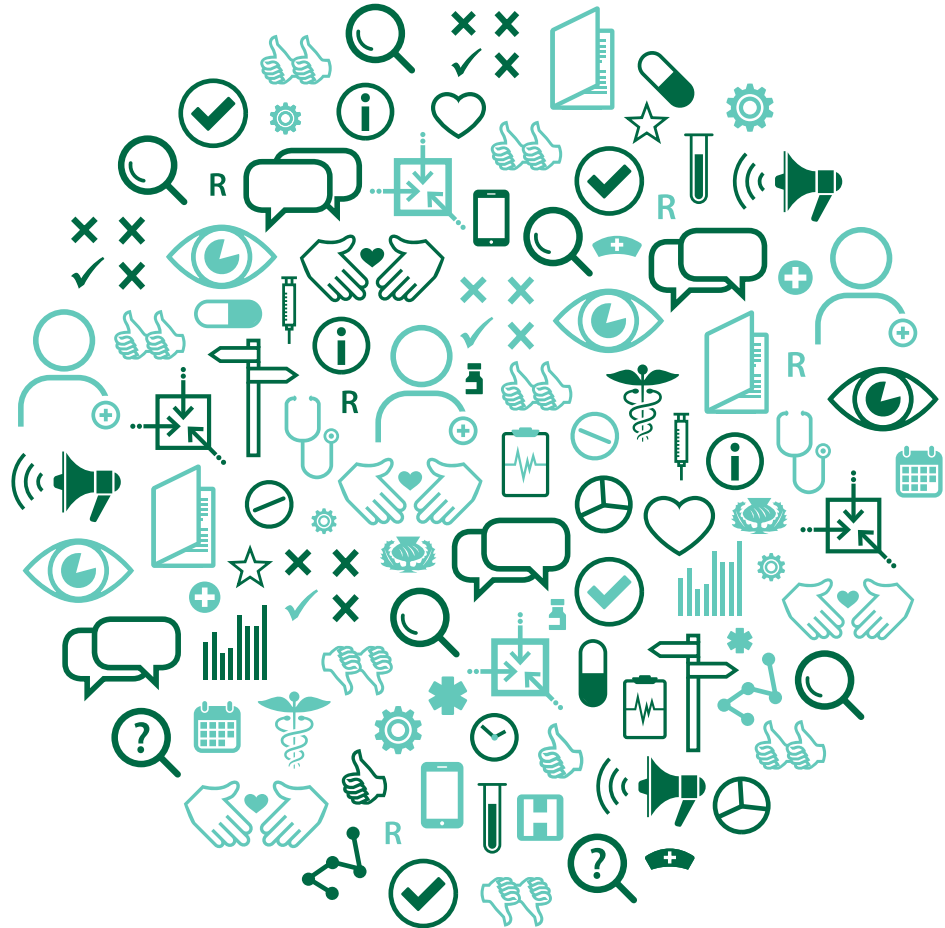


SIGN 100

A handbook for patient and carer representatives

March 2019



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A handbook for patient and carer representatives


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1 Introduction

Who is this handbook for?

The Scottish Intercollegiate Guidelines Network (SIGN) has written this handbook for patient, and carer representatives who are 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 SIGN patient, service user or carer representative.

We have explained the terms we have used in this handbook on pages 48–63.

Throughout this handbook, we have used the term ‘patients, service users and carers’ to cover the groups of people who are involved in our work. This includes people who are living with a condition that affects their health, people who are caring for someone, a patient’s family and friends, a member of the public or people who work for voluntary organisations. These ‘representatives’ are not health and social care staff.

We hope that, as a representative, you can help give us an idea of what it is like to live with a condition and access health and social care.

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

Phone: 0131 623 4740

Email: karen.graham2@nhs.net

2 About SIGN

What does SIGN do?

We write clinical guidelines for all NHS staff – including doctors, nurses, dentists, physiotherapists and other healthcare professionals such as 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, service users, carers and members of the public.

The guidelines are based on the most up-to-date scientific and medical evidence.

SIGN is part of Healthcare Improvement Scotland which is a public body that provides advice and guidance to the NHS in Scotland and inspects hospitals and help them to improve what they do to ensure they are safe and clean.

SIGN Council

SIGN Council is the part of our organisation that sets 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 SIGN Council are nominated by their Royal College or another professional organisation. SIGN Council members represent their speciality or discipline and consult other specialist societies in their field. Healthcare Improvement Scotland public partners also represent patients, service users, carers and the public on SIGN Council.

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

All members of SIGN Council have a say on which topics should be developed into guidelines and who should be chosen as members of guideline groups.

SIGN Executive

The SIGN Executive is the name for the team of staff we employ to run the organisation. They are responsible for putting SIGN Council's decisions into practice and carrying out the guideline programme on time and in line with our budget. All these members of staff are employees of the public body Healthcare Improvement Scotland. Our staff work closely with other parts of Healthcare Improvement Scotland and keep to their policies and procedures.

What are your guidelines for?

We write guidelines to:

- help professionals, service users and patients understand medical evidence so they can use it to make decisions about a person's care
- help people to get the best care available, no matter where they live
- help to improve the quality of health and social care across Scotland.

We want to make sure that everyone in Scotland receives the best health care, so our guidelines recommend the best proven treatments.

“The various guidelines have helped me to get the best care possible and to understand the best way to look after my heart.”

Patient with cardiovascular disease

What are your guidelines based on?

Our guidelines are based on the most up-to-date scientific evidence. We read research papers to find evidence for the best way to diagnose, treat and care for people. If no research has been done, health and social care professionals can use their experience and judgement to suggest treatments. They will highlight this as an area where more research is needed.

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

Who decides which guidelines are needed?

Anyone in Scotland can suggest a topic for a guideline. This includes health and social care staff, voluntary organisations, charities, patients, service users, carers, and members of the public. To suggest a guideline topic you can visit our website and fill in our topic proposal form <http://www.sign.ac.uk/patient-topic-proposal.html>.

We choose a topic if we know that hospitals or general practitioners (GP) in different areas of Scotland offer different tests and treatments for the same condition, and if this difference results in different outcomes for patients. We also select particular topics if there is uncertainty over which treatments work best to reduce the effects of disease or death levels associated with conditions or disabilities.

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 people can trust the recommendations that the guidelines make. Our Evidence and Information Scientists do a very wide search of the scientific and medical research papers available. They do this to make sure there is enough good-quality evidence to make developing a guideline possible.

Who funds the guideline development process?

As part of the public body Healthcare Improvement Scotland, we are funded by the Scottish Government. This funding supports:

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

Do you look at how your recommendations can affect NHS resources?

The NHS has limited resources and ever-increasing costs, so it is important to weigh up the cost of individual items of care against the benefits to patients.

We use health economic databases in our literature searches. A Health Economist helps to assess economic studies on the cost effectiveness of tests or treatments. This information is used when we move from the evidence to making recommendations (considered judgement). You can read more about this in section 7.

If the guideline group makes a recommendation that could cost a lot of money or need a change in the way a service is delivered, the Health Economist can do a model of the estimated costs.

3 Guideline development groups

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
- patient, carer and service user representatives, and
- voluntary sector 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. The guideline development group has a mix of the following experience and 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 team working skills, and
- 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 are valuable. Whatever their area of expertise, all members of the guideline development group have equal status.

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.
- **Evidence and Information Scientist** - they carry out literature searches (searching medical and scientific research papers) to find all the relevant research on a particular topic. They also decide what research has been done well and can be used in the guideline.
- **Guideline Co-ordinator** - they provide administrative support to the guideline development group.
- **Patient Involvement Advisor** - they are responsible for managing our activities in involving patients and the public in our work.
- **Health Economist** - they look at the costs involved with treatments and whether or not they are good value.

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

The length of time a guideline group will be together varies depending on the topic and how much research has been done, but is usually between 15 and 29 months.

The guideline development group meets around every two to three months. Some groups may form subgroups which meet between the main group meetings.

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 six.

Declaring interests

We ask all members of SIGN Council, members of guideline development groups, SIGN Executive staff and our advisors to declare any potential competing interests.

This asks you about interests which may (or may be thought by others) to influence your judgement on the content of the guideline under discussion. For example, if you are involved with an organisation which campaigns for a particular type of therapy which might be approved in the guideline; or if you have shares in a pharmaceutical company which makes a medicine which might be recommended in the guideline.

Conflicts of interest can damage SIGN's reputation or trust and confidence in our guidelines. You are asked to declare not only your own interests but those of your partner, close relatives, employer or business in which you are involved.

Non-financial as well as financial interests are to be declared and you are asked to look ahead to any interest you can see arising in the future.

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. This stops group members being contacted by individuals who may have a special interest in our guidelines, for example pharmaceutical companies. You can find copies of these forms in Annexes 1 and 2.

Why do you have patient, service user and carer representatives on guideline development groups?

We believe it is very important for patients, service users and carers to be involved in the decisions that are made about their care. By involving them in the guideline development process, we can identify their concerns and use their views to complement findings from scientific research and the knowledge and experience of health and social care professionals.

Patients, service users and carers can help the guideline development group understand what it is like to live with a condition and how different forms of treatments can affect their lives. The types of things we are interested in hearing about include:

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

As a patient, service user or carer representative on a guideline development group, you can remind the other group members of any limitations of the scientific findings in relation to a person'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 person'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 person's religion or beliefs might make it difficult for them to have certain treatment (for example, in relation to their diet or taking medication).

How do you involve patients, service users and carers in the guideline development process?

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

- voluntary organisations including equality and diversity groups
- charities
- NHS public involvement workers, for example, staff from Health and Social Care Partnerships
- the SIGN Patient and Public Involvement Network (see section below), and
- SIGN Council.

SIGN Patient and Public Involvement Network

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

- help identify people and organisations that can work with us on specific projects
- help us consult people on our work
- promote national open meetings (see section 8a) to a wider audience
- help share our knowledge
- provide networking opportunities, and
- help distribute and raise awareness of our guidelines.

Members of the patient and public involvement network receive a newsletter twice a year, which includes details of:

- opportunities for people to get involved in our work, for example, open consultations
- published guidelines and when they are being launched
- public involvement seminars run by other organisations
- conferences, and
- opportunities for patients to get involved in other organisations' work such as that of the Scottish Government.

There is also the opportunity to keep in touch with us through our Facebook page.

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

We consider all the applications we receive. We base our decision on careful comparison of the role description and the qualities shown by applicants. 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 team-working 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 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 not well represented.

How big a commitment would I have to make as a patient, service user or carer representative?

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

1 Full member – for people who will be able to attend all of the group meetings over the 15 to 30 months it takes to develop the guideline.

2 Key stage member – for people who prefer to be involved only at certain stages of the guideline development process. We would ask you to attend the first group meeting and bring a patient perspective to the discussion. This helps us to ensure the patient issues are addressed by the key questions. We would also ask you to attend the meeting where we are considering the evidence and making recommendations (considered judgement).

3 Advisor – those who have experience of living with or caring for someone with the condition but are unable to commit to the full group. We would ask you to attend the first meeting and that you would be willing to be contacted by email or phone to provide a patient, service user or perspective when required.

“It was a privilege to be part of a fantastic multi-disciplinary team who have showed such dedication and compassion to my disease. I found it extremely interesting even though you do sometimes flinch when you realise this could be me!”

Patient, guideline development group (key stage) member

What role do patient, service users and carer representatives play as members of guideline development groups?

One of your vital roles will be to make sure that patient, service user and carer 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

- Helping us identify issues that are relevant to patients, service users and carers, for example by helping to prepare discussion points for use with focus groups.
- Helping us to arrange meetings to consult patients, service users and carers and members of the public, for example through their own networks.
- Making sure that the main questions that guide how evidence is collected are informed by issues that are important to patients and carers.

When developing recommendations

- Considering the evidence from a patient, service user or carer perspective.
- Giving input to the patient preferences section of the considered judgement form and making sure that the guideline development group considers patients, service users and carers when drafting their recommendations.
- Considering how the recommendations reflect patients' and carers' concerns.
- Helping to write the 'Provision of information' section of the guideline.
- Making sure that the guideline is sensitively worded, for example, treating patients and service users 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.
- Giving a talk on the patient, service user or carer perspective at the national open meeting.

At the end of the process

- Helping to produce versions of the guidelines for patients, service users, carers and the public.
- Raising awareness of the guideline among groups of representatives, for example, support groups and voluntary organisations.
- Taking part in the launch of the guideline.

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

Sometimes, patients, service users 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.

“My biggest contribution was helping with the guideline but also the patient leaflet and getting other parents/carers involved. I feel if you are in an opportunity to make a difference then you should take it”.

Parent of child with autism, (full) guideline development group member

What skills do patient, service users and carer representatives bring to guideline development groups?

You do not need any formal qualifications to be a patient, service user 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, or service users, 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, service user 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 team-working skills.
- Enthusiasm and commitment.
- An understanding of keeping 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.

What training and support is there for patient, service user and carer representatives?

SIGN buddies

It may help to speak to someone who has already been a patient, service user or carer 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.

Training

We will provide you with a general introduction to the work of Healthcare Improvement Scotland and SIGN. This will also cover health and safety and reimbursement of expenses. We offer training about guideline development to patient, service user and carer representatives involved with SIGN to help them make an effective contribution to the development process. This is either in the form of one-to-one induction training or as group induction.

Group induction training – 'Introduction to SIGN' course

This is a one-day course which covers how patients, service users 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.

SIGN methodology training

This course aims to provide patients, service users and carers with an understanding of the following:

Searching for evidence and synthesising data

Types of study designs

Process of making recommendations from the evidence

Critical appraisal awareness

'Critical appraisal' is the name we give to the process of reading and assessing scientific and medical research papers. Although we don't ask you to critically appraise papers, it is helpful for you to know about the different types of trials, what makes them good trials and what faults they could have. We encourage you to complete the course 'Making Sense of Health Evidence: The Informed Consumer' which you can access free of charge www.futurelearn.com/courses/informed-health-consumer. This will help you to gain an understanding of research and how to use it effectively. Information about the types of research used as 'evidence' is in section 5. You can also ask your Programme Manager or Evidence and Information Scientist to tell you more about the research if you need anything explained.

Developing patient versions of guidelines training

This is a one day course which aims to provide patient, service user and carer representatives with an understanding of the development process for patient versions of guidelines and their roles in the process.

Equality and diversity training

SIGN is committed to providing equal opportunities. Patient and carer representatives have the responsibility to treat others with dignity and respect irrespective of their age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion and belief, sex, sexual orientation, political conviction, membership or non-membership of a trade union/professional organisation or health status.

To make sure that patient, service user and carer representatives have an understanding of equality and diversity issues, we ask you to attend, equality and diversity training run by Healthcare Improvement Scotland Public Involvement staff.

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. We can provide you with a rail warrant to cover your travel. You can request this from your Guideline Co-ordinator.

An expense claim form should be used for all other expenses. These will be available at each meeting. You should then give these to the Guideline Co-ordinator who is responsible for your guideline development group. You can find an example of an expenses form in Annex 3.

“I was not sure what the group would be like and what health professionals would be there. However my friend, was a patient rep on another guideline so it was very useful to talk to her beforehand to get a good idea of what I would need to do and my purpose as a patient representative. I think the contact of a SIGN buddy is very useful”.

Patient, (full) guideline development group member

4 Including patient, service user and carer issues in the guideline development process

Are patient, service users and carer issues covered in the research papers?

Before the guideline development group meets for the first time, our Evidence and Information Scientists will do a literature search to look for evidence on relevant patient, service user and carer issues. They will do this early on to make sure these views influence 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 conclusions of a research study) from this search into themes to highlight patients', service users' and carers' main concerns. Our Public Involvement Advisor presents these themes to the members of the guideline development group, who then take the themes into account.

The studies identified often include patients', service users' 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 when making decisions about their treatment, and
- their overall satisfaction with the care they received.

How else do you identify the issues that concern patients, service users, and carers?

Consulting the voluntary sector

Four months before the guideline development group's first meeting, we write to the organisations and charities that represent patients, service users and carers. We 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.

Consulting the SIGN Patient and Public Involvement Network

Many of the members of the SIGN Patient and Public Involvement 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, service users or can raise relevant issues on their behalf.

Consulting patients, service users and carers

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

Using social media

SIGN's patient and public involvement Facebook page allows us to ask people what they think our guideline should cover: www.facebook.com/SIGNPatientnetwork

“It is so important to engage with young people when looking at health care for the management of epilepsy as there are many issues that arise. Growing up with a medical condition is an added complication when a young person is developing at such an influential stage of their life. The young person is at the centre but often has so many inputs from people within their life and medical/social teams that we need to make sure that they are being listened to, informed in a way they understand and can engage in so that they have control in the treatment of their condition. Having SIGN consult and engage through an interactive session with our Epilepsy Scotland Youth Group brought up thought provoking issues and a chance for the young people to share what they had been through and would like to change for their future support or for that of others. Listening to the people that are directly affected empowers young people to raise issues that are important to them and that they want to see reflected in the in guidelines for practitioners and support networks”.

Youth Worker, Epilepsy Scotland

5 Introducing research methods

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

The research process is set out below.

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

There are two approaches to research.

1

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.

2

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 normally used. Quantitative researchers use methods like clinical trials and surveys. You can read more about clinical trials in section 5.

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

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, diagnostic studies and health economic 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, 2012 - 2017). These studies will all look at a particular research question. The researchers 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 reasons for including and excluding information, for example, including studies which only look at people over the age of 18 or excluding studies which look at people with learning disabilities, and
- assessing research papers against methodological standards. You can read more about this in section 6.

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.

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 11 for a glossary of terms) or with the best treatment currently available. Testing against a placebo shows whether or not the treatment is effective. Testing against existing treatments shows whether the new treatment is effective and better than those that are currently used.

Clinical trials are used to test medicines and other types of healthcare treatment, for example surgery. There are different 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.

1. 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.

2. 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

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. New tests may be compared to the best test currently available.

Health economic studies

This type of study involves assessing the cost of individual care against the benefits to patients.

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 5,600 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.
- **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 research papers in a database.

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

6 Using research to develop guidelines

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.

How are relevant research papers identified?

The guideline development group decides what aspects of the condition the guideline will cover (called the 'remit'). The group then poses a set of 'key questions' about how to manage the condition.

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.

Our Evidence and Information Scientists use the databases listed on page 26 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 use the key questions to develop search strategies to search for relevant research papers. The search focuses on the best available evidence to answer each key question. Well defined and clear key questions are vital in developing a successful guideline.

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 we start to critically appraise the research papers, our Evidence and Information Scientist will take out any papers that are clearly not relevant. Two members of the guideline development group will look at the abstracts of the remaining papers and reject any that do not meet the conditions the guideline development group agreed.

Reviewing the research papers

Once papers have been chosen as possible sources of evidence, the Evidence and Information Scientists will assess the study methods to see how well the study has been carried out. This assessment is based on a number of questions in a checklist. The questions vary between the different types of study, and we have designed checklists for each type. These checklists bring a degree of consistency to the appraisal process. 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 help us to make an informed assessment of 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.

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 (see section 5 for study types). 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 for a period of time and specific outcomes are measured 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 to possible causes of cancer in the past.

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?

We make sure that the study has included the groups of people we are interested in by asking 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 selection 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 service user who visited their GP that day.

- Who was included and excluded in the study?

Some trials in the UK exclude patients for example who already have an illness or who do not speak English. This can introduce selection bias. The results of a trial of medicine done in young healthy males may not apply to older females.

- Are the patients in study groups similar?

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. This can include age, gender, stage of disease, and social background as well as other features. Bias is anything which influences the conclusions of a study and affects how the groups in the study are compared.

- 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 look at the research.

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 preschool 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 we have asked these questions, we should be able to tell:

- what sort of study it was
- how many people were involved in the study
- where 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.

The Evidence and Information Scientists will rate each study as high quality (with a very low risk of bias), acceptable (with a low risk of bias) or low quality (with a high risk of bias). We can then decide if the paper can be used in the guideline or whether it is not good enough and we should reject it.

Reviewing the papers will usually take about six months. The results of this assessment will decide how much evidence is relevant.

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', 4th Edition, BMJ Books, 2010.

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

7 Making recommendations in guidelines

Looking at the evidence

SIGN Executive staff produce evidence tables based on the quality assessments of individual studies.

Evidence tables summarise all the accepted 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.

Evidence to decision framework

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 the guideline development group came to their recommendations, given the evidence they had to base them on. To tackle this problem, we go through steps to get from evidence to a decision. We call this 'considered judgement'.

During 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 studies 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.
- Whether the treatments are effective and if there are any side effects or harms.
- The resources needed to take on new treatments.
- How acceptable the treatments are to patients.
- How practical it would be for the NHS in Scotland to put the recommendation into practice.

Guideline development groups are given a form to record the main points of their considered judgement. Once the groups have considered these issues, they summarise their view of the evidence and make the recommendation.

Levels of evidence

The 'level of evidence' tells you how likely it is that the conclusions of a research paper are true. It 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.

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 (see section 11 for a glossary of terms)
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

Two Evidence and Information Scientists who appraise the quality of the study decide on the level of evidence depending on how well the study has been carried out (see section 6).

Making recommendations

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 based on the evidence as a whole, and should not rely on a single study.

You will be involved in assessing whether the draft recommendations:

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

Grading recommendations

If you have looked at any of our guidelines published between 2000 and 2012, you will have noticed that the recommendations have letters next to them. During this time we used the letters A to D to grade the recommendations according to the strength of the evidence. The guideline group graded the recommendations based on their assessment of the design and quality of each study, as well as whether the study was consistent and relevant and whether the evidence was valid. The aim was to make a recommendation that was based on the evidence, but also relevant to the way in which health care is provided in Scotland.

SIGN stopped grading recommendations using the 'ABCD' method from 2013. We now make 'strong' or 'conditional' recommendations based on the evidence but taking account of benefits and harm and patient preferences.

A strong recommendation is made where:

- the evidence is of high quality
- we are quite certain that the treatment will improve outcomes for patients and service users
- there are few downsides of the treatment, and
- treatment or therapy is highly accepted among patients.

A conditional recommendation is made where:

- there are weaknesses in the evidence
- there is some doubt that the treatment will produce the expected improvement in outcome for patients
- we need to balance the benefits and harms of the therapy, and
- varying levels of acceptance among patients is likely.

Through the considered judgement process, the members of the guideline development group can also lower a recommendation from strong to conditional 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.

Equally, when the evidence is poor quality and the treatment has no downsides, a strong recommendation may be made.

Good-practice points

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 good clinical practice that no-one is likely to formally study it, and so no evidence has been published).

Points like this are shown as '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.

Consensus statements

Sometimes a guideline group may feel strongly about making a recommendation even though there is no good evidence. In these situations there are established methods that can be used to make a consensus recommendation.

Consensus recommendations are clearly identified in the guideline with a statement.

8 Consultation and peer reviews

National open meetings

Once the guideline development group has reviewed the evidence, it will prepare a draft guideline containing the 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 health and social care professionals, voluntary sector representatives, patients, service users, carers and members of the public.

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.

Open consultation

If a guideline has been updated but there are no significant changes to the recommendations we will not hold a national open meeting. Instead we have an open consultation and invite the people who would usually come to national meetings to comment on the draft on our website.

Peer review

All our guidelines are independently reviewed by other health and social care staff and academic experts before they are published. The draft is also sent to people who can provide us with comments from a patient, service user or carer perspective. 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', service users and carers' views.

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

We invite patient organisations and members of the Patient and Public Involvement Network to take part in the peer review process. We have produced specific guidance for lay peer reviewers 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 or individual 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 all relevant NHS staff and voluntary organisations in Scotland are made aware of it.

What do patient organisations and other public representatives comment on?

Language

Although we write our guidelines for health and social care professionals, we aim to make them available to as many other people as possible.

When patients, service users, carers and members of the public review the guidelines, we ask them to consider the following.

- 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 8d2).
- If they can, suggest plain, non-technical wording to help healthcare professionals explain areas of the guideline to patients.

‘Provision of information’

Each guideline contains a section called ‘Provision of information’. This section is designed for professionals to use when they discuss a condition with patients, service users 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 any 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.

“The lay representatives had separate meetings to discuss ideas for presenting the updated recommendations to the Provision of information. This section reflects issues likely to concern patients and carers and are matters we felt should be considered when health professionals treat and communicate with patients and carers. These resulting discussions became very lively at times due to differing opinions but we worked together and felt we had produced a checklist which really reflected what a patient needed and deserved.”

Patient representative, guideline development group (key stage) member

9 Presentation

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 differences in treatments or outcomes across Scotland, and
- what the guideline aims to do, and who it is aimed at.

The structure of the main part of the guideline reflects 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 including a few recommendations that the guideline development group feels should be prioritised
- 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 best practice based on their experience
- tools and activities to help put recommendations into practice and 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.

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
- a smartphone app which has the quick-reference guides and other material from the guidelines, and
- a patient version, which explains the guideline's recommendations in a way that patients, service users, 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 NHSScotland. We also send copies to relevant patient organisations.

Patient versions of our guidelines

We produce versions of the clinical guidelines for patients, service users and carers to:

- help them to understand what the latest evidence supports around diagnosis, treatment and self care
- empower people to participate fully in decisions about management of their condition in discussion with health-care professionals, and
- highlight to people where there are areas of uncertainty.

These booklets include:

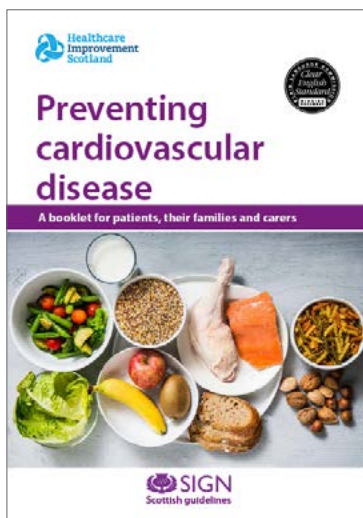
- a brief summary of the condition
- a summary of tests, treatments and procedures we recommend
- how professionals can support people to help themselves, and
- details on where people and their families can find more information about the conditions.



We normally start work on these booklets when the guideline is at the editorial review stage of the development process. A small group is formed from the guideline development group to work on patient versions of guidelines and consists of professionals, patients, service users, and carers. A Public Partner from Healthcare Improvement Scotland also participates in this group to provide an objective user perspective to determine content of patient versions of guidelines. They can help to ensure that our information is accessible, user-friendly and easy to understand.

The group decides which recommendations can help empower people to take an active role in decision-making. The following questions are asked about the recommendations to help the group decide which are helpful to people and their families:

- Can they empower people to understand their own condition?
- Do they highlight to people those interventions which have the greatest evidence of benefit?
- Do they recommend lifestyle interventions and ways in which the person can take steps to manage their condition?
- Do they identify a treatment for which there is no evidence and is it useful for people to know this?



“I’ve never seen this kind of thing and it helped me understand. I’m at high risk of a heart attack so I’m really clear about what I can do now to be a bit healthier. It’s quite hard to eat the right things and get your exercise but this is realistic and gives helpful tips. My GP makes me feel like I’m to blame, but this explains things well.”

Patient at risk of cardiovascular disease

Once the group has decided which recommendations should be included in the patient version, they are translated into plain language to allow them to be understood by everyone. Patient versions of guidelines are written in the second person using a question and answer format to ensure relevance and sensitivity.

Patient versions are an accurate translation of the clinical guideline and only those procedures/interventions recommended in the guideline are included. Often, there is a need for further information to help people understand the recommendations and additional content is included for this purpose only. Patient versions of guidelines can also signpost people to other sources of information, for example from the voluntary sector. Patient, service user and carer representatives on the group are often in a good position to advise on groups that can provide help.

Consultation with a wider group of people ensures that the patient version is accessible to those who have not been involved with the clinical guideline. The purpose of consultation is to ensure the patient version is:

- readable
- relevant
- useful, and
- sensitively worded.

Consultation is carried out using various methods depending on the intended audience of the patient version. Methods include:

- circulation of the document to the SIGN Patient and Public Involvement Network and voluntary organisations for comment
- requesting reviewers through the Patient and Public Involvement facebook page, and
- use of discussion groups to provide feedback, for example a discussion group with children and young people may be more effective than written consultation.

10 Putting the guideline 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 team working, 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 SIGN Council are also involved in promoting guidelines.

A group of public partners known as 'Awareness Volunteers' helps raise awareness of SIGN and their guidelines in more general terms. Their roles include:

- contributing to advertising materials, for example posters
- helping SIGN to exhibit at events, hospitals and conferences
- giving talks to patient groups, health-care professionals and medical students, and
- encouraging other groups to be aware of, and get involved in, SIGN's work.

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 Health and Social Care Partnerships), professionals and other patient representatives to help put the recommendations into practice at a local level.

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 SIGN Council and other relevant 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, we make a decision about the need for a review. There are four options at this stage.

- Confirm that the guideline is still valid
- Carry out a full review of the guideline
- Choose parts of the guideline to update
- 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.

11 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.
Bias	In research, bias can be described as deviation from 'true' results. It happens when something distorts the results. Bias can affect the findings of studies and how they are reported. If bias exists, health decisions may be made on incorrect information. Researchers and clinicians try to identify possible sources of bias, so they can eliminate or compensate for possible bias.
Blinding	Participants and researchers do not know which treatment individuals are being given.

Term	Definition
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.
Case	Participant taking part in a study.
Case-control study	Patients with a particular disease or condition are indentified or 'matched' with controls. Data is then collected, for example by looking back at medical records or by asking them to recall their own history. Case-control studies are concerned with what caused a condition rather than how it should be treated.
Case study	A case study describes the medical history of someone in the form of a story.
Causal relationship	<p>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.</p> <p>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.</p>

Term	Definition
Clinical research	<p>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.</p> <p>Clinical researchers will also sometimes analyse the information in patients' records or the data from health and lifestyle surveys.</p>
Clinical trial	<p>A research study which compares a new or different type of treatment with the best treatment currently available, or with 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.</p>
Cohort study	<p>Cohort studies are used to find out what happens to patients over a length of time. For example, they could investigate how long patients with acute low-back pain take to recover. Cohort studies may have a control group who will be followed for the same length of time.</p>
Concealment method	<p>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.</p>

Term	Definition
Confidentiality	<p>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.</p> <p>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.</p> <p>This confidentiality will only be broken in extreme circumstances - that is, if it is:</p> <ul style="list-style-type: none"> • 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	<p>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.</p> <p>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.</p>

Term	Definition
Consensus	General agreement from a group of people.
Considered judgement	<p>Even when evidence is available, decisions may not always be clear cut and benefits and harms of treatments may need to be debated. The balance may be different for different patient groups or individuals.</p> <p>Guideline group members consider the evidence reviews, clinical expertise and patient preferences when making recommendations.</p>
Consultation	<p>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.</p> <p>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.</p>
Control group	In a clinical trial, a control group is generally a group of people who do not receive any kind of treatment. This group will be compared with the experimental group to study the effects of the intervention.
Critical appraisal	'Critical appraisal' is the name we give to the process of reading and assessing scientific and medical papers.
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).

Term	Definition
Database	An organised collection of information that can be easily accessed, managed and updated.
Data protection	<p>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:</p> <ul style="list-style-type: none"> • 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.
Diagnostic 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. New tests may be compared to the best test currently available.
Dissemination	<p>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:</p> <ul style="list-style-type: none"> • producing reports (often these are made available on the internet) • publishing articles in journals or newsletters • issuing press releases, or • giving talks at conferences. <p>It is also important to make research findings available to the people who took part in the study.</p>

Term	Definition
Economic study	This type of study involves assessing the cost of individual items of care against the benefits to patients.
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 of 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 or social care topic, such as how well a treatment or a service works. Health 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.
Evidence table	Evidence tables summarise all the validated studies identified from the systematic review relating to each key question.
Evidence to decision (EtD) framework	The purpose of EtD frameworks is to help guideline development groups making recommendations move from evidence to decisions.

Term	Definition
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.
GP	General Practitioner

Term	Definition
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. This material is becoming more and more widely available on the internet.
Guidelines	Statements to help healthcare professionals and patients make decisions about appropriate 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 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.

Term	Definition
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 or social care professionals.
Literature review	A review of published research in a particular area. Published research is often referred to as 'the literature'.
Literature search	A search for medical and scientific research papers to find all the relevant research work on a particular topic.
Members of the public	<p>We use this term to cover:</p> <ul style="list-style-type: none"> • patients and potential patients • people who use health and social care services • unpaid carers and family members • parents • charities that represent specific health conditions, 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.

Term	Definition
Methodology	The techniques or processes that have been used to complete a piece of research. In other words, how information is collected and analysed.
Observational study	Cohort and case-control studies are collectively referred to as observational studies.
Participant (or subject)	Someone who takes part in a research project or trial. Sometimes participants are referred to as 'subjects' or 'cases'.
Patient and public involvement	Involving patients, service users, carers and their representatives in their own care, and in planning, monitoring and developing health services. Patients, service users, carers and members of the public may have different views to health and social care professionals about getting the most from care providers.
Peer review	<p>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.</p> <p>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.</p>

Term	Definition
Placebo	<p>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.</p> <p>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.</p>
Probability	<p>The chances or risks of something happening (for example, the chance of throwing a six with a dice is one in six).</p> <p>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.</p>
Prospective study	<p>Studies that follow patients up over a period of time.</p>
Qualitative research	<p>Qualitative research is used to explore and understand people's experiences, attitudes or behaviours. It asks questions about how and why.</p> <p>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.</p>

Term	Definition
Quantitative research	<p>Where researchers collect data in the form of numbers (in other words, they measure things or count things).</p> <p>Quantitative research might ask a question like how many people visit their GP each year, what percentage of children have had a vaccination for measles, mumps and rubella (MMR) or whether a new drug lowers blood pressure more than the drugs that are currently used. Quantitative researchers use methods like clinical trials and surveys.</p>
Questionnaire	<p>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.</p>
Randomised controlled trial (RCT)	<p>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.</p> <p>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.</p> <p>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.</p> <p>This is important because it means that the researcher can be sure that any differences between the groups are only due to the treatment.</p>
Reliability	<p>Whether the use of a measure, procedure or instrument gives the same result in repeated trials.</p>

Term	Definition
Remit	The aspects of a condition that the guideline will cover. For example the remit of a guideline may be assessment and management of adults with chronic non-malignant pain in non-specialist settings. Children would be outwith the remit.
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 paper	Results from research studies are written up and published in scientific and medical journals as 'papers'.
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.
Retrospective study	Studies that trace what happened to people in the past.

Term	Definition
Service user	Someone who uses or has used health and social care services because they have an illness or a disability.
Statistics and statistical analysis	<p>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).</p> <p>Statistical analysis uses a set of mathematical rules to analyse quantitative data. It can help researchers decide what data mean. 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.</p>
Systematic review	<p>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, 2010 to 2015).</p> <p>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.</p> <p>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.</p>

Term	Definition
Validity	Whether the results of a study are likely to be true and free from bias.
Variable	<p>Characteristics that vary among and between people and that can be observed and measured.</p> <p>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.</p>

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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

Declaration of interest form (part 1)



SIGN

SIGN policy on conflict of interests with form for completion by individuals, carers, voluntary organisations and members of the public to declare potential competing interests

SIGN welcomes the participation of patients, carers, voluntary organisations and members of the public in the preparation of guidelines. The help of individuals and voluntary organisations helps SIGN to produce guidelines which are clear, comprehensive and patient centred.

We ask everybody participating in guideline development to declare any potential conflict of interest, or any possible competing interest.

To help SIGN to be sure that you are an appropriate person to participate, please, complete and sign the attached form returning it no later than 14 days from the date on which you received it. You may wish to make a copy of the completed form in case you want to refer to it in the future.

What do we mean by a conflict of interest or a competing interest?

Put simply a conflict of interest or a competing interest is an interest which may (or may be thought by others) to influence your judgement on the content of the guideline under discussion. For example, if you are involved with an organisation which campaigns for a particular type of therapy which might be approved in the guideline; or if you have shares in a pharmaceutical company which makes a medicine which might be recommended in the guideline. Conflicts of interest can damage SIGN's reputation or trust and confidence in our guidelines. You are asked to declare not only your own interests but those of your partner, close relatives, employer or business in which you are involved. Non-financial as well as financial interests are to be declared and you are asked to look ahead to any interest you can foresee might arise in the next 12 months.

Competing interests include financial and non-financial interests. Competing interests may be relevant to the guideline topic or they may be relevant to the work of SIGN in general.

Financial interests include:

- Details of any gifts or hospitality received which may be relevant to SIGN (for example, a link with a pharmaceutical company or with an organisation which has paid for you to attend a conference)
- Money from being:
 - employed or self employed
 - a partner in a firm
 - a director of a company
- Any allowance received in relation to being a member of an organisation
- Healthcare related shares
- Non-financial interests including membership of
 - Other public bodies
 - Clubs, societies or other organisations
 - Voluntary organisations; and
 - Trade unions.

What happens to the declaration of interests forms?

The SIGN Senior Management Team will consider whether it is appropriate for you to participate in the guideline development process.

The SIGN Programme Lead will hold all declarations of competing interests. These are made available in summary on the SIGN website.

Declaration of interest form (part 2)

Form for completion by patients, carers, voluntary organisations and members of the public to declare any potential competing interests

Tell us who you are

Name: _____

Address: _____

Which of the following options best describes you? (Please tick)

A past patient A member of the public
 A present patient A Healthcare Improvement Scotland public partner
 A carer Representing a patient organisation If so please name the organisation here
 A family member _____

Please tell us about any interests that may be relevant to the work of SIGN

Category	Please give details of the interest and whether it applies to yourself or, a partner or a close relative
Details of paid employment which may be relevant to SIGN (this includes self employment)	
Details of any partnership you have in a firm where you are paid a salary	
Details of any limited company that you are a director of	
Details of any healthcare related shares you have (you do not need to tell us the value of these)	
Details of other public bodies you are involved with	
Details of voluntary organisations you are involved with	
Details of other organisations or clubs you are a member of	
Details of any gifts or hospitality received during the last 12 months which may be relevant to SIGN (for example, a pharmaceutical company or an organisation has paid for you to attend a conference)	

Please return this form to _____ by _____

Annex 2

Confidentiality agreement

Confidentiality agreement between

Jane Smith

and

Scottish Intercollegiate Guidelines Network

SIGN, Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB

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 Confidentiality 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.

Confidentiality agreement (continued)

- 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.

CONFIDENTIALITY UNDERTAKING BY:

Jane Smith

Considering that the Recipient is to participate in an assessment in respect of:

Management of 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.

Confidentiality agreement (continued)

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.


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 3

Expenses form (part 1)

		EXPENSES CLAIM FORM (NON-NHS STAFF*) *Secondees, Independent Contractors, GPs and GDPs <u>must not</u> use this form				
<p>This form is for non-NHS Employees only. Please complete in BLOCK CAPITALS and ensure all sections are completed in full. Failure to do so will result in the claim form being returned to you and will therefore delay payment. Original tickets and receipts must also be attached before we can process this claim. <u>Please return the form to your Event Organiser/Key Contact at Healthcare Improvement Scotland as soon as possible and no later than three months after the Event.</u></p>						
<p>Please read the Guidance notes overleaf BEFORE completing all sections of this form.</p>						
Name (Including Title):		Status (Volunteer, Member of Public etc.):				
Home Address (include Postcode):		Event (Meeting/Interview/Review Visit/Focus Group/Conference etc.):				
Name of Event Organiser or Key Contact:						
<p>Bank details will only be used for the purposes of direct payments to bank account by BACS. Where not supplied, payments will be made by cheque to your home address.</p> <p>Claimant's Bank Details: if payment directly to bank account is preferred</p>						
Account Number		Sort Code	Account Holders Name			
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>			
<p>I declare that the mileage allowances and expenses claimed herein were incurred solely on journeys in the service of Healthcare Improvement Scotland, 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 adequately insured by me for Business purposes.</p> <p>Signature: _____ Date: _____</p>						
Please complete all boxes in this section (please refer to the guidance notes overleaf)						
Date DD/MM/YY	Expense Incurred –Subsistence/ Rail /Flight/Accommodation/ Taxi/ Mileage etc. (please state exact start and end points together with any diversions for mileage).	No. of Hours absent	No. of Miles	Mileage Rate per mile	Amount	
					£	P
	ORIGINAL RECEIPTS <i>MUST BE PROVIDED</i>					
	ORIGINAL RECEIPTS <i>MUST BE PROVIDED</i>					
	ORIGINAL RECEIPTS <i>MUST BE PROVIDED</i>					
	ORIGINAL RECEIPTS <i>MUST BE PROVIDED</i>					
	ORIGINAL RECEIPTS <i>MUST BE PROVIDED</i>					
Total						
FOR OFFICIAL USE ONLY						
Cost Code	Account Code	Project Code	Amount Due	Finance Use:		
				Claimant Number		
				Register Number		
				Batch Number		
				Finance Signature (if claim is over £200)		
		Total				
Authorised Signatory 1 (Print and Sign Name)					Date:	
Claim checked and verified by (Print and Sign Name)					Date:	

Expenses form (part 2)

Important Guidance Notes: Please read carefully to avoid delays in payment

Multiple Events may not be claimed on one form. ALL Travel and Expenses must be agreed in Advance by the Event Organiser and be within the rate limits specified below. Public Transport must be used at all times and Healthcare Improvement Scotland will only reimburse standard class travel. You may use your own Car in exceptional circumstances.

Please complete Healthcare Improvement Scotland regret that they cannot reimburse claims which are over three months from the date of the expense.

1. Claimants should complete their name, address (including postcode), status, event, event Organiser legibly in **BLOCK CAPITALS**.
2. Expense claims must be completed by the person who has incurred the expense(s) or a nominated representative.
3. Bank details should be provided for each claim to ensure we hold current and up to date bank details at all times. If you do not provide bank details a Cheque will be issued to your home address.
4. The Inland Revenue direct that mileage be calculated from either the place of work or home (whichever is shortest) to the destination. Please ensure you provide your departure address and destination for mileage claims. If claiming passenger mileage please provide the full name of Passenger(s). Only exact mileage will be reimbursed. To satisfy the Inland Revenue, mileage claims will be checked via software package and may be adjusted.
5. When claiming subsistence, the number of hours absent from home must be entered in the No of hours absent column. Please note subsistence claims can only be made when Healthcare Improvement Scotland has not provided meals/accommodation.

- **ACCOMMODATION**

Actual receipted costs of bed and breakfast up to a maximum of £90.00 per night and only if an event starts before 9am and/or finishes after 7pm and/or the travel time exceeds two hours each way.
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 home.

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. Itemised bills must be submitted for Restaurants etc. as alcohol cannot be included

- **TRAVEL**

Car/Van	£0.45 per mile (up to 10,000 miles) £0.25 per mile (thereafter)
Passenger	£0.05 per mile per passenger
Motorcycle	£0.24 per mile
Bicycle	£0.20 per mile

6. Healthcare Improvement Scotland is able to make a maximum payment for child care or carer's allowance at the rate of £25.00 per day per individual being cared for. This payment can only be made when a receipt is obtained, and Healthcare Improvement Scotland 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.
7. No payment will be made for attendance at any Event, Course, meeting etc.; however any loss of earnings which can be demonstrated for attendance, e.g. payslip showing loss of earnings, will be reimbursed.
8. Miscellaneous items (e.g. 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.

Further information relating to claims is available within the non-NHS Staff Expenses policy.



Healthcare Improvement Scotland

Edinburgh Office

Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB
0131 623 4300

Glasgow Office

Delta House
50 West Nile Street
Glasgow
G1 2NP
0141 225 6999