A guideline developers' handbook

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Section 1. Executive Summary

1.1. Introduction

Clinical practice guidelines are recommendations on the appropriate treatment and care of people with specific diseases and conditions. They are based on the best available evidence. Guidelines help health professionals in their work, but they do not replace their knowledge and skills.
Good clinical guidelines aim to improve the quality of healthcare. They can change the process of healthcare and improve people's chances of getting as well as possible. For example, well-constructed and up-to-date clinical guidelines:

- provide recommendations for the treatment and care of people by health professionals
- can be used to develop standards to assess the clinical practice of individual health professionals
- can be used in the education and training of health professionals
- can be used by government for priority setting and for improvement of efficiency
- can help patients to make informed decisions, and improve communication between the patient and health professional.

Definitions

Evidence-based medicine is the *conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients*.

Clinical Practice Guidelines are *systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.*

Health technology assessments are *recommendations on the use of new and existing medicines, medical devices, diagnostic techniques and surgical procedures.*

There is a rapid increase in knowledge of medical efficacy and effectiveness and of basic science. Clinical practice guidelines have made a contribution both to the methodological progress of evidence-based medicine and to the management of the health problems they address. Although the percentage of care based on evidence continues to increase dramatically, 80 percent of health care still cannot be related to a strong scientific foundation. Development of clinical guidelines therefore is not a one-dimensional activity of taking evidence from international literature; it requires consensus building amongst stakeholders and inclusion of local cultural and economical factors. It is a

misunderstanding that clinical practice guidelines can just be copied from other countries, without further analysis or adaptation.

In the history of development of guidelines three generations can be distinguished:

- consensus conferences: experts producing guidelines based on their clinical experience
- evidence based medicine guidelines: using evidence from international literature, collected from various sources
- evidence based medicine and cost-effectiveness analysis, which not only looks at the quality aspect, but also at the value for money aspect

The latter type of guidelines is appropriate to reduce costs, although not enough cost-effectiveness studies have been carried out so far to cover all areas of medicine.

Experiences from other countries can be used to develop an organisational set-up and structure for development of guidelines. In the preparation of this document the experiences from the United Kingdom (NICE), Scotland (SIGN), New Zealand (NZGG) and the Netherlands (CBO) have been used. The respective websites provide further information on specific elements.
Internationally guideline developing organisations work together in the Guideline International Network (G-I-N), with more than 50 organisations and experts represented. The network publishes all guidelines, and maintains a website with links to relevant websites of national organisations.

1.2. The guideline development process

Typically a guidelines development process looks like presented in the following table:

1. Organisation of guideline development
2. Selection of guideline topics
3. Composition of the guideline development group
4. Systematic literature review
5. Formulation of recommendations
6. Consultation and peer review
7. Presentation and dissemination
8. Local implementation
9. Audit and review

The steps are discussed below in more detail

1. Organisation of guideline development

A formal independent organisation must be formed to take charge of the guideline development process. The proposed structure for the Slovak situation is discussed in the next paragraph.

2. Selection of guideline topics

The selection of priority areas to be tackled is important, as production of guidelines takes time, and resources are limited. It should be avoided that lack of clarity over the selection criteria leads to a political process of guideline selection.
Reasons may be:

- Areas of clinical uncertainty, with a wide variation of clinical practices and health outcomes, i.e. those areas where apparently very different approaches are possible.
- Areas where effective treatment has been proven, and reduction of morbidity and mortality can be achieved
- Iatrogenic diseases or interventions carrying significant risks for the patients
- Priority areas as selected by stakeholders, e.g. affecting large groups in the population like cardio-vascular diseases, diabetes, mental illnesses
- Areas selected by professional groups

One of the activities in the selection process is scoping, whereby the exact questions which are to be answered by the guideline are formulated.

In some countries, like in the Netherlands there is a special organisation for developing guidelines for general practitioners. In the selection of the topics and areas it is important to define the target group for the guideline.

3. Composition of the guideline development group

The composition of the guideline development group is essential, as the group must have the necessary authority to be acceptable to all professionals in the country. The most important is the selection of the chair, who should not be a party in disputes around the topic selected. The chair should be a professional who can facilitate the professional debate. Furthermore, there should be a multidisciplinary representation in the group, including representatives of patient or consumer organisations. In general, organisations or individuals who have a commercial interest in the area are banned from participation in guideline development groups, especially pharmaceutical companies.

4. Systematic literature review

Based on the scoping of the guideline, detailed research questions are formulated. For example questions regarding sex, age, or ethnic background of patients may lead to specific search for evidence. The search starts with clinical practice guidelines developed in other countries, recent overview documents, meta analysis documents, like the Cochrane library, and other information, e.g. economic analysis. Standardised review of the available evidence allows the guideline development group to get a clear overview. In general, the guideline development organisation employs professionals for this review process.

5. Formulation of recommendations

The obtained evidence is graded carefully, based on the amount of evidence found, and homogeneity of conclusions of research. Guideline development organisations developed a system of considered judgement, where the members of the group use transparent criteria to formulate recommendations.
Nowadays, in many cases the resource implications are considered as well. When recommended practices would be too expensive, adjusted recommendations are formulated, which have feasible resource implications.

6. Consultation and peer review

Guideline development organisations use different methods for consultation and peer review. Some pilot or pre-test guidelines amongst practitioners, to assess whether they are implement able. Some organisations use juries. It is also possible to distribute draft guidelines to professional organisations, organise feed back through internet, organise conferences, etc. After feed back the guidelines are edited and prepared for presentation. A formal approval procedure is applied in the guideline development organisation, by a higher body than the development group.

7. Presentation and dissemination

The presentation is very important. Organisations give clear instructions on the language used, formats of tables, algorithms, references, etc.
Most organisations have clear standardised formats for presentation. For example the NICE standard looks like this:

- summary of recommendations and algorithm
- introduction
  - responsibility and support for guideline development
  - funding
  - GDG membership
  - patient and carer involvement
  - epidemiological data
  - experience of those receiving care, or service use
  - outcomes
  - clinical issues
  - aim and scope of the guideline
- methods
  - literature-search strategy
  - sifting and reviewing the literature
  - synthesising the evidence
  - economic analysis
  - assigning levels to the evidence
  - areas without evidence and consensus methodology
  - forming recommendations
  - consultation
  - related guidance: details of related NICE technology appraisals or

clinical guidelines that are published or in preparation
- guideline recommendations
  – evidence statements
  – recommendations
  – audit criteria
  – scheduled review of the guideline
  – recommendations for research
- references
- clinical questions
- appendices, which may include:
  – evidence tables (preferably on a CD-ROM)
  – details of search strategies.

Besides the formal guideline, there can be a summary, which concentrates on the recommendations, a quick reference guide which is used in "bed-side" situations and patient information leaflets containing information for the general public.
Many organisations aim at publication of these materials simultaneously.

8. Local implementation

Implementation of guidelines is only possible in the context of quality assurance programmes. There are many barriers to implementation, like financial barriers, peer group pressure amongst professionals, individual factors of professionals (lack of continuing professional development), patient demands, etc.
There has been research into effective ways of implementation of guidelines. Education and audits are important, but also regulations, financial incentives and other methods, like patient empowerment. The most successful is the combination of strategies, whereby carrot- and stick methods are combined. Isolated development of guidelines, without introduction of quality systems has very limited, of no effect at all. Therefore, the guideline development should be accompanied by an implementation plan, outlining proposed combination of measures to facilitate the implementation.

9. Audit and review

After publication, continuing monitoring of the guidelines takes place. On the one hand the implementation in practice is monitored, which may lead to adjustments in guidelines. On the other hand international scientific developments are monitored. In case of quick developments early review of the guidelines may be considered. In several countries as a standard after four or five years guidelines are reviewed.

Time scale for development of guidelines

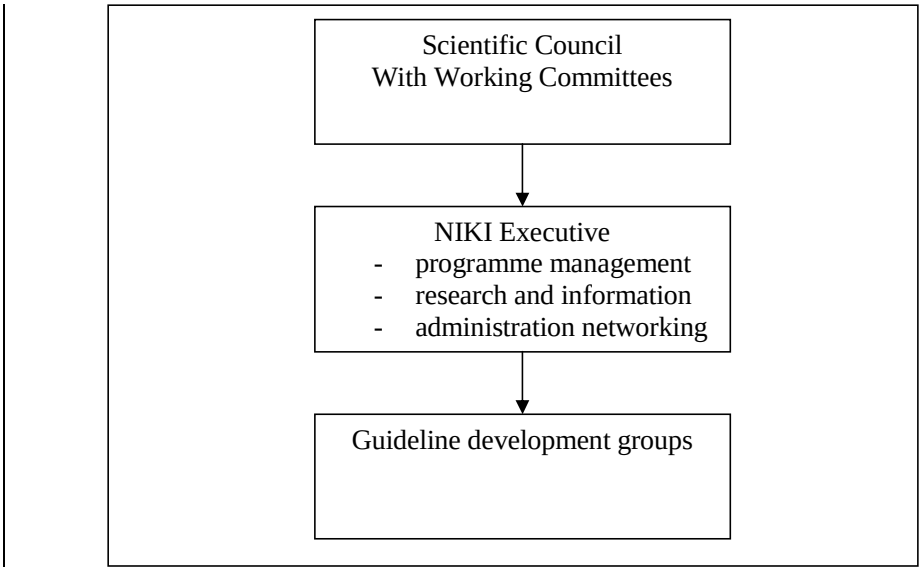
The average time scale for development of guidelines in the UK and Scotland is about 30 months:
- 6 months: scoping and group composition
- 12 months: systematic review and formulation of recommendations

- 9 months consultation and peer review
- 3 months publication

1.3. National Institute for Quality and Innovation

The National Institute for Quality and Innovation is still under development. The structure could be adapted from other Guideline Development Organisations in other countries.

The structure could be as follows:



The Scientific Council has representatives of relevant stakeholders, like Slovak Medical Association, Association of Private Physicians, Slovak Medical Chamber, Universities, Organisation of Private Practitioners, other professional associations, Hospital Association, patient organisations.

The Scientific Council is the supreme body in NIKI, which determines the overall direction of the organisation, sets priorities and approves composition of the development groups and finally approves the draft guidelines.
Under the scientific council specific working committees are operational, e.g. a committee which defines and reformulates methodological instructions for working groups, a committee which maintains international contacts, a committee which supervises the executive.
For the council and the working committees detailed terms of reference will be produced.

The executive performs day-to-day activities and has three departments:

- administration and networking which takes care of administrative issues, dissemination and publication, etc.
- research and information: professionals for systematic review of literature
- programme management: support unit for the groups which are producing guidelines, assisting the development groups to rigorously follow the scientific methodology.

Guideline development groups
As mentioned above, the guideline development groups are multidisciplinary. The chair has an important role in facilitating the process. The members of the working groups are volunteers, who get only costs reimbursed.

Funding mechanisms

In many countries the funding mechanisms differ. The contribution can come from:
- government, providing subsidies to the organisation
- insurance companies
- professionals (through their organisations)
- other funding (whereby any interference in the contents of guidelines is strictly avoided).

Section 2. Introduction

2.1. Clinical guidelines and NIKI

The National Institute of Quality and Innovations (NIKI) was established in 2005 by five individuals, out of it four Slovak medical professionals and a Dutch expert, to develop evidence-based clinical guidelines for the Slovak health care system. The organization is a legal body registered administratively by Slovak authorities as “civic organization” or an NGO[1]. The initiative developed upon a direct request from the Minister of Health SK to sustain results of the joint project between Dutch and Slovak governments (Building Quality Development Programme in Slovakia, Senter, MAT03/SK/9/1). The project MATRA held series of meetings with representatives from hospitals, General Practitioners and health insurance cmpanies in June 2005 to discuss the process of guidelines development process suitable for Slovak needs. Based on a suggestion of prof. Niek Klazinga from the University of Amsterdam, who is an author of AGREE instrument, the decision was to adopt the process developed by SIGN[1] was unanimously accepted.

Clinical practice guidelines have been defined as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."[2] They are designed to help practitioners assimilate, evaluate and implement the ever-increasing amount of evidence and opinion on best current practice. Clinical guidelines are intended as neither cookbook nor textbook but, where there is evidence of variation in practice which affects patient outcomes and a strong research base providing evidence of effective practice, guidelines can assist doctors and other health care professionals in making decisions about appropriate and effective care for their patients.

The accepted criteria for validity of guidelines have evolved from the 'essential elements of good guidelines' identified by the US Institute of Medicine in 1990. These recommended 'attributes of good guidelines' included validity, reliability, clinical applicability, clinical flexibility, clarity, multidisciplinary process, scheduled review, and documentation. The recommendations were underpinned by the twin themes of credibility and accountability: "The link between a set of guidelines and the scientific evidence must be explicit, and scientific and clinical evidence should take precedence over expert judgement." SIGN's original Criteria for Appraisal of Clinical Guidelines for National Use[3], and the more recent AGREE (Appraisal of Guidelines, Research and Evaluation for Europe) guideline appraisal instrument are based on these founding principles of guideline development. The AGREE criteria are reproduced in Annex A. The full appraisal instrument can be downloaded from the AGREE website: http://www.agreecollaboration.org

[1] NGO Non Governmental Organization

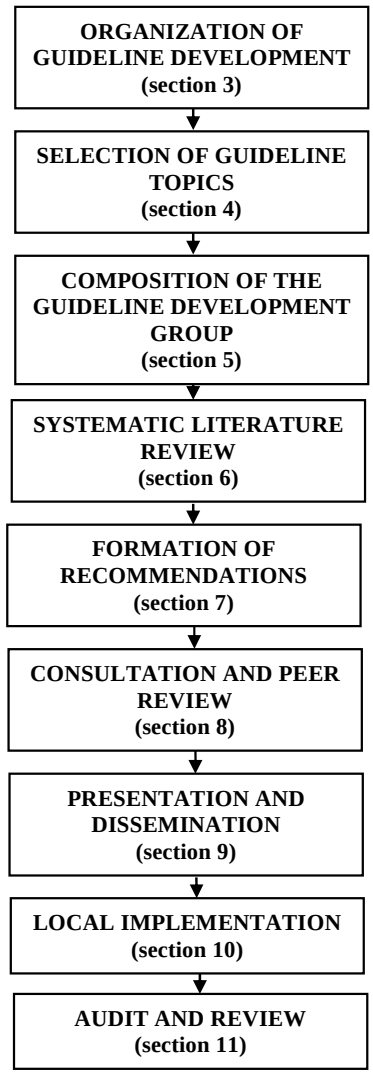


Figure 2-1Overview of the NIKI guideline development process

2.2. Aim and structure of this report

This description of the guideline development methodology used by NIKI is intended to support both the development of national guidelines for health care in Slovak Republic and their local adaptation and implementation. It provides guideline users with information on the methodology by which NIKI guidelines are developed, and resources for groups embarking on new guideline development projects. It has therefore been produced in a loose-leaf format to allow photocopying of the various templates and forms which are provided in the Annexes.

As the number of guidelines available to practitioners grows, guideline developers have an increasing obligation to be transparent about the methods they have used to develop their guideline. Users can then see with confidence that the potential biases of guideline development have been addressed adequately and that the recommendations are both internally and externally valid, and feasible for practice. However, guidelines are also intended as tools for busy practitioners, therefore it is important not to overload every guideline with repetition of the same methodological detail. The handbook outlines the key elements of the development process common to all NIKI guidelines. Only details specific to the topic under consideration or any variations from the standard processes described here are reported in individual NIKI guidelines. An overview of the NIKI guideline development process and the structure of this report is provided below.

2.3. Guidelines in context

In practice, guideline development, implementation, and review should really be seen not as a linear process as in Figure 1.1, but as a cycle of interdependent activities. These in turn are part of a range of complementary activities to translate research into practice, set and monitor standards, and promote clinical excellence in the health care in Slovak Republic, as illustrated in Figure 2.2. The highest standards of patient care and improved outcomes are the ultimate goal.

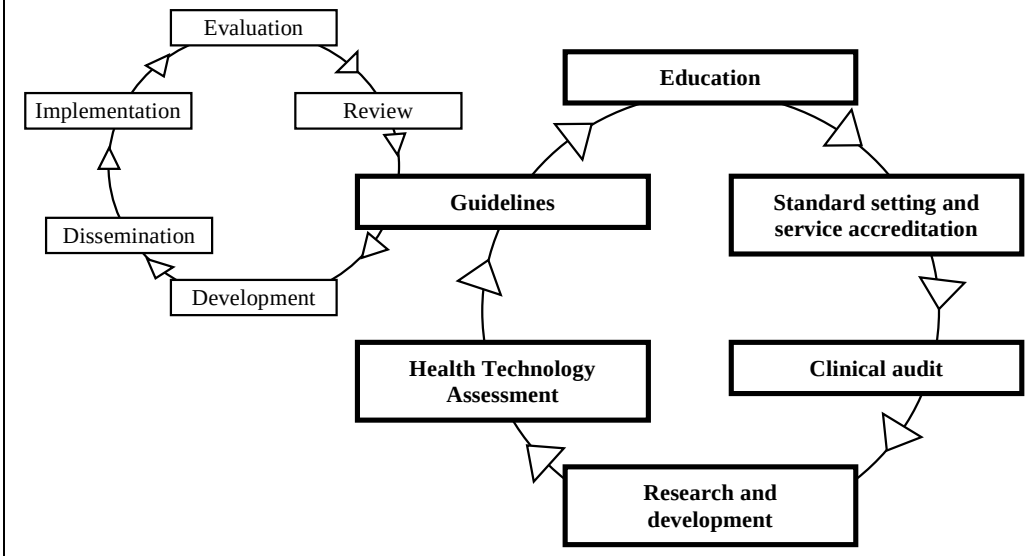


Figure 2-2Guidelines in context: The clinical effectiveness cycle

Guidelines can achieve better treatment outcomes for patients, but local ownership of the implementation process is crucial to success in changing practice. For this reason, NIKI is responsible for the development of national guidelines and their implementability, but not directly for their implementation into practice. This is a responsibility of each individual health service provider (hospital, practitioner, specialist) and the standard setting and review components of Health Care Surveillance Authority. However, there is a role for national facilitation of local guideline implementation activities, and this is discussed in section 9.
Links with local and national audit projects are also an essential part of guideline implementation, and NIKI is prepared to work closely with those, who will start this activities in future. In the meantime NIKI includes minimum datasets (or indicators) to facilitate prospective audit. This is discussed in section 10.

2.4. Medico-legal implications of guidelines

Potential medico-legal implications were addressed from the very start of the NIKI programme.
Hurwitz[4] summarised the role of guidelines in court thus: "Guidelines could be introduced to a court by an expert witness as evidence of accepted and customary standards of care, but they cannot be introduced as a substitute for expert testimony. Courts are unlikely to adopt standards of care advocated in clinical guidelines as legal "gold standards" because the mere fact that a guideline neither exists does nor of itself establish that compliance with it is reasonable in the circumstances, or that non-compliance is negligent. Also, clinical guidelines cannot offer thought-proof mechanisms for improving medical care. However well linked to evidence, clinical guidelines need so be interpreted sensibly and applied with discretion'.

Guidelines do not provide the answers to every clinical question; nor does adherence to guidelines ensure a successful outcome in every case. The ultimate decision about clinical management of an individual patient will always depend on the clinical circumstances (and wishes) of the patient, and on the clinical judgment of the health care team. Clinical guidelines are recommendations for the care of individuals by healthcare professionals; they are based on the best available evidence. They have been defined as "systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances", although they are also important for health service managers and commissioners.[5] Guidelines assist the practice of healthcare professionals, but do not replace their knowledge and skills. Good clinical guidelines can change the process of healthcare and improve outcomes. For example, well-constructed and up-to-date clinical guidelines:

- provide recommendations for the management of patients by healthcare professionals;
- can be used to develop standards to assess the clinical practice of healthcare professionals (for example, by the professionals themselves, health insurance companies, health authorities or primary care groups);
- can be used in the education and training of healthcare professionals;
- can help patients to make informed decisions, and improve communication between the patient and healthcare professional.

Occasionally, individual members of NIKI or its guideline development group ask if they could be successfully sued for developing a guideline. Legal advice to NIKI is that this is very unlikely, because developers of clinical guidelines in general do not owe a duty of care to patients. To clarify this, all NIKI guidelines include a Statement of Intent, which states:

'This guideline is not intended to be construed or to serve as a standard of medical care'. However, guidelines are necessarily general, and there will be instances when they will not be appropriate, either wholly or in part, for an individual patient. A guideline (and all Institutes Guidance) represents the view of the Institute, and has been arrived at after careful consideration of the evidence available. Health professionals are expected to take it fully into account when exercising their clinical judgment. The guidance does not, however, override the individual responsibility of health professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer. Healthcare professionals should document the reasons for not following a guideline.

NIKI guidelines are funded mostly by Ministry of Health SR, written for health care providers in Slovak Republic by Slovak experts and their patients, and have a robust development process including a national open meeting and peer review. It is therefore unlikely that their recommendations would be viewed as idiosyncratic or dangerous.

2.5. Review and updating

It is intended that SIGN 50 should be a 'living' publication, continually revised to reflect future developments in SIGN methodology. Details of any updates and new sections will be available on the NIKI website: http://www.healthnet.sk/NIKI . Comments are welcome and should be sent to the NIKI Executive, Cukrova 6, 81101 Bratislava, lenartova@igeh.org

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References to section 1

[1] SIGN 50: A guideline developers' handbook. SIGN Publication No. 50, Published February 2001, Last updated May 2004. Scottish Intercollegiate Guidelines Network 28 Thistle Street, Edinburgh EH2 1EN
http://www.sign.ac.uk/guidelines/fulltext/50/index.html

[2] Field MJ, Lohr KN (editors). Institute of Medicine Committee to Advise the Public Health Service on Clinical Practice Guidelines. Clinical practice guidelines: directions for a new program. Washington DC: National Academy Press; 1990.

[3] Scottish Intercollegiate Guidelines Network (SIGN). Clinical guidelines: criteria for appraisal for national use. Edinburgh: SIGN; 1995

[4] Hurwitz B. Legal and political considerations of clinical practice guidelines. BMJ 1999;318:661-4

[5] The definition is from: Committee to Advise the Public Health Service on Clinical Practice Guidelines. Institute of Medicine. Field MJ, Lohr KN, editors (1990) Clinical Practice Guidelines: Directions for a New Program. Washington, DC: National Academy Press.

Section 3. Organisation of guideline development

3.1. NIKI's Network

The National Institute of Quality and Innovations (NIKI) was established in 2005 by the five private persons, each representing an important partner in fulfilling the mission: to develop evidence-based clinical guidelines for the health service in Slovakia. Because of this the Institute is in early stages of it's development. This followed the publication of a 6 laws in 2004, stipulating the need to establish quality of care processes. Derived from them was a call from Dr. Rudolf Zajac, Minister of Health in Slovak Republic seconded by Dr. Svatopluk Hlavacka, Direcor General, General Health Insurance in Slovakia, who both highlighted the need for national, evidence-based clinical guidelines to be developed by "the specialist associations of the health care professionals and relevant educational bodies."

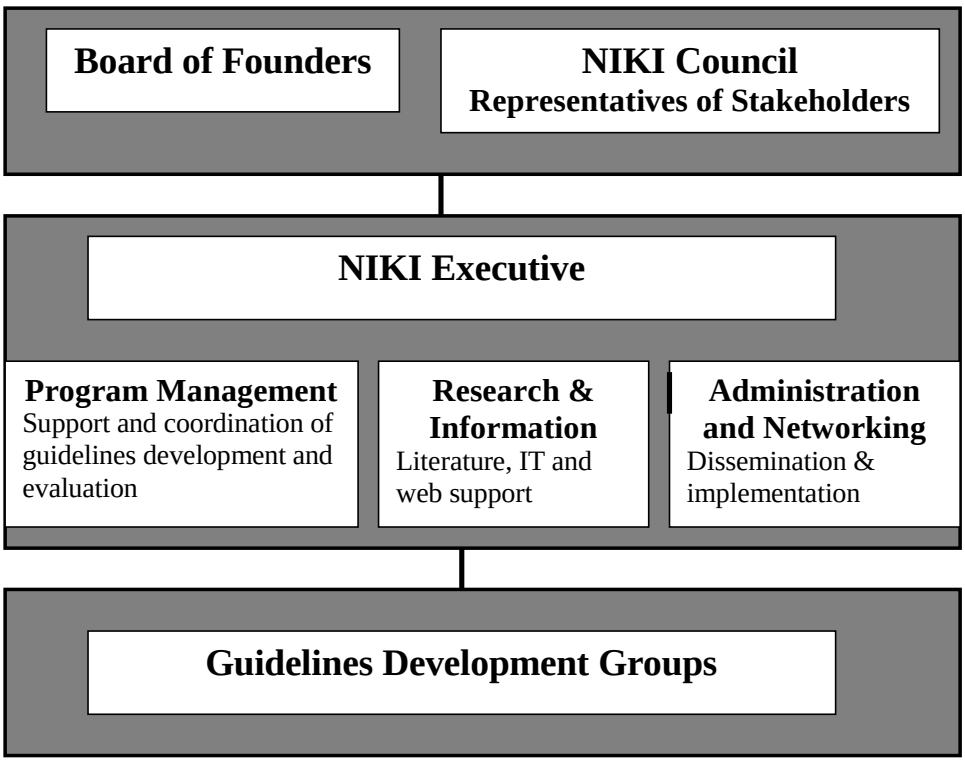

Figure 3-1 Structure of NIKI

NIKI is a collaborative initiative - a network of clinicians, patients' representatives and other health care professionals, including all the medical specialties, nursing, pharmacy, dentistry, professions allied to medicine, and health services management. Patients are represented on NIKI by patients' organizations. Members of NIKI are nominated by a particular section of Slovak Medical Association and the Association of Private

Physicians or other professional organization or committee, but also represent their specialty or discipline in a wider sense and consult widely with other specialist societies in their field. NIKI also works closely with other relevant national groupings and agencies within Slovak Republic, such as Ministry of Health, Agency for Health Supervision, Health Insurance Companies, Physicians' Chamber, Slovak Association in Quality, universities, and the research community.
Members of NIKI Council determine the overall direction of NIKI's development and play a key role in shaping the SIGN guideline programme. Some members of NIKI Council are also actively involved in aspects of the guideline development process -as members of Advisory Groups, or on the editorial group for specific guidelines, or as chairs or members of individual guideline development groups - and all provide input into the selection of topics for guideline development and the composition of guideline development groups (see sections 3 and 4).
The structure of NIKI is illustrated in the Figure 3-1.

3.2. Funding for guideline development

The NIKI guideline development programme is funded by the Slovak Ministry of Health, General Insurnce Company and Slovak Health Surveillance Authority. This funding supports the NIKI executive, expenses associated with individual guideline development projects (e.g. on-line search costs, library and copyright fees to obtain copies of articles for review, guideline development group meeting expenses), and the costs of printing and distributing published NIKI guidelines.
Additional sources of income for NIKI are the sale of guidelines and a small amount of sponsorship for NIKI national meetings (see section 7.1) from the health care industry. In addition, NIKI undertakes a small amount of consultancy work in the UK and overseas.

3.3. Timescale for guideline development

The time taken to develop a NIKI guideline varies widely according to the scope of the topic under consideration, the volume of relevant literature to be critically appraised, the amount of feedback received during the consultative phases of development and, most importantly, the competing pressures on the time of members of guideline development groups. The average time taken by recent guideline development groups is illustrated in the figure 3-2 (see also Figure 4.2).

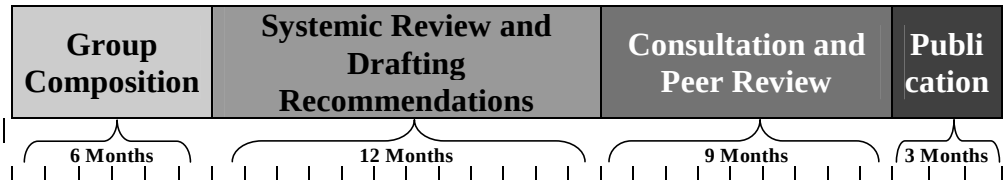

Figure 3-2 Average timescale for NIKI guidelines development

3.4. The future for NIKI

NIKI structure and functions are still a subject of changes and amendments. Debates with the Ministry of Health SR and other stakeholders will be continued.

Section 4. Selection of guideline topics

4.1. The NIKI programme

The experience guideline developers has shown that selection of appropriate topics for guideline development is crucial. Guidelines should address a specific health care need and there should be an expectation that change is possible and desirable and that, if the guidelines are followed, there is potential to improve the quality of care and/or patient outcomes. There must also be robust evidence of effective practice on which to base guideline recommendations.
There are limited resources for guideline development. As a result it is important to identify topics which are most amenable to guideline development. Likewise, when a published guideline is due for review it must be judged against potential new topics for inclusion in NIKI's programme.

4.2. Criteria for selection of topics

Guideline topics selected for inclusion in the NIKI programme are chosen on the basis of the burden of disease, the existence of variation in practice, and the potential to improve outcome. The following criteria are considered by NIKI in selecting and prioritising topics for guideline development:

- Areas of clinical uncertainty as evidenced by wide variation in practice or outcomes.
- Conditions where effective treatment is proven and where mortality or morbidity can be reduced.
- Iatrogenic diseases or interventions carrying significant risks.
- Clinical priority areas for the Slovak health care: presently these are coronary heart disease and stroke, cancer, and mental health. The strategic aims of the the Slovak health care are also considered. These are improving health and tackling inequalities, especially with regard to children and young people, developing primary and community care and reshaping hospital services.
- The perceived need for the guideline, as indicated by a network of relevant stakeholders.

Details of the NIKI guideline programme are given at Annex B. For updated information, see the NIKI website.

4.3. Topic selection process

Any group or individual may propose a guideline topic to NIKI. In addition, NIKI will establish specialty subgroups which use established clinical networks to identify a "wish-list" of guideline topics for which health care practitioners agree there is a need.

The Guideline Programme Advisory Group oversees the progress of the specialty subgroups and ensures that there is appropriate communication and interaction between the specialty subgroups, as most topics are relevant to more than one specialty. The group also has representatives from the Ministry of Health. This should ensure that, wherever possible, NIKI's programme and the programmes of clinical standards and health technology appraisals will be complementary. The Guideline Programme Advisory Group will also consider the work programme of other guideline developers, in particular guidelines that have been commissioned by NICE (the National Institute for Clinical Excellence) in England & Wales or CEBO in The Netherlands, to minimize efforts.

Specialty subgroups submit their prioritised lists of potential guideline topics to the Guideline Programme Advisory Group, who will then select a number of topics to be worked up into detailed proposals for discussion and prioritisation at an annual topic selection meeting of NIKI Council. The Guideline Programme Advisory Group uses a suitability screen tool to assist in the process of prioritisation. This tool identifies the extent to which the proposal fulfils the criteria listed in section 4.2 but also probes whether the benefits that were likely to accrue from a successful implementation of the guideline recommendations would outweigh the efforts required to develop it.

NIKI Council undertakes the final stage in the process of topic selection. NIKI Council dedicates one meeting each year to the prioritisation of guideline topics which have been accepted as suitable candidates for the NIKI guideline development programme. At this meeting the Council is presented with fully worked up guideline proposals and sorts these into a ranked list from which the new and review topics for the following financial year will be drawn. To assist with this process, a modified version of the suitability screen tool used by the Guideline Programme Advisory Group is adopted. Topics ranked highest are included in NIKI's proposed programme. Proposals which are not ranked sufficiently highly to be accepted on to the programme will be reconsidered at the next topic prioritisation meeting alongside new and review topics. If the proposal still receives a low ranking on its second reading it will be returned to the SIGN specialty subgroup for reconsideration or revision.

The resulting topics for guideline development form the proposed NIKI programme. This is forwarded to the Ministry of Health SR for approval for funding

4.4. Application procedure

When a group or individual proposes a guideline topic to NIKI, their suggestion is discussed initially with the Guideline Programme Advisory Group. If this group agrees that the proposed topic has the potential to meet the selection criteria, it is allocated to the most appropriate specialty subgroup.

As part of the preparatory work done before a guideline proposal is submitted to the Guideline Programme Advisory Group to be considered for inclusion in the programme, a scoping search is carried out. This is a very broad search of the literature relevant to the

condition that is to be the topic of the guideline. No attempt is made to focus on specific questions at this stage. The intention is only to establish the general extent of the literature in the clinical area to see if there is likely to be sufficient good quality evidence to make evidence based guideline feasible.

Searches are restricted to systematic reviews produced by the Cochrane Collaboration or covered by the Database of Abstracts of Reviews of Effectiveness (DARE) (www.york.ac.uk/inst/crd/darehp.htm) and randomised controlled trials (RCTs) identified from either Embase or Medline during the previous three years. In exceptional cases where RCT evidence is likely to be limited for ethical or practical reasons, the search may be extended to cover observational studies.

At this stage a check is also made to see if any other good quality guidelines have been produced on the subject by searching the following Web sites:

- Guidelines International Network (www.g-i-n.net)
- National Electronic Library for Health Guidelines finder (www.nelh.nhs.uk)
- National Guideline Clearinghouse (www.guideline.gov)
- National Institute for Clinical Excellence (www.nice.org.uk).

The specialty subgroup uses their multidisciplinary clinical networks to judge whether there is general agreement on the need for a guideline in this area and to determine the broad scope of the guideline. Once this has been established the specialty subgroup works with the original proposer on the preparation of a formal proposal to NIKI Council.

NIKI's standard guideline application form requests the following information:

1. A summary of the clinical problems and outcomes to be addressed.
2. Details of the group(s) or institution(s) supporting the proposal.
3. A brief background to the clinical topic which will be addressed by the proposed guideline.
4. Evidence of variation in practice in the management of the condition.
5. An indication of the benefits likely to arise from the development and successful implementation of the guideline.
6. A definition of the patient group to which the guideline will apply.
7. A definition of the aspects of management of the clinical condition which the proposed guideline will address and an indication as to whether the guideline will apply to primary or secondary care, or both.
8. An indication of the health care professionals potentially involved in developing the guideline.
9. An indication of the size and strength of the evidence base which is available to support recommendations on effective practice, citing key supporting papers.10. Details of any existing guidelines or systematic reviews in the field.

The procedure for selection of NIKI guideline topics is illustrated in figure 4.1. The application form to request consideration by NIKI of a specific guideline topic and the

full guideline proposal form are available from the NIKI Executive or can be downloaded from the NIKI website.

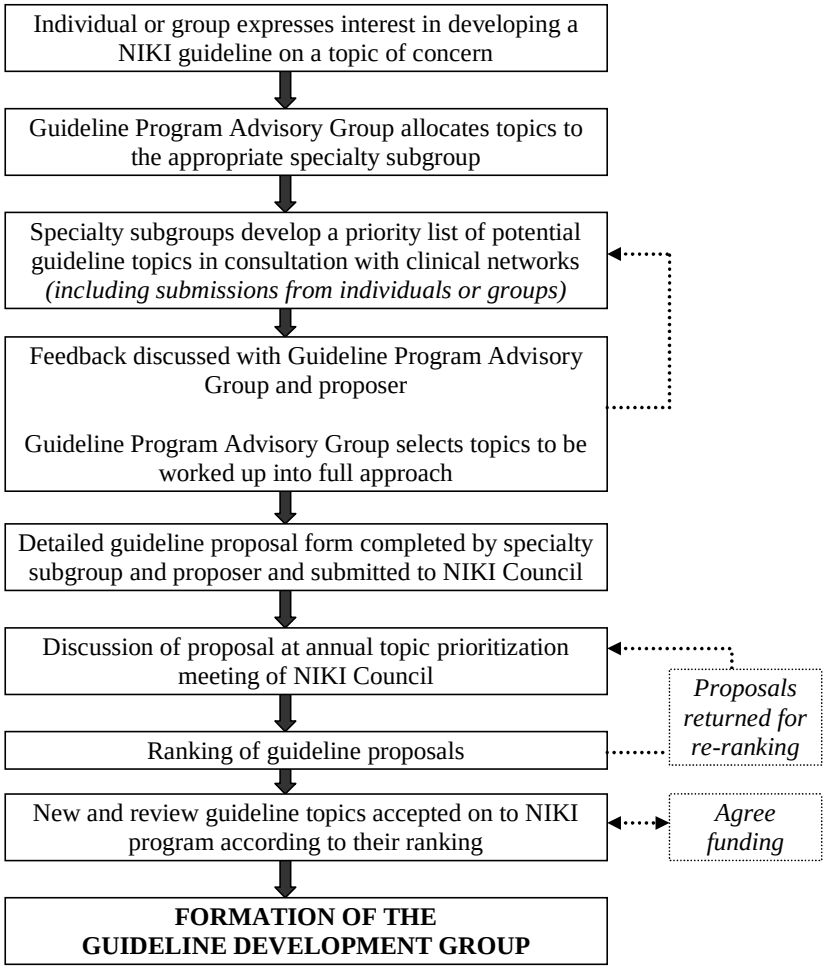

Figure 4-1Selection of topics for SIGN guideline development

Section 5. The guideline development group

5.1. Composition of the guideline development group

One of the US Institute of Medicine's strongest recommendations for 'good guidelines' was that the process of developing guidelines should include participation by representatives of key groups and disciplines affected.[1] Farmer has also stressed that guidelines should not be developed by academics and senior clinicians insulated from the day to day pressures involved in providing medical care, warning that "Unless a guideline accurately reflects the routine working practices of most doctors it will act only as a gold standard to be admired."[2]

A Canadian Medical Association workshop held in 1992 to establish the principles on which to base the formulation of individual clinical practice guidelines also recommended that clinical practice guidelines should be developed by physicians in collaboration with representatives of those who will be affected by the specific intervention(s) in question, including relevant physician groups, patients, and other health care providers as appropriate.[3] Studies have shown that the balance of disciplines within a guideline development group has considerable influence on the guideline recommendations.[4,5] Establishing a multidisciplinary guideline development group is therefore important to ensure that:

- all relevant groups are represented, providing expertise from all stages in the patient's journey of care
- all relevant scientific evidence will be located and critically evaluated
- practical problems with using the guideline will be identified and addressed
- stakeholder groups will see the guideline as credible and will cooperate in implementation.[6,7]

Following the acceptance of a guideline proposal into the NIKI development programme (see Section 4), the NIKI Executive discusses which specialties and professions should be represented on the guideline development group with the topic proposer(s), with advice from the appropriate Specialty Subgroup(s) and NIKI Council. This ensures that all of the relevant professions in Slovakia can input into and feel ownership over the guideline development process.

NIKI guideline development groups vary in size depending on the scope of the topic under consideration, but generally comprise between 15 and 25 members. There is necessarily a trade-off between the number of organisations or specialties that should be represented on the guideline development group, and achieving the optimum group size for effective decision making. Care is also taken to ensure that the group is balanced geographically, with representatives from across Slovak Republic.

In putting together a guideline development group, NIKI is aware of the many psychosocial factors, including the problems of overcoming professional hierarchies that can affect small group processes. Grimshaw (1995) states: "To ensure that guidelines achieve their full potential…requires a programme of research and development that accords at least as much thought to the psychology of group dynamics as the science of systematic reviews"[8] Research into the progress and functioning of NIKI's own guideline development groups has shown the impact of professional or status differences on

members' contributions to group discussions. A clear relationship between the perceived status of a group member and their level of contribution to group discussions was identified. This may be difficult to avoid, as members with highest status often have the greatest amount of research expertise, which is of great benefit when interpreting evidence. Care is therefore taken to offer support to those who may feel at an initial disadvantage compared with the group's "experts" (see Section 5.3). This begins with selecting a balanced group that is not "top heavy" and a chairperson with an awareness of these hierarchies and with skills in facilitating full participation by all group members. The process for establishing NIKI guideline development groups is illustrated in figure 5.1.

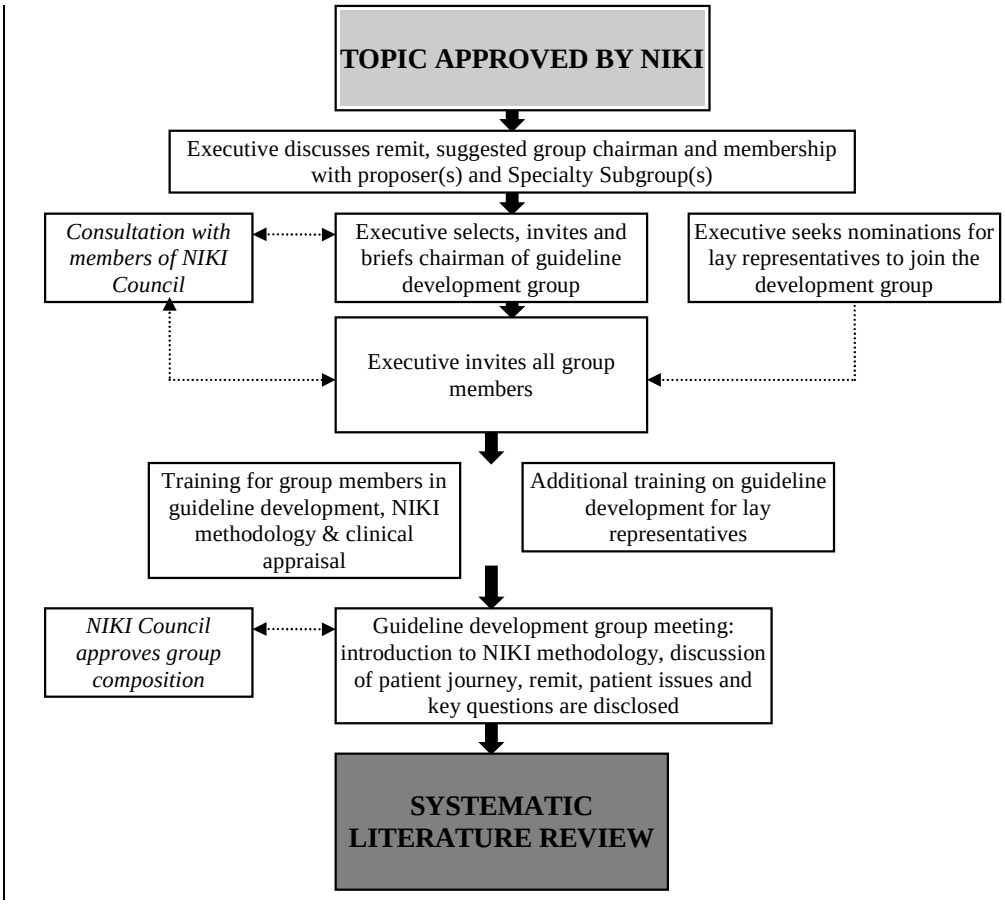

Figure 5-1 Establishing the guideline development group

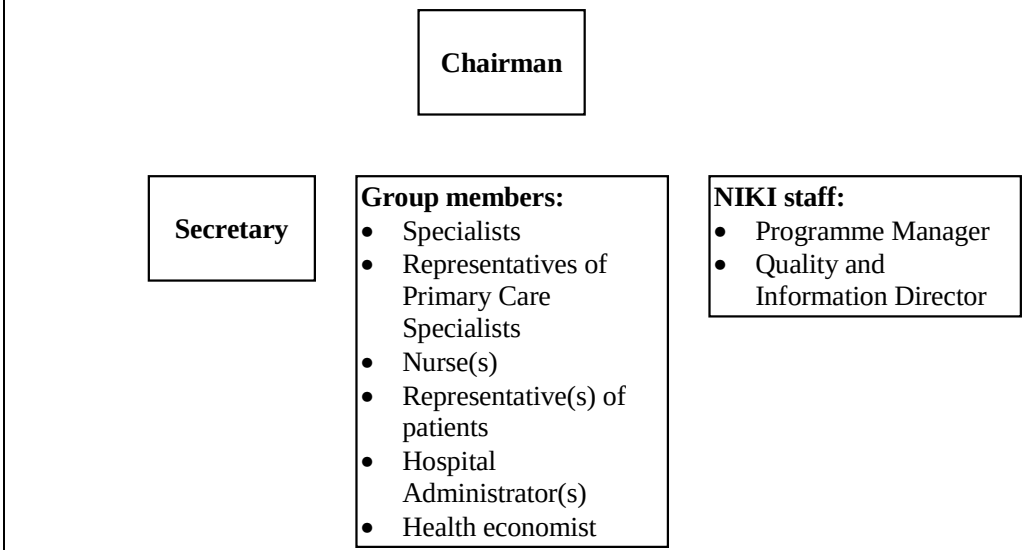

Figure 5-2 Membership of the NIKI guideline development group

5.2. Patient involvement in guideline development

The term patients is used throughout this document as a generic term to describe patients, lay representatives and those that represent and or support patients in the voluntary sector.

Patient involvement is 'the appropriate, active participation of patients, carers and patient representatives as partners in their own care and in the planning, monitoring and development of health services.[9] Patients and carers may have different perspectives on health care processes, priorities, and outcomes from those of health professionals. The involvement of patients, carers or their representatives in guideline development is therefore important to help ensure that guidelines reflect their needs and concerns. The purpose of patient and carer involvement is to ensure that the guideline addresses issues that matter to patients and carers' and that their perspectives are reflected in the guideline. Patients and carers can identify issues that may be overlooked by health professionals, can highlight areas where the patient's perspective differs from the views of health professionals, and can ensure that the guideline addresses key issues of concern to patients and carers.

Patient and carer representatives on guideline development groups can remind the other group members of the limitations of the scientific findings in respect of age, quality of life, gender, ethnicity, and life circumstances such as accessibility. They also help to ensure that the group is aware of patient concerns such as their information needs, health professionals' communication skills and the need for patient choice. Patient representatives can also assist the group on the use of clear and sensitive language in the guideline.

Patients and carers are involved in NIKI's guideline development in three broad ways:

1. Identifying patients' and carers' views

NIKI LITERATURE SEARCH
NIKI has developed a literature search to identify published studies, both qualitative and quantitative, that reflect patients' and carers' experiences and preferences in relation to the clinical topic. This search is performed at least three months prior to the first group meeting to ensure adequate time to obtain relevant papers and summarise their findings for presentation at the first guideline group meeting. The Patient Involvement Programme Manager presents this information to the guideline group, this ensures that group members know who to contact for further advice on patient involvement. Having a separate session dedicated to patient involvement at the first group meeting also underlines the significance of this aspect of guideline development.
The types of studies identified tend to include patients' and carers' views on:

- positive and negative experiences of the condition, including diagnosis, medication and other treatments, follow-up care and quality of life
- unfulfilled needs
- information needs and preferences
- participation in decision-making about treatment
- overall satisfaction with care received.

PATIENT ORGANISATIONS
NIKI writes to the organisations and charities that aim to represent and or lobby for patients and carers at least four months before the first meeting of the guideline development group, asking them to inform us of the issues that they think the guideline should address. A simple form is supplied to enable them to structure their feedback in a useful way and, importantly, to indicate the source(s) of their suggestions (e.g. telephone help line data, surveys). The information received from these organisations is summarised and presented at the first meeting of the guideline development group.

OTHER HEALTH CARE ORGANISATIONS
NIKI writes to various other health care organisations at least four months before the first meeting of the guideline development group to find out if any local research on patient views has been performed. This might include, for example, patient focus groups to help in the redesign of services, or questionnaire studies to gauge levels of patient satisfaction with existing services. Reports such as this tend not to be published even though they are in the public domain and can be very useful as a snap shot into current patient issues and concerns regarding particular NHS services and treatments.

DIRECT FEEDBACK FROM USERS OF THE SERVICE
Where published evidence is scarce and inadequate feedback from patient organisations has been received, patient and carer views may be sought via direct contact with users of the service. Techniques employed to date have included focus groups with patients in different regions of Slovak Republic, attending patient support group meetings, and NIKI organised meetings for patients and carers. All of these approaches have provided

valuable information that has been fed back directly to guideline groups to influence the remit and key questions underpinning the guideline.
Running focus groups requires that views be sought from both men and women of different age groups, in both rural and urban communities. Special efforts should also be made to include those who are socially excluded and may be less likely to join a local or national organisation. Focus groups require expert facilitation, the reimbursement of patients' travel expenses, the hire of fully accessible buildings and appropriate catering arrangements. NIKI is exploring ways of building appropriate funds into the NIKI budget to meet these costs.
The issues that emerge from all of the above approaches are synthesised and presented at an early meeting of the guideline development group by the Programme Manager with responsibility for Patient Involvement. The group is asked to take cognisance of these issues when they draft their key questions.

2. Recruitment to guideline development groups

NIKI recruits a minimum of two patient representatives to guideline development groups by inviting nominations from the relevant "umbrella", national and / or local patient focused organisations in Slovakia. Where organisation are unable to nominate, patient representatives are sought via other means, e.g. from consultation with members of the NIKI Patient Network. Where patients have been consulted directly (eg. if a focus group has been held) this may also provide a source of possible future patient and carer representatives.
The NIKI Patient Network is a database of patient, carer and other user representatives. The Network includes contacts for both individuals and organisations, including NHS Trust Designated Directors for patient and public involvement, previous and current patient representatives on SIGN guideline development groups, representatives from local health councils and patient advocacy services, representatives from patient organisations, and from relevant local and/or regional organisations where no umbrella bodies exist.
Details of the role of the patient representatives, the support they will be given, the commitment required and useful attributes are provided to allow informed nominations to be made.
NIKI supports patient representatives by:

- delivering training days for patient representatives
- offering telephone and email support
- inviting new patient representatives to join the NIKI Patient Network
- providing clear guidance on their roles and responsibilities within the group
- ensuring opportunities to attend the training opportunities are open to all guideline development group members are available (see section 4.4)
- in addition, NIKI is exploring the role of clinical mentors to support patient representatives on guideline groups.

3. Consultation processes

Further patient and public participation in guideline development is achieved by involving patients, carers and voluntary organisation representatives at the National Open Meeting which is held to discuss each draft guideline (see Section 8.1). The meetings are advertised widely and a limited number of free spaces are made available to patients and carers.
Patient representatives are invited to take part in the peer review stage of each guideline and specific guidance for lay reviewers has been produced.

4. Role of patient and carer representatives

Although their areas of expertise will vary, members of the guideline development group have equal status on the group. A key role for patient and carer representatives is to ensure that patient views and experiences inform the group's work. This includes:

- ensuring that key questions are informed by issues that matter to patients and carers
- identifying outcome measures that they think are important for each key question
- considering the extent to which the evidence presented by group members has measured and taken into account these outcome measures
- identifying areas where patients' preferences and choices may need to be acknowledged in the guideline
- making sure that the degree to which the evidence addresses patients' and carers' concerns is reflected in the guideline
- helping to write the Information to Patients section of the guideline
- raising awareness of patient and carer issues at the National Open Meeting
- helping to ensure that the guideline is sensitively worded (for example treating patients as people and not as objects of tests or treatments).

If any particular patients' concerns cannot be addressed within the guideline, either due to constraints caused by the scope of the guideline, or where no satisfactory evidence can be identified, this is stated in the guideline.

5.3. Responsibilities of development group members

The role of the group leader is crucial to ensure that the group functions effectively and achieves its aims.[10] Chairs of guideline development groups must be sensitive to pre-existing inter-professional tensions and hierarchies and ensure that all members of the group feel able to contribute fully to the guideline development process. The most successful guideline development groups have a Chair who is aware of and constantly attentive to small group processes (eg how the group interacts and communicates, decision making processes and chairing strategies). The Chair must be prepared to overcome potentially serious difficulties by careful negotiation. The NIKI Programme Manager assigned to each guideline helps the Chair to identify potential barriers to successful group work, to plan and progress the guideline development project, and will act as facilitator at group meetings. Some guideline development groups may be co-

chaired by the SIGN Programme Manager and the group leader in order to help reduce potential conflicts.

Guideline development group members in turn must make a full commitment to the group and the tasks involved in guideline development, and be responsible for indicating areas of concern to the Chair. Guideline development group members should also bear in mind that they represent both a geographical region and a specialty or professional group, and must be prepared to consult with colleagues to ensure that the widest possible range of views are considered.

Each guideline development group requires a mix of the following skills:

- clinical expertise (e.g. medical, surgical, nursing etc.)
- other specialist expertise (e.g. health economics, social services)
- practical understanding of problems faced in the delivery of care
- communication and team working skills
- critical appraisal skills.

A healthcare professional joining a guideline development group is not expected to be an expert in all of these areas. Many group members may feel they have only one or two of these skills, but at some point in the development of the guideline, their knowledge and experience will be invaluable. Many potential development group members are concerned that their critical appraisal skills may not be sufficient to complete the systematic review of the literature. To address this, NIKI runs a range of training seminars in critical appraisal skills that all group members are encouraged to attend. In addition, guideline development groups are also supported throughout the development process by the NIKI Executive. The Programme Manager and Quality & Information Director give regular presentations on NIKI methodology, and will also ensure that methodological checks are correctly applied and that the development process itself is fully documented.

The life span of each guideline development group is approximately 30 months, with groups meeting on average once every two months, although groups may form subgroups which meet more frequently. The development timetable of a typical guideline, and the associated tasks, is shown in figure 5.3. Guideline development groups are supported both administratively and financially by the Executive.

The work commitment of the healthcare professionals and patients who take part in the development of a NIKI guideline is significant and should be recognised before accepting an invitation to join such a group. In addition to taking on the responsibility of representing both a geographical region and a specialty group, group members need to pledge a considerable amount of their time to guideline development. Prospective guideline development group members are encouraged to attend critical appraisal training prior to joining a group to ensure that they understand the commitment they are about to undertake.

Months 1-3	o Define remit of guideline o Attend critical appraisal training o Plan development process o Share relevant knowledge and experience o Identify key questions/terms for literature search o (with advice from the SIGN Quality and Information	**Establish group & remit: 3 months**

	Director) o Discuss requirements of systematic literature review	
Months 4-11	o Review abstracts to select papers for detailed review o Clarify criteria used to select or reject papers o Detailed literature review, grading and synthesis of evidence (often undertaken in subgroups)	**Literature search & appraisal: 8 months**
Months 12-15	o Draft recommendations derived from evidence review o Draft guideline prepared o National open meeting held to present and discuss draft recommendations	**Draft guideline: 4 months**
Months 16-22 Months 23-24	o Feedback from national meeting incorporated into draft guideline. Draft is edited by group with assistance from SIGN Executive o Draft guideline submitted to NIKI for external refereeing and review by NIKI Editorial Group	**Post national meeting review: 9 months**
Month 25-30	o Feedback from external reviewers incorporated into draft guideline o Review by SIGN Editorial Group o Publication and dissemination	**Peer review, final editing: 6 months**

Figure 5-3Timetable for guideline development

5.4. Training for guideline development group members

All members of NIKI guideline development groups are offered training in the skills they are likely to need in order to make an effective contribution to the development process. Where possible, they are encouraged to take part in training before joining a development group so that they have a clear idea of the degree of commitment required.
The first meeting of each new group includes an introduction to NIKI methodology is provided. This covers:

- An outline of the NIKI development process, including the key stages in the process and the documentation required to establish the associated audit trail.
- A detailed description of the systematic review process used by NIKI, and the contribution that development group members are expected to make to that process.
- An indication of some of the key aspects of small group dynamics that may bias the development process, and some of the ways that they can be addressed within the group.

All participants in guideline development groups are expected to attend the above meeting and "catch-up" courses are offered to those unable to attend the first meeting of their particular group.
Separate courses on critical appraisal of the medical literature are offered to all group members. Attendance at a critical appraisal course is optional, but all members are strongly encouraged to attend at least one of these courses.
Critical appraisal courses are offered at two levels: an introductory critical appraisal course for those with no previous experience of critical appraisal, and an advanced course for those with some previous experience who wish to explore specific aspects of study design and evaluation in more depth.
The introductory critical appraisal course covers:

- basic principles of study design
- critical appraisal of systematic reviews, randomised controlled trials, and cohort studies.
- basic statistical concepts used in the presentation of study results
- the use of checklists to evaluate studies, and evidence tables to summarise evidence.

The advanced critical appraisal course covers:

- interpreting results and summarising evidence (a detailed look at the statistical concepts involved in presenting study results)
- interpreting the results of diagnostic studies (explores some of the concepts and issues specific to the design and evaluation of studies of diagnostic accuracy).

Practical exercises form a significant part of these courses. All NIKI methodology and critical appraisal courses qualify for CME (Continuing Medical Education) points.
NIKI, with support from Slovak Medical University, has produced a multi-professional continuing professional development (CPD) toolkit for guideline development group members. The toolkit provides models to guide members of groups in using their guideline development experience as a learning opportunity. It provides a step by step approach to understanding how to identify learning needs and outcomes and how to obtain postgraduate accreditation from the appropriate Royal College or professional society. Further details is available from the SIGN website at http://www.sign.ac.uk/methodology/cpd/index.html

Comment: Discuss with prof. Kristufek

5.5. Declarations of interests

All members of NIKI Council, members of guideline development groups, staff of the NIKI Executive and advisers to NIKI are required to complete a declaration of interests, both personal and non-personal, in line with the current policy approved by SIGN Council. NIKI guideline group members should be able to act as independently of external commercial influences as possible, therefore individuals who declare considerable personal interests may be asked to withdraw from the group. Details of the declarations of interest of any guideline development group member(s) are available on request from the NIKI Executive.
The current policy on declarations of interest and a copy of the form to be used for making declarations are included as Appendix I to this document

References to section 5

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Section 6. Systematic literature review

Guidelines based on a consensus of expert opinion or on unsystematic literature surveys have been criticised as not reflecting current medical knowledge and being liable to bias.[1,2] NIKI guidelines are therefore based on a systematic review of the evidence. Systematic review is defined as "an efficient scientific technique to identify and summarise evidence on the effectiveness of interventions and to allow the generalisability and consistency of research findings to be assessed and data inconsistencies to be explored".[3]

The NIKI approach leads to guidelines that are essentially the direct product of the systematic review. There is no separate report of the review or its conclusions, though all the stages of the review process are thoroughly documented (see below). Because the reviews are largely undertaken by members of NIKI guideline development groups working part time on the project, and within a limited timescale, their coverage of the literature may be more limited than those carried out by dedicated systematic review groups such as the Cochrane Collaboration. Nevertheless, the essential elements of systematic review are met:

- the literature is identified according to an explicit search strategy
- selected according to defined inclusion and exclusion criteria
- evaluated against consistent methodological standards.

The benefits of the NIKI approach derive from the close involvement of guideline developers with the synthesis of the evidence base, allowing them to apply their considered judgement when deriving recommendations (see section 6), and from encouraging a sense of ownership of the guideline amongst all those involved in the process.

6.1. Addressing patient issues in the literature search

Incorporating the patient's perspective from the beginning of the development process is essential if it is to influence the coverage of the final guideline. One of the measures used to achieve this is to conduct a specific search on patient issues in advance of the first meeting of the guideline development group. This search is designed to cover both quantitative and qualitative evidence, and is not limited to specific study designs. It is carried out over the same range of databases and sources as the main literature review, but will normally include both nursing and psychological literature even where these are not seen as particularly relevant to the later searches of the medical literature.

Once this search has been carried out, the results are sifted to identify those papers relevant to the guideline topic. Wherever possible the methodology of these papers is evaluated using standard checklists (see Section 6.4). The final results of this search and evaluation process are categorised into themes that highlight the main issues of concern to patients. These themes are then presented to the guideline development group as a means of ensuring that the key questions they specify take account of patient concerns.

6.2. Defining key questions

The training in critical appraisal and guideline development offered to members of NIKI guideline development groups encourages them to break down the guideline remit into a series of structured key questions that clearly identify the population concerned, the intervention (or diagnostic test, etc.) under investigation, the type of control used, and the outcome measures used to measure the effectiveness of the interventions. These questions then form the basis of the literature search, which is undertaken by a NIKI Information Officer.

The range of key questions may be influenced by existing guidelines. The guideline section of the scoping search carried out for the original guideline proposal (see Section 3) will be updated and extended to cover material found in Embase and Medline and the results presented to an early meeting of the guideline development group to allow them to consider what has been done already.

In some cases good quality, directly relevant guidelines will have been produced on some of the issues that fall within the remit of the new guideline. In these circumstances reference will be made to the existing guidelines rather than repeating work that has already been completed. All guidelines must be evaluated using the AGREE instrument (see Annex A) and be shown to have followed an acceptable methodology before they can be considered for use in this way.

In other cases existing guidelines may not be directly relevant to the health services in Slovak Republic, or may be found to have methodological weaknesses. If these guidelines are based on a well conducted systematic review, the guideline group may be able to use the evidence base from those guidelines as a starting point for their own review.

Definition of a set of clear and focused clinical questions is fundamental to the successful completion of a guideline development project. It is also important to be realistic about the number of questions that can be addressed in a single guideline if the final product is not to be too large to be useable. A large number of key questions also implies a very high workload for the developers, and care must be taken to ensure this is kept within manageable limits. Where the number of questions reaches 40 or more, serious consideration must be given as to whether the scope of the guideline needs to be redefined.

Deciding the key questions is entirely the responsibility of the guideline development group who must apply their knowledge and experience to ensuring the questions address the key issues in the area to be covered by the guideline.

6.3. Identifying and selecting the evidence

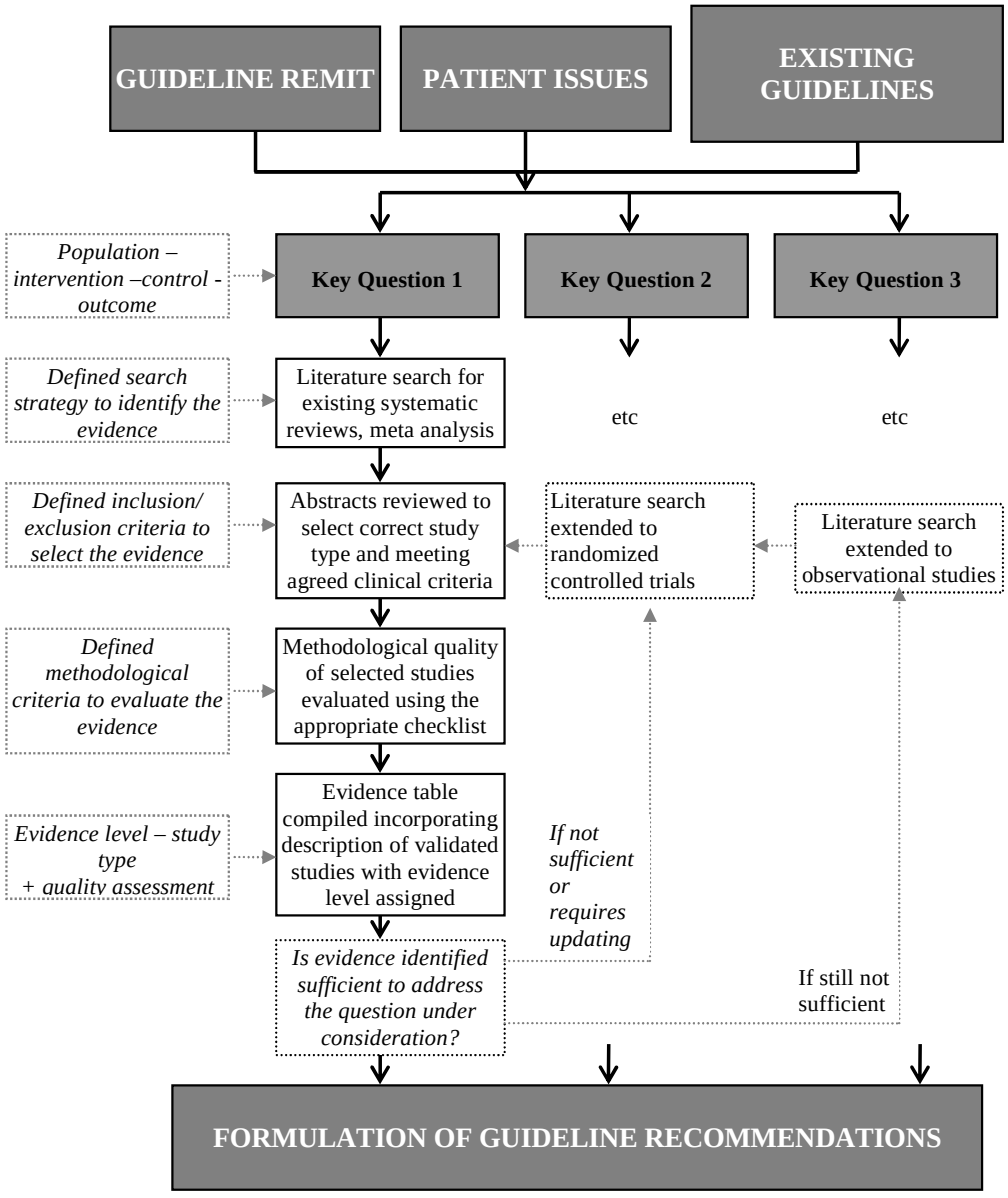

Figure 6-1Systematic literature review

The search must focus on the best available evidence to address each key question, and should ensure maximum coverage of studies at the top of the hierarchy of study types (see section 6). NIKI uses a set of standard search filters that identify:

- Guidelines
- Meta-analyses, and systematic reviews.
- Randomised controlled trials.
- Observational studies
- Diagnostic studies
- Economic studies
- Qualitative studies

These search filters are available from the SIGN Web site (www.sign.ac.uk). The systematic literature review procedure is illustrated in Figure 5.1 and an example protocol documenting all aspects of a literature review is shown in Annex E.

In order to minimise bias and to ensure adequate coverage of the relevant literature, the literature search must cover a range of sources. The Information Team reviews all search strategies in conjunction with members of the guideline development group. As a minimum, NIKI requires searches to cover the Cochrane Library, Embase, Medline, and the Internet. It is expected that in most cases the search will also cover additional sources specific to the topic under review, and the health economics literature.

The period that the search should cover will depend on the nature of the clinical topic under consideration, and will be discussed with the guideline development group. For a rapidly developing field a 10 or15-year limit to the search may be appropriate, whereas in other areas a much longer time frame might be necessary.

NIKI does not undertake hand searching of key journals as part of the literature review. It is accepted that this means some relevant trials may be missed, and introduces the possibility of a degree of bias in the process. However, given time and resource constraints, it is not feasible for this to form part of the process. Manual searching of indexes such as Index Medicus for papers published prior to the introduction of computerised databases may be necessary in some cases, however, and this will be included in the search process.

A listing of the Medline search strategies used for the guideline, plus notes of any significant variation on other databases, is published on the NIKI Web site (www.healthnet.sk/NIKI) at the time of the National Meeting associated with the guideline. This strategy will remain on the Web as part of the supporting material for the guideline when it is published.

Before any papers are acquired for evaluation, sifting of the search output is carried out to eliminate irrelevant material. A preliminary sift of each search result is carried out by staff at the NIKI Executive, normally by the individual that carried out the search. Papers that are clearly not relevant to the key questions are eliminated. Abstracts of remaining papers are then examined and any that are clearly not appropriate study

designs, or that fail to meet specific methodological criteria, will be also eliminated at this stage.

A final sift is carried out by one or two individuals from the guideline development group, who will reject other papers that do not meet clinical or other criteria that have been agreed by the development group. Only when all stages of search result sifting have been completed will the remaining papers be acquired for evaluation.

In practice, it is rare for a single search to cover all the questions being addressed within a guideline. Different questions may be best answered by different databases, or may rely on different levels of evidence. Guideline development groups are encouraged to take an iterative approach to the search, carrying out a search for high level evidence in the first instance. After the results of this search have been evaluated, the questions may be redefined and subsequent searches focused on the most appropriate sources and study types.

6.4. Evaluating the evidence

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. The result of this assessment will affect the level of evidence allocated to the paper, which will in turn influence the grade of recommendation that it supports (see section 7).

The methodological assessment is based on a number of key questions that focus on those aspects of the study design that research has shown to have a significant influence on the validity of the results reported and conclusions drawn. These key questions differ between study types, and a range of checklists is used to bring a degree of consistency to the assessment process. NIKI has based its assessments on the MERGE (Method for Evaluating Research and Guideline Evidence) checklists developed by the New South Wales Department of Health[4], which have been subjected to wide consultation and evaluation. These checklists were subjected to detailed evaluation and adaptation to meet SIGN's requirements for a balance between methodological rigour and practicality of use. Copies of these checklists and accompanying notes on their use are included in Annex C.

The assessment process inevitably involves a degree of subjective judgement. The extent to which a study meets a particular criterion - e.g. an acceptable level of loss to follow up - and, more importantly, the likely impact of this on the reported results from the study will depend on the clinical context. To minimise any potential bias resulting from this, each study must be evaluated independently by at least two group members. Any differences in assessment should then be discussed by the full group. Where differences cannot be resolved, an independent reviewer or an experienced member of NIKI Executive staff will arbitrate to reach an agreed quality assessment.

References to section 5

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Section 7. Forming guideline recommendations

7.1. Synthesising the evidence

Guideline recommendations are graded to differentiate between those based on strong evidence and those based on weak evidence. This judgement is made on the basis of an (objective) assessment of the design and quality of each study (as discussed in section 5) and a (perhaps more subjective) judgement on the consistency, clinical relevance and external validity of the whole body of evidence.[1] The aim is to produce a recommendation that is evidence-based, but which is relevant to the way in which health care is delivered in Slovak Republic and is therefore implementable.

It is important to emphasise that the grading does not relate to the importance of the recommendation, but to the strength of the supporting evidence and, in particular, to the predictive power of the study designs from which that data was obtained. Thus, the grading assigned to a recommendation indicates to users the likelihood that, if that recommendation is implemented, the predicted outcome will be achieved.

The process for synthesising the evidence base to form graded guideline recommendations is illustrated in figure 7-1.

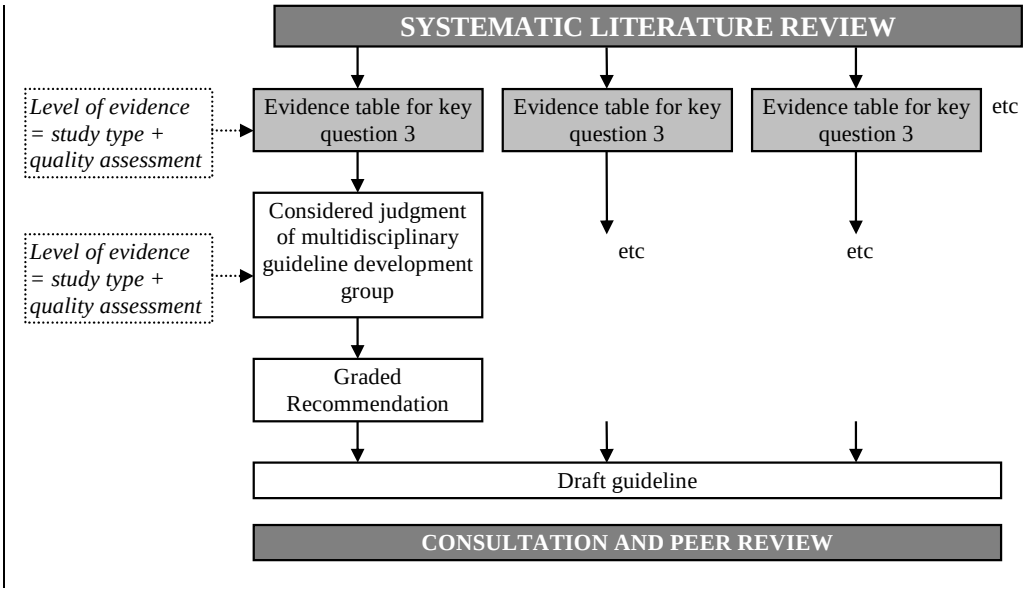

Figure 7-1Formation of guideline recommendations

Evidence tables are compiled by NIKI Executive staff based on the quality assessments of individual studies provided by guideline development group members. The tables summarise all the validated studies identified from the systematic literature review relating to each key question. They are presented in a standard format to make it easier to compare results across studies, and will present separately the evidence for each outcome measure used in the published studies. These evidence tables form an essential part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent. An example evidence table is shown in Annex E.

7.2. Considered judgement

It is rare for the evidence to show clearly and unambiguously what course of action should be recommended for any given question. Consequently, it is not always clear to those who were not involved in the decision making process how guideline developers were able to arrive at their recommendations, given the evidence they had to base them on. In order to address this problem, NIKI emplys the concept of considered judgement.

Under the heading of considered judgement, guideline development groups summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence
- Generalisability of study findings
- Directness of application to the target population for the guideline.
- Clinical impact (i.e. the extent of the impact on the target patient population, and the resources needed to treat them.)
- Implementability (i.e. how practical it would be for the health care in Slovak Republic to implement the recommendation.)

Guideline development groups are provided with a pro forma in which to record the main points from their considered judgement. An example of this form and the associated notes for users is included in Annex D. Once they have considered these issues, the group are asked to summarise their view of the evidence and assign a level of evidence to it, before going on to derive a graded recommendation.

7.3. Levels of evidence and grades of recommendation

NIKI uses the levels of evidence developed by the Scottish Intercollegiate Guidelines Network (SIGN)[2,3]. The grading system is shown in Figure 7-2.

The assignment of a level of evidence should involve all those on a particular guideline development group or subgroup involved with reviewing the evidence in relation to each specific question. The allocation of the associated grade of recommendation should involve participation of all members of the guideline

development group. Where the guideline development groups are unable to agree a unanimous recommendation, the difference of opinion should be formally recorded and the reasons for dissent noted.

The grading system is intended to place greater weight on the quality of the evidence supporting each recommendation, and to emphasise that the body of evidence should be considered as a whole, and not rely on a single study to support each recommendation. It is also intended to allow more weight to be given to recommendations supported by good quality observational studies where RCTs[†] are not available for practical or ethical reasons. Through the considered judgement process guideline developers are also able to downgrade a recommendation where they think the evidence is not generalisable, not directly applicable to the target population, or for other reasons is perceived as being weaker than a simple evaluation of the methodology would suggest.

Experience indicates that, as expected, the new grading system produces more Grade B recommendations, and fewer Grade A. It has also become clear that establishing the link between evidence and recommendation is a neglected aspect of the development process and there may be a need for some kind of formal consensus method to be introduced.

Levels of evidence	
1++	High quality meta analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well conducted meta analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1 -	Meta analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2++	High quality systematic reviews of case-control or cohort studies High quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal
2+	Well conducted case control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
2 -	Case control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4	Expert opinion
Grades of recommendation	
A	At least one meta analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+

[†] RCT Randomized Clinical Trial

C	A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+
Good practice points	
	Recommended best practice based on the clinical experience of the guideline development group

Figure 7-2 Grading system

On occasion, guideline development groups find that there is an important practical point that they wish to emphasise but for which there is not, nor is their likely to be, any research evidence. This will typically be where some aspect of treatment is regarded as such sound clinical practice that nobody is likely to question it. These are marked in the guideline as Good Practice Points, and are indicated  . It must be emphasised that these are not an alternative to evidence- based recommendations, and should only be used where there is no alternative means of highlighting the issue.

7.4. Resource implications

NIKI recognises that, in health care with limited resources and ever-increasing costs, the ability to cost individual items of care and weigh these against some quantification of patient benefit is important[4]. However, the science of economic analysis of health care is at a relatively early stage and many published studies do not meet the required methodological standard to be incorporated as part of the evidence base for a guideline. A number of approaches to the incorporation of resource issues into clinical guidelines are under development[5,6]but at this stage none are regarded as sufficiently well proven or appropriate for use in the SIGN methodology. Where there is published economic evidence this has to be identified and evaluated in a consistent manner. Health economic databases have been added to the coverage of literature searches (see section 6) and studies identified from those searches should be evaluated using NIKI Checklist, which is based on the criteria for evaluation of economic studies published in the British Medical Journal[7] This evidence can be considered alongside clinical evidence at the considered judgement stage (see section 7-2).

In other areas, the appropriate action may be inclusion in the guideline of a commentary on the main economic issues that should be considered in relation to the subject of the guideline. A final option is the provision of basic information that will allow guideline users to work out the cost implications for their own service, and examples of this approach can be seen in the guidelines on osteoporosis or epithelial ovarian cancer.

References to section 6

[1] Guyatt GH, Sackett DL, Sinclair JC, Hayward R, Cook DJ, Cook RJ. Users' guides to the medical literature. IX. A method for grading health care recommendations. Evidence-Based Medicine Working Group. JAMA 1995;274:1800-4.

[2] Scottish Intercollegiate Guidelines Network (SIGN). Methodology Review Group. Report on the review of the method of grading guideline recommendations. Edinburgh; SIGN: 1999.

[3] Harbour R, Miller J. A new system for grading recommendations in evidence based guidelines. BMJ 2001;323:334-6.

[4] Drummond MF, Stoddart GL, Torrance GW. Methods for the economic evaluation of health care programmes. 2nd ed. Oxford: Oxford University Press; 1997

[5] Mason J, Eccles M, Freemantle N, Drummond M. NICEly does it: economic analysis within evidence - based clinical practice guidelines. York; University of York: 1998. CHE Discussion Paper No.164. [cited on 16 May 2002]. Available from url: http://www.york.ac.uk/inst/che/DP164.pdf

[6] Eccles M, Mason J. How to develop cost-conscious guidelines. Health Technology Assessment 2001;5(16).

[7] Drummond MF, Jefferson TO. Guidelines for authors & peer reviewers of economic submissions to the BMJ. BMJ 1996;313:275-83

Section 8. Consultation and peer review

8.1. National open meeting

The criteria for appraisal of guidelines (see Annex A) suggest that guidelines should be pilot-tested prior to publication. SIGN considers that the pilot-testing phase is more appropriately carried out at a local level as part of the local implementation process, as testing the feasibility of implementation in one environment may not be applicable to another. However, as an early stimulus to this process, NIKI holds a national open meeting to discuss the draft recommendations of each guideline. This takes place whilst the guideline is still in development and gives the guideline development group the opportunity to present their preliminary conclusions and draft recommendations to a wider audience. The benefits of the national open meeting are twofold:

1. the guideline development group obtain valuable feedback and suggestions for additional evidence which they might consider, or alternative interpretation of that evidence
2. the participants are able to contribute to and influence the form of the final guideline, generating a sense of ownership over the guideline across geographical and disciplinary boundaries.

NIKI national open meetings are widely publicised and are usually attended by between 150 and 300 health care professionals and others interested in the guideline topic, including patient representatives, from across Scotland. The meetings are registered for CME (Continuous Medical Education). The draft guideline is also available on the NIKI web site for a limited period at this stage to allow those unable to attend the meeting to contribute to the development of the guideline.

The national open meeting is the main consultative phase of NIKI guideline development. Although the draft guideline is circulated to directors of public health and to a number of health service organisations at a later stage, this is more as a courtesy to inform them of the likely content of the final guideline than for consultation.

8.2. Peer review

All NIKI guidelines are reviewed in draft form by independent expert referees, who are asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline. A number of GPs and other primary care practitioners also provide comments on the guideline from the primary care perspective, concentrating particularly on the clarity of the recommendations and their assessment of the usefulness of the guideline as a working tool for the primary care team. The draft is also sent to a lay reviewer in order to obtain comments from the patient's perspective. The comments received from peer reviewers and others are carefully tabulated and discussed with the chairman and with the guideline

development group. Each point must be addressed and any changes to the guideline as a result noted or, if no change is made, the reasons for this recorded.

As a final quality control check prior to publication, the guideline and the summary of peer reviewers' comments are reviewed by the NIKI Editorial Group for that guideline to ensure that each point has been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised. Each member of the guideline development group is then asked formally to approve the final guideline for publication.

The full editorial and consultation phase is illustrated in figure 7.1. This process of extended consultation greatly enhances the validity of the final NIKI guideline and increases the likelihood that the guideline will be implemented successfully into local practice for the benefit of patients.

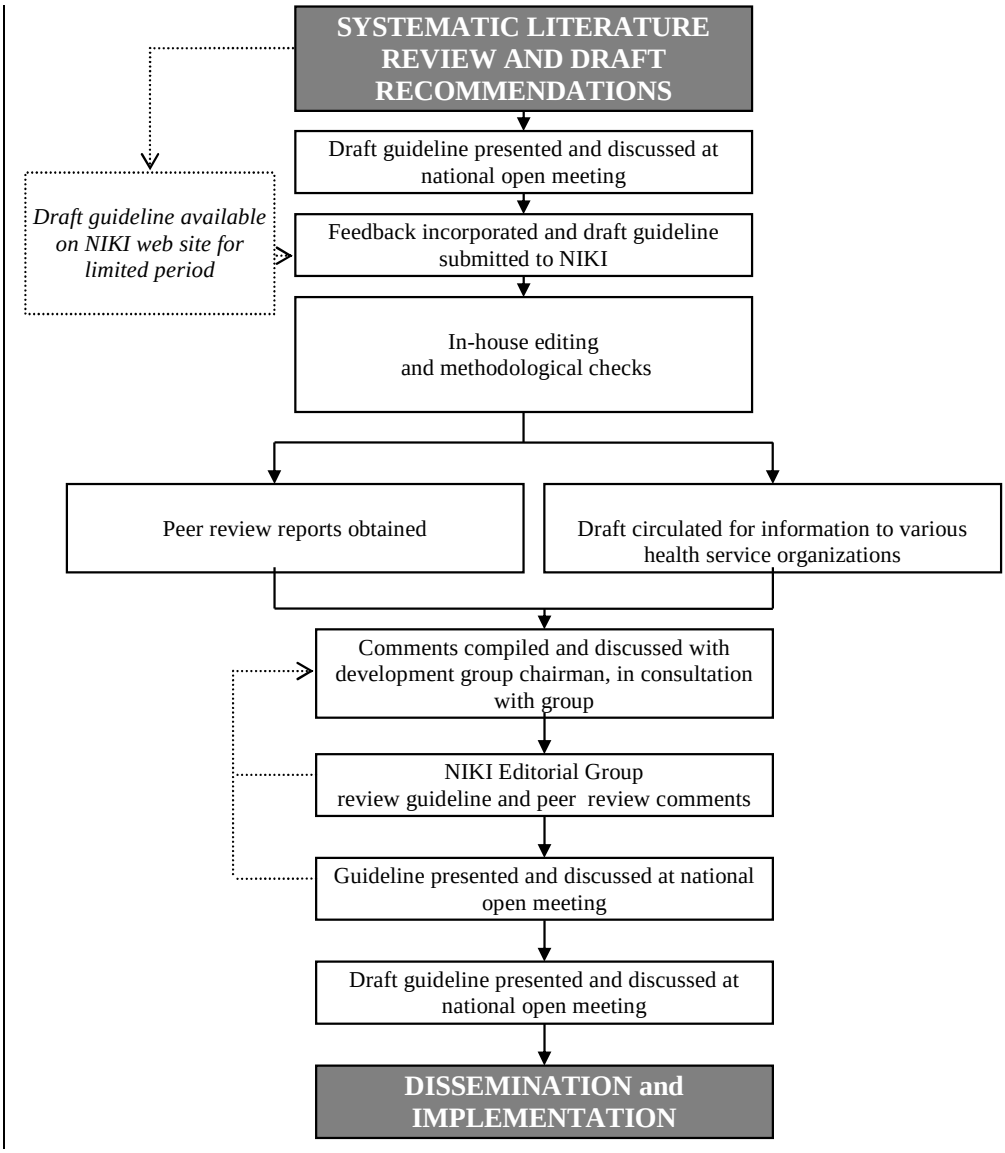

Figure 8-1Consultation and peer review

Section 9. Presentation and dissemination

9.1. Content and presentation of the guideline

Guidelines with a wide range of styles and formats have been shown to be effective in changing practice.[1] Whilst there is little information available on the effect that style and presentation have on the adoption of guidelines, clarity - of definitions, language, and format - is obviously important. Guidelines should, therefore, be written in unambiguous language and should define all terms precisely.[2] The best format for presenting guidelines will vary depending on the target group(s), the subject matter, and the intended use of the guideline.[3] Ideally, end users should be consulted regarding the most appropriate method of presentation for them.[4] This is an additional function of the extensive peer review process which all NIKI guidelines go through (see Section 8).

Each NIKI guideline includes an introduction, outlining the need for the guideline (including evidence of variation in practice) and defining carefully the remit of the guideline, including the patient and practitioner groups to which it applies. Within the main body of the guideline, the structure should as far as possible reflect the development process that the guideline development group has followed, i.e. (for each section):

- A clear statement of the question/issue under consideration.
- A brief explanation of the treatment options available.
- A summary of the conclusions drawn from the critical appraisal of the evidence (the evidence statement, annotated with the level of evidence and key references). This should provide the justification for the recommendation to follow - i.e. the evidence for improved outcome resulting from the recommended action.
- The recommendations that the group has derived from this evidence (graded according to the strength of the supporting evidence).
- A brief discussion of any practical points (e.g. resource/geographical considerations to be taken up in the discussion of local guidelines for implementation), or outstanding treatment options for which there is no evidence (the last should be stated clearly).
- Finally, if the group feels it is important to give guidance in any of these latter areas where there is no suitable evidence, a "good practice point" may be presented.

Having a well developed and defined template for presentation of the final guideline can greatly facilitate the development process, enabling guideline development groups to plan at the outset what type of information will be required and also to envisage what format the content will take. By following the model for systematic review and formation of guideline recommendations outlined in sections 5 and 6, guideline development groups will find that most of the required information will then be produced in a structured, accessible format, ready to slot into the guideline structure.

The guideline should also include key points for audit (accompanied where possible with a recommended minimum data set: see Section 11-2), suggested outcome measures, recommendations for further research, and information for patients and carers (see Section 9-4). Brief details of the systematic review on which the guideline recommendations are based should also be provided, although it is intended that the majority of this information should be made available for reference on the NIKI website, rather than included in the printed guideline.

9.2. Quick reference guides and key messages

Each NIKI guideline is published with an accompanying Quick Reference Guide (QRG). This provides a summary of the key recommendations and other information from the guideline, often following a loosely algorithmic format illustrating the recommended care pathway. The Quick Reference Guides are normally printed on the back cover of the guideline and as a separate leaflet, and have proved very popular with practitioners. It is important to note that the 'key' recommendations will not necessarily be the highest grade of recommendations (i.e. those with the strongest supporting evidence) but those considered by the guideline development group as having the greatest potential impact on patient care (see Section 7-5).

9.3. Electronic publishing

All NIKI guidelines and quick reference guides, along with any updates to guidelines, are available free of charge on the SIGN website: www.healthnet.sk/NIKI . There is tremendous scope for developing electronic publishing and dissemination of NIKI guidelines and other clinical effectiveness information in order to increase their accessibility and to make this information available when and where required, at minimal cost (both financial and environmental). We anticipate that electronic publishing will increasingly become the preferred medium for disseminating NIKI guidelines over the next few years.

9.4. Information for patients

All NIKI guidelines now include an 'information for patients and carers' section, which highlight those issues where patients and their families will most likely require information to help them understand and cope with the diagnosis, treatment options and possible outcomes. This section is targeted at health professionals, to help them produce local evidence-based information materials although patients and carers themselves may also find this section useful. The issues highlighted in this section are informed by the:

- results of patient views gathered earlier in the development process (see Section 5-2)
- patient representatives on the development group,
- other guideline development group members.

These sections also include appropriate general background explanations to the clinical condition and details of appropriate help lines, support groups and reading materials. In the future, NIKI hopes to be able to produce 'patient versions' or 'summaries' of the guidelines themselves.

9.5. Distribution

Guidelines must obviously be made as widely available as possible in order to facilitate implementation and NIKI guidelines are distributed free of charge throughout the health services in Slovak Republic. However, distribution of printed guidelines alone has been shown to be ineffective in achieving change in practice: guidelines are more likely to be effective if they are disseminated by an active educational intervention, and implemented by patient-specific reminders relating directly to professional activity.1 Distribution of NIKI guidelines in Slovak Republic is organised within each NHS Board by local distribution coordinators, who are often also responsible for facilitating implementation.

References to section 8

[1] Implementing clinical practice guidelines: can guidelines be used to improve practice? Effective Health Care 1994;1(8).[

[2] Field MJ, Lohr KN (editors). Institute of Medicine Committee to Advise the Public Health Service on Clinical Practice Guidelines. Clinical practice guidelines: directions for a new program. Washington (DC): National Academy Press; 1990

[3] Thomson R, Lavender M, Madhok R. How to ensure that guidelines are effective. BMJ 1995;311:237-42

[4] Conroy M, Shannon W. Clinical guidelines: their implementation in general practice. Br J Gen Pract 1995;45:371-5

Section 10. Implementation

10.1. Getting guidelines into practice

To achieve the objective identified in section 2-1 "to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances"[1] it is important not only to develop valid guidelines by a sound methodology, but also to ensure the implementation of the evidence based recommendations. As one of a range of tools to help health care professionals and organisations to improve clinical effectiveness and patient outcomes (see section 2-3), guidelines provide an opportunity for practitioners to improve shared clinical decision-making, increase team working, expand their evidence-based knowledge, and reduce variation in practice. They can also enable professionals to keep up to date and to assess their own clinical performance against the recommendations for best practice.

However, there is often a gap between the development of guidelines, as set out in the previous sections of this handbook, and their implementation into practice. Just as guidelines themselves help provide a bridge between research and practice, this section outlines the strategies that can assist practitioners, and health services to bridge the gap between guideline development and implementation.

10.2. Identifying barriers to implementation

There are two types of barriers to the implementation of guidelines: those internal to the guideline itself, and the external barriers relating to the clinical environment and particular local circumstances. Potential external barriers to guideline implementation include:

- Structural factors (e.g. financial disincentives)
- Organisational factors (e.g. inappropriate skill mix, lack of facilities or equipment)
- Peer group (e.g. local standards of care not in line with desired practice)
- Individual factors (e.g. knowledge attitudes, skills)
- Professional-patient interaction (e.g. problems with information processing).

NIKI addresses the internal barriers by developing guidelines according to a highly respected methodology, described in detail in the earlier sections. For successful implementation, the external barriers also need to be assessed and implementation strategies developed to address them.

10.3. Implementation initiatives

Implementation of guidelines is a local responsibility and many local initiatives have already been successful in overcoming these barriers to implementation. Most clinical facilities have a clinical effectiveness facilitators (or quality manager) supported by

quality committee with some resources to help local implementation. This is an opportunity to encourage team working and co-operation within primary and secondary care and at the interface between them.

Although its remit is limited to guideline development, NIKI seeks to facilitate guideline implementation with a number of approaches. These include wide dissemination of the guidelines at no cost to the practitioner, awareness raising initiatives and using electronic publishing to improve the availability of guidelines.

NIKI's guideline distribution policy (see section 9-5) encourages Boards to take responsibility for local dissemination, which further promotes local awareness and opportunities for local implementation. NIKI uses the media to promote the publication of guidelines when appropriate. Members of NIKI Council are also actively involved in promoting guidelines and developing projects.

Initiatives both nationally and locally have taken into account evidence on the effectiveness of different strategies to implementation: "evidence based medicine requires evidence based implementation".[2] Implementing guidelines is not simple or straightforward. Difficulties often centre on the need for personal, organisational or cultural change.[3] However, such change is being carried through in many areas of clinical practice and information to support a local evidence-based strategy is available from a variety of sources.

The Cochrane Effective Practice and Organisation of Care (EPOC) group has published a summary of 44 systematic reviews of implementation interventions, giving an indication of the most effective approaches[4] as summarised in Figure 9.1. The authors were quick to point out that there are "no magic bullets". Each implementation strategy is effective under certain circumstances, and a multifaceted approach is most likely to achieve change. The approach should be tailored to suit local circumstances taking into account any particular potential barriers. It is important to build in support and incentives and to consider the resources needed for successful implementation.

Variable effectiveness	Largely Effective
Audit and feedback	Reminders
Local consensus conferences	Educational outreach (for prescribing)
Opinion leader	Interactive educational workshops
Patient mediated interventions	Multi-faceted interventions

Figure 10-1Effectiveness of interventions to promote implementation

Figure 10-2, adapted from Palmer and Fenner[5] and the Effective Health Care Bulletin, [6] illustrates how each strategy can be used to form part of a local implementation strategy.

10.4. Practical steps

The first step in this process is to prioritise the topic for the team. This may be decided by the insurance company, or a local service or practice may identify a priority clinical area in which they wish to examine care and identify areas for improvement. It is important to recognise that clinical teams can only tackle one guideline at a time for an active implementation strategy. Indeed it may be that only certain key recommendations within the guideline are prioritised for implementation. However the clinical team should identify the strengths and weaknesses of present provision and not merely choose those areas that are most easily implementable. It is encouraging to identify what you are doing well but also important to identify where services could be improved ensuring that any changes that are planned are achievable.

METHOD	EFFECTIVENESS	LOCAL CONSIDERATIONS
Written materials	Variable findings; at best, small effect	Whilst impact is small, could be used to raise awareness of the guideline through materials or through medical journals or local publications. Useful in combination with other strategies.
Audit and feedback	Sometime effective; small to moderate effect but potentially important	This could be a valuable starting point to provide baseline information from which to develop an implementation strategy.
Education (group)	Variable effects which improve when the influence of peers is included	Identify a local multiprofessional group who can be supported with education from experts or by attending workshops or conferences. Facilitation at practice/unit level is helpful.
Education (individual)	More effective than other educational initiatives	Targeting stakeholders through individual education centred on the topic, or more general implementation issues. Consideration needs to be given to cost.
Opinion leaders	Mixed effects	Identify local and national opinion leaders and consider how they might be involved.
Product champions	No conclusive evidence	Identifying product champions might highlight innovative methods for implementation.
Academic detailing / educational outreach	Effects are small to moderate but of potential importance	Could be incorporated with individual education approach and written materials.
Mass media	May have a positive influence on how health services are used	Take advantage of mass media coverage and additionally local media sources.
Patient-mediated interventions	No conclusive research evidence	Consider local patients, consumer and pressure groups so that involvement is part of strategy at the outset

METHOD	EFFECTIVENESS	LOCAL CONSIDERATIONS
Continuous quality improvement	No conclusive research evidence	Include local audit/clinical governance/ effectiveness departments in developing the implementation strategy.
Financial incentives	Some appear to influence practice, but not all	This may only be available for some professional groups and would depend on the nature of the guideline, e.g. financial support for audit, prescribing incentives.
Policy / regulation	No conclusive research evidence	National standards drawn up by bodies such as the CSBS are supported by clinical guidelines are influential in supporting local implementation.
Reminder systems	Computerised records have supported the implementation of guidelines. Manual reminder systems were effective in many, but not all studies.	Implementation may prompt a review of the record keeping system and may initiate developments such as multiprofessional integrated care pathways. Computerised decision support is being developed.
Internet /on-line databases	No conclusive research evidence	If local services are networked this could form a useful medium for communication and information sources
Combinations of methods	Appear to be more effective than any one intervention on its own	Importantly, a local strategy needs to consider which of the above and in what combination such strategies may be helpful

Figure 10-2 Implementation strategies

Figure 10-3 outlines the likely steps that a local implementation group might take, adapted from the Royal College of Nursing Guidelines[7] and the SPICEpc (Scottish Programme for Improving Clinical Effectiveness in Primary Care) project (www.ceppc.org/spice/index.shtml) .

STEP	ACTION
1	Decide who will lead and co-ordinate the team and identify stakeholder representatives for the implementation group. It is often helpful to have a key facilitator for this process. The team should be multiprofessional in composition.
2	Determine where you are now. First, you have to know how you are doing and identify where changes need to be made. It is helpful to audit current clinical practice. It is also important to review the local environment considering people, systems, structures and internal and external influences. Through this process it is possible to identify potential barriers and facilitators to implementation.
3	Prepare the people and the environment for guideline implementation. It is important to ensure that the professionals are receptive with a positive attitude to the initiative and have the skills and knowledge to carry out the procedures. This

STEP	ACTION
	requires time, enthusiasm and commitment with good communication and offers of tangible help. It is important also to involve patient groups in planning the initiative so they are involved from the outset and can influence the way that the guideline is implemented into local services. It is important to take into account patient preferences and views e.g. Scottish Consumer Council publications, local surveys. In preparing the environment it may be necessary to acquire new equipment or change forms or access services in a different way. It may be possible to consider the inclusion of reminder notes or computer assisted reminders.
4	Decide which implementation techniques to use to promote the use of the clinical guidelines in practice. This should take into account the potential barriers already identified and use the research evidence on effective strategies.
5	Pulling it all together. This requires an action plan for the improvement process. It requires everyone to agree the aims with a named person responsible for the action plan; a time scale identified with contingency plans to deal with any problems along the way.
6	Evaluate progress through regular audit and review with feedback to the team. Rewarding achievements is important. Plans may be required to be modified in the light of difficulties or surprises found during the implementation process. It is always important though to celebrate successes and aim for small achievable steps along the way to improve the quality of patient care.
7	Monitoring of guideline implementation is part of the responsibilities of NHS Quality Improvement Scotland (NHSQIS). NHSQIS clinical standards focus on clinical issues and are evidence based, although levels and types of evidence vary. Where possible they are based on standards drawn from SIGN and other evidence based guidelines as well as good practice statements.

Figure 10-3 Practical steps towards guideline implementation

References to section 10

[1] Institute of Medicine. Committee to Advise the Public Health Service on Clinical Practice Guidelines. Clinical practice guidelines: directions for a new program. Washington DC: National Academy Press; 1990.

[2] Grol R, Grimshaw J. Evidence-based implementation of evidence-based medicine. Jt Comm J Qual Improv 1999;25:503-13.

[3] Grol R, Grimshaw J. From best evidence to best practice: effective implementation of change in patients' care. Lancet 2003;362(939):1170

[4] University of York. NHS Centre for Reviews and Dissemination. Getting evidence into practice. Effective Health Care 1999;5. [cited 16 May 2002]. Available from url: http://www.york.ac.uk/inst/crd/ehc51.pdf

[5] Palmer C, Fenner J.Getting the message across. Review of research and theory about disseminating information within the NHS. London: Gaskell; 2000.[

[6] University of York. NHS Centre for Reviews and Dissemination. Getting evidence into practice. Effective Health Care 1999;5. [cited 16 May 2002]. Available from url: http://www.york.ac.uk/inst/crd/ehc51.pdf

[7] Pressure ulcer risk assessment and prevention: implementation guide and audit protocol 2003. London: Royal College of Nursing; 2003

Section 11. Audit and review

11.1. Scheduled review

All NIKI guidelines state that they will be updated as new evidence becomes available. NIKI is also currently piloting the concept of living guidelines, where the guideline is kept under constant review and regular updates are published electronically as new evidence is published.

11.2. Review proposals and procedures

All NIKI guidelines for review are circulated to the relevant NIKI specialty subgroup (see section 4-3) which will use its clinical networks to gather feedback that will inform the review proposal. Information is gathered using a report form that tries to assess the impact of the guideline, whether there have been changes in the field or if new treatments are available, and if there is improved or new evidence. Reviewing a guideline provides an opportunity to reconsider the guideline's original remit, and opinion is also sought from expert referees as to whether the remit of the guideline remains appropriate or should be either widened or narrowed.

Having gathered this information, the specialty subgroup and the Guideline Programme Advisory Group make a decision about the need for review and the specialty subgroup will prepare a review proposal for NIKI Council that reflects this position. There are four possible outcomes for a guideline that has reached this stage. A full review of the guideline may be required, alternatively the guideline may simply require to be updated. There may be a need to modify the remit of the guideline, or it may be that the guideline has achieved its purpose, or is no longer relevant and should be archived.

Information on the status of guidelines due for review is provided on the NIKI website.

11.3. Links with audit

Development, dissemination and implementation of a guideline should be monitored and evaluated through clinical audit. During the development of the guideline, the development group identifies key points for audit. These should allow the implementation of the guideline recommendations and the impact of these on the processes and, where possible, the outcomes of care to be measured objectively. Often these process and outcome indicators are presented in the form of a minimum data set.

Clinical audit of guidelines can provide valuable information for standard setting and service accreditation. NIKI guidelines provide the evidence base for many of the national standards developed and monitored by the Clinical Standards Board for Scotland, now part of NHS Quality Improvement Scotland (see section 9.5). This joint approach to

producing evidence based guidelines, which contain national datasets, which in turn are used to set clinical standards that are audited, should, in theory at least, improve the quality of healthcare delivered. Audit in turn is able to inform guideline reviews and further improve the implementation of specific recommendations.

11.4. Recommendations for research

NIKI guidelines themselves may act as a stimulus to research. An important subsidiary outcome of the guideline development process is in highlighting gaps in the evidence base and guidelines contain a chapter or annex listing the guideline development group's recommendations for research. . The review of a guideline is an opportunity to discover whether any of the gaps in the evidence base have been filled.

11.5. Monitoring and interim updates

All comments received on published NIKI guidelines or information on important new evidence in the field are fed back to the guideline development group, either for immediate response or for more detailed consideration on review of the guideline. Any updates to the guideline which might be required in the interim period prior to review are noted on the NIKI website.