

Professional standards, guidance and frameworks process development handbook

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Introduction

About this manual

This manual describes how we develop professional standards.

The term 'standards' used throughout this document also refers to guidance and frameworks.

About us

We are the professional body for pharmacists in Great Britain constituted by Royal Charter. We represent all sectors of pharmacy in Great Britain and lead the support and development of the pharmacy profession including the advancement of science, practice, education and knowledge in pharmacy.

The structure and governance of our organisation is detailed in our governance handbook which is available [online](#).

About our professional standards, guidance and frameworks

The objectives of our professional standards, guidance and frameworks are to:

- Describe good practice, systems of care or working.
- Provide a broad framework to support pharmacists and their teams to develop their professional practice, improve services, shape future services and deliver high quality patient care across all settings and sectors.
- Act as a framework to help commissioners and those contracting services to design, implement, deliver and monitor high quality practice through pharmacy.
- To support the development and delivery of consistently high quality services and evaluation of those services.
- Be supportive, enabling and professionally challenging.

The topics and questions addressed by our standards typically apply to different healthcare settings delivering pharmacy services or describe best practice applicable to pharmacy activities related to medicines.

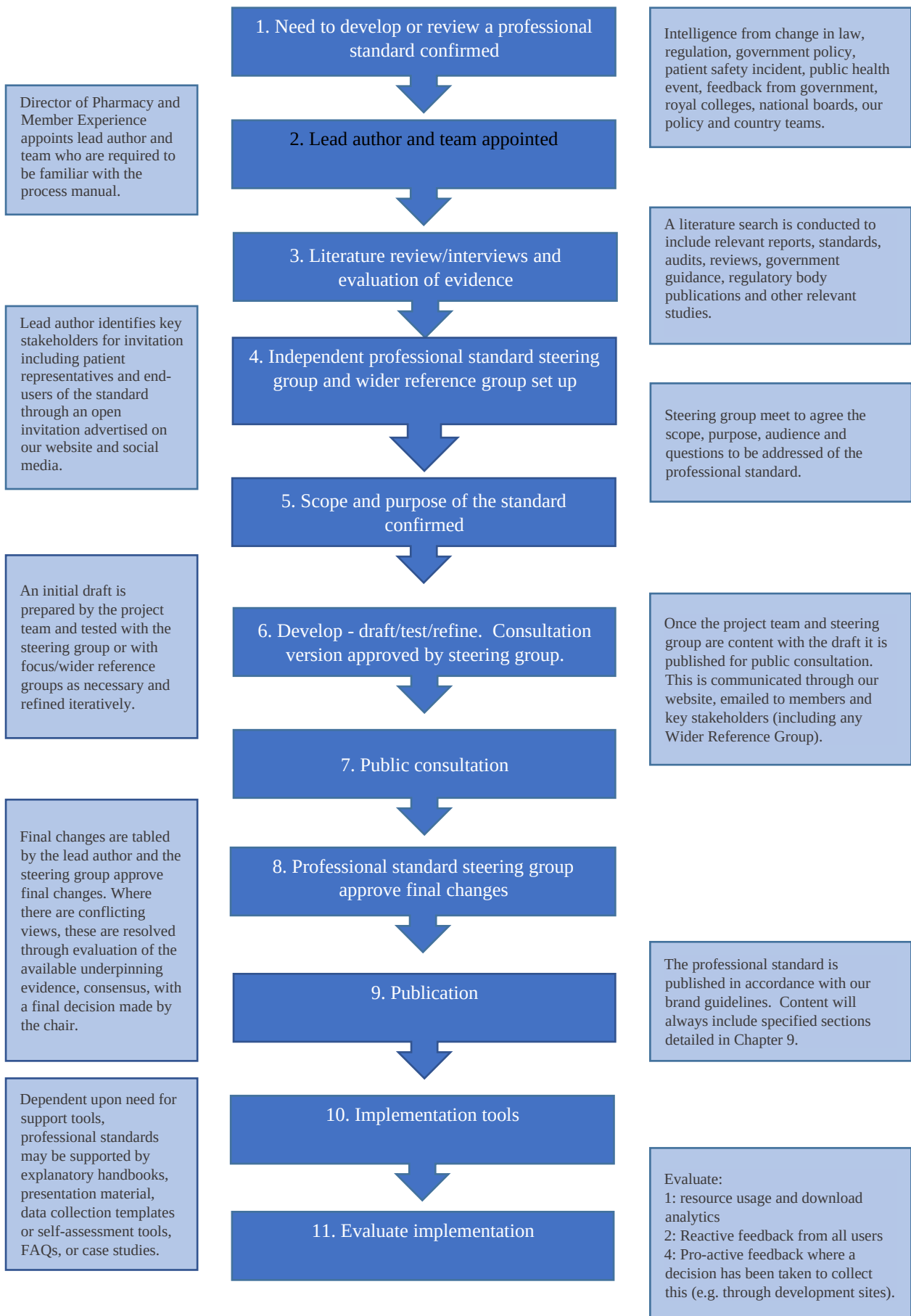
How we are funded

The [RPS annual review](#) available on our website. We are mainly funded by membership subscription and publication activities of [Pharmaceutical Press](#). From time to time, we may be commissioned by the government to undertake research or develop reports.

Statement of editorial independence

Professional standards, guidelines and frameworks developed through this process are evidence-based and editorially independent. This process safeguards the editorial independence of the professional standards steering group from the funding body and conflicts of interest.

Professional standards development process



1. Identifying need to develop or review a professional standard, guidance or framework

The need to develop or review a professional standard, guidance or framework and questions to be addressed may be identified from multiple source of intelligence and a decision to progress is confirmed by the Director of Pharmacy and Member Experience.

Sources of intelligence

- Change to legislation, regulation, government policy
- Patient safety or public health incidents
- Feedback from pharmacists and the pharmacy team
- Feedback from government, royal colleges, other pharmacy organisations, other healthcare professionals, patients and patient groups
- Our campaigns and policy priorities led by the national boards for England, Scotland and Wales

The topics addressed by our standards typically include the delivery of pharmacy services through different healthcare settings or pharmacy activities related to medicines.

2. Appointing the lead author and project team

Our Director of Pharmacy and Member Experience appoints the lead author and project team.

The lead author may be any member of staff, secondment colleague or externally commissioned.

A copy of our professional standards, guidance and frameworks process development manual is provided and it is required that the lead author and project team are familiar with the process.

If the lead author leaves the role mid-project, the Director of Pharmacy and Member Experience will appoint a new lead author.

3. Literature review and evaluation of evidence

The literature review can be conducted by the lead author or external contractor.

The methodology for the literature review is as follows:

- I. Identify search question
- II. Identify inclusion and exclusion criteria
- III. From the search question, identify key words, spelling variations, synonyms and associated terms
- IV. Using the search question and key words, check the following

Document type with link to topic area	Publisher
a. Legislation	a. UK or developed government
b. Standards	b. UK or GB regulatory bodies, including healthcare regulatory bodies
c. Guidance	c. UK or GB healthcare organisation, Royal College, non-government organisation (NGO) or registered charity
d. Reports	d. European Union (EU) or EU decentralised agency (such as the European Medicines Agency) etc
e. Audits	e. International Pharmaceutical Federation (FIP)
f. Reviews	f. International government, healthcare or pharmacy regulatory or professional body
g. Studies and published trials	g. Catalogued bibliographic databases (where applicable) <ul style="list-style-type: none"> • International pharmaceutical abstracts • Medline • Cinahl • Biomedical Reference Collection corporate edition

V. Where the topic of the standard is not supported by published literature or grey literature, consider conducting interviews with key stakeholders to obtain expert opinion

VI. Record the date of the search.

Evaluation of evidence

Documents and studies and data collected from the literature review process are evaluated against the inclusion and exclusion criteria and then discussed between the person conducting the literature review and the project lead, bearing in mind the [Scottish Intercollegiate Guidelines Network \(SIGN\) grading system 1999-2012](#) which uses the following hierarchy of levels of evidence.

- 1++ *High quality meta-analyses, systemic reviews of RCTs, or RCTs with a very low risk bias*
- 1+ *Well-conducted meta-analyses, systemic reviews, or RCTs with a low risk of bias*
- 1- *Meta-analyses, systemic reviews, or RCTs with a high risk of bias*
- 2++ *High quality systematic reviews of case control or cohort or studies*
High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is casual
- 2+ *Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate*
probability that the relationship is casual
- 2- *Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not casual*

3 *Non-analytic studies, e.g. case reports, case series*

4 *Expert opinion.*

4. Setting up the independent professional standard steering group

Constitution

The independent professional standard steering group is chaired by the lead author or a nominee appointed by our Director of Pharmacy and Member Experience.

The chair may not have a conflict of interest in the topic area and is responsible for ensuring that all other members of the independent professional standard steering group have declared relevant interests. The chair does not need to have expertise in the topic area but should have experience chairing meetings.

The lead author will oversee the publication on our website and via social media of an open invitation for people to become part of the independent professional standards steering group.

The lead author will oversee the process to identify who to invite to join the independent professional standard steering group. This should include a representative range of stakeholders including:

- A minimum of two lay people, representative of users of the services underpinned by the standard or guidance or framework
- Users of the guideline, e.g. pharmacists and pharmacy teams or other members of the healthcare team currently working in the topic area at a practical, management and strategic level across the different sectors linked to the topic area
- Representatives of organisations or networks with a link to the topic area including pharmacy or healthcare organisations
- Pharmacists with a recognised national or international leadership role or expertise in the topic area.

Where lay representatives do not respond to the advert, they may be sought and found through National Voices.

The lead author will contact the list of people for invitation (see Appendix A for a suggested wording for the invite), a Declaration of Interests form (see Appendix B), details of the Terms of Reference (see Appendix C), and a copy of our professional standards, guidance and frameworks process manual.

Role

The role of the independent professional standard steering group is to:

- Confirm the purpose and scope of the standard, guidance, framework
- Confirm the questions to be addressed by the standard, guidance, framework.
- Working with the lead author and project team, contribute and review content throughout the development of the standard
- Consider and provide opinion on the wider impact and implications of the professional standards/guidance developed
- Review iterations of the standard/guidance and comment on specific issues identified by the project lead

- Reviews and sign off the final version of the guidance.

The independent professional standard steering group may discuss and decide issues by email, teleconference, or face-to-face, meetings as needed.

Managing conflicts of interest

All members of the independent professional standard steering group including the chair are required submit completed declarations of interests and to agree to participate under the Terms of Reference before serving on the independent professional standard steering group.

Declarations of Interest are collated by the project team and these will be made available upon request.

At the start of each meeting¹ the Chair will ask the group to confirm any changes to Declarations of Interest. It then is at the discretion of the Chair whether the individual member declaring an interest may take part in the discussion, remain for the discussion, but not take part or vote, or should leave the meeting for the duration of the item. Declarations of Interest and the decision of the Chair on how the declarer will take part in the meeting will be noted in the minutes.

A template Declaration of Interest can be found in the Appendix B.

Decisions of the independent professional standard steering group

Drafts are developed and refined through consensus of the independent professional standard steering group in the context of the evidence-base from the literature review and evaluation, the circulation for comment together with the agreed scope and purpose of the professional standard.

All members of the independent professional standard steering group are given the opportunity to speak to present their views, including on issues of disagreement.

Where consensus cannot be reached prior to public review the issue of conflicting views or lack of evidence should be specifically highlighted and reviewed as part of the public and peer review process.

Where consensus cannot be reached post public and peer review, the issue should be resolved through a vote of the independent professional standard steering group. Dissenting views should be recorded in the minutes, and where appropriate within the final published standard.

The independent professional standard steering group should discuss:

1. From a patient perspective, the benefits and the risks or unintended consequences of the recommendations made
2. Organisational and financial barriers to implementation
3. Any unintended consequences of the recommendations made.

A summary of these should appear in the final draft.

¹ Meetings may not be face-to-face: may be Skype, email consultation etc.

Wider Reference Group

At this point, the lead author may also decide to form a Wider Reference Group. This would typically be a group of interested parties (e.g. those who applied to be on the independent professional standard steering group but who were not required/suitable).

An open invitation to join the Wider Reference Group can be added to the page on our website.

Generally, the Wider Reference Group would NOT be acknowledged in the published document.

5. Confirming the scope and purpose of the professional standard

The scope, purpose and intended audience of the professional standard are confirmed at an initial meeting of the independent professional standard/guidance steering group and included within the final document

- Purpose of professional standard
- Scope of professional standard
 - Including exclusions from scope
- Intended audience of the professional standard
- The questions to be answered by the guidance.

6. Developing the professional standard and refinements

The first draft is developed by the lead author and project team with consideration to:

- I. The evaluation of results from the literature or grey literature review
- II. Agreed purpose, scope, audience and questions to be addressed
- III. Ensuring that the language used is suited to the target audience. This will usually be pharmacists and pharmacy teams, and occasionally the wider multi-disciplinary healthcare team. Our professional standards are not developed for a patient audience.
- IV. The impact, risks and benefits of the recommendations within each professional standard
- V. Different options that can be used to meet the recommendations within the guideline, framework or standard.
 - E.g. professional standards are outcome focussed and there may be a range of options to achieve these outcomes

The draft is refined through feedback and comment of the independent professional standard steering group. In some cases additional expertise will be needed and depending upon the issues small focus groups or a Task and Finish group of stakeholders can be setup by the project lead to provide additional feedback and testing of drafts. These will include representative users of the standard e.g. users currently working in the topic area at a practical, management or strategic level.

7. Public consultation

The draft is iteratively refined until the independent professional standard steering group agree the draft is ready for public consultation.

The consultation should include a question regarding organisational and financial barriers to implementation.

The draft is published on our website (www.rpharms.com) and made available for and open-access consultation to any interested party for at least a period of at least 4-6 weeks.

Key stakeholder organisations are made aware of the public consultation by email and press release and invited to respond. Key stakeholders vary between work programmes and may include:

- Any project Wider Reference Group, sub-group and/or task and finish group
- Pharmacists and pharmacy professionals
- Patient groups and patient charity representatives
- Affiliates and partners (as appropriate, i.e. GPhC, APTUK, GMC, RCN, RCM, RCP, RCGP, NMC, CQC, Health Improvement Scotland, Welsh Pharmaceutical Committee, Chief Pharmaceutical Officers)
- NHS groups
- Royal Colleges
- Pharmacy Academics
- Government bodies, regulators and relevant executive agencies
- Stakeholder groups
- Other interested parties (i.e. relevant expert advisory groups; those who have expressed an interest) and healthcare professionals.

Send, for information only, to:

- President and Chief Executive Officer
- PLB/PLF
- Board Chairs
- Comms Team
- Pharmacy and Member Experience team
- PJ
- SupportTeam

The project team monitors responses to the public consultation and will intervene to send reminders or to seek additional views if comments are not received from the public consultation.

8. The final draft

When the consultation period has ended, the project team will collate feedback from the consultation, review the responses using a thematic analysis and revise the document.

Comments are added to the draft standard as tracked changes and the document is shared with the independent professional standard steering group.

The independent professional standard steering group are asked to discuss the responses and proposed changes, any areas of conflicting feedback, and to approve the proposed changes. The independent professional standards steering group should also review any feedback regarding organisational and financial barriers.

The project team will evaluate the feedback from the independent professional standard steering group and make refinements to the standards.

The independent professional standard steering group or T&F group approve the final draft for publication.

9. Publication

The professional standard is published as an open-access document on our website. All or part of the standard may also be published in hard copy or as a pdf.

How our standards are formatted

Each standard should meet our brand guidelines and content should include the following:

- Title page
- Publication date
- Review date
- Foreword (optional)
- Contents page (may be as drop-down menu if published as a web page)
- Purpose and scope of standard (this may be in the form of FAQs)
- Intended audience (could be as an FAQ)
- Summary of professional standards (optional)
- Detail of professional standards
- Definitions for terms used in the standards (optional)
- Acknowledgements
- Literature review:
 - Summary of methodology
 - Summary of search strategy
 - Inclusion and exclusion criteria
 - Date of evidence search
- Summary of benefits and risks
 - Including unintended consequences of the recommendations made.
 - Financial and organisational barriers to implementing the recommendations
- References for recommendations (where appropriate)
- Our contact details
- Endorsing organisations (where appropriate).

10. How we support implementation of our standards

Publication of the standard is promoted by a communications programme delivered through:

- Press release and social media through our media team and press officer
- Communications to all members through our membership and marketing team
- Emailed communications to key stakeholder organisations with an interest in the topic area.

Support tools are developed to aid implementation of our standards, these can include:

- Handbook guidance documents
- Self-assessment templates and data collection forms
- Power-point presentations
- Audit tools
- Frequently asked questions
- Case-studies
- Webinars
- Checklists

Our professional support service, an enquiry service accessible by phone and email is also available to members with day to day queries about standards, guidance and frameworks.

11. How we measure effectiveness of our standard

Effectiveness of our standards, guidance and frameworks are measured in a variety of ways including:

1. We have access to analytics data for web-page and professional standard download statistics.
2. Where development sites are testing the professional standards in practice, feedback will be pro-actively collated and analysed.
3. We reactively collates qualitative feedback from all users of the standard for future review by the project team and contact details are available on all our standards
4. Use or reference to standards, guidance, frameworks by NHS, health or training systems e.g. NHS benchmarking reference to Hospital Standards and CPPE reference to Public Health Standards.
5. Formal adoption of standards by other organisations.
6. Accreditation or endorsement by other organisations.

12. Review of the standard

Triggers for review include:

- Routine review four years after publication.
- Patient safety or public health incident prompting the need for an unscheduled review of standards, depending upon the issue, a report may be commissioned
- Change in legislation, regulation, practice or feedback from users

Our approach to standards, frameworks, guidance review is detailed below:

Scoping

- Review in the context of the trigger
- Consider commissioned report or literature search to identify omissions or changes required

Updating

- Standard/framework/guideline updated
- All changes tracked to facilitate review

Reviewing and updating

- Comments reviewed and standard/framework/ guideline refined
- Final refinements sent to the steering group for review

Review of recommendations

- Steering group held to review the report and recommendations
- Modifications to the original standard/framework/ guideline agreed

Circulation for comment

- Refined standard/framework/guideline (tracked) circulated for comment
- Circulated to steering group and all other stakeholders involved in original standards development
- Public consultation

Sign off & Launch

- Standard/guideline/framework updated
- Publication on our website and communications to all stakeholders

Appendix A: Independent Professional Standard Steering group invite (example)

Invitation letter or email wording

Dear

We are pleased to announce that the Royal Pharmaceutical Society is establishing an independent professional standard steering group to help us develop professional standards/guidance for

The guidance/standards aim to support.....

The steering group will support the work of the RPS by providing a source of expertise on.....

We would like to invite you to be a member/nominate a representative of your organisation to be a member of the professional standard steering group.

The group will typically meet formally face-to-face [.....] over the duration of the project; Additional meetings will be scheduled as required and may be conducted via teleconference, webinar or email discussion.

The first meeting will be on Other meetings will be scheduled at the first steering group meeting. I have attached a draft Terms of Reference for the group and a Declaration of interest form.

I do hope you are able to join this steering group and look forward to hearing from you in due course. If there are any queries about the group feel free to contact

Kind regards

.....

Appendix B: Declaration of Interests template

RPS Declaration of Interests

I declare that the interests recorded below include each and every interest, which might be considered to have a potential to influence the exercise of impartial judgement by me in my connection with the Royal Pharmaceutical Society.

Name _____
Signature _____
Date _____

Please record your interests under the appropriate heading in the table below.

1. Remuneration
<i>List the names of any organisations (including your present employer) from which you currently draw a salary or other remuneration including honoraria, long-term or regular consultancies, and any directors' fees or other emoluments from private companies or PLCs. Short-term or one-off consultancies need not be included unless the organisation concerned is likely – or possibly seeking – to do business with the Royal Pharmaceutical Society. In no case are you expected to disclose the level of salary or other payments.</i>
2. Directorships
<i>List the names or any private companies or PLCs of which you are currently a director, or of which you have been a director at some point during the last three years, or of which you expect to become a director within the next year (whether paid or unpaid). You are not expected to disclose the level of any directors' fees or other emoluments.</i>
3. Significant share-holdings

List the names of any companies or businesses – whether private or publicly-quoted – in which you hold a significant share-holding. ‘Business’ should be taken to include consultancies, partnerships and the like; you will be deemed to have a ‘significant share-holding’ if you own more than 5 per cent or more of the business (normally 5 per cent or more of the issued share capital). You are not expected to disclose the level of your financial interest in these companies or businesses.

4. Unremunerated activities related to those of the Royal Pharmaceutical Society

List the names of any unpaid offices you hold – for example, in a company, higher education institution, charity or voluntary or public body – which you consider might have a bearing on your role. You should include any charity trusteeships you hold, or any other way in which you participate in the management of a charity.

5. Political pressure groups or associations where their objectives are related to the activities and objects of the Royal Pharmaceutical Society

6. Family interests

List any interests you have through your members of your family having interests which might be considered to have a potential to influence the exercise of impartial judgement by you in your connection with the Royal Pharmaceutical Society.

Appendix C: Terms of Reference

Terms of Reference

The Terms of Reference will include the following headings:

- Background
- Purpose of the independent professional standard steering group
- Functions
- Accountability
- Duration
- Commitment
- Membership of the group

Appendix D: Professional standards development NICE checklist and gap analysis

Title of standard/guidance

Director of Pharmacy and Member Experience has reviewed the conflict of interest declaration of the lead author/chair	
Details of the search criteria including date of evidence search, inclusion and exclusion criteria are described within the final document or supporting documents/web resources	
There has been an open invitation on our website and through social media inviting stakeholders to join the independent professional standards steering group	
Patients or patient groups are represented on the independent professional standards steering group	
Representative end-users of the standard, guidance, framework are included within the independent professional standards steering group	
Representatives of key organisation with links to the topic area have been included in the independent professional standards steering group	
Declarations of interests for all members of the independent professional standards steering group have been collected and available upon request	
All members of the independent professional standards steering group has agreed to work under the terms of reference and are aware of our professional standards, guidance and framework process manual	
The independent professional standards steering group has agreed the purpose, target audience, and questions to be addressed by the standards and these are clear within the document	
The independent professional standard steering group has discussed barriers and unintended consequences of recommendations including financial and organisational	
There has been a public consultation open to interested parties	
There have been sufficient responses to the consultation to inform development	
In the rare event of unresolved dissenting views of the professional standards steering group: have these been considered for acknowledgement within the final document.	
The language used within the document is suitable for the intended audience	
The standards, guidelines, framework are clear and unambiguous	
There are specific examples within the document describing how the recommendations will be supported through implementation	
Publication, amendment and review dates are current and published on the final document	

Gap analysis

Domain 1: Scope and purpose is concerned with the overall aim of the guidance, the specific health questions and the target population. These criteria consider whether the guidance producer has a policy in place and adhered to that requires them to explicitly detail:		Suggestions for guidance content include:	
1.1 The overall objective of the guidance	Does the guidance specifically state its aims? A full description of how the objective was reached and by whom would be welcome, for example by a topic selection panel. The process documentation should describe how the topic selection and scoping is done and explain how this will appear in the guidance if fit for purpose.	• intent(s) such as prevention, screening, diagnosis, treatment	
		• expected benefit or outcome	
		• target(s) (for example, patient or service user population, society)	
1.4 The clinical, healthcare or social questions covered by the guidance	Does the process describe how these questions will be found in the guidance examples? Is there enough information provided in the questions for anyone to initiate the development of guidance on this topic? A full description should include how these questions or issues were reached and how the questions will look in the guidance examples.	• target population	
		• intervention(s) or exposure(s)	
		• comparisons (if appropriate)	
		• outcome(s)	
1.9 The population and/or target audience to whom the guidance applies	Who is the guidance to inform? Are there sections within the guidance which targets any specific audience? If so is this described in the process documentation and implemented in the guidance? What population does the guidance cover? What population does each specific question cover and if different, is this obvious from the guidance? Is the population information specific enough so that the correct and eligible individuals would receive the action recommended in the guidance? The process documentation should describe how to define the specific target audience and patient or service user populations covered by the guidance and explain where the evidence of the implementation of this process will be found in each piece of guidance.	• target population, gender and age	
		• clinical condition (if relevant)	
		• severity/stage of disease (if relevant)	
		• comorbidities (if relevant)	
		• excluded populations (if relevant)	

1.4 That the producer ensures guidance includes clear recommendations in reference to specific clinical, healthcare or social circumstances	Does the process ensure that recommendations are clear so that they can be implemented appropriately for the right target population in the right circumstances?	• describe how the development group link and use the evidence to inform recommendations	
	Is it clear what audience/procedure/circumstances the recommendation covers?	• ensure that all recommendations clearly describe the specific circumstances in which they are to be used	
	Can the recommendations be traced back to the evidence base specific to that recommendation? The process manual should request that the recommendations are formulated and described covering particular populations/circumstances and guidance should show considerations to ensure they are implemented appropriately. Within the guidance we would expect to see specific recommendations backed up by evidence.	• ensure that the implementation of the recommendation is considered in the wording to ensure a clear meaning, linked to the scope/key questions where relevant	

<p>Domain 2. Stakeholder involvement focuses on the extent to which the guidance represents the views of its intended users and those affected by the guidance (patients and service users).</p> <p>These criteria consider whether the guidance producer has a policy in place and adhered to that means it includes:</p>		<p>Suggestions for guidance content include:</p>	
<p>2.1 Individuals from all relevant stakeholder groups including patients groups in developing guidance</p>	<p>Are the members an appropriate match for the topic and scope? Potential candidates could include clinicians from relevant disciplines, content experts, social care or public health experts, researchers, policy makers, clinical administrators, and funders. There may also be a methodology expert included in the development group (for example, systematic review expert, epidemiologist, statistician, library scientist).</p> <p>Have people relevant to the guidance under development been involved in the guidance development process?</p> <p>Information about the composition of any groups involved with the development of the guidance should be indicated in the process manual with the evidence of implementation clearly demonstrated where relevant.</p>	<p>Where relevant, for each guidance development stakeholder, the following information may be included:</p> <ul style="list-style-type: none"> • name • discipline/content expertise (for example; neurosurgeon, methodologist) • institution or affiliation (for example, NICE) • description of the member’s role in the guidance development group 	
<p>2.2 Patient and service user representatives and seeks patients views and preferences in developing guidance</p>	<p>Who is involved in guidance development that can provide the perspectives of patients or service users? Are patients, service users or organisations that represent these groups involved, and in what circumstances is the use of each justified? What support is provided for any public representatives involved in guidance development? Which groups involved in the guidance development process contain public representation? Is the process of feedback and consideration of patient or service user views adequately described in the documentation? How is this feedback treated and how does it inform the guidance development process?</p>	<ul style="list-style-type: none"> • a description of type of strategy used to capture patient or service user views and preferences (for example, participation in the guidance development group, literature review of values and preferences) • the methods by which preferences and views were sought (for example, evidence from literature, surveys, focus groups) • what views and preferences were identified • a description of how the information gathered was used to inform guidance development or formation of the recommendations. 	

<p>2.3 Representative intended users in developing guidance</p>	<p>Are specific professions described as intended users for a piece of guidance? If so is there evidence as to how and when the specific intended user is involved in the development of the guidance? Does the guidance include information to demonstrate how users have been involved in development? Evidence that the target audience are involved in guidance development should be demonstrated.</p>	<ul style="list-style-type: none"> • a clear description of the intended guidance audience and how the guidance may be used will define the types of professions to evidence 	
		<ul style="list-style-type: none"> • explanation of when and how any intended users should be included in the guidance development process (for example, always include a pharmacist at the peer review stage of guidance development) 	

<p>Domain 3. Rigour of development relates to the process used to gather and synthesise information and the methods used to formulate recommendations and update them.</p> <p>These criteria consider whether the guidance producer has a clear policy in place and adhered to that:</p>		<p>Suggestions for guidance content include:</p>	
<p>3.1 Requires the guidance producer to use systematic methods to search for evidence and provide details of the search strategy</p>	<p>Does the process describe a routine and systematic approach to identifying evidence relevant to the guidance?</p> <p>Is the search relevant and appropriate to answer the clinical, health or social care question?</p> <p>Does the process ensure that the search strategy is as comprehensive as possible and executed in a manner free from potential biases and sufficiently detailed to be replicated?</p>	<ul style="list-style-type: none"> named electronic database(s) or evidence source(s) where the search was performed (for example, MEDLINE, EMBASE, PsychINFO, CINAHL) 	
		<ul style="list-style-type: none"> time periods searched (for example, January 1, 2004 to March 31, 2008) 	
		<ul style="list-style-type: none"> the date the search was performed 	
		<ul style="list-style-type: none"> search terms used (for example, text words, indexing terms) 	
<p>3.2 Requires the guidance producers to state the criteria and reasons for inclusion or exclusion of evidence identified by the evidence review</p>	<p>Does the process ensure that there is a rationale given for the stated inclusion/exclusion criteria?</p> <p>Do inclusion/exclusion criteria align with the health/ clinical/ social care /safety question(s)?</p> <p>The process should ensure that guidance describes when and why specific exclusions and inclusions are used and where this can be found. The reasoning behind the inclusions/exclusions should be clear. There may be more than one point for inclusion and exclusion. First there may be exclusions specified during the evidence searching, for example, only English language studies used. Secondly evidence should be provided as to why a piece of evidence is excluded after being identified by the evidence</p>	<p>explanation of what criteria have been used for inclusion/exclusion of evidence or reference to where these criteria can be found. Specific inclusion/exclusion criteria may be based on:</p> <ul style="list-style-type: none"> target population (patients service users, public) characteristics 	
		<ul style="list-style-type: none"> study design 	
		<ul style="list-style-type: none"> comparisons (if relevant) 	

	search, for example excluded on grounds of relevancy. This should be documented and provided as evidence of implementation of the process.	<ul style="list-style-type: none"> • outcomes • language (if relevant) • context (if relevant). 	
3.3 Describes the strengths and limitations of the body of evidence and acknowledges any areas of uncertainty	<p>Has an assessment tool or other form of critical appraisal tool been used and if so is this fit for purpose and the choice of appraisal explained?</p> <p>Are the different grades showing the evidence strength described in full?</p> <p>Are the descriptions appropriate, objective and unbiased?</p> <p>All interpretations should be systematically applied. If a weaker evidence base has been used is it clear why this was chosen?</p>	<ul style="list-style-type: none"> • type of evidence used and why • descriptions of how the body of evidence was evaluated for bias and how it was interpreted. <p>Aspects upon which to frame descriptions include the:</p> <ul style="list-style-type: none"> • study design(s) included in body of evidence • study methodology limitations (sampling, blinding, allocation concealment, analytical methods) • appropriateness/relevance of primary and secondary outcomes considered • consistency of results across studies • direction of results across studies • magnitude of benefit versus magnitude of harm • applicability to practice context. 	
3.4 Describes the method used to arrive at recommendations (for example, a	Is it clear what process was used to arrive at the recommendations?	<ul style="list-style-type: none"> • a description of the recommendation development process (for example, steps used in modified Delphi technique, voting procedures that were considered) 	

voting system or formal consensus techniques like Delphi consensus)	<p>Were the methods appropriate?</p> <p>How does the process used to manage any conflicts of interest affect how recommendations are reached?</p> <p>A description of the methods used to formulate the recommendations and how final decisions were arrived at should be provided. Areas of disagreement and methods of resolving them should be specified. For example, in a voting system what is the resolution process?</p> <p>Does the chair have the power of veto?</p>	<ul style="list-style-type: none"> • the outcomes of the recommendation development process (for example, extent to which consensus was reached, outcome of voting procedures) 	
		<ul style="list-style-type: none"> • a description of how the process influenced the recommendations for example, results of Delphi technique influence final recommendation, alignment with recommendations and the final vote. 	
3.5 Requires the guidance producers to consider the health benefits, side effects and risks in formulating recommendation	<p>Is the discussion of benefit versus risk an integral part of the guidance development process in weighing up the alternatives and arriving at recommendations?</p> <p>Does the process describe how benefits and harms are weighed up and evaluated in making recommendations?</p> <p>This may only be noted in the recommendations. For example, this may be done by comparing treatments or describing the risks for each treatment considered or simply an explanation as to why the guidance recommends a treatment even if the risks are significant.</p>	<ul style="list-style-type: none"> • supporting data and report of benefits/harms/side effects/risks 	
		<ul style="list-style-type: none"> • reporting of the balance/trade-off between benefits and harms/side effects/risks 	
		<ul style="list-style-type: none"> • recommendations reflect considerations of both benefits and harms/side effects/risks 	
3.6 Describes the processes of external peer review	<p>Are the external reviewers relevant and appropriate to the scope of the guidance?</p> <p>Was there a rationale given for choosing the included reviewers?</p> <p>How was information from the external review used by the guidance development group?</p> <p>The methodology by which the process of external peer review is performed should be documented. External reviewers should be independent from the specific guidance production process.</p>	<ul style="list-style-type: none"> • purpose and intent of the external review (for example, to improve quality, gather feedback on draft recommendations, assess applicability and feasibility, disseminate evidence) 	
		<ul style="list-style-type: none"> • methods taken to undertake the external review (for example, rating scale, open-ended questions) 	
		<ul style="list-style-type: none"> • description of the external reviewers (for example, number, type of reviewers, affiliations) 	

		<ul style="list-style-type: none"> • outcomes/information gathered from the external review (for example, summary of key findings) 	
		<ul style="list-style-type: none"> • description of how the information gathered was used to inform the guidance development process and/or formation of the recommendations (for example, guidance panel considered results of review in forming final recommendations). 	
3.7 Describes the process of updating guidance and maintaining and improving guidance quality	<p>Is enough information provided to know when an update will occur or what criteria would trigger an update for a piece of guidance? Is the updating schedule documented for the guidance development process?</p> <p>A clear statement about the procedure for updating the guidance should be provided. The timescales for reviews of process should also be documented. There may be an internal review group which aims to look at the quality of the guidance development process at defined intervals.</p>	<ul style="list-style-type: none"> • a statement that the guidance will be updated, and a description of what would cause an update 	
		<ul style="list-style-type: none"> • the explicit time interval or criteria to guide decisions about when an update will occur 	
		<ul style="list-style-type: none"> • the methodology for the updating procedure is reported. 	

<p>Domian 4. Clarity and presentation deals with the language and format of the guidance.</p> <p>These criteria consider whether the guidance producer ensures that:</p>		<p>Suggestions for guidance content include:</p>		
<p>4.1 The recommendations are specific, unambiguous and clearly identifiable</p>	<p>Are the key recommendations appropriately selected and do they reflect the questions and issues intended to be addressed by the guidance?</p>	<ul style="list-style-type: none"> • a description of recommendations highlighted in some way to ensure they are clearly identifiable 		
	<p>Are the recommendations precisely worded to avoid ambiguity?</p>	<ul style="list-style-type: none"> • specific recommendations that are grouped together in one section 		
	<p>Are the circumstances and recommendations clearly linked so that it is clear what action is required under the circumstances?</p>	<ul style="list-style-type: none"> • identification of the intent or purpose of the recommended action (for example, to improve quality of life, to decrease side effects) 		
	<p>Are recommendations displayed prominently or highlighted in the relevant sections?</p>	<ul style="list-style-type: none"> • identification of the relevant population (for example, patients, public) 		
			<ul style="list-style-type: none"> • caveats or qualifying statements, if relevant (for example, patients or conditions for whom the recommendations would not apply) 	
			<ul style="list-style-type: none"> • an explicit statement reflecting any uncertainty in the interpretation and discussion of the evidence, within the recommendations. 	
<p>4.2 The different options for management of the condition or options for intervention are clearly presented</p>	<p>This criterion may be more relevant to guidance that is broad in scope (for example, covering the management of a condition or issue rather than focusing on a particular set of interventions for a specific condition/issue). Is the guidance broad or narrow in scope? In the event of multiple recommendations (for example, management guidance), is it clear what each recommendation applies to?</p>	<ul style="list-style-type: none"> • a description of options 		
		<ul style="list-style-type: none"> • a description of population or situation most appropriate to each option 		

	It is important to note that in some instances, evidence is not always clear cut and there may be uncertainty about the best care option(s). In this case, the uncertainty should be stated in the guidance with supporting evidence	<ul style="list-style-type: none"> • a link back to the specific questions and issues covered by the guidance 	
4.3 The date of search, the date of publication or last update and the proposed date for review are clearly stated	From looking at the guidance can you clearly see: <ul style="list-style-type: none"> • the date of publication • the date the guidance was last updated • the date the guidance is to be reviewed • the dates covered by the evidence search? Does the process documentation provide a coherent structure for how the dates are monitored? Does the process describe with reasoning how any dates are decided and where the evidence for these dates will be found in guidance examples?	<ul style="list-style-type: none"> • dates of production and publication 	
		<ul style="list-style-type: none"> • date of next review and updating schedule (for example, a three year updating schedule is followed) 	
	<i>Publication, amendment and review dates are current and published on the final document</i>	<ul style="list-style-type: none"> • dates of all searches covered (for example if the guidance is an update there may be more than one set of dates of search indicated). 	
4.4 The content and style of the guidance is suitable for the specified target audience. If the public, patients or service users are part of this audience, the language should be appropriate	Does the language used in the guidance match the target audience (as defined in response to criterion 1.3)? Technical language used in guidance may be appropriate if the target audience is a technical one, for example policy guidance for a laboratory audience.	<ul style="list-style-type: none"> • a description of target audience, including patients where appropriate 	
		<ul style="list-style-type: none"> • evidence that different formats have been considered, linking to the equality impact assessment. 	

Domain 5. Applicability deals with the likely organisational, behavioural and cost implications of applying the guidance.		Suggestions for guidance content include:		
These criteria consider whether the guidance producer routinely consider:				
5.1 Publishing support tools to aid implementation of guidance	Is there information about the development of the implementation tools and validation procedures?	• an implementation section, or reference to where this can be found		
	Has the use of each piece of guidance been considered?	• tools and resources to facilitate application, for example:		
	For example if the guidance is designed for use at a hospital bedside are the support tools appropriate for this rather than producing the same support tools in all cases.	- guidance summary documents		
		- links to check lists, algorithms o		
		- links to how-to manuals		
		- solutions linked to barrier analysis (see criterion 5.2)		
		- outcome of pilots and lessons learned		
	• directions on how users can access tools and resources.			
5.2 Discussion of potential organisational and financial barriers in applying its recommendations	Does the guidance suggest specific strategies to overcoming the barriers?	• identification of the types of cost information that were considered (for example, economic evaluations, drug acquisition costs)		
	Were appropriate experts or intended users involved in finding and analysing cost/organisational information?	• the methods by which the cost information was sought (for example, a health economist was part of the guidance development panel, the use of health technology assessments for specific drugs)		
		• identification of the types of facilitators and barriers that were considered		
		• the methods by which information regarding the facilitators and barriers to implementing recommendations were sought (for example, feedback from key stakeholders, pilot testing of guidance before		

		widespread implementation)	
		<ul style="list-style-type: none"> • a description of, or information on the types of facilitators and barriers that emerged from the inquiry (for example, practitioners have the skills to deliver the recommended care, sufficient equipment is not available to ensure all eligible members of the population receive mammography). 	
5.3 Review criteria for monitoring and/or audit purposes within each product	Are a range of criteria provided including process measures, behavioural measures, and clinical, health or social care outcomes?	<ul style="list-style-type: none"> • identification of criteria to assess guidance implementation or adherence to recommendations 	
	Is a process in place for audit or monitoring of guidance implementation?	<ul style="list-style-type: none"> • the criteria for assessing impact of implementing the recommendations 	
	The process documents and/or the guidance should explain how the implementation of each piece of guidance will be assessed as applicable. This may be done by a physical audit, feedback or a data collection tool.	<ul style="list-style-type: none"> • advice on the frequency and interval of measurement 	
		<ul style="list-style-type: none"> • descriptions or operational definitions of how the criteria should be measured. 	

<p>Domain 6. Editorial Independence is concerned with the independence of the recommendations, acknowledgement of possible conflicts of interest, the credibility of the guidance in general and their recommendations in particular.</p> <p>These criteria consider whether the guidance producer:</p>		<p>Suggestions for guidance content include:</p>	
<p>6.1 Ensures editorial independence from the funding body</p>	<p>How did the guidance development group address potential influence from the funding body/people involved in developing the guidance?</p>	<ul style="list-style-type: none"> • a clear description of the authoring process used by the guidance producer 	
	<p>A fit for purpose policy on the authoring process is required. It should include an explicit statement that editorial independence has been achieved and explain how it considers that this has been done.</p>	<ul style="list-style-type: none"> • document the guideline development group to explain its independence from the funding body 	
		<ul style="list-style-type: none"> • a statement that bias is negated for people involved in the guidance development process and a description as to how this bias has been negated. 	
<p>6.2 Is transparent about the funding mechanisms for its guidance</p>	<p>Does the organisation have transparent funding arrangements for its guidance development? Are the processes used to gather and disperse funds been described in enough detail? The guidance producer should ensure that a full description of how the organisation receives and disburses its funding should be documented and auditable.</p>	<ul style="list-style-type: none"> • the name of the funding body or source of funding (or explicit statement of no funding) 	
		<ul style="list-style-type: none"> • a statement that the funding body did not influence the content of the guidance. 	
<p>6.3 Records and states any potential conflicts of interest of individuals involved in developing the recommendations</p>	<p>The NICE interpretation for this criterion details high-level requirements for a rigorous and robust conflicts of interest policy. However, it is important that a policy is appropriate to the type of guidance and can be used in practice. It is detrimental to have a policy that prevents individuals from taking part if they can make a valid contribution without compromising the integrity or safety of the recommendations. Some types of guidance will demand more comprehensive policies and will be applied more strictly, because of the overall risk of harm from bias.</p> <p>One way to evaluate this risk is to assess both the risk of bias</p>	<ul style="list-style-type: none"> • who declared an interest and what the interest was 	

	<p>occurring, and the potential harm that might arise from any bias in the recommendations. Factors increasing the risk of bias might include significant commercial implications or an emotive issue with vocal pressure groups; the potential for harm might be increased if the recommendations are widely used or deal with serious risks or side effects. Taking these two factors into account, a guidance product with a high risk of bias and the potential for harm, for example a technology appraisal, would need a very robust conflicts of interest policy. Such a policy might prohibit the involvement of individuals deemed to have any conflicts of interest except under controlled circumstances, whereas a policy for guidance with a lower potential for harm might allow greater inclusion or involvement. Ultimately a submitting organisation must be able to explain in the accreditation application why its policy is balanced and appropriate for the type of guidance it produces.</p>	<ul style="list-style-type: none"> • what action was taken for those declared interests 	
		<ul style="list-style-type: none"> • information on where the policy for declaring interest can be found 	
<p>6.4 Takes account of any potential for bias in the conclusions or recommendations of the guidance</p>	<p>What measures were taken to minimise the influence of competing interests on guidance development or formulation of the recommendations?</p> <p>Have all areas open to bias been considered and measures put in place to reduce or remove bias?</p>	<ul style="list-style-type: none"> • a description of the types of competing interests considered • the methods by which potential competing interests were sought . • a description of the competing interests • a description of how the competing interests influenced the guidance production process and development of recommendations 	

Appendix E: NICE accreditation – evidence to be submitted

Standard title.....

Evidence to be submitted to NICE:	Where it can be found
Scope etc	
Literature review	
Terms of reference for Task and Finish group	
List of contributors – steering group, Task and Finish groups, includes lay members and relevant organisations	
Declaration of interests for steering group and Task and Finish groups	
Terms of Reference for steering group	
Terms of Reference for Task and Finish groups I and II	
Consultation	
Consultation responses	
Implementation support/tools: FAQs, case studies, audit tool, Administration guidance	
NICE accreditation check list	
Professional standards guidance and frameworks process development manual	
Our process manual – supporting handbook to ‘Professional standards guidance and frameworks process development manual’	
Steering group meeting notes	

Task and Finish group meetings notes	
Website statistics	

About Us

The Royal Pharmaceutical Society (RPS) is the professional body for pharmacists and pharmacy in Great Britain. We represent all sectors and specialisms of pharmacy in Great Britain and we lead and support the development of the pharmacy profession to deliver excellence of care and service to patients and the public. This includes the advancement of science, practice, education and knowledge in pharmacy and the provision of professional standards and guidance to promote and deliver excellence. In addition, we promote the profession's policies and views to a range of external stakeholders in a number of different forums.

