University Hospitals of Leicester NHS
NHS Trust

Policy for the development, ratification, publication, maintenance and storage of antimicrobial guidance.

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REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

March 2016 – no changes

November 2022 – clarification on what constitutes antimicrobial guidance, clarification of post antimicrobial working party process

KEY WORDS

Policy for Antimicrobial Guidance

Developing and Approving Antimicrobial Guidance

SUMMARY

1.0 This policy sets out the process for developing, approving, publishing and storing antimicrobial guidance documents.

2.0 Antimicrobial Guidance is guidance which recommends the use of an antimicrobial.

3.0 All AGs should use a UHL guideline templates when submitted for approval.

1 INTRODUCTION

1.1. This document sets out the University Hospitals of Leicester (UHL) NHS Trusts Policy and Procedures for the ratification, publication, maintenance and storage of UHL Antimicrobial Guidance (AGs).

1.2. A formal process is required for the maintenance of UHL antimicrobial online content where AG's are maintained and published. AGs will help clarify operational requirements and bring consistency to day to day practice. In addition they can improve the quality of work and increase the successful achievement of objectives.

1.3. A common format and approval structure for such guidance helps to reinforce corporate identity and, more importantly, helps to ensure that AGs in use are current and reflect an organisational approach.

1.4. A standard format will also avoid confusion and to assist staff (and patients) in following the Antimicrobial Working Party (AWP) requirements. Equally important is the use of plain English and the avoidance of jargon.

1.5. It is the responsibility of the AWP to ensure that all AGs are appropriately evidence based, rigorously developed, formally approved, effectively implemented and routinely monitored and reviewed.

2 POLICY AIMS

To provide a robust assurance framework and practical system for the management of UHL antimicrobial guidance.

2.1 The aim of this policy is to ensure that guidance on the antimicrobial website/Microguide are fit for purpose by:

a) Providing a clear process for robust development and consultation of all AG documents.

b) Ensuring that the template (appendix 1) is used for developing and submitting UHL AG.

c) Setting out the appropriate approval and publication process for all AG.

3 POLICY SCOPE

3.1 This Policy applies to all members of staff working within UHL who are involved in any aspect of AG development, the members of the Antimicrobial Working Party, and the persons responsible for the contents and maintenance of the UHL Antimicrobial website/Microguide.

3.2 This policy applies to all AG documents used in the Trust.

3.3 The policy applies to the development and approval of guidelines whose remit extends beyond recommending the use of an antimicrobial in a specified clinical situation and infection management. Such guidelines should be reviewed and approved in accordance to Trust Policy for Policies. (Ref (B16/2004);

3.4 This policy covers all UHL AG which relates to patient care throughout the Trust.

4 DEFINITIONS

For the purpose of this policy 'UHL Antimicrobial Guidance' is any guidance which recommends the administration of an antimicrobial to a UHL patient.

In line with the UHL definitions:

Antimicrobial

A general term for natural or synthetic compounds which at certain concentrations inhibit growth of, or kill, micro-organisms. The term antimicrobials is a collective for antivirals, antibacterials, antifungals and antiprotozoals.

Guidance

A document that sets out the preferred method of operation. Other methods are not prohibited but a reason for deviation from the guidance should be fully justifiable and agreement from senior staff (ST4 or above) sought in all cases of any doubt.

Guidance is mainly used in the clinical setting where they provide a clear indication of the best choices for the management of a patient's clinical condition.

Guidance should relate to an overarching policy but may be stand alone. Again where more specific clinical detail is required this should be contained within a supporting procedural document

List of Abbreviations

AG	Antimicrobial guidance
AIS	Antimicrobial Internet Site
AWP	Antimicrobial Working Party
CMG	Clinical Management Group
ID	Infectious Diseases
NICE	National Institute for Health and Care Excellence
PGC	Policay and Guidelines Committee
TIPAC	Trust Infection Prevention Committee
UHL	University Hospitals of Leicester

5 ROLES AND RESPONSIBILITIES

Responsibilities within the Organisation

5.1 Executive and Operational Responsibility

The Executive Director responsibility for this policy shall be the Medical Director and they shall notify the Trust Board of any matters or issues regarding this policy.

5.2 Director of Infection Prevention

Challenge non-compliance with this policy.

5.3 Corporate and Clinical Management Groups

5.3.1 Directors, Clinical and Managerial Leads for Clinical Management Groups, Microbiology Consultants, Infectius Diseases physicians and Antimicrobial pharmacists are responsible for identifying the need for antimicrobial guidance documents that support specialist practice in the Trusts and their CMGs. In addition for ensuring that any such documents are developed in line with this policy and that the guidance within the document is in line with any existing Trust-wide guidelines.

5.3.2 CMG Medical Leads and Managers are responsible for ensuring that processes for agreeing antimicrobial guidance in their areas fulfil the requirements of this policy.

5.4 Committee/Service/Individual requesting antimicrobial guidance

5.4.1 The need for development of an antimicrobial guidance will normally be identified by either a service or the AWP committee. The lead consultant clinician of the service must oversee the development of the guidance.

5.4.2 The lead consultant clinician, lead consultant microbiologist and CMG pharmacists are responsible for addressing any implementation issues with support and advice from the antimicrobial pharmacists.

5.4.3 Authors and/or CMG medical leads (as appropriate), are responsible for establishing the monitoring process of the final AG.

5.5 Antimicrobial Guidance Authors

5.5.1 Lead AG authors take overall responsibility for the development, consultation, approval and dissemination of their guidance documents.

5.5.2 In most cases, but dependant upon the AG scope and subject, there would also be a microbiology/ID Physician, antimicrobial pharmacist author in which case both would be responsible for the following:

5.5.3 Ensuring that there is appropriate representation of ‘experts’ in the development stage

5.5.4 Ensuring robust evidence and national guidance documents such as NICE are used to inform the AG recommendations where applicable

5.5.5 Ensuring the consultation is wide and involves all necessary staff groups and specialties

5.5.6 The Lead AG author is responsible for implementation of the AG including identification and actioning of any training, financial or other implementation issues.

5.5.7 Ensuring dissemination of approved guidance to all necessary staff groups

5.5.8 Identifying appropriate timescales and lead for review of the AG

5.5.9 The AG authors are specifically responsible for ensuring the document content and layout meet the standards as detailed in Appendix 1of this policy.

5.6 UHL Staff Members

5.6.1 Whilst all members of staff are responsible for being aware of policies and guidelines relevant to their area, the following specific roles and responsibilities will only be relevant to those directly involved in the development and approval process.

5.6.2 All UHL staff are responsible for informing relevant managers and clinical leads if there are any implementation or compliance issues with newly developed AG and for participating in the monitoring of compliance as applicable.

5.7 UHL Policy and Guidelines Committee

5.7.1 The Policies & Guidelines Committee (PGC) reports directly to the Executive Team.

5.7.2 The Committee is responsible for reviewing this policy and approving trust-wide policies and procedural documents.

5.8 Trust Infection Prevention Assurance Committee (TIPAC)

The TIPAC should be informed of any non-adherence issues to this policy, specifically:

- any AG out of date that has not been reviewed in a suitable timely manner without a valid reason.
- deliberate and consistent non-adherence to AG by prescribers/CMG's.

5.9 Antimicrobial Working Party

5.9.1 The AWP reports directly to the TIPAC,.

5.9.2 It is responsible for reviewing all AG and either approving them for adoption, (with or without further amendments), or not approving them.

5.9.4 It is responsible for ensuring that authors of AG's are reminded when AG review dates are forthcoming and to monitor the timely review of AG's.

5.10 Antimicrobial website/app manager/administrator

5.10.1 Must be competent in using the websites latest technology and computer programme, and also be aware of Trust governance arrangements for the storage of guidance documents

5.10.2 Responsible for ensuring effective administration of the UHL antimicrobial website e.g. the timely uploading of revised guidance, removal of out of date or inaccurate guidance, additions to the past development section and the alert/news section.

5.11 Antimicrobial meeting lead

Responsible for co-ordinating and managing the AWP workload, and provide administrative support to the AWP meetings.

6 POLICY STATEMENTS, STANDARDS*, PROCESSES*, PROCEDURES* AND ASSOCIATED DOCUMENTS

This policy details the process for the ratification, maintenance, publication and storage of UHL Antimicrobial Guidance.

Prior to commencing development of a new AG, confirmation should be sought, as to whether a similar AG is already under development, or is planned; also to identify whether any related or overlapping Policy and Guideline exists.

In order to confirm the above, one of the following must be contacted:

a) Antimicrobial website manager or administrator (refer to AIS for upto date contact details)

b) Antimicrobial Pharmacists or Lead Consultant Microbiologist for the hospital site/clinical area.

The AG template (Appendix 1) must be used to confirm that all aspects of AG development have been appropriately considered.

Any antimicrobial guidelines or guidance the Trust's PGC receives should be referred to the AWP prior to discussion and approval at PGC.

If the AWP receives any antimicrobial guidance or guidelines that are relevant for the Trusts PGC to receive, AWP approval should be received prior to its referral onto the PGC.

All AG must be co-authored or reviewed with a nominated consultant microbiologist /ID Physician prior to submission to the AWP.

New AG's to be submitted, with a completed template (Appendix 1), to AWP meeting lead for submission to the next AWP meeting for ratification.

AG's to be reviewed every 3 years. Authors to submit new versions (or versions stating no amendments), with a completed template (Appendix 1), to the AWP meeting lead 2 weeks prior to the next AWP meeting, for submission to the AWP meeting and ratification.

6.1 Approval, Adoption and Registration of AG

6.1.1 All new AG documents need to be submitted to the AWP via the AWP meeting lead.

6.1.2 Any AG submitted for approval, must have been through an appropriate review and consultation process beforehand.

6.1.3 All new AGs, must be formally approved by AWP before being implemented.

6.2 Process for Submitting Antimicrobial Guidance documents for Approval

6.2.1 All submitted AG document must be accompanied by a completed an AG Template (Appendix 1)

6.2.2 Equality Issues

a) When drafting AGs, due care should be taken to ensure they do not contain or could be interpreted as containing any matters of a discriminatory nature, including but not limited to age, sex, race, culture or sexual orientation.

b) The AWP prior to ratifying an AG, will ensure a full impact assessment should be undertaken with support from the Service Equality Team (ext 14382), if an adverse impact is likely. Any changes made as a result of the impact assessment need to be consulted on (UHL's Service Equality Panel undertake this function) and the full impact assessment published alongside the policy.

c) The AIS to include the following statement to confirm that an Equality Impact assessment has been carried out:

The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

6.2.3 Consultation

a) All AGs being submitted to the AWP for approval must have the consultation section of the AG template completed (Appendix 1)

b) Consultation should specifically include key stake holders.

c) Where consultation has been included as part of a meeting, this should be clearly documented.

d) If the AG is a major departure from current practice, patient or patient representatives must form part of the consultation process as required by section 242 of the Health and Social Care Act (2001).

6.2.4 Dissemination of AGs

The responsibility for dissemination remains with the authors. The AWP meeting lead will email lead authors, CMG medical and pharmacy leads raising awareness and encouraging staff to read the document. Antimicrobial website/app manager or administrator to upload new version, complete 'New in this version' section of AIS and publish it in line with the usual website/app process. Lead authors to further disseminate to other relevant colleagues via email, making them aware of the new version is available on the AIS).

6.3 Process for Approving AG Documents

6.3.1 **Following review of the AG document, the AWP will either:**

a) Approve in full

a) Approve subject to minor changes

b) Not approve – changes to be made and AG to be resubmitted for future AWP's review

6.3.2 **Trust P&G Documents Requiring Urgent Approval**

a) Where there is a Trust-wide policy or other guidance document that needs to be 'fast tracked' due to clinical expediency or legal requirements, the Chair of the AWP should be contacted via AWP Meeting coordinator.

b) When sending the AG for Chair's action, the author also needs to provide the relevant completed paperwork, (Appendix 1).

c) Once contacted, the AWP Chair will confirm the necessity of fast-tracking and ensure there is clarification about the development process of the document. The Chair may suggest that specific consultation or input from other relevant AWP members is also sought as a matter of urgency.

Following review of the AG and supporting documentation, in collaboration with other AWP members as applicable, the Chair would then be able to advise whether the AG document met the agreed criteria for approval. Full review of the AG will then take place at the next AWP meeting at the discretion of the Committee Chair.

6.3.3 Minor Changes

If minor changes are required to the AG before its formal review date, then these can be presented to the AWP in the form of a letter and approval requested.

Minor changes could be an update to a form that is attached to the document as an appendix, job title changes or due to new national guidance which does not materially change the scope or intention of the AG.

Approval of minor changes without full consultation, submission of proformas etc will be at the AWP discretion.

6.3.4 Submitting Reviewed AGs for Approval

The process for submitting fully reviewed and / or updated AG's to the AWP is the same as for the development and approval of new documents.

a) Changes made

Upon submission of a reviewed and/or revised policy, details of changes or additions to the policy must be described in the AG Template (Appendix 1). Where the AG has been completely rewritten, this should be explicitly stated.

b) No changes made

If an AG has been reviewed and supporting evidence checked but no changes are needed, there should be a statement to say that the document has been reviewed and is 'fit for purpose' and that the original supporting evidence is still applicable. This should be documented in the AG Template (Appendix 1).

6.3.4 Following AWP approval

Followign AWP approval all documents should be progressed through processes laid out in the B16/2004 Policy for Developing and Approving Clinical and Non-Clinical Policies and Other Guidance1 Documents (known as 'Policy for Policies').

6.4 Process for AG Document Registration, Version Control and Archiving

6.4.1 Registration of AGs

All AGs are recorded on the AWP AG Register, maintained and kept up to date by the AWP meeting lead.

6.4.2 Uploading of AGs

Once approved and further to any amendments requested by the AWP, the AWP meeting lead will notify the Antimicrobial website manager or administrator, in order for the document to be 'uploaded' onto the AIS once available on the policy and guidelines library.

6.4.3 AGs not approved / requiring amendments:

AWP meeting lead to inform authors of AWP comments and suggestions, and dates of the next AWP meeting.

Authors to re-submit, if applicable, new version to AWP meeting lead, with a completed template (Appendix 1), for submission to the next AWP meeting for ratification.

6.4.4 Approved AGs:

AWP meeting lead to inform authors of AWP comments and approval. If minor amendments are required, the authors should make these amendements and send amended versions to AWP meeting lead.

AWP meeting lead:

- Word version to be stored in current '/AWP/Guidelines' on the 'Antimicrobial' drive.

Antimicrobial intranet site:

Antimicrobial website manager or administrator:

- Add link to document from external facing policy and guidelines library to relevel antimicrobial website/app site.
- Edit existing sections/pages which have been ratified by the AWP, ensuring that other relevant pages are updated and cross linked with new pages / guidance.

6.5 Process for version control, document archiving and review of the AGs.

Antimicrobial website manager or administrator:

If replacing older version, old version to be filed 'AWP/Guidelines' folder under the relevant clinical folder 'old version' folder on the 'Antimicrobial' drive. 'Old version' folders to be kept indefinitely as a complete record of all guidance copies in place at any particular time.

AWP meeting lead:

AWP timetable database to be updated, with information on when new guidance or versions were ratified, and uploaded.

AWP timetable to be maintained and kept indefinitely as a complete timeline record of when guidance documents were in place at any particular time

6.6 AG Review

6.6.1 AG Review Dates

The first review of new AG documents should be within 3 years of approval. Subsequently each AG must state a 'commencement of review date' which is no more than 3 years from original development or latest review unless otherwise explicitly stated.

6.6.2 AG Review Lead

There must be an identified individual who is responsible for ensuring the review takes place. Job titles should be used rather than names as staff may change posts before a review date is due.

6.6.3 Submitting Reviewed AGs for Approval

The process for submitting fully reviewed and / or updated AGs to the AWP is the same as for the development and approval of new documents.

a) Changes made

Upon submission of a reviewed and/or revised policy, details of changes or additions to the policy must be described in the AG Template (Appendix 1). Where the AG has been completely rewritten, this should be explicitly stated.

b) No changes made

If an AG has been reviewed and supporting evidence checked but no changes are needed, there should be a statement to say that the document has been reviewed and is 'fit for purpose' and that the original supporting evidence is still applicable. This should be documented in the AG Template (Appendix 1).

6.6.4 Delayed Reviews and Extending the Review Period

a) Any AG not reviewed within the 3 year timeframe must be referred to the AWP with
   - rationale for delay
   - anticipated timescales for completion
   - any associated risks.

b) The AWP will then assess whether the review period can be extended or the AG needs to be removed from circulation

c) Any delayed beyond 6 months of expiry, with no valid reason must be referred to the TIPAC for information, and discussion.

7 EDUCATION AND TRAINING FOR THIS POLICY

7.1 For further advice or clarification regarding the developing AGs or the approval process, please contact the AWP meeting lead – name and contact details on AIS.

7.2 Training sessions on literature searching and reviewing clinical evidence is available through the clinical libraries.

8 EQUALITY IMPACT ASSESSMENT

8.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

8.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

UHL Policy for Developing and Approving Clinical and Non-Clinical Policies and Other Guidance[1] Documents (known as 'Policy for Policies' – Trust Ref B16/2004

This policy is supported by the following found in the associated documents as detailed below, which must be used in conjunction with this policy:

Procedure / Process / Standard	Appendix
Antimicrobial Guidance template	1

10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

This document will be uploaded onto SharePoint and available for access by Staff through INsite. It will be stored and archived through this system.

Review details must be described in the Policy and must give details of timescale and who will be responsible for review and updating of the document

[1] Guidelines, Procedures, Standard Operating Procedures, Protocols and any other document that provides guidance to staff.

11 PROCESS FOR MONITORING COMPLIANCE

11.1 AWP meeting lead every 6 months to report to AWP, and TIPAC any AG reviews not ratified within required timeframe.

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements	Lead(s) for acting on recommendations
Number of AG's not reviewed on time	AWP meeting lead	AG review date against the AWP ratification date	6 monthly	AWP and annually to Trust Infection Prevention Assurance Committee (TIPAC)	TIPAC

APPENDIX 1

Antimicrobial Guidance (AGs) Template to accompany AGs being submitted for approval

Antimicrobial Guidance Title:	
Approved By:	
Date Approved:	
AWP Reference Number:	
Version:	
Supersedes:	
Originator Author(s):	
Review Authors	
Latest Review Date	
Next Review Date:	

Checklist for the Review and Approval of Antimicrobial Guidance

		Yes / No /	Comments
1.	**Format in Arial Font size 11, margins justified, line spacing set at 1 or single and content in line with Antimicrobial Guidance Policy**		
2.	**Details of Consultation Process** (state below)		
3.	**AG contains the following:**		
	Clinical condition when to use the recommended antimicrobial. Empirical and/or directed treatment, as appropriate.		
	Allergy information and alternatives		
	Target patient group		
	Timing of administration (if clinically appropriate)		
	Duration of therapy (IV and oral, and total duration)		
	Therapy de-escalation advice		
	IV to Oral therapy switch		
	Monitoring requirements		
	Definitions – where applicable		
4.	**Supporting references, evidence Base and Related Guidelines/Policies** (state below)		
5.	**Details of any changes made** (state below)		
6.	**Process to Monitor Compliance**		
	Is there a requirement for additional monitoring of compliance (in addition to the 6 monthly Trust wide antimicrobial prescribing adherence audits)?		
	Have audit timescales and audit lead been identified?		