



**Health  
Information  
and Quality  
Authority**

An tÚdarás Um Fhaisnéis  
agus Cáilíocht Sláinte

Health Information  
and Standards

# Evidence synthesis process

Methods in the development of National  
Standards, Guidance and Recommendations for  
the Irish health and social care sector

September 20 18

*Safer Better Care*

Date	Version	Change
September 2018	1.0	First draft

## About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent authority established to drive high-quality and safe care for people using our health and social care services in Ireland. HIQA's role is to develop standards, inspect and review health and social care services and support informed decisions on how services are delivered.

HIQA aims to safeguard people and improve the safety and quality of health and social care services across its full range of functions.

HIQA's mandate to date extends across a specified range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children and Youth Affairs, HIQA has statutory responsibility for:

- **Setting Standards for Health and Social Services** — Developing person-centred standards, based on evidence and best international practice, for health and social care services in Ireland.
- **Regulation** — Registering and inspecting designated centres.
- **Monitoring Children's Services** — Monitoring and inspecting children's social services.
- **Monitoring Healthcare Safety and Quality** — Monitoring the safety and quality of health services and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health Technology Assessment** — Providing advice that enables the best outcome for people who use our health service and the best use of resources by evaluating the clinical effectiveness and cost-effectiveness of drugs, equipment, diagnostic techniques and health promotion and protection activities.
- **Health Information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

# Contents

<b>1</b>	<b>Introduction .....</b>	<b>6</b>
<b>3</b>	<b>Evidence synthesis process .....</b>	<b>8</b>
3.1	Process Outline.....	8
<b>4</b>	<b>Strengths and limitations of the process .....</b>	<b>13</b>
<b>5</b>	<b>Summary .....</b>	<b>15</b>
	<b>References .....</b>	<b>16</b>

## Key terms used in this document

**Agreement chain:** An agreement chain is where one researcher reviews articles for initial inclusion. A second researcher then reviews only the articles the first researcher is unsure whether or not to include. A third researcher then reviews only the articles that are still contentious. This chain continues until a decision has been made on all articles.

**Background document:** A background document contains a review of the national and international literature and evidence base undertaken and used to inform the drafting of standards and guidance. It is published as part of the process of developing standards and guidance.

**Search protocol:** A search protocol is information on how a search for relevant evidence will be conducted. It is specific for each search and written with enough detail and clarity that it can be reproduced.

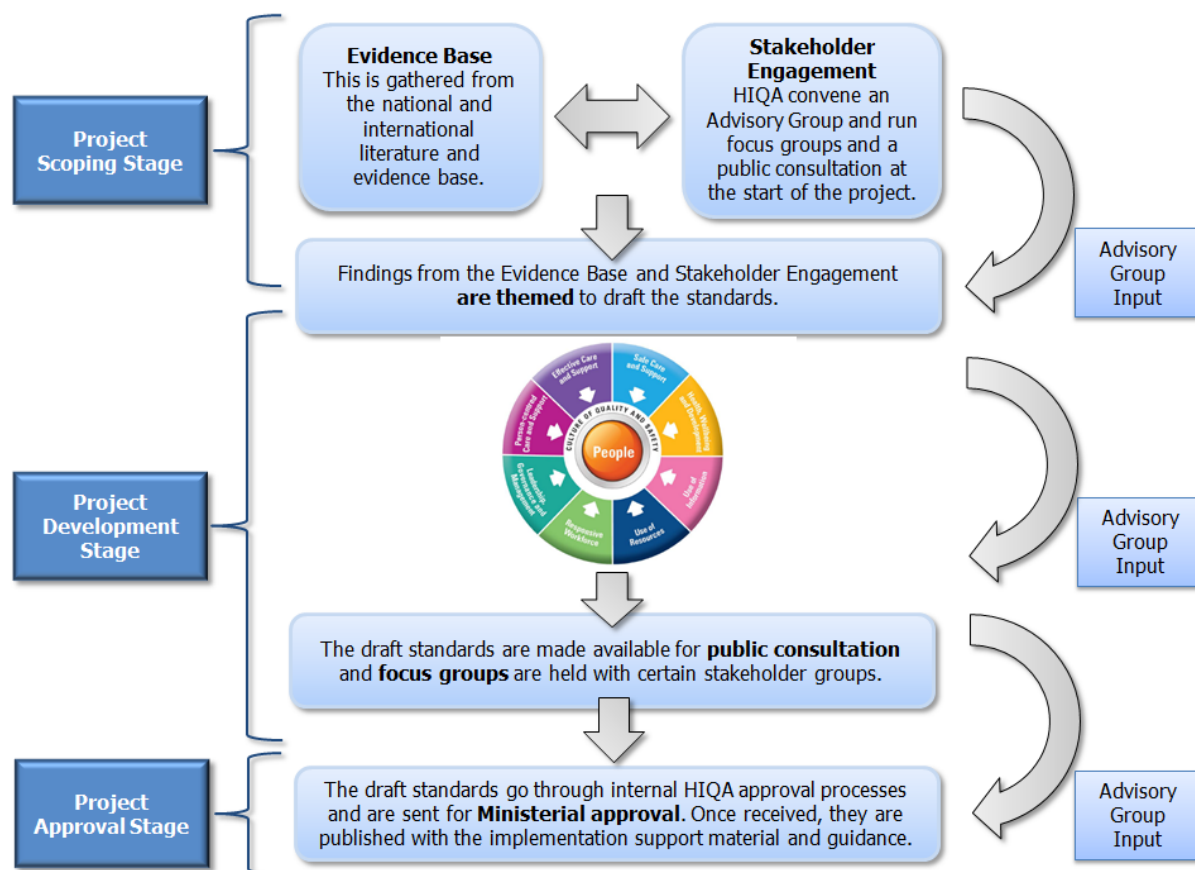
**Stakeholder:** A stakeholder is a group, person or expert who is significantly involved with, interested in or affected by the topic under discussion. It includes organisations and individuals external to HIQA.

**Subject matter expert:** An individual with in depth knowledge of the area within which the standards or guidance are being developed, or of standards or guidance themselves. They may be internal or external to HIQA.

**Targeted web browser searches:** These are targeted searches for key articles such as searches for legislation, policy, pre-existing standards or guidance. The decision is made before the search is conducted as to what article specifically is needed and only that article is retrieved.

## 1 Introduction

HIQA's Health Information and Standards Directorate uses an established process to develop national standards for health and social care. This process was developed following a review of national and international evidence, engagement with national and international experts and applying HIQA's knowledge and experience of the health and social care context. The following figure provides an overview of the standards development process. Guidance and recommendations are also developed using a similar process.



When developing standards, guidance and recommendation, the Health, Information and Standards Directorate undertakes a detailed synthesis and review of existing literature and evidence. This review describes the Irish and international context against which the work is being conducted, and ensures that the work is informed by quality evidence and reflects international best practice.

This document details the process by which an evidence synthesis is conducted.

This document is published for transparency and as a resource for others conducting reviews for the development of standards, guidance, recommendations or in other health services research.

## 2 Purpose of evidence synthesis

Evidence syntheses are undertaken to collect, appraise and summarise the available information about a topic. They are usually employed to underpin decision making or the development of policy or standards or other similar activities to ensure that they are based on evidence and not on opinion. There are many different methods of conducting an evidence synthesis but to be considered high quality, the method needs to be systematic and explicit.

HIQA's Health Information and Standards Directorate uses a defined evidence synthesis process to develop the evidence base from which standards, guidance and recommendations are then developed. It involves clearly documenting and describe the steps taken, including justifying the decisions made at each stage. The researchers apply the process to allow them

- Formulate a clear research question
- Identify relevant art
- Appraise the quality
- Interpret the findings

Evidence-Synthesis-Process-For-development-of-standards-and-guidance

The process applied is standardis low it to be adapted to various standards, guidance and recomm ken by the Health Information and Standards Directorate. It aims to be systematic and traceable, and therefore reproducible and transparent. It also aims to accommodate short timelines without sacrificing scientific rigour.

The resulting summary document, referred to as the Background Document, is as such a clearly justified, unbiased and high quality summary of the relevant literature.

### **3 Evidence synthesis process**

The evidence synthesis process employed by the Health Information and Standards Directorate is divided into two phases.

**Phase 1** is a scoping review. This is a preliminary assessment of the potential size and scope of the existing literature and evidence which characterises the literature with relevance to time, location, source, and origin. It is conducted to inform the systematic review and the development of a tailored research question, search terms and search limiters. The scoping review is undertaken in consultation with subject matter experts to help steer the search using their in depth knowledge of the topic. The aim is to identify relevant databases and websites, and agree on targeted web browser searches. The emphasis of the search is on relevance rather than comprehensiveness, and there is a predetermined amount of time allocated to its completion.

**Phase 2** has three main steps:

1. systematic search of identified databases, identified websites and targeted web browser searches
2. article screening
3. quality appraisal.

A report describing and critically evaluating the articles is prepared to complete the process.

#### **3.1 Process Outline**

**Phase 1:** Scoping review

- As a project team, a time limit for the scoping review is agreed on and subject matter experts are identified as part of the stakeholder engagement planning.
- Liaising with subject matter experts, relevant grey\* and academic databases, topic specific websites, standards and guidance specific websites and targeted web browser searches are identified and search terms, population and contexts of interest developed.
- Identified search databases, websites and targeted web browser searches are documented.

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\* Grey literature refers to information and research that is not commercially published. Some examples of grey literature include: newsletters, government reports and policy statement.



- Iterative searches<sup>†</sup> and continued liaison with subject matter experts are used to refine included databases, websites, search terms, population and contexts of interests.
- Search returns are catalogued by type of article. The extent of the literature is summarised including comments on attributes such as quality, publication date, geography and origin that will be helpful in setting the search criteria and limiters for Phase 2.
- The results are used to predict timelines for completion of Phase 2 and are included as an appendix in the final published report of the Phase 2 findings.

## Phase 2: Systematic search and literature review

- Informed by the scoping review the project team
  - develop a research question in line with SPICE/PICo/PICOS as appropriate.<sup>‡</sup>
  - develop a search strategy to include grey and academic literature databases, key word searches of identified websites and targeted web browser searches.
- Search terms and search limiters are defined. Search limiters are derived from the research question (for example, context, population, settings). To ensure relevance, country of origin (for example, to reflect similarities of healthcare system) or date of publication (for example, to reflect significant change in legislation) or article quality (grey literature only) can also be considered as search limiters.
- If the scoping review has unearthed a review that answers the research question that has been developed, the existing review is assessed for quality. If it is appropriate the review is adopted and updated.
- The project team agree and document the search protocol detailing the phrasing used for each different databases, the key word searches used for different websites and the targeted web browser searches. This search

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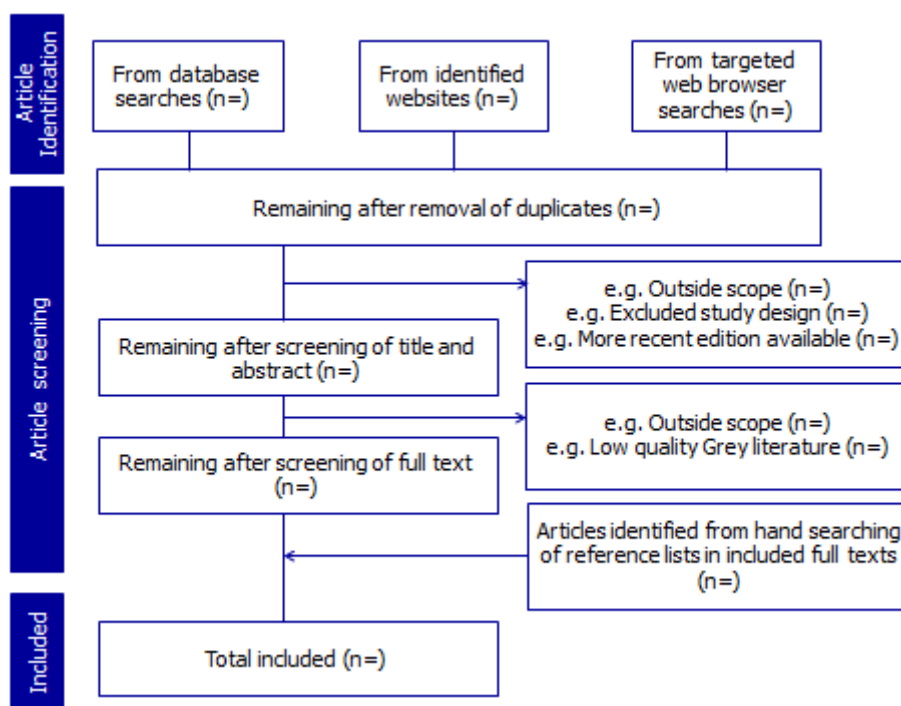
<sup>†</sup> Iterative searching refers to repeated searches. The researcher learns from the results of each search and creates a more refined and informed subsequent version.

<sup>‡</sup> Examples of frameworks for developing research questions: SPICE (Setting, Perspective, Intervention or exposure or interest, Comparison, Evaluation); PICo (Population or problem, Interest, Context); PICO/PICOS (Population or problem, Intervention or exposure, Comparison, Outcome, Study type). One framework is used per project and is chosen based on relevance to the topic.

protocol is included with the final review report, with enough detail to allow it to be reproduced.

- The search is conducted. Search returns are documented per website and database along with the number of articles extracted through targeted web browser searches.
- Articles are reviewed for inclusion by screening abstracts, forwards and content lists and using a researcher agreement chain to reach consensus on included articles.
- Reasons for exclusion for example, duplication, outside scope, new edition available, are documented.
- Full texts are reviewed. All possible options to retrieve the full text are exhausted and, again, a researcher agreement chain is used to reach consensus on articles to include.
- Reference lists of included articles are hand searched for other articles to include.
- The final set of included articles and decisions are documented using a flow chart (see Figure 1).

**Figure 1. Flow chart for inclusion of articles**



- All included articles are stored using a reference manager.
- Data to be extracted are decided on and a template is created. The template accounts for likely differences in relevant fields dependant on the source of data, that is to say, grey literature versus traditional studies.
- Data extraction is completed.
- A quality assessment is undertaken using AACODS, GRADE and CASP as appropriate for the included articles.<sup>1-3</sup>
- A report is compiled with all elements of a reporting checklist (see Table 1) included. This is written thematically and provides a brief description and a critical appraisal of each article. This report is published as a Background Document. Details of the quality appraisal are not published but reference to the quality of each article is included in the critical appraisal. The results of the scoping review are also included as an appendix.
- Once published, the report is placed in an indexed repository<sup>§</sup>.

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<sup>§</sup> An indexed repository is an online catalogued archive. Placing documents in an indexed repository makes them easier for people to find as they are catalogued by key words and by publisher and can be retrieved using search engines without the need to know the full name of the document.

**Table 1 Reporting checklist**

Topic	#	Checklist item	Reported (✓)
Title	1	Identify as a systematic search and literature review.	
Summary	2	Provide a summary including, as applicable: background; overarching aims; research questions; scope; brief description of methods; findings; study specific limitations and or summary of quality appraisal; conclusions and implications or next steps.	
Rationale	3	Describe the rationale and or remit for the review.	
Objectives	4	Provide an explicit statement of questions being addressed (utilise PICO/PICo/SPICE).	
<b>Methods</b>			
Protocol	5	Give a brief overview of the search protocol.	
Search limiters	6	Specify search limiters and justify their inclusion.	
Sources	7	Describe all information sources. Include the date last searched.	
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated. Present key word searches for websites. Present targeted web browser searches.	
Article selection	9	Present the screening process (chain agreement, in duplicate). Include detail where quality is used to exclude grey literature articles.	
Data extraction process	10	Describe method of data extraction from reports (for example, piloted forms, independently, in duplicate) and any steps taken to obtain and confirm data from investigators.	
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	
Quality of data	12	Describe methods used for assessing quality of articles.	
<b>Narrative</b>			
Article selection	13	Give numbers of articles screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	
Article characteristics	14	For each article, present characteristics for which data were extracted (for example, study size, PICOS, organisation) and provide citation.	
Quality of data	15	Include a quality appraisal at individual study or theme level.	
Summary of evidence	16	Summarise the main findings including the strength of evidence; consider their relevance to key groups (e.g. healthcare providers).	
Limitations	17	Discuss limitations at article level (for example, quality), and at review-level (for example, incomplete retrieval, reporting bias). Reference process for further discussion of limitations.	
Conclusions	18	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	
<b>Contributions and funding</b>			
Funding	19	Describe any sources of funding for the review and other support (for example, supply of data); role of funders for the review.	
Contributions	20	Describe demographics and role of any stakeholders involved in the review. List stakeholders if appropriate.	
<i>Adapted from PRISMA reporting checklist. <sup>4</sup></i>			

## 4 Strengths and limitations of the process

All study designs have strengths and limitations. In this section, the strengths and limitations of this evidence synthesis process are acknowledged and the implications they have on the reviews produced are discussed.

One limitation of this evidence synthesis process is the risk that relevant articles may be omitted. While the focus of the review is not on exhaustiveness, efforts are made to reduce this risk by utilising multiple sources to identify articles. This includes: subject matter expert knowledge, grey and academic databases, websites and targeted web browser searches. The risk is further reduced by utilising a three pronged approach which includes scoping, carrying out systematic searching and undertaking hand searching of reference lists.

Another limitation of the process is the application of search limiters. Search limiters are necessary to ensure the review can be completed; however, they may skew how information is represented. One way this is countered is by involving subject matter experts in the refinement of the research question, search terms and search limiters. This promotes informed decision-making and capture of relevant data which is in keeping with the aim of the review.

Best practice in the field of evidence synthesis is for two researchers to independently review articles and to screen and extract data in duplicate. This evidence synthesis process uses a single researcher to review articles for screening and for data extraction. In practice this could be one researcher evaluating all articles, or two or more researchers evaluating a portion each. This facilitates the short timelines associated with the development of standards, guidance and recommendations. However, it is a source of potential human error and or bias. This source of potential error is reduced by utilising the three pronged approach mentioned above and having an iterative nature to the scoping phase. As this source cannot be fully eliminated, findings are interpreted in this context.

There are both strengths and limitations to using quality appraisal in the inclusion criteria for grey literature. As there are no formal cut points for removing low quality articles, the point at which articles are excluded is open to researcher interpretation. While excluding articles based on quality is not best practice for reviews of more traditional studies and literature (that is to say, black literature\*\*), the sheer quantity and variety of grey literature requires such a filter to ensure the review is

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\*\* Black literature refers to the academic literature and studies that have been published through a review process by a commercial publisher. Some examples of black literature include: publication of meta-analyses, trials, surveys, scientific studies.

manageable. It is therefore necessary to set a filter while acknowledging the potential for bias. While black literature is peer reviewed, grey literature does not undergo peer review. As such, this filter can also be viewed as an equalising step.

In contrast, using quality appraisal in writing the final report facilitates critical appraisal and allows the discussion to reflect the quality of underlying evidence. This is a key strength of the process as customarily reviews of grey literature have not emphasised quality appraisal.

A particular strength of this process is the interaction between researchers whose knowledge base is the development of standards, guidance recommendations, and subject matter experts. This interplay, along with the iterative and learning nature of the scoping review, adds to the robustness of the decision-making in developing the conceptual framework<sup>††</sup> for the systematic search and literature review and, ultimately, the final set of included articles that form the evidence base for the standards, guidance or recommendations.

A further strength of this process is the requirement for detailed documentation throughout and *a priori*<sup>‡‡</sup> decision-making before undertaking Phase 2, the systematic search and literature review. This minimises the potential for research bias and encourages transparency.

Finally, the process has a range of other characteristics that add to its robustness. These include: no language, time or geographic limiters unless justified explicitly, and the requirement of all efforts to be made to acquire a copy of the full text where inclusion is indicated.

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<sup>††</sup> Conceptual framework refers to the researchers' knowledge of the subject of research. It maps out the actions required in the study given their understanding of and observations on the subject.

<sup>‡‡</sup> In this context *a priori* is used to mean conceived beforehand.

## 5 Summary

The breadth and nature of the evidence base required to underpin the development of standards and guidance makes it incompatible with the methodologies and reporting guidelines of the gold standard in evidence synthesis, namely systematic reviews and meta-analyses. Nonetheless, it is important to have a rigorous, transparent methodology to ensure a robust output. The evidence synthesis process described in this document was designed in keeping with the scientific principle that studies should be, first and foremost, fit for purpose.

The difficulties of evidence synthesis for the development of standards, guidance and recommendations are:

- the broad and varied evidence base, largely comprised of grey literature
- the pressing demand for the development of standards, guidance and recommendations
- the initial absence of a conceptual framework.

As such, the process was designed to align with the principles of carrying out a systematic review for aggregating literature<sup>4</sup> and, the principles of configuring review practices for determination of the conceptual framework.<sup>5</sup>

The process values relevance over comprehensiveness in terms of included articles, and encompasses justified scope limiters and search curtailment in line with the aims of the review in order to facilitate timeliness and applicability. It is designed to be systematic, traceable, reproducible and transparent, scientifically rigorous and robust. Particular attention has been paid to areas of quality appraisal and potential researcher bias. Steps to mitigate error and bias are included. Furthermore, the limitations of the process are acknowledged to ensure any evidence base resulting from this process is appraised and interpreted in light of them.

The process has been published to promote transparency of the scientific methodologies employed by HIQA in the development of standards, guidance and recommendations under the Health Information and Standards Directorate. It is also published as an open resource for others conducting reviews for health services projects.

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