DRAFT FOR CONSULTATION

National Institute for Health and Clinical Excellence

The development and updating of local formularies

Draft for consultation, September 2012

NICE good practice guidance X

Contents

Section 1 – Background

1.1 Purpose of this guidance

The purpose of this guidance is to provide good practice recommendations for the systems and processes required to ensure NHS organisations develop and update local formularies effectively and in accordance with statutory requirements. The current changes within the NHS provide a good opportunity to review local formulary arrangements and plan for the future.

The scope of the guidance does not include suggested methods for implementation and performance management of the local formulary. Furthermore, the guidance does not seek to define an optimum population size or number of provider organisations involved in the development and updating of a local formulary, but provides recommendations for practice that will allow organisations to balance the risks and benefits of different models locally.

1.2 Definition of a local formulary

A definitive definition of a local formulary has not been established within published literature and therefore the guidance development group (GDG), has devised the following:

A local formulary is the output of processes to support the managed introduction, utilisation or withdrawal of healthcare treatments within a local healthcare system, service or organisation.

For the purposes of this guidance document the term 'medicine' is used to cover all entries on a local formulary, although there are other healthcare treatments that may be considered within local formularies. Examples include wound care products, appliances and vaccines.

1.3 Purpose of a local formulary

Evidence gathered for the development of this guidance indicates that local formularies across England vary in a number of aspects including the number of NHS organisations covered by a local formulary, the range of medicines the formularies includes, and the processes for developing and updating the formularies.

Local formularies have the following potential benefits:

- improving local care pathways in relation to medicines and prescribing
- improving collaboration with clinicians and commissioners
- improving quality by reducing variations in clinical care
- improving quality through rapid 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

- support to prescribers to follow good practice guidance published by professional regulatory bodies in relation to medicines and prescribing
- supporting the inclusion of patient factors in decision-making about medicines.

1.4 Decision-making groups

Evidence gathered for the development of this guidance showed that in the majority of organisations decisions relating to medicines to be included within a local formulary are taken by a formally constituted decision-making group. Evidence showed that the name and the relationship of the group with other local policy development groups vary. Examples of formulary decision-making groups include Trust formulary groups, drug and therapeutic committees, interface formulary groups or area prescribing committees.

1.5 Context

NHS constitution

The NHS Constitution for England (Department of Health 2009, revised 2012) 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 within the formulary adopted by the local healthcare providers and commissioners.

> **'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 [and treatments] 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.

> **'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.'

Following publication of the NHS Constitution, the National Prescribing Centre produced a set of key documents to support rational local decision-making. The Guiding Principles for local decision-making and the accompanying Handbook for local decision-makers underpin the good practice recommendations for the systems and processes for developing and updating local formularies.

Statutory responsibility

There are Directions issued by Secretary of State for Health which 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.

Innovation health and wealth – Accelerating adoption and diffusion in the NHS report

The report Innovation health and wealth – Accelerating adoption and diffusion in the NHS, published by Department of Health, December 2011, 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 local systems and processes for the access to medicines supports innovation where appropriate. The report states:

> 'We will require that all NICE technology appraisal recommendations are incorporated into relevant local NHS formularies in a planned way that support safe and clinically appropriate practice.'

The Department of Health has now 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 clinically and cost-effective medicines their doctors believe they need.'

The Department of Health has stated that all NHS organisations should publish information which sets out which NICE technology appraisals are included in their local formularies by 1st April 2013 at the very latest. '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 1st April 2013, this will be a standard term and condition in NHS contracts.

Section 2 – Key priorities for implementing this guidance

This good practice guidance has been developed to support the NHS to develop and update local formularies.

The recommendations for good practice have been developed by the local formularies guidance development group (GDG) and use the Guiding principles for local decision-making, published by Department of Health, 2009 as the foundation for good practice.

The key priorities for implementation of this guidance will be compiled following the period of consultation.

Section 3 - How this guidance has been developed

The development of this good practice guidance followed the methodology described in the NICE Interim process statement – Good practice guidance.

Following the publication in December 2011 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 the development and updating of local formularies.

3.1 Scope

Early discussions between NICE and the Department of Health defined the initial scope of the good practice guidance. The scope covers the systems and processes for the development and updating of local formularies. The scope does not include processes relating to implementation and management of the local formulary. Parallel work streams overseen by the Department of Health have been established to provide support to the NHS to implement this good practice.

3.2 Information gathering workshop

An initial information gathering workshop held which included representatives from NHS service providers and commissioners, clinical networks, pharmaceutical industry, and patients and the public. The workshop was held to inform the formal process for the development of the good practice guidance.

3.3 Guidance Development Group

A GDG was formed to work with the NICE project team. The recruitment process for both members and the group chair followed the **NICE recruitment processes** for committees and groups.

3.4 Evidence gathering

A literature search was undertaken based on the scope of the guidance.

3.5 Sifting and selecting the evidence

The project team sifted the search results, applying first exclusion and then inclusion criteria:

First sift

This process removed evidence based on the following exclusion criteria:

- articles of poor relevance against search terms
- non-English language abstracts or non-English language articles with English abstract.

Second sift

This sift of evidence included relevant primary research that addressed the systems and processes for developing and updating the local formularies. For this good practice guidance there were no systematic reviews or randomised controlled trials

available. The best available evidence on which to produce this good practice guidance therefore included evidence other than randomised controlled trials.

3.6 Gap analysis

Following the appraisal of the published literature the project team determined there was insufficient published evidence to address a number of important issues identified.

3.7 Additional evidence

The GDG reviewed the evidence and the project team's gap analysis. The GDG determined the most appropriate method to address the gap analysis was a call for evidence from service providers and commissioners.

The NICE project team sent an electronic survey to its database of NHS staff with a significant role or interest in medicines and prescribing issues. Respondents were able to submit evidence by completing either a web-based or Word version and were able to supply additional information via email.

78 completed submissions were received from NHS organisations across England. This evidence was appraised by the project team and GDG, again using the above inclusion and exclusion criteria.

The GDG invited 8 organisations to give further evidence orally, and 7 organisations were able to attend.

Section 4 – Evidence and recommendations

In its review of current practice, the GDG 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 formulary decision-making groups. The literature and evidence gathered by the GDG demonstrates that there are a number of key components which are inherent in the development and updating of local formularies:

- relationships with other decision making bodies
- formulary scope
- terms of reference
- membership
- resourcing
- accountability and reporting arrangements
- stakeholder consultation and engagement
- processes for the identification and prioritisation of relevant medicines
- processes for the adoption of NICE technology appraisal recommendations
- setting decision criteria
- evidence and information gathering
- assessment of financial and commissioning impact
- deliberating and reaching decisions
- documentation of processes and decisions
- decision outputs
- meeting frequency
- communication and dissemination
- appeals
- review and updating.

Each of these is discussed in this chapter with recommendations for design and development of formularies put forward.

4.1 Relationships with other decision making bodies

The GDG found that local formulary decision-making groups rarely operate in isolation and it is therefore important that formulary design is based on a clear understanding of existing arrangements for the management of medicines and other healthcare treatments across the local area. The GDG considered that good practice was represented by active consideration and incorporation of information from key national bodies such as NICE. Local formularies should be developed with decision-makers such as area prescribing committees, drug and therapeutics committees, commissioner-based prioritisation groups, and clinical networks.

Recommendations

4.1.1 Before designing a local formulary or reviewing existing arrangements, it is important to map and understand the functions of existing medicines related decision-making groups in the local area and in neighbouring healthcare economies. The local formulary should also be responsive to publications from national bodies such as NICE.

Integration of the local formulary with other local decision-making groups and national bodies relating to medicines helps with:

- developing local integrated clinical pathways across primary and secondary care, taking account of commissioning priorities and clinical requirements for service development and operation
- risk assessing of treatments and positioning of medicines within pathways. This 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 decision-making group
- increasing the consistency in care across neighbouring healthcare providers or health economies.

4.1.2 The number of organisations involved in the development of local formularies should be considered. There is a need to secure engagement and buy-in with all relevant clinicians. This should include non-medical prescribers, community pharmacies and other community services.

4.2 Formulary scope

The GDG 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 formulary also varied from a single secondary care trust, a small number of primary care providers and one commissioning organisation to local formularies spanning multiple commissioning organisations, extensive primary and secondary providers together with specialist tertiary services, community services and care homes.

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

The GDG found no evidence to indicate that any formulary scope was any more appropriate than any other. However the GDG concluded that a simple list of

medicines may not be suitable to ensure that the formulary integrates with local care pathways.

Recommendations

4.2.1 The scope of a local formulary should be determined explicitly and agreed in consultation with stakeholders.

4.2.2 Duplication of work should be avoided by liaison with other local decision-making groups and formally agreeing terms of reference.

4.2.3 When considering the scope of the local formulary the following should be taken into account:

- patient population
- range of healthcare treatments
- range of provider organisations
- resources required to develop and maintain the local formulary.

4.3 Terms of reference

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

Recommendations

4.3.1 Local formulary groups should have terms of reference.

4.3.2 These should include local arrangements for implementation and performance management relating to governance arrangements, lines of accountability for decision-making groups and reporting arrangements.

4.3.3 Terms of reference should also include:

- clarification of budgetary responsibility
- 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
- actions of the Chair
- frequency of meetings.

4.4 Membership

The GDG found evidence showing variation in the membership of formulary decision-making groups. This variation could reflect differences in formulary scope and function. The GDG 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 GDG concluded that explicit consideration and inclusion of all relevant stakeholders was a necessary requirements for the development and updating of local formularies.

The GDG noted that The local decision-making competency framework produced by National Prescribing Centre, March 2012, can be used to assess the membership of the group and identify any gaps in skills and expertise.

Recommendation

4.4.1 Members of the local formulary decision-making group should be drawn from participating healthcare organisations and other key stakeholders such as patients and the public. The group should include a locally-defined mix of members with the appropriate range of skills and expertise. As a collective body, the formulary group should provide the necessary competencies to undertake the activities.

4.5 Resourcing

Setting of the scope of the formulary and remit of the decision-making group has implications for the resources the group requires. The GDG found that resource levels should be proportionate to the tasks undertaken. The GDG concluded that combination of the following skills will be required:

- Technical: including for example resources and expertise in searching for evidence
- Analytical: including for example collating and critical assessment of evidence
- Financial: including for example a budget to resource routine functioning of formulary arrangements.

Recommendations

4.5.1 When designing local formularies due attention should be paid to the resource requirements implied by its scope and the requirements for updating in response to an ever changing evidence base..

4.5.2 Organisations operating a formulary within a small population size and single healthcare provider should consider the benefits of collaboration and establishing joint processes with neighbouring formulary groups.

4.6 Accountability and reporting arrangements

Formularies are located in sometimes complex contexts ranging from single units such as one provider hospital to large arrangements across multiple providers and commissioners within health communities. The GDG found that the evidence suggests that where successful, design of local formularies has been accompanied by clear lines of governance, reporting and accountability.

Recommendations

4.6.1 Review the local formulary decision-making group, ensuring corporate governance arrangements are firmly established with clear lines of accountability.

4.6.2 The formulary decision-making group should report to relevant corporate governance bodies appropriately and as a minimum annually and by exception when required.

4.7 Stakeholder consultation and engagement

The GDG found variation in how stakeholders were defined, identified and consulted, resulting in variation in the level of engagement with the local formulary. The engagement activities of formulary decision-making groups will vary in scale and scope and should be proportionate to the type of decision being made and the medicine being considered. Wide stakeholder engagement can help to increase transparency of decisions, buy-in from those affected by or implementing the decisions. Engagement can also be costly and time-consuming.

Examples of engagement activities include:

- requesting additional information from clinical experts and/or manufacturers of medicines
- notification on the participating Trusts' website and inclusion in any communication briefings to relevant stakeholders
- local population mail shot and media coverage.

Recommendation

4.7.1 There is no one-size model of engagement that will be equally appropriate to all decisions made by the formulary group. However, as a general principle, strategies should include engagement with:

- clinical groups and networks – especially where a formulary decision requires specific knowledge and expertise and/or has direct implications for a clinical practice area
- local citizens and communities – for example in setting formulary decision criteria and where a formulary decision is likely to impact on specific communities
- patients and/or patient representative groups – for example where a formulary decision would benefit from the insights of patient groups affected
- relevant manufacturers of medicines – for example where the latter can offer additional evidence and insight that can assist with decision-making.

4.8 Processes for healthcare treatment identification

The GDG found variation in approaches to selection and prioritisation of healthcare treatments. Some groups operated an extensive horizon scanning process to proactively identify key healthcare treatments. Other groups had an approach which focused on the NICE forward planner, national horizon scanning services and clinician requests. The GDG also identified different levels of awareness of horizon scanning resources.

There was variation in the approach taken by decision-making groups for the inclusion of medicines recommended by a NICE technology appraisal into the formulary. Some groups had standing agenda items for their meetings to ensure such items are not overlooked.

The GDG also found variation in the local approach to considering individual requests from clinicians for the inclusion of a medicine within a local formulary. A number of healthcare treatment application forms used in practice by NHS organisations were submitted as part of the call for evidence.

There was also wide variation in resources allocated locally to support the identification and prioritisation of healthcare treatments.

Recommendations for proactive identification of healthcare treatments for consideration

4.8.1 Local formulary groups should utilise evidence summaries produced by national and regional national horizon scanning organisations and drug safety updates and not duplicate effort locally.

4.8.2 Medicines with a positive NICE technology appraisal should be included in a local formulary automatically. This could be achieved by having NICE technology appraisals as a standing agenda item with discussions and actions focused on inclusion of the medicine within the relevant care pathway(s).

4.8.3 Medicines and Healthcare products Regulatory Agency drug safety updates should be routinely incorporated into local formularies. This could be achieved by having patient safety updates as a standing agenda item.

4.8.4 Where a NICE technology appraisal does not recommend a medicine, discussion and action should focus on decommissioning and withdrawing the use of the medicine as appropriate within local care pathway(s).

4.8.5 Healthcare treatments not subject to a NICE appraisal should be prioritised for consideration on local formulary groups using explicit criteria. These prioritisation criteria should be well known, clear and transparent. Criteria would include:

- timelines for new medicines reaching the market
- severity of disease and patient numbers affected

- patient safety
- gaps in treatment or other available treatments
- impact on patient care
- clinical effectiveness
- cost effectiveness/resource impact
- inappropriate variation in local current practice.

Recommendations for reactive identification of healthcare treatments for consideration

4.8.6 When identification of a new medicine or new indication is proposed by a clinician for inclusion in the local formulary, decision-making groups should ensure that the process for inclusion, updating or removal of healthcare treatments from the formulary is clear, robust and transparent. Applications should be submitted by a clinician, although manufacturers may support evidence gathering.

4.8.7 Application forms should be readily accessible and information should be provided to explain to the applicant how the process will operate. Formulary decision-making groups may wish to invite the applicant to the meeting to allow for constructive discussion.

4.8.8 Applications for new healthcare treatments should include the following:

- details of the clinician making the application, including a declaration of interests
- details of the medicine, including strength, formulation, therapeutic drug class, indication, monitoring requirements, cost
- local patient population
- evidence submission with relevant supporting literature, including efficacy, safety and cost effectiveness
- comparison with existing treatments
- likely place in therapy
- resource impact.

4.9 Adoption of NICE technology appraisal recommendations

The GDG found variation in the approach for adoption of NICE technology appraisal recommendations. In some groups there was automatic adoption with associated work focusing on engagement with clinicians and integration of the medicine within the local care pathway. Other groups conducted additional evidence assessments, or had yet to develop a systematic approach to planning ahead for technology appraisals.

The GDG also found some evidence that indicated variation in the local interpretation of the term ‘option for treatment’ used by NICE.

Recommendations

4.9.1 Local formulary processes should support the planned and timely adoption of medicines recommended by a NICE technology appraisal.

4.9.2 Where a NICE technology appraisal states 'option for treatment' the medicine should be adopted onto the local formulary and decision-making groups should assess its place in the local pathway.

4.10 Setting decision criteria

From the evidence provided, the GDG found there was relatively little explicit consideration of how local formulary groups make decisions. Where this has been considered there was variation in the clarity, consistency and transparency of processes adopted. The literature search identified a number of multi-criteria decision tools developed for this purpose. [DN These will be fully referenced in the final published guidance]

The GDG also received examples of locally developed tools from the NHS and heard 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 GDG reviewed existing resources available to support the NHS in the development of legal and ethical frameworks for decision-making. The 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 groups.

Recommendation

4.10.1 Local formularies decision-making groups should define clearly, and then consistently apply, standard criteria for decision-making. Local formularies groups should develop and/or apply a multi-criteria decision tool. This should included:

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

4.11 Evidence and information gathering

The GDG found that, where there is a NICE technology appraisal, most organisations did not conduct additional appraisal of topics. A small number would consider looking at additional evidence alongside the technology appraisal in their considerations. When there is no NICE technology appraisal, some formulary

decision-making groups commission evidence synthesis specialist services to produce information for the decision-making group on key topics.

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

Evidence provided to the GDG suggested variation in how local formulary groups gather relevant information relating to commissioning arrangements and financial arrangements for local care pathways.

Recommendations

4.11.1 For medicines where there is no NICE technology appraisal local appraisal of the evidence may be required. Local formulary groups should use nationally available evidence summaries, ensuring the summary is relevant to the medicine and indication being considered.

4.11.2 If local evidence synthesis and critical appraisal is required, localities will need individuals with specialist skills and competencies including:

- searching
- appraising
- interpreting and contextualising evidence.

4.11.3 Evidence gathering strategies should comprehensively reflect the requirements as set out in the formulary's decision criteria.

4.12 Assessment of financial and commissioning impact

The GDG found that many organisations have developed their decision-making processes for formulary decisions to include consideration of the financial impact of the new medicine or new indication and the associated commissioning arrangements that may be required. Some organisations have effective assessment and planning processes as part of their decision-making that take account of the financial and commissioning arrangements across a whole health community. However, some organisations appeared to be operating within a financial vacuum and make decisions without regard for the impact on healthcare budgets for the community.

The GDG concluded that clinically and cost effective treatments may impact positively on healthcare budgets. Some organisations undertake cost-benefit analysis to demonstrate positive impact on budgets beyond medicines procurement costs.

Recommendation

4.12.1 Decision-making groups should identify where barriers exist that may delay the speed of adoption of medicines on to the formulary such as delayed or absent business planning, budget identification and service design. This will

usually include routine and regular engagement with commissioning and financial managers at an appropriate level of seniority.

4.13 Deliberating and reaching decisions

The GDG reviewed the limited published evidence on the use of multi-criteria decision-tools. It also recognised the lack of evidence on the effect of the use of such tools on inclusion and exclusion of medicines from formularies. In its review, the GDG found that formulary decision-making groups typically engage in discussion and deliberation following receipt of the evidence and additional information from stakeholders. The GDG also found variation in arrangements in reaching decisions ranging from informal consensus to formal voting arrangements.

The GDG considered that the role of the Chair is important to effective functioning of the decision-making group. Characteristics of effective chairmanship include:

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

Recommendations

4.13.1 It is important that deliberation is guided by explicit principles formally articulated by the formulary group – for example in mission statements, terms of reference, decision criteria and/or legal and ethical frameworks.

4.13.2 Suitable individuals undertaking this role should be supported by the organisation with the provision of training and constructive feedback.

4.13.3 Formulary groups should consider explicitly how they should reach final determinations.

4.14 Documentation

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

Recommendation

4.14.1 The group should ensure that procedures and the rationale for each decision are documented thoroughly. A local approach should be taken for the

mechanism for recording the deliberations and actions from meetings and decisions of the group, however the process and secretariat functions must be sufficiently effective and competent that technical information is accurately recorded.

4.15 Decision outputs

The GDG found that the style of many local formularies was more than a simple list of medicines to be used within a local organisation. Examples of processes currently operating in practice for considering medicines on the formulary include the development of a range of outputs. These can include implementation policies, guidelines, treatment protocols, shared care agreements, patient pathways and recommendations to other bodies within the organisation or health community for changes to commissioning or funding arrangements.

Recommendation

4.15.1 The development of relevant outputs resulting from the inclusion of a new medicine or new indication should be undertaken in a timely manner to prevent delays in access to treatment. Close working with other local decision-making groups such as the area prescribing committee, local clinicians and clinical networks will facilitate discussions and the development of these essential documents.

4.16 Frequency of meetings

Formulary groups identified by the GDG tended to vary in the frequency of their meetings and, as a result, the volume of their decisions. This is an important consideration as excessive delay can jeopardise the actual and perceived effectiveness of the formulary decision-making group.

Recommendation

4.16.1 Meetings should be held sufficiently frequently to ensure decisions are made in a reasonable and practical timeframe but without compromising the requirements for due process.

4.17 Communication and dissemination

The GDG found that local formularies are now usually disseminated digitally either over an intranet or the world-wide web. Some groups operated a fully transparent process where all the formulary and associated policies are publicly accessible. In other cases, the formulary itself may be publically available but the decisions and how they were arrived at are available to internal personnel by electronic communication methods such as intranet notifications. Many of the NHS organisations that provided evidence to the GDG have established dedicated pages on their organisations' website for hosting relevant formulary information.

The GDG found variation in communication approaches with other local decision-making groups, ranging from written briefings as standing agenda items for local

decision-making groups, such as the area prescribing committee, to direct web links sent to key personnel involved in managing medicines across the health community.

Recommendations

4.17.1 In line with the NHS Chief Executive's letter sent to all NHS Trusts in August 2012, all organisations should publish information which sets out which NICE technology appraisals are included in their local formularies by 1st April 2013 at the very latest.

4.17.2 Local formulary decision-making groups should use a standard format for notes and minutes which ensures that the key points are summarised for all decisions. The group should develop a communication framework, reviewed annually, to:

- disseminate concise, targeted information to the key individuals and groups who need to know about the decision
- routinely communicate with neighbouring local formulary decision-making groups to share practice, particularly where there are cross-boundary patient flows
- anticipate media response to decisions
- ensure communication uses clear language and is in an appropriate form.

4.17.3 Communications should include any associated policies, formalised arrangements for shared-care across primary and secondary between primary and specialist clinicians and recommendations for commissioners. Communications should be electronic to support easy access, public availability and version control of documents.

4.18 Appeals

The GDG found 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 GDG found variation in the processes and criteria for appeals.

Recommendations

4.18.1 Organisational policies should clearly define the acceptable grounds for appeal and this process should be made easily accessible. Clinicians should have the ability to appeal the decision made by a decision-making group about the inclusion of a particular medicine on a local formulary if they consider either or both of the following circumstances have occurred:

- due process has not been followed
- significant additional information has become available which requires a reconsideration of the evidence.

4.18.2 An independent panel should assess the validity of the appeal. Formulary decision-making groups may wish to collaborate with neighbouring groups to provide an independent cross-organisational appeal panels.

4.19 Review and updating

The GDG found variation in the approach and processes for review and updating of local formularies. Some groups did not have a comprehensive approach, while others operated a process that responds promptly to the publication of important new evidence, such as local data and utilisation of established medicines as well as new NICE technology appraisals and safety alerts. The GDG found that some formularies are regularly reviewed and updated with a comprehensive rolling schedule. Others do not appear to have a structured approach to reviewing and updating all content on a regular basis.

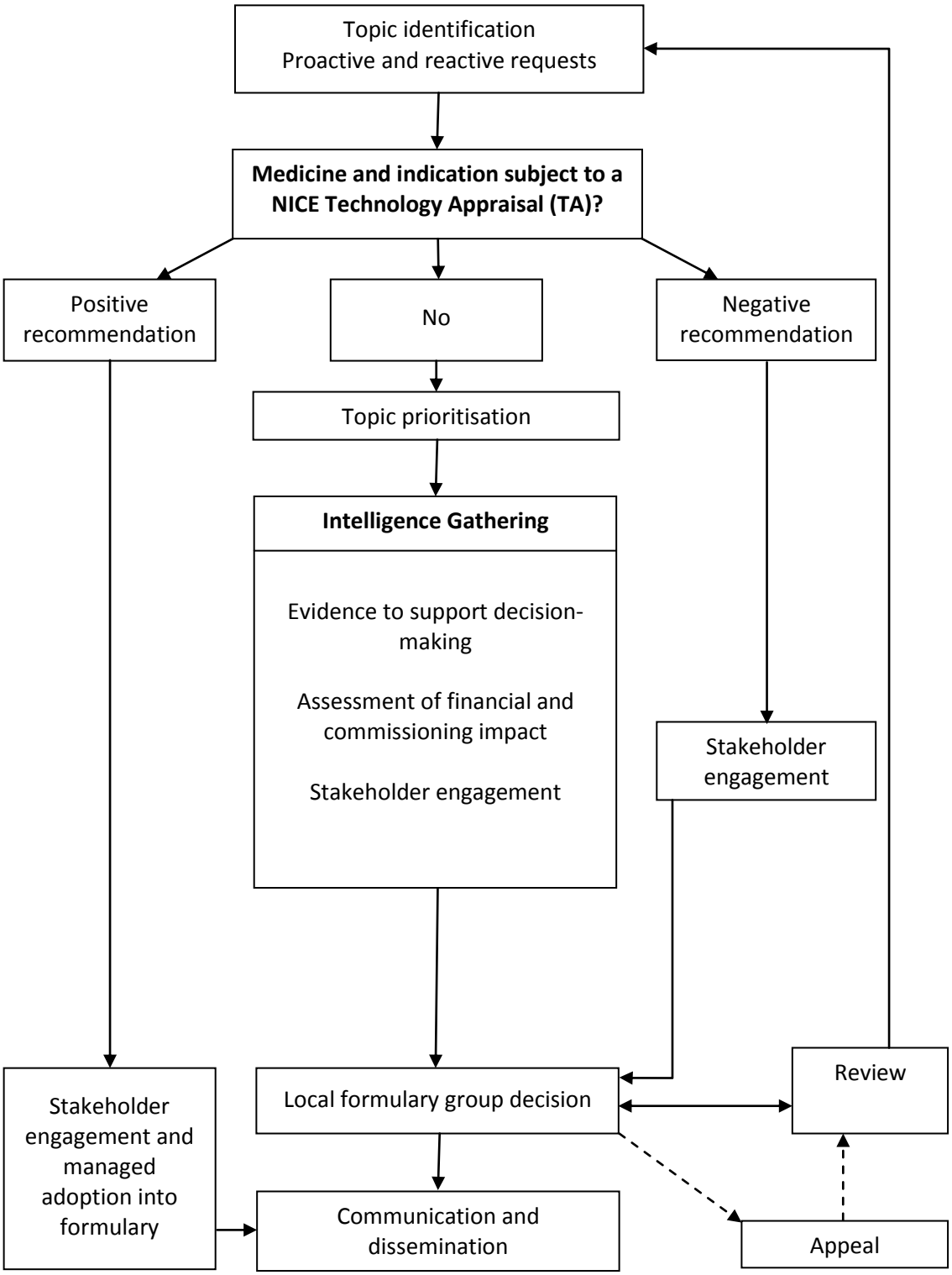
Recommendations

4.19.1 Local formulary groups should ensure there is a structured review of the formulary at appropriate intervals. Documents or web-based publications of the formulary should state the date of last review.

4.19.2 Robust and transparent processes should be established to ensure important new evidence and local data is considered in a timely manner and the local formulary reviewed and updated as appropriate.

4.19.3 Robust and transparent local procedures for the development and updating of local formularies should be operated, ensuring appropriate and effective collaboration with relevant clinicians and other local decision-making groups.

4.20 Overarching process for managed entry of new medicines and changes to established medicines on the formulary



Appendix 1 – Contributors

Appendix 1 of this guidance will be compiled following the period of consultation but will include:

- NICE project team members
- GDG members
- Organisations providing written evidence submissions
- Organisations providing oral evidence