NICE Medicines and prescribing centre

Developing and updating local formularies

NICE guideline

Methods, evidence, recommendations and appendices

October 2015

National Institute for Health and Care Excellence

Update information

September 2019: Information about regional decision-making groups added to recommendation 1.1.2.

Changes can be seen in the short version of the guidance at https://www.nice.org.uk/guidance/mpg1

Disclaimer

This guidance represents the view of NICE, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summaries of product characteristics of any drugs.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Contents

1 Introduction

1.1 Background and policy context

1.1.1 NHS constitution

The NHS Constitution for England, produced by the Department of Health (2012, revised 2015), provides patients with the right that medicines (and treatments) that have been considered by NICE through the technology appraisal process and given a positive assessment should be made available to patients, where appropriate, and therefore be included in the formulary adopted by the local healthcare providers and commissioners. The Constitution states:

'You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you.'

In addition, the Constitution provides a second right for patients. Medicines that have not yet been considered by, or have not received a positive recommendation for use in the NHS through, a NICE technology appraisal process should be considered by the local NHS using a robust assessment of the best available evidence. The Constitution states:

'You have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you.'

After publication of the original NHS Constitution in 2009, a set of key documents were produced to support rational local decision-making. Defining guiding principles for processes supporting local decision making about medicines (2009), produced by the National Prescribing Centre and Department of Health, and the accompanying Supporting rational local decision-making about medicines (and treatments) (2009), produced by the National Prescribing Centre, underpin the good practice recommendations for developing and updating local formularies.

1.1.2 Statutory responsibility

Directions issued by the Secretary of State for Health (2010) make it a statutory obligation for commissioners to make funding available within 3 months for medicines that have been recommended by a NICE technology appraisal, unless they are directed otherwise by the Secretary of State for Health.

1.1.3 Innovation health and wealth

The Department of Health's report Innovation Health and Wealth, Accelerating Adoption and Diffusion in the NHS (2011, updated 2012) sets out the aspiration for the Government to support the NHS to embrace innovation to meet the current and future healthcare challenges. In particular, the NHS should ensure that local systems and processes for accessing medicines support innovation where appropriate. The report states:

'Formulary processes should proactively consider the impact of new NICE technology appraisals, and all NICE technology appraisal recommendations should – where clinically appropriate – be automatically incorporated into local formularies. This process should take place within 90 days to support compliance with the three month funding direction and the NHS constitution ensuring that these medicines are available for health professionals to prescribe, should they choose to, in a way that supports safe and clinically appropriate practice.'

1.1.4 NICE compliance

In this report, the Department of Health introduced a NICE compliance regime for the funding direction attached to NICE technology appraisals to ensure rapid and consistent implementation throughout the NHS. The compliance regime aims to 'reduce variation and assure patients of their access to the clinically and cost-effective technologies and medicines their doctors believe they need'.

NICE has defined what constitutes compliance with a NICE-approved medicine or treatment:

Commissioners have a statutory responsibility to make funding available for a drug or treatment recommended by a NICE technology appraisal or highly specialised technologies evaluation within the timeframe recommended in that guidance. Compliance is therefore achieved if a health professional and the patient think a health technology is the right treatment and it is available on the NHS, as described in the NHS Constitution, and without any local funding or local formulary restrictions.

For the avoidance of doubt, when NICE recommends a drug as 'an option', this is an option for the health professional and patient to consider alongside other potential treatments, not an option for commissioners or providers to not make the treatment available.

In a letter from the NHS Chief Executive, Innovation, Health and Wealth publication of NHS formularies (2012), the Department of Health stated that all NHS organisations should publish information which sets out which NICE technology appraisals are included in their local formularies by 1 April 2013 at the very latest. The Chief Executive stated that 'It will be important that the publications are online, and are clear, simple and transparent, so that patients, the public and stakeholders can easily understand them'. From 1 April 2013, this became a standard term and condition in NHS standard contracts.

1.2 Terms used in the guideline

Biosimilar medicines

A biosimilar medicine is a medicine that is developed to be similar to an existing biological medicine. Biosimilar medicines have the potential to offer the NHS considerable cost savings, especially as they are often used to treat long-term conditions. NICE has published a position statement and process for developing guidance and advice for these medicines.

Local formulary

For the purposes of this guideline, a local formulary is defined as 'the output of processes to support the managed introduction, utilisation or withdrawal of healthcare treatments within a health economy, service or organisation'.

Medicine

The term 'medicine' includes all healthcare treatments that may be considered in local formularies. Examples include wound care products, appliances and vaccines.

Local formulary decision-making group

A formally constituted group that makes decisions relating to medicines to be included within a local formulary. The name of the group and its relationship with other local policy committees may vary. Examples of local formulary decision-making groups include trust formulary groups, drug and therapeutics committees, interface formulary groups and area prescribing committees.

Organisations

The term 'organisations' includes all commissioners and providers, unless specified otherwise in the text.

Commissioners are those individuals who undertake commissioning which is 'the process used by health services and local authorities to: identify the need for local services; assess this need against the services and resources available from public, private and voluntary organisations; decide priorities; and set up contracts and service agreements to buy services.

Providers are organisations that directly provide health or social care services to people (such as social enterprises, dentists, GPs, pharmacies, out-of-hours services, hospitals).

2 Development of a NICE guideline

2.1 What is a NICE guideline

The purpose of this guideline is to provide good practice recommendations for the systems and processes needed to ensure NHS organisations develop and update local formularies effectively and in accordance with statutory requirements. This guideline is for people involved in handling, prescribing and commissioning medicines within the NHS, to support the development of local formularies that reflect local needs, reduce variation in prescribing, and allow rapid uptake of innovative medicines and treatments.

The guideline is written in the context of the NHS in England. However, the recommendations are also applicable to developing and updating local formularies in Wales and Northern Ireland.

2.2 Remit

NICE received the remit for this guideline from the Department of Health. NICE commissioned the NICE Medicines and Prescribing Centre to produce the guideline.

2.3 Who developed the guideline

A multidisciplinary Committee comprising health professionals and lay members developed this guideline (see appendix A1 for the list of Committee members).

The Committee was convened by the NICE Medicines and Prescribing Centre and was chaired by Alan Silman in accordance with Good practice guidance – Interim process statement and the NICE interim methods guide for developing good practice guidance.

The Committee met regularly during the development of the guideline. At the start of the guideline development process all Committee members declared interests including consultancies, fee-paid work, share-holdings, fellowships and support from the healthcare industry. The details of declared interests and the actions taken are shown in appendix A3.

Staff from the NICE Medicines and Prescribing Centre provided methodological support and guidance for the development process. The NICE guideline developing team included an assistant project manager, senior advisers, information scientists and a project lead. They undertook systematic searches of the literature, appraised the evidence and drafted the guideline in collaboration with the Committee.

2.4 What this guideline covers

This guideline covers the systems and processes for developing and updating local formularies. The guideline defines what a local formulary is, and its role and purpose. The guideline also describes a process for producing a local formulary.

2.5 What this guideline does not cover

The guideline does not include processes relating to the implementation and performance management of local formularies.

2.6 Related NICE guidance

Details are correct at the time of publication of the guideline (October 2015). Further information is available on the NICE website.

2.6.1 Published NICE guidance

General

- Medicines optimisation (2015) NICE guideline NG5
- Patient experience in adult NHS services (2012) NICE guideline CG138
- Service user experience in adult mental health (2011) NICE guideline CG136
- Medicines adherence (2009) NICE guideline CG76
- Antimicrobial stewardship (2015) NICE guideline NG15

NICE guidance in development

- The safe use and management of controlled drugs (2016) NICE guideline. Publication expected March 2016

3 Methods

This chapter sets out the methods used to review the evidence and to generate the recommendations that are presented in subsequent chapters. This guideline was developed in accordance with the methods outlined in NICE's Good practice guidance – Interim process statement and the NICE interim methods guide for developing good practice guidance.

After publication of the report Innovation Health and Wealth, Accelerating Adoption and Diffusion in the NHS, the Department of Health commissioned NICE to produce guidance for the NHS with recommendations for good practice for developing and updating local formularies.

3.1 Identifying the evidence

3.1.1 Literature searching

A systematic literature search was undertaken by Keele University in February 2012 to identify previous guidelines, technology assessment reports, and key reports relevant to the topic, published between February 2002 and February 2012. The evidence search strategies can be found in appendix B1. Searches were carried out according to the methods in the NICE interim methods guide for developing good practice guidance.

3.1.2 Scoping workshop

A scoping workshop was held to inform the formal process for developing the guideline. It included representatives from NHS service providers and commissioners, clinical networks, pharmaceutical industry, and patients and the public. See appendix B2 for a list of attendees.

3.2 Reviewing the evidence

The evidence retrieved from the search strategy was systematically reviewed. Evidence identified from the literature search was reviewed by title and abstract (first sift).

Full papers of the included studies were requested. All full text papers were then reviewed (second sift). The second sift included searching for relevant primary research that addressed the systems and processes for developing and updating local formularies.

3.2.1 Inclusion and exclusion criteria

Selection of relevant studies was carried out by applying the exclusion criteria below:
- articles of limited or no relevance against search terms
- non-English language abstracts or non-English language articles with English abstract.

3.2.2 Types of studies

Only evidence in the English language was considered.

There were no systematic reviews or randomised controlled trials identified. Therefore, the next best available evidence was used to produce this guideline.

3.2.3 Additional evidence – a call for evidence

After appraisal of the published literature, the guideline developing team determined there was insufficient published evidence to address a number of important issues that were identified. Therefore, the guideline developing team conducted a gap analysis.

The Committee reviewed the evidence and the guideline developing team's gap analysis, and determined that the most appropriate method to address the gap analysis was a call for evidence from NHS commissioning and provider organisations.

The guideline developing team sent a request to its database of NHS staff with a significant role or interest in medicines and prescribing issues. Respondents submitted evidence by completing a web-based or Word version template, and were able to supply additional information by email.

Sixty-three completed submissions were received from NHS organisations across England. This evidence was appraised by the guideline developing team and Committee, using the inclusion and exclusion criteria in 3.2.1. See appendix B3 for organisations that submitted written evidence.

The Committee invited 8 organisations to give further evidence orally, of which 7 were able to attend. See appendix B4 for organisations that provided oral evidence.

No papers published after the date of the search were considered in the evidence review.

3.3 Understanding the key themes

Early discussions between NICE and the Department of Health defined the initial scope of this guideline. From the scoping workshop key themes and challenges emerged that were to be considered during guideline development, including:

- a need to ensure robust processes are in place for all aspects of development, including decision-making, appeals, review, maintenance, communication and monitoring
- decision-making processes must comply with requirements of the NHS Constitution for transparency, fairness and the patient's right to an explanation as to why a medicine is not being funded
- capacity and resource limitations impact on training for decision-makers and the development and maintenance of processes
- timelines for adoption of NICE approved medicines and treatments
- the need to avoid a reactive response to a funding or formulary request; a proactive approach and effective horizon scanning will allow for better planning and review of the evidence
- the need for accountability and governance arrangements to be clear; clarity on the roles and functions of the groups that feed into the formulary development system (for example, area prescribing committees and clinical networks)
- concepts of disinvestment and opportunity costs within the decision-making process for the whole health economy
- the practical challenges when care crosses locality boundaries and different formularies are in operation.

Evidence used to develop this guideline indicated that local formularies across England vary in a number of aspects, including the number of NHS organisations covered by the formulary, the range of medicines the formulary includes, and the processes for developing and updating the formulary.

The Committee considered that the benefits of local formularies may include:

- improving patient outcomes by optimising the use of medicines
- supporting the inclusion of patient factors in decision-making about medicines
- improving local care pathways
- improving collaboration between health professionals and commissioners
- improving quality by reducing inappropriate variations in clinical care

- improving quality through access to cost-effective medicines
- supporting the supply arrangements of medicines across a local health economy
- supporting financial management and expenditure on medicines across health communities
- supporting prescribers to follow guidance published by professional regulatory bodies in relation to medicines and prescribing.

Evidence gathered to develop this guideline showed that, in the majority of organisations, decisions relating to medicines to be included within a local formulary were made by a formally constituted decision-making group. Evidence showed that the name of the group and its relationship with other local policy development groups varied. Examples of local formulary decision-making groups include trust formulary groups, drug and therapeutics committees, interface formulary groups and area prescribing committees.

In its review of current practice, the Committee found that many organisations have already established groups for making formulary decisions. However, as a result of changes to NHS commissioning arrangements, many of these groups have identified the need to review their structures. Furthermore, the evidence collected showed that the current picture is one of variation in the size and scope of local formularies. In addition, there is variation in the processes used by local formulary decision-making groups.

The literature and evidence gathered by the Committee demonstrated that there are a number of key elements which are inherent in developing and updating local formularies:

- relationships with other decision-making bodies
- local formulary scope
- the local formulary decision-making group – membership, meeting frequency, resourcing, accountability and reporting arrangements
- stakeholder engagement
- processes for the adoption of medicines recommended by NICE technology appraisal guidance
- processes for selecting medicines to be considered for inclusion in the local formulary
- setting decision criteria
- evidence and information gathering
- incorporating new information from regulatory authorities
- assessing the financial and commissioning impact when making decisions
- deliberating and reaching decisions
- documentation
- developing decision outputs to support local formulary decisions
- communicating and disseminating information about the local formulary
- reconsidering and appealing local formulary decisions
- reviewing and updating the local formulary.

Parallel work streams overseen by the Department of Health and NHS England have been established to provide support to the NHS to implement this guideline.

3.4 Developing recommendations

The Committee reviewed the evidence in the context of the key themes to develop recommendations that would be useful to health professionals and commissioning and provider organisations.

The guideline does not seek to define an optimum population size or number of provider organisations involved in developing and updating local formularies, but provides recommendations for practice that will allow organisations to balance the risks and benefits of different models locally.

The recommendations were drafted based on the Committee's interpretation of the evidence presented. Informal discussions of the available evidence and interpretation of this was captured in the 'Linking evidence to recommendations' (LETR) table for each key theme.

Where evidence was of poor quality, conflicting or absent, the Committee drafted recommendations based on its expert opinion and information gathered from the call for evidence (see section 3.2.3). Consensus based recommendations considered the balance between potential benefits and harms, economic costs compared with benefits, current practice, other guideline recommendations, patient preferences and equality issues, and were agreed through discussion with the Committee.

The wording of the recommendations took into account the strength of the evidence and wording was based on the NICE interim methods guide for developing good practice guidance principles; 'some recommendations are 'strong' in that the Committee believes if others (including health and social care professionals and patients) considered the evidence in the same way they would agree with the recommendations'. This is generally the case if the Committee is confident that, for the majority of people and organisations, the benefits from the recommended practice will outweigh any harm, represent good practice and is cost effective (if cost effectiveness has been assessed). Where the balance between benefit and harm is less clear cut, then the recommendations are 'weaker'; some people or organisations may choose to practice differently with similar benefits to that of the recommended practice. Recommendations for practice that 'must' or that 'must not' be followed are usually included only if there is a legal requirement to apply the recommendation, except occasionally when there are serious consequences of not following a recommendation (for example, if there is a high risk to patient safety).

See section 9 of Developing NICE guidelines: the manual for more information on developing and wording recommendations.'

3.4.1 Research recommendations

The Committee did not make any research recommendations.

3.5 Validation process

This guideline was subject to a 4-week public consultation. This allowed stakeholders, members of the public and other NICE teams to peer review the document as part of the quality assurance process. All comments received from registered stakeholders within the specified deadline were responded to. All comments received and responses given were posted on the NICE website (see section 13 of the NICE interim methods guide for good practice guidance).

3.6 Updating the guideline

The guideline will be updated in accordance with the process outlined in section 15 of Developing NICE guidelines: the manual.

4 Guideline summary

4.1 Recommendations

Recommendations are made that address the principles for developing and updating local formularies.

Relationships with other decision-making bodies

1. When developing or reviewing the local formulary, map and understand the functions of existing medicines-related networks and decision-making groups in the local and neighbouring health economies.

2. Avoid duplicating work by collaborating with other local decision-making groups.

3. Proactively identify, discuss and implement recommendations in publications from national decision-making bodies, such as NICE, taking appropriate actions.

Local formulary scope

4. Determine the scope of the local formulary through consultation with all locally defined stakeholders. Take account of the:

   - size of patient population to be covered

   - range of healthcare treatments to be included

   - range and number of partner organisations adopting the formulary.

5. Ensure local arrangements take account of:

   - consistency of care pathway arrangements across the patient population

   - clinical engagement

   - resources needed to operate formulary processes.

The local formulary decision-making group

6. Agree and document terms of reference for the local formulary decision-making group. This should include:

   - clarification of budgetary responsibility

   - lines of accountability and reporting arrangements

   - members' roles and responsibilities

   - declaration of interest arrangements

   - arrangements for quoracy

   - arrangements for deputies

   - pre-meeting preparation and post-meeting actions

   - the method by which final decisions will be made, recorded and disseminated

   - actions of the Chair

- frequency of meetings.

7. Include a locally-defined mix of members from partner organisations and key stakeholders, such as patients and the public.

8. Ensure that the local formulary decision making group has the range of skills and expertise needed to undertake all necessary activities.

9. Hold meetings sufficiently frequently to ensure decision-making is robust and decisions are made in a reasonable and practical time frame.

10. Take account of the resources needed to undertake all functions of the local formulary decision-making group, as determined by the scope and geographical coverage of the local formulary. [amended 2015]

11. If operating a local formulary covering a small population, consider sharing resources and establishing joint processes with neighbouring local formulary decision-making groups to avoid duplicating work.

12. Ensure corporate governance arrangements are firmly established with clear lines of accountability for each partner organisation.

13. Report to relevant corporate governance bodies for each partner organisation appropriately, and as a minimum annually, and by exception when needed.

Stakeholder engagement

14. Ensure local formulary stakeholder engagement includes:

- clinical groups and networks, especially if a formulary decision needs specific knowledge and expertise or has direct implications for a clinical practice area

- patients or patient representative groups

- local people and communities

- relevant manufacturers of medicines, for example, when the company can offer additional evidence and insight that can assist with decision-making

- other relevant decision-making groups.

15. Ensure stakeholder engagement is proportionate to the type of decision being made and the medicine being considered.

Processes for the adoption of medicines recommended by NICE technology appraisal guidance

16. Include NICE technology appraisals as a standing agenda item in local formulary decision-making group meetings.

17. When a NICE technology appraisal recommends a medicine, adopt the medicine into the local formulary automatically, if clinically appropriate and relevant to the services provided by the organisation. This process should take place within 3 months. Include the medicine within the relevant care pathway(s) provided by local organisation(s), in line with NICE recommendations.

18. When a NICE technology appraisal does not recommend a medicine, focus discussions and actions on withdrawing and decommissioning the medicine if applicable, in line with NICE recommendations.

Processes for selecting medicines to be considered for inclusion in the local formulary

Recommendations for proactive identification of medicines not subject to a NICE technology appraisal for consideration

19. Ensure that there is a robust and transparent process for adopting, removing or updating medicines or indications not covered by NICE technology appraisal guidance.

20. Include horizon scanning as a standing agenda item in local formulary decision-making group meetings.

21. Prioritise medicines not subject to a NICE technology appraisal for consideration using explicit criteria. Ensure these prioritisation criteria are well known, clear and transparent. Assess:

    - patient safety

    - impact on patient care

    - timelines for new medicines reaching the market

    - severity of disease and patient numbers affected

    - clinical effectiveness

    - gaps in treatment or other available treatments

    - cost effectiveness

    - resource impact, for example biosimilar medicines

    - inappropriate variation in local current practice.

Recommendations for reactive identification of medicines by health professionals for consideration

22. Applications to consider a medicine or new indication for inclusion in the local formulary should be submitted by a health professional, although manufacturers may support evidence gathering.

23. Provide information to the applicant to explain the process for considering a medicine or new indication for inclusion in the local formulary and ensure application forms are readily available. Think about inviting the applicant to a meeting to allow for constructive discussion.

24. Ensure the following information is included in application forms to consider a medicine or new indications:

    - details of the health professional making the application, including a declaration of interests

    - local patient population

    - details of the medicine, including strength, formulation, therapeutic drug class, indication, monitoring requirements and cost

    - evidence submission with relevant supporting literature, including efficacy, safety and cost effectiveness

    - comparison with existing treatments

    - likely place in therapy

    - recommendation for the decommissioning of a current formulary medicine, if applicable

    - resource impact, for example biosimilar medicines.

Setting decision criteria

25. Clearly define and consistently apply standard criteria for decision-making. Develop and/or apply a multi-criteria decision tool, which should include:

- patient safety

- clinical effectiveness

- cost effectiveness or resource impact

- strength of evidence

- place in therapy relative to available treatments

- national guidance and priorities

- local health priorities

- equity of access

- stakeholder views.

Evidence and information gathering

26. When there is a NICE technology appraisal for a medicine, do not duplicate NICE's evidence assessment or challenge the technology appraisal recommendations.

27. When there is no NICE technology appraisal for a medicine, use NICE guidelines and advice, and other sources of high-quality information produced by national and regional horizon scanning organisations, if available. Ensure these are relevant to the medicine and indication being considered. Avoid duplicating effort locally.

28. If local critical appraisal and evidence synthesis is needed, ensure that evidence-gathering strategies comprehensively reflect the requirements set out in the local formulary's decision-making criteria.

29. If local critical appraisal and evidence synthesis is needed, ensure that individuals with specialist skills and competencies are available. This includes skills in:

- literature searching

- critical appraisal

- interpreting and contextualising evidence.

Incorporating new information from regulatory authorities

30. Incorporate medicines safety advice from regulatory authorities routinely into the local formulary. This could be achieved by having patient safety as a standing agenda item.

Assessing the financial and commissioning impact when making decisions

31. Routinely engage with commissioning and financial managers at an appropriate level of seniority and align local formulary decisions within the framework of clinical commissioning.

32. Consider addressing barriers that may delay the speed of adoption of medicines into the formulary, such as multiple applications to different

decision-making groups, delayed or absent business planning, budget identification or service design. [amended 2015]

Deliberating and reaching decisions

33. Use explicit principles that are formally documented to guide deliberation in the local formulary decision-making group, such as mission statements, terms of reference, decision criteria and legal and ethical frameworks.

34. Support members of the local formulary decision-making group in deliberation and decision-making by providing appropriate training and constructive feedback.

35. Determine explicitly how local formulary decision-making groups reach final decisions.

Documentation

36. Document the deliberations and actions from local formulary decision-making group meetings, the outcomes of decisions, the rationale for each decision and all formulary policies.

37. Use a standard format for notes and minutes of local formulary decision-making group meetings, which ensures that the key points are summarised for all decisions. Ensure secretariat functions are sufficiently competent so that technical information is accurately recorded.

Developing decision outputs to support local formulary decisions

38. Develop decision outputs with stakeholders (including clinical groups and networks) and other local decision-making groups in a timely manner, to prevent delays in access to treatment.

39. Develop decision outputs related to a NICE technology appraisal within a time frame that does not delay the adoption of the medicine into the formulary beyond the statutory requirements.

Communicating and disseminating information about the local formulary

40. Publish all relevant local formulary information online, in a clear, simple and transparent way, so that patients, the public and stakeholders can easily understand it. This includes formulary policies, minutes of meetings, decision outcomes and associated decision outputs.

41. Publish information that sets out which NICE technology appraisals are included in the local formulary, in line with the NHS Chief Executive's 2012 letter Innovation, Health and Wealth publication of NHS formularies.

42. Develop a local communication framework for the local formulary, in consultation with stakeholders, reviewed annually, to:

    - disseminate targeted, concise information to other decision-making groups and key stakeholders, including patients and the public who need to know about the decision

    - routinely communicate with neighbouring local formulary decision-making groups to share practice, particularly when there are cross-boundary patient flows

    - anticipate media response to decisions.

Reconsidering and appealing local formulary decisions

43. Establish a robust and transparent process for reconsideration or appeals of decisions made by the local formulary decision-making group. Ensure relevant information is clear and easily accessible.

44. Clearly define the criteria for a health professional to request a reconsideration of a decision made by the local formulary decision-making group. This should include circumstances in which:

    - significant new information such as a medicines safety alert has become available, which requires a reconsideration of the evidence

    - the decision was based on inaccurate or incomplete information.

45. Clearly define the acceptable grounds for a health professional to appeal a decision made by the local formulary decision-making group. This should include circumstances in which the local formulary decision-making group is judged not to have followed the published process.

46. Ensure the validity of a formal appeal is assessed by an independent appeals panel. The appeals panel should inform the health professional, in writing, if the appeal does not satisfy the defined grounds. The appeals panel should direct appeals that do satisfy the defined grounds to the most appropriate decision making group for further consideration.

47. Ensure the appeals panel has a clear statement of purpose. Members should together have the skills and expertise necessary to enable them to make the decisions being asked of them.

48. Consider collaborating with neighbouring groups to ensure that adequate training and resources for the appeals process are available. This may include providing independent cross-organisational appeals panels. [amended 2015]

Reviewing and updating the local formulary

49. Establish a robust and transparent process for reviewing and updating the local formulary. This includes:

    - ensuring new positive NICE technology appraisal recommendations are incorporated into the formulary automatically

    - ensuring that when a NICE technology appraisal does not recommend a medicine, the medicine is withdrawn from the formulary, in line with NICE recommendations

    - responding to important new evidence on all medicines included in the formulary in a timely manner, including withdrawing or amending the position of a medicine in the care pathway(s)

    - responding promptly to important new information on medicines safety, such as serious adverse effects

    - reviewing and updating associated decision outputs

    - ensuring requests to review and reconsider the evidence are evaluated in a timely manner

    - responding promptly to the identification of technical errors

- responding promptly to the outcome of appeals

- establishing a rolling schedule of structured formulary review.

50. Collaborate effectively with relevant stakeholders, including health professionals and other local decision-making groups, when reviewing and updating the local formulary.

5 Relationships with other decision-making bodies

5.1 Evidence to recommendations

Table 1: Linking evidence to recommendations (LETR)

The Committee found that local formulary decision-making groups rarely operated in isolation and it is therefore important that local formulary design is based on a clear understanding of existing arrangements for managing medicines across care pathways.

The Committee agreed that good practice was represented by actively considering and incorporating information from key national bodies such as NICE. Local formularies should be developed in collaboration with other local decision-making groups, such as area prescribing committees, drug and therapeutics committees, commissioner-based prioritisation groups, and clinical networks.

The Committee found that collaboration with other local decision-making groups and national bodies relevant to medicines helps with:

- reducing variation in patient care across neighbouring healthcare providers or health economies
- reducing duplication of evidence assessment activities
- developing local integrated care pathways across primary and secondary care, taking account of commissioning priorities and clinical requirements for service development and operation
- risk assessing and positioning of medicines in care pathways, which may include adopting risk stratification tools such as traffic light systems and shared-care arrangements
- disseminating the local formulary together with the outputs of the local formulary decision-making group.

5.2 Recommendations and research recommendations

1. **When developing or reviewing the local formulary, map and understand the functions of existing medicines-related networks and decision-making groups in the local and neighbouring health economies.**

2. **Avoid duplicating work by collaborating with other local decision-making groups.**

3. **Proactively identify, discuss and implement recommendations in publications from national decision-making bodies, such as NICE, taking appropriate actions.**

6 Local formulary scope

6.1 Evidence to recommendations

Table 2:   Linking evidence to recommendations (LETR)

The Committee found evidence of a range of models of local formulary development, from simple lists of drugs to highly detailed summaries of evidence linked electronically to local care pathways and policies. In addition, the range of healthcare providers covered by a local formulary also varied from a single secondary care trust, a small number of primary care providers and 1 commissioning organisation, to local formularies spanning multiple commissioning organisations, extensive primary and secondary care providers together with specialist tertiary services, community services and care homes.

Evidence was presented showing local variation in the medicines covered by different formularies. Some organisations operated local formularies that included medicines for adults, medicines for children, dressings and appliances, whereas other organisations developed a number of separate formularies for specialised areas of care.

The Committee found no evidence to indicate that any formulary scope and population coverage was more appropriate than any other. However, the Committee concluded that:

- a simple list of medicines may not ensure that the formulary integrates with local care pathways
- a formulary operating solely in 1 organisation (for example, a single secondary care trust) is not likely to cover the whole care pathway
- health economies covering a large patient population with multiple partner organisations may have differing care pathways for treating the same condition. Local formularies spanning such economies may find engagement with specialist health professionals challenging. Effective communication and dissemination of formulary decisions to key stakeholders may also be difficult to achieve.

6.2 Recommendations and research recommendations

4. **Determine the scope of the local formulary through consultation with all locally defined stakeholders. Take account of the:**
   - size of patient population to be covered
   - range of healthcare treatments to be included
   - range and number of partner organisations adopting the formulary.

5. **Ensure local arrangements take account of:**
   - consistency of care pathway arrangements across the patient population
   - clinical engagement
   - resources needed to operate formulary processes.

7 The local formulary decision-making group

7.1 Evidence to recommendations

Table 3:   Linking evidence to recommendations (LETR)

Terms of reference

The Committee found evidence of variation in the clarity and robustness of the terms of reference used in practice. The Committee concluded from the evidence submitted that local formulary decision-making groups should have robust, documented terms of reference.

Membership

The Committee found evidence showing variation in the membership of local formulary decision-making groups. This variation may reflect differences in formulary scope and function. The Committee found that many organisations had considered including representation from patients and public interest groups, but very few had secured regular membership from such groups.

The Committee concluded that explicit consideration and inclusion of all relevant stakeholders was needed when developing and updating local formularies.

The Committee noted that the Local decision-making competency framework, produced by the National Prescribing Centre (2012), could be used to assess the membership of the local formulary decision-making group and identify any gaps in skills and expertise.

Frequency of meetings

Local formulary decision-making groups identified by the Committee varied in the frequency of their meetings and, as a result, the volume of their decisions. The Committee concluded that this is an important consideration because excessive delay can jeopardise the actual and perceived effectiveness of the local formulary decision-making group.

Resourcing

Setting the formulary scope and remit of the local formulary decision-making group has implications for the resources needed to operate the formulary. The Committee found that, in some areas, organisations had dedicated staff to undertake technical and administrative functions related to the formulary. In other areas, these functions were not resourced. The Committee agreed that formulary functions were limited when there appeared to be insufficient resources or an absence of dedicated staff.

The Committee concluded that a combination of the following skills was needed:

- technical: for example, resources and expertise in horizon scanning and searching for evidence
- analytical: for example, collating and critical assessment of evidence
- administrative: for example, secretarial and document resourcing
- communication: for example, stakeholder engagement and website management.

Accountability and reporting arrangements

The Committee found that local formularies operated in sometimes complex environments, ranging from single units, such as 1 provider hospital, to multiple providers and commissioners in health communities. The Committee agreed that, when multiple organisations are involved, lines of accountability for each partner organisation can become blurred.

The Committee concluded that local formularies operate more effectively when there are clear lines of governance, reporting and accountability.

7.2 Recommendations and research recommendations

6. **Agree and document terms of reference for the local formulary decision-making group. This should include:**

    - clarification of budgetary responsibility
    - lines of accountability and reporting arrangements
    - members' roles and responsibilities
    - declaration of interest arrangements
    - arrangements for quoracy
    - arrangements for deputies
    - pre-meeting preparation and post-meeting actions
    - the method by which final decisions will be made, recorded and disseminated
    - actions of the Chair
    - frequency of meetings.

7. **Include a locally-defined mix of members from partner organisations and key stakeholders, such as patients and the public.**

8. **Ensure that the local formulary decision making group has the range of skills and expertise needed to undertake all necessary activities.**

9. **Hold meetings sufficiently frequently to ensure decision-making is robust and decisions are made in a reasonable and practical time frame.**

10. **Take account of the resources needed to undertake all functions of the local formulary decision-making group, as determined by the scope and geographical coverage of the local formulary. [amended 2015]**

11. **If operating a local formulary covering a small population, consider sharing resources and establishing joint processes with neighbouring local formulary decision-making groups to avoid duplicating work.**

12. **Ensure corporate governance arrangements are firmly established with clear lines of accountability for each partner organisation.**

13. **Report to relevant corporate governance bodies for each partner organisation appropriately, and as a minimum annually, and by exception when needed.**

8 Stakeholder engagement

8.1 Evidence to recommendations

Table 4: Linking evidence to recommendations (LETR)

The Committee found variation in how stakeholders were defined, identified and consulted, resulting in variation in the level of engagement with the local formulary. Engagement activities of local formulary decision-making groups varied substantially in scale and scope. Stakeholder engagement was seen to be time-consuming.

Examples of stakeholder engagement activities included:

- requesting additional information from specialist health professionals or manufacturers of medicines
- seeking the views of specialist health professionals and other relevant prescribers
- seeking the views of patients and the public
- notification of formulary decisions on the participating trusts' websites
- communication briefings to relevant stakeholders
- local population mailings and media coverage.

The Committee concluded that there is no one-size model of engagement that will be equally appropriate to all decisions made by the local formulary decision-making group.

8.2 Recommendations and research recommendations

14. Ensure local formulary stakeholder engagement includes:

- clinical groups and networks, especially if a formulary decision needs specific knowledge and expertise or has direct implications for a clinical practice area
- patients or patient representative groups
- local people and communities
- relevant manufacturers of medicines, for example, when the company can offer additional evidence and insight that can assist with decision-making
- other relevant decision-making groups.

15. Ensure stakeholder engagement is proportionate to the type of decision being made and the medicine being considered.

9 Processes for the adoption of medicines recommended by NICE technology appraisal guidance

9.1 Evidence to recommendations

Table 5: Linking evidence to recommendations (LETR)

There was variation in the approach taken by local formulary decision-making groups for identifying medicines recommended by a NICE technology appraisal for inclusion in the local formulary. Some groups had standing agenda items for their meetings to ensure such items were not overlooked. The Committee concluded that local formulary decision-making groups should proactively plan ahead for NICE technology appraisals, rather than waiting until they are published.

The Committee found variation in the approach for adopting NICE technology appraisal recommendations. In some groups, there was automatic adoption with associated work focusing on engaging with health professionals and integrating the medicine in the local care pathway. Other groups conducted additional evidence assessments, or had yet to develop a systematic approach to planning ahead for NICE technology appraisals.

The Committee was also aware that in some circumstances, a NICE technology appraisal may not be relevant to a particular local formulary. For example, it would not be appropriate to include NICE technology appraisal recommendations on a specialist cancer treatment in a local specialist mental health formulary.

The Committee also found some evidence that indicated variation in the local interpretation of the term 'option for treatment' used by NICE. The Committee identified that the following standard wording is now used in NICE technology appraisals:

'The technology in this appraisal may not be the only treatment for [condition]. If a NICE technology appraisal recommends use of a technology, it is as an option for the treatment of a disease or condition. This means that the technology should be available for a patient who meets the clinical criteria set out in the guidance, subject to the clinical judgement of the treating health professional. The NHS must provide funding and resources when the health professional concludes and the patient agrees that the recommended technology is the most appropriate to use, based on a discussion of all available treatments.'

9.2 Recommendations and research recommendations

16. **Include NICE technology appraisals as a standing agenda item in local formulary decision-making group meetings.**

17. **When a NICE technology appraisal recommends a medicine, adopt the medicine into the local formulary automatically, if clinically appropriate and relevant to the services provided by the organisation. This process should take place within 3 months. Include the medicine within the relevant care pathway(s) provided by local organisation(s), in line with NICE recommendations.**

18. **When a NICE technology appraisal does not recommend a medicine, focus discussions and actions on withdrawing and decommissioning the medicine if applicable, in line with NICE recommendations.**

10 Processes for selecting medicines to be considered for inclusion in the local formulary

10.1 Evidence to recommendations

Table 6: Linking evidence to recommendations (LETR)

The Committee found variation in approaches for identifying, prioritising and selecting medicines to be considered by the local formulary decision-making group. Some groups operated an extensive horizon scanning process to proactively identify key medicines. Other groups had an approach that focused on the NICE forward planner, national horizon scanning services and reacting to requests made by health professionals. The Committee also identified different levels of awareness of horizon scanning resources.

The Committee also found variation in the local approach to considering individual requests from health professionals for the inclusion of a medicine in the local formulary. A number of application forms used in practice by NHS organisations were submitted as part of the call for evidence. The Committee concluded that application forms were the most appropriate method for considering health professional requests to ensure consistency.

There was also wide variation in resources allocated to support the identification, prioritisation and selection of medicines locally.

10.2 Recommendations and research recommendations

Recommendations for proactive identification of medicines not subject to a NICE technology appraisal for consideration

19. **Ensure that there is a robust and transparent process for adopting, removing or updating medicines or indications not covered by NICE technology appraisal guidance.**

20. **Include horizon scanning as a standing agenda item in local formulary decision-making group meetings.**

21. **Prioritise medicines not subject to a NICE technology appraisal for consideration using explicit criteria. Ensure these prioritisation criteria are well known, clear and transparent. Assess:**
    - patient safety
    - impact on patient care
    - timelines for new medicines reaching the market
    - severity of disease and patient numbers affected
    - clinical effectiveness
    - gaps in treatment or other available treatments
    - cost effectiveness
    - resource impact, for example biosimilar medicines
    - inappropriate variation in local current practice.

Recommendations for reactive identification of medicines by health professionals for consideration

22. **Applications to consider a medicine or new indication for inclusion in the local formulary should be submitted by a health professional, although manufacturers may support evidence gathering.**

23. **Provide information to the applicant to explain the process for considering a medicine or new indication for inclusion in the local formulary and ensure application forms are readily available. Think about inviting the applicant to a meeting to allow for constructive discussion.**

24. **Ensure the following information is included in application forms to consider a medicine or new indications:**
    - details of the health professional making the application, including a declaration of interests
    - local patient population
    - details of the medicine, including strength, formulation, therapeutic drug class, indication, monitoring requirements and cost
    - evidence submission with relevant supporting literature, including efficacy, safety and cost effectiveness
    - comparison with existing treatments
    - likely place in therapy
    - recommendation for the decommissioning of a current formulary medicine, if applicable
    - resource impact, for example biosimilar medicines.

11 Setting decision criteria

11.1 Evidence to recommendations

Table 7: Linking evidence to recommendations (LETR)

From the evidence provided, the Committee found there was relatively little explicit consideration of the process for how local formulary decision-making groups make their decisions. When the process had been considered, there was variation in the clarity, consistency and transparency of processes adopted. The Committee reviewed a number of multi-criteria decision tools[a] developed to aid decision-making.

The Committee also reviewed examples of locally developed tools from the NHS and heard from organisations presenting oral evidence that these tools can help to provide a consistent decision framework for considering key elements, such as clinical evidence and legal and ethical criteria. The Committee reviewed resources that were available at the time of guidance development to support the NHS in developing legal and ethical frameworks for decision-making. The Committee concluded that e-learning resources published by the National Prescribing Centre to support decision-making groups developing legal and ethical frameworks can be helpful to local formulary decision-making groups.

11.2 Recommendations and research recommendations

25. **Clearly define and consistently apply standard criteria for decision-making. Develop and/or apply a multi-criteria decision tool, which should include:**

- patient safety
- clinical effectiveness
- cost effectiveness or resource impact
- strength of evidence
- place in therapy relative to available treatments
- national guidance and priorities
- local health priorities
- equity of access
- stakeholder views.

[a] Office of Health Economics (2011) Incorporating Multiple Criteria in HTA: Methods and Processes.

12 Evidence and information gathering

12.1 Evidence to recommendations

Table 8: Linking evidence to recommendations (LETR)

The Committee found that when a NICE technology appraisal exists for a particular medicine, most organisations did not conduct additional appraisal of the medicine and indication. A small number of organisations would consider looking at additional evidence alongside the technology appraisal in their considerations. When there is no NICE technology appraisal, some local formulary decision-making groups commissioned evidence synthesis specialist services to produce information for the local formulary decision-making group on key topics.

The Committee was aware of a number of organisations providing relevant resources, for example:
- All Wales Medicines Strategy Group
- British National Formulary (BNF) and BNF for Children
- NICE Clinical Knowledge Summaries
- Electronic Medicines Compendium
- European Medicines Agency
- London New Drugs Group
- Manufacturers
- Medicines and Healthcare products Regulatory Agency
- Midlands Therapeutics Review and Advisory Committee (MTRAC)
- National Institute for Health Research – Horizon Scanning Centre
- NICE
- North East Treatment Advisory Group (NETAG)
- Regional Drug & Therapeutics Centre
- Scottish Intercollegiate Guidelines Network
- Scottish Medicines Consortium
- The Cochrane Library
- UK Medicines Information

The Committee found variation in the way evidence and information was gathered locally to support decision-making.

Evidence provided to the Committee suggested variation in how local formulary decision-making groups gather relevant information about commissioning and financial arrangements for local care pathways.

12.2 Recommendations and research recommendations

26. **When there is a NICE technology appraisal for a medicine, do not duplicate NICE's evidence assessment or challenge the technology appraisal recommendations.**

27. **When there is no NICE technology appraisal for a medicine, use NICE guidelines and advice, and other sources of high-quality information produced by national and regional horizon scanning organisations, if available. Ensure these are relevant to the medicine and indication being considered. Avoid duplicating effort locally.**

28. If local critical appraisal and evidence synthesis is needed, ensure that evidence-gathering strategies comprehensively reflect the requirements set out in the local formulary's decision-making criteria.

29. If local critical appraisal and evidence synthesis is needed, ensure that individuals with specialist skills and competencies are available. This includes skills in:

- literature searching
- critical appraisal
- interpreting and contextualising evidence.

13 Incorporating new information from regulatory authorities

13.1 Evidence to recommendations

Table 9: Linking evidence to recommendations (LETR)

The Committee recognised the importance of incorporating important new information from regulatory authorities, such as the Drug Safety Update from the Medicines and Healthcare products Regulatory Agency (MHRA). The Committee found that only a small number of local formulary decision-making groups described a formal process for responding to medicines safety advice or alerts.

The Committee felt that a comprehensive approach to developing and updating local formularies would include consideration and inclusion of new medicines safety advice or alerts from regulatory authorities relating to medicines.

13.2 Recommendations and research recommendations

30. **Incorporate medicines safety advice from regulatory authorities routinely into the local formulary. This could be achieved by having patient safety as a standing agenda item.**

14 Assessing the financial and commissioning impact when making decisions

14.1 Evidence to recommendations

Table 10: Linking evidence to recommendations (LETR)

The Committee found that many local formulary decision-making groups have developed their decision-making processes for formulary decisions to incorporate the financial impact of the new medicine or new indication and the associated commissioning arrangements that will be needed.

Some local formulary decision-making groups had effective assessment, budgetary and planning processes as part of their decision-making, which took account of the financial and commissioning arrangements across a whole health economy. However, some groups appeared to be operating within a financial vacuum and made decisions without considering the impact on healthcare budgets for the community.

The Committee found that clinically and cost-effective treatments may impact positively on healthcare budgets. Some organisations carried out cost–benefit analyses to demonstrate positive impact on budgets beyond medicines procurement costs.

The Committee recognised that financial and commissioning impact was an important consideration for the Department of Health work stream providing support to the NHS to implement this guideline.

14.2 Recommendations and research recommendations

31. **Routinely engage with commissioning and financial managers at an appropriate level of seniority and align local formulary decisions within the framework of clinical commissioning.**

32. **Consider addressing barriers that may delay the speed of adoption of medicines into the formulary, such as multiple applications to different decision-making groups, delayed or absent business planning, budget identification or service design. [amended 2015]**

15 Deliberating and reaching decisions

15.1 Evidence to recommendations

Table 11: Linking evidence to recommendations (LETR)

The Committee reviewed the limited published evidence on the use of multi-criteria decision-tools. It also recognised the lack of evidence on the effect of using such tools for including or excluding medicines from local formularies. In its review, the Committee found that local formulary decision-making groups typically engage in discussion and deliberation after receiving evidence and additional information from stakeholders. The Committee also found variation in the arrangements for reaching decisions, ranging from informal consensus to formal voting arrangements.

The Committee considered that the role of the Chair is important for effective functioning of the local formulary decision-making group. Characteristics of effective chairmanship include:

- allowing sufficient time for all members to express their views without feeling intimidated or threatened
- allowing for assumptions to be debated
- ensuring discussions are open, constructive and unbiased
- checking that all members of the group agree to endorse any decisions or recommendations made
- ensuring that decisions reached are aligned with organisational policies
- ensuring decision-making processes are transparent, fair and reasonable.

15.2 Recommendations and research recommendations

33. **Use explicit principles that are formally documented to guide deliberation in the local formulary decision-making group, such as mission statements, terms of reference, decision criteria and legal and ethical frameworks.**

34. **Support members of the local formulary decision-making group in deliberation and decision-making by providing appropriate training and constructive feedback.**

35. **Determine explicitly how local formulary decision-making groups reach final decisions.**

16 Documentation

16.1 Evidence to recommendations

Table 12: Linking evidence to recommendations (LETR)

The Committee found that many organisations had recognised the need to document the decisions made and the rationale for each decision. The Committee found that a range of approaches were used in practice, with personnel documenting the meetings having a range of skills.

16.2 Recommendations and research recommendations

36. **Document the deliberations and actions from local formulary decision-making group meetings, the outcomes of decisions, the rationale for each decision and all formulary policies.**

37. **Use a standard format for notes and minutes of local formulary decision-making group meetings, which ensures that the key points are summarised for all decisions. Ensure secretariat functions are sufficiently competent so that technical information is accurately recorded.**

17 Developing decision outputs to support local formulary decisions

17.1 Evidence to recommendations

Table 13: Linking evidence to recommendations (LETR)

The Committee found that the style of many local formularies was more than a simple list of medicines to be used in a local organisation. A range of decision outputs aligned to the local formulary support the effective use of medicines. These included:

- implementation policies
- prescribing guidelines
- treatment protocols
- shared care agreements
- patient care pathways
- patient information
- recommendations to commissioners and relevant decision-making groups.

17.2 Recommendations and research recommendations

38. **Develop decision outputs with stakeholders (including clinical groups and networks) and other local decision-making groups in a timely manner, to prevent delays in access to treatment.**

39. **Develop decision outputs related to a NICE technology appraisal within a time frame that does not delay the adoption of the medicine into the formulary beyond the statutory requirements.**

18 Communicating and disseminating information about the local formulary

18.1 Evidence to recommendations

Table 14: Linking evidence to recommendations (LETR)

The Committee found that information about local formularies were usually disseminated digitally using an intranet or the internet. Some local formulary decision-making groups operated a fully transparent process whereby the formulary and associated policies were publicly accessible. In other cases, the formulary itself may have been publically available, but the decisions and how they were arrived at were available only to internal personnel. Many of the NHS organisations that provided evidence to the Committee had established dedicated webpages on their organisation's website for hosting relevant formulary information.

The Committee found variation in communication approaches with other local decision-making groups, ranging from written briefings as standing agenda items for local decision-making groups, to direct weblinks sent to key personnel involved in managing medicines across the health community.

18.2 Recommendations and research recommendations

40. **Publish all relevant local formulary information online, in a clear, simple and transparent way, so that patients, the public and stakeholders can easily understand it. This includes formulary policies, minutes of meetings, decision outcomes and associated decision outputs.**

41. **Publish information that sets out which NICE technology appraisals are included in the local formulary, in line with the NHS Chief Executive's 2012 letter Innovation, Health and Wealth publication of NHS formularies.**

42. **Develop a local communication framework for the local formulary, in consultation with stakeholders, reviewed annually, to:**
    - disseminate targeted, concise information to other decision-making groups and key stakeholders, including patients and the public who need to know about the decision
    - routinely communicate with neighbouring local formulary decision-making groups to share practice, particularly when there are cross-boundary patient flows
    - anticipate media response to decisions.

19 Reconsidering and appealing local formulary decisions

19.1 Evidence to recommendations

Table 15: Linking evidence to recommendations (LETR)

The Committee found that only a small number of local formulary decision-making groups had a formal appeals process. For those that did offer a right to appeal, the Committee found variation in the processes and grounds for appeals.

The Committee agreed that appeals panels would not, in general, consider new evidence emerging after the local formulary decision had been made. In circumstances in which significant new information becomes available, or a formulary decision was based on incomplete or inaccurate information, the Committee agreed that the local formulary decision-making group may need to review the new information and reconsider their decision. The Committee concluded that the appeals process should generally be reserved for when the local formulary decision-making group is judged not to have followed their published processes.

The Committee also concluded that a health professional is best placed to submit a formal appeal on behalf of their patient population for the inclusion of a medicine in a local formulary. The Committee agreed that if a health professional considers an individual patient to be exceptional to a commissioning policy, funding for a medicine should be requested through the local individual funding request (IFR) process. Repeated IFR requests may prompt a review of commissioning policy.

19.2 Recommendations and research recommendations

43. **Establish a robust and transparent process for reconsideration or appeals of decisions made by the local formulary decision-making group. Ensure relevant information is clear and easily accessible.**

44. **Clearly define the criteria for a health professional to request a reconsideration of a decision made by the local formulary decision-making group. This should include circumstances in which:**
    - significant new information such as a medicines safety alert has become available, which requires a reconsideration of the evidence
    - the decision was based on inaccurate or incomplete information.

45. **Clearly define the acceptable grounds for a health professional to appeal a decision made by the local formulary decision-making group. This should include circumstances in which the local formulary decision-making group is judged not to have followed the published process.**

46. **Ensure the validity of a formal appeal is assessed by an independent appeals panel. The appeals panel should inform the health professional, in writing, if the appeal does not satisfy the defined grounds. The appeals panel should direct appeals that do satisfy the defined grounds to the most appropriate decision making group for further consideration.**

47. **Ensure the appeals panel has a clear statement of purpose. Members should together have the skills and expertise necessary to enable them to make the decisions being asked of them.**

48. **Consider collaborating with neighbouring groups to ensure that adequate training and resources for the appeals process are available. This may include providing independent cross-organisational appeals panels. [amended 2015]**

20 Reviewing and updating the local formulary

20.1 Evidence to recommendations

Table 16: Linking evidence to recommendations (LETR)

The Committee recognised that many local formularies are already in operation. However, there was variation in the approach and processes for reviewing and updating local formularies. Some local formulary decision-making groups did not have a comprehensive approach, whereas others operated a process that responds promptly to the publication of important new evidence, such as NICE technology appraisals, MHRA drug safety updates and relevant local data.

The Committee found that some local formularies were regularly reviewed and updated with a comprehensive rolling schedule. Others did not appear to have a structured approach to reviewing and updating all content on a regular basis. The Committee agreed that, as local formulary decision-making groups review and update their processes, there will be a particular need to review formulary content developed under previous processes.

20.2 Recommendations and research recommendations

49. **Establish a robust and transparent process for reviewing and updating the local formulary. This includes:**

    - ensuring new positive NICE technology appraisal recommendations are incorporated into the formulary automatically
    - ensuring that when a NICE technology appraisal does not recommend a medicine, the medicine is withdrawn from the formulary, in line with NICE recommendations
    - responding to important new evidence on all medicines included in the formulary in a timely manner, including withdrawing or amending the position of a medicine in the care pathway(s)
    - responding promptly to important new information on medicines safety, such as serious adverse effects
    - reviewing and updating associated decision outputs
    - ensuring requests to review and reconsider the evidence are evaluated in a timely manner
    - responding promptly to the identification of technical errors
    - responding promptly to the outcome of appeals
    - establishing a rolling schedule of structured formulary review.

50. **Collaborate effectively with relevant stakeholders, including health professionals and other local decision-making groups, when reviewing and updating the local formulary.**

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22 Glossary

Decision output

A locally developed output that is aligned to local formulary decisions. Examples include implementation policies, prescribing guidelines, treatment protocols, shared care agreements, patient care pathways, patient information and recommendations to commissioners and other decision-making groups.

Multi-criteria decision tool

A tool that is used to aid decision-making, where decisions are based on more than one criterion, which make explicit the impact on the decision of all the criteria applied and the relative importance attached to them.

Robust and transparent

Robust and transparent processes, including sharing of information and appropriate collaboration with relevant stakeholders, aims to improve the consistency of decision-making about medicines and ensure that patient safety is not compromised. This should reduce inappropriate variation in patient care when decisions are made due to inconsistent, inadequate or unsafe processes and policies.

Appendices

Appendix A: Guideline Committee

A.1 Committee members

Name	Job title
Gary Barnfield	Deputy Head of Medicines Management, NHS Sheffield
Trevor Beswick	Director, South West Medicines Information & Training, University Hospitals Bristol NHS Foundation Trust
David Campbell	Chief Pharmacist, Northumbria Healthcare NHS Foundation Trust
Andrew Cohen	Consultant in Anaesthetics, Leeds Teaching Hospital NHS Trust
Brian Eadon	Formulary Pharmacist, Betsi Cadwaladr University Health Board
Leslie Galloway (Deputy Chair)	Chairman, Ethical Medicines Industry Group (EMIG)
Anne Hines	Cancer Network Lead Pharmacist, Merseyside and Cheshire Cancer Network
William Horsley	Lead Pharmacist, NHS North East Treatment Advisory Group
Sian Khesro	Senior Pharmacist, North West London Hospitals NHS Trust
Jackie Lamberty	Consultant, Self-employed
Ivor Nathan	Patient and Public Involvement representative
Stephen Pike	GP Prescribing Lead, West Sussex Primary Care Trust, Seldon Medical Centre and Costal West Sussex Federation
Jonathan Roberts	Medicines Management Lead, South Devon and Torbay Clinical Commissioning Group
Mark Robinson	Pharmaceutical Consultant, Association of British Healthcare Industries (ABHI), M and C Consultancy
Chris Roome	Principal Clinical Effectiveness Pharmacist, NHS Devon
Alan Silman (Chair)	Medical Director, Arthritis Research UK
Cliff Snelling	Patient and Public Involvement representative
Iestyn Williams	Lecturer, Health Services Management Centre, University of Birmingham
Tina Worth	Health Economy Liaison Manager, Grünenthal Ltd
John Yorke	Principal Pharmacist, Medicines Information Centre, Calderdale Royal Hospital

A.2 NICE guideline developing team

Name	Job title
Harriet Lewis	Project Lead and Associate Director Medicines

Name	Job title
	Advice (until 12 October 2012)
Neal Maskrey	Project Lead (from 12 October 2012) and Consultant Clinical Adviser
Louise Picton	Senior Adviser, Medicines Advice
Ian Pye	Assistant Project Manager, Medicines Advice

A.3   Declarations of interest

The following members of the Guideline Development Group made declarations of interests. All other members of the Group stated that they had no interests to declare.

Member	Interest declared	Type of interest	Decision taken
James Buchan	Paid columnist 'Nursing Standard'; nursing adviser	Personal pecuniary	Declare and participate
James Buchan	Professional adviser, NHS Centre for Workforce Intelligence	Non-personal pecuniary	Declare and participate
Ann Casey	Part of the team that developed the Safer Nursing Care Tool	Personal non-pecuniary	Declare and participate

Appendix B: How this guideline was developed

B.1   Search strategies for the guideline

Literature search and search strategy

Pubmed searches

Limits: Human; last 10 years; terms in title or abstract.

1.   NICE and {implement* or adoption or decision*}

2.   formular* and NICE

3.   formular* and {implementation or development or adoption or adherence or management or decision*}

4.   formular* and {UK or stakeholder* or guid*}

5.   formular* and {benefit* or advantage* or disadvantage* or challenge* or success or 47conomy*}

Sources searched for the guideline

EMBASE, HMIC, CINAHL, HEALTH BUSINESS ELITE searches

As for Pubmed, but with formular* in title only.

NeLM and Google searches

Formularies and (development or implementation or implement or adoption or adherence or management)

Formularies, UK

B.2 Scoping workshop attendees

Sotiris Antoniou
Consultant Pharmacist, North East London Cardiovascular and Stroke Network and Barts and the London NHS Trust

Kate Arnold
Senior Prescribing Adviser, Solihull Primary Care Trust and Birmingham and Solihull Cluster

Judith Bell
Assistant Director of Public Health, NHS Derby and NHS Derbyshire County

Jill Bloom
Medicines Information Pharmacist, Moorfields Eye Hospital NHS Foundation Trust

James Carr
Network Pharmacist, Avon, Somerset, and Wiltshire Cancer Services

Cathy Cooke
Head of Medicines Management, Bristol Community Health Community Interest Company

Leslie Galloway
Chairman, Ethical Medicines Industry Group (EMIG)

Peter Golightly
Director, Trent Medicines Information Service, UK Medicines information (UKMi)

Amanda Gulbranson
Clinical Effectiveness Pharmacist, Devon Partnership NHS Trust

Robyn Hughes
Director of Brands, Specialities & Secondary Care, Teva UK

Simon Nicholson
Head of Partnership Development, MSD

Stephen Pike
GP Prescribing Lead, West Sussex Primary Care Trust, Seldon Medical Centre and Costal West Sussex Federation

Mark Randerson
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John Reynolds
Consultant Clinical Pharmacologist and General Physician, Oxford University Hospitals NHS Trust

Karen Robinson
General Practitioner, Southlea Group Practice

Charlotte Skitterall
Chief Pharmacist, University Hospital of South Manchester

Cliff Snelling
Patient and Public Involvement representative

David Thomson
Appraisal Committee Lay Member, NICE

Paula Wilkinson
Chief Pharmacist, NHS Mid-Essex

Victoria Young
Lead Pharmacist Medicines Management, Wirral University Teaching Hospitals NHS
Foundation Trust

B.3 Organisations providing written evidence submissions

- Avon, Somerset and Wiltshire Cancer Services
- Bristol Primary Care Trust, but working on behalf of Bristol, North Somerset and South Gloucestershire Primary Care Trusts
- Bromley Clinical Commissioning Group
- Calderdale and Huddersfield NHS Foundation Trust
- Clatterbridge Cancer Centre NHS Foundation Trust
- Colchester Hospital University NHS Foundation Trust
- Doncaster and Bassetlaw Hospitals NHS Foundation Trust
- Dorset County Hospital
- Dorset HealthCare University NHS Foundation Trust
- Dudley Group NHS Foundation Trust
- Gateshead Health NHS Foundation Trust
- Gloucestershire Hospitals NHS Foundation Trust
- Great Western Hospitals NHS Foundation Trust
- Greater Manchester Formulary Subgroup
- Harrogate & District NHS Foundation Trust
- Heart of England NHS Foundation Trust
- Heart of England NHS Foundation Trust, Solihull Primary Care Trust and Birmingham East and North Primary Care Trust (joint submission)
- Leeds Teaching Hospitals NHS Trust
- Liverpool Heart and Chest Hospital NHS Foundation Trust
- London and South East Regional Medicines Information Service
- Medway NHS Foundation Trust
- Mid Essex Hospitals NHS Trust
- NHS Blackburn with Darwen Care Trust Plus
- NHS Devon
- NHS East Lancashire
- NHS Kent and Medway
- NHS Lothian
- NHS Plymouth
- NHS Portsmouth
- NHS South of Tyne and Wear
- NHS Suffolk
- NHS Tees
- NHS Torbay
- Norfolk & Norwich University Hospital
- North Bristol NHS Trust
- North East Treatment Advisory Group (NETAG)
- North Essex Partnership NHS Foundation Trust

- North West London Hospitals NHS Trust
- Northern Devon Healthcare
- Northumbria Healthcare NHS Foundation Trust
- Nottinghamshire Area Prescribing Committee
- Oxford University Hospitals NHS Trust
- Peterborough and Stamford Hospitals NHS Foundation Trust
- Pinderfields Hospital
- Royal Cornwall Hospitals NHS Trust
- Royal Liverpool & Broadgreen Hospitals NHS Trust
- Sandwell and West Birmingham Hospitals NHS Trust
- Sheffield Teaching Hospitals NHS Foundation Trust
- Sherwood Forest Hospitals
- South of Tyne & Wear and Sunderland Teaching Primary Care Trust
- South Staffordshire Primary Care Trust
- South West Yorkshire Partnership NHS Foundation Trust
- Southampton, Hampshire, Isle of Wight and Portsmouth Primary Care Trust Cluster
- Spectrum Community Health (Primary care prison service)
- St Christopher's Hospice
- St Helens & Knowsley Hospitals NHS Trust
- University Hospital Bristol NHS Foundation Trust
- University Hospital Southampton NHS Foundation Trust
- University Hospitals of Leicester
- Western Sussex Hospitals NHS Trust
- Whipps Cross University Hospital NHS Trust
- Yeovil District Hospital
- York Hospitals NHS Foundation Trust

B.4 Organisations providing oral evidence

- Colchester Hospital University NHS Foundation Trust
- Greater Manchester formulary subgroup
- NHS East Lancashire
- North East Area Prescribing Committee
- North East Treatment Advisory Group (NETAG)
- Nottinghamshire Area Prescribing Committee
- University Hospitals of Leicester