NICE National Institute for Health and Care Excellence

Key therapeutic topics – Medicines management options for local implementation: Interim process statement

Process and methods

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Contents

1 Introduction

This is not the current process. From May 2013, medicines optimisation: key therapeutic topics were developed using the integrated process statement.

1.1 Introduction to interim process statement

This interim process statement has been produced by the National Institute for Health and Clinical Excellence (NICE) to guide the development of the QIPP key therapeutics document, 'Key therapeutic topics – Medicines management options for local implementation' (hereafter referred to as the QIPP key therapeutics document). It provides an overview of the key process and principles, and describes all stages of the development of the QIPP key therapeutics document. These procedures are designed to ensure that a robust, quality-assured document is developed for the NHS in an open, transparent and timely way, with appropriate input from key groups. This interim process statement uses the NICE Implementation Support Tool process as an overarching guide to the principles of its development.

This interim process statement will be superseded when the final process guide is issued later in 2013, following engagement and discussions with key groups.

1.2 Background to the QIPP key therapeutics document

NICE is part of the NHS. NICE's evidence-based guidance and other products help resolve uncertainty about which medicines, treatments, procedures, technologies and devices represent the best quality care and offer the best value for money for the NHS. Further information about NICE and its work is available on the NICE website (www.nice.org.uk).

The NICE Medicines and Prescribing Centre provides advice and support for delivering safety, efficiency and effectiveness in the use of medicines. The Medicines and Prescribing Centre is responsible for developing the QIPP key therapeutics document, which will be published as an implementation tool.

The NICE Medicines and Prescribing Centre has been working since autumn 2010 to support the Department of Health with its QIPP medicines use and procurement work stream. QIPP is a large scale transformational programme for the NHS with national work streams designed to support the NHS to achieve a number of quality and productivity challenges. During 2011/12, the NHS made a total of £5.8 billion of QIPP savings, with £700 million associated with medicines use and prescribing. The QIPP medicines use and procurement work stream aims to ensure that value for

money is further enhanced while quality of care is maintained or improved, by optimising the use of medicines. Medicines optimisation is about ensuring patients get the best possible health outcomes from their medicines, while organisations make the best use of their medicines resource. The QIPP key therapeutics document summarises the evidence base on topics identified to support the QIPP medicines use and procurement work stream. These are usually therapeutic areas where there are potential opportunities for maintaining or improving quality and improving value. Releasing resources from one area of healthcare while maintaining or improving quality of care means those resources are available, for example, for the prescribing of innovative medicines.

The Health & Social Care Information Centre (H&SCIC) is responsible for the development of QIPP prescribing comparators for these therapeutic topics. These are developed under a separate process by the H&SCIC. Not every therapeutic topic has one or more comparators. This is because of technical limitations with currently available prescribing data which on occasion precludes the production of meaningful comparators. Importantly, **the QIPP key therapeutics document will not constitute formal NICE guidance** and this will be clearly stated on the publication.

2 QIPP key therapeutics document

2.1 Aims

The aim of the QIPP key therapeutics document is to inform local medicines optimisation activity. The document supports the implementation of NICE guidance either directly or by signposting the NHS to therapeutic evidence or prescribing practice relevant to existing guidance. The QIPP key therapeutics document is reviewed and updated annually.

2.2 Key audiences

The QIPP key therapeutics document is written for NHS professional staff and has the following target audiences:

- local medicines optimisation services across all areas of the NHS
- clinicians.

2.3 Key activities

The key activities involved in the production of the QIPP key therapeutics document are:

- identifying, prioritising and selecting the key therapeutic topics
- summarising the best available evidence for each topic (usually NICE guidance or other 'high-level' evidence, such as MHRA recommendations, Cochrane reviews, or NICE Medicines and Prescribing Centre evidence summaries or commentaries)
- signposting to the relevant QIPP prescribing comparator(s) for each topic (where these are available)
- providing a commentary on variations shown in the prescribing comparators using data provided by the Health & Social Care Information Centre (H&SCIC) and NHS Business Services Authority (NHSBSA).

3 Who is involved in producing the QIPP key therapeutics document?

3.1 The Medicines and Prescribing Centre

The Medicines and Prescribing Centre is part of NICE's Centre for Clinical Practice (CCP). The Medicines and Prescribing Centre consists of a programme director, associate directors and clinical, technical, project and administrative staff. For the production of the QIPP key therapeutics document, senior members of the medicines evidence or medicines advice teams within the Medicines and Prescribing Centre assist the Department of Health's QIPP Medicines Use and Procurement Wider Reference Group (WRG) in the review of existing, and the identification of new, key therapeutic topics. They are also responsible for:

- developing and reviewing processes and methods for producing the QIPP key therapeutics document
- prioritising and selecting therapeutic content for the QIPP document once the key therapeutic topics have been selected
- preparing the QIPP key therapeutics document for publication, including identifying the best available evidence for each topic
- liaising with key groups to help ensure the content is relevant and useful
- providing editorial and technical quality assurance of the content of the QIPP key therapeutics document
- ensuring timelines and quality assurance standards are followed
- reviewing and updating content of the QIPP key therapeutics document where required.

3.2 Other NICE teams

To develop the QIPP key therapeutics document, the Medicines and Prescribing Centre works closely with members of other NICE teams, particularly wider NICE teams involved with QIPP, to avoid overlap with other programmes and potential duplication of effort. These include; Topic Selection, Technology Appraisals, Clinical Guidelines, Communications (including Publishing), Evidence Information Services and Guidance Information Services. Their roles will be defined in the final version of the process guide.

3.3 The Health & Social Care Information Centre (H&SCIC) and NHS Business Service Authority (NHSBSA)

The H&SCIC is responsible for the development of QIPP prescribing comparators, using data provided by the NHSBSA. The NICE Medicines and Prescribing Centre liaises with the H&SCIC and the NHSBSA at regular intervals to ensure that their work on prescribing data and comparators is relevant to the QIPP key therapeutics document.

3.4 Department of Health

The Department of Health runs 2 groups to support the QIPP medicines use and procurement work stream. The QIPP WRG oversees this work stream and membership includes representatives of NHS organisations. The QIPP Partners Group includes representatives from medicines and devices trade associations. The QIPP WRG and QIPP Partners Group provide feedback on the scope and content of the QIPP key therapeutics document at various points throughout the process, but NICE approves the process and content for the QIPP key therapeutics document.

3.5 Conflicts of interest

NICE staff will be required to comply with the NICE code of conduct on conflicts of interest. For more information about how NICE deals with conflicts of interest, please see A code of practice for declaring and dealing with conflicts of interest.

4 Topic identification, prioritisation and selection

4.1 Stage 1: Topic identification

Each year the Department of Health's QIPP Wider Reference Group (WRG) will identify potential key therapeutic topics to be retained, retired or added to the current topics. These therapeutic topics will be identified from the wide range of medicines optimisation areas of work based on the criteria defined in box 1.

Box 1 Identification, prioritisation and selection criteria for QIPP key therapeutic topics

Therapeutic topic with a potential opportunity for improving quality, innovation, productivity or prevention because of:

- safety issue or risk:benefit issue
- large productivity savings
- large variations in clinical practice, with data demonstrating under usage or over usage
- positive technology appraisal
- potential opportunity to prevent the development of illness or complications, including by reducing service utilisation (for example, admissions)
- high clinician and/or patient interest.

4.2 Stage 2: Topic prioritisation

The Department of Health's QIPP WRG will prioritise these topics according to the criteria defined in box 1, to produce a draft list of the key therapeutic topics to be retired, retained or added. This list will be uploaded and made available online on the NICE website for consultation. Comments will be invited from NHS organisations and trade associations, and internally from key NICE teams including clinical guidelines and technology appraisals, for a 2-week period. Feedback will be collated by NICE Medicines and Prescribing Centre staff and draft responses produced for each element of feedback.

4.3 Stage 3: Topic selection

The Department of Health's QIPP WRG will consider feedback on the draft list of topics and apply the criteria defined in box 1 to the topics suggested during consultation. A final list of the key

therapeutic topics selected for the QIPP key therapeutics document will then be produced by the NICE Medicines and Prescribing Centre and confirmed by the NICE Guidance Executive. The Department of Health's QIPP Partners Group will receive a copy of the final key therapeutic topics selected to be retired, retained or added for information, and the final topic list will be published on the NICE website. At the same time, the Health & Social Care Information Centre (H&SCIC) will commence work on updating QIPP prescribing comparators, where appropriate.

5 Production

5.1 Equality and diversity considerations

The QIPP key therapeutics document is developed in accordance with the NICE equality scheme.

5.2 Process and timescales

The QIPP key therapeutics document is not formal NICE guidance and therefore is not subject to the same intensity of process as other NICE products.

Table 1 shows the key steps in the annual update of the QIPP key therapeutics document.

Table 1 Key steps of development of the QIPP key therapeutics document with timelines

Key Step	Timescale
Topic identification, prioritisation and selection	
QIPP WRG identify potential key therapeutic topics to be retained, retired or added, to produce draft scope	Early July
QIPP WRG prioritise topics and amend draft list of topics as appropriate	End July/ Early August
Draft list of topics published on NICE website for feedback: Partners and NHS organisations feedback commences	Mid Sept
Partners and NHS organisations feedback ends	Mid Oct
QIPP WRG consider feedback, NICE Medicines and Prescribing Centre produce final list of topics to be agreed by NICE Guidance Executive	End Oct
Production	
NICE Medicines and Prescribing Centre scope individual topic content	Early Nov
NICE Medicines and Prescribing Centre senior advisers author content	Early Nov
NICE Medicines and Prescribing Centre senior advisers technical check of content	Mid Nov

Check of content by NICE Medicines and Prescribing Centre associate director and programme director	End Nov
Draft document sent to QIPP WRG and QIPP Partners Group	Early Dec
NICE Medicines and Prescribing Centre revise draft as appropriate	Mid December
NICE Medicines and Prescribing Centre senior advisers editorial check of content	Mid December
Final check of content by NICE Medicines and Prescribing Centre associate director and programme director	End December
Editorial check of content by NICE Editorial team	Early January
NICE Publication Executive sign off	Mid January
Publication on NICE website	End January

5.3 Scoping of selected topics for the QIPP key therapeutics document

The NICE Medicines and Prescribing Centre will hold an internal meeting to scope the content for each selected key therapeutic topic (either an existing topic or a new topic) to:

- Identify and review important, 'high-level', therapeutic evidence for each key therapeutic topic, such as NICE guidance, MHRA recommendations, or NICE Medicines and Prescribing Centre outputs.
- Identify QIPP prescribing comparators and other relevant prescribing data for each key therapeutic topic.
- Agree the content for each key therapeutic topic, to ensure current best practice and prescribing issues for each topic are up to date.
- Agree if any key therapeutic topic requires a literature search. A literature search is only considered if national guidance, advice or policy is not available. For most topics a literature search will not be required.

5.4 Authoring of the QIPP key therapeutics document

NICE Medicines and Prescribing Centre senior advisers draft the content of the QIPP key therapeutics document using a standard template, which includes the following sections:

- Title and contents page
- Date and version control information
- Foreword
- For each key therapeutic topic
    - Options for local implementation
    - Evidence context
    - Prescribing data.

5.5 Review of the QIPP key therapeutics document

The NICE Medicines and Prescribing Centre sends the draft QIPP key therapeutics document to key NICE teams, including clinical guidelines and technology appraisals, and the Department of Health's QIPP Wider Reference Group (WRG) and QIPP Partners Group for comment. Comments will be invited ONLY for a 2-week period. Feedback will be collated by NICE Medicines and Prescribing Centre staff and draft responses produced for each element of feedback. Any comments received will be considered within the production of the revised draft.

5.6 Quality assurance of the QIPP key therapeutics document

NICE Medicines and Prescribing Centre senior advisers quality assure the document to a checklist. This will involve a detailed check of all content to ensure all sections of the document contain statements and conclusions that are fair and balanced. They must accurately reflect the evidence reviewed and be substantiated by an explicit and appropriate source of evidence. A further check for clarity, grammar, spelling and style is also undertaken. All drafts and any changes to drafts are recorded for audit purposes.

The NICE Medicines and Prescribing Centre, in conjunction with the NICE Editorial team, produce a final draft. Once sign-off is received from the Programme Director of the NICE Medicines and Prescribing Centre, NICE Publication Executive reviews the QIPP key therapeutics document and

if appropriate approves the document for publication, ensuring that due process has been followed in its development.

5.7 Publication of the QIPP key therapeutics document

The final QIPP key therapeutics document will be uploaded and made available on the NICE website.

6 Review

The process for the review of the QIPP key therapeutics document will be considered as part of the consultation for the production of the final process guide. It is currently anticipated that the QIPP key therapeutics document will be reviewed using this full process annually.

7 About this interim process statement

This interim process statement was used to develop key therapeutic topics published up to 31 January 2013, but key therapeutic topics published after this date have used the integrated process statement.

For published 'Key therapeutic topics', see the list on the NICE website

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