NICE National Institute for Health and Care Excellence

The NICE public health guidance development process (third edition)

Process and methods

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www.nice.org.uk/process/pmg5

Contents

1 Introduction

This is not the current manual. From January 2015, guidelines were developed using Developing NICE guidelines: the manual.

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation that provides national guidance on the promotion of good health and the prevention and treatment of ill health. NICE also produces quality standards that set out what high-quality care in the NHS should look like, and support tools for providers and commissioners in the NHS and local authorities. From 2013, NICE will produce quality standards for social care, as part of its expanding remit.

Box1.DevelopingNICEpublichealthguidance

This is the process manual for public health guidance produced by the Centre for Public Health Excellence (CPHE) at NICE. The process manual is about how guidance is produced, and explains the stages of guidance development, the different activities, roles and responsibilities of different groups of people involved at different stages.

The CPHE methods manual, which has been produced alongside this process manual, explains the methods for appraising the evidence and economic modelling, and how these are presented to the committees and used to develop guidance.

1.1 Background

NICE develops guidance across a number of different areas and on a range of topics.

All types of NICE guidance are developed using the best available evidence and involving stakeholders in a transparent and collaborative manner. Stakeholders include national organisations that represent the public, patients and carers, practitioners, community interests and companies that have an interest in the guidance in development.

NICE guidance is:

- based on a rigorous assessment of the evidence base

- developed by independent advisory bodies, with input from the public, patients, carers, service users, health professionals and other professional groups
- developed using a transparent process and methods
- subject to a consultation with stakeholders
- regularly reviewed.

This guide details the processes that the Centre for Public Health Excellence (CPHE) at NICE uses to produce public health guidance. It is the third edition, and includes changes to the previous (2009) edition that were consulted on with stakeholders and agreed with the NICE Board between 2011 and 2012. Information on the methods used for appraising the evidence and developing recommendations can be found in Methods for the development of NICE public health guidance – third edition (2012).

1.2 Equality and social value judgements

NICE is committed to promoting equality, eliminating unlawful discrimination and considering the implications of its guidance for human rights. It aims to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women
- eliminate unlawful discrimination on grounds of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation in the way it carries out its functions and in its employment policies and practices.

NICE's revised equality scheme sets out how it is meeting these obligations on equality and discrimination and what it still needs to do. In line with NICE's equalities scheme, this manual includes explicit consideration of how the development of guidance will consider equalities issues at the scoping, development, and validation stages, and how an audit trail of this activity will be maintained.

All NICE guidance, and the procedures NICE uses to develop its guidance, follow the principles set out in Social value judgements: principles for the development of NICE guidance (second edition).

1.3 Who is this overview for?

From 2006 to 2013, NICE produced guidance on public health using 2 processes. The 'intervention guidance process' was used to produce guidance on clearly defined topics for particular population groups or settings, and the 'programme guidance process' was used for guidance on wider topics that required action by many different groups in a range of settings. Further information on these methods and processes can be found in the first and second editions of Methods for the development of NICE public health guidance and The NICE public health guidance development process: an overview for stakeholders including public health practitioners, policy makers and the public (second edition).

Following stakeholder consultation in 2011, and Board approval in 2012, the CPHE adopted a single guidance development process. This document gives an overview of the new single process. It also describes the role of stakeholders, the Public Health Advisory Committees (PHACs), and the roles of the evidence review teams, other contractors and the staff of CPHE.

This overview is for stakeholder organisations, staff at NICE and the evidence review teams, other contractors, and members of the PHACs that develop guidance. It is also likely to be useful and of interest to national and international groups responsible for the development of guidance for health improvement.

The guidance development process and this guide have been developed by drawing on the expertise of the staff of CPHE and other guidance development centres at NICE, and the experience of members of our independent advisory committees. This guide is based on knowledge acquired during the first 7 years of producing NICE public health guidance.

1.4 Public health guidance

NICE public health guidance makes recommendations for England on what is known from research and practice about the effectiveness and cost effectiveness of interventions and broader programmes, including the systems in which they are delivered, and the methods used to deliver them.

NICE public health guidance is relevant to health professionals working in clinical and community settings, and commissioners, managers and team leaders with responsibility for health improvement in the NHS, local authorities, schools, and public, private and voluntary sectors. It is also relevant to people interested in improving their own health or

the health of their children or other people they care for, and to the wider community.

NICE public health guidance can:

- Help NHS organisations and local authorities (including social care and children's services) to meet standards for public health (for example, the Public Health Outcomes Framework, 2012), and work towards the requirements of national planning and commissioning frameworks.
- Enable national and local public sector organisations and partnerships to improve health and reduce health inequities.
- Support local authorities and schools in fulfilling their duty to promote the wellbeing of communities.

The implementation of public health guidance can help all those involved in delivering public health improvement to benefit from identified cost savings, and from opportunities for re-directing resources.

1.4.1 The framework for developing public health guidance

The process of developing public health guidance is informed by a conceptual framework which explains how human behaviour and environment, social and economic factors result in patterns of preventable diseases and influence the promotion and protection of good health and wellbeing. This framework, described in more detail in chapter 1 of Methods for the development of NICE public health guidance – third edition (2012), implies the following.

- Public health activities may be direct or indirect. They can relate to the direct provision of a health-related service, for example, contraception or smoking cessation services, or may result from the activities of wider services that affect health, for example, in education, employment and environment.
- Public health guidance may cover a range of approaches to changing knowledge, attitudes and behaviour, including interventions delivered to individuals by public health professionals, or working with and developing communities, and local and national campaigns. Guidance may focus on health protection, health improvement, health promotion, or service provision, and on both communicable and non-communicable diseases and conditions.

- CPHE methods and process ensure that the best available evidence is selected and assessed according to well-defined criteria, and then graded according to sound and transparent principles. Several types of evidence are considered, including evidence from practice.
- Recommendations may be made at individual, family, group, organisational, community or population level. They may focus on an intervention itself, on the practice and system in which it is commissioned, delivered or provided, or on the skills and capabilities required to effect change.
- Stakeholders have a central role in the development of public health guidance. Their views and experiences are actively sought throughout the development process to ensure that recommendations are realistic and appropriate.
- The work of CPHE is based on NICE's quality assurance principles, which are designed to ensure that NICE guidance is credible, robust and relevant.

For more information about the core principles of NICE guidance development, please see our Strategic Plan (2010–2013) on the NICE website.

1.4.2 Guidance on public health interventions and programmes, 2006–2013

Between 2006 and 2013, public health guidance was produced using 2 different processes: the intervention guidance process and the programme guidance process.

Guidance produced using the intervention guidance process focused on local, clearly circumscribed and defined actions that aimed to reduce the risk of developing a disease or condition, or that helped to promote or maintain good health. Interventions were typically those delivered by front-line staff, and targeted at or limited to certain populations, communities or individuals. Examples include:

- providing needles to prevent infection in illicit drug users
- giving advice to help employees to stop smoking
- promoting the social and emotional wellbeing of children in primary school.

Public health guidance produced using the programme guidance process was concerned with multiagency and multifaceted policies, services, systems and interventions.

Programmes were topic-, setting- or population-based, sometimes involving changes to organisational infrastructures. Examples include:

- Provision of smoking cessation advice and support by primary care services, pharmacies, local authorities and in the workplace for people of all ages who smoke, with a particular focus on low-income groups, pregnant women who smoke and hard-to-reach communities.
- Promoting and creating built or natural environments that encourage and support increased levels of physical activity. This includes activities ranging from traffic management to ensuring that public open spaces, public paths and new workplaces are linked to walking and cycling networks.
- Management of long-term sickness and incapacity for work, for primary care and employers. This includes strategies to reduce the number of employees moving from short- to long-term sickness absence and policies to help employees who have been on long-term sickness absence to return to work.

1.4.3 Public health guidance from 2012 onwards

The methods and processes used to develop NICE public health guidance are subject to regular internal review. The CPHE agreed with stakeholders and the NICE Board to remove the distinction between programme and intervention guidance for the 2012 update, and to produce public health guidance using one process. This single process would be implemented gradually across newly referred guidance topics from 2012 onwards. The single process can be completed over varying periods of time, generally between 14 and 18 months, depending on the nature and scope of the referral. (This refers to the time taken from publication of the final scope to consideration of the guidance by NICE's Guidance Executive). The Public Health Advisory Committees (PHACs) replace the Programme Development Groups (PDGs) and the Public Health Interventions Advisory Committee (PHIAC).The remainder of this guide sets out NICE's public health guidance process for guidance developed from mid-2012 onwards. Earlier versions of the guide detail past methods and processes (see Public health guidance process and methods guides on the NICE website).

1.5 Groups involved in public health guidance development

The key groups involved in developing public health guidance and their main roles and responsibilities during guidance development are listed below.

CentreforPublicHealthExcellence(CPHE)

- Prepares or commissions briefings for the public health Topic Advisory Workshop (TAW) (see chapter 2).
- Identifies, encourages and facilitates stakeholder registration (see chapter 4).
- With the agreement of the Board, appoints the Chairs and members of the PHACs (see chapter 5).
- Prepares a draft scope for the guidance and revises the scope after stakeholder consultation (see chapters 3 and 4).
- Manages the consultation process, compiles the responses to consultation comments on the draft scope, the evidence and the draft guidance (see chapter 3).
- Advises and supports the Chairs, members and co-opted members of the PHACs (see chapter 5).
- Commissions a contractor to produce reviews and economic analysis to inform the guidance (see chapter 7).
- Quality assures the evidence reviews and economic analysis (see chapter 7).
- Drafts the guidance and the recommendations following PHAC discussion.
- When appropriate, commissions and manages fieldwork consultation on the draft recommendations with key local professional and practitioner groups (see chapter 8).
- Revises the guidance in response to stakeholder comments and any fieldwork results, for approval from the PHAC (see chapter 3).
- Advises on and supports the publication, dissemination and implementation of the guidance (see chapter 7).
- Manages the updating of the guidance (see chapter 11).

Evidenceproviders

- Develop the protocols for the evidence reviews and economic analysis, in liaison with, and for approval by CPHE (see chapter 6).
- Prepare reviews of the evidence for consideration by the PHAC.
- Amend draft reviews in response to comments and discussions agreed by the PHAC.
- Assess additional evidence submitted by stakeholders.
- Assist the CPHE project team (see chapter 7) with responses to stakeholder comments on the evidence.
- Prepare an economic analysis, including economic modelling for consideration by the PHAC.

PublicHealthAdvisoryCommittees(PHACs)

- Consider the evidence on the guidance topic and develop recommendations for policy and practice.
- Are collectively responsible for the development of the final guidance submitted to NICE.
- Agree amendments to draft guidance in response to stakeholder consultation and fieldwork.
- Work with NICE to develop the implementation tools for the guidance (see chapter 9).

PatientandPublicInvolvementProgramme(PPIP)

- Advises the CPHE project team on public, community, service user and carer issues (see chapter 9).
- Identifies and approaches potential community and voluntary sector stakeholders for each public health guidance.
- Encourages and facilitates applications from community members (people who either have direct experience of public health interventions or are members of a relevant organisation or support group) who are interested in becoming PHAC members.
- Advises, supports and provides training for community members of PHACs.

- Comments on the draft scope and the draft guidance from a public, community and carer perspective.

OtherNICEteamsandstructures

- Information services team: part of the Evidence Resources Directorate, the information services team contributes to the scoping searches, and helps to quality assure the search strategies used for the evidence reviews. From time to time, the information services team may develop and implement search strategies in-house, in collaboration with the CPHE project team (see chapter 7).
- Press team: part of the Communications Directorate, the press team and communications lead support PHAC members and the NICE project team on all media and communications activity, and issues management, throughout the guidance development process.
- Editors: the lead editor works with the NICE project team and the PHAC to ensure that the guidance and related products are written and presented in a way that is clear and accessible to a range of different audiences.
- Implementation team: the implementation lead works with the PHAC and the NICE project team to identify and develop tools to support those wishing to put guidance recommendations into practice. Field consultants, part of the implementation team, work with external stakeholders to promote the guidance and may identify potential areas for new guidance.
- Costing team: the costing lead works with the PHAC, the NICE project team and the implementation lead to develop appropriate costing tools for those wishing to implement the guidance.
- Quality systems team: if the guidance has been identified as a topic for a quality standard, the quality systems team – part of the Health and Social Care Directorate – manage the production of the quality standard once the guidance has been developed.

1.6 Information about public health guidance

As it becomes available, the following information about each set of public health guidance can be found on the NICE website:

- a list of registered stakeholders
- details of the NICE (CPHE) project team
- details of the cross-NICE leads (for example, communications, implementation)
- details of the relevant PHAC and its membership
- a schedule for development of the guidance
- project history, and information on progress of the guidance
- the consultation draft of the scope
- the final scope
- a table of stakeholder comments on the consultation draft of the scope and responses to the comments
- the draft guidance and the evidence for consultation
- a table of stakeholder comments on the draft guidance and responses to the comments
- the final published guidance
- final versions of the evidence
- a fieldwork report, where available
- details of related NICE guidance
- tools to support implementation of the guidance
- details of scheduled updates.

2 Topic selection

Topics for public health guidance are referred to NICE by the Department of Health, based on discussion at the public health Topic Advisory Workshop (TAW).

This chapter describes how NICE manages the process.

2.1 What is topic selection?

Topic selection is the process used to identify and prioritise which approaches to the promotion and protection of health and the prevention of ill health should be the subject of NICE guidance.

It is important that topics are relevant and timely, and that they address priority issues that will help to improve the health of the population. The topic selection process also ensures that the selection of public health and clinical guidance topics is coordinated.

2.2 Topic suggestions to NICE

Suggestions for topics come from a variety of sources including:

- stakeholders
- NICE advisory committees
- TAWs
- the guidance review process
- other NICE guidance-producing centres.

The Centre for Public Health Excellence (CPHE) also liaises with a range of key stakeholder and practitioner groups to identify topics, for example, the Association of Directors of Public Health, the Faculty of Public Health and the Royal Colleges, as well as the key stakeholders mentioned in the consultation proposals (Department of Health, Public Health England and Local Government).

Once a topic has been proposed it is considered by the NICE internal topic selection group – a cross-institute group with representation from CPHE, implementation and field team leads, and quality systems.

2.3 The topic selection process

The topic selection process consists of the following stages:

- Topics are suggested (see above). These can be broad topic areas, or specific suggestions.
- NICE considers suggested topics at quarterly internal topic selection group meetings to assess whether they meet NICE's remit.
- NICE produces a background briefing paper for those topics that meet the remit (see section 2.2 of Methods for the development of NICE public health guidance – third edition (2012).
- NICE convenes a TAW of experts and stakeholders, including Public Health England and the Department of Health, where the briefing paper and areas for draft referrals are agreed (see section 2.2.4 of Methods for the development of NICE public health guidance – third edition (2012).
- NICE conducts an internal check to ensure a good fit between proposed public health topics and any related clinical topics.
- Draft referrals are discussed with policy leads at the Department of Health, who then prepare a submission to ministers for formal consideration.
- Once ministers have considered the submission, 1 or more formal ministerial referrals may be made to NICE to develop public health guidance in the topic area.
- Final responsibility for public health guidance referrals remains with the Secretary of State for Health.

Once a topic has been referred to NICE by the Department of Health, the CPHE senior team (consisting of the centre director, associate director and project managers) decides whether the resulting guidance should follow a standard or abbreviated PHAC development process, and to which PHAC the referral should be allocated. In some circumstances, it may be helpful to hold an expert panel to discuss the referral. The CPHE

senior team may also decide that it is appropriate to develop more than one set of guidance, or to allocate related referrals across more than one PHAC. The CPHE senior team also make decisions about the relative priority of guidance referrals, based on public health priorities and available resources.

3 The guidance development processes

3.1 Process overview

The key stages in the development of public health guidance are:

- Scoping.
- Development.
- Validation.
- Publication and dissemination.

The process usually takes between 14 and 18 months from publishing the final scope on the NICE website to approval of the final guidance by the NICE Guidance Executive (see chapter 10). The time taken at each stage may vary slightly, for example to take account of public holidays.

3.2 Development track and committee

Whether to develop the guidance using a standard (18 months) or short (14 months) process is decided following formal referral of a public health guidance topic to NICE by the Department of Health. The Centre for Public Health Excellence (CPHE) senior team considers the subject of the referral, including:

- whether it covers single or multiple interventions
- whether the intervention is delivered at one level or in one setting, or across multiple levels and settings
- sensitivities or complexities unique to the topic.

The topic is then allocated to one of the Public Health Advisory Committees (PHACs). The choice of PHAC depends on timing and resources. It may also depend on expertise on the topic among standing members of the PHAC, although in most cases topic expert members will be recruited to the PHAC for the duration of each topic, or co-opted for specific meetings.

3.3 Scoping

All the issues specified in the referral from the Department of Health are addressed in the scope. Occasionally, it may be necessary to seek clarification from the Department of Health on the remit for guidance, although this will usually be addressed during the topic selection process.

The scope sets out the need for the guidance and defines what will and will not be covered, so that the guidance stays within the area indicated through the topic development and selection process, and the referral from the Department of Health. The scope describes:

- the policy context and the need for the guidance
- the populations and groups to be included (for example, socially disadvantaged young people) or excluded (for example, certain age groups or people with certain clinical conditions)
- the settings to be included and excluded (for example, primary healthcare, education or community)
- the types of interventions to be included and excluded (for example, education, preventive care, environmental design, mass media, community support, lifestyle advice and information); the scope is as specific as possible about the type of interventions the guidance is intended to cover
- the main outcomes that will be considered
- links with other relevant NICE guidance (see chapter 9).

The draft scope is edited and then published on the NICE website for a 4-week period of consultation. Comments are invited from registered stakeholder organisations (see chapter 4).

Once consultation has closed, the CPHE team consider and respond to all comments from stakeholders, and revise the scope in the light of comments received. This final scope is published on the NICE website, with a table of all the stakeholder comments and NICE's responses to them, which documents the actions taken.

The scoping stage normally takes around 7 months for both standard and short guidance,

although it may take longer for some complex areas of guidance.

3.4 Development

Once the final scope has been agreed, a contractor is appointed to form the review team that works with the CPHE project team (see chapter 7) to develop a protocol for carrying out the evidence reviews. The protocol sets out detailed research questions, based on the scope. It also specifies how and where evidence will be searched for and identified, and the planned methods for appraisal and synthesis. The protocol is refined and agreed by the CPHE project team with the support of the NICE information services team, which is responsible for checking the quality and accuracy of the search strategy (see Methods for the development of NICE public health guidance – third edition [2012], chapters 3, 4 and 5).

If resources and expertise are available, the CPHE senior team may occasionally decide to develop search strategies or evidence reviews in house. When in-house evidence searches or reviews are undertaken, the CPHE senior team and the NICE information services team will allocate an independent quality assurance lead within the wider team, who will check that all searches and reviews are developed according to NICE processes and standards.

Studies identified by the searches are reviewed for relevant and appropriate evidence, which is then interpreted and synthesised in order to address the review questions. If sufficient evidence of cost effectiveness is not available from published studies, further economic analysis and modelling is carried out (see Methods for the development of NICE public health guidance – third edition [2012], chapter 6).

In addition to evidence identified through formal searches, the CPHE project team may invite registered stakeholders to submit evidence at any point during development, although this usually occurs early in the development process. When a call for evidence is made, registered stakeholders are invited to submit additional published or unpublished evidence that is relevant to the scope questions.

If evidence is weak or absent, key programmes or interventions are in progress and not fully evaluated, or evidence about specific practice issues is needed, the PHAC may invite one or more expert witnesses to give testimony. Expert testimony – spoken evidence, based on a summary paper – from professional or community experts may be considered by the PHAC during the development of the guidance.

The Chairs and members of the PHAC then consider the evidence and other relevant issues such as equality, implementation and commissioning issues. Based on their deliberations, the CPHE project team formulates draft recommendations for providers, practitioners and commissioners of public health interventions and programmes, as well as recommendations for further research, to be discussed at the next PHAC meeting.

The development stage normally takes around 13 months for standard guidance and 9 months for short guidance.

3.5 Validation

The draft guidance (containing the recommendations and research recommendations, and details of how they were developed) is issued for a 6-week consultation with stakeholders. Stakeholders can comment on the evidence reviews that the draft guidance is based on.

At the same time as the consultation, the draft recommendations may be tested in fieldwork with professionals, practitioners, commissioners or end users of the guidance to gather more information on their views on the draft recommendations, including the feasibility of putting the recommendations into practice. Fieldwork is carried out only if there are complexities or issues with the guidance topic or recommendations that require in-depth consideration with stakeholders.

Once the consultation and any fieldwork are complete, the CPHE team and PHAC consider all responses, and agree changes to the guidance. The draft guidance is then revised accordingly (see chapters 4 and 8 and Methods for the development of NICE public health guidance – third edition [2012]). A full table of consultation comments, including responses and actions taken by the CPHE project team (see chapter 7), is published alongside the final guidance.

The guidance is submitted to NICE's Guidance Executive – a committee made up of NICE's executive directors, guidance centre directors, and the communications director – for approval before publication (see chapter 10).

The validation stage normally takes around 5 months for both standard and short guidance.

3.6 Publication and dissemination

The guidance will normally be published on the NICE website within 6 weeks of approval by the Guidance Executive, on the fourth Wednesday of the month.

The guidance includes sections on:

- recommendations for practice and for research
- relevant policy and practice
- considerations that informed the recommendations and interpretation of evidence
- appendices, including details of reviews, methodology, economic analysis, other sources of evidence and fieldwork, PHAC members and CPHE project team (see chapter 7) members
- related NICE guidance
- references.

The following guidance products are also produced:

- NICE Pathway, an online tool that provides a graphic representation of the guidance recommendations, and links to key information about development and implementation, and to related NICE products
- supporting documents, including evidence reviews, other sources of evidence (for example, expert testimony), economic analysis and fieldwork reports (see chapter 8)
- stakeholder consultation comments and responses, for scope and guidance consultations.

3.7 Implementation

The NICE implementation team works with the CPHE project team (see chapter 7) and members of the PHAC to encourage and support the uptake of NICE guidance recommendations (see section 9.5.1 for further information on implementation).

4 The role of stakeholders in the guidance development process

Stakeholder organisations have an essential role in the development of public health guidance. This chapter describes how potential stakeholders are identified and encouraged to contribute.

The process is managed by the Centre for Public Health Excellence (CPHE) project team (see chapter 7) in conjunction with the Patient and Public Involvement Programme (PPIP). Stakeholders comment on:

- the draft scope
- the draft guidance and the evidence.

These consultation documents are available on the NICE website.

Stakeholders in relevant areas may also be invited to contribute to Topic Advisory Workshops (TAWs) (see chapter 2).

4.1 Who are stakeholders?

For the purposes of NICE's public health guidance development process, stakeholders are:

- national patient, carer, voluntary organisations or charities that directly or indirectly represent the public health interest, or disease prevention, relating to people covered by the guidance in England
- national organisations representing public health, healthcare and other professionals who provide the activities and services covered by the guidance in England
- local authorities, and representative bodies of local government
- public and private utilities in England
- providers and commissioners of public health, health and social care in England

- commercial industries which are relevant to the public health arena, whose interests may be affected by the guidance
- The Department of Health and other relevant Government departments and agencies
- statutory organisations including Care Quality Commission, Ofsted, National Screening Committee, Joint Committee on Vaccination and Immunisation, and Local Government Association
- Government or national statutory organisations in Wales, Northern Ireland and Scotland, including NHS Health Scotland, the Welsh Assembly Government
- research organisations and academic institutions across the UK
- overseas agencies that have a remit covering England, including the World Health Organisation, European Centre for Disease Prevention and Control
- Equalities groups.

A 'national' organisation is defined as one that covers England. NICE public health guidance applies to England only, although other parts of the United Kingdom may choose to review and adapt it to their own circumstances.

Registered stakeholders for each guidance topic are listed on the NICE website.

4.1.1 People not considered as stakeholders

For practical reasons, individuals cannot usually register as stakeholders. However, they can participate by expressing their views to a registered stakeholder, such as their national professional body or organisation.

4.2 Stakeholder registration

To participate in the early stages of the guidance development process, potential stakeholders are advised to register as soon as possible, ideally within 6 weeks of the announcement of a new topic on the NICE website. However, they can register at any time.

4.2.1 How NICE alerts potential stakeholders

To publicise new topics for guidance development, NICE:

- posts the topics on its website, with details on how to register as a stakeholder
- contacts stakeholder organisations that registered for previous relevant guidance
- writes to relevant stakeholders of previous guidance that will be updated by the new guidance
- writes to community and professional organisations that may have an interest in the new topic.

4.2.2 How to register an interest

Stakeholders register an interest by completing the stakeholder registration form for public health guidance. This form is available on the NICE website on the relevant guidance topic page.

Forms can be completed online, emailed to phguidance@nice.org.uk or returned to NICE by mail.

4.3 Stakeholders' input to the scope

The scope is drafted by the CPHE project team (see section 3.3 and chapter 7).

The draft scope is published on the NICE website for a 4-week consultation period. Registered stakeholders are sent a copy, and are asked to submit their comments (see section 4.3.2).

4.3.1 Stakeholder meeting

By exception, where a referral in a new area has been received, or where a guidance topic or an area of practice has unique complexities, a stakeholder meeting may be held. All registered stakeholder organisations are invited to a stakeholder meeting, during the scope consultation. Presentations are given by key staff from the CPHE project team (see chapter 7) and the PPIP. The purpose of the meeting is to:

- provide an overview of NICE
- provide an overview of the public health guidance development process

- describe the opportunities for stakeholders to contribute throughout the guidance development process
- discuss the scope and hear stakeholders' views
- discuss the role of the PPIP and opportunities for community stakeholders
- discuss how the Public Health Advisory Committee (PHAC) is recruited, and how it functions.

All stakeholders registered for the topic are invited to attend the meeting. Organisations are allowed to send a maximum of 2 people.

A stakeholder meeting does not replace the formal process of submitting comments via the official email address for the project.

4.3.2 Commenting on the scope

All stakeholders are invited to comment on the scope during the consultation. Stakeholders are asked to bear in mind the following points when commenting on the scope:

- NICE public health guidance applies to a wide audience including the NHS and people working in local government, education, public utilities, the private sector, the voluntary sector and central government developing public and social policy.
- Guidance is published within 2 years of the development process starting (see chapter 3), so that information is up to date at the point of publication. If the scope is too wide it will not be possible to complete the work in time, so the scope must be restricted to what can be realistically covered.
- The scope may specify or exclude certain groups. It is helpful if stakeholders can comment on whether such inclusions or exclusions discriminate on the grounds of race, disability, age, gender, sexual orientation and gender reassignment, pregnancy and maternity, religion or belief, or socioeconomic status.

Box2.Aguidetocommentingondraftsofthescopeandguidance

When the draft scope or guidance arrives, stakeholders should:

- nominate a coordinating contact within their organisation
- circulate the draft within the organisation, making it clear that it is for consultation and asking recipients to respond to the organisation's stakeholder contact (rather than directly to NICE)
- submit the comments by the closing date for the consultation
- send comments to the dedicated email address for the topic, including the stakeholder organisation's name in the subject box.

Stakeholders are asked to bear in mind that:

- NICE will accept only one response from each stakeholder organisation; NICE does not have the resources to respond to individuals within registered stakeholder organisations
- all comments received from stakeholders will be made public on the website
- comments will not be considered if they are not on the correct form or if they are received after the deadline
- NICE reserves the right not to respond to stakeholder comments if they could be considered offensive or are promoting particular services or products; such comments will not be made public on the NICE website
- submissions of evidence are not invited at the draft scope consultation stage.

4.3.3 Finalising the scope

Once the consultation has closed, the CPHE project team (see chapter 7) produces a final version of the scope, taking into account the stakeholder comments received and the referral from the Department of Health for the guidance. The final scope is signed off by the centre director for the CPHE. All stakeholder comments – and the response to each comment – are published on the NICE website when the scope is finalised. All the responses are sent to stakeholders 5 days before publication to check that all their comments have been included and have been correctly understood.

4.4 Stakeholders' role in providing evidence

Once the scope has been agreed, the review team starts by developing the review and search protocols, then searching for evidence to answer the research questions.

In some topic areas or for some research questions the CPHE project team (see chapter 7), the evidence provider, or the advisory committee may believe that there is relevant evidence in addition to that identified by the search. In these situations, the CPHE project team may invite stakeholders to submit evidence.

A call for evidence specifies the research question being addressed and the type of evidence sought. It may be made at any point during the development of public health guidance, although usually occurs in the earlier stages of development, and stakeholders are generally given 4 weeks to respond.

For copyright reasons, NICE cannot accept copies of full papers – in electronic or hard copy form – in response to a call to evidence. Stakeholders are asked to submit references or links only, or details of contacts for unpublished research. Once all responses from stakeholders have been received, the CPHE project team then follow up all responses and obtain the relevant papers or reports.

Box3.Typesofinformationnoteligibleforconsiderationinacallforevidence

Promotional material.
Unsubstantiated or non-evidence-based assertions of effectiveness.
Opinion pieces.
Potentially unlawful or other inappropriate information.

The call for evidence may request relevant published or unpublished data or studies. Any confidential material should be clearly marked as such in the submission.

4.4.1 Confidential information

Box 4 explains what types of information may be considered confidential and NICE's approach to handing confidential information. When submitting evidence that contains confidential data, stakeholders should indicate which sections are confidential, for example by using the highlighter function in Microsoft Word.

When documents are prepared for consultation, any information that is still confidential will be removed, and a note added to explain what has been done. However, as a minimum, a summary or abstract of the study or economic model must be publicly available by the time the draft guidance is published for consultation. NICE needs to be able to justify the recommendations in public health guidance on the basis of the evidence considered by the PHAC. NICE and the evidence provider work with the data owners to agree a compromise between confidentiality and transparency.

Box4.Informationondatathatmaybeconsideredconfidential

Information that may influence share price values ('commercial in confidence') or is deemed intellectual property (that is, awaiting publication) is deemed confidential.
The relevant part of a sentence, a particular result from a table or a section of code is deemed confidential (that is, information deemed confidential should be kept to an absolute minimum).
NICE will not agree to a whole study being designated confidential. At a minimum, a structured abstract of the study or economic model must be made available for public disclosure during consultation on the guidance.
Results derived from calculations using confidential data are not considered confidential unless releasing those results would enable back-calculation to the original data.

4.5 Stakeholders' input to draft guidance

Registered stakeholders are informed via email and the NICE website when the draft guidance (containing the draft recommendations and supporting information) and the evidence reviews are available for consultation. They are given 6 weeks to comment.

Stakeholders are asked to submit comments on the form provided via the dedicated email address for the guidance. The scope should be considered when commenting on the guidance. Stakeholders may wish to include issues for consideration by the CPHE project team (see chapter 7) and the PHAC, such as:

- a general view (either positive or negative) of the quality and content of the guidance
- points or areas that seem to fall within the scope but are not covered by the guidance

- potential inconsistencies in the interpretation of the evidence
- disagreement with the interpretation of the evidence
- the practical value of the guidance
- issues relating to equality, diversity and potential discrimination
- wording (for example, the clarity of the recommendations and definitions)
- observations on the resource implications of the guidance or specific recommendations
- suggestions for new guidance topics that arise from the draft guidance.

All the responses are sent to stakeholders on the day of publication for 5 days to check that all their comments have been included and understood. Stakeholder comments and the responses to them are then posted on the website once the guidance has been published. Stakeholders are not invited to check the guidance again before publication.

Comments received from non-registered stakeholders, and comments received after the deadline, are not considered or responded to; such comments are returned to the sender, with an explanation.

4.6 Keeping up to date with guidance topics

NICE produces a monthly e-newsletter, which gives details of forthcoming guidance, consultations on guidance in development, and future events. It also provides an e-alert facility. Both are available on the NICE website.

NICE emails reminders of consultation periods and other dates for a specific topic to all registered stakeholders. Stakeholders can also keep up to date with the progress of a project via the NICE website.

4.7 Patient and Public Involvement Programme

The main role of the PPIP is to work with the NICE project team and the PHACs to develop and support opportunities for people to be involved in developing NICE guidance (see section 9.5.4). This includes the public, members of a relevant organisation or support group and people, including carers, who will be affected by the guidance ('community

members').

5 The role of the Public Health Advisory Committees (PHACs) in the development of public health guidance

Public Health Advisory Committees (PHACs) are the standing committees responsible for the development of NICE public health guidance. Each PHAC consists of a Chair, core and topic expert members. NICE has multiple PHACs in operation at any one time. Guidance topics are allocated to one of the PHACs following referral from the Department of Health.

The allocated PHAC considers the evidence and makes recommendations for people working in the NHS, local government and in the wider public, private and voluntary sectors.

This chapter explains how the PHACs work, including the appointment and role of the Chairs and committee members.

5.1 General principles of the PHACs

Each PHAC is multidisciplinary and its members bring with them different knowledge, expertise, values and experience. It is important that all these perspectives are listened to, and that each member has an equal voice in the process of guidance development. If PHAC members cannot reach consensus in a particular area, this is reflected in the wording of the recommendation.

The Chairs and members of the PHACs act in accordance with NICE's procedures and policies, including those relating to the declaration of interests and confidentiality. Each PHAC is collectively responsible for the recommendations it makes to NICE.

5.2 Composition of the PHACs

PHACs include around 12 professional and community members with both general and specialist expertise in public health. Each PHAC includes a Chair, and a core of members. This core, usually consisting of between 3 and 6 members, may include a health economist, a public health practitioner (such as a director of public health), and 1

community member. Core members usually serve a 3-year term on a single PHAC committee.

In addition to the core membership, professional topic expert members join a PHAC for each new guidance topic. Topic expert membership of each PHAC may include topic specialist professionals, practitioners and technical experts drawn from the NHS, education, social care, environmental health, occupational health, local government or the voluntary sector. They will usually be recruited for a specific guidance topic, but may be appointed for up to 3 years so that they can work on subsequent guidance. The membership of each PHAC will also include an additional community member with relevant topic expertise who will be recruited by Patient and Public Involvement Programme (PPIP).

Community PHAC members either have direct experience of public health interventions or are members of a relevant organisation or support group. PHAC members are selected for their individual expertise and do not represent their organisations.

All core and topic expert committee members, including the Chairs, have voting rights.

If any additional skills or expertise are required on the PHAC, individuals may be co-opted to 1 or more meetings.

PHAC members do not submit comments during the stakeholder consultations on the draft scope and the draft guidance.

Details of how people are appointed to the PHACs and the procedural rules for managing the committee's work can be found in the standing orders and the terms of reference for the committee (see Developing NICE public health guidance on the NICE website).

5.2.1 Role of the PHAC Chairs

The PHAC Chairs guide each PHAC in developing the guidance, focusing on the referral, scope and timescale. Chairs also ensure that the perspectives of all members are listened to, and that each member has an equal voice in the process of guidance development. It is important to check that all members understand all the terminology used.

Chairs ensure that a range of possible approaches to the development of the guidance is considered, and checks that all the members agree to endorse any recommendations.

PHAC Chairs are experts in public health but may not have expertise in individual guidance topic areas. The Centre for Public Health Excellence (CPHE) associate director is the NICE lead for the guidance, and works with the CPHE project team (see chapter 7) and the PHAC to provide topic support and advise the Chairs on issues of process and method.

5.2.2 Role of the core PHAC members

Some core PHAC members will have been involved in commissioning or implementing public health interventions at regional and local levels. Others will have specific expertise in assessing the quality of the evidence presented to the committee, and in its interpretation.

Community members are expected to ensure that the committee's recommendations are relevant to specific groups of people, or to the general public. They also help to identify where the guidance should acknowledge general or specific preferences and choice.

5.2.3 Topic expert members

When a new guidance topic is allocated to one of NICE's PHACs, it is complemented by a number of topic expert members. The topic expert members are usually recruited for a specific guidance topic, but may be appointed for up to 3 years so that they can work on subsequent guidance. They are recruited through a competitive process, following relevant NICE recruitment policy (see section 7.4). The process of appointing or allocating topic expert PHAC members is completed at least 6 weeks before the first committee meeting on that topic. Topic expert members are part of the committee, join in discussion and contribute to the formulation of recommendations. They have full member status, including voting rights, and count towards the quorum.

5.2.4 Co-opted members

If required, additional members may be co-opted to the PHAC for 1 or more specific meetings. The process of identifying and co-opting PHAC members is agreed with the Chairs and completed at least 6 weeks before a committee meeting. Co-opted members are part of the committee, join in discussion and contribute to the formulation of recommendations, however they are not full members, do not have voting rights and do not count towards the quorum.

5.2.5 Invited experts and observers

Each PHAC may also invite external experts to help in its consideration and interpretation of the evidence. Experts may be drawn from a wide range of areas as appropriate, including government and policy, research, practice, or the community and voluntary sector. They are invited to present their evidence in the form of expert testimony at a PHAC meeting as a presentation based on a written paper, and to answer questions from members of the committee. The expert paper is made available on the NICE website with other sources of evidence when the guidance is published (see section 3.4 for further information about expert testimony). These experts are not members of the PHAC, and should not be involved in decision making, or take part in formulating recommendations.

Observers, including NICE staff, need permission from the PHAC Chairs to attend a PHAC meeting. An observer should sit apart from the committee and should not enter into the discussions unless invited to do so by the Chairs. Observers do not have voting rights.

5.2.6 Meetings in public

Members of the public may attend a PHAC meeting as public observers. They are not involved in the business of the meeting and cannot ask questions, take part in voting or put their views to the committee. Public observers must register for the meeting via the NICE website (see Meetings held in public). Registration opens 20 working days before the meeting, and closes 10 working days before the meeting. Up to 20 places are available. The meetings-in-public coordinator at NICE is responsible for coordinating and liaising with public observers.

Holding advisory body meetings in public is part of NICE's commitment to openness and transparency. It enables stakeholders and the public to better understand how evidence is assessed and interpreted, how consultation comments are taken into account and how recommendations are formulated.

PHAC meetings may be held entirely in public or split into 2 parts: part 1 with the public present and part 2 with the public excluded. A closed session or part 2 may be required if for example, expert evidence involves the disclosure of an individual's health problems, or the consideration of national public health policy that has not been agreed by ministers, or if the drafting of recommendations might affect commercial interests. On rare occasions a meeting may be entirely closed.

5.3 Recruitment of the PHAC Chairs and members

PHAC chairs and members are recruited in accordance with NICE's policy on appointments to guidance-producing bodies advisory to NICE. Chairs of the PHAC are appointed after advertisement on the NICE website and notification to stakeholders, submission of a curriculum vitae (CV) and covering letter, and interview.

Core and topic expert members of PHACs are normally appointed after advertisement on the NICE website and notification to stakeholders, and submission of a CV and covering letter, in line with NICE's policy. Core members are appointed for 3 years and are eligible for reappointment. Core PHAC members are allocated to 1 PHAC for the duration of their term. The topic expert members are usually recruited for a specific guidance topic, but may be appointed for up to 3 years so that they can work on subsequent guidance. This might mean they move between PHACs during their term, depending on the guidance being produced. All members are eligible for reappointment after 3 years.

Appointment of community members to a PHAC is undertaken by CPHE in liaison with the PPIP at NICE (see section 9.5.4).

5.4 Code of conduct and conflicts of interest

5.4.1 Declaring interests

Declarations of interests should be made by committee members and participants in line with NICE's policy (see Code of practice for declaring and dealing with conflicts of interest [2008] on the NICE website). Everyone participating in PHAC meetings, including standing and co-opted committee members, experts, evidence providers and members of the evidence review teams, should complete a declaration of interests form before the meeting takes place. Any potential conflicts are considered by the Chairs and the CPHE directors before the meeting; any decisions to exclude participants should be documented. Any relevant interests, or changes to interests, should also be declared publicly at the start of the meeting. Any changes to a member's declaration of interests should be recorded in the minutes of the meeting.

5.4.2 Confidentiality

All PHAC members – and all those who see the documents, or who are party to

discussions before public consultation on the draft guidance – must sign a confidentiality agreement form before becoming involved in guidance development. The CPHE project team (see chapter 7) keeps copies of the signed forms.

5.5 Producing guidance

5.5.1 Induction

On joining a PHAC or the topic expert pool, all new core and topic expert members attend an induction session organised by the CPHE project team (see chapter 7). At this meeting, the CPHE project team presents and discusses the process of guidance development and the development of recommendations, the role of evidence of effectiveness and cost effectiveness in decision making, how members contribute, and the role of the PHAC. Members are also informed of the principles outlined in the report Social value judgements: principles for the development of NICE guidance, and NICE's equality scheme.

Staff from the PPIP and other NICE teams may also explain other aspects of the guidance development process.

Before beginning their work in a PHAC, new topic expert members may also be invited to observe another PHAC meeting.

5.5.2 Before the first PHAC meeting

Core PHAC members and the Chairs may wish to be involved in preparing the scope, although the responsibility for this is with the associate director and the CPHE project team.

5.5.3 PHAC meetings

There are usually 8 PHAC meetings for guidance topics following a standard process, and 3 for those following a short process. PHAC meetings are generally held at intervals of 6 weeks. Meeting papers are usually sent to the PHAC members 8 working days before the meeting. PHAC meetings are held in public, although these meetings may be divided into 2 sections as described in section 5.2.6.

The quorum of the PHAC meeting is 50% of all members (including the Chair). Guidance recommendations cannot be developed if the meeting is not quorate. PHAC meetings are formally recorded and the minutes are approved at the next meeting. The agreed minutes are published on the NICE website.

A draft outline agenda for the meeting is posted on the website 20 working days before the committee meeting. The final agenda is posted 5 working days before the meeting.

5.5.4 The first PHAC meeting

At its first meeting, the PHAC will consider the background to the referral, the scope, and plans for the evidence reviews and economic analysis that will address the scope. Topic expert members may be invited to present on their area of work, practice or experience, in order to familiarise core members with key topic issues. If a contracted evidence review team are providing some or all of the evidence reviews, they will usually be invited to present their plans to the PHAC for comment.

The PHAC will be asked to consider and discuss whether the planned evidence reviews and economic analysis are likely to answer the key questions, and make suggestions for any amendments or improvements. They may also be asked to discuss any gaps in the scope and plans, to suggest potential areas for expert testimony, and experts to provide that testimony, and to discuss and consider evidence. Members of the evidence provider team normally attend the first PHAC meeting, but do not contribute to the development of any recommendations.

5.5.5 Development meetings: reviewing the evidence

Evidence is reviewed during the first 6 meetings for guidance following a standard process, or 2 meetings for guidance following a short process. The PHAC considers each evidence review, the economic appraisal, and any additional evidence, (for example, expert testimony, see section 3.4), discusses whether these answer the key questions in each review, and summarises each area of evidence.

Members of the review team normally attend the PHAC meetings at which the evidence reviews are considered. They do not contribute to the development of recommendations.

The role of the review team in the PHAC meetings is to:

- Summarise the main issues arising from the preparation of the evidence reviews. The review team members do not provide detailed accounts of the evidence because it is assumed that all PHAC members have read the relevant evidence review, evidence tables and any supporting papers.
- Answer questions about the evidence and, if asked by the PHAC, contribute to discussions.

5.5.6 Drafting recommendations

The PHAC produces draft recommendations that are informed by the evidence and economic analysis. They also suggest recommendations for research to address uncertainties and gaps in our understanding.

The CPHE project team drafts the guidance document (see section 5.5.6), including the recommendations, according to evidence presented at the PHAC meetings and decisions made by the PHAC. The PHAC then revises the draft, to produce the consultation version of the guidance.

The PHAC also considers the impact of potential recommendations on equity and the extent to which they promote equality and diversity, and ensures that they are in line with NICE's equality scheme.

5.5.7 Finalising recommendations

The PHAC holds a final meeting after the consultation on the draft guidance (see section 3.5). At this meeting, the PHAC amends the recommendations in light of the consultation responses and the results of any fieldwork (to test recommendations against the experience of practitioners). For more information on the PHAC's role in drafting the recommendations see Methods for the development of NICE public health guidance – third edition (2012).

5.5.8 Revising the guidance

After the final PHAC meeting, the CPHE project team revises the guidance document, including the revised recommendations, according to the decisions made by the PHAC. The final guidance document includes:

- an introduction and background (including the Department of Health referral)
- recommendations for practice
- recommendations for research
- considerations (discussion of the evidence and factors influencing the development of the recommendations)
- information about implementing the guidance
- a summary of the methods used
- a summary of the evidence (main conclusions and evidence statements, summarising the main findings).

5.5.9 Finalising the guidance

When the Chairs, associate directors and CPHE director have approved the final guidance, it is submitted for sign off by the NICE Guidance Executive (see chapter 10).

5.5.10 Implementation

The Chairs and designated members of the PHAC may work with the CPHE project team and the implementation lead to develop and approve tools to support implementation of the guidance (see section 3.7).

6 The role of evidence providers

Unless a decision is made by Centre for Public Health Excellence (CPHE) senior team to produce evidence reviews in-house, NICE commissions independent evidence review teams and health economists to review evidence and undertake economic analyses to inform the Public Health Advisory Committee (PHAC) in developing guidance.

The evidence providers:

- agree milestones with the project team for what is to be delivered and by what date, based on the contents of the scope
- prepare review protocols for sign off by the CPHE project team (see chapter 7)
- may prepare search protocols and strategies for sign-off by the CPHE project team, if these are not being undertaken by NICE
- may undertake searches for the evidence in relevant databases and websites, if this is not being undertaken by NICE
- appraise and synthesise the evidence
- prepare reviews of the evidence
- prepare an economic modelling protocol for sign off by the CPHE project team
- prepare an economic analysis, including economic modelling, and writes a report
- amend evidence reviews and the economic analysis report in response to PHAC comments, as required
- assess evidence submissions from stakeholders, if a call for evidence is made
- help the CPHE project team to respond to stakeholder comments on the evidence.

Members of the evidence provider team attend meetings of the PHAC to present the main issues arising from each evidence review and economic analysis report. They also answer questions from the PHAC members and contribute to discussions if asked. They follow NICE's code of conduct, and make a declaration of interests at the start of each guidance project and at PHAC meetings.

NICE owns the intellectual property of the guidance and the evidence provider owns the intellectual property of the evidence reviews.

6.1 Reviewing the evidence

Depending on the length of the guidance process followed and the nature of the referral, between 1 and 4 evidence reviews, and 1 economic modelling report are usually undertaken.

All evidence reviews and economic analyses are developed and delivered in accordance with chapters 4, 5 and 6 of Methods for the development of NICE public health guidance – third edition (2012).

The evidence reviews and economic analysis focus principally on the key questions posed in the scope. Studies are reviewed to identify the most appropriate data to address these questions, so that the recommendations are based on the best available evidence. The systematic review process should be explicit and transparent. It involves 5 main steps:

- identifying and selecting relevant evidence
- assessing its quality
- assessing its applicability
- interpreting, synthesising and presenting the results
- developing evidence statements.

The process is common to all evidence reviews, and is applied to all studies and to evidence supplied by stakeholders.

6.2 Summarising and presenting evidence reviews

For each evidence review, all data is extracted and presented in a narrative summary with an accompanying evidence table. The evidence table provides a basis for comparison among studies. It also provides sufficient information for any subsequent recommendation to include an entry in the Evidence Intervention Library – a feature of the NICE Pathway that summarises key study details supporting public health recommendations, including cost, impact and effectiveness.

The key features of the evidence are summarised in a short evidence statement. For details about how evidence reviews and evidence statements are developed, see chapter 5of Methods for the development of public health guidance – third edition (2012).

7 The role of the CPHE project team

The Centre for Public Health Excellence (CPHE) is responsible for the development of public health guidance and for assuring the quality of the guidance so that it is up to date, credible, robust and relevant. The CPHE project team ensures that guidance is developed to the agreed timetable and in accordance with this manual and with Methods for the development of NICE public health guidance – third edition (2012).

Each member of the CPHE project team understands his or her personal responsibility for quality assurance through the application of these processes and methods.

7.1 CPHE project team

Centredirector
The director of CPHE is responsible for all NICE public health guidance and for ensuring that it is produced in accordance with the published process and methods, including the appointment of Public Health Advisory Committee (PHAC) Chairs and members.

Associatedirector
Each associate director in CPHE is responsible for the development and quality assurance of specific sets of guidance, and has delegated responsibility for approving consultation and other documents. An associate director acts as the topic lead for each set of guidance, working with the CPHE team and the PHAC to provide topic and technical support to the Chair. The associate director also advises the Chair on matters of method and process.

CPHEseniorteam
The senior team is made up of the centre director and the associate directors. They meet regularly with the project managers to oversee the development of all public health guidance.

Leadanalyst
The lead analyst is responsible for the technical quality assurance of the evidence reviews and the technical aspects of the guidance, working with the associate director and other members of the project team.

Technicaladviser(healtheconomics)
The technical adviser is responsible for ensuring the technical quality of the economic evidence and economic analysis, working with the health economics contractor and other members of the CPHE project team.

Analyst
One or more analysts work with the lead analyst to assure the technical quality of the evidence reviews and other technical aspects of the development of the guidance. If applicable, 1 or more analysts take responsibility for commissioning and coordinating the fieldwork.

Projectmanager
The project manager is responsible for planning the work of CPHE, scheduling, planning and timetabling the Centre's programme of work.

Supportteam
The coordinator and other members of the support team provide administrative support to the PHACs, arranging meetings, liaising with stakeholders and all individuals and organisations contributing to the development of public health guidance.

7.2 Topic selection briefing paper

Members of CPHE team prepare topic selection briefing papers for the Topic Advisory Workshops (TAWs) (see chapter 2), in collaboration with external experts and members of the NICE information services team.

Each topic briefing paper includes the epidemiological and policy importance of the topic in question, the extent of variation in practice and any relevant health equity and inequality issues.

Topic briefing papers do not specify referrals, nor do they specify whether guidance should be produced through the standard or fast-tracked process. The CPHE senior team decides this once the final topic referral has been made by the Department of Health (see chapter 2).

7.3 Facilitating stakeholder consultation

Potential stakeholders are identified and encouraged to contribute to the development of the guidance by the CPHE project team, working with the Patient and Public Involvement Programme (PPIP) (see chapter 9). For more details about the role of stakeholders and how to register as a stakeholder see chapter 4.

7.4 Appointing Chairs and members of the PHACs

The positions of PHAC Chairs are advertised on the NICE website. They may also be advertised in other appropriate places identified by the CPHE project team. The CPHE project team also informs stakeholder organisations about the advertisement.

The PHAC Chairs are appointed after interview by the selection panel, in accordance with NICE's policy on appointments to guidance-producing bodies advisory to NICE.

The CPHE project team informs registered stakeholder organisations about advertisements for core and topic expert members. PHAC core and topic expert members are appointed in line with NICE's policy.

PHAC co-opted members are selected by the associate director leading the development of the guidance, and agreed with the PHAC Chairs. Appointments are subject to confirmation by the CPHE director.

7.5 Preparing the scope

The CPHE project team prepares the scope for the guidance topic (see section 3.3). This work is conducted in the following stages:

- Developing a preliminary search while working with NICE information services. This search is intended to identify other relevant guidance, such as previous clinical guidelines and key systematic reviews. This search should not aim to be exhaustive or to address potential review questions in any detail.
- Drafting the scope in consultation with the PHAC Chairs, and PHAC core members (see chapter 3), as appropriate. For more information on scope development, including the use of 'logic' or conceptual models, see section 2.2.1 of Methods for the development of NICE public health guidance – third edition (2012).

- Consulting with stakeholders on the draft scope. The CPHE project team may also arrange a public meeting for registered stakeholders during the 4-week consultation period.
- Writing responses to all stakeholder comments on the draft scope. Responses are documented in a 'scope consultation table' which is published on the NICE website with the final scope.
- Finalising the scope after consultation. The scope includes key questions that cover all aspects of the guidance remit, without going beyond it.

For more information about the role of stakeholders see chapter 4.

7.6 Assuring quality of evidence reviews and economic analysis

The CPHE project team commissions and manages the development of the evidence reviews and economic analyses produced by the evidence provider (contractor).

The CPHE associate director approves the review protocol, which has been developed by the review team, the CPHE project team, and information specialists in both organisations.

The CPHE project team discusses and agrees the organisation, presentation and interpretation of the evidence reviews with the review team.

The CPHE project team and the review team agree criteria for the inclusion of studies and how to identify relevant economic studies that are likely to inform the PHAC.

The CPHE project team works closely with the health economist from the review team and the PHAC to select interventions or questions for further economic analysis (including modelling) and to ensure that the economic modelling carried out by the review team is appropriate and plausible and results are accurately interpreted.

7.7 Supporting the PHACs

The CPHE project team plans and organises PHAC meetings, in consultation with the respective PHAC Chairs. The project team is responsible for setting the dates of the meetings, planning the agenda, sending out papers, keeping records of meetings, and

(with the Chairs) signing off minutes to be posted on the NICE website.

The CPHE project team will hold an initial induction meeting for new co-opted PHAC members for each new topic, to familiarise them with NICE methods and processes. They may also be invited to observe a working PHAC meeting.

The first full PHAC meeting for a new guidance topic provides an introduction to the topic area, and discussion of planned evidence reviews for the PHAC Chairs and the members. At this meeting, the CPHE project team presents the scope, and the evidence provider presents plans for the evidence reviews and economic analysis. PHAC members discuss these plans and suggest appropriate amendments, and also identify areas or individuals for expert testimony.

7.8 Calling for additional evidence

If evidence is missing or is unclear, the CPHE project team may ask stakeholders for evidence. The project team specifies the question being addressed, along with details of the type of evidence being sought, and stakeholders are given 4 weeks to respond. This usually happens in the early stages of guidance development.

7.9 Compiling responses to consultation comments on the evidence and the draft guidance

Consultation with stakeholders on all the evidence reviews and on the draft guidance is an important part of the quality assurance process (see chapter 4). The CPHE project team addresses and responds to all stakeholder comments on the evidence and guidance with the support of the review team.

Each comment is acknowledged and answered as fully and as factually as possible. If changes are made to the guidance as a result of any comment, this is made clear in the response. If no changes have been made, the response from the project team explains why not.

The CPHE project team summarises and presents the comments and responses to the PHAC. All comments are taken into consideration in developing the final guidance.

Comments and responses are made available on the NICE website when the final guidance

is published.

7.10 Drafting guidance

The CPHE project team drafts the guidance following PHAC discussion and direction, seeking approval for drafts and subsequent revisions. The CPHE project team ensures the draft recommendations are clearly linked to evidence.

From time to time, PHAC members may draft specific sections of the guidance, working with the CPHE project team. All amendments to the recommendations must be approved by the PHAC Chair.

When the draft and final versions of the guidance are prepared for publication, the CPHE project team ensures that any confidential information is replaced by a note stating that confidential information has been removed, so that the public is aware of exactly where confidential data have been used.

7.11 Managing fieldwork

Fieldwork may be commissioned by exception during the consultation process, when a PHAC is developing guidance in a novel or sensitive area. Fieldwork tests the feasibility of the draft recommendations with end users of the guidance (see chapter 8). The CPHE project team commissions a contractor to carry out the fieldwork on behalf of NICE. The fieldwork contractor should agree the plans, participants to be contacted, venues, methods and the content of all communications and supporting materials with the CPHE project team.

7.12 Advising on publication, dissemination and implementation

The project team submits the final draft of the guidance to NICE's Guidance Executive (see chapter 10) and makes any changes that may be required, advising the PHAC Chairs as appropriate.

The CPHE project team also works closely with the editors to ensure that the guidance and related NICE products, including the NICE Pathway, are unambiguous and appropriate

for the intended audience.

The project team also works with the NICE communications lead to prepare for the launch of the guidance. This may include a press conference or a more targeted approach for specialist audiences.

The CPHE director and the project team work with the communications lead to contribute to communicating key messages about the guidance to the press and media and to promoting the guidance to wider public health audiences, and producing press articles at the time of, and after publication.

7.12.1 Implementation support tools

NICE's implementation team produces tools to support implementation of public health guidance (see section 1.5). The CPHE project team contributes to the development of these tools to ensure that they are accurate, and relevant to the guidance and to the target audiences.

7.12.2 Post-publication support

The CPHE project team may also support implementation in other ways including:

- speaking at relevant conferences or events, and encouraging and supporting PHAC members to do so
- contributing to or writing journal articles about the guidance
- supporting workshops and regional events
- working with field consultants (see section 1.5)
- providing feedback and encouraging organisations to submit short reports about how they have implemented the guidance for the NICE shared learning database
- supporting the development of educational support tools.

7.13 Updating guidance

After the guidance is published the CPHE project team collects and collates information

that might affect any future updates from stakeholders, the review team, the Chairs and members of the PHAC. However the project team does not actively seek new evidence on any published guidance before the scheduled 3-year review, unless the original guidance indicates that an early review will be necessary (for example, when the PHAC know in advance that new evidence is due within the 3-year period).

When an update is considered, the CPHE project team consults experts and members of the relevant PHAC, as appropriate, to identify any changes in practice or additional relevant published evidence. The project team may then ask the information team to search for new evidence. In addition, the project team reviews any information that is available on the implementation and uptake of the guidance (see chapter 11).

8 Fieldwork

Fieldwork may be included in the validation stage of the NICE process. When draft guidance on novel, complex or sensitive areas is issued for consultation, the Centre for Public Health Excellence (CPHE) senior team may decide that the draft recommendations should also be simultaneously tested with professionals and practitioners.

Further details on all aspects of fieldwork are given in appendix M of Methods for the development of NICE public health guidance – third edition (2012).

9 Links to other NICE centres and guidance programmes

This chapter describes how the work of other guidance development centres, directorates and teams at NICE links to the development of public health guidance. It also outlines the approaches to be taken if:

- NICE asks a Public Health Advisory Committee (PHAC) to incorporate or update existing published guidance during the course of its work
- NICE is asked by the Department of Health to develop combined guidance on the prevention and treatment of a particular condition
- related guidance is being developed concurrently by another centre at NICE.

9.1 Coordinating with technology appraisal guidance

Independent technology appraisal committees advise NICE on what the guidance should say. The appraisal committees are stakeholders for public health guidance (see about technology appraisals on the NICE website).

9.1.1 Dealing with overlaps

If a referral for a new public health guidance topic covers an area in which there is existing technology appraisal guidance, there are 2 options:

- The technology appraisal guidance is incorporated into the public health guidance unchanged, and is acknowledged in the public health guidance. For example, the technology appraisal guidance on varenicline is incorporated into the public health guidance on smoking cessation services.
- The technology appraisal guidance is updated (either in full or in part) through the public health guidance development process (see section 10.2.1).

If a public health guidance topic is being developed simultaneously with a related

technology appraisal, timing is coordinated to ensure that the recommendations are consistent (see section 10.2).

A decision on whether published technology appraisal guidance is to be incorporated or updated in public health guidance is taken by the NICE Guidance Executive while the draft scope for the guidance is being developed.

9.1.2 Updating technology appraisal guidance in public health guidance

Any proposed update to the recommendations in technology appraisal guidance is discussed with the NICE technology appraisals team and agreed by the Guidance Executive (see chapter 10). There should be an update only if a technology appraisal recommendation extends into the setting or circumstances for the use of the public health guidance, or if the marketing authorisation for the product has been extended to different population groups and the appraisal recommendation is being superseded by a systematic review of the effectiveness and cost effectiveness of that aspect in the public health guidance. The reasons for any change should be documented clearly in the full version of the public health guidance.

Superseded recommendations are withdrawn from the technology appraisal guidance when the public health guidance is published; this withdrawal is indicated on the NICE website. Once technology appraisal recommendations have been updated in public health guidance, the funding direction that related to the original recommendations no longer applies. (The funding direction requires local NHS organisations to fund medicines and treatments recommended by NICE technology appraisal guidance, normally within 3 months of publication of the guidance).

9.1.3 Simultaneous development of public health guidance and technology appraisal guidance

If technology appraisal guidance is being developed around the same time as related public health guidance, the final recommendations in both should be complementary and consistent. The timetables for the development of the technology appraisal and the public health guidance should be coordinated so that the published technology appraisal recommendations can be incorporated into the consultation draft of the public health guidance. If the public health guidance is issued for consultation before the technology appraisal has been published, the guidance should cross refer to the technology appraisal

consultation document.

9.2 Interventional procedures

Interventional procedures guidance is concerned with the safety and efficacy of surgical and clinical interventions, but not with their clinical and cost effectiveness (for more details see about interventional procedures guidance on the NICE website).

If published interventional procedures guidance is identified as relevant to a public health guidance topic (for example, interventional procedures guidance on division of ankyloglossia for breastfeeding and public health guidance on infant nutrition), it is referred to in the 'Related NICE guidance' section of the public health guidance scope and the final published guidance. Because the interventional procedures programme does not examine cost effectiveness, an economic appraisal may be needed in these circumstances.

9.3 Medical technologies guidance

Medical technologies guidance is designed to help the NHS adopt efficient and cost-effective medical devices and diagnostics more rapidly and consistently. It covers medical devices that deliver treatment such as those implanted during surgical procedures, technologies that give greater independence to patients, and diagnostic devices or tests used to detect or monitor medical conditions (for more details see Medical technologies evaluation programme on the NICE website).

If published medical technologies guidance is identified as relevant to a public health guidance topic, it is referred to in the 'Related NICE guidance' section of the public health guidance scope and the final published guidance.

9.4 Clinical guidelines

Clinical guidelines are concerned with the appropriate treatment and care of people with a particular disease or condition (for more details see about clinical guidelines on the NICE website).

If a published clinical guideline is relevant to a public health guidance topic (for example, the clinical guideline on the management of depression in children and young people and

the public health guidance on the social and emotional wellbeing of children in primary education), the clinical guideline is referred to in the 'Related NICE guidance' section of the public health guidance scope and the final published guidance.

NICE clinical guidelines are developed by independent national collaborating centres. National collaborating centres for relevant clinical guidelines are stakeholders for public health guidance.

9.4.1 Combined clinical guideline and public health guidance

The Department of Health may ask NICE to develop combined guidance on both the prevention and clinical management of a particular condition.

The NICE Centre for Clinical Practice and the Centre for Public Health Excellence (CPHE) manage referrals for combined guidance jointly (for example, the prevention and management of obesity, or the prevention, early identification and management of alcohol use disorders in adults and adolescents). When a joint referral is received, the Centre directors consult with senior staff and relevant committee Chairs, before deciding how to develop the guidance. Joint or combined processes may be implemented over varying periods of time, as appropriate.

A joint referral may be developed in 1 of 3 ways:

- both clinical and public health aspects of the guidance are developed by 1 combined committee, with 1 Chair, using either the clinical or public health guidance development processes, or
- both clinical and public health aspects of the guidance are developed by 1 combined committee, with 1 Chair, using both sets of processes, or
- clinical and public health aspects of the guidance are developed by 2 separate committees, which may have some shared membership, using separate processes.

In general, where joint guidance is developed through a single process, the methods and quality assurance for clinical and public health aspects of the guidance will be managed by the relevant guidance development centre team. In these circumstances, there will usually be one combined scope and guidance document, with clinical and public health areas clearly defined and described. Where joint guidance is produced through two processes, with 1 or 2 committees, then it may be more appropriate to produce separate scopes and

guidance documents.

Where PHAC and guideline development group meetings are held separately, it can be helpful to have at least 1 joint meeting to ensure consistency and to avoid overlaps or gaps.

To help ensure consistency, where PHAC and GDG meetings are held separately an internal steering group will be set up, composed of senior staff from both centres. Combined guidance usually involves the PHAC developing public health guidance on the prevention, early identification or protection aspects of a condition, and a guideline development group producing a clinical guideline on clinical management, treatment and care. A joint Chair for both the development groups may be appointed. The joint Chairs should have a good understanding of both public health and clinical issues. If it is not possible to appoint a joint Chair, the steering group is responsible for communication between the 2 Chairs and the 2 development groups.

Where the guidance is developed through 1 process, then it may be appropriate to develop a combined scope. Where 2 processes are used, 2 scopes may be more appropriate: 1 for the public health guidance and 1 for the clinical guideline. The draft scopes are issued for consultation simultaneously, and the final scopes for the public health guidance and the clinical guideline are agreed through discussion between guidance centre directors, topic leads (associate or programme directors) and relevant Chairs.

Where the guidance is developed through more than 1 process, the draft clinical guideline and public health guidance are usually issued for consultation at the same time. The CPHE project team (see chapter 7) is responsible for responding to stakeholder comments on the draft public health scope and guidance. The collaborating centre for the clinical guideline deals with responses to stakeholder comments on the draft clinical scope and guideline. The guidance centre directors and topic leads ensure consistency between responses.

The steering group also decides whether the prevention and management aspects will be published as integrated joint guidance, or as separate public health guidance and a clinical guideline to be published at the same time.

Once both areas of the guidance are complete, a NICE Pathway will be produced linking the two.

9.5 Working with other NICE teams

The CPHE and the other guidance-producing centres work with the following directorates and teams:

- Implementation Directorate
- Communications Directorate
- Evidence Resources Directorate, including information services
- Patient and Public Involvement Programme (PPIP)
- Health and Social Care Directorate, including the quality systems team.

9.5.1 Implementation

The Implementation Directorate supports the guidance development process by providing implementation tools and resources. It continues to support implementation of NICE guidance once it is published, for example through follow-up visits by regional implementation consultants. The implementation adviser assigned to the CPHE project team (see chapter 7) is known as the implementation lead. In addition, a costing lead and an audit lead produce costing and audit support tools.

For each set of guidance, the implementation lead undertakes an implementation needs assessment and works with the CPHE project team, members of the PHAC and other key stakeholders to develop an implementation support plan. The needs assessment and development of the implementation tools usually start during consultation and continue through to publication of the guidance.

The implementation support plan summarises the education and learning needs and other levers and barriers identified through needs assessment derived from intelligence gathered during development (for example, there may be a quality standard available). The plan sets out the proposed action to address any barriers and specifies what tools and resources will be developed to support implementation of the guidance. Tailored solutions are then developed according to need.

The implementation lead, costing lead and audit lead work with members of the PHAC and key stakeholders to develop the tools. The guidance-related support tools provided by

NICE are designed to support each of the key steps to implementation. These are outlined in How to put NICE guidance into practice: a guide to implementation and How to put NICE guidance into practice and improve the health and wellbeing of communities: practical steps for local authorities, and may include:

- Tailored education and learning tools which focus on topic-related education and learning for individuals and organisations, for example online resources developed with BMJ Learning, or support for scrutiny committees developed with the Centre for Public Scrutiny. See Into Practice on the NICE website for examples of the types of tailored tools that are produced.
- Audit support and a data collection tool. These help organisations to carry out audits based on some of the measurable recommendations in the guidance. They consist of audit standards, data collection tools and action plans. Some will also be produced as Excel electronic audit tools that provide a basic data analysis and clinical audit report.
- Costing tools to help organisations assess the cost of implementing the guidance. The costing analyst assesses the recommendations to identify those with the greatest resource impact (see Assessing cost impact: methods guide [2011] on the NICE website). NICE usually provides two types of costing tools to accompany each public health guidance:
  - a costing report, which summarises the estimated national costs and savings associated with implementing the guidance and discusses the assumptions made in reaching this figure
  - a costing template, which allows users to estimate the local impact of implementing the guidance based on their population and to change the assumptions and variables to reflect local circumstances.
  - Occasionally, implementing the recommendations in the guidance may not be estimated to result in significant additional costs or savings. No costing report or costing template is produced in these cases. Instead, a costing statement is produced that explains why the cost impact is not considered to be significant.
- A commissioning guide.

Draft versions of tools and other resources are consulted on with the CPHE project team, volunteers from the PHAC and other key stakeholders before they are finalised for publication.

9.5.2 Communications Directorate

Three teams in the Communications Directorate are involved in the guidance development process.

- The publishing team provides editorial support to the CPHE project team (see chapter 7), including the development of editorial processes for key documents. It edits documents during guidance scoping, development and validation stages, develops the NICE Pathway and coordinates publication of the guidance and the Pathway.
- The website team is responsible for publishing all information relating to the project on the website, including consultation documents and final guidance.
- The press team is responsible for managing all media matters relating to the guidance, writing and coordinating press and journal articles and advising on issues arising during guidance development, dissemination and following publication.

9.5.3 Evidence Resources Directorate

The information services team is part of the Evidence Resources Directorate. It contributes to the search strategy involved in developing the scope. This specialist team helps to assure the quality of the search strategies that the evidence providers use for the evidence reviews. In addition, staff may help to identify links to NICE guidelines or technology appraisals on similar topics – either in development or already published – and the implications for topic selection and public health guidance in development. From time to time, the information services team may develop and implement search strategies in-house, in collaboration with the CPHE project team (see chapter 7).

9.5.4 Patient and Public Involvement Programme

The PPIP supports community involvement in the development of public health guidance. This includes:

- identifying and supporting contributions to guidance development from stakeholder organisations that promote the interests of specific population groups or service users, or the wider public (usually national voluntary or non-governmental organisations)

- commenting on the community focus of the draft scope for the guidance, and giving a presentation at the stakeholder meeting about the opportunities for community involvement in guidance development
- supporting the identification and recruitment of community members and co-opted community members to the PHACs
- providing induction and training to community members and additional briefing and support to community members and co-opted community members, when needed
- commenting on the draft guidance.

9.5.5 Health and Social Care Directorate

NICE quality standards are produced by the quality systems team, which is based in the Health and Social Care Directorate. NICE quality standards are a concise set of statements designed to drive and measure priority quality improvements within a particular area of care. They are derived from the best available evidence such as NICE guidance and other evidence sources accredited by NICE (such as NHS Evidence). Where a quality standard is to be produced based on NICE public health guidance, the CPHE project team (see chapter 7) link with the quality systems team and provide information and support on the evidence and guidance. For more details see NICE quality standards on the NICE website.

10 Guidance Executive

The Guidance Executive of NICE comprises NICE executive directors, centre directors and the communications director. The Guidance Executive considers and approves guidance and implementation tools for publication on behalf of the Board.

10.1 Guidance approval

When considering a guidance document for publication, the Guidance Executive assesses whether the guidance:

- addresses all the issues identified in the scope
- is consistent with the evidence quoted
- follows the agreed process and methods
- promotes equality and avoids unlawful discrimination
- is cogent and follows the agreed template.

If any major issue is identified by the Guidance Executive it may be necessary to reconvene the Public Health Advisory Committee (PHAC) to address the problem.

The Guidance Executive does not comment at other stages during the development of guidance.

10.2 Consistency of NICE guidance

If technology appraisal guidance is incorporated into public health guidance, any proposed change in the wording must be discussed with the relevant appraisals committee and agreed by the Guidance Executive (see section 10.1).

10.2.1 Updating guidance

The Guidance Executive decides whether technology appraisal or other guidance is to be updated within public health guidance. It also takes the final decision about the need for

an update of any guidance, including public health guidance (see chapter 11).

11 Updating public health guidance

NICE guidance is published with the expectation that it will be reviewed and updated as necessary. NICE public health guidance is updated if new evidence emerges or if sections of the guidance are no longer relevant. NICE usually checks for evidence 3 years after publication, and then at 3-yearly intervals, to decide whether all or part of the guidance should be updated. If important new evidence is published at other times, NICE may decide to update the recommendations at that time.

Any decision to update public health guidance must be balanced against the need for stability, because frequent changes to published recommendations would make implementation difficult and might delay the production of new guidance on other public health issues.

11.1 Post-publication information

After the guidance is published NICE collects and collates information that might affect the timing and content of subsequent updates. This information may come from stakeholders, the review team, the Chairs and members of the Public Health Advisory Committee (PHAC). It may also come from an Evidence Update or similar product from another team at NICE. However, NICE does not actively seek new evidence on any published guidance before the scheduled 3-year review unless it is indicated in the guidance that important new information may emerge before the planned review date.

11.2 Exceptional update

If substantial new evidence becomes available within 3 years of guidance publication, the centre director, the associate director who led the project team and the lead analyst for the guidance review it. If there is sufficient evidence that 1 or more recommendations need updating in a way that will significantly change practice, a meeting with the Chairs and members of the PHAC may be arranged. Following these discussions the Guidance Executive decides whether an update is needed before the 3-year period has elapsed. If an exceptional update is necessary, the original scope is used and stakeholders are informed.

11.3 Review after 3 years

The need for, and extent of, any update is determined in the following stages.

- The centre director convenes a meeting of a project team that will do an initial appraisal of the case for updating the guidance. The centre director and the project team consult a guidance update review panel to identify any changes in practice since the guidance was published and any additional evidence. The panel may consist of professionals, practitioners, technical experts and community representatives. The panel may include the Chairs and members of the PHAC that developed the guidance.
- The project team, working with information specialists from the Evidence Resources Directorate, may carry out a rapid search and review of new published literature. The project team review any information that is available on the implementation and uptake of guidance recommendations, including post-publication queries and comments.
- The centre director and project team assess the results of the findings and consults with stakeholders on its proposal as to whether the guidance requires:
  - an update
  - deferral of the planned update for a further 3 years
  - no further planned update
  - withdrawal.
- The project team may amend its proposal, in light of feedback from stakeholder consultation and makes a recommendation to the Guidance Executive.
- The Guidance Executive takes the final decision about updating the guidance.
- The Centre for Public Health Excellence (CPHE) senior team allocate guidance to be updated to a PHAC according to the topic area and available resources.

11.4 3-yearly review

The review process is repeated at 3-yearly intervals for any guidance that was deferred at the 3-year review stage.

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