NHS Greater Glasgow and Clyde Clinical Guideline Framework

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

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Approved by	Board Clinical Governance Forum
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1. Executive Summary

Clinical Guidelines Framework

Purpose of the Framework
To establish a consistent and transparent process for the development, review, approval, implementation, and oversight of all clinical guidelines across NHSGGC.

Purpose

- Consistent, transparent process for developing, reviewing, approving, implementing, and overseeing all clinical guidelines

Scope

- All clinical guidelines, medicine and non-medicine
- Principles: evidence-based, patient-centred, equality, legal compliance, clarity
- Reviewed every 3 years; medicines also reviewed by ADTC

Aims

- Ensure evidence-based, safe, person-centred care
- Standardise processes to maintain quality and compliance
- Improve patient outcomes through oversight and continuous improvement

Roles and Responsibilities

Executive Board Medical Director:
Overall accountability for framework implementation

Director of Clinical and Care Governance:
Strategic leadership, oversight, communication

Director of Pharmacy Services:
Expert advice on medicine-related guidelines

Clinical Guideline Lead Authors:
Develop, update, and review guidelines

Clinical Guideline Approving Groups:
Review and approve guidelines

Clinical Guideline User Group:
Stakeholder engagement and feedback

Directors and General Managers:
Ensure local implementation

Line Managers:
Ensure staff access and training

Employees and Guideline Users:
Apply guidelines in practice

Monitoring and Review

- Formal review every 3 years
- Continuous monitoring by governance and feedback
- Annual Clinical Governance Forum reports
- Updates reflect new evidence, regulations, and user needs

2. Introduction

2.1 NHS Greater Glasgow and Clyde (NHSGGC) recognise the need for a robust process for the development, review, approval and monitoring of clinical guidelines

2.2 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

2.3 The accepted criteria for validity of guidelines were first set out as the essential elements of good guidelines by the US Institute of Medicine in 1990[1]. These recommended attributes of good guidelines included validity, reliability, clinical applicability, clinical flexibility, clarity, multidisciplinary process, scheduled review and documentation. The recommendations were underpinned by the twin themes of credibility and accountability: The link between a set of guidelines and the scientific evidence must be explicit, and scientific and clinical evidence should take precedence over expert judgement

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

3. Scope

3.1 The NHSGGC Clinical Guideline Framework incorporates in its scope both medicine and non-medicine-related clinical guidelines

3.2 Outside the NHSGGC centralised processes for clinical guidelines (as described in 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 should be considered against the definition of a clinical guideline to determine whether they fall within the scope of this framework or are managed under these local arrangements

3.3 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

3.4 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 Clinical Guideline Toolkit

4. Aims

4.1 The NHSGGC Clinical Guideline Framework supports the delivery of the NHSGGC Clinical Governance Policy (2023)[4] which documents the strategic aim to reliably provide safe, effective, person centred care for every person

4.2 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

5. Roles and responsibilities

5.1 Executive Board Medical Director, Responsible Director

- The Executive 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

5.2 Director of Clinical and Care Governance/ Clinical Governance Support Unit

- Provide strategic leadership in the development, governance, and continuous improvement of the NHSGGC Clinical Guideline Framework
- Lead author and custodian of the NHSGGC Clinical Guideline Framework, ensuring it is clear, accessible, and aligned with national standards
- 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
- Support effective dissemination of the framework across relevant governance and clinical structures
- Ensure governance mechanisms are in place to support implementation, monitoring, and compliance with the framework
- 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 all versions uploaded to the NHSGGC Clinical Guideline Platform are retained and can be retrieved when required to support transparency, audit, and legal compliance
- Facilitate cross-sector collaboration, supporting consistency and integration of clinical guidelines across Acute, Primary Care, Mental Health, and Community Services
- Oversee the governance of the online platform that hosts clinical guidelines

5.3 Director of Pharmacy Services/ NHSGGC Pharmacy Services

- Joint author and contributor to the development of the NHSGGC Clinical Guideline Framework
- Provide expert advice and oversight on all medicine-related clinical guidelines, collaborating with guideline authors to ensure content is clinically accurate, evidence-based, and prioritised according to clinical importance and risk, in line with regulatory standards and safety best practices, and support their implementation across NHSGGC

5.4 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
- The lead author is expected to respond in a timely manner to reminders regarding guideline review dates
- Coordinate cross sector/ specialty input to ensure the guideline is comprehensive and relevant to all intended areas of practice
- Notify the guideline team and arrange handover of responsibility to another colleague when changing posts or no longer responsible for the guideline

5.5 Clinical Guideline Approving Groups

- Review the clinical guideline against agreed criteria, and approve the guideline if the criteria have been met
- Coordinate with the Clinical Governance Support Unit to ensure that approved clinical guidelines are uploaded to the NHSGGC Clinical Guideline Platform and incorporated into clinical guideline monitoring processes
- Support processes for the review and updating of clinical guidelines to ensure accuracy and relevance

5.6 Clinical Guideline User Group

- Provide a forum to bring together key stakeholders and users of the NHSGGC 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 NHSGGC Clinical Guideline Platform or associated clinical guideline processes
- Promotes cross-disciplinary engagement and champions the effective use of clinical guidelines to support evidence-based practice across NHSGGC

5.7 Directors and General Managers

- Ensure adherence to the NHSGGC Clinical Guideline Framework within their directorates and services
- Ensure systems are in place to review and implement relevant approved clinical guidelines in their operational areas
- Champion a culture of clinical governance and continuous improvement by supporting clinical guideline awareness, accessibility, and integration into clinical practice

5.8 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 official maintained version, while any printed copies are considered 'Uncontrolled' and may not contain the latest updates or amendment
- 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

5.9 Employees/ Guideline users

- All NHSGGC staff should be aware of the existence of a framework for clinical guidelines
- All staff should refer to NHSGGC clinical guidelines when making decisions about appropriate and effective care for their patients
- Guidelines are 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 valid reasons for not following a guideline, it is good practice to document these decisions and communicate them to all others involved in the patient's care

6. Principles For Guideline Development and Approval

6.1 Principles for Guideline Development

Clinical guidelines within NHSGGC must only be developed when there is clear, evidence based justification, and where their implementation is expected to directly enhance patient safety, quality of care, and clinical outcomes. The development of guidelines should not be undertaken unless there is a recognised gap in practice, variation affecting patient safety, or new evidence that necessitates change

Proposals for new guidelines must include a documented rationale, which can include reference to patient safety concerns, audit findings, practice variation or gaps in practice

All guidelines must be underpinned by robust evidence and include an assessment of their anticipated impact on patient safety and clinical effectiveness

6.1.1 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
- Not site-specific: Clinical guidelines that are applicable to only a single hospital site should be avoided. If felt necessary, a rationale will be required for consideration during approval

6.1.2 Applicability

Clinical guidelines should only be developed for individual Sector/ Directorate/ HSCPs where they are exclusively relevant to that area

6.1.3 Guideline Approval

Clinical guidelines are subject to approval by an appropriate group before publication. An assessment of the rationale for development of the guideline, and its impact on patient safety and clinical effectiveness will inform approval decisions

6.1.4 Equality and Legal Compliance

NHSGGC must show 'due regard' to meeting the requirements of the Equality Act (2010) [5] and aligned Public Sector Equality Duty[5]. 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

6.1.5 Patient-Centred Care

Clinical guidelines should uphold the Patient Rights (Scotland) Act 2011[6] and the set of Healthcare Principles[7] 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 their needs
  - Ensure staff are clear about their role in the delivery of patient-focused care and the need to ask if patients require support
- Seek to include the views and experiences of patient groups who will be affected by the guideline
- Ensure resources are used efficiently and avoid unnecessary duplication of effort

6.1.6 NHSGGC clinical guidelines should conform to the principles outlined in the criteria in the AGREE II guideline appraisal instrument[3]:

- Domain 1. Scope and purpose:
  - The overall objective(s) of the guideline is (are) specifically described
  - The health question(s) covered by the guideline is (are) specifically described
  - The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described

- Domain 2. Stakeholder involvement:
  - The guideline development group includes individuals from all relevant professional groups
  - The views and preferences of the target population (patients, public, etc.) have been sought
  - The target users of the guideline are clearly defined
- Domain 3. Rigour of development:
  - Systematic methods were used to search for evidence
  - The criteria for selecting the evidence are clearly described
  - The strengths and limitations of the body of evidence are clearly described
  - The methods for formulating the recommendations are clearly described
  - The health benefits, side effects, and risks have been considered in formulating the recommendations
  - There is an explicit link between the recommendations and the supporting evidence
  - The guideline has been externally reviewed by experts prior to its publication
  - A procedure for updating the guideline is provided
- Domain 4. Clarity of presentation:
  - The recommendations are specific and unambiguous
  - The different options for management of the condition or health issue are clearly presented
  - Key recommendations are easily identifiable
- Domain 5. Applicability:
  - The guideline describes facilitators and barriers to its application
  - The guideline provides advice and/or tools on how the recommendations can be put into practice
  - The potential resource implications of applying the recommendations have been considered
  - The guideline presents monitoring and/or auditing criteria
- Domain 6. Editorial independence:
  - The views of the funding body have not influenced the content of the guideline
  - Competing interests of guideline development group members have been recorded and addressed

6.1.7 Alignment with NHSGGC Policies

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
- NHSGGC Consent Policy
- NHSGGC Unlicensed Medicines Policy

6.1.8 Evidence-Based Development and Review

Clinical guidelines shall be developed based on the best available evidence and reviewed at least every 3 years to ensure continued relevance and accuracy

6.2 Principles for Guideline Approval

6.2.1 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, off-label, or unlicensed medicines
- Clinical guidelines developed for new medicines specifically at the request of Area Drugs and Therapeutics Committee or its subcommittee

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

6.2.2 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):

- The clinical guideline relates to more than one Sector/ Directorate or HSCP
- There are significant new cost implications beyond a single Sector/ Directorate or HSCP
- 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)

6.2.3 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 service 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 outside Oncology or where there are significant implications for Primary Care should be referred to ADTC

6.2.4 Clinical guidelines involving antimicrobial medicines

Guidelines which relate to treatment or prophylaxis of infection or include use of an antimicrobial medicine 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

6.2.5 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 (ggc.therapeutics.handbook@nhs.scot)

7. Principles for Monitoring and Review

7.1 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

7.2 Information on the development, review, approval and implementation of clinical guidelines will be provided routinely at the Clinical Governance Groups/ Forums/ meetings

7.3 Clinical guidelines should be kept under continuous review, particularly to reflect new evidence. More formal review should not exceed 3 years from guideline development

7.4 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 and implementation

7.5 Feedback from guideline users will be collected and reviewed to support ongoing improvement, revision, and updates to clinical guidelines

7.6 Issues identified through monitoring will be escalated and managed through established clinical governance structures and processes to ensure accountability and timely resolution

Clinical Guideline Framework Status and Supporting Resources

This framework is a high-level document developed to standardise the processes for the development, review, approval, implementation, and monitoring of clinical guidelines across NHSGGC. It sets out the overarching principles, governance arrangements, and responsibilities.

Detailed operational processes, templates, and supporting guidance are available within the Clinical Guideline Toolkit, which should be used alongside this framework to support practical implementation.

8. References

1. Institute of Medicine (US) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines. *Clinical Practice Guidelines We Can Trust.* Washington (DC): National Academies Press (US); 2011. Available from: https://nap.nationalacademies.org/catalog/13058/clinical-practice-guidelines-we-can-trust
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