Surveillance proposal consultation document

2019 surveillance of Developing and updating local formularies (NICE guideline MPG1)

Surveillance proposal

We propose to not update the guideline on developing and updating local formularies (NICE guideline MPG1).

Reasons for the proposal to not update the guideline

During this surveillance review, no new evidence was identified relevant to the processes and systems for developing and updating local formularies. The absence of evidence suggests that an update of NICE guideline MPG1 recommendations is not needed at present.

For further details and a summary of all evidence identified in surveillance, see appendix A below.

Overview of 2019 surveillance methods

NICE's surveillance team checked whether recommendations in developing and updating local formularies (NICE guideline MPG1) remain up to date.

The surveillance process consisted of:

- Feedback from topic experts via a questionnaire.
- A search for new or updated Cochrane reviews and national policy.
- Examining related NICE guidance and quality standards and NIHR signals.
- A search for ongoing research.
- Examining the NICE event tracker for relevant ongoing and published events.
- Literature searches to identify relevant evidence.
- Assessing the new evidence against current recommendations to determine whether or not to update sections of the guideline, or the whole guideline.
- Consulting on the proposal with stakeholders (this document).

For further details about the process and the possible update decisions that are available, see ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual.

Evidence considered in surveillance

Search and selection strategy

We searched for new evidence related to the whole guideline. No relevant studies were found in a search for systematic reviews, randomised controlled trials and observational studies published between 01 March 2014 and 09 November 2018.

From all sources, no studies were considered to be relevant to the guideline.

Ongoing research

We checked for relevant ongoing research; none were assessed as having the potential to change recommendations.

Intelligence gathered during surveillance

Views of topic experts

We considered the views of topic experts, including those who helped to develop the guideline. For this surveillance review, topic experts completed a questionnaire about developments in evidence, policy and services related to NICE guideline MPG1.

We sent questionnaires to 13 topic experts and received 6 responses. The topic experts were recruited to the NICE Centre for Guidelines Expert Advisers Panel to represent their specialty.

Regional Medicines Optimisation Committees

Several topic experts emphasised that the guideline should include the role of Regional Medicines Optimisation Committees (RMOCs) in local formulary decision-making. We acknowledge that the advisory outputs of RMOCs are aimed at groups who will be involved in local formulary decision-making. As such, we propose to refresh recommendation 1.1.2 to include collaboration with regional decision-making groups, such as the RMOCs.

Other local formulary guidance

One topic expert commented that NICE guideline MPG1 recommendations should be reviewed against local formulary guidance from other national decision-making bodies. We recognise the importance of ensuring that this guideline remains up to date and the assessment of new information on current recommendations is incorporated into our surveillance review process.

Multi-criteria decision tool

A topic expert commented that the development of recommendation 1.7.1 was "probably too aspirational" and questioned the utility of a multi-criteria decision tool in NHS formulary decision-making. However, the recommendation was developed to provide a consistent decision framework and a list of key criteria that should be considered during decision-

making. During this surveillance review, we did not identify any evidence that contradicts the development and/or use of a multi-criteria decision tool in local formulary decision-making.

Medicines recommended by NICE technology appraisal

Expert feedback also focused on developments in the processes for the adoption of medicines recommended by NICE technology appraisal (TA) guidance, which may result in variation to the statutory funding requirement of 3 months. This included consideration of the NICE fast track appraisal (FTA), NICE/NHS England budget impact test, the early access to medicines schemes (EAMS) and the accelerated access pathway (AAP) under recommendation 1.5 of the guideline. It is important to note that the context section of NICE guideline MPG1 includes a cross-referral to the definition of compliance with a NICE-approved medicine or treatment, which refers to these newer processes.

Medicine safety alerts

A topic expert expressed concern on the provision of medicine safety alerts following the potential exit of the United Kingdom (UK) from the European Union. However, no impact is anticipated given that the Medicines and Healthcare products Regulatory Agency (MHRA) will remain the regulator for medicines and medical devices in the UK.

Decommissioning of medicines

An expert suggested to consider the joint NHS England and NHS Clinical Commissioners guidance in determining which medicines to decommission from the local formulary, referring to recommendation 1.16 of the guideline. The use of such guidance has been addressed by existing recommendations in NICE guideline MPG1 as detailed in appendix A.

Implementation of the guideline

One topic expert commented that the uptake of NICE guideline MPG1 recommendations vary across NHS organisations in England. The expert suggested that an exemplary model formulary may aid in the interpretation and implementation of recommendations. Whilst we acknowledge that this may be beneficial, the nature of the local formulary will be dependent on the type of organisation and care provided. The guideline therefore aims to provide good practice recommendations that will allow organisations to balance the risks and benefits of different models locally.

See appendix A: summary of intelligence from surveillance below for details of all evidence considered, and references.

Views of stakeholders

Stakeholders are consulted on all surveillance reviews except if the whole guideline will be updated and replaced. Because this surveillance proposal is to not update the guideline, we are consulting with stakeholders.

See ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual for more details on our consultation processes.

Equalities

No equalities issues were identified during the surveillance process.

Editorial amendments

During surveillance of the guideline we identified the following points in the guideline that should be amended.

In the changes after publication section of the guideline, we will remove the text under the heading "changes to the recommendation wording for clarification only", dated August 2013. This change is dated prior to publication of this guideline, therefore this information is not relevant.

We propose to refresh recommendation 1.1.2 to include regional medicine decision-making groups, such as Regional Medicines Optimisation Committees.

Overall surveillance proposal

After considering all evidence and other intelligence and the impact on current recommendations, we propose that no update is necessary.

Appendix A: Summary of evidence from surveillance

2019 surveillance of Developing and updating local formularies (2014) NICE guideline MPG1

Summary of evidence from surveillance

A literature search was completed for this surveillance review on developing and updating local formularies (NICE guideline MPG1). However no studies relevant to this guideline were identified. For 9 recommendations of the guideline, no other new information was identified from other sources including topic expert input. Therefore, these recommendations are not included in this summary of evidence as follows:

- 1.3 The local formulary decision-making group
- 1.4 Stakeholder engagement
- 1.8 Evidence and information gathering
- 1.10 Assessing the financial and commissioning impact when making decisions
- 1.11 Deliberating and reaching decisions
- 1.12 Documentation
- 1.13 Developing decision outputs to support local formulary decisions
- 1.14 Communicating and disseminating information about the local formulary
- 1.15 Reconsidering and appealing local formulary decisions

The evidence summary addresses the remaining 7 recommendations of the guideline where information was identified through feedback from topic experts.

1.1 Relationships with other decision-making bodies

Recommendations in this section of the guideline

1.1.1 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.

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

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

Surveillance proposal

This section of the guideline should not be updated.

Editorial amendments

We will refresh recommendation 1.1.2 to include regional decision-making groups, such as the Regional Medicines Optimisation Committees.

2018 surveillance summary

No relevant evidence was identified.

Intelligence gathering

A topic expert commented that NICE guideline MPG1 recommendations should be reviewed against local formulary guidance from other national decision-making bodies. We acknowledge the importance of ensuring that this guideline remains up to date. As such, the process of checking for new information and evaluating the impact on guideline recommendations is incorporated into the surveillance review process.

Several topic experts highlighted the need for recommendations to include the role of Regional Medicines Optimisation Committees (RMOCs) in local formulary decision-making. Initial intelligence also identified the Regional Medicines Optimisation Committees Operating Model (April 2017) by NHS England, which outlines the role of the 4 regional committees in providing recommendations and advice on the optimal use of medicines for the benefit of patients and the NHS. A key aim of the RMOCs is to reduce duplication of medicines optimisation activity across England to minimise variation in the NHS.

The policy details the key operational functions of the committees including identification and prioritisation of medicines optimisation topics, evidence review and the development of pragmatic recommendations. Recommendations are initially distributed to all 4 committees which are then disseminated to stakeholders for use by local decision-makers.

Impact statement

Intelligence gathering highlighted topic expert feedback concerning the need to include Regional Medicines Optimisation Committees (RMOCs) in NICE guideline MPG1 under recommendations on relationships with other decision-making bodies.

Advisory RMOC recommendations on medicines optimisation activity are aimed at local Area Prescribing Committees and Drug and Therapeutic Committees, who will be involved in local formulary decision-making. As such, we will refresh recommendation 1.1.2 to consider the outputs of regional decision-making groups, such as the Regional Medicines Optimisation Committees.

New evidence is unlikely to change guideline recommendations.

1.2 Local formulary scope

Recommendations in this section of the guideline

1.2.1 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.

1.2.2 Ensure local arrangements take account of:

- consistency of care pathway arrangements across the patient population
- clinical engagement
- resources needed to operate formulary processes.

Surveillance proposal

This section of the guideline should not be updated.

2018 surveillance summary

No relevant evidence was identified.

Intelligence gathering

A topic expert commented that recommendation 1.2.2 required the addition of "up to date" in relation to care pathway arrangements across the patient population. Establishing a robust and transparent process for reviewing and updating the local formulary is addressed by recommendation 1.16.1 which includes reviewing and updating decision outputs. Such decision outputs, as defined in the guideline, would include shared care agreements and patient care pathways. Therefore, no impact on the recommendations is expected.

Impact statement

The absence of new evidence indicates that there is no need to update this section of the guideline.

New evidence is unlikely to change guideline recommendations.

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

Recommendations in this section of the guideline

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

1.5.2 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.

1.5.3 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.

Surveillance proposal

This section of the guideline should not be updated.

2018 surveillance summary

No relevant evidence identified.

Intelligence gathering

Initial intelligence gathering identified the 2017/19 NHS Standard Contract (May 2018) which supports the recommendations in NICE guideline MPG1.

Several topic experts suggested that recommendation 1.5.2 should also include the NICE fast track appraisal (FTA) process for assessing technologies for adoption into the local formulary. If a positive recommendation is made through the FTA process, NHS England/commissioners have committed to providing funding for technologies within 30 days of guidance publication.

A topic expert highlighted that the recommendation could make reference to the Medicines and Healthcare products Regulatory Agency (MHRA) early access to medicines scheme (EAMS). Initial intelligence also identified the Office for Life Sciences EAMS: how the scheme works guidance (May 2016), which details how EAMS aims to give patients with life-threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation. The EAMS operational guidance also from the Office for Life Sciences details the key steps of the scheme, including NICE and NHS England engagement. The scheme involves initiation of a NICE technology appraisal (TA) during the EAMS period, which if positive, results in commissioning of the product within 30 days of guidance publication.

Topic expert feedback also highlighted the recently introduced NICE/NHS England budget impact test for technologies within the TA programme, which may be of relevance to recommendation 1.5.2. The test will assess the financial impact of a technology over the first 3 years of its use in the NHS. If the budget impact exceeds £20 million, in any of the first 3 years, NHS England may engage in commercial discussions with the company. In cases where a discussion may not lead to an agreement, NHS England may request a variation to the statutory funding requirement.

Intelligence gathering also identified the Making a reality of the Accelerated Access Review: Improving patient access to breakthrough technologies and treatments in a cost-effective model (November 2017) from the Department of Health and Social

Care and the Department for Business, Energy & Industrial Strategy. The document details recommendations from the review to deliver the best technologies to patients more quickly and cheaply. This includes an accelerated access pathway (AAP) which was also highlighted by a topic expert. The pathway will streamline the current route for transformative technologies to market, providing earlier access for patients to innovative products. The paper highlights that the AAP will build on the existing NICE FTA process, NICE/NHS England budget impact test, EAMS and the cancer drugs fund.

Impact statement

Initial intelligence highlighted topic expert feedback on developments in the processes for the adoption of medicines recommended by NICE technology appraisal (TA) guidance. These include the NICE fast track appraisal (FTA), NICE/NHS England budget impact test, the early access to medicines schemes (EAMS) and the accelerated access pathway (AAP).

Recommendation 1.5.2 covers adopting medicines for inclusion into the local formulary automatically, if clinically appropriate and relevant, when a NICE TA recommends a medicine. The recommendation also states that this process should take place within 3 months, which still remains the statutory obligation for commissioners to make funding available within this timeframe.

Intelligence gathering has highlighted that newer processes of NICE TA may result in variation to the statutory funding requirement of 3 months. The context section of NICE guideline MPG1 includes a cross-referral to the definition of compliance with a NICE-approved medicine or treatment. This definition also covers compliance with these newer processes for assessing technologies. As such, no impact on the guideline is anticipated.

New evidence is unlikely to change guideline recommendations.

1.6 Process 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

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

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

1.6.3 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

1.6.4 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.

1.6.5 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.

1.6.6 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.

Surveillance proposal

This section of the guideline should not be updated.

2018 surveillance summary

No relevant evidence was identified.

Intelligence gathering

A topic expert commented that the recommendations should make reference to the outputs of Regional Medicines Optimisation Committees in reviewing medicines which are not subject to a NICE technology appraisal (TA), for inclusion in the local formulary.

Impact statement

Intelligence gathering highlighted topic expert feedback concerning the inclusion of recommendations made by Regional Medicines Optimisation Committees (RMOCs) for selecting medicines for inclusion in the formulary, not subject to a NICE technology appraisal (TA).

As noted in the section on relationships with other decision-making bodies, we will refresh recommendation 1.1.2 to consider the outputs of RMOCs. Additionally, NICE guideline MPG1 includes recommendation 1.8.2 on using NICE products, as well as other sources of high-quality information produced by national and regional horizon scanning organisations, when there is no NICE TA for a medicine.

As such, the role of RMOCs highlighted by the topic expert will be addressed by both of these recommendations. Therefore, no impact on the guideline is anticipated.

New evidence is unlikely to change guideline recommendations.

1.7 Setting decision criteria

Recommendations in this section of the guideline

1.7.1 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

Surveillance proposal

This section of the guideline should not be updated.

2018 surveillance summary

No relevant evidence was identified.

Intelligence gathering

A topic expert commented that this particular recommendation "was probably too aspirational and reliant on academic and theoretical constructs, such that I am not aware that multi-criteria decision aids as defined in the glossary have found widespread utility in NHS formulary practice". The expert also commented that a surveillance review will not find evidence of the use of such a tool in practice.

Impact statement

Initial intelligence gathering highlighted topic expert feedback on the clinical value of a multi-criteria decision tool in formulary decision-making.

During the development of the recommendation, it was noted that there was variation in the decision-making approach adopted by local formulary decision-making groups in selecting medicines for inclusion in the local formulary. As such, the recommendation was developed to provide a consistent decision framework and a list of key criteria that should be considered during decision-making.

Whilst we did not find any new evidence to support this recommendation, we also did not identify any evidence that contradicts the development and/or use of a multi-criteria decision tool. As such, no impact on the guideline is anticipated.

New evidence is unlikely to change guideline recommendations.

1.9 Incorporating new information from regulatory authorities

Recommendations in this section of the guideline

1.9.1 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.

Surveillance proposal

This section of the guideline should not be updated.

2018 surveillance summary

No relevant evidence was identified.

Intelligence gathering

A topic expert commented that medicine safety alerts may become impacted following the potential exit of the United Kingdom (UK) from the European Union, and thus alternative sources may become necessary. Whilst we acknowledge that there is some political uncertainty in this area, the Medicines and Healthcare products Regulatory Agency will remain responsible for the provision of safety alerts and recalls for drugs and medical devices in the UK. As such, no impact on the recommendations is anticipated.

Impact statement

The absence of new evidence indicates that there is no need to update this section of the guideline.

New evidence is unlikely to change guideline recommendations.

1.16 Reviewing and updating the local formulary

Recommendations in this section of the guideline

1.16.1 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.

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

Surveillance proposal

This section of the guideline should not be updated.

2018 surveillance summary

No relevant evidence was identified.

Intelligence gathering

A topic expert highlighted the Items which should not routinely be prescribed in primary care: Guidance for Clinical Commissioning Groups (CCGs) (November 2017) in determining medicines to decommission from the local formulary. The guidance was developed by NHS England in collaboration with NHS Clinical Commissioners to ensure the effective use of prescribing resources to maximise patient outcomes at a local level.

Impact statement

Initial intelligence highlighted topic expert feedback on guidance which includes recommendations on products which should not be routinely prescribed in primary care. The guidance was developed to provide a national approach to aid in local formulary decision-making, using NICE guidance where relevant as an evidence source to develop recommendations.

NICE guideline MPG1 includes recommendation 1.6.1 to ensure that there is a robust and transparent process for adopting, removing or updating medicines or indications not covered by NICE technology appraisal guidance. In addition, recommendation 1.1.3 states to proactively identify, discuss and implement recommendations in publications from national decision-making bodies, such as NICE, taking appropriate actions. Therefore, the use of such guidance has been addressed by existing recommendations. As such, no impact on the guideline is anticipated.

New evidence is unlikely to change guideline recommendations.