

Senior Management Team

6 January 2010

Report of	Peter Belfield, Medical Director
Paper prepared by	Bob Bury, Clinical Guidelines Committee (Chair)
Subject/Title	Policy for the development and approval of clinical guidelines
Background papers	Previous papers to Clinical Governance Steering Group relating to Clinical Guidelines Committee and its responsibilities
Purpose of Paper	To review the clinical guidelines policy
Action/Decision required	SMT is asked to consider and approve the clinical guidelines policy
Link to: ➤ NHS strategies and policy	
Link to: ➤ Trust's Strategic Direction ➤ Corporate objectives	Improving clinical outcomes
Resource impact	None
Consideration of legal issues	None applicable
Acronyms and abbreviations	None

THE LEEDS TEACHING HOSPITALS NHS TRUST
SENIOR MANAGEMENT TEAM - 6 January 2010
POLICY FOR THE DEVELOPMENT AND APPROVAL OF CLINICAL
GUIDELINES

1. Introduction

This revised policy has been developed by the Trust's Clinical Guidelines Group.

2. Background

The purpose of this revised and updated policy is to provide a clear mechanism governing the development, publishing and review of clinical guidelines used in the Trust. It applies to all employees involved in developing and implementing clinical guidelines within the Trust.

The effect of the policy will be to ensure that guidelines are only implemented following a full process of consultation with potential stakeholders, and that they are based on the best evidence available. All clinical guidelines will be reviewed and approved by the Trust's Clinical Guidelines Group. This process has been reviewed by the Clinical Governance Steering Group.

The process for the review and approval of *clinical policies* is currently subject to further review, led by the Medical Director. All clinical policies are subject to review and approval by SMT.

3. Recommendation

SMT are asked to review and approve the policy for the development and approval of clinical guidelines.

Bob Bury

Clinical Guidelines Group (Chair)

POLICY FOR THE DEVELOPMENT AND APPROVAL OF CLINICAL GUIDELINES IN LEEDS TEACHING HOSPITALS TRUST

Policy Title	Policy for the Development and Approval of Clinical Guidelines in Leeds Teaching Hospitals Trust
Version:	Version 3.0
Approved by:	Senior Management Team (SMT)
Date of approval:	
Policy supersedes:	Policy for the Development and Approval of Clinical Guidelines in Leeds Teaching Hospitals Trust - Version 2.0
Name of originator/author:	Dr Bob Bury, Chair Clinical Guidelines Group, Julia Roper, Quality Manager and Katy Warburton, Leeds Health Pathways Manager
Name of responsible committee/individual:	Trust Clinical Guidelines Group / Medical Director
Date issued:	January 2010
Review date:	January 2012
Target audience:	Accountability - Medical Director Responsibility - Divisional Managers Implementation - All Trust healthcare professionals involved in guideline development
Keywords	Clinical guidelines, development , approval, ratification, Leeds Health Pathways

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EXECUTIVE SUMMARY

The purpose of this policy is to provide a clear mechanism governing the development, publishing and review of clinical guidelines used in the Trust. It was developed on behalf of Leeds Teaching Hospitals Trust by members of the Clinical Guidelines Group (CGG), and it applies to all employees involved in developing and implementing clinical guidelines within the Trust.

The effect of the policy will be to ensure that guidelines are only implemented following a full process of consultation with potential stakeholders, and that they are based on the best evidence available. Authors of guidelines will be responsible for the development of a communication and implementation plan.

A multi-professional Clinical Guidelines Group will be responsible for quality assurance of the process of guideline production, and will ratify guidelines that meet the required quality standard. These will then be made available to Trust staff via the clinical guidelines database hosted on Leeds Health Pathways (LHP).

The LHP publication process will incorporate a mechanism to ensure that guidelines are subject to a regular review and updating process. Where the review process is not completed for whatever reason within the prescribed timescale, the guideline will be archived and made unavailable.

1. INTRODUCTION

This policy was developed on behalf of Leeds Teaching Hospitals Trust by members of the Clinical Guidelines Group, and it applies to **all** employees involved in developing and implementing clinical guidelines within the Trust.

It sets out a development, peer review and ratification process for clinical guidelines which will ensure that they comply with an agreed set of quality standards and that they undergo regular review and updating.

This policy should be read in conjunction with the Policy on Implementation of NICE Guidance.

2. PURPOSE

The purpose of the policy is to ensure, as far as is possible, that clinical guidelines used within the Trust are evidence-based and fit for purpose, and that they have been through a process of consultation and peer-review. It will also ensure that guidelines are made available electronically to Trust staff, and are subject to regular review and, where necessary, revision or removal.

This policy will ensure that clinical staff have ready access, to the best, current, evidence-based guidance available. The intention is not to impose constraints on clinical freedom, and while there is an understanding that ratified guidelines will be followed, staff are free to deviate from them where in their professional opinion they are not appropriate to the needs of any individual patient, but must be able to justify that decision if necessary.

The key **principles** underpinning the policy are:

- That clinical guidelines should be available for the management of the majority diseases and conditions in our patients
- That those guidelines should be based on the best evidence available and produced according to the agreed peer review system
- That guidelines should only be implemented following a process of consultation with all affected staff groups/individuals
- That author/s of guidelines are responsible for the development of a communication and implementation plan
- That a multi-professional Clinical Guidelines Group should be responsible for quality assurance of the process of guideline production, and for ratifying guidelines that meet the required quality standards
- That ratified guidelines should be made available to Trust staff via the Leeds Health Pathways clinical guidelines database, and subject to the agreed regular review and updating process.

Failure to follow this policy could result in the instigation of disciplinary procedures.

3. DEFINITIONS

3.1 Clinical Guideline

There is a great deal of formal and informal guidance in daily use in clinical practice, and it is important to be as clear as possible about the type of document to which this policy applies. The working definition of a clinical guideline adopted by the CGG is:

'a systematically-developed, evidence-based statement that assists healthcare professionals to make decisions concerning the appropriate care for specific clinical conditions'.

The CGG will also deal with clinical protocols and standard operating procedures (SOPs) where appropriate, but will not consider clinical policies.

3.2 Care Pathway

These tend to apply to wider areas of practice than guidelines, but a care pathway may well include a number of individual guidelines to which this policy would apply.

4. POLICY EFFECT

4.1 Producing the Guideline

A case of need for a new guideline must first be established, and this will require (at least) a search for existing available guidelines using the NICE and LHP guidelines databases.

The need for a new guideline may be based on the identification by the relevant professionals of an unacceptable level of variation in practice in the face of convincing evidence of the superiority of one particular management regime. In other cases the impetus may come from a clinical risk assessment exercise, a new National Service Framework (NSF) or the promulgation of national guidance by the National Institute for Clinical Excellence (NICE) or professional bodies.

The flowchart ([Appendix D](#)) outlines the stages involved in guideline production, and it is important that potential authors refer to the guideline pack available on the guidelines database search page. If any clarification on the process is needed they should contact the LHP manager for advice.

During the development process all guidelines should be subject to peer review and the steps taken to consult with appropriate individuals likely to be affected by the guideline, should be documented.

The impact of the clinical guideline on the local health community in primary care should be considered and input from primary care should be sought where appropriate.

Guidelines that have been developed jointly across the Leeds health organisations will be ratified individually through each organisation's clinical governance arrangements.

The format of each clinical guideline will be standardised and a standard template for this can be found in the guideline pack. The Trust requires that all new clinical guidelines follow this standard format. Existing guidelines should be reformatted as they are reviewed.

When the guideline development is considered to be complete, the lead author must contact the LHP manager to arrange submission to the CGG for ratification.

4.2 Ratification of Guidelines

When the development process is considered to be complete, the guideline will be submitted to the Clinical Guidelines Group (CGG) by the lead professional designated as taking overall responsibility for its content. The chair or representative of a multi-disciplinary team or cross-city group may also submit the guideline. A representative of the group responsible for the guideline (usually, but not necessarily, the lead author) will attend the relevant

meeting of the CGG in order to present it to the Committee, and to answer any questions from members. If the Committee considers that the guideline has been developed following the correct process and meets all the relevant quality standards, the Chair will write to the lead author to notify them that their guideline has been ratified, and that it will be made electronically available to all potential users via the LHP guidelines database.

Guidelines relating specifically to drugs will be ratified by the Drug and Therapeutics Committee; those that relate to antimicrobials by the Improving Antimicrobials Prescribing Group, rather than the CGG.

The CGG may opt to review guidelines individually or in 'bundles' as it considers appropriate.

Following ratification, it is the responsibility of the authors to contact the relevant Directorates to draw their attention to the existence of the new guideline on the database and to have a communication and implementation plan in place.

4.3 Publication and Guideline Review

Once a guideline is ratified by the CGG, it will be published electronically on the LHP Clinical Guidelines database. This will facilitate access and use by others within the Trust and throughout the Leeds healthcare community, as appropriate.

There should only ever be one version of a published document currently available to users at any one time. To ensure this, all electronic copies of documents shall be stored on the Leeds Health Pathways server and made available via a central facility - whether accessed directly from the LHP 'Clinical Guidelines' pages, or linked from a guidelines option on a departmental website, on the Trust's Intranet.

Each guideline on the guidelines database will be supported by unambiguous information pertaining to guideline provenance and applicability: a minimum set of information will accompany each electronic document.

Guidelines will be subject to regular review at intervals of two years, unless there are specific reasons for varying that period in the case of a particular guideline.

Authors of guidelines will be notified by automated email of the imminent need for review, three months prior to the specified date. Guidelines will remain available on the database and flagged as 'Under Review' while the review process is taking place, unless authors request them to be made unavailable during this period.

If authors fail to respond there is a system in place for follow up or removal of expired guidelines. Please see Appendix E

All outdated documents (i.e. those superseded or declared obsolete) shall be stored in a central archive database and will only be made available on a strictly controlled basis. Requests must be made by email to the LHP Manager, on the clear understanding that these documents no longer hold the Trust's approved status.

Continuous monitoring of the number of 'visits' to all guidelines within the database is undertaken and can be used for audit purposes.

Reports of guideline-related activity (e.g. numbers and types of guideline accessed, and by whom) will be sent to Divisions/Directorate Management Teams on a quarterly basis.

5. DUTIES WITHIN THE ORGANISATION

5.1 The Medical Director

The Medical director is responsible for establishing a mechanism to ensure that all clinical guidelines used in the Trust are evidence-based, subject to appropriate consultation and peer-review, and that once implemented, they are subjected to regular review and, where necessary, updating.

5.2 Divisional Medical Managers and Divisional Nurses

Divisional Medical managers and Divisional Nurse Managers are responsible, on behalf of Divisional General Managers, for ensuring that Clinical Directors/Lead Clinicians and Matrons meet the responsibilities set out below.

5.3 Clinical Directors/Lead Clinicians and Matrons

Clinical Directors and Matrons are responsible for:

- Commissioning development of clinical guidelines where needed
- Nominating guideline authors
- Ensuring all clinical guidelines used in their area are ratified by the CGG, held on LHP Clinical Guidelines database, and subject to regular review.
- Ensuring that following ratification, all guidelines are communicated across relevant directorates.
- Oversight of implementation of all new guidelines relevant to their area.
- Ensuring that where intentional non-compliance or partial compliance with NICE guidance has been agreed by the Trust Board, appropriate alternative Trust guidelines are developed, ratified and implemented.

5.4 Authors

Authors of clinical guidelines are responsible for:

- Drawing up guidelines in accordance with the standards set out in **Appendix B**.

- Submitting guidelines to the CGG.
- Communicating ratified guidelines to relevant directorates/specialties/individual clinical teams.
- Following the review process as laid out in **Appendix E**

5.5 Clinical Guidelines Group

The CGG will be responsible for:

- Reviewing the processes of development and peer review of guidelines in the Trust.
- Ratifying guidelines that have met the appropriate standards.
- Overseeing the process of electronic publication and routine review.

The CGG will note any NICE Guidance that is fully implemented within the Trust and formally endorse the guidance as a Trust Clinical Guideline. The CGG will also review and ratify where appropriate any parallel/supporting Trust guidelines.

Instances of intentional non-compliance or partial compliance with NICE guidance agreed by the Trust Board will be reviewed by the CGG to determine whether appropriate alternative Trust guidelines are in place and, if not, to highlight the need for their development.

The CGG's Terms of reference can be seen in [Appendix C](#)

5.6 Leeds Health Pathways (LHP)

The LHP staff will be responsible for the electronic publishing of **all** ratified guidelines on the LHP clinical guidelines database.

They will also manage the guideline review process as laid out in Appendix E. Reports will be sent monthly to the CGG informing them of the status of any outstanding reviews.

They will provide quarterly activity reports to DMMs, DCNs, CDs and Matrons, and for review by CGG.

6. EQUALITY IMPACT ASSESSMENT

The Policy has been assessed for its impact upon equality, Appendix A.

The Leeds Teaching Hospitals Trust is committed to ensuring that the way that we provide services and the way we recruit and treat staff, reflect individual needs, promote equality and does not discriminate unfairly against any particular individual or group

7. CONSULTATION AND COMMUNICATION WITH STAKEHOLDERS

The final version of the revised policy will be presented to the Medical Directorate Team and Clinical Governance Committee before submitting to the Senior Management Team for approval

8. APPROVAL AND RATIFICATION

This policy will be approved by the Senior Management Team.

9. PROCESS FOR REVIEW/REVISION

This policy will be subject to review every two years.

10. COMMUNICATION AND DISSEMINATION

Directors – communication directly by e-mail

Senior operational and corporate managers – communication directly by e-mail and to be notified by Directors through line management briefing

All staff – Policy will be available on the 'Policies' section of the Intranet

11. IMPLEMENTATION

Clinical Directors and Matrons will be advised to implement this policy in their areas.

12. MONITORING COMPLIANCE AND EFFECTIVENESS

The Clinical Guidelines Group will ensure that all guidelines which come to its attention comply with the requirements of this policy.

Quarterly performance reports will be produced by LHP

Internal Audit will be asked to include review of compliance with this policy on their rolling programme.

13. STANDARDS/KEY PERFORMANCE INDICATORS

- All Trust Clinical Guidelines will be held on the LHP Clinical Guidelines database. Internal Audit will be asked to routinely review compliance.
- The Clinical Guidelines Group will meet monthly.
- Quarterly performance reports will be produced by LHP for Divisional/Directorate and presentation to the Clinical Guidelines Group.

- All clinical guidelines will be subject to review at intervals of two years unless specific reasons for not doing so have been agreed by the CGG.
- Where intentional non-compliance or partial compliance with NICE guidance has been agreed by the Trust Board appropriate alternative Trust guidelines will be in place.

14. REFERENCES/ASSOCIATED DOCUMENTATION

Appendix A

Equality Impact Assessment – Trust policies and functions must comply with equalities and human rights legislation which briefly is to promote equality and human rights and eliminate unlawful discrimination.

Name of policy or function:		Lead Person:	
1. Screening How relevant is this function or policy and its associated procedures to promoting equality and human rights and to eliminating discrimination? (indicate in boxes below)			
	Not relevant	Partly relevant (which parts?)	Very relevant
Race/ethnic group:	v		
Disability ¹ :	v		
Gender (including transsexuals):	v		
Age:	v		
Sexual Orientation:	v		
Religion:	v		
Human rights ² :	v		
Carers or other group (please state):	v		
2. Assessing Impact :To be completed where the policy and associated procedures or the function has been determined as relevant in the screening process above			
Please specify, in the rows below, anything that you have included or done to ensure that equality and human rights are promoted and that no one will be unlawfully disadvantaged			

¹ Disability covers physical, sensory and mental impairments which include mental illness and learning disability. Long term conditions such as cancer, HIV and Multiple Sclerosis are included and any other condition at the point at which it begins to have an impact on a person's capacity to carry out normal day to day activities.

² To comply with human rights legislation a policy or function must, where possible, promote (in addition to equality), dignity, respect, fairness and autonomy

(discriminated against) as a result of this policy or function	
	There will now be a requirement for a completed form to be submitted along with the checklist for ratification of new clinical guidelines.
Race/ethnic group:	
Disability:	
Gender (including transsexuals):	
Age:	
Sexual Orientation:	
Religion:	
Human Rights:	
Carers or other group (please state:)	

APPENDIX B - STANDARDS TO BE APPLIED WHEN DEVELOPING CLINICAL GUIDELINES

To ensure the quality of information provided in Trust guidelines, the following standards should be applied to the development process:

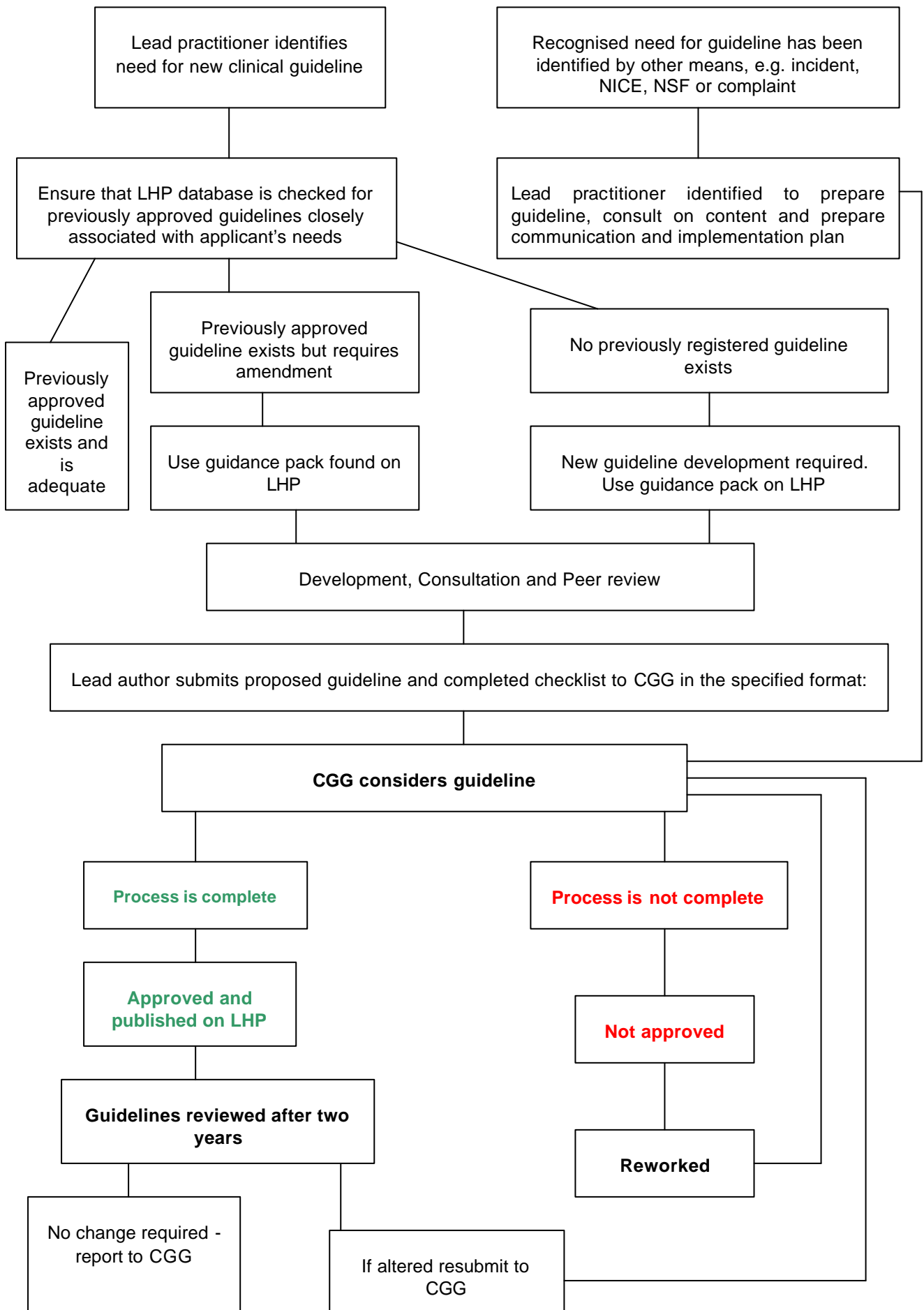
- Guidelines should address a specific healthcare need
- The aims and objectives of guidelines must be clearly stated and must be achievable
- Guidelines should be based on scientific evidence and should state clearly the source and strength of that evidence
- Guidelines should be developed by a team that includes representatives from all key groups
- The consultation process should be described, and should name the groups, professional bodies and individuals who took part in that process
- In most cases, the guideline should be subjected to a process of peer-review before submission
- Resource implications should be considered in the development and use of guidelines, including training needs
- The means of ensuring that guidelines reach their target audience should be outlined
- Strategies for implementing the guidelines should be specified
- The processes behind the development, dissemination, implementation and evaluation of guidelines should be fully documented
- The effect of guidelines on patient outcomes should be evaluated to determine if the aims and objectives have been achieved
- Guidelines should be regularly reviewed and revised with date stated and responsible post holder named
- Guidelines should be reviewed every two years unless accumulating experience, the availability of new evidence or the emergence of new national guidance indicates a need for earlier review
- Guidelines should be written in clear concise language and be presented in an easy-to-use format
- All guidelines should be prepared in a consistent style, using the approved template found in the guideline pack

APPENDIX C - CLINICAL GUIDELINES GROUP TERMS OF REFERENCE

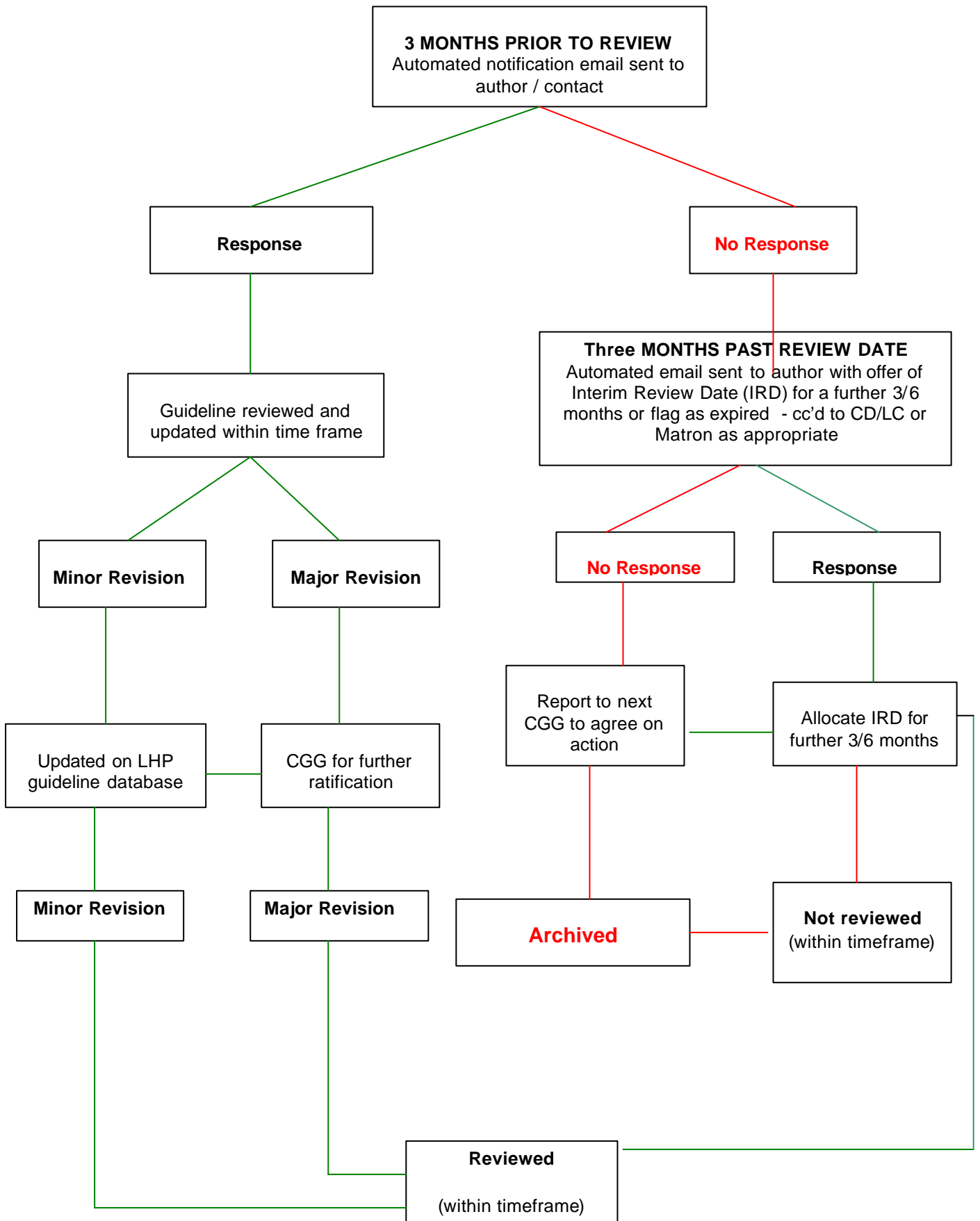
- To provide advice to those professionals developing clinical guidelines
- To review the processes of development and peer review of guidelines in the Trust.
- To assure the quality of guidelines published by LTHT
- To review all proposed guidelines against a standard checklist to confirm that the process of guideline production has covered all the necessary steps.
- To refer back to the originator any guideline where there is doubt that the process has been followed, or where other questions remain about the content, and providing them with advice on how to proceed.
- To approving guidelines that meet the required standard.
- To reconsider applications which are resubmitted following amendment after initial referral back to the originator.
- To place approved guidelines on the LHP Clinical Guidelines database to facilitate their implementation.
- To receive for review each approved guideline every two years.
- To report outstanding issues to the relevant group with oversight for clinical governance

It is not the task of the CGG to undertake additional scientific or clinical review, it is not constituted to do this, but it should satisfy itself that the guideline applicant has already undertaken adequate review and consultation to support the nature of the guideline under consideration.

APPENDIX D - Clinical Guidelines Development Process



Appendix E - Guideline Review Process



Appendix F - Checklist for the Review and Approval of Policy

To be completed and attached to the policy when submitted to the appropriate committee for consideration and approval.

	Title of document being reviewed:	Yes/No/Unsure	Comments
1.	Title		
	Is the title clear and unambiguous? Is it positively named in respect of the behaviour, actions, established position it seeks to achieve?		
	Is it clear whether the document is a policy, guideline, protocol or standard?		
2.	Rationale		
	Are reasons for development of the document stated?		
3.	Development Process		
	Is the method described in brief?		
	Are people involved in the development identified?		
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?		
	Is there evidence of consultation with stakeholders and users?		Divisional Medical Managers and Clinical Governance Steering Group
4.	Content		
	Is the objective of the document clear?		
	Is the target population clear and unambiguous?		
	Are the intended outcomes described?		
	Are the statements clear and unambiguous?		
	Is the content sufficiently concise and straightforward to be clear?		
	Can any detail or complex material be transferred to an appendix?		

	Title of document being reviewed:	Yes/No/Unsure	Comments
5.	Evidence Base		
	Is the type of evidence to support the document identified explicitly?		
	Are key references or supporting documents cited?		
6.	Approval		
	Does the document identify which committee/group will approve it?		
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?		
7.	Dissemination and Implementation		
	Is there a communications plan to identify how this will be done?		
	Does the implementation plan include the necessary training/support to ensure compliance?		Supported by Guideline Development Pack
8.	Document Control		
	Does the document identify where it will be held?		
	Have archiving arrangements for superseded documents been addressed?		
9.	Process to Monitor Compliance and Effectiveness		
	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?		
	Is there a plan to review or audit compliance with the document?		
10	Review Date		
.	Is the review date identified?		
	Is the frequency of review identified? If		

	Title of document being reviewed:	Yes/No/ Unsure	Comments
	so is it acceptable?		
11	Overall Responsibility for the Document		
	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?		

Individual Approval

If you are happy to approve this document, please sign and date it and forward to the chair of the committee/group where it will receive final approval.

Name		Date	
Signature			

Committee Approval

If the committee is happy to approve this document, please sign and date it and forward copies to the person with responsibility for disseminating and implementing the document and the person who is responsible for maintaining the organisation's database of approved documents.

Name		Date	
Signature			

Appendix G - Plans for Dissemination and Communication of Policy

To be completed and attached to any policy before being submitted to the appropriate committee for consideration and approval.

Title of document:	Policy For The Development And Approval Of Clinical Guidelines In Leeds Teaching Hospitals Trust		
Date finalised:		Dissemination lead:	Katy Warburton LHP Manager
Previous document already being used?	Yes (Please delete as appropriate)	Print name and contact details	Tel: 66870 email@katy.warburton@leedsth.nhs.uk
If yes, in what format and where?	Electronic copy held on the LHP database and linked to Policies section on the Intranet		
Proposed action to retrieve out-of-date copies of the document:	Old version will be archived in line with LHP review process		
To be disseminated to:	How will it be disseminated, who will do it and when?	Paper or Electronic	Comments
	Via the LHP database and linked to Policies section on the Intranet. Notification in eBulletin of revised Policy	Electronic	

Dissemination Record - to be used once document is approved.

Date put on register / library of policies		Date due to be reviewed	
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Disseminated to: (either directly or via meetings, etc)	Format (i.e. paper or electronic)	Date Disseminated	No. of Copies Sent	Contact Details / Comments
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Communication of Policy – sample outline plan

Objectives of communications plan

State clearly the outcomes that are required for those affected by the policy to:

- i) know of its existence,
- ii) understand its purpose, and
- iii) understand their role in implementation.

Key messages

These are the ‘headlines’ or key points you want people to be aware of so that they understand the implications and desired effect of the policy and will know whether they need to find out more details,

Target Audience

In order to develop an effective communications plan it is important to understand the perspective of the target groups, e.g. what is their position/opinion/knowledge in relation to the policy; how do they prefer to receive important information; where are they and what are their working conditions like; what do they know already?

Do not adopt an indiscriminate, general or random approach, thinking that if you tell everyone or most people you are bound to reach the groups who need to know.

State as precisely as possible the groups who need to be informed about the policy either so that they can implement it or so that they are aware of the intended effect.

For each group there is likely to be separate information they need to know so it is helpful to segment or break up the overall target audience and specify what information each group needs. Each group may also have other characteristics or needs to distinguish it; try to identify them.

Stakeholders

These are normally people with an interest in the policy or in its impact, often external to the organisation and may be neither subject to, nor directly affected by it. They will often have some kind of power or responsibility in relation to the organisation or to groups of users, consumers, taxpayers, voters etc.

Think about how you will keep them in the picture about the things that matter to them.

Timing

Dates of communications activity that will happen? Include any key start or end dates; key milestones, anniversaries, events or opportunities to reach the target groups, including existing scheduled corporate, Trust-wide or group-specific communications

Channels/mechanisms

It is important to select a range of effective channels or mechanisms to reach target groups. People need to see information several times before they take it in fully. It is also helpful to ensure there are multiple opportunities for any target group to see the information they need.

Do not invent new mechanisms, e.g. newsletters, intranet sites, without seeking advice from Marketing and Communications department who will help you ensure whether this is likely to be the most effective means of communication with your target audience, whether there are better alternatives, and whether your aim can be supported by, or will undermine, other Trust-wide communications.

Table of activity

Summarise the work you are planning in a table showing the key actions, assigning responsibility and indicating the timescale for each element.