NHS LANARKSHIRE
Guidance on the Development, Approval, Review and Monitoring of Medicine and Non-Medicine Related Guidelines

Lead Manager	Director of Quality
Responsible Director	Medical Director
Developed by	Clinical Guidelines Project Group
Approved by	Healthcare Quality Assurance and Improvement Steering Group
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Replaces previous version (if applicable)	
Version	Version 1

DOCUMENT HISTORY

Version	Changes by	Changes made	Date
Version 1.1	Comments made by Clinical Guidelines Project Group	Changes made to text and appendix 3	8 and 12 January 2015
Version 1.2	Reviewed by HQAISG	Ratified by	20 January 2015
Version 2	Eileen McGinley Dr Mehrdad Malekian George Lindsay	Document redrafted and ratified by ADTC	October 2017

Introduction

NHS Lanarkshire Guidance on the Development, Approval, Review, and Monitoring of Medicine and Non-Medicine Related Guidelines aims to ensure that NHSL clinical guidelines are developed and agreed, ensuring all key staff are involved and informed, and that the guidelines reflect best practice. Furthermore the process aims to ensure that clinical guidelines are kept under regular review and up to date.

A central web based directory of approved clinical guidelines is available to all staff and independent contractors in NHSL via NHSL's website. This will support standardisation and review of clinical guidelines and help to reduce potential duplication. The directory is called the NHS Lanarkshire Clinical Guideline Website.

When a guideline has been developed/reviewed and ratified, the lead author will submit the guideline to the Clinical Guidelines Team (CGT) via the generic account clinicalguidelines@lanarkshire.scot.nhs.uk. The team will upload the guideline to the website where it will be widely and easily accessible to NHSL staff and contractors.

A standard review process will be initiated when the guideline is posted on the website. The lead author of the guideline is responsible for its review and will receive emails from the CGT prompting a review to be undertaken, at 90, 60 and 30 days prior to the review date specified.

Principles of Guideline Development - Medicine and Non Medicine Related Guidelines

NHS Lanarkshire clinical guidelines may be developed at one of the following levels (with ratification):

- NHS Lanarkshire wide
- An individual operational entity, or groups of operational entities
- An individual department/service/specialty/directorate (only where exclusively relevant to that area)

Clinical guidelines should only be developed where there is a need for a clinical guideline. Such development should ensure that:

- the guideline has clearly defined authorship
- the guideline contains a review date
- the title of the guideline accurately reflects the content and scope of the guideline
- the target users of the guideline are clearly defined
- the population to whom the guideline applies is specifically described
- the guideline's development has been informed by individuals from all relevant professional groups
- the potential cost implications of applying the recommendations have been considered
- the guideline recommendations are specific and unambiguous
- implementation and evaluation plans have been considered

Clinical Guideline Checklist Completion

A checklist should be completed for each new and updated clinical guideline. A copy of the checklist is included in the Supplementary Information Section.

- The lead author completes sections A-C of the checklist and submits it along with the guideline to their AMD or HoD for review.
- The AMD/HoD reviews the guideline and the checklist and approves both or refers back to the lead author for additional work.
- If approved, the AMD/HoD submits the guideline and checklist to the Approved Ratifier* as appropriate for ratification.

- Once ratified the Approved Ratifier advises the lead author that the guideline and checklist should be submitted to the CGT via clinicalguidelines@lanarkshire.scot.nhs.uk for posting on the NHS Lanarkshire Clinical Guidelines Website.

*The Approved Ratifier is at a level that can take a strategic overview for the organisation e.g. at the level of Associate Medical Director, Area Drugs and Therapeutic Committee.

Approval for Clinical Guidelines Involving Medicines

Clinical guidelines involving medicines
Where guidelines involve medicines, the Guidance on the Production of Guidelines and Protocols Involving Medicines must be followed.

Guidelines fulfilling one or more of the following criteria should be referred for review by ADTC

1. The clinical guideline involves use of medicine(s) and has clinical implications for multiple directorates within Acute and/or is expected to be used across Acute and Primary Care
2. There are significant new cost implications beyond a single Acute Service and for Primary Care
3. There are significant new service implications beyond a single Acute Service and for Primary Care
4. The clinical guideline has been produced by a Managed Clinical Network
5. The clinical guideline includes non-formulary medicines
6. Clinical guidelines developed for new medicines specifically at the request of Area Drugs and Therapeutics Committee or its subcommittee.

Where there is uncertainty about the guideline needing ADTC approval, advice should be sought from chair of ADTC.

Clinical guidelines for cancer medicines
The West of Scotland (WoS) Regional Cancer Advisory Group develops and approves a large number of clinical guidelines for the treatment of cancer. Clinical guidelines for the use of chemotherapy 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-PAG). These guidelines are ratified by the Area Drugs and Therapeutic Committee.

Clinical guidelines involving antimicrobial medicines
Antimicrobial guidelines which meet specific criteria are reviewed by the Antimicrobial Management Team. Please refer to the Guidance on the Production and Approval of Guidelines/Protocols Involving Antimicrobial Medicines.

Expired Guidelines

When a guideline approaches its review date, the lead author will be notified at 90, 60 and 30 days prior to review date. It is the lead authors' responsibility to advise whether the guideline is valid, has been superseded or is obsolete.
- If the guideline remains valid the lead author should refresh the document with updated review date, and complete a new checklist. The new checklist is required to ensure reviewer and ratifier details remain current.
- If the guideline has been superseded, a new checklist should be completed to accompany the new guideline. The expired guideline will thereafter be removed from the web site.

Should the review of a guideline not be concluded by its specified review date, and following the prompt periods, the CGT will provide a report to the appropriate Associate Medical Director (AMD) / Head of Department (HoD) who will in turn raise it with the lead author and may escalate to the Divisional Medical Director (DMD).

Any guideline which is out of date and awaiting decision by the appropriate DMD will be prefixed on the directory to reflect its 'Beyond Review Date' status

Roles and Responsibilities of Individuals

Medical Director

- Overall responsibility for the NHS Lanarkshire Guidance on the Development, Approval, Review, and Monitoring of Medicine and Non-Medicine Related Guidelines process.
- Ensure that the requirements of the NHS Lanarkshire Guidance on the Development, Approval, Review, and Monitoring of Medicine and Non-Medicine Related Guidelines process are followed.

Lead Manager

- Ongoing review of NHS Lanarkshire Guidance on the Development, Approval, Review, and Monitoring of Medicine and Non-Medicine Related Guidelines to ensure they remain fit for purpose.
- Ensure that the guidance is reviewed by the specified review date.
- Ensure a database of clinical guidelines is maintained and that the documents are readily accessible to all relevant staff and independent contractors.

Directors and General Managers

- Ensure that the requirements of the NHS Lanarkshire Guidance on the Development, Approval, Review, and Monitoring of Medicine and Non-Medicine Related Guidelines are followed.
- Ensure systems are in place to review and implement relevant approved clinical guidelines in their areas.

Lead Authors

- Adhere to the principles outlined in NHS Lanarkshire Guidance on the Development, Approval, Review, and Monitoring of Medicine and Non-Medicine Related Guidelines when developing clinical guidelines.
- Ensure an appropriate implementation and communication process is in place for approved clinical guidelines
- Identify training needs.
- Forward the approved completed checklist and clinical guideline to the Clinical Guidelines Team via: clinicalguidlines@lanarkshire.scot.nhs.uk
- Remove duplicate or conflicting guidelines from any other repository.
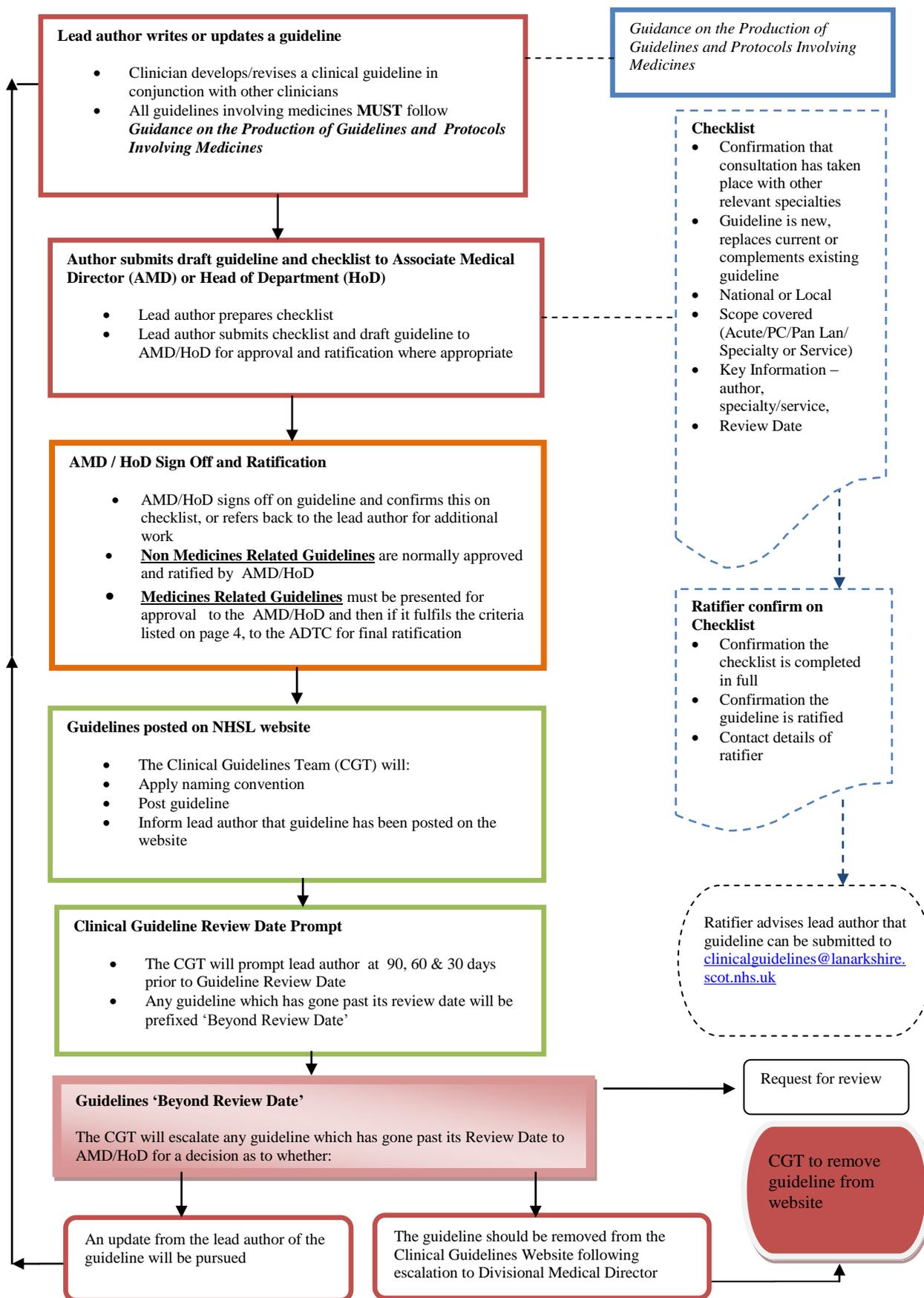
Line Managers

- Ensure clinical guidelines are accessible for all their staff, either in paper or electronic format.
- 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.

All NHS Lanarkshire Personnel

- Be aware of NHS Lanarkshire Guidance on the Development, Approval, Review, and Monitoring of Medicine and Non-Medicine Related Guidelines.
- Be familiar with accessing the web based system on the NHS Lanarkshire website.
- Refer to NHS Lanarkshire clinical guidelines when making decisions about appropriate and effective care for their patients when correct action is not already known by them.

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

Lead author writes or updates a guideline

- Clinician develops/revises a clinical guideline in conjunction with other clinicians
- All guidelines involving medicines **MUST** follow *Guidance on the Production of Guidelines and Protocols Involving Medicines*

Guidance on the Production of Guidelines and Protocols Involving Medicines

Author submits draft guideline and checklist to Associate Medical Director (AMD) or Head of Department (HoD)

- Lead author prepares checklist
- Lead author submits checklist and draft guideline to AMD/HoD for approval and ratification where appropriate

Checklist

- Confirmation that consultation has taken place with other relevant specialties
- Guideline is new, replaces current or complements existing guideline
- National or Local
- Scope covered (Acute/PC/Pan Lan/ Specialty or Service)
- Key Information – author, specialty/service,
- Review Date

AMD / HoD Sign Off and Ratification

- AMD/HoD signs off on guideline and confirms this on checklist, or refers back to the lead author for additional work
- **Non Medicines Related Guidelines** are normally approved and ratified by AMD/HoD
- **Medicines Related Guidelines** must be presented for approval to the AMD/HoD and then if it fulfils the criteria listed on page 4, to the ADTC for final ratification

Ratifier confirm on Checklist

- Confirmation the checklist is completed in full
- Confirmation the guideline is ratified
- Contact details of ratifier

Guidelines posted on NHSL website

- The Clinical Guidelines Team (CGT) will:
- Apply naming convention
- Post guideline
- Inform lead author that guideline has been posted on the website

Clinical Guideline Review Date Prompt

- The CGT will prompt lead author at 90, 60 & 30 days prior to Guideline Review Date
- Any guideline which has gone past its review date will be prefixed 'Beyond Review Date'

Ratifier advises lead author that guideline can be submitted to clinicalguidelines@lanarkshire.scot.nhs.uk

Guidelines 'Beyond Review Date'

The CGT will escalate any guideline which has gone past its Review Date to AMD/HoD for a decision as to whether:

Request for review

CGT to remove guideline from website

An update from the lead author of the guideline will be pursued

The guideline should be removed from the Clinical Guidelines Website following escalation to Divisional Medical Director

Supplementary information

DEFINITIONS

NHS Lanarkshire sets out definitions for a policy, procedure, guideline and protocol in its policy *How to Write a Policy* on FirstPort

There are no definitive 'official' definitions for clinical guidelines and protocols. This information has been brought together from a number of online sources, and is provided as a point of reference to support the labelling of decision making support tools.

NHS Lanarkshire has a process whereby clinical guidelines are approved by an Approved Ratifier. The Approved Ratifier is at a level that can take a strategic overview for the organisation e.g. at the level of Associate Medical Director, Area Drugs and Therapeutic Committee or Antimicrobial Management Team.

Policy
A policy is a specific statement of principles/guiding actions that provide a basis for consistent decision-making and resource allocation. Basically, a course of action established as a guide towards accepted objectives.

> *Key features*
> - *A broad statement of intent*
> - *Who is your target group?*
> - *Statement of 'What' and 'Why'*

Procedure
A procedure is a series of steps followed in regular order taken to implement a policy.   Procedures can be mapped using a flowchart.

Protocols
Protocols are a set of measurable, objective standards which determine a course of action.

> *Key features*
> - *A more specific document*
> - *Narrow application*
> - *Stated in detail*
> - *'How', 'When' and 'Who'*
> - *Describes process*

Clinical Guideline
Guidelines are often used to underpin a policy. They are a set of standards or rules which assist in the decision on how to:
- apply the policy or
- manage specific conditions.

Key Features
Clinical guidelines are evidence-based statement (or series of statements) used to assist clinicians in the decision-making process about appropriate treatment and care in specific circumstances. Clinical guidelines are not intended to replace clinical freedom; however they should normally be followed unless there is a good reason not to do so. Clinical guidelines often include algorithm/flowcharts – if A happens do B; if X happens do Y and Z.

- Clinical guidelines are not the ultimate decision makers regarding a particular clinical procedure or treatment plan. The ultimate decision must be made by the practitioner in the light of each individual patient's condition, circumstances, and the diagnostic and treatment options available.

- What are clinical guidelines for?
  - Guidelines provide recommendations for effective practice in the management of clinical conditions where variations in practice are known to occur and where effective care may not be delivered uniformly throughout Scotland.
  - Guidelines can be used to develop standards to assess the clinical practice of health professionals.
  - Guidelines can be used in the education and training of health professionals.

- Guidelines can help patients to make informed decisions, and improve communication between the patient and health professional.

- Guidelines are often spoken interchangeably with protocols. Some clinicians take the view that protocols must be followed, whereas clinical guidelines are only there to advise and inform decision-making. However, it is doubtful whether in law this distinction is helpful or meaningful. Whether you call something a guideline or a protocol, if agreement has been reached that this document constitutes best practice, you should be able to justify any occasion where it is not followed.

- Guidelines direct clinicians along preferred treatment pathways by outlining detailed management plans for discrete clinical conditions judged amenable to stepwise decision making processes (flowcharts, algorithms).

- Guidelines can be detailed descriptions of the steps taken to deliver care or treatment to a patient and are sometimes called the 'integrated care pathway'.

- Medline definition: '*Precise and detailed plans for the study of a medical or biomedical problem and/or plans for a regimen of therapy*'.

CHECKLIST FOR CLINICAL GUIDELINE DEVELOPMENT, REVIEW, APPROVAL AND POSTING ON INTERNET

INSTRUCTIONS FOR COMPLETION
- **Lead Author** to complete sections A-C (blue) of the checklist and submit with the clinical guideline to the Head of Department for sign off.
- **Head of Department** to review sections A-C (blue) of the checklist against the criteria in section D (green) and sign off.
- **Approved Ratifier (Associate Medical Director, Head of Department)** to ratify guideline section E (purple) and email guideline and checklist to Clinical Guideline Team generic account: clinicalguidelines@lanarkshire.scot.nhs.uk

SECTION A: CLINICAL GUIDELINE INFORMATION (*Please check boxes and complete*)

Name of the clinical guideline: *This **MUST** be in line with the naming convention: Drug name / Procedure, Condition, Patient Group, (Scope)** *Refer for guidance to **Key List of Terms** (MESH) available on Website* **Scope = primary care referral/acute care/specialty or service/general use/specific professional group e.g.* • Glycaemic Control in Adults with Type 1 Diabetes (acute) • Antifungal Agent Selection Guideline for Invasive Fungal Infections in Adult Patients (acute general ward)	Please specify the review date for the clinical guideline: **dd/mm/yyyy:** *The review date must not exceed 3 years from date of guideline development.*
Does the clinical guideline supersede existing guideline? **Yes** ☐ **No** ☐	If yes, please specify the title of the superseded guideline:
Lead Author Details **Name:** **Designation:** **Email:** **Telephone number:**	**Department:** **Directorate:** **Work address:**

SECTION B: CLINICAL GUIDELINE DEVELOPMENT (*Please check boxes and complete*)

Consultation has taken place within specialty, with other relevant specialties / services, uni-disciplinary / multidisciplinary / primary care / acute ☐	Please specify stakeholders consulted:
Are there any additional cost implications / service implications associated with the introduction of the clinical guideline?	**Yes** ☐ **No** ☐ If yes, where / who has agreed the additional cost:
Is it a national or local guideline?	**National** ☐ **Local** ☐
Is guideline in line with a national guideline?	**Yes** ☐ If yes, which one: **No** ☐ If no, provide reason:
Has the guideline been approved by a Drugs and Therapeutic Group?	**Yes** ☐ **No** ☐ If yes, which one:
Does the guideline include non-Formulary or unlicensed/off label medicines?	**Yes** ☐ **No** ☐
Have you developed an implementation and evaluation plan for the clinical guideline? (*if based on SIGN guideline utilise NHSL SIGN evaluation process*)	**Yes** ☐ **No** ☐ If yes, please provide the Head of Department with the implementation and evaluation plan along with the completed checklist.

SECTION C: CLINICAL GUIDELINE CLASSIFICATION (*Please tick all that apply*)

Please note: The **primary search** of the NHS Lanarkshire Clinical Guideline Website will be on the **clinical guideline title**. To enable easier storage and retrieval of the clinical guideline, please **tick all** that apply from the classification below.

Acute Services Division	All Acute	HM	MK	WGH	Associated Hospitals	Health and Social Care Partnerships	Both HSCPs	North HSCP	South HSCP
	☐	☐	☐	☐	☐		☐	☐	☐

Service / Specialty		Service / Specialty		Service / Specialty		Service / Specialty	
Acute Pain	☐	Endoscopy	☐	Minor Injury & Nurse Treatment	☐	Psychiatry	☐
Addictions	☐	ENT Surgery	☐	Neonatology	☐	Psychological Services	☐
Anaesthetics	☐	Gastroenterology	☐	Neurology	☐	Public Health Medicine	☐
Audiology	☐	General Medicine	☐	Obstetrics	☐	Radiology	☐
Biochemistry	☐	General Surgery	☐	Occupational Therapy	☐	Renal Medicine	☐
Cancer Services	☐	Genito-urinary Medicine	☐	Oncology	☐	Respiratory Medicine	☐
Cardiology	☐	Gynaecology	☐	Ophthalmology	☐	Rheumatology Medicine	☐
Care of the Elderly	☐	Haematology - Labs	☐	Oral & Maxillofacial Surgery	☐	Sexual Health Service	☐
Child Protection	☐	Haematology - Medicine	☐	Orthodontics	☐	Stop Smoking Service	☐
Community Nursing	☐	Healthcare Associated Infection	☐	Orthoptics	☐	Speech & Language Therapy	☐
Continence Service	☐	High Dependency	☐	Out of Hours	☐	Stroke	☐
Critical Care	☐	Infectious Diseases	☐	Outpatients	☐	Surgical Pre-assessment	☐
Day Surgery	☐	Intensive Care	☐	Paediatrics - Medicine	☐	Theatres	☐
Dental Services - Acute	☐	Learning Disabilities	☐	Paediatrics - Surgery	☐	Tissue Viability	☐
Dental Services - Community	☐	Long-Term Conditions Nursing	☐	Palliative Care	☐	Transfusion Services	☐
Dermatology	☐	Mental Health - Adult	☐	Pathology	☐	Trauma & Orthopaedic Surgery	☐
Dietetics & Nutrition	☐	Mental Health - Child & Adolescent	☐	Pharmacy	☐	Urology	☐
Emergency Medicine	☐	Mental Health - Forensic Services	☐	Physiotherapy	☐	Vascular Surgery	☐
Emergency Receiving	☐	Mental Health - Old Age Psychiatry	☐	Podiatry	☐	Other, specify below	☐
Endocrinology & Diabetes	☐	Microbiology	☐	Prisoner Healthcare	☐		

SECTION D: HEAD OF DEPARTMENT SIGN OFF

Based on the checklist information A - C the guideline is signed off by Head of Department.

Is the guideline agreed?	Is the checklist completed in full?
Yes ☐　　　**No** ☐　*If no, return to lead author for changes.*	**Yes** ☐　　　**No** ☐　*If no, return to lead author for changes.*

Head of Department Details

Name:

Designation:

Email:

Telephone number:

Department:

Work address:

SECTION E: APPROVED RATIFIER FOR RATIFICATION

Based on the checklist information A - D the guideline is ratified by Approved Ratifier.

Is the guideline ratified?	Is the checklist completed in full?
Yes ☐　　**No** ☐　*If no, return to lead author for changes.*	**Yes** ☐　　**No** ☐　*If no, return to lead author for changes.*

Approved Ratifier Details

Name:

Designation:

Email:

Telephone number:

SECTION I: SUBMISSION DETAILS

Please email the following to clinicalguidelines@lanarkshire.scot.nhs.uk

☐ **Clinical guideline (in Microsoft word format if possible)**

☐ **Fully completed checklist and, where appropriate, the implementation and evaluation plan**

If you have any questions regarding this checklist or process, please contact clinicalguidelines@lanarkshire.scot.nhs.uk