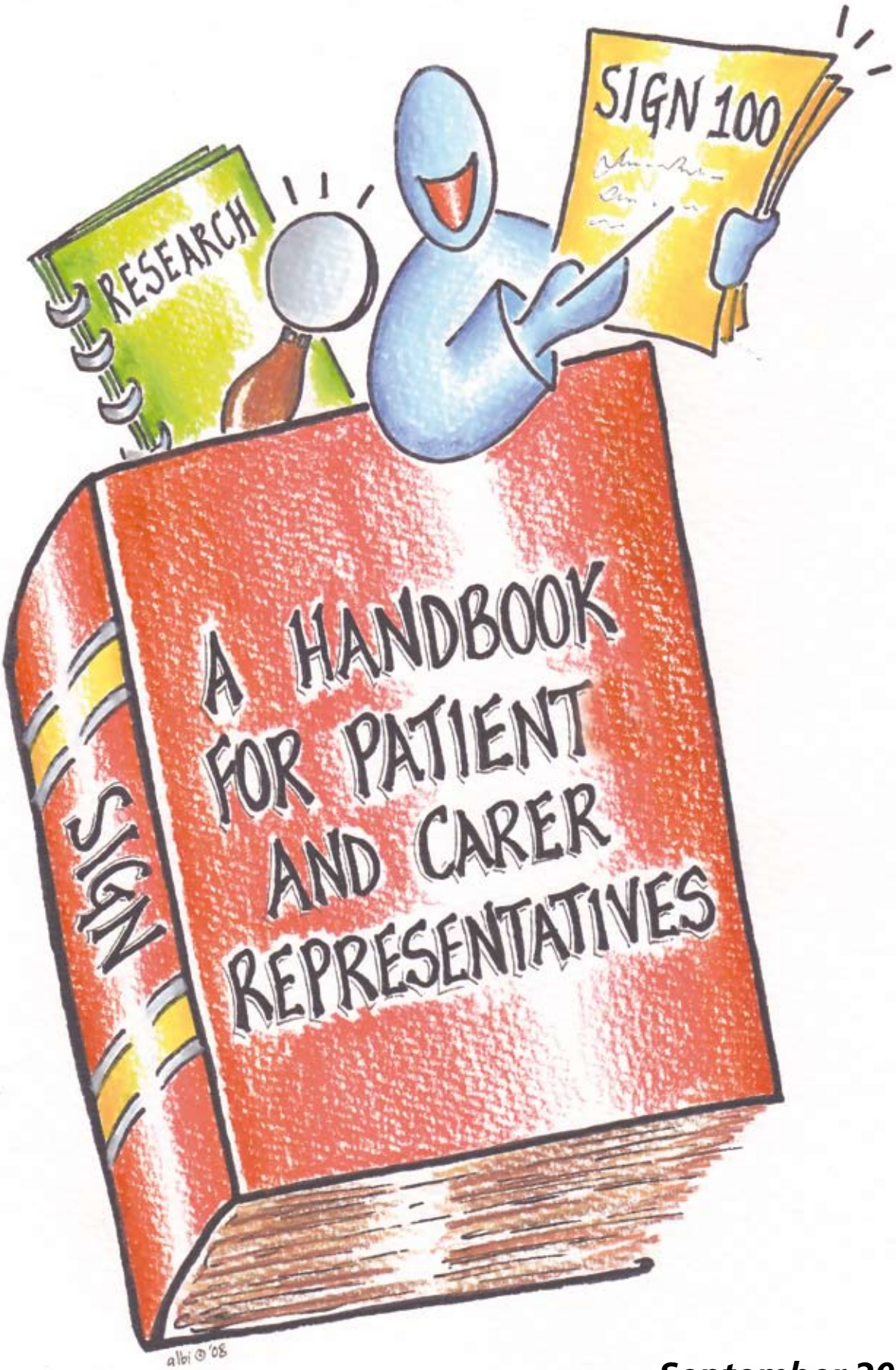
SIGN

Scottish Intercollegiate Guidelines Network

NHS Quality Improvement Scotland



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SIGN 100

a handbook for patient and carer representatives

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Scottish Intercollegiate Guidelines Network
Elliott House, 8 -10 Hillside Crescent
Edinburgh EH7 5EA

www.sign.ac.uk

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1 Introduction

1a Who is this handbook for?

The Scottish Intercollegiate Guidelines Network (SIGN), have written this handbook for patient and carer representatives who have become involved in our work. It explains how we develop clinical guidelines for the NHS in Scotland. You can read more about us in section 2. The handbook aims to:

- explain the process we use to develop clinical guidelines;
- show how you can become involved in developing guidelines; and
- help you understand the role of a patient or carer representative.

We have explained the terms we have used in this handbook on page 40.

Throughout this handbook, we have used the term 'patients and carers' to cover the groups of people who are involved in our work. This includes people who have a medical condition, people who are caring for someone, a patient's family and friends, or people who work for voluntary organisations that represent patients.These 'representatives' are not medical staff. We hope that, as a representative, you can help give us an idea of what it is like to use the health service from day to day.

If you want to know more about anything in this handbook, you can speak to Karen Graham, the Patient Involvement Officer.

Phone: 0131 623 4740 • E-mail: karen.graham2@nhs.net • Write to: SIGN, Elliott House, 8-10 Hillside Crescent, Edinburgh, EH7 5EA

2 About us

2a What we do

We write clinical guidelines for all NHS staff – including doctors, nurses, physiotherapists, dentists and occupational therapists – and patients. These guidelines give advice on the best treatments that are available. We write them by working with doctors, nurses and other NHS staff, as well as with patients, carers and members of the public. The guidelines are based on the most up-to-date medical evidence.

2a1 SIGN Council

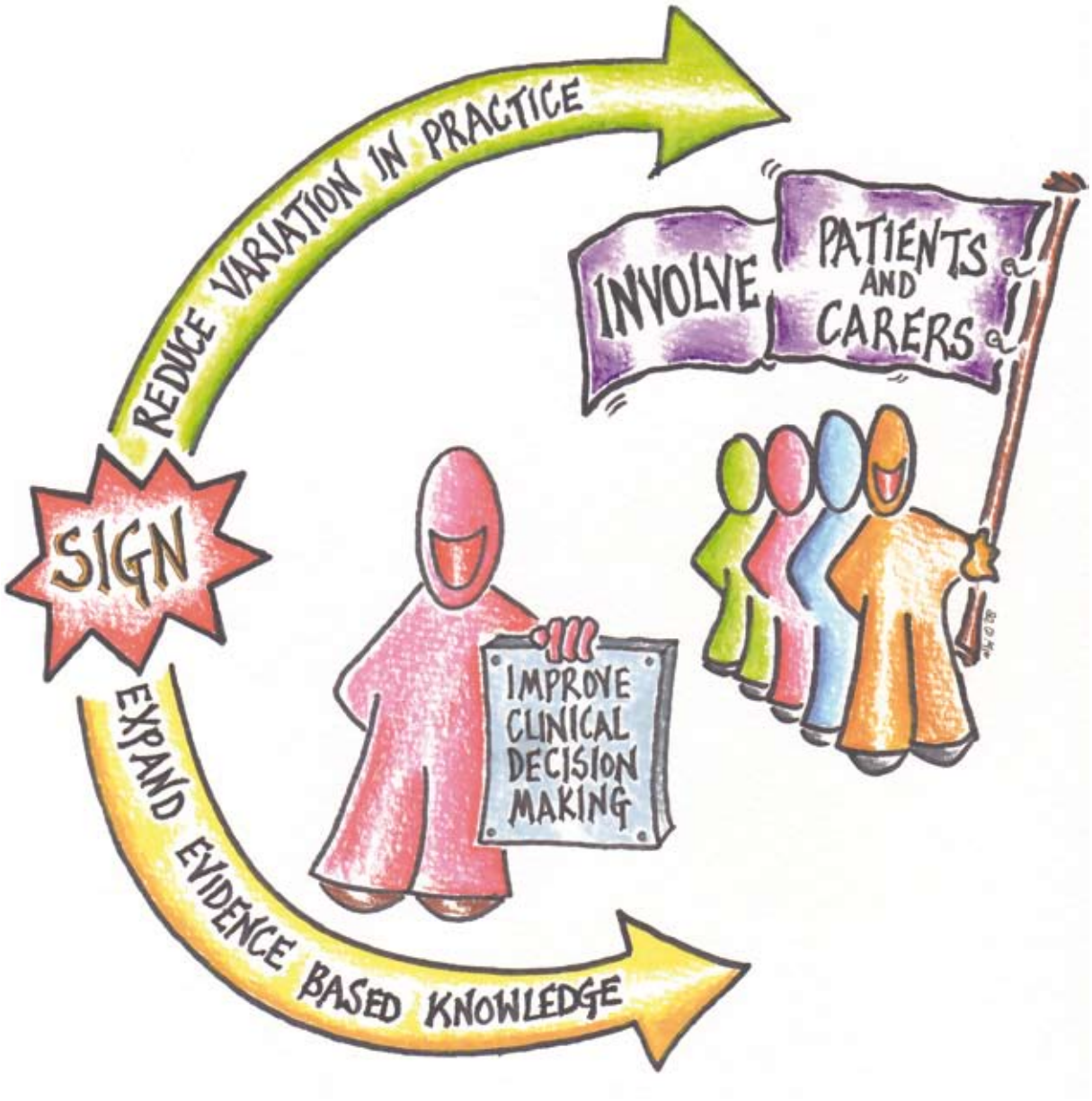
SIGN Council is the part of our organisation that makes our policies. Its members make decisions on how we plan to develop overall and play a vital role in shaping our programme for developing guidelines. Members of the SIGN Council are nominated by their Royal College or another professional organisation. They represent their speciality or discipline and consult other specialist societies in their field.

Some members of the SIGN Council are involved in the guideline development process as members of advisory groups, editorial groups or guideline development groups.

All members of the SIGN Council have a say on which topics to choose for developing guidelines and who should be chosen as members of guideline groups.

2a2 SIGN Executive

The SIGN Executive is the name for the staff we employ to run the organisation. They are responsible for putting the SIGN Council's decisions into practice and carrying out the guideline programme on time and in line with its budget. All these members of staff are employees of NHS Quality Improvement Scotland (NHS QIS). NHS QIS is a special health board which provides advice and guidance to the NHS in Scotland. Our staff work closely with other parts of NHS QIS and keep to their policies and procedures.



The staff you will work closely with during your time on a guideline development group are as follows.

Programme manager – they oversee the work of the guideline development group and manage the guideline development process.

Information officer – they carry out literature searches (searching medical and scientific research papers) to find all the relevant research work on a particular topic.

Guideline co-ordinator – they provide administrative support to the guideline development group.

Patient involvement officer – they are responsible for managing our activities in involving patients and the public in our work.

2b What are your guidelines for?

We write guidelines to:

- help NHS staff and patients make decisions about health care that are based on the most up-to-date evidence;
- make sure patients get the best care available, no matter where they live; and
- improve health care across Scotland.

2c What are your guidelines based on?

Our guidelines are based on medical and scientific research. The term 'research' means different things to different people, but it mostly involves gaining new knowledge and providing evidence that could lead to changes to treatments, policies or care.

Members of guideline development groups read research papers and base the guidelines on the evidence they find. If no research has been done in relation to a particular question, the guideline development group will highlight this as an area where research is needed.

For more information on research and how we use it to develop our guidelines, read sections 5 and 6.

2d Who decides which guidelines are needed?

Anyone in Scotland can suggest a topic for a guideline. This includes NHS staff, voluntary organisations, charities, patients and carers. If you want to suggest a topic for a guideline, you will need to fill in our topic proposal form. You can download this from our website at www.sign.ac.uk/about/proposal.html or phone 0131 623 4740 to ask for a paper copy.

We choose a topic if we know that health services in different areas offer different tests and treatments for the same condition, and if this difference results in different outcomes for patients. We want to make sure that everyone in Scotland receives the best health care, so our guidelines recommend the best proven treatments.

Before we decide whether to develop a guideline, we make sure there is enough evidence. This is because our guidelines are based on evidence, which means that health-care professionals and patients can trust the recommendations that the guidelines make. Our information officers do a very wide search of the scientific and medical documents available. They do this to make sure there is enough good-quality evidence to make developing a guideline possible.

2e Who funds the guideline development process?

As part of the special health board NHS QIS, we are funded by the Scottish Government. Funding from NHS QIS supports:

- the SIGN Executive;
- expenses associated with individual guideline development groups (such as paying library fees to get copies of research papers);
- the consultation process; and
- costs for printing and distributing published guidelines.

We also receive extra income from:

- selling guidelines (for example, to health-care professionals outside Scotland);
- teaching medical students and other international guideline developers; and
- doing consultancy work in the UK and abroad.

2f Do you look at how your recommendations can affect the NHS's resources?

The NHS has limited resources and ever-increasing costs, so it is important to assess the cost of individual items of care against the benefits to patients. We use health economic databases in our literature searches. However, many published economic studies do not meet the necessary standard for us to be able to include them in the evidence for a guideline. We can consider any good-quality evidence alongside clinical evidence at the considered judgement stage (see section 8b).

We are currently reviewing the process for including economic issues in our clinical guidelines.

3 Guideline development groups

3a Who sits on guideline development groups?

To develop a guideline, we bring together a group of people from across Scotland. The guideline development group includes:

- NHS staff (for example, hospital doctors, nurses, GPs, psychiatrists and physiotherapists);
- staff from areas such as education and social work; and
- patient and public representatives.

The size of a guideline development group will depend on the topic, but most have 15 to 25 members.

Each member of a guideline development group represents both a geographical region and a speciality or professional group. We try to put a group of people together who have a mix of the following skills.

- Clinical expertise, such as nursing
- Other specialist expertise, such as social services
- A practical understanding of the problems faced when providing care
- Communication and teamworking skills
- Critical appraisal skills

We do not expect the people in the group to be experts in all these areas. Most people will only have one or two of these skills but their knowledge and experience is valuable. Whatever their area of expertise, all members of the guideline development group have equal status.

The guideline development group meets around every six to eight weeks. The group looks at research evidence and then produces a draft guideline that makes recommendations about how people should be treated according to the evidence. The recommendations are based on an assessment of how well different types of treatments work. For more information on how we develop a guideline, read section 6.

Each guideline development group will be together for around 28 months. Some groups may form subgroups which meet between the meetings held by the full group.

Each guideline development group is chaired by a health-care professional.

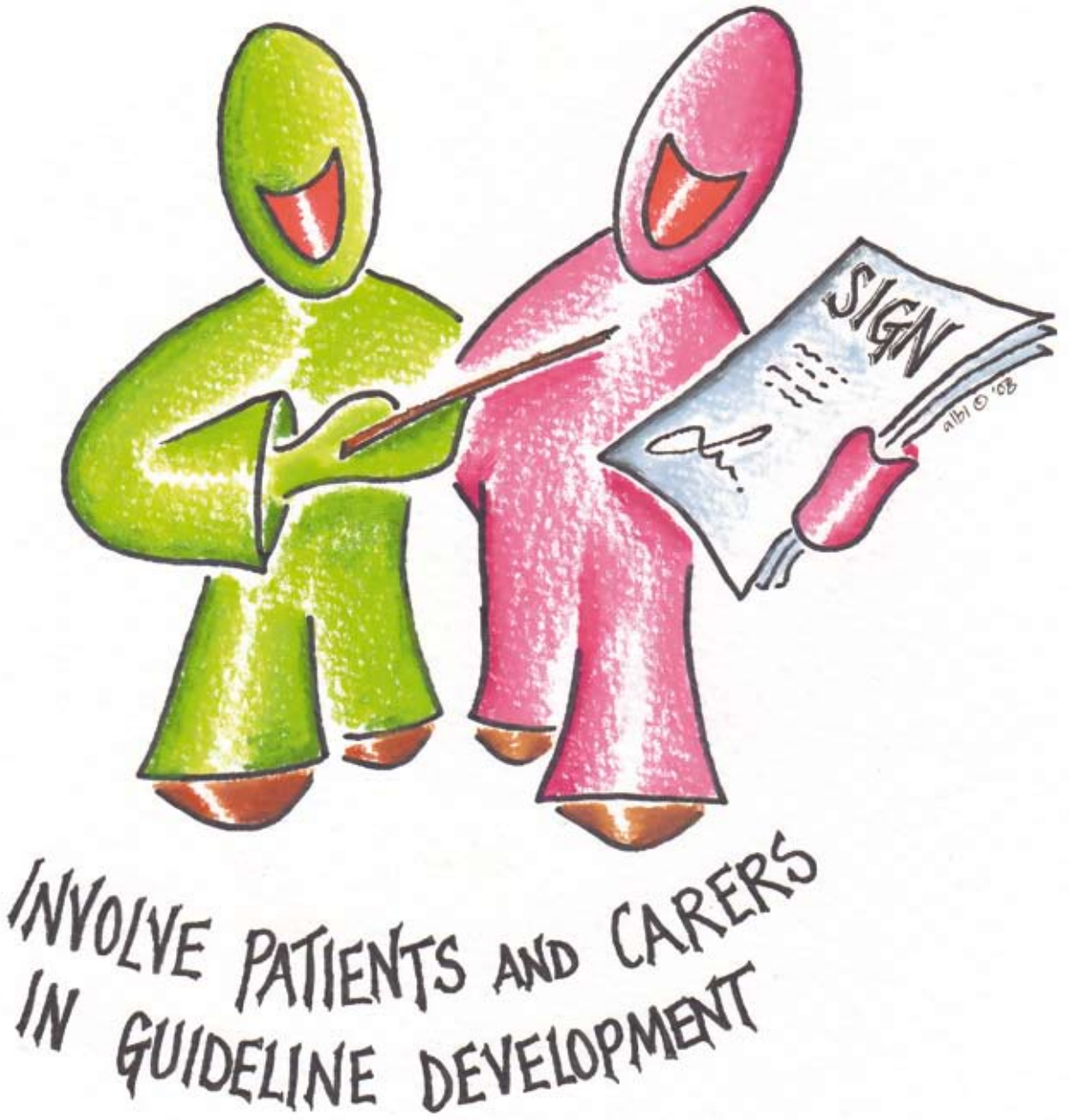
3b Declaring interests

We ask all members of the SIGN Council, members of guideline development groups, SIGN Executive staff and our advisors to sign a declaration of interests form. You can find a copy of our policy form in annex 1. This asks you about your personal and non-personal interests in commercial companies that might be involved in, for example, producing new drugs. As a member of a guideline development group, you should be able to act as independently as possible. If you have significant personal interests, we may ask you to withdraw from the group. We also ask guideline development group members to sign a confidentiality agreement to make sure that they do not make the work of the group public until the consultation stage of the guideline development process. You can find copies of these forms in annexes 2 and 3.

3c Why do you have patient and carer representatives on guideline development groups?

We believe it is very important for patients and carers to be involved in the decisions that are made about their care. By involving patients and carers in the guideline development process, we can identify their concerns and use their views to support scientific research and the knowledge and experience of health-care professionals. Patients and carers can help the guideline development group understand what it is like to live with a medical condition and how different forms of treatments can affect their lives. The types of things we are interested in hearing about include:

- what patients want from their treatment;
- whether patients and carers accept different treatments;
- patients' preferences;
- how patients and carers think their care could be improved;
- the needs of different groups of patients (for example, in relation to their sex, age, and ethnic background); and
- information and support needs for patients with specific conditions.



As a patient representative on a guideline development group, you can remind the other group members of any limitations of the scientific findings in relation to a patient's age, disability, gender, ethnic background, sexuality, quality of life and other personal circumstances (such as their ability to travel to receive services). You can help to make sure that the guideline development group considers specific needs such as information and communication.

Factors such as a patient's age and gender may influence what treatment they choose – for example, men may be less likely to go to a GP – and you can remind the group of this.

You can also raise a wide range of other issues to make sure the guideline development group considers the needs of everyone who is affected by a condition. The influence of a patient's religion or beliefs might make it difficult for them to have certain treatment (for example, in relation to their diet or taking medication).

3d How do you involve patients and carers in the guideline development process?

We recruit at least two patient representatives to each guideline development group. Before the first group meeting, we ask relevant organisations to nominate patient and carer representatives. We invite nominations from:

- voluntary organisations (including equality and diversity groups);
- charities;
- NHS patient involvement workers (for example, staff from community health partnerships who are part of a public partnership forum);
- the SIGN Patient Network (see section 3d1); and
- SIGN Council.

3d1 SIGN Patient Network

The SIGN Patient Network is a group of people and representatives from organisations who have an interest in our activities to involve patients in our work. The purpose of the network is to:

- help identify people and organisations that can work with us on specific projects (for example, nominating patient and carer representatives, focus groups, reference groups);
- help us consult people on our work;
- promote national open meetings (see section 9a) to a wider audience;
- help with training;
- help share our knowledge;
- provide networking opportunities;
- act as a source of support for members of guideline development groups; and
- help distribute the guidelines.

Members of the patient network receive a newsletter every two months, which includes details of:

- opportunities for patients to get involved in our work;
- published guidelines and when they are being launched;
- public involvement seminars (run by other organisations);
- conferences;
- informal lunches;
- in-house training dates; and
- opportunities for patients to get involved in other organisations' work (such as that of the Scottish Government).

3e How do you choose patient and carer representatives for guideline development groups?

We consider all the applications we receive (see section 3d). When we make a decision, we take account of the experiences and skills people can offer. We would be more likely to choose someone who is living with a condition over someone who simply tells us they have an interest in the topic. Someone who has a condition can draw on their experience of the disease and their experiences of health services. We look at how people would be suited to particular roles by looking at their skills. For example, someone who is a member of a support group is likely to have good teamworking skills and be able to represent the views of a wider group of people. We will invite any nominees whose applications are not successful to take part in other parts of the development process, if possible (for example, consultation).

We would like to work with people from a range of backgrounds. We particularly welcome applications from people with disabilities, people from ethnic minorities, young people and other social groups who are currently under-represented.

3f How big a commitment would I have to make as a patient and carer representative?

We know that people will be able to spare different amounts of time for the guideline development process. You can choose how involved you would like to be in the guideline development process. We offer a range of options.

Full member – for people who will be able to attend all group meetings over the two and a half years the guideline is developed.

Key stage member – for people who prefer to be involved only at certain stages of the guideline development process. As a key stage member, you would attend all group meetings until the 'key questions' have been finalised (usually the first three to four meetings). You can also choose to be involved in the national open meeting (see section 9a) for the guideline and you may like to nominate someone for a peer review (see section 9b).

Advisor – for people who have in-depth knowledge of a condition but who are unable to commit to being a full member. As an advisor, you would attend the first two meetings of the development group to put across patients' views at the beginning of the guideline development process. You may want to use your expertise to give a talk to the development group at either the first or second group meeting. You might also want to talk about the patient's perspective at the national open meeting (see section 9a) and be involved in peer reviews (see section 9b). You should also be happy to be contacted (by e-mail, letter or phone) at other stages of the guideline development process to help with any specific questions.

3g What role do patient and carer representatives play as members of guideline development groups?

One of your vital roles will be to make sure that patients' views and experiences influence the guideline development group's work. This may include any or all of the following.

At the start of the process

- Making sure that the main questions that guide how evidence is collected are informed by issues that are important to patients and carers.
- Helping us identify issues that are relevant to patients and carers (for example, by helping to prepare discussion points for focus groups to use with other patients or support groups).
- Helping to put us in touch with voluntary organisations.
- Helping us to arrange meetings to consult patients, carers and members of the public (for example, through their own support groups).

When developing recommendations

- Considering how the recommendations reflect patients' and carers' concerns.
- Reading research papers from a patient's or carer's perspective. For example, do the papers consider the issues that patients and carers think are important? Did the researchers consider patients' and carers' views when drawing their conclusions?
- Making sure that the guideline development group considers patients and carers when drafting their recommendations.
- Helping to write the 'Provision of information' section of the guideline.
- Making sure that the guideline is sensitively worded (for example, treating patients as people and not as objects of tests or treatments).

At the national open meeting and peer review

- Helping to identify representatives to take part in the national open meeting and peer review process.

At the end of the process

- Raising awareness of the guideline among groups of representatives (for example, support groups and voluntary organisations).
- Taking part in the launch of the guideline.
- Helping produce versions of the guidelines for patients.

Don't worry – we don't expect you to be able to do all of this on your own.

Sometimes, patients and carers may have concerns that cannot be dealt with in the guideline. Or, your area of interest might fall outside the scope of the guideline or there will not be enough evidence to make recommendations. If this happens, we will say this in the guideline.

3h What skills do patient and carer representatives bring to guideline development groups?

You do not need any formal qualifications to be a patient or carer representative. It may help if you have some of the following.

- Direct experience of the condition the guideline relates to (for example, as someone who has or has had the condition, or the carer or family member of someone who has the condition).
- An understanding of the needs and concerns of a wider network of patients (for example, as a member of a support group).
- Time to commit to the work of the group (by attending meetings, doing background reading and commenting on drafts).
- A willingness to put across the views of patient and carer groups who are not represented on the guideline development group.
- The ability to put views across clearly, constructively and sensitively, taking into account other people's responsibilities, views and expertise.
- Some experience of working in large groups.
- A willingness to become familiar with medical terms and phrases.
- Good communication, listening and teamworking skills.
- Enthusiasm and commitment.
- The ability to keep information confidential, if necessary.

Before you join a guideline development group, you should be aware that it is not unusual to get upset when the work touches on issues that are important to you personally. Before you join, we will ask if you have friends and family that you can call on for support. If, for example, you have been nominated by a voluntary organisation, we would ask them to support you during the time you are involved in our work.

3i Training and support for patient and carer representatives

3i1 SIGN buddies

It may help to speak to someone who has already been a patient representative on a guideline group. We call these people 'SIGN buddies'. They can offer support to you on a one-off basis or throughout the whole time you work with us. If you would like to be put in touch with one of our buddies, please let us know.

3i2 Training courses

We offer training to all members of guideline development groups to help them make an effective contribution to the development process. This includes an 'Introduction to SIGN' course and three 'critical appraisal' courses.

'Introduction to SIGN' course

This is a one-day course delivered by our Patient Involvement Officer. It covers how patients and carers can contribute to the guideline development process and focuses on the skills they need to take part in a guideline development group (for example, communication skills).

Critical appraisal training

'Critical appraisal' is the name we give to the process of reading and assessing scientific and medical papers. We offer critical appraisal training to all group members. You do not have to attend but we encourage you to do so, whether or not you are reviewing papers, as the course will give you a strong understanding of our methods. We offer three levels of critical appraisal.

- **Critical appraisal for all** – this is aimed at patient and carer representatives who have joined groups. It focuses on giving patients and carers the skills they need to review evidence.
- **Introduction to critical appraisal** – this is aimed at all group members who do not have any previous experience of critical appraisal. It focuses on critically appraising various types of studies and using checklists to assess them.
- **Advanced critical appraisal** – this is aimed at any group member who has some previous experience of critical appraisals and who wants to assess research papers in more depth.

All three courses include practical exercises.

Informal events

We hope to be able to invite all patient and carer representatives to an informal lunch at least once a year. This is an opportunity for you to meet other patient and carer representatives and share your experiences. Sometimes, if we are looking for feedback on particular projects, we will do this informally at these events.

3i3 Expenses

We will not pay you for taking part in a guideline development group, but we will cover certain expenses (for example, costs for travel, childcare and loss of earnings). After each meeting, we will ask you to fill in an expense form and provide receipts. You should then give these to the guideline co-ordinator who is responsible for your guideline development group. You can find an example of a filled-in expense form in annex 4.

4 Including patient issues in the guideline development process

4a Searching for patient issues in research papers

Before the guideline development group meets for the first time, our information team will do a literature search to look for evidence on relevant patient issues. They will do this early on to make sure the patient's point of view influences the final guideline right from the start of the development process. This search covers both 'quantitative evidence' (studies that look at numbers) and 'qualitative evidence' (studies that look at people's experiences, beliefs and attitudes). The team identifies research papers using the same databases that they use for the main literature review. You can read more about literature searches in section 6.

The literature search will identify around 500 papers, some of which may not be directly relevant to the guideline. We then choose the papers that are relevant to the guideline topic and group the abstracts (brief summaries of the aims, methods, results and conclusion of a research study) from this search into themes to highlight patients' and carers' main concerns. Our patient involvement officer presents these themes to the members of the guideline development group, who then take the themes into account.

The studies identified often 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;
- which of their needs have not yet been met;
- their needs and preferences for information;
- the decision-making about their treatment; and
- their overall satisfaction with the care they received.

4b How else do you identify the issues that concern patients?

4b1 Consulting the voluntary sector

Four months before the guideline development group's first meeting, we will write to the organisations and charities that represent or lobby for patients and carers. We will ask them to fill in a form to tell us about the issues they think the guideline should deal with, and their reasons for making these suggestions (for example, as a result of information they have gathered from their telephone helplines or surveys). We then summarise the information we receive from these organisations and present it to the guideline development group at its first meeting.

4b2 Consulting the SIGN Patient Network

Many of the members of the SIGN Patient Network have experience of living with or caring for someone who has the conditions our guidelines relate to, so we ask them to tell us about the issues they think our guideline should cover. Likewise, many of our members work with groups of patients and can raise relevant issues on their behalf.

4b3 Consulting other NHS organisations

We also write to other NHS organisations such as the National Institute for Health and Clinical Excellence (NICE) and the health board patient involvement staff to find out if they have done, or know of, any local research on patients' views. This might include patient focus groups set up to help redesign services, or questionnaire studies to see how satisfied patients are with the services they received. These kinds of reports are not usually published in scientific journals but they are available to the public and can be very useful for getting an idea of patients' issues and concerns.

4b4 Consulting patients and carers

Sometimes our literature searches find a significant amount of evidence, but not enough feedback from patient organisations. In these situations, we may consider other ways of getting information. We may consult patients and carers through focus groups or by attending patient support group meetings. These approaches can provide valuable information that we can then pass on to guideline development groups.

5 Introducing research methods

5a What is 'research' and what is 'evidence'?

The world of research may be new to you. Since our guidelines are based on medical and scientific research, we thought it might be helpful to explain the basic principles of research. By having an understanding of the research process and different types of research, you may feel more comfortable about contributing to the guideline development process.

Research is about investigating new ideas and finding new information that could lead to changes to treatments, policies or care. There are a number of different research methods that researchers use to collect and analyse information. These research methods include interviews, questionnaires, diaries, clinical trials, experiments, analysing documents or statistics, and watching people's behaviour. Sometimes a piece of research is called a 'study'.

The research process is set out below.

1. Ask a research question.
2. Design a method to help to answer the question.
3. Collect data (observations or results from trials or experiments).
4. Analyse the data.
5. Share the results (also known as 'outcomes').

There are two approaches to research.

- **Qualitative research** – this is used to explore and understand people's beliefs, experiences, attitudes or behaviour. Qualitative research asks questions about how and why. It might ask questions about why people want to stop smoking, but it won't ask how many people have tried to stop smoking. It does not collect data in the form of numbers. Qualitative researchers use methods like focus groups and telephone or face to-face interviews.
- **Quantitative research** – this is used to collect information in the form of numbers by counting or measuring things. This type of research might ask a question like how many people develop heart disease each year, or whether a new drug lowers blood pressure more than the drugs that are usually used. Quantitative researchers use methods like clinical trials and surveys. You can read more about clinical trials on page 21.

The results from both qualitative and quantitative research studies are written up and published in scientific and medical journals as papers or articles.

5b What type of research do you use in your guidelines?

There are four main types of study we use in our guidelines – systematic reviews, clinical trials, observational studies and diagnostic studies.

Systematic reviews

Systematic reviews bring together the results of all the studies that have been carried out around the world in a particular time frame (for example, 2005 to 2008). These studies will all look at a particular research question. We then combine the results to give a more complete picture of what the evidence says. Systematic reviews can also tell us about the quality of all the research that has been done.

The vital parts of a systematic review include:

- identifying research papers using clearly defined search methods;
- choosing research papers using clearly defined conditions for including and excluding information (for example, include studies which only look at people over the age of 18 or exclude studies which look at people with learning disabilities); and
- assessing research papers against methodological standards (you can read more about this in section 6c).

You may hear the term 'meta analysis' when you discuss research papers at SIGN. A meta analysis is a special type of systematic review that uses statistical methods to combine the results of two or more studies that considered the same research questions in the same way.

5c Clinical trials

5c1 What are clinical trials?

Clinical trials are studies done with groups of patients, which compare a new or different type of treatment either with no treatment (using a placebo – see section 12) or with the best treatment currently available. Testing against a placebo shows whether or not the treatment is effective. Testing against existing treatments also shows whether the new treatment is better than those that are currently used.

Clinical trials are used to test drugs and other types of health-care treatment (for example, surgery).

5c2 Types of clinical trials

Randomised controlled trial (RCT) – this compares two groups of people – an experimental group who receive the new treatment, and a control group who receive the usual treatment or a placebo. In an RCT, the decision about which group a person joins is random (that is, based on chance) and the analysis of the results is blinded. Blinding means that the people involved with the study should not know who is getting which treatment. This is important as often researchers accidentally let their own personal views influence the results. Researchers may be enthusiastic about a new treatment and may subconsciously record a better outcome for the patients who receive it. This problem can be avoided if researchers are not aware which treatment each group is receiving.

Observational studies – patients are put into groups by "exposure status" (for example, if they are a smoker or non-smoker) or "outcome status" (for example whether or not they have been diagnosed with cancer). With observational studies, researchers have no control over the exposure or outcome status (in this case for example, whether the patients are smokers or not) and they do not do anything to the patients. There are two types of observational studies as follows.

- *Cohort studies* – patients are put into groups by exposure status and followed up over a set period of time. Cohort studies may include a comparison or control group which will be chosen at the same time and followed up for the same time
- *Case control studies* – patients are put into groups by outcome status and researchers try to find out which factors are associated with that outcome

Diagnostic studies can be observational or experimental. The study aims to investigate the best way to diagnose a condition. The studies look at how well a test identifies a patient with the condition.

5d How are research studies identified?

There are many international databases of scientific and medical research results. These databases help researchers to search for and bring together studies that may be published in different or unexpected journals. The most widely used medical and scientific databases are as follows.

- MEDLINE – this is maintained by the National Library of Medicine in the United States and lists over 5000 journals.
- PubMed – this is a service provided by the National Library of Medicine in the United States. It includes over 17 million references from MEDLINE and other life science journals.
- Cochrane library – this is maintained by the Cochrane Collaboration, an international, independent organisation which produces systematic reviews of health care and promotes the search for evidence in the form of clinical trials and other studies.
- Embase – this focuses on drugs and clinical medicine, and has better European coverage than MEDLINE.
- Allied and Complementary Medicine (AMED) – this is produced by the British Library and covers a range of complementary and alternative medicine including homeopathy, chiropractic and so on.
- CINAHL – this is a nursing and health-related database that covers all aspects of nursing, health education, occupational therapy, social services and other related disciplines.
- PsycINFO – this is produced by the American Psychological Association and covers psychology, psychiatry and related subjects.

There are two ways to search for papers that summarise study results in a database.

- Using key words (for example, words in the title or abstract, authors' names, or where the research was done).
- Using medical subject headings (for example, heart disease).

Our information team uses these databases to search for papers that are relevant to the guideline. The members of the team are professionally trained to search scientific and medical databases. They write very detailed search strategies to identify the papers that are needed to develop a guideline.

6 Using research to develop guidelines

6a What if someone has already written a guideline in the same area?

Sometimes good-quality guidelines will have already been written in the area the new guideline will cover. The new guideline will refer to these existing guidelines and will try not to repeat work that has already been done. However, before we refer to any existing guidelines, we will make sure they have been developed using acceptable methods. Sometimes existing guidelines may not be directly relevant to patients in Scotland, or may have been developed using poor methods.

6b Identifying the research papers

Our information team are trained to use databases to search for medical and scientific research papers. They use 'key questions' to develop search strategies to search for relevant research papers. The search focuses on the best available evidence to consider each key question. Well-defined and clear key questions are vital in developing a successful guideline. The guideline development group have to be realistic about the number of key questions that can be answered in a single guideline. If the guideline development group set too many key questions, their workload can become too difficult to manage. Deciding what the key questions are is the responsibility of all the members of the guideline development group.

We design searches to look for:

- guidelines;
- meta analyses and systematic reviews;
- randomised controlled trials (RCTs);
- observational studies;
- diagnostic studies;
- economic studies; and
- qualitative studies.

To limit bias and to make sure all the relevant papers are covered, the literature search will use a range of sources. This will normally include the Cochrane library, Embase, MEDLINE, the internet and any other relevant databases.

The time period that the search will cover depends on the guideline topic. The guideline development group will decide this. Some searches may cover research from the past five to 10 years while others may go back further.

A typical search strategy will identify between 400 and 500 papers. These are presented in the form of abstracts that summarise the paper.

Before the guideline development group start to critically appraise the research papers, our information officer will take out any papers that are not clearly relevant. One or two members of the group, including the Chair, will look through the abstracts and reject other papers that do not meet the conditions the guideline development group agreed.

6c Reviewing the research papers

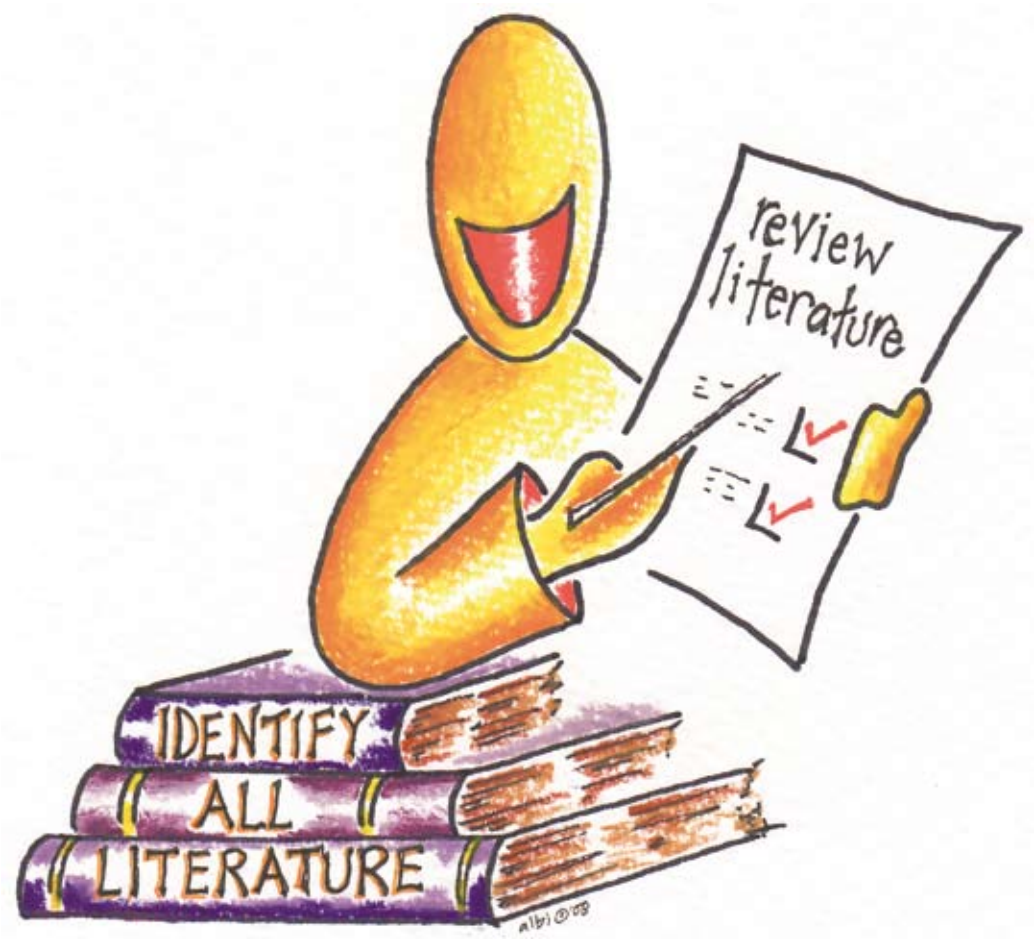
Once papers have been chosen as possible sources of evidence, the guideline development group will review the evidence and assess the study methods. This assessment is based on a number of questions in a checklist. The questions focus on the parts of the study's design that are known to have a significant influence on whether the results and conclusions are valid.

The questions will help you to make an informed judgement on the findings of the study and how they are relevant to clinical practice. For each question, there are notes that explain and expand on what is being assessed. These questions vary between the different types of study, and we have designed a range of checklists for each type. These kinds of checklists bring a degree of consistency to the appraisal process.

Reviewing the papers will usually take the group about 15 months. The results of this assessment will decide how much evidence is relevant, which in turn will influence the grade of the recommendation in the guideline. You can read more about grades of recommendations in section 8.

7 Practical tips for reviewing a paper

We have provided some practical tips to help you when you are reviewing research papers. If it would help to have more information about any of these tips, you can speak to the information officer on your guideline development group.



You should keep the following questions in mind when you review research papers.

7a What was the research question and why was the study needed?

The introduction to a research paper should give the background to the research and why the research is being done. The research question is the broad question that the research is trying to answer. If you cannot find the research question in the paper, it tends to suggest that the authors did not have a clear aim and that they may not have designed the study very well.

How was the study done and was the design appropriate to the question? Some studies follow patients up over a period of time – these are known as 'prospective studies'. Others trace what happened to people in the past and are known as 'retrospective studies'.

What type of study should have been used depends on the research question. Below are some examples with the research question in bold.

- **How many breast cancer patients die each year?** This question is best answered by a survey as we are interested in numbers of patients.
- **Is cigarette smoking dangerous?** This question is best answered by a cohort study where two or more groups are chosen based on how exposed they are to cigarette smoke, and are followed up over a period of time to see what the outcome is.
- **Does hormone replacement therapy (HRT) improve bone density?** The question we are asking is does it work? This is best answered by a randomised controlled trial where patients are randomly given either HRT or a placebo. Patients in both groups are followed up and analysed in terms of specific outcomes, such as an improvement in bone density.
- **Does living under a power line increase your chance of developing cancer?** This is best answered by a case-control study where people with a particular disease or condition are identified and 'matched' with controls (patients who live in an area free from power lines). In this case, data would be collected on how exposed people have been in the past to possible causes of cancer.

7b Assessing the quality of the study

Can we trust all published studies?

It is important to remember that just because a research paper has been published in a journal, it doesn't mean that we can trust it. Published studies may still have a number of flaws. This is why it is important that all studies used in our guidelines are critically appraised first.

Who is the study about?

You want to make sure that the study has included the groups of people you are interested in. You should ask yourself the following questions.

- **How were the people who took part in the study recruited?** If you wanted to find out patients' preferences for a treatment, you could put an advert in the local paper. However, this would introduce bias as only the people who were motivated to take part and read papers would do so. It would be better to issue a questionnaire to every user who visited their GP that day.
- **Who was included and excluded in the study?** Some trials in the UK exclude patients who already have an illness or who do not speak English. This can introduce bias. The results of a drugs trial done with young healthy males may not apply to elderly females.

Did the study limit bias as much as possible?

Bias is anything which influences the conclusions of a study and affects how the groups in the study are compared. To help limit bias, in all types of studies, (RCT, cohort study or a case-control study), the groups being compared should be as like one another as possible.

Was the assessment blind?

Blinding means that the people involved in the study do not know who is getting which treatment.

- If patients knew, they might overestimate how much better they feel.
- If investigators knew, they might overestimate the effect of the medicine.

Did the study look at statistical questions first?

Understanding statistics is a challenge for most guideline group members. It may help to consider the following two areas when you review papers.

1. **The size of the sample** – the trial should be big enough to have a high chance of detecting any statistically worthwhile effect and be sure that no benefit really exists if it is not shown in the trial.
2. **How long the study will follow up the people who took part –** a study must take place for a long enough period of time for the effect of the treatment to be reflected in the outcomes. If researchers were looking at the effects of a new painkiller used after operations, they may only need a follow-up period of 48 hours. If they were looking at how nutritional supplements taken by pre-school children affected their final height as adults, the researchers would need to follow up the people who took part for a number of decades.

Once you have asked yourself these questions, you should be able to tell:

- what sort of study it was;
- how many people were involved in the study;
- where these people came from;
- what type of treatment was offered;
- how long the follow-up period was; and
- what methods were used to measure the outcomes of the study.

If you are clear about these things before you read the rest of the paper, the results will be easier to understand. It will also help you decide if the paper can be used in the guideline or whether it is not good enough and you should reject it.

If you are interested, the following books can explain more about critical appraisal.

Greenhalgh, T, 'How to read a paper: the basics of evidence-based medicine', Oxford: Blackwell Publishing, 2006.

Crombie, I, 'The pocket guide to critical appraisal', BMJ Publishing Group, 2003

8 Making recommendations in guidelines

8a Looking at the evidence

If you have looked at any of our guidelines, you will have noticed that the recommendations have letters next to them. We use the letters A to D to grade the recommendations according to the strength of the evidence. The guideline group grade the recommendations based on their assessment of the design and quality of each study (annex 5 shows you the different studies and grades), as well as whether the study was consistent and relevant and whether the evidence was valid. The aim is to make a recommendation that is based on the evidence, but also relevant to the way in which health care is provided in Scotland.

You will also be involved in assessing whether the draft recommendations:

- are sensitively worded;
- consider the treatments and outcomes that are important from the patients' and carers' perspectives;
- take account of patients' and carers' preferences; and
- consider the needs of relevant groups of patients (for example, ethnic minorities).

The grading does not relate to the clinical importance of the recommendation, but to the strength of the supporting evidence. The grading of a recommendation shows users how likely it will be that the predicted outcome will be achieved if the recommendation is put into practice.

SIGN Executive staff produce evidence tables based on the quality assessments of individual studies provided by members of the guideline development group. Evidence tables summarise all the validated studies identified from the systematic 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 measured.

8b Considered judgement

It is rare for the evidence to show clearly what course of action should be recommended for any key question. It may not always be clear to people who were not involved in the decision-making process how guideline developers came to their recommendations, given the evidence they had to base them on. To tackle this problem, we introduced the idea of 'considered judgement'.

Under the heading of considered judgment, guideline development groups give a summary of all of the evidence covered by each evidence table. This summary should cover the following.

- The amount and quality of the evidence, and whether it is consistent.
- Whether the findings of the study carried out on a sample of people can be applied to the wider population.
- Whether the evidence can be applied directly to the people the guideline is aimed at.
- The effects of the evidence on these people, and the resources needed to treat them.
- Patient issues.
- How practical it would be for the NHS in Scotland to put the recommendation into practice.

Guideline development groups will be given a form to record the main points of their considered judgement. Once the groups have considered these issues, they will summarise their view of the evidence and give it a level (see section 8c) before they go on to grade the recommendation.

8c Levels of evidence

Annex 5 shows the grading system we use.

The 'level of evidence' tells you how likely it is that the conclusions of a research paper are true. All members of the guideline development group who reviewed the evidence for that specific question should be involved in giving the evidence a level. If the guideline development group cannot agree on a level, the members should keep a formal record of this and the reasons for why they cannot come to an agreement.

The level of evidence corresponds to the design of the study and how well it was carried out. Systematic reviews of randomised controlled trials (RCTs) and well-designed randomised controlled trials are the highest level, followed by observational studies such as cohort and case-control studies Case studies and personal opinion are the lowest level.

Our grading system places a lot of importance on the quality of the evidence that supports each recommendation. It emphasises that a recommendation should be graded according to the evidence as a whole, and should not rely on a single study. It also allows more importance to be placed on recommendations that are supported by good-quality observational studies if RCTs are not possible for practical or ethical reasons. Through the considered-judgment process, the members of the guideline development group can also lower a recommendation's grade if:

- they do not think the findings of the study can be applied to the wider population;
- the evidence cannot be directly applied to the people the guideline is aimed at; or
- they think the evidence is weaker than a simple assessment of the study methods would suggest.

8c1 What happens if there is no evidence for something that the group feels is important?

Sometimes, guideline development groups find there is an important practical point that they want to emphasise but there is no evidence to support it (for example, if a specific kind of treatment is considered to be such strong clinical practice that no-one is likely to formally study it, and so no evidence has been published). Points like this are shown 'good practice points' and are marked with a tick. These are not a substitute for evidence-based recommendations, and should only be used if there is no other way to highlight an issue.

9 Consultation and peer reviews

9a National open meetings

Once the guideline development group has reviewed the evidence, it will prepare a draft guideline containing draft recommendations. We will then hold a national open meeting to discuss the draft. At this meeting, the guideline development group discuss their draft guideline with doctors, nurses, physiotherapists, GPs and other NHS staff, and ask for feedback.

We usually write to voluntary organisations and charities well beforehand to tell them about our national open meeting. We ask them to invite patients and carers to attend the meeting and to comment on the draft document.

Our national open meetings are widely advertised, and between 150 and 300 health-care professionals and representatives usually attend. For people who are not able to attend the meeting, we will put the draft guideline on our website for four weeks and provide a way for them to make any comments.

After the national open meeting, the guideline development group meet to discuss the comments made and to make any changes to the guideline.

9b Peer reviews

All our guidelines are independently reviewed by other health-care staff, academic experts and members of the public before they are published. This is known as the peer review process. We ask peer reviewers to comment on the guideline, particularly:

- the way the guideline development group has interpreted the evidence;
- whether the recommendations are clear and easy to understand;
- whether the guideline is useful; and
- whether the guideline reflects patients' and carers' views.

We also ask the peer reviewers to suggest improvements to the guidelines.

We invite patient organisations to take part in the peer review process. We have produced specific guidance for members of these organisations and put this on our website at www.sign.ac.uk/pdf/patientpeerreviewleaflet.pdf. It is important that we hear the views of patients and carers at this stage, especially if an organisation has concerns about any of the recommendations in the draft guideline.

We put all the comments we receive from peer reviewers into a report, which the guideline development group will then discuss. The group will consider each point and change the guideline if it is appropriate to do so. If it does not make any changes, we will record the reasons for this.

As a final check, the SIGN Editorial Group will review the guideline and a summary of peer reviewers' comments to make sure that we have considered each point the peer reviewers made. Once the guideline has been checked, we will publish it and give it to all relevant NHS staff and voluntary organisations in Scotland.

9c What do patient organisations and other public representatives comment on?

9c1 Language

Although we write our guidelines for health professionals, we aim to make them available to as many other people as possible. When patient organisations and other public representatives review the guidelines, we ask them to consider the following.

- Our overall use of jargon, and whether there are any terms they do not understand.
- Whether we can explain anything more clearly or more briefly.
- The tone of the guideline, particularly in the 'Provision of information' section (see section 9c2).
- If they can, suggest plain, non-technical wording to help health professionals explain areas of the guideline to patients.

9c2 'Provision of information'

Each guideline contains a section called 'Provision of information'. This used to be called 'Information for discussion with patients and carers'. This section is designed for health professionals to use when they discuss a condition with patients and carers. It is not meant to be detailed educational material designed for patients. We particularly ask public representatives to comment on this section and make a note of the following.

- Whether there is any jargon or technical terms that we need to explain.
- The tone of this section.
- Whether the wording deals with the condition sensitively.
- Whether the information is useful for patients and carers.

10 Presentation

10a Format

We aim to write our guidelines in clear language and to define all terms precisely.

Each guideline includes an introduction, which explains:

- why the guideline is needed, including evidence of any changes in normal practice (if this applies); and
- what the guideline aims to do, and who it is aimed at.

The structure of the main part of the guideline should reflect the development process that the guideline development group has followed. Each guideline has:

- a clear statement of the question or issue that has been considered;
- a brief explanation of the treatment options available;
- a summary of the conclusions drawn from the critical appraisal of the evidence;
- the recommendations that the group has made from this evidence (graded according to the strength of the supporting evidence);
- a brief discussion of any practical points (for example, how the recommendations affect resources, or whether there are geographical issues to consider);
- good-practice points if the group feels it is important to give guidance on areas where there is a lack of evidence;
- key points to assess how the service performs against the guideline recommendations;
- recommendations for further research;
- a 'Provision of information' section; and
- brief details of the search strategy and databases used.

Having a well developed and defined template for presenting the final guideline can make the development process a lot easier, as it allows the guideline development group to plan, at the beginning of the process, what type of information will be needed and what format the guideline will use. By following the process set out in this handbook, the guideline development group will find that most of the information needed will be produced in a structured, easy-to-access format which can be slotted into the guideline structure.

10a1 Information for patients and carers

All our guidelines include a 'provision of information' section. This section highlights the areas where patients and their families are most likely to need information to help them understand and cope with the diagnosis, treatment options and possible outcomes. This section is aimed at health-care professionals.

10b Different versions of guidelines

We produce:

- the full guideline, which contains the guideline group's recommendations, details of how they were developed, and information about the evidence they were based on;
- a quick-reference guide, which is a summary of the main recommendations and other information; and
- a patient version, which explains the guideline's recommendations in a way that patients, carers and members of the public can understand.

All our guidelines, quick-reference guides and patient versions are available free of charge on our website. We make our guidelines as widely available as possible to make it easier for the recommendations to be put into practice. The local distribution co-ordinators in each NHS board are responsible for organising how our guidelines are distributed throughout NHS Scotland. We also send copies to relevant patient organisations.

10b1 Patient versions of our guidelines

We have started to produce versions of the clinical guidelines for patients and carers. These booklets include:

- a brief summary of the condition;
- a summary of tests, treatments and procedures we recommend; and
- details on where patients and their families can find more information about the conditions.

We normally start work on these booklets when the guideline is at the peer review stage. We invite members of the guideline development group to give their views on the structure and content of the patient version and help us translate clinical terms into language which is easy to understand. We also encourage patient and carer representatives to get involved, particularly by telling us whether the information is suitable for the people it is aimed at.

11 Putting the guideline's recommendations into practice

We expect NHS organisations such as hospitals, general practices and NHS boards to follow the recommendations made in our guidelines. The guidelines provide an opportunity for medical staff to improve their decision-making and teamworking, expand their evidence-based knowledge, and make sure their practices are consistent.

Our guideline distribution policy encourages NHS boards to take responsibility for making the guidelines available locally. We use the media to publicise guidelines if this is appropriate. Members of the SIGN Council are also involved in promoting guidelines.

11a Can patient organisations help?

Patient and carer organisations can use their networks and influence to publicise the guideline, and encourage and support other local and national organisations to put the recommendations into practice. They can do this by:

- publicising the guideline on their website and in the information they send out to members;
- including the main messages from the guideline in leaflets and other material for patients and carers; and
- working with NHS organisations (such as community health partnerships), health-care professionals and other patient representatives to help put the recommendations into practice at a local level.

11b When do you review the guidelines?

Three years after a guideline has been published, we will look again at the evidence which was used to make the recommendations.

We prepare a review report for all guidelines which are due to be reviewed. This report summarises any new evidence, the effects of the original guideline, and any changes in the medical field or new treatments. We give the report to the SIGN Council and other relevant health-care professionals and organisations, and gather feedback to consider as part of the review.

Reviewing a guideline is a good opportunity to reconsider the guideline's original aims, and we ask experts if the aims of the guideline are still appropriate or whether they should be widened or narrowed. After this consultation, the guideline programme advisory group makes a decision about the need for a review. There are four options at this stage.

- Carry out a full review of the guideline
- Choose parts of the guideline to update
- Make changes to the guideline's aims
- Confirm that the guideline has achieved its purpose or that it is no longer relevant and should be withdrawn

If we receive any comments about published guidelines, or if information on important new evidence in the field becomes available before the review is due, we will pass this to the guideline development group, either for the members to make an immediate response or to consider whether to review the guideline. If the guideline needs to be updated before it is reviewed, we will report this on our website.

12 Glossary

We have provided a glossary to help you:

- understand some of the terms we have used in this handbook; and
- become familiar with terms you may hear in guideline development group meetings.

Term	Definition
Abstract	A brief summary of a research study. It should tell you why the study was done, how the researchers went about it and what they found.
Analysis	An analysis of data involves examining and processing research data to answer the questions that the project is trying to consider. It involves identifying patterns and finding the main themes, and is often done with special computer software.
Carer	A relative, friend or partner who provides (or plans to provide, or used to provide) a significant amount of care to another person on a regular basis, but not necessarily through living with them.
Causal relationship	A causal relationship develops when an intervention causes a change in an outcome. For example, you are a smoker and you only walk to the local shop each morning. You are very breathless and quit smoking and start to take longer walks. You start to feel much better, less breathless and are able to walk further. You would probably conclude that giving up smoking has caused the change. There is clearly an association between the two. A researcher however, would question this. You might have had an undiagnosed chest infection which was causing the breathlessness, you might have changed your diet or the air quality in your area may have improved. These are known as confounding variables.

Clinical research	Clinical research aims to find out the cause of human illness and how it can be treated or prevented. This type of research is based on examining and observing people with different conditions and sometimes comparing them with healthy people. It can also involve research on samples of blood or other tissues, or tests such as scans or X-rays. Clinical researchers will also sometimes analyse the information in patients' records or the data from health and lifestyle surveys.
Clinical trial	A research study which compares a new or different type of treatment with the best treatment currently available, or against a placebo. They test whether a new or different treatment is effective and any better than what already exists. No matter how promising a new treatment may appear during tests in a laboratory, it must go through clinical trials before its benefits and risks can really be known.
Concealment method	The process used to make sure that the researcher entering a person into a clinical trial does not know whether the person will be getting the new treatment being tested or a placebo. In other words, the method used to decide which patients get which treatment must be hidden ('concealed') from the investigators. It must be impossible for investigators to guess who is getting which treatment.

Confidentiality	During a research project, the researchers must put data-protection measures in place to make sure that all the information collected about the people who are taking part in the study is kept confidential. Researchers must get these people's permission, in writing, before they look at their medical or social-care records. Any information that might identify the people in the study cannot be used or passed on without those people's permission. For example, when researchers publish the results of a project, they are not allowed to include people's names. This confidentiality will only be broken in extreme circumstances – that is, if it is: • vital for the person's care, treatment or safety; • needed under a court order (for example, in a criminal investigation); or • necessary to protect the public.
Confounding variable	This an extra factor that hasn't been taken into account that can affect the outcome of a study. If researchers do not account for confounding variables, this could mean their study is neither valid nor reliable. For example, a study might examine the association between a vegetarian diet and the risk of heart disease. Confounding variables would be other factors that can influence the risk of heart disease, such as exercise, family history, and smoking. The study could not reliably estimate the association between being vegetarian and suffering from heart disease unless it took these other factors into account.
Consultation	Consultation involves asking people not directly involved in the research, for example, members of the public, for their views, and then using those views to help make an informed decision. Consultation can be about any part of the research process – from identifying topics for research through to thinking about the effects of the research findings. Having a better understanding of people's views should lead to better decisions.

Control group	In a clinical trial, a control group is generally a group which does not receive any kind of treatment. This group will be compared with the experimental group to study the effects of the intervention.
Data	Information collected through research. It can include written information, numbers, sounds and pictures. It is usually stored on computer, so that it can be analysed, interpreted and then given to other people (for example, in reports, graphs or diagrams).
Data protection	All personal information is protected in the UK by the Data Protection Act (1998). Researchers have to put all necessary measures in place to protect the confidentiality of the information they collect about the people who are taking part in the research. They should use the patients' information sheet to explain: • how the data will be collected; • how it will be stored securely; • what it will be used for; • who will have access to the data that identifies the people who are taking part in the study; • how long it will be kept; and • how it will be destroyed securely.
Dissemination	Dissemination involves making the findings of, for example, a research project available to a wide range of people who might find it useful. This can be done through: • producing reports (often these are made available on the internet); • publishing articles in journals or newsletters; • issuing press releases; or • giving talks at conferences. It is also important to make research findings available to the people who took part in the study.
Effect size	The amount of change created by an intervention, especially in an experimental study.

Empowerment	This is the process by which people gain the knowledge, skills and resources they need to be able to take control over decisions and resources. It often involves people becoming more confident in their own strengths and abilities. It does not always mean people take control over all decisions or all resources.
Evaluation	This involves assessing whether an intervention (for example, a treatment, service, project or programme) is achieving its aims. A project can be evaluated as it goes along or right at the end. It can measure how well the project is being carried out as well as its effects. The results of evaluations can help with decision-making and planning.
Evidence base	A collection of all the research data currently available about a health-care or social-care topic, such as how well a treatment or a service works. Health-care and social-care professionals use this evidence to make decisions about the services they provide and what care or treatment to offer people who use their services.
Exclusion criteria	Exclusion criteria are used to decide, for example, who won't be able to take part in a clinical trial. In many trials, women who are pregnant or planning to become pregnant may be excluded to avoid any possible danger to the baby.
Experimental group	A group of patients taking part in a scientific study who receive a treatment or procedure and who are then compared to a control group.
Experts by experience	Service users and carers who are experts through their experience of illness or disability and services.
Extrapolated evidence	If there is evidence from a clinical trial about the effect of a drug in a Japanese population, but no evidence about the effect of the same drug in a Scottish population, then the guideline group might 'extrapolate' from the Japanese evidence about what might happen in Scottish patients. This is sometimes called 'indirect evidence' and guideline development groups will place less importance on this type of evidence.

Focus group	A small group of people brought together to talk. The purpose is to listen and gather information. It is a good way to find out how people feel or think about an issue, or to come up with possible solutions to problems.
Generalisability	Whether research findings and conclusions from a study carried out on a sample of people can be applied to the wider population.
Grey literature	Material that is less formal than a research paper in a journal or a chapter in a book. It includes internal reports, committee minutes, conference papers, fact sheets, newsletters and campaigning material. 'Grey literature' does not usually go through the peer review process but we may make it available for peer reviews if we are asked to. This material is becoming more and more widely available on the internet.
Guidelines	Statements to help healthcare staff and patients make decisions about appropriate health care for specific circumstances.
Hypothesis	An unproven theory that can be tested through research.
Implementation	Implementation is about putting research findings into practice. This means using research findings to make appropriate decisions and changes to health-care and social-care policies and practice.
Inclusion criteria	Inclusion criteria help researchers decide, for example, who can take part in a clinical trial. Some trials only include people who are a certain age or at a particular stage of their illness.
Intervention	Something that aims to make a change and is tested through research. For example, giving a drug, providing a counselling service, improving the environment or giving people information and training are all described as interventions.

Interview	In research, an interview is a conversation between two or more people, where a researcher asks questions to get information from the person (or people) being interviewed. Interviews can be carried out in person or over the phone.
Journal	A regular publication in which researchers formally report the results of their research to people who share a similar interest or experience. Each journal usually specialises in one particular topic area. A research paper must go through the peer review process before it can be published. The British Medical Journal, British Journal of Social Work and The Lancet are examples of journals.
Lay (lay person)	The term 'lay' means non-professional. In research, it refers to people who are neither academic researchers nor health-care or social-care professionals.
Lay summary	A brief summary of, for example, a research project or a research proposal that has been written for members for the public, rather than researchers or professionals. It should be written in plain English, avoid using jargon and explain any technical terms that have been included.
Literature review	A review of published research in a particular area. Published research is often referred to as 'the literature'.
Members of the public	We use this term to cover: • patients and potential patients; • people who use health-care and social-care services; • unpaid carers; • disabled people; • people who may be involved in health promotions programmes, public-health programmes or social-service interventions; and • organisations that represent people who use services.
Meta analysis	A systematic review that uses statistical methods to combine the results of two or more studies that considered the same research questions.

Methodology	The techniques or processes that have been used to complete a piece of research. In other words, how information is collected and analysed.
Participant (or subject)	Someone who takes part in a research project or trial. Sometimes participants are referred to as 'subjects'.
Patient involvement	Involving patients, carers and their representatives in their own care, and in planning, monitoring and developing health services. Patients and carers may have different views to health-care professionals about getting the most from the NHS.
Peer review	Where a research proposal or report (such as a journal article) is read and commented on by people who have similar interests and expertise to the people who wrote the proposal or report. Peer reviewers might be members of the public, researchers, or other professionals. Peer reviews help to check the quality of a report or research proposal.
Placebo	A treatment that is harmless and ineffective. It allows researchers to test for the 'placebo effect'. It is given to allow researchers to compare its effect with those of a real drug or other intervention. The placebo effect is a psychological response where people feel better because they have received a treatment, and not because the treatment itself has a specific effect on their condition. By comparing responses to the placebo and to the treatment being tested, researchers can tell whether the treatment is having any real benefit.
Probability	The chances or risks of something happening (for example, the chance of throwing a six with a dice is one in six). Probability is usually described using decimal fractions, where one in six will become 0.167. Probabilities range between 0.0 and 1.0, where zero means an event will never happen and 1.0 means it is certain to happen.

Qualitative research	Qualitative research is used to explore and understand people's experiences, attitudes or behaviours. It asks questions about how and why. Qualitative research might ask questions about why people want to stop smoking. It won't ask how many people have tried to stop smoking. It does not collect data in the form of numbers. Qualitative researchers use methods like focus groups and telephone and face-to-face interviews.
Quantitative research	Where researchers collect data in the form of numbers (in other words, they measure things or count things). Quantitative research might ask a question like how many people visit their GP each year, what percentage of children have had an MMR vaccine, or whether a new drug lowers blood pressure more than the drugs that are currently used. Quantitative researchers use methods like surveys and clinical trials.
Questionnaire	A prepared set of written questions used to gather information from research participants. Questionnaires can be filled in on paper, using a computer, or with an interviewer.
Reliability	Whether the use of a measure, procedure or instrutment gives the same result in repeated trials.
Randomised controlled trial (RCT)	A controlled trial compares two groups of people – an experimental group who receive the new treatment, and a control group who receive the usual treatment or a placebo. Using a control group allows the researchers to see whether the treatment they are testing is any more or less effective than the usual or standard treatment, or no treatment. In a randomised controlled trial, the decision about which group a person joins is random (that is, based on chance). For example, a computer will decide rather than the researcher or the participant. Having a random selection makes sure that the two groups are as similar as possible, except for the treatment they receive. This is important because it means that the researcher can be sure that any differences between the groups are only due to the treatment.

Representative	Someone who is representing a wider group of people (for example, the public or a patient support group). If you've been asked to get involved as a representative of a particular group, you may want to think about how you can be confident that you are representing a wider range of people's views, rather than just offering your own perspective.
Research	Carrying out experiments, trials, or other studies to find out new information that could lead to changes to treatments, policies or care.
Research methods	The ways researchers collect and analyse information. These include interviews, questionnaires, diaries, clinical trials, experiments, analysing documents or statistics, or watching people's behaviour.
Research proposal	Usually an application form or set of papers that researchers fill in to explain what research they want to do and how they want to do it. It will also cover who will be involved (both as participants and in carrying out the research), the timescale and the cost.
Service user (or user)	Someone who uses or has used health-care or social-care services (or both) because they have an illness or a disability.
Statistics and statistical analysis	Statistics is the manipulation of numbers (quantitative data) collected through research (for example, the average age of a group of people, or the number of people who use a service). Statistical analysis uses a set of mathematical rules to analyse quantitative data. It can help researchers decide what data means. For example, statistical analysis can assess whether any difference seen between two groups of people (for example, between the groups of people in a clinical trial) is a reliable finding or simply due to chance.

Systematic review	A systematic review brings together the results of all the studies about a particular research question that have been carried out around the world in a set time frame (for example, 2005 to 2008). They provide a detailed and unbiased summary of the research. For example, a single clinical trial may not give a clear answer about the effectiveness of a treatment because the difference between the treatments being tested was very small, or because only a small number of people took part in the trial. Systematic reviews are used to bring together the results of similar trials and assess the quality of the combined evidence. Combining the results from a number of trials may give a clearer picture.
Validity	Whether the results of a study are likely to be true and free from bias.
Variable	Characteristics that vary among and between people and that can be observed and measured. Studies normally try to concentrate on a single variable and how it changes in response to an intervention. Variables include age, gender, smoking status, and test results.

References

Greenhalgh, T, 'How to read a paper: the basics of evidence-based medicine', Oxford: Blackwell Publishing, 2006.

Crombie, I, 'The pocket guide to critical appraisal', BMJ Publishing Group, 2003.

INVOLVE, 'How to get actively involved in NHS, public health and social care research: jargon buster', 2007.

The Cochrane Collaboration, 'Glossary of terms in the Cochrane Collaboration' Version 4.2.5, updated May 2005

Annex 1
Scottish Intercollegiate Guidelines Network Policy on Declaration of Competing Interests

SIGN is committed to open declaration of competing interests in all its activities.

Accordingly, all persons involved in the development of SIGN guidelines are requested to declare all competing interests on the enclosed form, to be returned to the Director via the Executive Secretary to SIGN Council at the SIGN Executive within one month of receipt. (The Director is the equivalent of the Standards Officer, defined in the Clinical Standards in Public Life, Note of Registers of Interest for Devolved Public Bodies1 as the employee of a devolved public body who is appointed by the body to set up, maintain and make available for public inspection the register of interests.)

Competing interests are defined as any interest of the person, their partners or close relatives **(personal)** or their department/employer/business **(non-personal)** which may potentially influence the content, including recommendations, of SIGN guidelines. For clarity, the interest of partners or close relatives is restricted to employment in, or share holdings in, healthcare organisations.

Competing interests include financial and non-financial interests.

Financial interests include:-

- Any gifts or hospitality received
- Remuneration from being
  - Employed or self-employed (including all consultancies or other fee paid work commissioned by commercial healthcare organisations)
  - The holder of an office
  - The director of an undertaking
  - A partner in a firm
  - Involved in undertaking a trade, profession, vocation or any other work

- Any allowance received in relation to membership of any organisation
- The name (and registered name if different) of any applicable employer, self-employment, partners, undertaking or organisation
- The nature and regularity of the work that is remunerated
- The name of the directorship and the nature of the applicable business
- A description (but not the value) of shares or securities in a company, undertaking or organisation that may be significant to, of relevance to, or bear upon, the work or operation of SIGN (ie all bodies involved in health care).

Non-financial interests include:-

- A description of such interests as may be significant to, of relevance to, or bear upon, the work or operation of SIGN, including without prejudice to that generality membership of or office in:-
  - Other public bodies
  - Clubs, societies and organisations
  - Trades unions; and
  - Voluntary organisations.

Competing interests may be specific or non-specific. **Specific interests** are those relevant to the topic/remit of an individual SIGN guideline. **Non-specific interests** are other interests, which are still relevant to the work of SIGN.

The relevant time period for declaration of interests is the year prior to the declaration, and the year following the declaration.

Declaration of interest forms will be circulated as follows:-

- SIGN Council members (on appointment or annual request 1 December, return by 31 January)
- SIGN Executive members (on appointment or annual request 1 December, return by 31 January)
- All co-opted members to SIGN subcommittees and national open meetings
- All Guideline Development Group (GDG) members

  - At start of guideline development
  - Annually as above
  - At time of circulation of final draft
- All peer reviewers (at time of letter of invitation)
- Advisors to SIGN (annually as above)
- All who submit proposals to SIGN.

If, during the course of any SIGN meeting, an individual becomes aware of a potential competing interest this should be declared **at that time**. This includes members of the audience who make comments from the floor during open meetings.

Written declarations of competing interests will be monitored by **chairs** of meetings of:

- SIGN Council
- SIGN Executive Senior Management Team
- SIGN Subcommittees
- Strategy Group
- Guideline Programme Advisory Group
- Methodology Group
- GDG meetings.

Written declarations of competing interests for speakers at National Open Meetings will be monitored by the relevant Programme Manager.

Where the level of declared interest could be seen to limit the independence of the individual, such individuals will not chair any SIGN meetings. Eligibility for GDG membership or peer review will be considered by the SIGN Senior Management Team on the basis of balance of risks and benefits and availability of alternative members or reviewers.

The SIGN Director will hold all declarations of competing interests. These are available for public inspection at the SIGN office upon written request at all reasonable hours and without charge. This policy will be regularly reviewed and audited by the SIGN Strategy Group.

1 Ethical Standards in Public Life (Scotland) Act 2000. Codes of Conduct for Board Members. Annex (available on www.scotland.gov.uk)

Annex 2
Register of Interests

Having read the attached SIGN Policy on Declaration of Competing Interests I declare the following competing interests for the previous year, and the following year. I understand that this declaration will be retained by the SIGN Director for three years, and made available for public inspection at the SIGN Executive.

Signature:

Name: Jane Smith

Relationship to SIGN: Patient Representative on:

Personal Interests				
Remuneration from Employment				
	Name of Employer and Post held	Nature of Business	Self or partner/ relative	Specific?
Details of Employment held which may be significant to, or relevant to, or bear upon the work of SIGN	N/A			
Remuneration from self employment				
	Name of Business	Nature of Business	Self or partner / relative	Specific?
Details of self employment held which may be significant to, or relevant to, or bear upon the work of SIGN	N/A			

Remuneration as holder of paid office				
	Nature of Office held	Organisation	Self or partner/ relative	Specific?
Details of office held which may be significant to, or relevant to, or bear upon the work of SIGN	N/A			
Remuneration as a Director of an Undertaking				
	Name of Undertaking	Nature of Business	Self or partner/ relative	Specific?
Details of directorship held which may be significant to, or relevant to, or bear upon the work of SIGN	N/A			
Remuneration as a Partner in a Firm				
	Name of Partnership	Nature of Business	Self or partner/ relative	Specific?
Details of Partnership held which may be significant to, or relevant to, or bear upon the work of SIGN	N/A			
Shares and Securities				
	Description of organisation	Description of nature of holding (value need not be disclosed)	Self or partner/ relative	Specific?
Details of interests in shares and securities in commercial healthcare companies, organisations and undertakings	N/A			

Remuneration from consultancy or other fee paid work commissioned by, or gifts from, commercial healthcare companies, organisations and undertakings				
	Nature of work	For whom undertaken and frequency	Self or partner/ relative	Specific?
Details of consultancy or other fee paid work which may be significant to, or relevant to, or bear upon the work of SIGN Details of gifts which may be significant to, or relevant to, or bear upon the work of SIGN	N/A			

Non-Financial Interests				
	Description of interest		Self or partner/ relative	Specific?
Details of non-financial interests which may be significant to, or relevant to, or bear upon the work of SIGN	Member of Cancer UK		Self	Utilize the information and emotional support provided by Cancer UK

Non Personal interests				
	Name of company, organisation or undertaking		Nature of interest	
Details of non-personal support from commercial healthcare companies, organisations or undertakings				

Please return to:
Lesley Forsyth, Executive Secretary to SIGN Council, SIGN,
Elliott House, 8-10 Hillside Crescent, Edinburgh, EH7 5EA

Date received at SIGN:

Annex 3
Confidentiality Agreement

Confidentiality Agreement between

Jane Smith
and
Scottish Intercollegiate Guidelines Network

SIGN, Elliott House
8-10 Hillside Crescent, Edinburgh EH7 5EA

EXPLANATION OF THE CONFIDENTIALITY UNDERTAKING

Anyone who may have access to confidential information in the course of his or her involvement with the Scottish Intercollegiate Guidelines Network (SIGN) is required to enter into a Confidentially Undertaking in a standard form. The intent of this document is to clearly advise the recipient of such information of their obligation to keep such information confidential and to advise of the consequences of a failure to comply with this obligation.

To summarise the Undertaking, anyone in receipt of confidential information (in any form) must not disclose that information to a third party unless such disclosure is for the purpose set out in clause 2. If a breach of this obligation leads to a claim against SIGN or to a loss or expense being suffered by SIGN, the individual concerned may be personally liable for that claim, loss or expense in terms of Clause 3.

EXAMPLES OF THE EFFECT OF THE CONFIDENTIALITY UNDERTAKING

- An individual working on a SIGN guideline development group will be bound by the Confidentiality Undertaking in respect of the contents of a draft guideline, its evidence tables, checklists and considered judgement proformas until the date of the National Meeting for the guideline development group, at which time the material will be available in the public domain and therefore no longer covered under Clause 2. Further revisions, which will not be publicly available, are subject to the Undertaking.

- The names, designations, details and roles of individuals working on guideline development groups will be subject to the Confidentiality Undertaking and may not be disclosed until such time as they become publicly announced by SIGN.

- Discussions conducted during meetings which are convened by SIGN in order to further the development of a guideline are bound by the Confidentiality Undertaking and may not be disclosed to a third party, notwithstanding the exclusions listed in Clause 2.

CONFIDENT IALITY UNDERTAKING by Jane Smith

Considering that the Recipient is to participate in an assessment in respect of Management Lung Cancer being carried out by the Scottish Intercollegiate Guidelines Network (SIGN), and further considering that as a result of this participation the Recipient may obtain or have access to Confidential Information (whether written, oral or otherwise).

Now, therefore, the recipient does hereby undertake and confirm that the Recipient shall at all times preserve complete confidentiality in relation to any such information acquired by the Recipient and that subject to the following conditions:

1. INTERPRETATION

For the purposes of this Undertaking, the term "Confidential Information" means any and all information which is now or at any time hereinafter in the possession of SIGN and to which the Recipient may have access, including without limitation, guideline text, data, formulae, processes, designs, photographs, drawings, specifications, software and samples and any other such material whether disclosed in writing or verbally and which SIGN has designated as confidential.

2. SCOPE

Confidential Information may be revealed to employees of the Recipient but only to the extent that it is necessary to further communications with SIGN or to carry out work for SIGN. The Recipient will bind such employees to keep such information confidential both during and after their current employment and will take all appropriate steps to enforce the obligations for such employees in relation thereto.

This Undertaking shall not apply to information which is:

- At the date hereof in the public domain or subsequently comes into the public domain through no fault of the Recipient;
- Proved to be already known to the Recipient at the date of disclosure;
- Otherwise properly and publicly available to the Recipient.

3. INDEMNITY

The Recipient shall indemnify and keep indemnified SIGN, its servants and agents against all claims, actions, losses, damages, costs, and expenses which may be brought against or incurred or suffered by SIGN, its servants or agents in connection with the Confidential Information if the same are directly or indirectly attributable to the actions, omissions, neglect or fault of the Recipient or any person for whom the Recipient is responsible at law.

4. GOVERNING LAW

The construction, validity and performance of this Agreement shall be governed by the Law of Scotland.

Place of Execution.....	Place of Execution .....
Date	Date.....
Signed by	Signed by.....
Print Name	Print Name .....
The Recipient	Witness.....

Annex 4
Expenses Form

BLUE PAPER

SIGN Executive
Elliot House, 8-10 Hillside Crescent, Edinburgh, EH7 5EA (T) 0131 623 4720 (F) 0131 623 4503

CLAIM FORM FOR TRAVEL, SUBSISTENCE AND CHILD CARE/CARER EXPENSES (NON-STAFF)

CLAIMS MUST BE MADE WITHIN THREE MONTHS FROM THE DATE OF THE EXPENSE

Please complete the form in BLOCK CAPITALS and return to the above address.
Please read the notes overleaf before completing this form.

For the period from	21/7/08 to 21/7/08	Incurred by	JANE SMITH
Home Address	00123 MAIN STREET	Status	PATIENT REPRESENTATIVE
	HAMPTON GROVE	HQ/Hospital	
	EDINBURGH	Address	
Post Code	EH00 0LS	Post Code	

To be stated in all cases:

Project Group	LUNG CANCER REVIEW GROUP
Meeting/ Review Visit/Conference etc.	GROUP MEETING
Organiser	MORAY NAIRN

TRAVEL & SUBSISTENCE CLAIM

Date	Please state full particulars of journey (ie exact start and end points together with any diversions) and other expenses	No. of hours absent	Day and night subsistence allowances £	p	Mileage: Milometer readings Start/End		Rate	Amount £	P	Rail Fares/ Tolls/ Taxis etc £	p
21/7/08	Train: Edinburgh to Dundee									14	65
21/7/08	Home to Haymarket				31024	31044		8	00		
		Sub Totals						8	00	14	65
				(a)					**(b)**		**(c)**

Claimants are entitled to claim for **CHILD CARE/CARER** expenses provided a receipt is obtained and no more than allowance specified overleaf (see note 7).

Date	Location	Amount Due £	p
21/7/08	Home address	20	70
	Total Amount Due		
		(d)	

TOTAL (a) + (b) + (c) + (d) = £ 43.35

I declare that the mileage allowances and expenses claimed herein were incurred solely on journeys in the service of the Board, carried out at the request of the Board, and that the charges are in accordance with the NHS Regulations in force at present; that, where the full mileage rate has been claimed, public transport would not have been appropriate; that any motor vehicle(s) of which I am the owner and used on Board business is/are insured by me to satisfy all the requirements of the Scottish Home & Health Department Memo, SHM 65/1966.

Signature _____ **Date** _____

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Annex 4
Expenses Form

Notes for Claims for Travel, Subsistence and Child Care/Carer Expenses
Rates as at October 2005

Please ensure that this form has been completed in full and that tickets, childcare/carer receipts etc are attached. Failure to do so will result in the claim form being returned to you and will therefore delay payment.

1. Due to administrative costs, claims for less than £5.00 cannot be reimbursed. If your claim is for less than £5.00, please retain it and forward several claims together until the total to be reimbursed is £5.00 or more.
2. Claimants should complete their name, address, etc, legibly in BLOCK CAPITALS and include BOTH home and business address (including postcodes) if appropriate.
3. Expense claims must be completed by the person who has incurred the expense(s).
4. Cheques are sent to the claimant's home address or residence, therefore the home address must be quoted. BACS payments can also be made, provided claimant attaches bank account details to claim form to NHS QIS.
5. The Inland Revenue direct that mileage be calculated from either the place of work or home (whichever is shortest) to the destination. Both addresses must therefore be quoted. Only exact mileage will be reimbursed. To satisfy the Inland Revenue, mileage claims will be checked via software package and may be adjusted.
6. When claiming subsistence, the number of hours absent from home (work) must be entered in the No of hours absent column. Please note subsistence claims can only be made when NHS QIS has not provided meals/accommodation.
7. NHS QIS are able to make a maximum payment for child care or carer's allowance at the rate of £20.70 per day per individual being cared for. This payment can only be made when a receipt is obtained, and NHS QIS can only reimburse at the rate stated irrespective of the actual cost incurred.
   Under exceptional circumstances a higher allowance may be paid, but written permission must be obtained before the expense is incurred. A copy of the letter approving the higher allowance must accompany the claim form when it is submitted.
8. No payment will be made for attendance, however any loss of earnings which can be demonstrated, eg payslip showing loss of earnings, will be reimbursed.
9. Miscellaneous items (eg newspapers, video hire, tips, etc) cannot be reclaimed. The cost of phone calls may be reimbursed if the call(s) was/were business related. Any claim for the cost of phone calls must be supported by a letter stating to whom the call was made and a brief reason for the purpose of the call.
10. **NHS QIS regret that they cannot reimburse claims which are over three months from the date of the expense.**

- **ACCOMMODATION**
  Actual receipted costs of bed and breakfast up to a maximum of £90.00 per night**.**
  Non-commercial accommodation: £25.00. (This amount includes the 24-hour meal allowance).
- **SUBSISTENCE (MEALS)**
  Actual receipted costs of meals up to the maximum detailed below. Meal costs can only be reimbursed if the applicant has travelled more than 5 miles from their normal place of work.
  Absent from home for 5-10 hours (must include 12.00 – 2.00 pm): a maximum of £10.00
  Absent from home for more than 10 hours (must end after 7.00 pm): a maximum of £20.00
  Full 24-hour period: a maximum of £30.00
- **TRAVEL**

Up to 10,000 miles	0.40p per mile
Thereafter	0.25p per mile

Further procedures relating to claims are available within Procedure 12 Non-NHS QIS Staff Expenses.

All claims for reimbursement of costs relating to train, plane, taxi, etc must be accompanied by receipts.
The cheapest mode of travel must be used at all times and NHS QIS will only reimburse standard class travel.

FOR OFFICIAL USE ONLY

Entitlement to Expenses Confirmed (*1st Authorised Signatory)* _____ Date _____
Entitlement to Expenses Confirmed (*2nd Authorised Signatory)* _____ Date _____
Checked by _____ Date _____

Claim checked by Finance:		Date	Reclaim VAT YES/NO	
Cost Code	**Account**	**Job**	**Narrative**	**Amount**
Qnnnnn	nnnn	Qnnnnnnn		£nnnn.nn
HQ Check	**Journal Reference**		**Total**	

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Annex 5
Key to evidence statements and grades of recommendation

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, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews, 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 or bias and a high probability that the relationship is causal
2+	Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, eg case reports, case series
4	Expert opinion
Grades of recommendation	
Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.	
A	At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; 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+
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.

Illustrations by Albi Taylor • www.albitaylor.com

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Scottish Intercollegiate Guidelines Network
Elliott House, 8 -10 Hillside Crescent
Edinburgh EH7 5EA

www.sign.ac.uk