

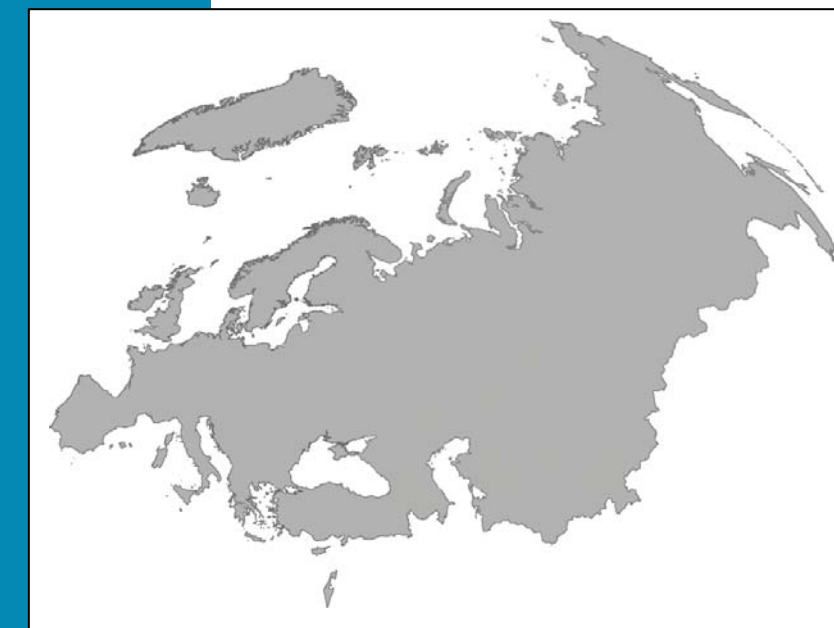
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HEALTH INFORMATION FOR PATIENTS AND THE GENERAL PUBLIC,
PRODUCED BY THE GERMAN INSTITUTE FOR QUALITY AND EFFICIENCY IN HEALTH CARE
A REVIEW BY THE WORLD HEALTH ORGANIZATION
2008/2009



By: Kees de Joncheere
Gerald Gartlehner
Laragh Golligly
Pertti Mustajoki
Govin Permanand

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Health information for patients and the general public

**produced by the
German Institute for Quality and Efficiency in Health Care**

**A review by the World Health Organization
2008/2009**

**By: Kees de Joncheere, Gerald Gartlehner, Laragh Gollogly,
Pertti Mustajoki, Govin Permanand**

ABSTRACT

The German Institute for Quality and Efficiency in Health Care (IQWiG) is responsible for providing evidence assessments for decision-makers in the German healthcare system as well as health information to patients and the general public.

In 2008, IQWiG requested the WHO Regional Office for Europe to evaluate its programme of developing an evidence-based “encyclopaedia” for patients and the general public. The WHO team of experts reviewed methods and processes, their scientific robustness, the results of internal and other external evaluations, and the views of stakeholders. A series of health information products were reviewed. The review was conducted during 2008 and 2009, with two visits to IQWiG late in 2008.

The report contains a series of recommendations on how IQWiG could develop this programme and strengthen the Institute’s reputation and importance as a leading producer of patient-centred and evidence-based health information. Increasingly it has become clear that a publicly funded and scientifically independent body can and should play an important role in providing objective and non-biased information to patients, and the Institute’s efforts are an important initiative in this direction.

Keywords

INFORMATION DISSEMINATION – review
ACADEMIES AND INSTITUTES – review
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Acknowledgements

It has been a privilege for the members of the review team to be asked to carry out this review, and we hope that our comments and recommendations will be useful for the continuing development of the Health Information programme of the German Institute for Quality and Efficiency in Health Care (IQWiG).

The review team would like to acknowledge the generous assistance, efficiency and cooperation of all the staff in the Institute. We would also like to thank the stakeholders who kindly agreed to be interviewed for their great help during the review.

In particular, for their tireless enthusiasm and hospitality during the review, the team would like to thank Professor Peter Sawicki, Director of the Institute for Quality and Efficiency in Health Care, and Ms Hilda Bastian, Head of the Health Information programme together with her team of dedicated people.

We also acknowledge the considerable help provided by Mrs Heidemarie Kufner-Rausch and her colleagues in handling all the logistics and interviews and ensuring that the team had all the relevant documents and connections during their visits to the Institute.

List of abbreviations

BAK	Bundesärztekammer (the federal German Medical Association)
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices)
EMA	European Medicines Agency
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
the Institute	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)
WHO	World Health Organization

Executive summary

The German Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen – IQWiG) was established in 2004 as a nongovernmental, not-for-profit foundation, funded through a levy on health care transactions. The Institute was mandated to provide health technology assessments to the Federal Joint Committee (Gemeinsamer Bundesausschuss), which determines coverage of these technologies by Germany's statutory health insurance schemes. It is an independent scientific institute that investigates the benefits of and harms from medical interventions for patients and that provides information about the potential advantages and disadvantages of different diagnostic and therapeutic interventions.

The World Health Organization was asked by the Institute to evaluate the methods by which the content of its web site [Gesundheitsinformation.de](http://www.gesundheitsinformation.de/) (<http://www.gesundheitsinformation.de/>), and the English version [informedhealthonline](http://www.informedhealthonline.org/) (<http://www.informedhealthonline.org/>), both accessed 29 January 2010), is developed, as well as the adequacy of the Institute's mechanisms for quality assurance, selection of topics, routine monitoring and evaluation, and the quality and accuracy of the information that it provides to the public. The review was carried out through study of the Institute's documents and web site (especially the *General methods manual*, version 3.0), a review of published material and interviews with staff and relevant stakeholders. Three topics were selected for review from the IQWiG web site which were used as case studies and for understanding the processes used by the Institute.

The review team concluded that the Institute's programme has not only produced an impressive quantity of health information in a few years, but it has also managed to incorporate evidence-based principles for medicines in a practical and useful manner in this difficult area. It has also succeeded in introducing new methodological developments, and incorporating qualitative information from patients and patients' groups in a transparent manner into their products.

The Institute functions in a health care environment where changes are taking place on an almost continuous basis. In addition, it is continuously evolving, so several processes that the team was reviewing were developing and changing during the review period.

Achievements that are particularly important for continuing quality development are: the use of best available evidence for decision-making and the inclusion of qualitative information from patients and patients' groups; the dedication, high technical competence and commitment of the Institute management and staff; the inclusiveness of the process; and the participation of relevant stakeholders.

The team was impressed by the commitment that IQWiG makes to evidence-based medicine principles, and how it puts these into practice in the area of health information while recognizing the importance of the softer qualitative information from patients. The team also recognizes the pressure that the Institute is under to produce a substantial quantity of information products in a short time. It is already starting to make its mark in producing relevant, objective and independent patient

information, as well as by its efforts to develop its web site in both German and English. Increasingly it has become clear that a publicly funded and scientifically independent body can and should play an important role in providing objective and non-biased information to patients, and the Institute's efforts are an important initiative in this direction.

The Institute has also been undertaking other reviews of its processes with a view to continuous quality development.

During the review and the preparation of the report, the team focused on areas with potential for improvement and where controversies exist (inter)nationally.

Specifically, the team would like to highlight the following recommendations.

- In view of the ambitious targets and needs for information, sustainability should be planned for with a higher staffing level and a staff development plan.
- Transparency should be enhanced by further development of the *General methods manual* so that it comprehensively documents the workflows, including timelines, roles, tasks and decision algorithms. The manual should also incorporate the criteria on selection of topics and the priority-setting process, so that it is clear to all stakeholders why and how guidance is developed.
- For reasons of quality and transparency, a system should be developed to assure stakeholders that their comments have been acknowledged and considered adequately (this recommendation was being implemented during the review period).
- There should be more translations, both as an opportunity for quality assurance and to reach English-speakers (and speakers of other non-German languages) in Germany, as well as to strengthen the Institute's reputation and importance as a leading producer of patient-centred and evidence-based health information.
- The web site should be more intensively promoted to health professionals and patients, in collaboration with all stakeholders and with the Institute's communication department, and the excellent access to the site needs to be maintained. Compliance with accessibility guidelines should be regularly checked.
- Now that the health information programme is well developed, the impact of the work should be evaluated and an assessment made as to whether and how patients and health professionals benefit from it.

The Institute and its governing bodies are to be commended for its enormous body of work and impressive achievements. These recommendations aim to support the Institute in its continuing initiatives to develop and improve its work, and will hopefully contribute to enhancing its health information programme.

Introduction

Background to the review

The German Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen – IQWiG) was established in 2004 as a nongovernmental, not-for-profit foundation, funded through a levy on health care transactions. Its mandate is to provide health technology assessments to the Federal Joint Committee (Gemeinsamer Bundesausschuss) which determines coverage of these technologies by Germany's statutory health insurance schemes. The Institute is an independent scientific institute that investigates the benefits of and harms from medical interventions for patients and that provides information about the potential advantages and disadvantages of different diagnostic and therapeutic interventions.

The Institute's mandate includes the specific production of "understandable general information for the general public on the quality and efficiency of the health care services". In April 2007, this was broadened to include: "... as well as diagnosis and treatment of diseases of epidemiological importance".

The legal mandate for the aims, functions, responsibilities and funding for the Institute was laid down in the *Social Code Book V*. The relevant paragraphs are Nos. 139a - General information (establishment, legal form, etc.), 139b – Conduct of tasks, 139c – Funding, and 35b – Assessing the benefit and cost of drugs.

This legislative remit was intended to strengthen patients' autonomy and enable the public to benefit from the Institute's work. The Institute fulfils this role in part by maintaining a German- and English-language patient information web site, with the aim of developing a "comprehensive online encyclopædia of evidence-based health information by 2012."¹

The Institute in 2008 employed 75 staff and had a planned budget of €15 million. It has eight departments: drug evaluation, statistics, non-drug interventions, health economics, quality of care, communications, administration and health information (Annex 1). This review examines the work of the health information department.

The Institute is funded through levies on hospitalizations and medical and dental outpatient services reimbursed by statutory health insurance schemes. The Federal Joint Committee determines the levies imposed through both hospital and outpatient services and thus provides the Institute's budget.

The Institute is officially overseen by its Foundation (Stiftung) and is governed by a Board of Directors (Stiftungsvorstand) and a Foundation Council (Stiftungsrat) (Annex 1).² The Board of Directors has five members, representing the National Association of Statutory Health Insurance Physicians, the Federation of Salaried Employees Health Insurance Funds, the State Secretary in the

¹ Full funding was not, however, available for this task.

² Institute for Quality and Efficiency in Health Care [web site]. Cologne, 2010 (<http://www.iqwig.de/organe.23.html>, accessed 27 January 2010).

Ministry of Health, the Federal Association of the Craft Guild Health Insurance and the German Hospital Federation. The Foundation Council has 12 members, representing the Health Insurance Funds, the Hospital Federation and the German Medical Association. The chairperson of the Federal Joint Committee sits on this Council in an advisory capacity.

The Institute has two advisory bodies, a Board of Trustees (Kuratorium) and a Scientific Advisory Board. The Board of Trustees is consulted on patient information and reports that are prepared by the Institute. It has 30 members, including representatives of health professionals' and patients' organizations, other social partners, the pharmaceutical industry and the Federal Government's Commissioner for Patients' Affairs. The Scientific Advisory Board consists of up to 12 members and is composed of scientists appointed by the Board of Directors who provide advice to the Institute's management.

The Institute's Steering Committee (Steuergremium) is composed of the Director, Professor Peter Sawicki, the Deputy Director and the eight department heads, and is responsible for advising the Institute Director.

The Health Information Department has an approved staffing level of 14 full-time equivalents and is headed by Hilda Bastian.

Through its web site, the Institute strives to reach directly both patients and members of the public who are looking for health information on the internet. It also tries to maximize the diffusion potential for internet information and enhance the multiplier effects by patients themselves, as well as health professionals and people seeking health information in general.

According to the legislation, the Institute is directed to provide "general, understandable information for the general public on the quality and efficiency of the health care services as well as diagnosis and treatment of diseases of epidemiological importance", and to communicate "the results of its work in a format that is understandable for the general public, but not to give advice to patients".

The Institute produces patient information for its web site [Gesundheitsinformation.de](http://www.gesundheitsinformation.de) (<http://www.gesundheitsinformation.de/>), and the English version [informedhealthonline](http://www.informedhealthonline.org) (<http://www.informedhealthonline.org/>), both accessed 29 January 2010, in the form of:

- feature articles or information reports, which are comprehensive in-depth articles on a health topic (Informationsbericht);
- newsletters, quizzes and short films;
- fact sheets giving shorter overviews of a topic (Merkblätter);
- research summaries, which are brief summaries of systematic reviews, health technology assessment reports or trials (a kind of scientifically-based frequently asked questions) (Kurzantwort).

In 2008, the Institute requested the World Health Organization (WHO) to evaluate the methods by which the content of the web site is developed, as well as the adequacy of its mechanisms for quality

assurance, topic selection, routine monitoring and evaluation, the quality and accuracy of the information that the Institute provides to the public and stakeholder views.

Methods and approaches of the review

In discussions between WHO and the Institute, it was agreed that the review would be carried out through study of the Institute's documents and web site (especially the *General methods manual*, version 3.0), a review of published material and interviews with staff and relevant stakeholders. Three topics were selected by WHO for review from the web site which were used as case studies and for understanding the process of selecting content. These were the reports on asthma, allergies and postnatal depression. As the Institute is developing rapidly, these three topics cannot be seen as representative but merely as illustrative examples. The review team visited the Institute twice in late 2008; more than 20 interviews were held with staff members and with stakeholders from the Ministry of Health, the Federal Joint Committee, the Institute's Board of Trustees and patients' representatives and external experts who work with the Health Information Department (Annex 2).

In the review of the case studies and the discussions, the team considered the quality of the reports and information products, the relevance and quality of the supporting material, and the views of the stakeholders and the authors on the quality and usefulness of the reports. It also considered the independent user evaluations conducted by the Universities of Bremen and Hanover.

The review team attended an editorial meeting and had numerous discussions with the staff of the department (including during 2009) to clarify outstanding questions. The discussions were used as a basis to identify any aspects of the process that could be modified to improve the quality and usefulness of the reports, and to identify areas where the methodology for the information reports could be improved. Finally, the team discussed its draft recommendations with the Director of the Institute prior to finalizing its report.

Production of health information: process and findings

General issues

The key principles used by the Institute in its work on patient information relate to the public health relevance of the topics it addresses, its scientific independence, the use of the best available evidence, the transparency of its processes, the consultation with stakeholders, its focus on patients' needs and its adaptation to change.

The processes used by the Institute for producing its health information are described in the *General methods manual*, version 3.0 of 27 May 2008.

The time frame for producing a health information product depends on the types of product that will be developed and ranges from 8 weeks to 18 months.

The process starts with selection of a topic and deciding the scope of the health information product. For a feature article (Infoberichte) or commission, a project group is formed and tasks are allocated. Systematic reviews are carried out together with a review of qualitative data from the literature and contacts with patients' groups. A first draft is produced by the lead staff member (sometimes by an external writer) and discussed with the project group for key messages; following a peer review, comment and approval by the Institute's Steering Committee it is sent out for consultation. Simultaneously with the consultation phase, user testing is carried out with patients and members of the general public. Comments are reviewed and a second draft is produced by the staff of the department; this is then reviewed by the project group and/or editorial conferences before being approved by the Steering Committee.

There are no formal project groups for the fact sheets and research summaries but otherwise the process is similar in the steps that are followed.

Selection of topics

Topics are chosen in three ways:

- they are selected by the Federal Joint Committee (G-BA) either directly or (as laid down in the mandate) in the form of health information related to the topics covered by the specific health technology assessments produced by the Institute for the Committee: this accounts for up to 24 topic areas annually;
- they are selected by the Institute, based on perceived gaps in health information, suggestions for particular content from stakeholders (including patients) and recent additions to the evidence base on specific conditions;
- one topic has been commissioned and funded by the Ministry of Health.

The priority-setting process for the selection of topics is guided by article No. 139a of the Social Code Book V setting out the task for the Institute as: "Provision of easily-understandable general information to citizens on the quality and efficiency of health care services, as well as on the diagnosis of and therapy for diseases of substantial epidemiological relevance".

In order to translate this into concrete criteria, the Institute uses a range of considerations to come to a decision, including information on mortality, incidence and prevalence of disease, utilization of health services, current public health controversies, and absence from work. Tables 1 and 2 list the criteria and data sources used by the Institute to make a scientific and objective selection of topics and to set priorities as between potential topics.

Table 1. Theoretical framework for priority-setting criteria

Health care evidence	Editorial considerations	Patients'/consumers' interests
Systematic reviews of the effects of health and self-care	Balanced mixture of topics	Patients'/consumers' concerns
Evidence of impact of information as an intervention in topic area	Currently topical issues	Information sought by patients/consumers
	Potential adverse effects of publishing information	Topics that attract readers' interest
	Priorities of commissioning bodies (payers)	Unmet information needs
	Workload and other resource issues	Burden of disease
		What experts believe patients/consumers need to know

Table 2. Potential data sources for determinants of topic interest

Determinant	Some potential data sources
Patients'/consumers' concerns	<ul style="list-style-type: none"> • Surveys and primary qualitative research • Reviews of primary qualitative research
Information sought by patients/consumers	<ul style="list-style-type: none"> • Surveys and reviews of surveys • Data on information requests to advisory services such as call centres and self-help groups • Search terms entered on web sites and search engines
Unmet information needs	<ul style="list-style-type: none"> • Surveys and reviews of surveys which reveal patients'/consumers' knowledge gaps • Gaps in relevant comparable information sources
Topics that attract readers' interest	<ul style="list-style-type: none"> • Frequency of readership (e.g. web site visits) • Reader ratings or recommendation behaviour such as "e-mailing to a friend"
Burden of disease	<ul style="list-style-type: none"> • Surveys of disease prevalence, lifetime risk or burden of disease, including days of work lost and costs to patients • Routine data collections of health service use
What experts believe patients/consumers need or want to know	<ul style="list-style-type: none"> • Opinions of health professionals, patients'/consumers' representatives, policy-makers • Contents of other information services • Topics covered in mass media • Topics linked to by web sites

The information and sources used are the:

- the Institute's evidence criteria for health information (good quality up-to-date evidence of benefit)
- clinical relevance: MORE ratings plus local considerations (McMaster Online Ratings of Evidence)

- questions to statutory sick funds' call centres
- burden of disease
- web site use and ratings
- articles and surveys of patients' interests in Germany.

The Institute uses additional sources to inform its own decision-making process on the selection of topics, including surveys and on-line polls and questionnaires, feedback from health care providers, information from the search engine for the Gesundheitsinformation.de web site, and feedback from patients' and consumers' groups. Members of the public can suggest topics via the web site. The Institute looks for qualitative research carried out with patients in Germany, and a staff member keeps a register of all studies identified on what interests patients in Germany.

The Institute has developed these draft criteria to help guide its topic selection process via a range of activities, including a survey that included patients and key stakeholders. Its methods foreshadow a formalization of criteria in the future through a consultative process. They include a formal consideration of the quality of evidence according to set criteria, clinical relevance and patients' interest.

The other side of the topic selection process is that the Institute actively searches for evidence to enable it to address on a priority basis health issues for which an evidence-based answer is possible. As a result, it scans for evidence for its topic selection process and has established collaboration with the Centre for Reviews and Dissemination in the UK and others.

The Steering Committee ratifies decisions regarding the selection of topics. It is clear, however, that more transparency should be brought into the process. The draft criteria have not yet been included in the *General methods manual* and are being further developed. Naturally topic selection will continue to be a matter of judgement and cannot be a mathematical process.

There are also certain legal obligations on the Institute in this area (the commissions received from the Federal Joint Committee) but criteria for weighing the importance, relevance and potential impact of producing health information need to be set out more precisely. In discussions with departmental staff this was clearly acknowledged as "work in progress". One approach taken by the department is to monitor and evaluate the number and types of topic that are finally selected vis-à-vis the draft criteria.

In order to guarantee the scientific independence of the Institute, the Federal Joint Committee's general commission to the Institute in December 2004, extended in March 2008, allows both the Committee to participate in the selection of topics and the Institute to select topics for scientific evaluation independently. Those topics do not have to be approved by the Committee or the Federal Ministry of Health. The scientific independence of the Institute is of paramount importance within the health system, and the content of its reports cannot be determined by industry, the statutory health insurance funds or politics.

At the same time, the Institute is required to monitor constantly the scientific literature as well as developments in the health system as a whole, and decide which health information currently on the web site should be updated. This could be in response to new evidence as well as to questions and issues emerging on this particular issue in the health system.

Apart from public health relevance and evidence, it is important that the topic selection process takes into account the overall work planning of the department and the number of slots available in terms of the total and the variety of health information products that the department can deliver.

The Institute has established procedures for deciding on updating and correcting existing information. An evidence scanning system has been developed, including the UK Centre for Reviews and Dissemination's database of reviews of effects, a network of other health information providers working with the Institute, safety alerts, and additional literature scanning. The rest of the health information products are in principle reviewed every three years. All in all, this means that information on the site will generally not be older than three years. The dates of the updates are reported online, including to the subscribers to the site.

From an organizational point of view, the Institute's approach regarding updates of existing health information appears to be feasible only when the necessary resources are available. Once the goal of 1000 health information products has been attained, more than 300 products will have to be updated on an annual basis. From a scientific point of view, a three-year interval is an ideal period because methods research has shown that after three years about 90% of evidence-based recommendations are still valid. After five years this proportion drops to about 50%. An interval longer than three years for updating existing products would, therefore, be problematic because a substantial proportion of health information products would no longer be up to date after 2012.

When selecting a topic, the Institute also defines its scope at the start of the process, that is to say, the precise width and depth of the clinical problem or the health issue to be covered under the topic. The initial discussion by the Steering Group/project group defines the scope and therewith the product(s) that will need to be developed (full article, fact sheet, research summary). However, it appears that as the research and the evidence- and information-gathering takes place, the scope may have to be adapted depending on those initial findings. The project group meets after the systematic reviews have been completed in order to discuss the key messages, and at this point the scope could be adjusted.

Identification and review of evidence

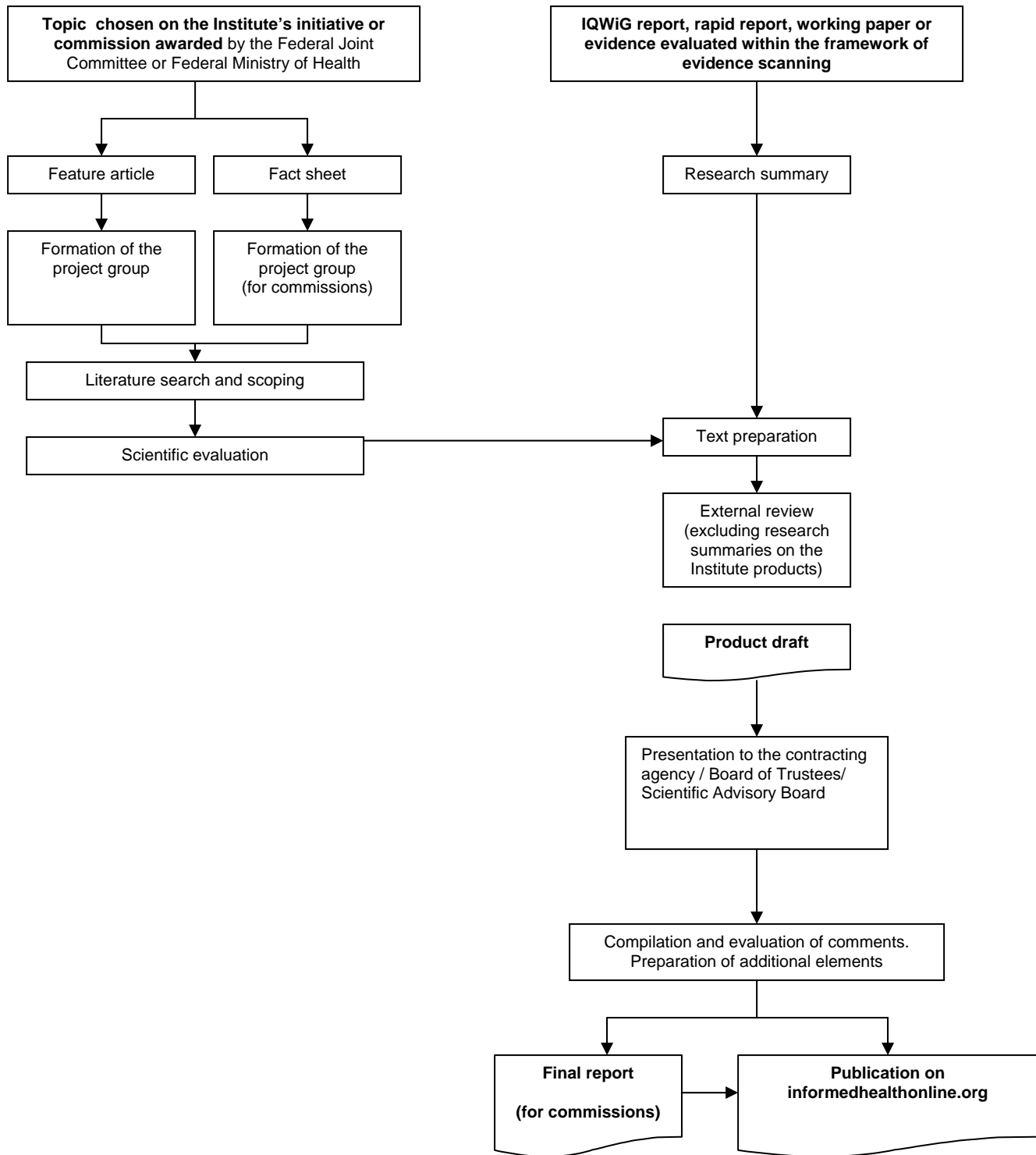
General process for the clinical evidence reviews

After multiple interviews with employees and reviews of documents, the main steps can be summarized as follows (Fig. 1).

1. The topic is chosen. If the format selected is a feature article or the topic has been commissioned by Federal Joint Committee or Ministry of Health, a project group is formed consisting of members of the health information department plus at least one person from another department.

2. The next step for feature articles includes literature searches. For all other products, the literature search is largely completed before the topic proposal. For all health information products, systematic literature searches are conducted in multiple databases to identify systematic reviews and meta-analyses. For feature articles and most fact sheets, literature searches are expanded to qualitative research.
3. Except for qualitative studies, two persons independently review the systematic reviews that are used for the evidence statements, identify relevant research and rate the internal validity of the studies included.
4. Based on the best available evidence, authors write first drafts of health information documents. An internal departmental review, including editors, ensures that the quality and readability is of an adequate level.
5. Drafts are then sent to external peer reviewers. Once their comments are incorporated, an updated draft is submitted to the Steering Group. A final draft is submitted to the Board of Trustees, which includes all the stakeholders, the contracting agency and the Scientific Advisory Board, for comments, as well as other bodies such as the national independent patient advice organization. This draft is also sent to an independent academic institution (the Patient University in Hanover), for usability testing. Pilot usability testing is also starting now with the Beratungsstelle patient group in Hamburg.
6. Comments and feedback from the Scientific Advisory Board and the stakeholders as well as the results of the usability testing are reviewed by the project group and the departmental editorial conference. The comments and feedback, along with a final draft and the recommendations of the editorial conference, are sent to the Steering Group for final comments and approval.
7. The final product is published online.

Fig. 1. Procedure for producing health information



Overall, the review team found that the reported methods represent a valid, high-quality approach that minimizes the risk of bias. Staff involved in the development of the health information products have a thorough understanding of the process and the underlying methodological issues, and have gained important experience over recent years in producing the information. Key staff members have impressive methodological expertise and can provide guidance for less experienced colleagues. In addition, the Institute's methodologists from the HTA and medical statistics departments are available for methodological and additional guidance.

The focus on systematic reviews as the best available evidence is an efficient and sound basis for health information products, especially given the annual goal of an output of 150–200 products. The *a priori* exclusion of systematic reviews funded by industry is debatable for practical reasons, because it is conceivable that for certain research questions only systematically reviewed evidence funded by industry might be available. Nevertheless, such a policy will not compromise the internal validity of the products.

Feature articles, which are the most comprehensive products, employ an impressively extensive approach to provide an in-depth picture of the evidence emphasizing patients' needs for specific information. In addition to findings from systematic reviews, consideration is given to qualitative studies and results from interviews with patients. The inclusion of information gained through these interviews and the review of qualitative evidence add a valuable perspective to these products. One of the unique features of this approach is that it highlights discrepancies between patients' needs for information and the outcomes assessed in the studies. The challenge is how to reflect these in the information product.

Although the approach outlined in the Institute's manual represents a well-thought-through standardized framework that is applied to each project, it does not yet provide a fully transparent and reproducible algorithm for individual methodological steps. Most of this is available already in internal documents (which are close to finalization) but has not yet been incorporated into the manual, i.e. the improved detailed workflow documents for the fact sheets and research summaries, and others for newsletters and quizzes. The exact methods employed for each product, therefore, are not entirely transparent for interested readers of information products or stakeholders. Both the sample of guidelines reviewed in detail and the interviews clearly indicated to the review team that the methods used by the Institute are methodologically valid and applied in a consistent manner. Staff involved in the development of these products consistently reported the same steps that have to be followed as part of the workflow. Nevertheless, neither the manual nor some of the other internal documents reviewed provided a detailed step-by-step algorithm of the exact workflow for different products. The department is working on completing these internal workflow documents as part of a larger editorial management system, which is under development.

Various external interviewees also pointed to a general lack of clarity regarding the exact methods of the development of health information products.

It was also apparent that stakeholders or the Board members who comment on the draft information product do not get feedback on whether their comments had been taken on board and, if not, why not. On the one hand, there is clearly the potential for a high workload in responding and engaging in discussions about comments from individual stakeholders; on the other hand, the lack of a

response risks jeopardizing the interest of the stakeholders and other interested parties in reviewing and commenting on the drafts. The review team recommended that the comments and suggestions received might be tabulated together with a short explanation as to whether they had been adopted or not. During the course of the review, another senior methodologist was employed in the department (and a further recruitment was in progress) who has already implemented this recommendation, so that stakeholders are now getting feedback on their comments and how these were reviewed and dealt with. It is clear that this is a time-consuming process, and the workload for existing staff as well as the possible staffing implications need to be looked at.

Ensuring quality and accuracy

The review team identified four main layers of quality assurance: internal, departmental review; external peer review; comments and feedback from stakeholders; user testing.

Internal review (including the medical review) is carried out by the department members, members of the project group for feature articles, the translator and the editorial team. The departmental editors improve the readability of the health information document. The head of the department performs the role of editor-in-chief and final guarantor to the Steering Committee. According to staff interviews, a methodologist checks the main messages and the correctness of the reported data to ensure that reported findings reflect the underlying scientific evidence.

External peer review is an additional important step for quality assurance. All products undergo some form of external peer review. Research summaries and the other health information products are always sent to the authors of the underlying systematic reviews. As most of these authors do not speak German, translation into English is a key element of the Institute's quality assurance process. Where articles are commissioned, the comments received during external peer review are shared with the commissioning agency.

In order to exclude a potential conflict of interest, the Institute has published clear guidance on its web site, and now uses a standard form for external reviewers for the assessments of evidence and research assignments. However this form is not legislatively required for peer review of health information and is not used for the authors of the systematic reviews because of the additional burden and barrier to quality assurance that this would pose. The authors are asked to declare anything that is not yet declared in their systematic review,.

Final drafts are sent to the Board of Directors and Board of Trustees for comments and feedback. Some members of the Board of Trustees indicated in the course of interviews that they often submitted comments and feedback to the Institute. Even so, the review team encountered frustration on the part of stakeholders regarding a lack of transparency as to whether any action is ever taken based on these comments and what these actions entail. Internally, the Institute considers comments from stakeholders in detail during weekly editorial meetings.

The review team considers that it is crucial for successful cooperation that the results of the Institute's meetings are communicated to stakeholders who have provided comments. As stated above, this feedback process has already been started.

The final write-up of the health information product is done by the department. The Institute uses writers' guidelines, but these too are under development with the addition of a special section on patient-centredness, as part of the whole editorial management process. The team considered that it is both useful and important for this specific style guide to be finalized in line with the Institute's mandate, style and approaches.

User testing is an important part of quality assurance with regard to the readability, usability and acceptability of the final products by patients and their relatives.

Since early 2008, the Institute has contracted the Patient University in Hanover to test information products for usability before publication. This process provides valuable feedback that helps to improve the usability and acceptance of health information products.

A concern that arose during an interview with a representative of the Patient University in Hanover was that the people testing the products might not be representative of the target population; they may also have been involved in a series of tests to the extent where they would no longer be representative of the patient community. Testers at the University are primarily interested lay-people, and not patients. This occasionally may have led to some differences between testers and the target population: for example, people testing the information product on postnatal depression were aged between 41 and 54 years (two men and three women). None of the women were pregnant or of an age where pregnancy would be likely.

It is important to bear in mind that the user group tests a number of products, and thus this group may be more related and representative for some products than others. Nowadays patients are involved in only one testing exercise with several products, so as to avoid them becoming too much "expert patients". The Institute and the University also strive to incorporate people from the target population into the testing group, although this is not always possible. To take full advantage of the possibilities of user testing, the Institute has to continue working with the University to use diverse populations that also include patients or relatives of patients with certain diseases, so that the usability of products will be of real benefit.

The Institute's health information products are of a non-directive nature: they do not tell patients what to do in certain situation but basically lay out the evidence on the topics. This is not a black/white issue and de facto if the evidence is very clear, that in itself holds a recommendation in it. As was commented some patients, however, find this non-directive information somewhat irritating, as they are coming to the web site precisely to obtain guidance on what to do in certain situations. At the same time, the evaluations carried out by the Universities of Bremen and Hanover showed that a majority of patients in fact very much appreciated the non-directive nature of the patient information, and that this added elements of credibility and truthfulness to the information.

The other issue relating to usability that needs to be addressed is how the Institute's health information, specifically that related to medicines, relates to the summary of product characteristics and the patient information leaflet as approved by the Bundesinstitut für Arzneimittel und Medizinprodukte BfArM (Federal Institute for Drugs and Medical Devices) or the European Medicines Agency (the regulatory authority) for those specific products. These are texts with legal connotations, very often couched in professional language and hard to follow for the lay-patient.

The Institute reviews the leaflets published by the European Medicines Agency and the BfArM when writing their products. Contacts have been established between the Institute and the BfArM, but concrete results and collaboration have yet to emerge.

Dissemination, monitoring and evaluation

Indicators to monitor the Institute's patient information include those that assess readability, accuracy, reach and impact. The Institute's patient information programme disseminates its content almost exclusively through its web site and therefore relies heavily on usage statistics and unsolicited feedback from readers. The site is currently receiving about 3000 visits per day (about 90% of the hits to the German site and 10% to the English versions), an almost threefold increase in one and a half years. Occasional products are also distributed in printed form and pdf's are produced, but the Institute does not print the content it produces.

Readability

The Institute's Department of Health Information commissioned qualitative evaluations of its work from the Universities of Bremen and Hanover. Through its own reviews and in a series of interviews, the University of Bremen concluded that the material was professional, honest and credible. The non-directive nature of the information was also appreciated and was seen to convey high ethical standards. The University of Hanover also carried out usability testing, and concluded that generally the products are well understood, easy to read and credible, and that patients consider the information to be reliable and useful.

Many of the pages on both language versions of the web site include a "rate this page" feature. These ratings are used for helping to decide how much effort to put into updating. The Institute uses the online reader survey (see [http://www.gesundheitsinformation.de/survey/umfrage.php?p\[page\]=survey_start](http://www.gesundheitsinformation.de/survey/umfrage.php?p[page]=survey_start)) so that it can monitor and evaluate its web site. This survey has been developed by the University of Bielefeld and is used for evaluating patient information web sites in Germany.

Accessibility

Compliance with the Web Accessibility Initiative's content accessibility standards should be checked on a regular basis, as some of these guidelines do not appear to be fully implemented at present.

The Institute's use of different-sized fonts on its web site to facilitate legibility is a useful feature and is focused on making the site as accessible as possible. Any notifications of problems with access are immediately conveyed to the information technology contractor, who takes direct action to correct the problem. There is a possibility, however, that the functionality of the site might be affected on two levels. First, it may not be applicable to all computer/monitor settings. In some of the interviews conducted by the team, it was reported that material "drops off the screen". Members of the team did not themselves have these difficulties, and it seems that they happened in past years and were more related to computer problems experienced by the users themselves. The second minor problem is that it is not clear what size of page is displayed, or when maximum size has been

reached when clicking on the icons. Breaches of accessibility could not be verified, and a full compliance check was not done.

Accuracy

The accuracy of the Institute's patient information web sites is largely conditioned by the process taken in developing the content, as described above. Accuracy can also be affected by web publishing and hosting processes, but the review team found no areas for concern with the current arrangements made through the German Institute of Medical Documentation and Information (DIMDI).

Reach

The Institute commits resources to English translations of its content in order to facilitate further translations. One translator is working on these now, but the necessary partnerships to increase these translations have not been established. The Institute notes the need to reach Germany's migrant population but has not documented the extent to which this objective has been met.

Nevertheless the internet has clearly become an important source of patient information in Germany, with at least 40% of patients reporting getting information from it.

Impact

In general, impact evaluation of health promotion and health literacy activities is challenging, as changes in care-seeking behaviour and/or health outcomes can be ascribed to many different factors.

The evaluation reports indicate that generally patients are satisfied with the information they find on the Institute's web site and consider the information useful, relevant and trustworthy. No data are available regarding improvements in health resulting from changes in health-seeking behaviour.

Findings and specific recommendations

The Institute's health information programme has only recently been established and is evolving rapidly. Methods of selecting topics, deciding on their scope and developing content are constantly developing, and are thus a challenge to evaluate. In its first years of existence this programme has produced an impressive quantity of information, while at the same time developing and improving its methods. The staff of the Department are highly competent, motivated and committed, and have shown enormous discipline and production capacity.

The Institute is clearly committed to an evidence-based and non-directive patient information web site constructed through a combination of systematic reviews of the relevant evidence and comprehensive consultations with stakeholders.

The Institute and its governing bodies are to be commended for its enormous work and impressive achievements. Increasingly it has become clear that a publicly funded and scientifically independent

body can and should play an important role in providing objective and non-biased information to patients, and the Institute's efforts are an important initiative in this direction.

Selection of topics

The selection of topics is a continuing challenge, as the Institute's interpretation of "diseases of epidemiological importance" is not tied to a standard indicator (such as disability-adjusted life years or other measures of disease burden) and priority-setting also includes considerations such as a relative dearth of patient information on a given topic, as well as the availability of evidence for that specific area. It should also be recognized that the Institute has a certain legal obligation for the production of health information (in connection with the HTA reports issued by the Federal Joint Committee). It also has a clear legal brief for scientific independence from all stakeholders (industry, hospitals, doctors' associations, sick funds, etc.). It has, therefore, tried to develop and implement the use of objectively verifiable criteria that relate to public health issues without going through consultative decision-making processes, including input from stakeholders, as the Institute felt that this could bias their priorities. Thus it has developed a set of draft criteria to help guide its topic selection process via a range of activities, including a survey that included patients and key stakeholders. The Institute aims to formalize these criteria in the future through a consultative process, including a formal consideration of the quality of evidence according to set criteria, clinical relevance and patients' interest.

The Institute also regularly monitors and consolidates data on the topics chosen, in order to verify that they are broadly in line with their agreed criteria and principles.

There were some concerns that the selection of topics might be influenced by the numerical targets set in terms of the number of products to be published. These were initially 200 a year, reducing in following years to allow for the workload involved in updating. The goal is now 150; reaching the target of 1000 information products will depend on the availability of resources.

It is clear that numerical targets are necessary to establish critical mass and credibility for what is still a young organization. Careful attention will, however, need to be paid to ensuring that such targets do not unduly influence the agenda and become unrealistic in view of the resources committed and quality standards required.

In respect of the selection of topics, several interviewees expressed concern that patients' interests are insufficiently reflected. Nevertheless, the Institute clearly strives to use many data sources directly related to patients' groups, including data from call centres that receive patients' questions and a variety of printed material in order to ensure that patients' interests are appropriately represented. Any person can suggest a topic over the Institute's web site, and the Institute engages with many patient groups and carries out online surveys. It also looks for qualitative research carried out with patients in Germany, and one of the staff members keeps a register of all studies assessing patients' information needs in Germany. The review team thus finds the range of topics impressive and relevant to patients, but cannot necessarily comment on the degree to which they reflect the interests of German patients. The selection of topics is always going to be context-specific, and some engagement with patients in this area may help both to generate topics and mitigate criticisms of an elitist or distanced approach. As the Institute's selection of topics is in large part driven by the

available evidence, it is clear that some trade-offs or discordance will occur. Again, however, and as relates to the earlier point, it would seem to be in the Institute's interests that its aims in respect of patient information be made more explicit.

Recommendation

The team recommends that development of clearer criteria should be continued on the selection of topics and the priority-setting process, and it should be ensured that these are incorporated into the *General methods manual*. The Institute's legal mandate for scientific independence, combined with the directives of the Federal Joint Committee, make it more complicated to work with advisory committees that include representation by interested parties. It is, therefore, recommended that the work on making the indicators for the selection and prioritization of topics more explicit should be finalized swiftly. At the same time, monitoring and evaluation of the application of the criteria should also be made visible, so that at the end of each year it can be seen how the health information products relate to the criteria (burden of disease, queries from patients on Germany's help-lines, health care interventions, etc.).

The Institute also has a legal brief to produce information in connection with the Federal Joint Committee's HTA reports, as well as making its own choices. At the same, it should maintain a certain flexibility to enable it to decide to produce health information quickly in response to sudden and urgent health issues (such as influenza).

Clear criteria also need to be outlined regarding decisions on the scope of the health information product. When a topic is selected, the Institute should define the scope more explicitly at the start of the process, i.e. the width and depth of the clinical problem or the health issue to be covered under the topic should be more precisely defined. The initial proposal to the Steering Committee/Project Group defines the scope and the product(s) to be developed (feature article, fact sheet or research summary). The Project Group meets, having completed the systematic reviews, in order to discuss the key messages; at this point the scope could be adjusted.

It is recommended that this should be included in an annual workplan, which can be adapted as needed and which takes into consideration the slots available in the department for producing the health information products.

Review of the evidence

Overall, the review team found that the methods reported provided for a valid, high-quality approach that can minimize the risk for bias. Staff involved in the development of the health information products have a thorough understanding of the process and the underlying methodological issues, and have gained important experience over recent years in producing the health information. Key staff members have impressive methodological expertise and can provide guidance for less experienced colleagues. In addition, methodologists from the HTA and medical statistics departments are available for methodological questions and additional guidance. The inclusion of qualitative studies and results from interviews with patients adds a valuable perspective to these products and is clearly in line with the Institute's mandate on patient-centred and evidence-based information.

The approach outlined in the Institute's *General methods manual* is a clear standardized framework that is applied to each project, but the manual does not yet provide a fully transparent and reproducible algorithm for individual methodological steps. Nevertheless, the team found through the sample of guidelines reviewed and interviews with the staff that the Institute's methods are methodologically valid and applied in a consistent manner by the staff. Internally the methodological approaches are there and are applied in a standardized manner, but neither the Institute's manual, nor the other internal documents reviewed, provided a detailed step-by-step algorithm of the exact workflow for different products.

The review team also found some frustration among several of the interviewees about the lack of feedback on the comments that they provided on early drafts of the health information products. It was suggested that it might be feasible to produce a table with comments received plus a short explanation on whether the comment and suggestions were adopted, so as to avoid losing the involvement and interest of the stakeholders in contributing to the process.

Recommendation

The review team recommends the further development of the *General methods manual* so that the methodological steps are clearly outlined for the production of different health information products. Most of these documents are already available internally but need to be incorporated into the manual. The manual is crucial for transparency and clarity and is also necessary to avoid future problems with retaining knowledge if key staff leave the Institute. Given the sound methodological approach already employed, such a document, when publicly available, will also strengthen the public perception of reliability and scientific accuracy of the Institute's health information products.

The recommendation to provide feedback to stakeholders on the comments they send in the consultation phase was already being implemented during the review period.

Quality and accuracy

The review team acknowledges the wide range of quality assurance measures and approaches that the Institute has implemented in order ensure the validity and usefulness of its products, including an internal departmental review, external peer review, comments and feedback from stakeholders and user testing.

Each product is finalized with extensive involvement of the Institute's experts and with checks and double-checks in the process. The scientific knowledge, experience and dedication of the staff is impressive. Every product is signed by the Project Group (or equivalent) and is reviewed by the Board of Directors.

Many of the Institute's products are generally translated into English. This is done as a quality assurance measure, so that the products can be reviewed by the authors of the original systematic reviews or articles that underpin the product. It also facilitates access for the English-speaking community in Germany and presents the Institute as a leading institution globally for the production of patient-centred health information.

In every production cycle there is an extensive consultation phase with experts and a broad range of stakeholders, who can provide comments, additional information and suggestions. Whereas internally it is recorded which of these comments were acted upon, this was not always clear to stakeholders and they received no systematic feedback. During the review the suggestion to provide them with feedback was already implemented.

Every product undergoes user testing with the Patient University in Hanover. Initial concerns that the groups of patients were too small have basically been resolved. The University enlists new patients for almost every new test and tries to incorporate patients from specific target groups, as appropriate. Staff of the department actively seek and maintain contacts with patient groups to get them involved and ensure their perspectives are included.

The Institute's health information products are of a non-directive nature, and endeavour to confine themselves to laying out the evidence on the topics. If, however, the evidence is very clear, that in itself is a recommendation. Some patients find this non-directive information somewhat frustrating, as they come to the web site precisely in order to obtain guidance on what to do with certain problems. Nevertheless, the recent evaluation reports by the Universities of Bremen and Hanover suggest that patients increasingly accept and are getting used to handling and accepting uncertainties, and that the non-directive nature of the information in fact contributes to the trustworthiness of the Institute's information.

Recommendation

The review team encourages the Institute to develop a system that assures stakeholders that their comments have been acknowledged and adequately considered. This additional time and effort appears worthwhile to avoid any decrease in motivation of stakeholders for providing feedback. This recommendation was already being implemented during the review period.

Furthermore, the Institute should continue to work with the Patient University in Hanover to ensure that testers are, as far as possible, representative of the target population so as to guarantee the highest benefit during the usability testing phase.

More translations should be done, both as an opportunity for quality assurance and a way of reaching English- and other non-German-speakers in Germany, as well as to strengthen the Institute's reputation and importance as a leading producer of patient-centred and evidence-based health information. It would be a benefit if this information were available in other languages, where updated evidence-based health information is not easily available.

Continued development and formalization of the Institute's style guidance would enhance the quality and usefulness of the health information products.

Some coordination needs to be established with the BfArM in order to avoid discrepancies and contradictions in the texts on the package inserts and labels.

Further research and monitoring will be needed on the nature of the information provided, and whether patients appreciate the non-directive nature of this information or whether at times more directive information may be helpful. The evidence itself may in many cases already be directive for action.

Dissemination and evaluation

The review team considered several aspects of the dissemination and usefulness of the Institute's information, and how this is evaluated in terms of readability, accessibility, accuracy, reach and impact.

The recent evaluation reports from the Universities of Bremen and Hanover provide positive feedback on the acceptance, readability and usefulness of the Institute's patient information. Its non-directive nature is appreciated by many, and the same goes for the understandable language on the web site. The Institute systematically uses the data from the "rate this page" feature on each web page for possible review of content and language.

In spite of some comments from stakeholders on some problems with the web site, the team found the web site functional and easy to navigate. The team did not undertake a detailed compliance assessment and did not identify any breaches of the guidelines. The contract with the information technology maintenance company requires immediate action to be taken on any problem that may occur.

The Institute attempts to strike a balance between the bilingual provision of content and development of new content. As a result, there is a substantial difference in the amount of content available on the German version of the site and that on the English site. The translation appears to be high quality, particularly bearing in mind the need to make the language accessible to a non-specialist readership. The English version demonstrates sensitivity to the needs of an English-speaking lay audience rather than reading like a direct translation of the German.

The purpose of a bilingual service is on one hand a quality assurance measure as it allows the review of the material by the authors of the systematic reviews that underpin the Institute's products. On the other hand, the availability of material in English aimed at the English-speaking community in Germany (for example, migrants from Africa and Asia) also opens up the opportunity to gain a wider international readership. This may enable it to be taken up outside the German context, which will contribute to the Institute's international standing as a producer of independent evidence-based patient information.

Competition for influential patient information comes from industry-sponsored print publications distributed free through pharmacies and doctors' surgeries. Yet the Institute's default means of dissemination is online. Relatively few of its products are made available in printed form unless there is a major request from the Federal Joint Committee or the Ministry of Health, as was the case for asthma when 40 000 copies of the Institute's feature article were printed and disseminated by one of the sick funds. There is too little direct outreach yet to health professionals and patients' groups to try to engage them in using the Institute's health information in communication with patients.

The review team found, via various respondents, that there was no consensus on the use of a web-only approach. Acknowledging that it is a direct stipulation that the patient information be only available via the web site, this may be hampering its impact. On the one hand, many patients do not have access to the web and lack understanding of how to search for information and critically evaluate good versus poor quality material, or they are more likely to read and retain information disseminated in hard copy. Respondents pointed to the likelihood of the less educated, lower income groups, patients with disabilities or the elderly as examples of patient groups who might benefit from the information but who cannot currently access it in the web-only format. On the other hand, the web site lends itself to updating and comparative searches with other sources of information, and is an area in which the Institute's patient information group could potentially develop and compete. Hard copy versions are unlikely to be able to compete with information available from the industry and other sources in surgeries and pharmacies. Two potential options here are:

- the development of a targeted approach to printing particular products (most likely Fact sheets) not just on commission but where a topic has particularly wide coverage and is topical, or where the evidence base is strong and definitive in terms of a particular choice or direction;
- the strategic placing of a kind of advertisement in key printed media with a wide readership, such as newspapers or magazines (e.g. *Brigitte*), pointing to the independent, evidence-based patient information produced by the Institute and listing several examples of specific topics.

Related to the choice of media, many respondents thought that awareness of the Institute's patient information was still low. It was felt that patients generally were unaware of its existence and that doctors and pharmacists were also unlikely to know about it. Nevertheless, surveys indicate that at least 40% of patients in Germany report that they consult the internet for patient information, so the potential is clearly enormous.

Without an impact evaluation, the review team cannot comment on the degree to which the Institute's health information has (not) been acted upon or taken up by patients, doctors, pharmacists or, indeed, policy-makers. The consensus of views expressed by respondents, however, suggests that the impact is yet low. This clearly has to do with insufficient awareness of the Institute's work in this direction and a lack of marketing given the competition by other organizations. But it also has to do with a tradition in health which is doctor-led and often a black or white view. This may lead to – and as reported by numerous respondents - that many multipliers believe that the patient information as it is currently formulated: non-directive, evidence-based and therefore, often, inconclusive, is not what is needed or demanded by patients. The review team is sensitive to the Institute's mandate in this regard, and would suggest, therefore, that a more understandable (to patients) delineation of the aims of the Institute's patient information, its role in assessing evidence (where it is otherwise often seen simply as a rationing or cost-saving entity), and better marketing may help to mitigate this. It was argued by several interviewees that patients generally want to know what to do, rather than being presented with a choice of options on which the evidence is inconclusive. But better setting out the purpose of the Institute's health information and differentiating it from other material make help to make things clearer, as also indicated in the recent Bremen and Hanover University evaluation reports.

On the basis of interviews with members of the Institute staff, both within the patient information unit and outside it, the review team found that there is regular collaboration and interaction between the patient information work and that of the other departments. But there may also be opportunities to develop that: for instance, the communications unit works in principle for the Institute in its entirety but for the moment has too little capacity and resources to collaborate with specific health information material given the different audience; for now the communications unit seems more dedicated to the greater workload in respect of the HTA and evaluation reports.

It was also clear to the review team that until now the Institute had been concentrating on getting their web site populated with sufficient high quality content, in stead of promoting a web site with only few products, where people would not easily return.

After these 4 years the web site has now an impressive range of high quality information products, and it seems a good moment to further intensify the outreach activities, and promote the site both to health professionals as well as to patients themselves.

The question was raised regarding releasing the HTA report and patient information in tandem, but this is controversial. The Federal Joint Committee would prefer to inform patients (on the basis of their decision) rather than the Institute's report alone. This is leading to a time lag between the publication of the Committee's guidance and the Institute's patient information. While it is a requirement that all HTA reports are followed by accompanying patient information, this is not therefore the case at the time of publication.

Finally, the Institute has yet to develop ways of assessing the reach and impact of the information it produces with reference to its goals, namely:

1. improving understanding of:
 - a. physical, mental and emotional health;
 - b. medical and scientific information, including the concept of evidence-based medicine;
2. promoting health improving behaviour;
3. facilitating support by relatives and friends;
4. promoting the critical use of health care services; and
5. supporting active decision-making about health issues.

The Institute states that it does not provide direct advice to consumers and patients. Indeed, the review team found that the Institute's patient information was uniformly non-directive, although often the evidence itself can be so conclusive that it reads like a recommendation. Opinions from stakeholders varied on the usefulness of this attribute, as some felt that patients sought medical advice precisely because the profession represents knowledge, and that this advice is valued and actively sought as an integral part of the health care encounter. However, the Institute's stated intent is to inform choices on health issues, while prioritizing consumer and patient autonomy; and to encourage patients that for health or medical advice they should see their doctor.

Recommendations

It is recommended to intensify the promotion of the web site with health professionals, and with patients, now that sufficient material is available on the site; this could be done in collaboration with all stakeholders, but also by working with the communication department in the Institute itself – which would require additional resources in order to service this area. The Institute should also explore ways of using their material in targeted campaigns, also where appropriate using printed material.

Expanding the number of English translations will further enhance the role and reputation internationally, will provide important information for the English speaking community in Germany, and will help secure the quality of the information of the site. Currently the health information products are translated into English, but there is a considerable publication backlog because of limited resources. The English version of the web site is also useful as a source of information for other countries worldwide that are striving to increase the availability of health information for their populations, plus an important quality assurance mechanism, and a source of information for the English speaking community in Germany.

It is important to maintain the excellent access to the web site, check compliance with accessibility guidelines (as stated in the Institute methods manual) and ensure that any problems are immediately resolved.

At this point it is difficult to comment on the impact that the Institute information has had, and it is recommended that the Institute also undertake further methodological work in this area.

Key recommendations

Plan for sustainability

The production demand is high at around 100–150 pieces of information annually with a planned total volume of 1000 information products online. As this work is progressing, the review and updating of information will also need to be dealt with.

This results in a high workload for the staff; considering the working hours, it is hard to imagine how the current staff can maintain this volume of production and pace of work. It is recommended to review and increase the staffing levels in order to be able to reach the targets and maintain the quality of the information. Currently there is a highly motivated, competent and dedicated group of staff in the department, but in order to retain the staff it is recommended to explore how they can further grow professionally, for example through academic recognition of their work, and what other incentives can be offered.

Fully document the workflows, including timelines, roles, tasks, and decision algorithms

The review team recommends the development of a document that clearly outlines each methodological step during the production of different health information products. Such a document is crucial for transparency but also necessary to avoid future problems regarding

knowledge retainment if key staff leave the institute. Given the sound methodological approach that the institute already employs, such a document, when publicly available, will also strengthen the public perception of reliability and scientific accuracy of the Institute health information products.

The manual currently resembles more a textbook, and it needs to describe more explicitly the processes that the Institute is using and the studies it includes. Most of these internal documents are already available, but need to be incorporated in the manual.

It is recommended to further develop the existing guidance for authors on patient-centred writing, and also to develop guidance on how to explain uncertainties (NNT etc.).

Topic selection and scoping

The team recommends to continue developing more clear criteria on topic selection and the priority-setting process, and ensure that these are incorporated into the *General methods manual*. The legal mandate of the Institute of scientific independence and the directives of the G-BA make it more complicated to work with advisory committees with interested parties. It is recommended therefore that the work on making the indicators for topic selection and prioritization more explicit should be finalized swiftly and at the same time that the monitoring and evaluation of the application of the criteria is being made visible as well, so that one can see how at the end of each year the health information products relate to the criteria (burden of disease, queries from patients on help-lines, health care interventions etc.).

The Institute has a legal brief as well to produce information in connection with the G-BA HTA reports, as well as making its own choices, and at the same the Institute should maintain certain flexibility to be able to decide to produce health information quickly in response to sudden and urgent health issues (e.g. influenza).

For the scoping also clear criteria need to be outlined on how to decide on the scope of the health information product. When selecting a topic, the Institute should define more explicitly the scope at the start of the process, that is to say be precise in the width and depth of the clinical problem or the health issue that will be covered under the topic. The initial discussion by the Steering Group / Project Group defines the scope and the product(s) that will need to be developed (i.e. full article, fact sheet, research summary). The project group meets having completed the systematic reviews in order to discuss the key messages,; at this point the scope could be adjusted.

It is recommended to include this into an annual work plan, which can be adapted as needed, and that takes into consideration the “slots” available in the department for producing the health information products.

Review of evidence

The review team would recommend the further development of the General Methods manual document that clearly outlines each methodological steps during the production of different health information products. Most of these documents are already internally available, and need to be included in the Methods manual. That manual is important for transparency and clarity but also necessary to avoid future problems regarding knowledge retainment if key staff leave the institute.

Given the sound methodological approach that the institute already employs, such a document, when publicly available, will also strengthen the public perception of reliability and scientific accuracy of the Institute health information products.

Quality and accuracy

The review team encourages the Institute to develop a system that assures stakeholders that submitted comments have been acknowledged and considered adequately. This additional time and effort appears worthwhile to avoid any decrease in motivation of stakeholders for providing feedback. This recommendation de facto was already implemented during the review period.

Furthermore, the Institute has to continue to work with the Patient University Hanover to strive that testers are as much as possible representative of the target population so as to guarantee the highest benefit during the usability testing phase.

It is recommended to expand on the translations, both as an opportunity for quality assurance, as well as a means to reach English speakers in Germany, as well as to strengthen the Institute reputation and importance as a leading producer of patient-centred and evidence-based health information.

Continued development and formalizing the Institute style guidance would enhance the quality and the usefulness of the health information products.

Some coordination needs to be established with the BfArM in order to avoid discrepancies and contradictions on the texts in the package inserts and labels.

Further research and monitoring will be needed on the nature of the information provided, and how patients appreciate that this information non-directive, or whether at times more directive patient information may be helpful. The evidence itself in many cases may already be directive for action.

Dissemination and evaluation

It is recommended to intensify the promotion of the web site with health professionals, and with patients, now that sufficient material is available on the site; this could be done in collaboration with all stakeholders, but also by working with the communication department in the Institute itself – which would require additional resources in order to service this area. The Institute should also explore ways of using their material in targeted campaigns, also where appropriate use printed material.

Expanding the number of English translations will further enhance the role and reputation internationally, will provide important information for the English-speaking community in Germany, and will help securing the quality of the information of the site. Currently the health information products are translated into English, but there is a considerable publication backlog due to competing priorities. The English version of the web site is also useful as a source of information for other countries worldwide that are striving to increase the availability of health information for their populations (and translation into further languages would provide real benefits), plus an

important quality assurance mechanism, and a source of information for the English-speaking community in Germany (such as migrant populations from Africa and Asia).

It is important to maintain the excellent access to the site, check compliance with accessibility guidelines (as stated in the *General methods manual*) and ensure that any problems are immediately resolved.

At this point it is difficult to comment on the impact that the Institute's information has had, and it is recommended that the Institute also undertakes further methodological work in this area.

Design of an impact evaluation for the health information

The Health Information Department has successfully managed its first years with an impressive production of health information. It is now important to try to evaluate the impact of this work and assess whether and how patients and health professionals benefit from it.

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Annex 1

INSTITUTE FOR QUALITY AND EFFICIENCY IN HEALTH CARE: STRUCTURE

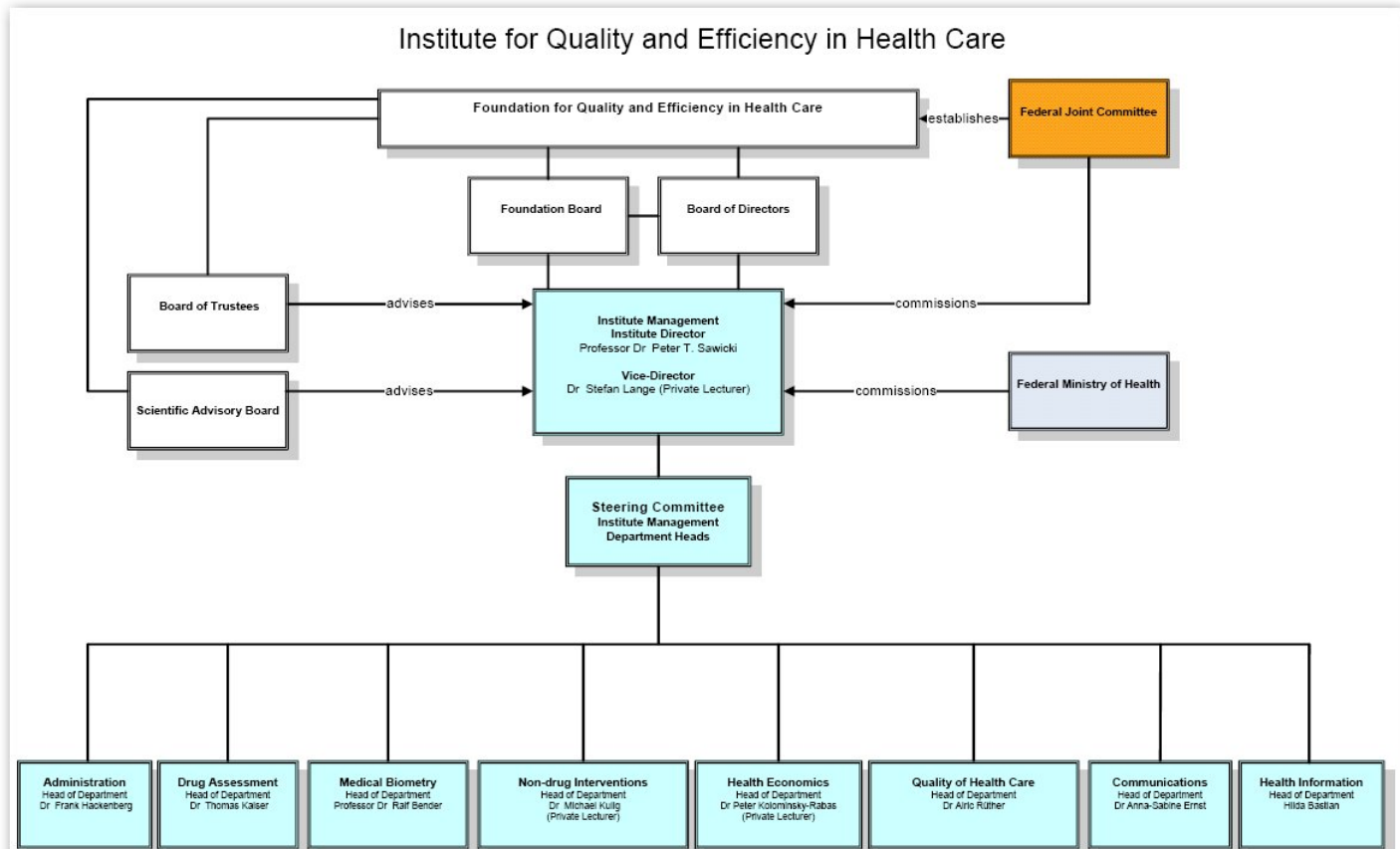


Figure 1: Organisation chart of the Institute for Quality and Efficiency in Health Care

Annex 2

INTERVIEWS

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Annex 3

REVIEW OF HEALTH INFORMATION ON ALLERGIES

The web site contains the following articles on allergies

- Fact sheet: Specific immunotherapy (6 pages)
- Quiz
- Fact sheet: Preventing allergies in children (7 pages)
- Research summary: Allergies: Can specific immunotherapy injections reduce hay fever and other forms of allergic rhinitis? (6 pages)
- Research summary: Allergies: What are the advantages and disadvantages of various antihistamines? (6 pages)
- Research summary: Babies with high-risk of allergy: Can soy formula prevent it? (4 pages)
- Research summary: Babies with high risk of allergy: Could probiotics in infant formulas make a difference? (5 pages)
- Research summary: Eczema: Does eliminating particular foods reduce the symptoms? (6 pages)

General

The allergy information is comprehensive but manageable. The issues are all relevant, topical or where there may be controversy, and one can see patients looking for information on the issues.

Process

From the available information it was concluded that the processes for developing the information products followed the steps as described in the manual and internal documentation of the Department.

Understandability and readability of the health information

The texts of the various products are good, to the point and understandable. They follow the pattern of addressing the health issues, a description of the intervention, its effectiveness and possible side-effects, and the advantages and disadvantages vis-à-vis other treatments and approaches.

The texts are generally short, precise and non-directive. It could be helpful to highlight certain areas with evidence, controversies, what is not known and the main messages.

All the products contain some references to articles in the scientific press. It is not totally clear if this is helpful for patients, although it may be helpful for health personnel in their discussions with patients about health problems.

Some of the words and information in the fact sheets and research summaries may be too complicated for groups of patients, but often explanations are included (e.g. anaphylaxis as an overwhelming and difficult-to-control allergic reaction).

Reviewing the evidence and presenting the information

The process of reviewing the evidence appeared thorough and reliable, and included relevant recent articles and comprehensive reviews.

The presentation of the results is always balanced and non-directive; patients are stimulated to read more and learn more if they wish, and they can subscribe to the newsletter. Other medications and interventions are always described, with some indications as to potential benefits and risks for certain patient groups. Both benefits and adverse effects are presented in a realistic and non-sensational manner.

Annex 4

REVIEW OF HEALTH INFORMATION ON ASTHMA

The web site contains the following articles on asthma:

- Asthma (29 e-pages, 26 printed pages)
- Merkblatt: Asthma (6 printed pages)
- Asthma-Medikamente: Wie wirken Fixkombinationen aus Kortikosteroiden und langwirksamen Beta-2-Mimetika im Vergleich zur getrennten Kombination? (3 pages)
- Merkblatt für Eltern von Kindern mit Asthma (4 pages)
- Erfahrungsbericht zum Thema “Asthma” (2 pages)
- Bewertung von internationalen Leitlinien: Untersuchungsverfahren zur Diagnose von Asthma bei Kindern zwischen 2 und 5 Jahren (3,5 pages)
- Asthma-Medikamente: Wie schneidet Montelukast im Vergleich ab? (3 pages)

General

The information is very comprehensive. The sites clearly contain relevant and suitable information for patients with asthma.

Understandability and readability

In general the quality of text is good and certainly readable (this is based on articles written in English).

Many articles are so extensive that it may be difficult for ordinary people to find the main message. For that reason a short summary or keynotes in each topic would help people better to understand the most important parts of the information. In the texts in which evidence for treatments is given, it would be useful to highlight (bold, box?) the sentence which gives the main message (e.g. “Keine Belege für eine Wirkung von [Akupunktur](#) bei [Asthma](#)”).

The text contains references to numerous scientific references in a similar way as in scientific articles. Is this relevant in popular articles?

The sites contain articles in which part of information may not be understandable to a majority of people. For example, the “Medikamente” articles may be too complicated to be absorbed by most laymen. Understandability and readability are tested by selected patients and use readability testing that aims at reaching the majority of patients, so selecting patients is an important step.

Reviewing and grading the evidence

The reviewing process for evidence is extensive and reliable, and the information in the asthma sites is based on latest evidence.

No fixed grading system is used. The evidence is expressed with different phrases, as “ohne Wirkungsnachweis”, “keine Belege für eine Wirkung von [Akupunktur](#) bei [Asthma](#)”, “It might be that it (breathing training) helps” and “die Kombination [Kortikoid](#) plus Montelukast die Beschwerden besser linderte als [Kortikoid](#) alleine”.

Annex 5

REVIEW OF HEALTH INFORMATION ON DEPRESSION

Example: postnatal depression

Postnatal depression was selected as a topic for a research summary in December 2007. In October 2008, the text was finalized and published on the web site. A protocol dated December 2007 summarizes the topic and outlines a possible message of the fact sheet based on a prior literature search. The rating of the clinical relevance in this protocol was medium to high. An in-depth review of the documents of this work reveals the following methodological approach.

Literature searches were conducted in multiple databases (PubMed, Cinahl, CRD, PsycINFO) using a strategy that concurs with current standards. Overall 77 records were detected through these searches. It is unclear from the printed documents how many people have reviewed abstracts and full text articles. According to staff interviews, the entire review of the literature is always done by two people (and later confirmed in this case as well).

One recent Cochrane review was selected as the best available evidence, and multiple other studies were retrieved as background information. The available documents indicate that one person rated the internal validity of the chosen systematic review, as was the rule before 2008 for the “Kurzantworten”. Information based on staff interviews indicates that from 2008 onwards quality ratings are always conducted by two people. The instrument used to rate the internal validity of the Cochrane review is a widely accepted tool that is valid and reliable to assess the risk for bias. The included review was rated as having minimal flaws and thus was used as the best available evidence to answer the proposed question. In August 2008 an informal update search of PubMed was conducted by one of the reviewers to supplement the routine updating procedure.

The first draft of the research summary was finished in August 2008 and subsequently sent out for external peer review and to the Patient University in Hanover for user testing. This was done through five evaluations plus a focus group of five people. The five reviewers at the Patient University evaluated the document (two men, three women). None of the women were pregnant or of an age where pregnancy would be likely (41–54 years). Therefore, testers were not likely to be representative of the target population, although it is of course recognized that also the persons around a patient with depression are the target group as well. Feedback from reviewers at the Patient University was generally positive. The short comments from external peer reviewers (including the author of the review) were basically affirmative.

The main messages of the research summary reflect the scientific evidence in the Cochrane report. Uncertainties in the evidence with respect to benefits and harms are adequately discussed, as well as the baseline risk for postnatal depression. Language and framing remain neutral and non-directive throughout the entire document.

In summary, although not all steps of the process could exactly be reproduced, the approach taken during the development of the patient information on postnatal depression appeared to

follow the methods manual and the methodological steps that staff described during various interviews.