# Advice for Guideline Development in Northern Ireland

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Revised: April 2017

Review: April 2018

**Contents** **Page**

**Background**

In spring 2004 a regional project was established to review arrangements supporting clinical and social care audit activity in Northern Ireland and to recommend how these should be strengthened to meet the agenda set out in *Best Practice-Best Care*.

A Steering Group was established from a range of disciplines and a Project Team developed the products for the project.

This review found there was a need for a single regional audit focus in place of the two current committees Northern Ireland Regional Audit Advisory Committee (NIRAAC) and Regional Multiprofessional Audit Group (RMAG). The Department of Health (Northern Ireland) (DH (NI)) supported the recommendations for a single regional focus through their amalgamation and asked that further consideration be given to how to integrate the work of the Clinical Resources Efficiency Support Team (CREST) in developing local clinical guidelines with the proposed new arrangements.

In August 2007 RMAG, NIRAAC and CREST merged to become a single entity known as the Guidelines and Audit Implementation Network (GAIN). The main function of GAIN is to promote leadership in safety and quality care through the development and integration of regional guidelines and audit and their implementation to improve outcomes for patients, clients and carers.

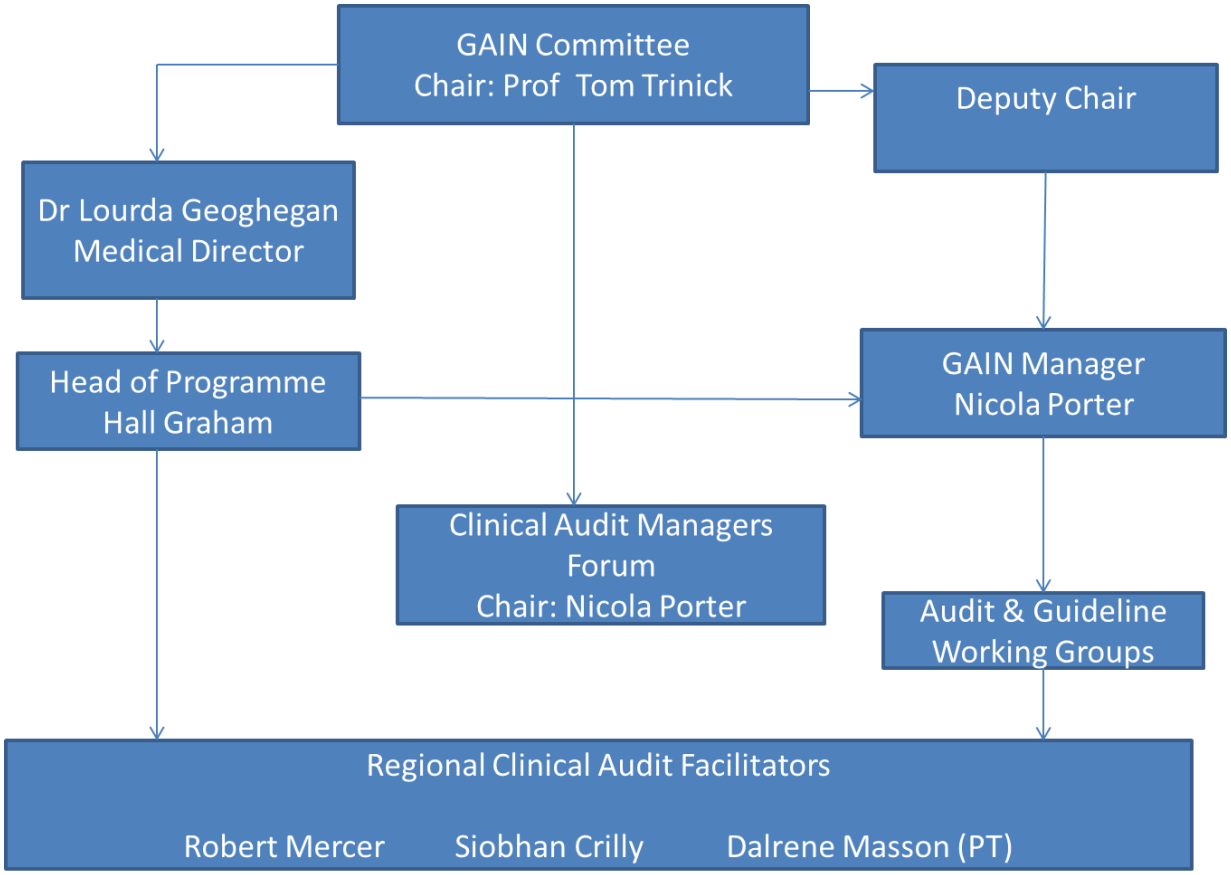
On the 1st April 2015, the responsibility GAIN transferred to The Regulation and Quality Improvement Authority (RQIA).

GAIN is now based at The Regulation and Quality Improvement Authority's headquarters which is located in central Belfast.

**Make-up of GAIN**

**GAIN Committee**, Chaired by Professor Thomas Trinick OBE, Consultant Chemical Pathologist, South Eastern HSC Trust is to be "*a representative multidisciplinary team to promote leadership in safety and quality care through the development and integration of regional guidelines and audit and their implementation*."

**Clinical Audit Managers Forum**, Chaired by Nicola Porter, GAIN Manager exists to "*provide a joint working and communication mechanism between the central GAIN facility and the Health & Social Care Trusts (HSCTs)*".



**Application and Approval Pathway**

Once a year GAIN invites the health community to apply for funding for the development of regional guidelines (as well as regional clinical audit). The application form can be found at www.rqia.org.uk (Appendix 1). Help in completing this form is available by contacting the GAIN office (Details in Appendix 8). It is worth noting that priority projects can be considered outside the given dates if appropriately completed and submitted.

| The invitation process | |
|---|---|
| June | Invitation to apply |
| September | Close of application submission process |
| November | Committee Meets to Adjudicate |
| December | All applicants informed of decisions |
| April | Commencement of all Guidelines and audits |

**Approval**

Please sign and return the GAIN Regional Guideline Project Approval Form (Appendix 3) which is sent with your successful funding letter.

**Link with GAIN Office**

Within a month of receiving your funding confirmation letter Project Leads **must** link with the GAIN Office to inform them of the scope and plans for progression of your project and regional plans. Failure to provide this outline may result in funding being withdrawn.

**GAIN Funding Policy/requests for information**

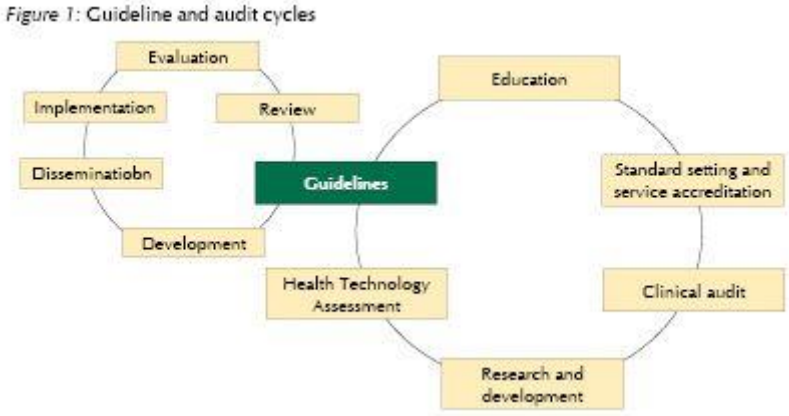
- Quarterly (June, August, November & February) the GAIN Office requests that you submit a monitoring form as per GAIN Funding Monitoring Policy (Appendix 4).
- Please respond to additional requests for information from the GAIN office.

## Clinical Guidelines

Guidelines can be used in a wide range of settings to promote effective and efficient healthcare – for example, to guide the introduction of new procedures or services, promote effective healthcare in primary or secondary care settings, encourage the adoption of cost-effective interventions and improve the timing and processes of the discharge of patients.[1]

According to SIGN[2] "Guideline development, implementation, and review should be seen not as a linear process, but as a cycle of interdependent activities. These in turn are part of a range of complementary activities to translate evidence into practice, set and monitor standards, and promote clinical excellence in NHS, as illustrated in Figure 1."

**Figure 1: Guideline and audit cycles**




## Definitions

**Guidelines** - The standard definition for clinical practice guidelines (CPG's) is Clinical "*systematically developed statements to assist practitioner and patient decisions about appropriate healthcare or specific clinical circumstances*".[3] Such guidelines can reduce unacceptable or undesirable variations in practice and provide a focus for discussion among health professionals and patients/clients/carers. They enable multiprofessional working to enable agreement regarding treatment as well as allowing professionals to devise a quality framework, against which practice can be measured. Guidelines can help commissioners and purchasers to make informed decisions and provide managers with a useful framework for assessing treatment costs. Guidelines are designed to support the decision-making processes in patient/client care. The content of a guideline is based on a systematic review of clinical evidence - the main source for evidence-based care.

[1] Effective Healthcare Bulletin No 8 Implementing Clinical Guidelines. Leeds: University of Leeds, 1994
[2] SIGN 50 – A Guideline Developer's Handbook Revised Edition January 2008
[3] Field & Lohr 1990 Page 38

**Protocols** – "*A plan or set of steps that defines how something will be done.*"[4] A protocol logically sets out a precise sequence of activities to be adhered to in the management of a specific clinical condition.

**Care Pathways** - "*anticipated care placed in an appropriate time frame, written and agreed by a multidisciplinary team. It has locally agreed standards based on evidence where available to help a patient with a specific condition or diagnosis move progressively through the clinical experience*". Care pathways form all or part of the clinical record, document the care given and help to evaluate outcomes for continuous quality monitoring.[5]

**Clinical Audit** - "*Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, process and outcome of care are selected and systematically evaluated against explicit criteria. Where indicated changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery*".[6]

**Potential barriers to developing good clinical guidelines**

1. The guideline has not been developed by a fully multidisciplinary group that is representative of those who will be using it, resulting in a lack of ownership.
2. If not truly multidisciplinary or representative recommendations can be influenced by the opinions, clinical experience and composition of the guideline group.
3. Recommendations not taking account of the evidence can result in suboptimal, ineffective or harmful practice.
4. There is often insufficient, misleading or misinterpreted evidence about what to recommend.
5. Guideline development groups often lack the time, resources and skills to gather and scrutinise evidence in detail.
6. Value judgements made by a guideline group may be the wrong choice for individual patients.
7. Patients' needs may not be the only priority in making recommendations; those of doctors, risk managers or politicians may also be involved. It is important that any

[4] National Institute for Clinical Excellence Glossary
[5] National Leadership and Innovation Agency for Healthcare, 2005. Page 8
[6] Principles for Best Practice in Clinical Audit (2002)

identified risks, benefits and side effects are considered during guidance development and they are appropriately communicated to the end user.

8. Conflicting guidelines from different professional bodies can confuse and frustrate practitioners.
9. Guidelines that are inflexible can cause harm by leaving insufficient room for clinicians to tailor care to patients' individual needs and personal circumstances.

**Legal implications**

Clinicians concerns about the legal status of guidelines and potential litigation resulting from non-compliance may be a barrier to their implementation. In the UK, mere deviation from a guideline is unlikely to be accepted as evidence of negligence by a court, unless the deviation itself was of a type that no doctor acting under ordinary skill and care would make. Doctors cannot be found negligent simply because they follow a practice that is rejected by another school of medical thought.

The NHS Executive has stated that: '*Clinical guidelines can still only assist the practitioner; they cannot be used to mandate, authorise or outlaw treatment options. Regardless of the strength of the evidence, it will remain the responsibility of the practising clinicians to interpret their application*.'[7]

**Equality**

GAIN are committed not only to meeting the statutory duties set out in Section 75 of the Northern Ireland Act 1998, but also to being proactive in meeting people's needs and promoting equality.

**Purpose of Guidelines**

- To describe appropriate care, based on the best available scientific evidence and broad consensus
- To reduce inappropriate variation in practice
- To provide a more rational basis for referral
- To provide a focus for continuing education
- To promote efficient use of resources
- To act as focus for quality control, including audit
- To highlight shortcomings of existing literature and suggest appropriate future research.

[7] NHS Executive Clinical Guidelines Leeds NHSE 1996:10

**Guideline Development**

In relation to the guideline development process in particular three areas are internationally agreed as important:

1. Identification and synthesis of evidence should be done using the methods of systematic review to maximise the appropriate identification of evidence.

2. The guideline development group should be appropriately multi-disciplinary to ensure a full discussion of relevant evidence, associated service delivery issues, and the appropriate construction of recommendations.

3. The recommendations in the guidelines should be clearly and explicitly linked to the evidence supporting them.

Before you submit your application to GAIN (Appendix 2), consideration should be given to the following:

1. Why are you planning to do this?
2. Who is requesting it?
3. Is there already guidance in this area available? (GAIN do not duplicate the work of SIGN, NICE or Royal Colleges)
4. What makes this a priority?
5. Is this in response to an emergency situation?
6. Do you have approval from your organisation?
7. Are you able to make a commitment to complete?
8. Have you included all relevant disciplines for involvement?

If you are unable to answer all of these questions then we suggest that you are not ready to start this work.

Consideration also needs to be given to:

**Who is your target audience?**

GAIN guidelines cross the whole Northern Ireland Health and Social Care arena and need to 'speak' to multiple audiences, which makes them challenging to produce. It is important that you have your key target audience in mind when drawing up your application form as it will make your task a lot easier - and you may even meet their needs! Writing documents that meet the

need of policy makers, health care managers and clinicians simultaneously is not simple and should be avoided wherever possible.

**What is our timeframe for completion?**

Realistically, producing good quality GAIN guidelines will take 12-18 months if all the evidence has already been synthesized, and you have someone to write it. If the guideline is going to cover a large number of questions, it may take up to 24 months to produce. Therefore you need to consider, do we really need this and do I have the time to commit to this project.

**Funding**

When completing your application for a GAIN guideline you need to consider requirement of funding for:

1. Do I need to pay locum or Service User/Carer expenses?
2. How much is the literature review going to cost?
3. Who is my external expert reviewer and appropriate costs?

**Are there existing guidelines documents that cover the same issue?**

If there is already guidance available whether from NICE, SIGN, Royal Colleges, etc what will be the added value and justification for a GAIN guideline? If you find that there is a need to have a Northern Ireland version, then the existing guidelines can be used as a starting point.

**What scientific evidence exists that can be used to guide recommendations?**

Do you know of existing systematic reviews? If not, it is worth doing a preliminary literature search at this stage to try to get a sense of what information is available. If there is no evidence - what will you base your guideline on?

**Who are the key external organisations, experts and stakeholders, who will need to be consulted or involved in this process?**

It is worth spending some time generating a list at the beginning of the process, for several reasons:

1. You need to identify potential members of your guideline group.
2. There may be additional experts or organisations who you may wish to consult on the scope of the document, the questions it covers, and also the choice of important outcomes for decision making,

3. There may be organisations and experts who could peer review your completed draft guideline. These may include groups likely to oppose or criticise the output on the basis of scientific or philosophical differences, and while it may not be possible to reach agreement with them, it is important that their input and comments are considered.
4. Many of these people will be key to implementation of the guideline recommendations and are more likely to help implement if they are involved from the beginning.

**Sustainability**

In recent years GAIN has steered away from printing guidelines where applicable as electronic versions can be more practical and are certainly cheaper. Therefore consideration must be given to the need and value for printing guidelines as well as wall charts, pamphlets, patient information leaflets, posters etc.

**GAIN Guidelines Groups**

To ensure that high-quality, robust guidelines are produced; all GAIN Project Teams must include representation from all key groups and disciplines concerned. By doing this we can ensure that:

- A real and relevant topic is being addressed
- Background and circumstances of topic being addressed are fully explained
- All relevant evidence will be critically evaluated
- All relevant questions and problems relating to the implementation and use of the guideline are addressed
- Guidelines will be deemed as high quality publications.

The Chair should be aware of all group dynamics and be prepared to overcome potentially serious difficulties through careful negotiation.

The Project Team should be multidisciplinary and include a mix of the skills relevant to all aspects of the guidance, such as:

- Clinical Expertise (eg Medical, Nursing)
- Other specialty expertise (eg social services, AHP's and where appropriate health economics)
- Practical understanding of problems faced in the delivery of care
- Communication and team working skills
- Critical appraisal skills[8]
- GAIN Manager

Secretarial support should be provided by a member of the Project Lead to ensure that the project teams' main focus is on the development of the guideline and not administration of meetings, this leads to continuity of service within the project team.

Each guideline should take no more than 18 months to develop. During that time it is envisaged that the group should plan to meet every 6-8 weeks, however, this is only a guide and groups can, if required, meet more frequently.

[8] Based on SIGN 50 A guideline developer's handbook Revised Edition 2008

**Commitment**

Project Group members should note that commitment will not only involve attendance at meetings but preparation and possible allocation of work strands to be completed. Therefore it is important that each person taking part has already factored into their schedule the time given to complete the guideline.

**Declaration of Interest Management**

It is imperative that all who participate in any GAIN work must declare an interest relevant to the meeting prior to their participation.

A requirement for all members to sign GAIN's 'Declaration of Interests' (See Appendix 3) will be requested at the first meeting. Thereafter at all subsequent meetings the Chair will ask for any changes in member's declaration circumstances as a standing item on the agenda. Should the meeting run over more than one financial year, a second form should be completed at the first meeting of the new financial year.

In addition, anyone invited to participate in a substantive role such as those who are involved in literature reviews, formulating the recommendations and/or writing the guideline must also complete a Declaration and Register of Interest form. Peer Reviewers and expert advisors are requested to complete and return a Declaration of Interest form to GAIN.

**Patient/Client & Carer Involvement**

GAIN adheres to the recommended core values underpinning the behaviour and attitude of HSC staff in their interactions with individuals and the public. These core values can be built upon by the mutual agreement of participants in public involvement activities.[9]

| | |
|---|---|
| **DIGNITY & RESPECT** | Each person is treated with dignity and respect. This includes individual responsibility to respect the views of all participants be they individuals, communities or HSC staff. |
| **INCLUSIVITY, EQUITY & DIVERSITY** | The PPI process should facilitate the inclusion of all those who need to be involved and who chose to do so. It must be sensitive to the needs and abilities of each individual. Each person's background, culture, language, skills, knowledge and experience will be valued, accommodated and respected. |
| **COLLABORATION & PARTNERSHIP** | The PPI process is based on collaboration and partnership working. Each person has a responsibility to build constructive relationships with others involved in the process. |
| **TRANSPARENCY & OPENNESS** | The PPI process should be open and transparent and each person has a responsibility to be open and honest in their interactions and relationships with others. |

GAIN ensure, (where appropriate), at least one patient /client and/or their carers to be involved in all their guideline and audit groups (were possible) as well as including relevant patient organisations.

It is reasonable for patient (PPI) representatives to be nominated through the Chair or other members of the Project Team.

GAIN requires that PPI representative(s):

- Have experience and/or knowledge of the subject at hand;
- Are able to give the required time commitment to take part in the group, such as attending meetings, background reading, making comment on draft copies, attending the launch;
- Have the ability to be objective;
- Are good communicators.

[9] DHSSPSNI Circular: HSC (SQSD 29/07

To help the PPI representative participate fully in working groups GAIN offers support through:

- Induction to GAIN
- Telephone, email and one to one advice and support
- Training in areas deemed beneficial to the representative, including clinical audit training.

It is important for the Group Chair to ensure that:

- The person(s) feel integrated into the project team
- Issues regarding a lack of acknowledgement of the PPI representative are addressed
- The PPI voice is heard
- Ensure that participation is **NOT** tokenistic.

In certain circumstances it may be more beneficial to have a PPI voluntary organisation representative present. This person should be offered the same courtesy as the patient/client or carer.

**Systematic Literature Review**

In order to start your literature search, GAIN would encourage you to use Health on the Net Northern Ireland (HONNI)

**Services for HSC Staff**

Library and information services are provided free of charge to HSC and Public Safety staff throughout Northern Ireland by Queen's University Medical & HSC Library, in partnership with the Department of Health, Social Services and Public Safety.

Services are provided from 6 main libraries in different parts of the province and through the HONNI website which is the primary gateway to electronic resources for local HSC professionals. Additionally, information resources for Social Services are available in various locations and limited facilities are available at most Hospitals across the province.

It is worth noting that while access to electronic resources is free, a small charge is payable for supply of photocopied or emailed articles.

You can use the library services to:

- Borrow books from any Medical & HSC Library site
- Search the online catalogue for details of available resources, both print and electronic, held in the different locations
- Search an extensive collection of databases and electronic journals (many in full-text)
- Place requests for books, and articles not available in full-text, either online or by filling in a form available from any of the libraries
- Renew books and manage your library account online
- Obtain training and support

Medical library staff can provide tailored advice on literature searching and training in the use of electronic resources in all 6 library areas.

Staff will assist users to make the best possible use of its resources. Healthcare Librarians and Subject Librarians can offer help in specific disciplines or areas of research.
Library Guides are available covering various aspects of library services including how to find resources in a particular field.

In order to access this facility you must register as a member of the Medical & HSC Library - all you need is proof of your HSC employment. You will be issued with a membership card, and a username and password to access electronic resources. You can then borrow from any of the libraries, log on to HONNI with the supplied username and password to access electronic resources, and avail of support and training.

Further information on the library service can be found at http://www.honni.qub.ac.uk/

**Systematic Review Training**

Once a year GAIN offer a Critical Appraisal Skills Course facilitated by SIGN (Scotland). Members of GAIN Guideline Groups are advised to attend.

GAIN also advises that all Guideline Development Groups adhere to Chapter 6 of "SIGN 50 A Guideline Developers Handbook".[10]

**Formulating Questions and Choosing Outcomes**

*(As SIGN deliver Critical Appraisal training for GAIN, this section is taken from SIGN 50).*

The training in critical appraisal and guideline development offered to members of GAIN guideline groups and delivered by SIGN encourages them to breakdown the guideline remit into a series of structured key questions using the PICO format:

**P**atients or population to which the question applies

**I**ntervention (or diagnostic test, exposure, risk factor, etc.) being considered in relation to these patients

**C**omparison(s) to be made between those receiving the intervention and another group who do not receive the intervention

**O**utcome(s) to be used to establish the size of any effect caused by the intervention.

The **Patients** or **population** to be covered by the literature searches is largely defined by the presence of the particular condition that the guideline will cover. It should be made clear at this stage, however, which age groups are to be covered. For searching the main medical databases these can be split into:

- Neonates <1 month

[10] http://www.sign.ac.uk/guidelines/fulltext/50/section6.html

- Infants up to 2 years
- Pre-school children aged 3-5 years
- Children aged 6-12
- Adolescents 13-18 years
- Adults 19-45 years
- Middle aged 46-64
- Aged 65-79 years
- Elderly 80+years.

Consideration should also be given as to whether any particular ethnic or social groups have particular needs in relation to the topic under review. If it is thought that any group needs particular consideration in relation to a key question (people of African origin who have sickle cell disease, for example, may need a different approach to antibiotic treatment) the needs of these groups should be specifically addressed in the key questions and subsequent literature searches.

It is worth emphasising here that questions should be addressed even if it is not thought there will be any good evidence. If there is in fact no good evidence, then highlighting it as an area for research is a useful outcome in itself.

Exclusion of any group from the population covered by the guideline should be identified when setting the key questions, and reasons given for their exclusion.

The **Interventions** (which in this context includes diagnostic tests, risk factors, risk exposure) must be specified clearly and precisely. The only exception is in drug therapy where drug classes should be used in preference to specific agents unless there is a clear reason for focusing on a named agent.

The decision on **Comparisons** is mostly between placebo/no treatment, or comparison with alternative therapies. It should be borne in mind that where there is an existing treatment comparison with placebo or no treatment are not ethically acceptable.
It is important to specify **Outcomes** in advance, and to think of these in terms of what outcomes will influence the views of guideline group members as to how effective a particular intervention is. For some questions there will be a wide range of outcomes used in the literature, and if

useful comparisons are to be made across studies it must be made clear which of these outcomes are important.

As far as possible outcomes should be objective and directly related to patient outcomes (eg length of time to next cardiovascular incident or survival time, rather than just reductions in blood pressure). It is also important to include outcomes that are important to patients, rather than focusing entirely on clinical outcomes.

These questions then form the basis of the literature search, which is undertaken by the Working Groups nominated person.

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

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

**Identifying and Selecting the Evidence**

The literature search must focus on the best available evidence to address each key question and should ensure maximum coverage of studies at the top of the study types. SIGN uses a set of standard search filters (See Appendix 4) that identify:

- Systematic reviews
- Randomised controlled trials
- Observational studies
- Diagnostic studies
- Economic studies.

These search filters are available at http://www.sign.ac.uk/methodology/filters.html

**Inclusion & Exclusion of Identified Evidence**

At the beginning of large systematic reviews, a series of inclusion and exclusion criteria should be developed to fit in with the question being asked.

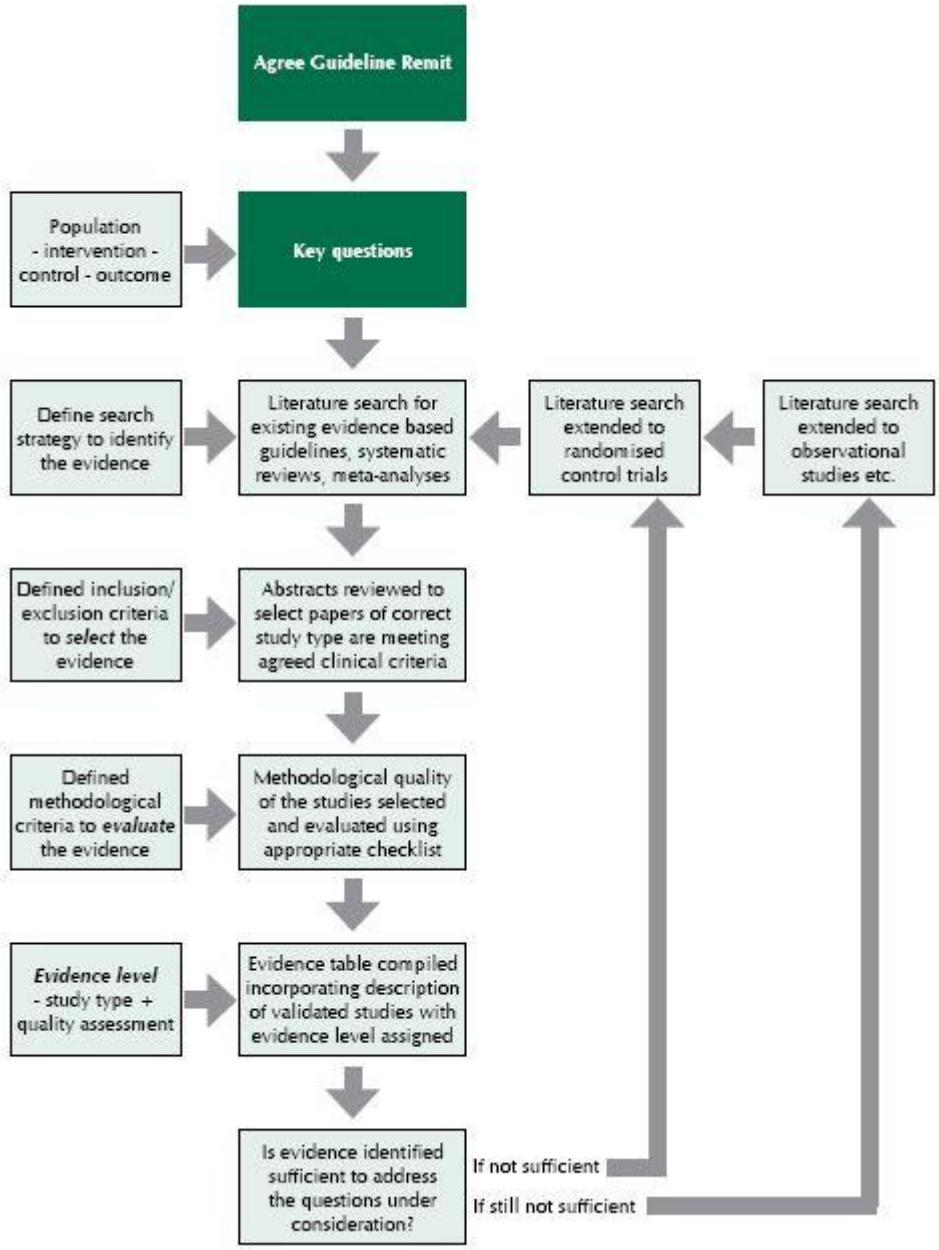
Evidence can often be excluded if it does not conform to certain study designs, such as they are not written in English or are outside a specific timeframe, eg 10 years. Caution needs to be applied in case of any bias that may be introduced into the review by adding certain inclusion or exclusion criteria. For example limiting to studies in English may miss important studies published in other languages (however, you need to be sure you have the resources to translate).

All decisions taken to include or exclude certain studies or groups of studies should be documented within the methods, thus showing the reason behind the project team's reason for focusing on some studies whilst excluding others. Agreement can be achieved using recognised methodologies, such as voting methodologies where appropriate if consensus is not possible. It also shows that the systematic process has been followed.

In large systematic reviews, the inclusion/exclusion criteria are applied to all the studies retrieved by the searches. At this stage the decisions are usually made using the titles and abstracts of the articles with those which are clearly irrelevant being excluded at this stage.

Full text papers are obtained for the remaining articles and the criteria reapplied. Those meeting the criteria are included in the review (although sometimes if too many papers are obtained the question and criteria are refined and the process repeated). This process is often represented using a flow diagram as shown below.

**SIGN Systematic Literature Review**




In order to minimise bias and to ensure adequate coverage of the relevant literature, the literature search must cover a range of sources. As a minimum, GAIN requires searches to cover Cochrane Library, Embase, Medline, NHS Economic Evaluations Database (NEED) and the Internet. It is expected that in most cases the search will also cover additional sources specific to the topic under review.

The search period covered will depend on the nature of the clinical topic under consideration, and will be discussed by the Working Group. For a rapidly developing field a 5 to 10-year limit to the search may be appropriate, whereas in other areas a much longer time frame might be necessary.

Before any papers are acquired for evaluation a sifting of the search output should be carried out to eliminate irrelevant material. Papers not clearly relevant to the key questions are eliminated. Abstracts of remaining papers are then examined and any that are clearly not appropriate study designs, or that fail to meet specific methodological criteria, will also be eliminated at this stage.

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

**Evaluating the Evidence**

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

The methodological assessment is based on a number of key questions that focus on those aspects of the study design that research has shown to have a significant influence on the validity of the results reported and conclusions drawn. These key questions differ between study types, and a range of checklists is used to bring a degree of consistency to the assessment process.

As stated previously GAIN use SIGN to deliver their systematic review training, therefore GAIN, like SIGN has based its assessments on the MERGE (Method for Evaluating Research and Guideline Evidence) checklists developed by the New South Wales Department of Health which have been subjected to wide consultation and evaluation. See Appendix 5 for copies of these checklists and accompanying notes on their use).

## Guideline Layout & Structure

Although the general formatting of the Guideline is left to the discretion of the GDG, it should be in an easy read format and should include the following areas:

**Title Page**

**Contents**

**Executive Summary**

This should contain the key recommendations of the guideline. As the executive summary is often read as a stand-alone document, the quality of evidence for each recommendation should be specified here as well as in the main body of the guideline.

**Introduction**

- Outline the need for the guideline, including evidence of variation in practice
- Define the remit of the guideline, including the groups of patients/clients/carers/ practitioners to which it applies.

**Methodology**

- Who is the guideline intended for?
- The Terms of Reference for the Guideline
- Declaration of Interests
- Involvement of Stakeholders
- Reference to evidence tables should include dates of search where appropriate
- Needs Assessment
- Who Developed the Guideline?
- Overview of the guideline
- The Guideline Development Group (GDG)
- Guideline Development Group Meetings
- Patient/carer Representatives
- Expert Advisers
- Updating the Guideline (date of publication should be on final documents)
- Funding

**Main Body**

- A statement of the question/issue under consideration
- Explanation of available options
- Summary of conclusions drawn from the critical appraisal of the evidence
- Recommendations and the development process used, ie: consensus and/or voting methodologies where appropriate
- Brief discussion of practical points or outstanding options for which there is no evidence
- Discussion of potential organisational and financial barriers to applying recommendations
- Good practice points
- Clinical audit requirements with a suggested clinical audit tool.

**Appendices**

- Brief details of systematic review (fuller piece can be added to website)
- Patient Leaflets
- Specialist Tools
- Assessment Charts
- Care Pathways
- Audit Tools
- Contact Information for relevant area (if necessary)
- Membership of Working Group
    - Including acknowledgement of Peer Reviewers and others who may have been co-opted in for a specific piece of work.
- Abbreviations.

**References**

Evidence tables will also be uploaded on to the RQIA website and will be available for viewing at www.rqia.org.uk/GAIN

**Consultation and Peer Review**

Once the Project Team are happy with the draft guidelines GAIN will send these out to all relevant parties for a wider consultation. This will include all Health & Social Care Trusts, the Public Health Agency, Health & Social Care Board (HSCB), Department of Health (Northern

Ireland) (DH (NI)), relevant patient/client and carer representative organisations and where appropriate the relevant Royal Colleges.

Following a pre-determined consultation period all comments received are collated and forwarded to the Project Team for their consideration.

Although the process of reviewing comments and responding to them should be transparent, it is not necessary to respond to every single comment individually. This should be made clear at the beginning of the process. However, an audit trail should be drawn up showing how comments were handled, either as a version of the document is the changes or as a separate summary.

Guidelines are then sent in their draft format for Peer Review to pre-selected, independent experts who are asked to give an impartial review on the comprehensiveness and accuracy of the information provided as well as its usability as a daily working tool.

It is advisable always to have more than one external peer reviewer. This gives the guideline project team a wider overview of the general consensus of accuracy and content of the guideline.

Your guideline should acknowledge the Peer Reviewers for their help and support during the development of the guideline.

**Expert Advisors**

During the development of the guideline the GDG will identify areas where there is a requirement for expert input on particular specialist topic areas. The topics should be addressed by either the production of a position paper or a formal presentation by a recognised expert who had been identified via the relevant registered stakeholder organisation. All relevant position papers should be presented as part of the evidence review. The guideline should state “This guideline was peer reviewed and informed by…” the members of relevant guideline group stakeholders.

**GAIN's Expectations for Peer Reviewer**

On receipt of the guideline the contents should be reviewed in light of best practice, clinical relevance, health benefits, potential risks and clarity.

**Dissemination of Guidelines**

To ensure widespread dissemination of the guidelines, it is advisable to organise a launch involving all health & social care staff involved in this particular area. This launch will look at the main areas of the guideline itself and where necessary include a training aspect. This will be organised by the GAIN Office in conjunction with the Working Group. It is the responsibility of the GAIN Office to produce and disseminate the launch invitation, programme (once programme has been agreed by the Working Group) and all relevant information.

Following the launch the guideline will be downloadable from www.rqia.org.uk/GAIN

**Implementation**

When considering who should be involved in the development of this guideline, people deemed as implementers within this specific area should be included in order to drive forward the implementation process. There is no use in having a guideline if there are no influential members on the Working Group.

**Review**

GAIN guidelines should be issued with a review date to provide an indication of how long the recommendations are expected to remain valid. GAIN would ask that consideration be given to reviewing validity on a three yearly basis. However, exceptions will be made where there are changes in evidence on the existing benefits and harms of interventions or changes in outcomes considered important.

If new evidence comes to light by the Project Lead, it is their responsibility to contact GAIN to trigger a review and update of the Guideline. If however, the evidence is brought to the attention of GAIN or another organisation, it is the responsibility of GAIN to contact the Project Lead.

If the project Lead is unavailable to review the GAIN guidelines, the Deputy Project Lead would be contacted. If this person is also unavailable to undertake the required changes, GAIN would seek to identify an expert in the required field.

**Clinical Audit**

It is important that the implementation and usage of each guideline is monitored through clinical audit. The Project Team along with the GAIN Regional Clinical Audit Facilitator will identify key areas within the guideline which can be audited and a clinical audit tool should be included within each guideline.

After a reasonable period of the guidelines becoming imbedded within daily routine, the GAIN Office will contact the guideline project lead to remind them of their responsibility to undertake or partake in the undertaking of an audit.

**References**


1. Andrews E. J. Redmond H.P. A Review of Clinical Guidelines. *British Journal of Surgery* 2004; 91; 8:956-954.
2. Eccles M., Mason J. Developing Valid Cost Effectiveness Guidelines; a methodological report from the north of England evidence based guideline development project. *Quality in Health Care* 2000;9;127-132.
3. Effective Healthcare Bulletin No 8 Implementing Clinical Guidelines. Leeds: University of Leeds, 1994
4. Field M. J., Lohr K.N. (eds). *Guidelines for Clinical Practice: From Development to Use*. Institute of Medicine. National Academy Press: Washington DC, 1992.
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6. National Institute for Clinical Excellence Glossary (www.nice.org.uk)
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8. NHS Executive Clinical Guidelines. Leeds NHSE 1996:10
9. Scottish Intercollegiate Guidelines Network, March 2004. (http://www.sign.ac.uk).
10. Frances A. et al. A New Method of Developing Expert Consensus Practice Guidelines. *The American Journal of Managed Care* 1998;4;7:1023-1029.
11. Eccles M., Mason J. How to develop Cost-Conscious Guidelines. (2001) *Health Technology Assessment 200;5:16*
12. http://www.agreecollaboration.org/pdf/agreeinstrumentfinal.pdf

**APPENDIX 1**

# Guideline Application form

**Proposed title of clinical/social care guideline**

| |
|---|
| |

**Contact person proposing topic for guideline development**

| | |
|---|---|
| **Name**: | **Position/Job Title**: |
| **Specialty (e.g. Nursing, Medical, AHP, Social Work etc)**: | **Email**: |
| **Address:**<br><br>**Postcode:** | **Telephone**: **Bleep**:<br><br>**Mobile**: |
| **Provide the name, job title and contact details of a deputy who will have a working knowledge of the guideline being developed and who will be able to act on your behalf** | |
| **Deputy Name**: | **Position/Job Title**: |
| **Specialty (e.g. Nursing, Medical, AHP, Social Work etc)**: | **Email**: |
| **Address:**<br><br>**Postcode:** | **Telephone**: **Bleep**:<br><br>**Mobile**: |

**Group(s) or institution(s) supporting the proposal** (e.g. Bamford Steering Group/subgroup, Northern Ireland Regional Nephrology Forum or Universities etc)

| Name | Group/Institution | Role within Guideline Development |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

**Indicate the professionals, service user/carers or representative organisations potentially involved in developing the guideline.**

| Name | Job Title | Group/Organisation |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
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| | | |
| | | |
| | | |
| | | |

**Please give brief details of any areas of concern for service user/carers or representative organisations** *(please describe how these issues have been identified e.g. reports from patient organisations, qualitative studies, help line statistics, testimonies from patients, etc).*

**Please define the areas the proposed guideline will address** *(e.g. screening, investigation, referral, management, and the patient groups to which it will apply)***.**

**Will the guideline apply to primary/secondary care, community or all?**

**Provide a brief background to the condition/topic which will be addressed by the proposed guideline.** (*This should include a description of the clinical/social care importance of the topic in terms of its appropriateness for inclusion in the GAIN programme*)

**What is the evidence of variation in practice in this area across Northern Ireland?**

**Please give an indication of the size and strength of the evidence base which is available to support recommendations on effective practice** *(including existing systematic reviews in this area).*

**Are there any existing guidelines relevant to this condition/topic? If so please comment on their quality and whether they are still valid.** (Please note that GAIN does not duplicate NICE guidance. Please provide source and date of publication).

**Provide any further information which you would like to be considered** *and* **how it relates to three key themes – Is care Safe, Effective, and Patient client focused.** *(e.g. links with audit programmes, educational initiatives, economic considerations, benefits of implementation, government strategies)*

**When do you plan to start the literature review?**

**How long do you estimate this project will take to complete (please attach project plan Template in Appendix 1)**

**When do you plan to have the guideline completed (including final report, recommendations, action plan and implementation plan)**

**Is there personal and public involvement (PPI) built into this guideline?**
http://www.publichealth.hscni.net/sites/default/files/PPI_leaflet.pdf
**Please give details of their involvement:**

**If there is no PPI please explain why?**

| |
|---|
| |

**Please provide details for your projects quality assurance process at each stage** (*eg name or designation of all reviewers*)**:**

| | |
|---|---|
| Literature Review | |
| Report writing | |
| Internal reviewers | |
| External reviewers (outside NI) | |

**How will the results be used? Please give examples:**

| |
|---|
| |

**Implementation**

**What plans have you put in place to carry forward the implementation of this guideline?**

| |
|---|
| |

**Do you have the support from all HSC Trust Executive Management Teams (EMT) to enable the recommendations to be taken forward?**

| | |
|---|---|
| Yes | No |

**If Yes, please provide details:**

| |
|---|
| |

**If No, how do you intend to implement the recommendations from the project?**

| |
|---|
| |

**Resources Required to develop the Guideline**

| Expenditure category | Amount £ | Guideline Financial Costs Additional Information/Comments |
|---|---|---|
| Literature Review Costs | £ | |
| Service user input/focus groups | £ | As per Trust/organisation policy |
| Service User Travel Costs | £ | As per Trust/organisation policy |
| Locum Costs | £ | As per relevant college guidelines |
| Project Lead Travel Costs | £ | As per Trust/organisation policy |
| Dissemination | £ | *As per GAIN |
| **Total** | **£** | |

***Please Note**: **Dissemination of Results**

Funding for dissemination events and printing of reports/leaflets is allocated to a maximum of £1,000. Any additional costs require supporting evidence prior to any dissemination event or printing being booked. A decision will be made on a case by case basis.

GAIN will not cover items such as laptops, recording machines, office furniture, stationery or University overheads.

**This application must be signed by the project lead**

By signing this form I agree to take responsibility to ensure the completion of this guideline, including quarterly monitoring, dissemination and the development of a implementation plan.

I understand that all guideline information resources, belong to GAIN may be made available to anyone on request.

| | | |
|---|---|---|
| | | |
| **Project Lead Signature** | **Name (printed)** | **Date** |

**This must be signed by the relevant Clinical Director**

I approve the project described above and confirm that it has been appropriately reviewed in relation to;

- Importance of topic/issue - aligned to NI HSC priorities and/or likely to improve healthcare outcomes,
- potential for process improvements,
- potential for change,
- sound methodology,

| | | | |
|---|---|---|---|
| | | | |
| **Clinical Director Signature** | **Name (printed)** | **Trust** | **Date** |

**Please return completed forms to:**

**GAIN**
**9th Floor, Riverside Tower**
**5 Lanyon Place**
**BELFAST**
**BT1 3BT**

**Tel: 028 9051 7465 (direct line)**
**Fax: 028 9051 7501**
**Email:** gain@rqia.org.uk
**Web:** www.rqia.org.uk

**APPENDIX 3**

**Project Approval Form**

| | |
|---|---|
| **Project Lead** | |
| **Audit Title** | |
| **Date Project Approved** | |

Approval of this audit project is subject to the commitment of the participants, overseen by the Project Lead and GAIN to:

- **Adhere to Common law on data protection and confidentiality**
- **Adhere to Freedom of Information Act 2000**
- **Comply with the Overarching GAIN Data Access Agreement and Trust Clinical Audit Policies and Procedures.**

**Project funding payment account details provided by Project Lead**

**Organisation to be paid:** _____

**Cost Centre:** _____

**Finance Officers Name:** _____

**Tel:** _____

**Finance Officers Email:**_____

| | |
|---|---|
| **GAIN Signature** N. Peters | **Date** _____/_____/_____ |
| **Project Lead Signature** | **Date** _____/_____/_____ |

**Guideline & Audit Funding Monitoring Policy**

Quarterly monitoring forms must be completed to ensure that accountability and transparency are in place for your project.

Project Leads must:

1. provide a breakdown of all expenditure;
2. sign form (electronic signature or scanned hard copy);
3. agree and sign off all travel claims;
4. return an expected expenditure for the following financial quarters.

Funded Projects are hosted by an individual HSC Trust /Organisation or University and it is the responsibility of the Project Lead to ensure that all team members are reimbursed for all their expenses relating to projects were applicable.

Table 1 is a Guide to expenditure, which provides some practical examples to assist Project Leads in the completion of the monitoring form. All completed monitoring forms should accurately reflect how the GAIN funding is being utilised per expenditure category.

**Table 1: Guide to Spend**

| Expenditure Category (As per project funding) | Amount £ | How to claim |
|---|---|---|
| Data Collector Training | | Travel costs as per Trust Policy |
| Casenote Retrieval | **3.00 per case note** | |
| Data Collection (e.g. 2 forms per hour /or as confirmed by Project Lead) | **15.00 per hour** | Claim as additional hours pro rata to the GAIN hourly rate of £15:00 e.g. if data cleansing relates to 10 hours project work they would calculate £15:00 x 10 hours = £150:00 then depending on their own personal hourly rate (for purpose of example hourly rate of £18:00) they would then divide the £150:00 by £18:00 = 8.3 hours to be claimed at single time on HRPTS/organisation payroll |
| Data Input (e.g.4 forms per hour/or as confirmed by Project Lead) | **10.00 per hour** | Claim as additional hours pro rata to the GAIN hourly rate of £10:00 e.g. if a data collector is claiming for 10 hours project work they would calculate £10:00 x 10 hours = £100:00 then depending on their own personal hourly rate (for purpose of example hourly rate of £15:00) they would then divide the £100:00 by £15:00 = 6.7 hours to be claimed at single time on HRPTS/organisation payroll |
| Data Cleansing | **15.00 per hour** | To a maximum of 20 hours |

| | | |
|---|---|---|
| | | Claim as additional hours pro rata to the GAIN hourly rate of £15:00 e.g. if data cleansing relates to 10 hours project work they would calculate £15:00 x 10 hours = £150:00 then depending on their own personal hourly rate (for purpose of example hourly rate of £18:00) they would then divide the £150:00 by £18:00 = 8.3 hours to be claimed at single time on HRPTS/organisation payroll |
| Data Analysis | **20.00 per hour** | To a maximum of 50 hours (Band 6)<br>Claim as additional hours pro rata to the GAIN hourly rate of £20:00 e.g. if a data analysis relates to 10 hours project work calculate £20:00 x 10 hours = £200:00 then depending on their own personal hourly rate (for purpose of example hourly rate of £18:00) they would then divide the £200.00 by £18:00 = 13.33 hours to be claimed at single time on HRPTS/organisational payroll |
| Literature review (GAIN Guidelines only) | 20.00 per hour | To a maximum of 100 hours (Band 7) as per example above |
| Report Writing/ amendments | 20.00 per hour | To a maximum of 120 hours (Band 7) as per example above |
| External Reviewer | 20.00 per hour | To a maximum of 25 hours (Band 7) |
| GP Locum costs (GAIN Guidelines only) | | As per Royal College |
| Travel & Subsistence | | As per Trust/Organisation Policy |
| Patient & Public Involvement (PPI) | | Travel costs as per Project Host Trust/Organisational Policy or RQIA Policy |

## GUIDELINE/AUDIT MONITORING FORM

| | |
|---|---|
| **Project Title** | |
| **Project Lead Contact** | |
| **Funding Received** | |
| **Date of work completed** | |

**Summary of Work Undertaken to Date**

**FUNDED GUIDELINE**

**Are there any known issues identified this quarter within the Guideline?**

Yes ☐ No ☐

**Have the issues been rectified?** Yes ☐ No ☐ N/A ☐

**FUNDED AUDIT**

**Are there any known issues identified this quarter within the Audit?**

Yes ☐ No ☐

**Have the issues been rectified?** Yes ☐ No ☐ N/A ☐

**If issues identified in your audit project did they involve**:

The audit process ☐ An urgent issue within clinical practice ☐ N/A ☐

**Please include details of the issues encountered**.

**Have these issues been rectified?** Yes ☐ No ☐ N/A ☐

**If the issue was with clinical practice, has the head of the department/service been notified?**

Yes ☐ No ☐ N/A ☐

**Funding Utilised in this Quarter** (Please provide a comprehensive breakdown of all costs)

| Expenditure category | Amount £ | Breakdown of costings |
|---|---|---|
| Data Collector Training (Audit only) | £ | |
| Casenote Retrieval ( £3 per case note) (Audit only) | £ | |
| Data Collection - (e.g. 3 proformas per hour) (Audit only) | £ | |
| Data Input - (e.g. 4 proformas per hour) (Audit only) | £ | |
| Data Cleansing (Audit only) | £ | |
| Data Analysis (Audit only) | £ | |
| Literature review (Guidelines only) | £ | |
| Report Writing/amendments | £ | |
| External Reviewer | £ | |
| GP Locum cost (Guidelines only) | £ | |
| Travel & Subsistence | £ | |
| Patient & Public Involvement (PPI) | £ | |
| Dissemination | £ | |
| Other please specify | | |
| **Totals** | **£** | |

| **Signed**** | **Date** |
|---|---|
| | |

**GAIN require that monitoring forms are returned with the signature of the Project Lead attached; either an electronic signature (if available) or a hard copy signed and then scanned and returned via email.

## TRAVEL EXPENSES CLAIM FORM

| |
|---|
| **Name of person claiming travel:** |
| **Name of Guideline/Audit:** |

| DATE OF TRAVEL | FROM | TO | PURPOSE OF TRAVEL | MILEAGE | AMOUNT CHARGED PER MILE | CLAIM AMOUNT (£) |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| Project lead signature: | | | | | **TOTAL** | |

**APPENDIX 5**

## Key Steps In the Development of the Guideline

1. Establish a clearly defined remit.

2. The nominated Chair appoints a Guideline Development Group (GDG).

3. Each member of the GDG receives GAIN information on guideline development and quality appraisal of clinical guidelines.

4. The group sets the key questions.

5. Members of the group then conduct systematic review searches, each member having responsibility for addressing a specific question.

6. The results of the searches are presented to the GDG and further searches may be commissioned.

7. Evidence tables are compiled for each of the key questions.

8. A draft guideline paper is submitted to GAIN based on the evidence search and evidence table check list.

9. This is circulated by GAIN to a large group of professionals with expertise in the area.

10. The results of the consultation process are forwarded to the GDG.

11. The GDG prepares a second draft of the guideline which may take account of the consultation process. The GDG also considers further key questions which may require additional searches.

12. The GDG present the second draft of the guideline to GAIN.

13. This is subject to a more limited consultation process of peer review.

14. The GDG then produces the final version of the guideline.

15. The guideline is launched at a regional meeting.

16. The GDG is reconvened by the Chairman after 2-3 years as part of the guideline review policy

**APPENDIX 6**

# Declaration and Register of Interests

| | |
|---|---|
| Lead Contact | Nicola Porter |
| Deisgnation of Lead Contact | GAIN Manager |
| Scope of Document | GAIN |
| Date | 19 February 2009 |
| Operational Date | 01 March 2010 |
| Review Date | 01 March 2017 |
| Version Number | V1.4 |
| Supersedes Previous | V1.3 |
| Lead Author | Nicola Porter |
| Lead Author, Position | GAIN Manager |
| Additional Authors | |
| Contact Details | Regulation & Quality Improvement Authority<br>9th Floor, Riverside Tower<br>5 Lanyon Place<br>BELFAST<br>BT1 3BT<br><br>Tel: 028 9051 7500<br>Fax: 028 9051 7501 |

| | | |
|---|---|---|
| Reference Number | Master Document Held By: | Issue Date: 01 March 2013 |
| | Nicola Porter | Review Date: 01 March 2017 |

## Introduction

GAIN is required to have in place a Policy to ensure the correct process is followed should a potential or perceived conflict of interest arise.

The standards of business conduct for NHS Staff – HSG (93)5 gives general guidance to staff on the declaration of interests and this policy ensures a robust process and guidance notes are available to staff.

## Purpose and Aim

This policy is intended to help GAIN Project and Committee Members understand their responsibility and to ensure that a register of interests is available for all, and if necessary, for public viewing.

The aim of this policy is to set out the procedure for handling conflicts of interest within The Guideline and Audit Implementation Network (GAIN). It describes:

- What is a conflict of interest
- The register of interests
- The procedures for handling conflicts of interest within Committee meetings and through fulfillment of GAIN duties

## Policy Statement

This policy supports a culture of openness and transparency in GAIN's business transactions.

The policy should be read in conjunction with the following documents, which also set out generic guidelines and responsibilities for NHS Trusts in relation to register of interests.

- Standards of business conduct for NHS Staff - HSG(93)5
- GAIN Statement of Purpose and Financial Management Statement
- Codes of conduct for NHS Managers

## Defining a Conflict Of Interest

Most Committee members have personal or professional interests, such as a hobby, an investment in a business or a desire to help friends and family members succeed in their own interests.

However, members who are in a position to directly or indirectly influence the outcome of GAIN business must take extra steps to ensure that their private interests do not compete with their professional duties. Examples of conflict would be:

- Directorships, including non-executive directorships held in private companies or PLCs;
- Ownership or part-ownership of private companies, business or consultancies likely or possibly seeking to do business with GAIN or the NHS
- Majority or controlling shareholdings in organisations likely or possibly seeking to do business with GAIN or the NHS
- A position of authority in a charity or voluntary body in the field of Health and Social Care
- Any connection with a voluntary or other body contracting for NHS services

**Procedure during Meetings, Opening Of Tenders or Other Business Matters**

During any meeting where subject matter leads a participant to believe that there could be a conflict of interest, this must be declared at the earliest convenient point. This can relate to their personal circumstances or anyone they are aware of at the meeting.

Declarations must be identified within the minutes of that meeting, including any need to withdraw and reasons for doing so.

Those with pecuniary interests should withdraw from the meeting and those with non-pecuniary interests will be allowed to stay, depending upon the circumstances. The meeting needs to determine whether there could be a matter of bias in the matter. The Chair of the meeting must take the decision as to the need for the member of the meeting to withdraw or not from the proceedings. Where this may involve the Chair, the Deputy Chair will take this decision.

If the Chair of a meeting is the person who the declaration of interests relates, the Chair should vacate the seat and the meeting for that item. If there is no Deputy Chair present at the meeting, the meeting must first elect a chair from within their number by a show of hands.

**Register of Interests**

All Committee members and Budget Holders (any member of staff who manages a budget, however small, or who is a signatory to a budget within their department) are required to complete an annual declaration of interests form.

A copy of the request for declaration and the declaration form are appended to this policy or can be obtained from the GAIN Secretary.

It is important to remember that conflicts of interest apply to all members, regardless of whether they complete a declaration.

**Procedure Notes for Declaring a Conflict Of Interest**

If after referring to the above guidance it is necessary for a member of the committee to declare a conflict of interest, in addition to the annual declaration, the following steps should be taken to ensure full compliance with this policy:

- Inform the GAIN Office;
- Ask for guidance if necessary from the GAIN Manager in order to confirm a conflict of interest;
- Contact the Chairman to inform them;
- Supply full detail of the conflict – this is required in writing via post or email

The Chairman will ensure the entry is completed on the register and that relevant forum is informed.

**Committee Members Awareness of the Policy**

Members will periodically be reminded of the policy and register at least annually. This will be undertaken via the GAIN Office, as well as the Committee Meetings.

**Breaches of the Policy**

Non-compliance with the above requirements will exclude a member from future involvement with GAIN and subsequent Committees, sub-committees, etc. If it is proven that actual fraud has taken place then criminal charges may be brought.

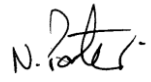
**Review and Audit**

The Policy will be reviewed annually by the GAIN Committee Chairman.

Details of the register will be reported to the GAIN Committee annually.

A Report on the register of interests for GAIN Committee Members will be presented to the Joint Strategic & Operational Committee Meeting annually.

Strategic Committee Chairman



GAIN Manager (Author)

Date: 01 March 2016

**Declaration of Interests**

Please ensure that this form is completed in full and submitted to the GAIN Office.

| Full Name |
| --- |
| |

| GAIN Project or Committee |
| --- |
| |

1) In the table below please give details of any Directorships (executive or non-executive), or other employment by public or private companies likely or possibly seeking to do business with GAIN or the NHS that you, or a close associate, currently hold or have held in the last 12 months.

| Name of External Organisation | Address | Position Held or Relationship |
| --- | --- | --- |
| | | |

2) In the table below please give details of any significant shareholdings in public or private companies or ownership or part-ownership of or employment by businesses or consultancies likely or possibly seeking to business with GAIN or the NHS, held by you or a close associate.

| Name of Company | Shareholding Held |
| --- | --- |
| | |

3) In the table below please give details of any remunerated or honorary positions and other connections with the NHS and other public sector bodies, held by you or a close associate, which may give rise to a conflict of interest.

| Name of Body | Position Held |
| --- | --- |
| | |

4) In the table below please give details of any membership, paid or unpaid, of any official committee (such as research council, government department, professional

institution, advisory body to an industrial company, or charitable organization) held by you or a close associate, which may give rise to a conflict of interest.

| Name of Organisation | Role Held |
|---|---|
| | |

5) In the table below please give details of any other interest of yourself, a close associate or a family member, which may give rise to a conflict of interest that you should declare.

| Name of Organisation | Role Held |
|---|---|
| | |

Please delete either (a) or (b) of the following and sign and date the form.

Either:

(a) I confirm that I have declared all relevant external activities of which I am personally aware set out on this form in accordance with the Conditions of GAIN Membership.

OR

(b) I confirm that I do not have any interest to declare in response to questions 1, 2, 3, 4 or 5

It is essential that each member keeps their interests and conflicts up to date on a regular basis as perceived by this Conflict & Declaration Policy.

I undertake to keep the declaration of interests up to date.

Signed: _____ Date: _____

Print Name _____

## Declaration of Interests

Please ensure that this form is completed in full and submitted to the GAIN Office.

| Full Name |
| --- |
| |

| GAIN Committee |
| --- |
| |

6) In the table below please give details of any Directorships (executive or non-executive), or other employment by public or private companies likely or possibly seeking to do business with GAIN or the NHS that you, or a close associate, currently hold or have held in the last 12 months.

| Name of External Organisation | Address | Position Held or Relationship |
| --- | --- | --- |
| | | |

7) In the table below please give details of any significant shareholdings in public or private companies or ownership or part-ownership of or employment by businesses or consultancies likely or possibly seeking to business with GAIN or the NHS, held by you or a close associate.

| **Name of Company** | **Shareholding Held** |
| --- | --- |
| | |

8) In the table below please give details of any remunerated or honorary positions and other connections with the NHS and other public sector bodies, held by you or a close associate, which may give rise to a conflict of interest.

| Name of Body | Position Held |
|---|---|
| | |

9) In the table below please give details of any membership, paid or unpaid, of any official committee (such as research council, government department, professional institution, advisory body to an industrial company, or charitable organization) held by you or a close associate, which may give rise to a conflict of interest.

| Name of Organisation | Role Held |
|---|---|
| | |

10) In the table below please give details of any other interest of yourself, a close associate or a family member, which may give rise to a conflict of interest that you should declare.

| Name of Organisation | Role Held |
|---|---|
| | |

Please delete either (a) or (b) of the following and sign and date the form.

Either:

(c) I confirm that I have declared all relevant external activities of which I am personally aware set out on this form in accordance with the Conditions of GAIN Membership.

OR

(d) I confirm that I do not have any interest to declare in response to questions 1, 2, 3, 4 or 5

It is essential that each member keeps their interests and conflicts up to date on a regular basis as perceived by this Conflict & Declaration Policy.

I undertake to keep the declaration of interests up to date.

Signed: _____ Date: _____

Print Name _____

**APPENDIX 7**

## Key to evidence statements and grades of recommendations

### 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 or studies<br>High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal |
| 2+ | Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal |
| 2- | Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal |
| 3 | Non-analytic studies, e.g. case reports, case series |
| 4 | Expert opinion |

### Grades of Recommendations

| | |
|---|---|
| A | At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; *or*<br><br>A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results |

| | |
|---|---|
| B | A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; *or*<br><br>Extrapolated evidence from studies rated as 1++ or 1+ |

| | |
|---|---|
| C | A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; *or*<br><br>Extrapolated evidence from studies rated as 2++ |

| | |
|---|---|
| D | Evidence level 3 or 4; *or*<br><br>Extrapolated evidence from studies rated as 2+ |

### Good practice points

| | |
|---|---|
| ✔ | Recommended best practice based on the clinical experience of the guideline development group |

**Appendix 8**

## Contact details of GAIN

| Name | Title | Email |
|---|---|---|
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