Healthcare Improvement Scotland | SIGN Evidence-based clinical guidelines

Rapid guideline methodology

A guideline developer's handbook

Draft 1.0: April 2021

NHS SCOTLAND

Contents

1 Introduction

1.1 Aims of this manual

The principal aim of this manual is to provide a reference tool that may be used to develop a guideline rapidly at times of urgent need. The usual development process for full SIGN guidelines is set out in SIGN 50: A guideline developer's handbook,[1] and this manual outlines where rapid guideline development differs from that process.

A secondary aim of this manual is to provide clear information about the methods used to develop rapid guidelines, and to instil confidence that the potential biases inherent in guideline development have been addressed adequately, and that the recommendations are both internally and externally valid, and feasible for practice.

1.2 Review and updating of this manual

This manual was issued in April 2021 and it is intended that it should be a 'living' publication, continually revised to reflect future developments in rapid guideline methodology. For this reason the definitive version of this manual is that published on the SIGN website. Comments on either content or presentation of this document are welcome and should be sent to the SIGN Executive, email: sign@sign.ac.uk

2 Rapid guidelines in context

Clinical guidelines are systematically developed statements which assist in decision making about appropriate health care for specific clinical conditions.[2] Evidence-based clinical practice guidelines that use the most rigorous methods can help inform clinical and policy decisions.[3]

While full guidelines remain the gold standard in guideline development, rapid guidelines may be necessary to provide important evidence-based guidance in times of urgency and emergency.[4] Rapid guidelines may need to be developed within a few days, weeks or months, while full guidelines take around two years to complete. The development time of a rapid guideline depends on the urgency of the referral, the complexity of the topic, the number of questions to be addressed, and the likely volume of evidence.

2.1 Definitions

A review of rapid guideline methodologies set out definitions for rapid and full guidelines,[4] while the definitions for systematic and rapid reviews can be found in the Health Technology Appraisal glossary; an official collaboration between International Network of Agencies for Health Technology Assessment (INAHTA), Health Technology Assessment international (HTAi) and other partner organisations.

Rapid guideline	WHO	Guidelines completed within a 1- to 3-month timeframe to provide guidance in response to an emergency, urgent need or new evidence
Full guideline	WHO	Guidelines provide complete coverage (eg surveillance, diagnosis, public health, and clinical interventions) of a health topic or disease

Rapid review	htaglossary.net/rapid-review	A report that usually includes a review of the highest level of evidence or of recent evidence and that may restrict the literature to one or two databases. The report does not always critically appraise the quality of the evidence base or provide information on costs and financial impact.
Systematic review	htaglossary.net/systematic-review	A synthesis that collates all empirical evidence fitting prespecified eligibility criteria in order to answer a specific research question. The methods used are selected with a view to minimising bias, thus providing more reliable findings from which conclusions can be drawn and decisions made.

2.2 Implications of rapid guideline development

Increased methodological expectations translate into increased guideline development time and costs. Developing a rapid guideline requires balancing time, rigour and resources and may mean shortening, omitting or accelerating the processes and methods used for developing full guidelines and it must be recognised that this may lead to a less robust final guideline. Alternatively, for some topics, ensuring that the guideline is of higher quality may be more important and under these circumstances it will be necessary to allocate more resources, for example more group members, to development. Full guideline development as set out in SIGN 50 requires active participation from a multidisciplinary group of healthcare professionals, who volunteer to be involved in the process. To speed up the process, a review of rapid guideline methodologies suggests involving topic experts with prior experience of guideline or rapid guideline development or technical experts skilled in systematic reviewing or guideline methodology.[4] Since focused or rapid guidelines may not be developed by a truly multidisciplinary group, the risks associated with this should be recognised and steps taken to mitigated these risks, such as broadening peer review and consultation.

3 Topic selection

Producing evidence-based clinical practice guidelines is a time and resource intensive process. To make best use of these resources, guidelines should address a specific healthcare need and there should be an expectation that change in clinical practice is possible and desirable and, if the guidelines are followed, that there is potential to improve the quality of care and/or patient outcomes.[5,6]

3.1 Topic selection process

Any group or individual may propose a guideline topic to SIGN. Proposals are considered through the HIS: Evidence process. Details of how the directorate takes on new work can be found on the Healthcare Improvement Scotland website. This process uses set criteria to select and prioritise topics. Principles to guide the development of rapid guidelines while maintaining a standardised, rigorous and transparent process have been set out to help with the development of guidelines in response to urgent situations.[4] The principles relating to priority setting state that the rationale for the need for development of a rapid guideline, as opposed to a full guideline, should be clearly defined.

Requests for rapid guidelines are considered as part of this process. If at the filter stage, in addition to the standard screening criteria, the topic meets the following additional criteria,[4] it will be developed as a rapid guideline.

3.2 Applicability criteria

Does the topic relate to:

- emergent and dangerous situations (eg epidemic of an infectious disease)
- new, urgent and recommendation-changing evidence about:
    - patient safety
    - efficacy that could change current knowledge or practice
    - cost-effectiveness.

4 Engagement

Guideline development groups should be multidisciplinary in their composition, with representation from all relevant professional groups, and participation of patients, carers and appropriate voluntary organisations.[7,8] This facilitates ownership of both the guideline development process and the resulting recommendations (see SIGN 50, section 2). When developing rapid guidelines, early engagement with potential group members, peer reviewers, editorial group and other stakeholders is essential to encourage active participation throughout the development process.[4] To help this process, roles and responsibilities, specific to rapid guideline development, for group members, peer and editorial reviewers are in development.

The potential contribution of patient representatives is recognised by SIGN, as are the difficulties in making that contribution meaningful (see SIGN 50, section 11).[9] People with lived experience are recruited according to our usual process. If the circumstances of rapid guideline development make this difficult we will approach patient organisations to provide representatives so that we get a wide range of views on the guideline topic.

5 Methodology

5.1 Core principles

SIGN guidelines are developed using an explicit methodology based on three core principles:

- Development is carried out by multidisciplinary, nationally representative groups.
- A systematic review is conducted to identify and critically appraise the evidence.
- Recommendations are explicitly linked to the supporting evidence.

When developing a rapid guideline, it may not be possible to carry out a systematic review and in these circumstances a rapid review will be more appropriate. Rapid reviews of the evidence to support rapid guidelines are carried out according to HIS: Evidence methodology (available on request from hisevidence@nhs.scot).

5.2 Overview of key components of methodology

Taking account of the principles guiding the development of rapid guidelines,[4] Table 1, shows where our rapid guideline development process differs from our full guideline process. [1] Any deviation from the rapid guideline methodology during development will be included as an Annex to the published rapid guideline.

Table 1: Overview of the key differences between full and rapid guideline development

Guideline development processes	Full guideline	Rapid guideline
Topic scoping	Discussion is held with the topic proposers to identify the key issues which require to be addressed in the guideline. A broad scoping search is conducted to ascertain the feasibility of producing evidence-based guidance on the topic. Issues of importance to patients and carers are sought through surveys, focus groups and a literature search. The scope and an early draft of the key questions (usually around 20) are made available for open consultation prior to the first guideline development group meeting.	Discussion is held with the topic proposers to identify the key issues which require to be addressed in the guideline. The scope is focused on key issues that need to be addressed urgently. To ensure the guideline is clinically meaningful, the number of key questions will vary and depend on the topic.

Multidisciplinary guideline development group	A multidisciplinary team of people with relevant clinical expertise is recruited to form a guideline development group (GDG). Declarations of interests are submitted by all GDG members and any potential conflicts of interest are addressed.	A multidisciplinary team of people with relevant clinical expertise is recruited to form a guideline development group (GDG). The number and range of members may be limited due to the scope of the guideline and time constraints. Declarations of interests are submitted by all GDG members and any potential conflicts of interest are addressed.
Patient/carer involvement	A minimum of two patient or carer representatives are recruited to participate in the GDG. Further patients and carers are invited to peer review the consultation draft of the guideline.	Patient or carer representatives, or representatives from patient organisations are invited to join the guideline development group. Patient and carer representatives are invited to peer review the consultation draft of the guideline.
Defining key questions	Key question are set using the People; Intervention; Comparison; Outcome (PICO) format	Key question are set using the People; Intervention; Comparison; Outcome (PICO) format. However, there may be a lack of evidence for comparisons and/or relevant outcomes in novel situations.
Literature searching	A systematic literature search is conducted for each key question, across relevant sources. A search is conducted for relevant economic studies. Searches are conducted by an Information Specialist. The search strategy and sources of evidence are documented in the guideline.	A systematic literature search is conducted for each key question, across relevant sources, but the date range may be shorter, the range of sources smaller and the inclusion/exclusion criteria more focused than for a full guideline. Searches are conducted by a Health Services Researcher and/or an Information Specialist.

Study selection and critical appraisal	After an initial sift by an Information Specialist, studies are selected by at least two members of the guideline development group. Selected studies are critically appraised by two Information Specialists and the clinical relevance of the studies is checked by GDG members. The evidence is summarised in evidence tables.	Studies are selected by a Health Services Researcher. Depending on the volume and/or the nature of evidence identified, studies are either critically appraised or a general observation is made about the robustness of the overall evidence base (eg if it includes preprints then a caveat is given that the quality of the evidence is undetermined).
Developing evidence statements and recommendations	GDG members complete considered judgement forms for each key question. The recommendations take into account: • The strength of the evidence base, and how applicable it is to the Scottish setting. • The balance of benefits over harms, including cost effectiveness, where appropriate • The feasibility of implementation, including resource implications. • Acceptability to patients. Information provided in the considered judgement form is used to produce the evidence statement presented in the guideline. The draft guideline is edited by the GDG and SIGN Programme Manager.	A Health Service Researcher produces a rapid review report of the evidence, including the results and strength of the evidence base and the balance of benefits over harms. The GDG meet to produce recommendations, based on the evidence review. Where evidence is lacking, a statement may be made that no recommendation can be made, or, if there is a need, a recommendation can be made using the informal consensus of the GDG. All recommendations should take into account: • The strength of the evidence base, and how applicable it is to the Scottish setting. • The balance of benefits over harms • The feasibility of implementation, including likely resource implications. • Acceptability to patients.

Consultation and peer review	The draft guideline is posted on the SIGN website for one month for open consultation. An open meeting is held to present and discuss the draft recommendations. At the same time as open consultation, targeted peer reviewers are invited to provide feedback on the interpretation of the evidence and feasibility of the recommendations. All feedback is addressed by the GDG and actions recorded in the consultation report.	Targeted peer reviewers (including patient and carer reviewers) are invited to provide feedback on the interpretation of the evidence and feasibility and appropriateness of the recommendations. All feedback is addressed by the GDG and actions recorded in the consultation report.
Editorial	The Editorial Group ensures that each point raised at consultation has been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised.	The Editorial Group ensures that each point raised at consultation has been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised.
Publication and dissemination	The guideline is published on the SIGN website and disseminated across NHSScotland.	The guideline is published on the SIGN website and disseminated across NHSScotland.
Review and update	The guideline is considered for review three years after publication. If not updated, the guideline is withdrawn from the SIGN website 10 years after publication.	A flexible approach to updating is used to ensure rapidly emerging evidence can be incorporated. The frequency of update is agreed and stated at publication. The option to withdraw the guideline is considered.

5.3 Updating a rapid guideline

As clinical practice continues to develop, guidelines inevitably fall behind current evidence for best practice. They must therefore be kept under review and updated when necessary.[10]

When rapid guidelines are developed in response to new and emerging situations, for example diseases or interventions, it is necessary to review and update them in response to new evidence and emerging issues. This is likely to mean that the guideline will be updated more frequently than a full guideline and the timescales for updating will be dependent on the nature of the situation and topic of the guideline.

5.3.1 Scoping for the need to update a rapid guideline

Timescales for review and updating are agreed at the time of publication and clearly stated in the rapid guideline.

All comments received on published rapid guidelines, or information on important new evidence in the field, or safety alerts, or evidence of impacts on equality groups are considered, either for immediate response or for more detailed consideration on review of the guideline.

5.3.2 Criteria for updating a rapid guideline

New evidence, data or information:

- that would significantly change a recommendation; either strengthen, for example from conditional to strong recommendation, or reverse it
- that would warrant a new KQ to cover new interventions, for example add another treatment option
- about patient safety, for example side effects from real-time data
- about patient preferences or equity.

New research that adds to the body of evidence supporting a recommendation without changing it would not warrant an update.

5.4 Withdrawing a rapid guideline

From time to time it is necessary to consider withdrawing guidelines which are outdated or no longer relevant. This is especially important for rapid guidelines developed under emergency or rapidly-changing conditions, or when there is an evolving or rapidly-emerging evidence base.

5.4.1 Criteria for withdrawing a guideline

Guidelines may be withdrawn for any of the following reasons:

- contextual changes render the guideline unnecessary
- superseded by a more recent or more comprehensive guideline
- evidence that the guideline is complied with by NHSScotland, and has become accepted practice
- emergence of new treatments or preventive measures that render the guideline irrelevant.

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6 References

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