summaries of the benefits and risks of medicines together with more comprehensive scientific data [16].

Apart from a few research initiatives, new developments in evidence-based patient information or shared decision making that aim to address patients' information and participation needs have yet to be introduced in diabetes care [17]. Ethical guidelines and criteria for this communication process have been issued [18–20]. Appropriate information tools require risk data that include information about personal risks, the natural course of the disease and benefits and harms of various options, including the option not to intervene. These data could be largely extracted from the research material used for guideline development. However, up to now the evidence has not been presented in a format that could aid shared treatment decision making by patients and healthcare providers.

Drug facts boxes for patients

Patients want and deserve data about drugs [15, 16]. To help people better understand how a drug helps or harms, Schwartz et al. have developed a tool called a Drug Facts Box and are working with the US Food and Drug Administration to determine how best to implement it [21]. A Drug Facts Box is a one page summary of a drug's benefits and side effects. The central information is provided in a table that shows the chance of various outcomes for people who do and do not take the drug. It has been shown that Drug Facts Boxes improve patients' knowledge, resulting in better treatment choices and correcting the overestimation of benefit in the setting of prevention [21]. Cochrane reviews have started to include summary-of-finding tables to improve understanding and rapid retrieval of key information [22, 23]. This kind of information would substantially aid the development of evidence-based patient information and evidence-based patient decision aids.

Until now patient participation in individual decision making has not been considered in guidelines. Patient versions of guidelines are increasingly being offered alongside the core guidelines directed at healthcare providers. They intend to translate the central messages of the main guidelines into patient-accessible language. However, they do not provide the information necessary for informed or shared decision making.

It is timely to consider patient needs right from the outset of the development of future guidelines. As an important step toward this goal, researchers with expertise in decision making should be invited to participate in guideline development [12]. Clinical diabetologists could act as pioneers and set standards for future guidelines.

Duality of interest I. Mühlhauser is dedicated to evidence-based medicine and patient participation in medical decision making. G. Schernthaner was her medical teacher during her early years in clinical diabetology.

References

1. Schernthaner G, Barnett AH, Betteridge DJ et al (2010) Is the ADA/EASD algorithm for the management of type 2 diabetes (January 2009) based on evidence or opinion? A critical analysis. Diabetologia 53:1258–1269
2. Nathan DM, Buse JB, Davidson MB et al (2009) Medical management of hyperglycaemia in type 2 diabetes mellitus: a consensus algorithm for the initiation and adjustment of therapy. A consensus statement from the American Diabetes Association and the European Association for the Study of Diabetes. Diabetologia 52:17–30
3. Kahn R, Gale EAM (2010) Gridlocked guidelines for diabetes. Lancet 375:2203–2204
4. Montori VM, Guyatt GH (2008) Progress in evidence-based medicine. JAMA 300:1814–1816
5. Oxman AD, Lavis JN, Fretheim A (2007) Use of evidence in WHO recommendations. Lancet 369:1883–1889
6. Nolan JJ (2010) Consensus guidelines, algorithms and care of the individual patient with type 2 diabetes. Diabetologia 53:1247–1249
7. Mühlhauser I, Kasper J, Meyer G; Federation of European Nurses in Diabetes (2006) Understanding of diabetes prevention studies:

questionnaire survey of professionals in diabetes care. Diabetologia 49:1742–1746
8. Strech D, Tilburt J (2008) Value judgments in the analysis and synthesis of evidence. J Clin Epidemiol 61:521–524
9. Sniderman AD, Furberg CD (2009) Why guideline-making requires reform. JAMA 301:429–431
10. Guyatt G, Oxman AD, Vist GE et al (2008) GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ 336:924–926
11. Schünemann H, Woodhead M, Anzueto A et al (2009) A vision statement on guideline development for respiratory disease: the example of COPD. Lancet 373:774–779
12. Guyatt F, Akl EA, Hirsh J et al (2010) The vexing problem of guidelines and conflict of interest: a potential solution. Ann Intern Med 152:738–741
13. Sackett DL, Sharon ES, Richardson WS, Rosenberg W, Haynes R (2000) How to practice and teach evidence-based medicine. Churchill Livingstone, Oxford
14. Guyatt G, Cook D, Haynes B (2004) Evidence based medicine has come a long way. BMJ 329:990–991
15. Hamann J, Neuner B, Kasper J et al (2007) Participation preferences of patients with acute and chronic conditions. Health Expect 10:358–363
16. European Medicines Agency (2009) Information on benefit–risk of medicines: patients', consumers' and healthcare professionals' expectations. EMEA/40926/2009. Available from www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500018433.pdf
17. Lenz M, Mühlhauser I (2009) Decision aids in diabetes. In: Edwards A, Elwyn G (eds) Shared decision-making in health care: achieving evidence-based patient choice, 2nd edn. Oxford University Press, Oxford, pp 285–295
18. General Medical Council (1999) Protecting patients, guiding doctors. Seeking patients' consent: the ethical considerations. GMC, London
19. General Medical Council (2008) Consent: patients and doctors making decisions together. Available from www.gmc-uk.org/Consent_0510.pdf_32611803.pdf, accessed 1 March 2010
20. Bunge M, Mühlhauser I, Steckelberg A (2010) What constitutes evidence-based patient information? Overview of discussed criteria. Patient Educ Couns 78:316–328
21. Schwartz LM, Woloshin S, Welch HG (2009) Using a Drug Facts Box to communicate drug benefits and harms—two randomized trials. Ann Intern Med 150:516–527
22. Schünemann HJ, Oxman AD, Higgins JPT, Vist GE, Glasziou P, Guyatt GH (2008) Presenting results and 'summary of findings' tables. In: Higgins JPT, Green S (eds) Cochrane collaboration handbook, 2nd edn
23. Rosenbaum SE, Glenton C, Oxman AD (2010) Summary-of-findings tables in Cochrane reviews improved understanding and rapid retrieval of key information. J Clin Epidemiol 63:620–626