



## **NHS Greater Glasgow and Clyde Clinical Guideline Framework**

Development, Review, Approval and Monitoring of  
Medicine and Non-Medicine Related Guidelines

Lead Managers	Director of Clinical and Care Governance Director of Pharmacy
Responsible Director	Board Medical Director
Approved by	Board Clinical Governance Forum
Original date of approval	February 2012
Date of update	February 2023
Date for review	February 2026
Replaces previous version (if applicable)	January 2018
Version	4

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## 1. Introduction

- 1:1 NHS Greater Glasgow and Clyde (NHSGGC) recognises the need for a robust process for the development, review, approval and monitoring of clinical guidelines.
- 1:2 Clinical guidelines have been defined as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances”. They are designed to help practitioners assimilate, evaluate and implement the ever increasing amount of evidence and opinion on best current practice. Where there is evidence of variation in practice which affects patient outcomes, and a strong research base providing evidence of effective practice, guidelines can assist healthcare professionals in making decisions about appropriate and effective care for their patients.
- 1:3 The essential elements of good guidelines were identified by the US Institute of Medicine in 1990<sup>1</sup> including validity, reliability, clinical applicability, clinical flexibility, clarity, multidisciplinary process, scheduled review, and documentation. The recommendations were underpinned by the twin themes of credibility and accountability, and highlighted that the link between a set of guidelines and the scientific evidence base must be explicit.

The Scottish Intercollegiate Guidelines Network (SIGN) original Criteria for Appraisal of Clinical Guidelines for National Use <sup>2</sup> and the AGREE (Appraisal of Guidelines for Research and Evaluation guideline appraisal instrument <sup>3</sup>are based on these founding principles of guideline development.

## 2. Scope

- 2:1 The NHSGGC Clinical Guideline Framework incorporates in its scope both medicine and non-medicine related clinical guidelines.
- 2:2 Outwith the NHSGGC centralised processes for clinical guidelines (this framework) and clinical policies (the NHSGGC Policy Development Framework), each service should determine appropriate arrangements for developing and approving other decision-making support tools, such as protocols and procedures. Documents will be considered against the definition of a clinical guideline when determining whether they fall within the scope of this framework and these arrangements.
- 2:3 The NHSGGC Clinical Guideline Platform has been developed to provide a central repository to access all NHSGGC clinical guidelines. The platform is provided by the Right Decision Service, and can be found at the following link: [NHSGGC Clinical Guideline Platform](#)
- 2:4 A toolkit has been developed to support the implementation of this framework, which will be regularly reviewed, evaluated and updated. This contains guidance on the distinction between guidelines, policies and other key decision-making support tools, templates for the documents and processes referred to within the framework, guidance for guideline authors and approval groups, as well as information on where to find support. The index and toolkit can be found on the NHSGGC Clinical Guideline Platform.

## 3: Aims

- 3:1 The NHSGGC Clinical Guideline Framework supports the delivery of the NHSGGC Clinical Governance Policy (2023)<sup>4</sup> which documents the strategic aim to reliably provide safe, effective, person centred care for every person.
- 3:2 The NHSGGC Clinical Guideline Framework aims to ensure that clinical guidelines:
- reflect best practice, and that all key staff are involved in their development and agreement
  - are reviewed and approved by an appropriate group
  - are up to date and kept under regular review

## **4: Roles and Responsibilities**

### **4:1 Board Medical Director, Responsible Director**

- The Board Medical Director has overall responsibility for the NHSGGC Clinical Guideline Framework, and ensures that the requirements of the NHSGGC Clinical Guideline Framework are followed.

### **4:2 Director of Clinical and Care Governance/ Clinical Governance Support Unit**

- Lead Author of the NHSGGC Clinical Guideline Framework
- Provides advice on the NHSGGC Clinical Guideline Framework and the supporting processes
- provide support to categorise decision-making support materials, and therefore determine whether a document fall within the scope of this framework
- Develop a communication and implementation plan for the framework
- Disseminate the framework as appropriate
- Ensure implementation of the framework, including the development of management systems to support
- Ongoing review of the framework and processes to ensure it remains fit for purpose
- Ensure that the framework is reviewed at the stated date
- Ensure clinical guideline processes are maintained
- Alert lead author(s) to prompt for a review of the clinical guideline, approximately 90 days prior to the review date specified.
- Ensure a reporting and escalation framework is in place to highlight to the appropriate clinical governance structures those clinical guidelines which have breached their review date.
- Maintain an archive of clinical guidelines to ensure that each version of a clinical guideline which has been uploaded on the Clinical Guideline Platform is retained and can be retrieved if required.

### **4:3 Director of Pharmacy Services/ NHSGGC Pharmacy Services**

- Joint author of the NHSGGC Clinical Guideline Framework
- Provides advice on medicine related guidelines and processes in support the NHSGGC Clinical Guideline Framework

### **4:4 Clinical Guideline Lead authors**

- Lead authors should adhere to the principles contained within this framework when developing or updating clinical guidelines
- Lead authors should advise of any changes to clinical advice when guidelines are updated.
- The lead author of the clinical guideline is responsible for the review of the clinical guideline, which should take place as a minimum every 3 years.

### **4:5 Clinical Guideline Approving Groups**

- Review the clinical guideline against agreed criteria, and approve the guideline if satisfied the criteria have been met
- Link to the Clinical Governance Support Unit to ensure that approved guidelines are uploaded to the Clinical Guideline Platform, and included in tracking processes
- Ensure clinical guidelines are reviewed and updated as required.

### **4:6 Clinical Guideline User Group**

- Provide a forum to bring together key stakeholders and users of the Clinical Guideline Platform and clinical guideline processes to share successes, discuss issues and potential solutions, or to request expertise / support from the Clinical Governance Support Unit.
- To support decision making in relation to any required changes or updates to the new Clinical Guideline Platform or associated clinical guideline processes.

#### **4:7 Directors and General Managers**

- Ensure that the requirements of the NHSGGC Clinical Guideline Framework are followed
- Ensure systems are in place to review and implement relevant approved clinical guidelines in their areas

#### **4:8 Line Managers**

- Ensure clinical guidelines are accessible to all staff. Staff should access clinical guidelines on the NHSGGC Clinical Guideline Platform, noting that the electronic version is the only version that is maintained, and that any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.
- Ensure staff have read and understood the clinical guidelines pertinent to their area
- Ensure systems exist to identify staff training needs on the implementation of new clinical guidelines

#### **4:9 Employees/ Guideline users**

- All NHSGGC staff should be aware that a framework exists for clinical guidelines
- All staff should refer to NHSGGC clinical guidelines when making decisions about appropriate and effective care for their patients. A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments. Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty. If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

### **5: Principles for guideline development and approval**

#### **5:1 Principles for guideline development**

5:1:1 NHSGGC clinical guidelines may be developed for one of the following:

- NHSGGC wide
- An individual Division e.g. Acute, Mental Health, Primary Care
- An individual sector/directorate/Health and Social Care Partnership (HSCPs)
- An individual department/service/ specialty

5:1:2 Clinical guidelines should only be developed for individual sector/directorate/HSCPs where they are exclusively relevant to that area.

5:1:3 Clinical guidelines should only be developed if required, and are subject to approval by an appropriate group.

5:1:4 NHSGGC must show 'due regard' to meeting the requirements of the Equality Act (2010) and aligned Public Sector Equality Duty. All clinical guidelines must evidence 'due regard' by ensuring they take all reasonable measures in implementation to eliminate unlawful discrimination, harassment and victimisation, promote equality of opportunity between different protected characteristic groups and foster good relations between those who share a protected characteristic and those who do not.

5:1:5 Clinical guidelines should uphold the Patient Rights (Scotland) Act 2011 and the set of Healthcare Principles that underpin quality care and treatment. Specifically guidelines and the accompanying recommendations should:

- Be patient focused:

- Ensure that the needs, circumstances and abilities of patients are taken account of and that support to access or receive health care is available.
- Ensure and maintain patients' dignity, respect, privacy and confidentiality.
- Ensure that the delivery of health care is both caring and compassionate.
- Ensure quality care and treatment and have regard to the importance of providing optimal benefit to the patient:
  - Consider the range of treatment options available.
  - Ensure that the health care provided avoids any unnecessary harm or injury to the patient.
  - Ensure that the environments in which patients receive health care are appropriate and as clean and safe as is reasonably possible.
- Enable patients to participate as fully as possible in decisions relating to their health and wellbeing:
  - Ensure that information about the patient's health and wellbeing and treatment options is communicated and available in a form that is clear, accessible, easy to understand and appropriate to the their needs.
  - Ensure staff are clear about their role in the delivery of patient focussed care and the need to ask if patients require support.
- Seek to include the views of the patient groups the guidelines will impact on.
- Avoid waste of resource

5:1:6 NHSGGC clinical guidelines should conform to the principles outlined in the criteria in the AGREE (Appraisal of Guidelines for Research and Evaluation) guideline appraisal instrument<sup>3</sup>

- There is a need for a local clinical guideline
- The overall objectives for the development of the clinical guideline are clearly described
- The clinical question(s) covered by the clinical guideline are specifically described
- The patients to whom the clinical guideline is meant to apply are specifically described
- The title of the clinical guideline accurately reflects the content and scope of the guideline
- The clinical guideline has clearly defined authorship
- The development group includes all individuals from all the relevant professional groups
- The target users of the clinical guideline are clearly defined
- The potential cost implications of applying the recommendations have been considered
- The clinical guideline recommendations are specific and unambiguous
- The key recommendations are easily identifiable
- The implementation and evaluation plan have been considered
- The clinical guideline presents key review criteria for monitoring and or/audit purposes
- The clinical guideline contains a review date
- The clinical guideline is evidence based
- The clinical guideline has a clear rationale for change

5:1:7 Clinical guidelines should be developed in line with relevant supporting NHSGGC guidance and policies, including:

- NHSGGC Clear To All guidance
- NHSGGC Policy Development Framework
- NHSGGC Equalities in Health guidance and principles

## 5:2 Principles for Guideline Approval

### 5:2:1 Clinical guidelines involving medicines

Only clinical guidelines that fulfil specific criteria will be presented to the Area Drugs and Therapeutics Committee (ADTC) for review and approval. Clinical guidelines fulfilling **one or more** of the

following criteria should be referred for review and approval by the ADTC.

Criteria:

- The clinical guideline is expected to be used across Acute **and** Primary Care
- There are significant new cost implications beyond a single sector/directorate /HSCP
- There are significant new service implications beyond a single specialty
- The clinical guideline has been produced by a Managed Clinical Network
- The clinical guideline includes non-formulary medicines
- Clinical guidelines developed for new medicines specifically at the request of Area Drugs and Therapeutics Committee or its subcommittee.

All other NHSGGC medicines related clinical guidelines not fulfilling the above criteria should be reviewed and approved for use within the appropriate clinical governance structures.

### **5:2:2 Clinical guidelines not involving medicines**

Only clinical guidelines that are expected to be used across Acute **and** Primary Care **and/or** Mental Health will be referred to the Board Clinical Governance Forum for review and approval.

Clinical guidelines fulfilling **one or more** of the following criteria should be referred for review and approval by the Acute Services Clinical Governance Forum **or** Primary Care and Community Governance Forum (following assessment to ensure that they do not have wider implications):

1. The clinical guideline relates to **more than one** Sector/Directorate or HSCP.
2. There are significant new cost implications beyond a single sector/directorate or HSCP.
3. There are significant new service implications beyond a single sector/directorate or HSCP.

Clinical guidelines which relate exclusively to an individual Department or Sector/ Directorate/HSCP can be approved by the relevant Departmental or Sector/Directorate/HSCP clinical governance committee/forum to which the clinical guideline applies (following assessment to ensure that they do not have wider implications), for example clinical guidelines which relate exclusively to Mental Health can be approved by the Mental Health Clinical Governance Forum (following assessment to ensure that they do not have wider implications).

Clinical guidelines which relate exclusively to one specialty can be approved by the relevant cross sector specialty clinical governance committee/forum (where this exists) to which the clinical guideline applies (following assessment to ensure that they do not have wider implications).

### **5:2:3 Clinical guidelines for cancer medicines**

The West of Scotland Regional Cancer Network develops and facilitates approval, via the Regional Cancer Advisory Group, of a large number of clinical guidelines for the treatment of cancer. These guidelines are then issued to individual health boards for ratification. It is recognised that additional arrangements are required to ensure that these guidelines are reviewed and implemented appropriately within NHSGGC. A separate process has, therefore, been devised for guidelines relating to cancer medicines.

Clinical guidelines for the use of systemic anticancer therapy and other adjunctive therapy in the management of cancer are generally developed and approved for use within the West of Scotland by the Regional Cancer Advisory Group/ Prescribing Advisory Subgroup (RCAG- PASG). Typically this is in response to national guidance but the initiative may also stem from a regional source e.g. via a Managed Clinical Network. In selected circumstances, clinical guidelines may also be developed locally within NHSGGC.

All clinical guidelines developed by the RCAG-PASG in response to national (NICE/SMC) guidance will be referred directly to ADTC (via Formulary and New Drugs Subcommittee) for ratification and formulary management, via the established RCAG-PASG reports to ADTCs.

Clinical guidelines which should be referred to the NHSGGC Regional Services Clinical Governance Group (RSCG) for ratification include those originating from a regional services or

## NHSGGC source

- where one or more of the medicines is being prescribed 'off label'
- where prescribing reflects 'custom & practice' and / or latest evidence base which is out with the Formulary
- where the regional approach varies from national advice
- The RSCG will fulfil a 'governance role', ensuring that due process has been followed with the development of the guideline, rather than undertaking further clinical review of the guideline content

Clinical guidelines which if implemented will result in significant service or cost implications should be referred to the Acute Services Prescribing Management Group (AS PMG) and if required to the Board Prescribing Management Group (PMG).

Clinical guidelines that have significant implications for directorates out with Oncology or where there are significant implications for Primary Care should be referred to ADTC.

### **5:2:4 Clinical guidelines involving antimicrobial medicines**

Antimicrobial guidelines which meet specific criteria will be reviewed by the Antimicrobial Utilisation (AUC) Subcommittee which will have devolved responsibility to approve these on behalf of the Area Drugs and Therapeutics Committee. On occasion, the AUC may request that guidelines which meet specific criteria are taken to ADTC for final ratification.

### **5:2:5 Clinical Guidelines in the NHSGGC Medicines Adult Therapeutic Handbook**

The NHSGGC Medicines Adult Therapeutics Handbook resource is intended as a reference source for education about the safe and effective use of medicines. The information provides a starting point for the immediate management of many common conditions and situations. The content is intended for use by healthcare professionals working in NHSGGC. All guidance included in the Adult Therapeutics Handbook must be agreed for use across all acute sites within NHSGGC.

Clinical guidelines in the Clinical Guideline Directory are not automatically included in the Adult Therapeutics Handbook. If Lead Authors wish their clinical guideline to also be included in the Handbook, they must also submit the guideline to the Adult Therapeutics Handbook Editorial Group for consideration. The Adult Therapeutics Handbook Editorial Group will review approved clinical guidelines for suitability and will communicate directly with the Lead Author regarding the decision.

Criteria for inclusion of guidelines in the Adult Therapeutics Handbook are available from the Adult Therapeutics Handbook Editorial Group. Further information can be found on the Therapeutic Handbook website.

## **6: Monitoring and Review**

- 6:1 Clinical guideline development, review, approval and implementation will be monitored locally through governance and management structures; and organisation wide by the Board Clinical Governance Forum.
- 6:2 Information on the development, review, approval and implementation of clinical guidelines will be provided routinely at the Clinical Governance Groups/Forums/meetings.
- 6:3 Clinical guidelines should be kept under continuous review particularly to reflect new evidence. More formal review should not exceed 3 years from guideline development.
- 6:4 The component parts of the organisation will produce an annual report on clinical governance that will be submitted to the Board Clinical Governance Forum, and will include information on clinical guideline development & implementation.



## 7: References

1. Field M, Lohr K. Institute of Medicine Committee to Advise the Public Health Service on Clinical Practice Guidelines. Clinical practice guidelines: directions for a new program. Washington (DC): National Academy Press; 1990.
2. Scottish Intercollegiate Guidelines Network (1995) Clinical guidelines: criteria for appraisal for national use. Edinburgh
3. The AGREE Collaboration. The Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument. Available from url: <http://www.agreetrust.org>
4. NHSGGC (2023) Clinical Governance Policy
5. Legislation.gov.uk. Patient Rights (Scotland) Act (2011). [http://www.legislation.gov.uk/asp/2011/5/pdfs/asp\\_20110005\\_en.pdf](http://www.legislation.gov.uk/asp/2011/5/pdfs/asp_20110005_en.pdf)
6. Scottish Government (2012). The Patient Rights (Health Care Principles) (Scotland) Directions 2012 (The Health Care Principles Directions). [http://www.sehd.scot.nhs.uk/mels/CEL2012\\_07ssiA.pdf](http://www.sehd.scot.nhs.uk/mels/CEL2012_07ssiA.pdf)