SCOTTISH HEALTH PROTECTION NETWORK
Promoting and Supporting Good Practice

Scottish Health Protection Network Guidance Group (SHPN-GG)

(Version 3.0 FINAL)

Protocol for the Rapid Development of Guidance

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1. Summary

Systematic reviews, with critical appraisal of the literature, remain the gold standard in finding evidence for health protection guidance; however the development of evidence-based guidelines (EBG) through the systematic review process is resource intensive. There are situations where a rapid review would be preferable, for example, for many reactive questions in public health and health protection, and where full systematic reviews would not be suitable given the short timescales involved. In this situation, condensed versions of the full systematic review or 'rapid reviews', where the review methodology is shortened in one or several ways and is more targeted, may be more appropriate.

While there are universally agreed methodologies for conducting full systematic literature reviews, the same does not exist for rapid reviews, largely due to the variety of approaches that can be employed to make a review more rapid (i.e. there is more than one approach). The term, 'rapid review' may mean very different things to different individuals or groups and in different contexts in terms of timescale, approach, rigorousness, scope etc.

This protocol provides a recommended good practice guide to the rapid development of guidance. Guidance produced by this method does not require review and sign off by the SHPN Guidance Group.

2. Background

Guidance can be produced internally under the badge of SHPN, or externally by recognised public health organisations outside Scotland (e.g. Public Health England [PHE], the European Centre for Disease Control [ECDC], the US Center for Disease Control [CDC], the World Health Organisation [WHO]) and approved for use by the SHPN.

The '*SHPN Framework for Health Protection Guidance Development'* outlines the categorisation and methods employed by the SHPN, encompassing:

- The development of new guidance;
- Reviewing and updating existing SHPN guidance; and
- Reviewing guidance produced externally to SHPN, for acceptability of use in Scotland.

Within this Framework, the SHPN-Guidance Group (SHPN-GG) has outlined two categories of health protection guidance in Scotland:

- Evidence Based Guidelines (EBG) - type A and A*
- Good Practice Guidance (GPG).

The SHPN has also produced four methodology documents to promote and support consistent implementation of the Framework:

- Evidence Based Guideline Methodology
- Good Practice Guidance Methodology
- Guidance Review and Update Methodology
- Review of External Guidance for Acceptability of Use in Scotland Methodology

Two further protocols have also been produced by the network:

- Protocol for the Rapid Development of Guidance
- Protocol for the Development of Consensus Based Recommendations

Formerly, SHPN had defined two additional categories of guidance (*Rapidly Developed Guidance (RDG) and Consensus Based Guidance (CBG).* Following a review, the SHPN concluded that these did not merit being considered as distinct types of SHPN guidance, as they referred primarily to protocols used to produce guidance documents. These categories have therefore been redefined as SHPN endorsed protocols to support guidance development.

All guidance categories and methodologies are discussed in the '*SHPN Framework for Health Protection Guidance Development'*.

Evidence based guidelines (EBG), where evidence and recommendations are generated from systematic literature reviews, are the preferred type of guidance *(see SHPN Evidence Based Guideline Methodology*). However, it is acknowledged that scientific evidence is not always available and public health organisations often face having to make decisions in situations where there is insufficient (or even conflicting) evidence and/or where the context plays an essential role and, therefore, needs to be considered. For this reason, the SHPN has outlined two different categories of guidance (Figure 2) that can be produced *de novo*: Evidence Based Guidelines (Guidance Category A/A*) and Good Practice Guidance (Guidance Category B). Please see the *'SHPN Framework for Health Protection Guidance Development'* for details of all guidance categories and methodologies.

3. Aims

(1) To describe how full systematic reviews can be shortened to produce a more rapid protocol, and (2) to describe a methodology to rapidly produce guidance using a rapid review of the literature.

Summary of Key Points

- Evidence is required to inform guidance.
- A systematic literature review and critical appraisal of the literature can provide evidence, however it is generally very resource intensive to conduct those with completeness.
- In certain situations, a targeted approach or 'rapid review' may be more appropriate.
- The term 'rapid review' can refer to a range of different methodologies but essentially it represents a condensed/shortened version of the full systematic review methodology (shortened by e.g. timescale, approach, rigorousness, scope etc.).
- The methodological framework outlined here is flexible so that it can be modified to meet the needs of a situation.
- The methods used should always be clearly stated.

4. Part 1 - Comparing rapid reviews to full systematic reviews

Rapid reviews are a form of knowledge synthesis in which components of the systematic review process are simplified or omitted to produce information in a timely manner[1]. While rapid reviews can be conducted in a systematic way, they are considered less resource intensive than full systematic reviews but are potentially at risk of bias[1-3].

There are several approaches that can be taken to conduct a rapid review and thus shorten or condense the full systematic review protocol, e.g. by restricting timescales, limiting number of search engines used, limiting number of reviewers, reducing rigor of or omitting critical appraisal step etc. Table 1 lists methodological criteria or steps in the process, the ideal approach of the full systematic review and examples of where it can be shortened to produce to make a more rapid approach. The term 'rapid review' is flexible and a methodology wouldn't necessarily need to adopt every criterion listed to be defined as rapid. To be defined as a rapid review, the methodology will represent a departure from the full systematic review by shortening, limiting or restricting by one or more of the methodological criteria and the result will be the rapid production of robust evidence to support development of recommendations.

Ticco *et al*[2] conducted a study to gather information on the preferred method of rapid review using a modified Delphi approach to reach a consensus among 113 stakeholders (including researchers, policy-makers, industry, journal editors, and healthcare providers). The preferred method was considered to be the most feasible, timely, and having a low perceived risk of bias. The stakeholders ranked the following method as preferred: a literature search limited by date and language; study selection by one reviewer only; and data abstraction and quality appraisal conducted by one reviewer and verified by a second reviewer. Similarly, Watt *et al*[3] assessed 36 rapid review protocols and suggested that to limit time taken to complete a review, important steps involved restricted research questions and truncated search strategies.

There is a risk of bias with rapid reviews as a consequence of streamlining the systematic review process. There must be acknowledgment of this and caution in interpretation findings[1-3]. Therefore, it is crucial to emphasise the importance of transparency in describing methodologies and reporting findings so that the reader is able to understand where shortcuts were taken [2;3].

Table 1: A comparison between rapid reviews and full systematic reviews.
The table highlights suggested ways in which full systematic reviews can be modified to make the procedure more rapid. Information is adapted from Ticco *et al*[2] and Khangura *et al*[1]. The steps that would ideally be fulfilled in a full systematic review can be shortened, restricted or limited in any of the listed ways so that a review can be conducted more rapidly.

#	Criteria	Rapid review approach	Systematic review approach
1	Timeframe	≤ 5 weeks[1] ≤6 months[2]	6 months to 2 years
2	Question	May be narrow in scope	May be narrow or broad
3	Number of search engines / databases	Restricted number of search engines	Often involves more than one search engine to maximum coverage of data
4	Sources - published articles, grey literature	Limited e.g. to published literature only	Often includes published literature and grey literature
5	Search date limits	Restricted e.g. to cover most recent years	Often covers longer or undefined time frame
6	Search language	Restricted e.g. to English only	Often unlimited

7	Selection strategies	Criterion-based and explicit, complete transparency	Criterion-based and explicit, complete transparency
8	Screening of literature - Title only, Title/abstract, full-text screening	Restricted e.g. to Title only or Title/abstract	Often Title/abstract, full-text screening
9	Number of reviewers performing screening of literature	Restricted, e.g. to one, although some examples of a large number of reviewers to speed up review process	Usually more than one reviewer to cross-check that method is reproducible and all articles have been captured
10	Number of reviewers carrying out data abstraction	Often restricted to one	Often more than one
11	Data appraisal / risk of bias assessment	Not always performed or fully performed, carried out by 1 person only.	Carried out by a second reviewer
12	Synthesis	May be descriptive summary of the data	Qualitative summary often with meta-analysis
13	Inferences	Can be limited/cautious interpretation of the findings, risk of bias	Evidence-based

5. Part 2 – Protocol for Rapid Development of Guidance

It is important that the protocol described below is considered a suggested framework that remains flexible and can be modified to meet the needs of a particular context (e.g. in an emergency situation with restricted timeframes, it may be appropriate to conduct a high level literature search only, and not to grade recommendations etc). Figure 1 is a flowchart of a suggested protocol, the steps of which are described below.

5.1 *Topic selection and scoping, and formation of guidance development group (GDG), if appropriate*

A decision should be made as to whether the guidance document is to be produced by (a) a SHPN-TG, i.e. in-house, or by (b) a specially-formed guidance development group (GDG). This decision is based on the availability of resources and necessary timescales.

5.2 *Identify key questions to be addressed*

Key questions focus on areas where recommendations are required and guide literature reviews (e.g., what is the evidence for/against antibiotic use in the treatment of HUS?) The aim is to fully answer those questions and convert results from a review into recommendations. Key questions are agreed in advance, i.e. by the GDG or SHPN-TG.

5.3 *Preliminary search and appraisal*

5.3.1 Preliminary literature search

This step is encouraged but may not be appropriate if timescales for guidance production are partixularly short. An initial high level literature search may be conducted to identify any key resources including:

research papers, legislation, mandatory guidance or recent guidelines. This search will be conducted by a healthcare scientist (HCS) and may be directed by experts in the field. The search may identify a recent high quality review article which can be invaluable in identifying further literature and may also help to validate search strategy (i.e. if rapid literature search with restricted timescale and limited search terms etc successfully identified relevant articles as described in high quality review, the methods are thus validated).

This high level search will enable:

i. A gap analysis to be carried out (i.e. to find where information is missing),
ii. Rapid identification of areas where new evidence is available,
iii. Evidence which conflicts with the existing recommendations or key questions.

And it might:

iv. Provide sufficient evidence to answer key questions,
v. Identify a high quality review article that can validate search strategy.

5.3.2 Review of results

Information identified during the preliminary literature search should be extracted from sources and collated (see Appendix 1 as an example). Collating evidence in such tables (one per key question) enables the identification and comparison of information, and also identifies areas where there are conflicting recommendations or gaps in the evidence. This informs the decision to conduct further literature reviews (i.e. whether a targeted literature review is needed, or a full systematic literature review).

If time allows, an appraisal the preliminary literature search should be conducted before moving on to the targeted literature review. Scottish Intercollegiate Guideline Network (and other) checklists may be used for critical appraisal of the literature.

5.4 *Targeted rapid literature search*

5.4.1 The search

Following the preliminary search, key questions may need to be refined for the targeted literature review.

'Search terms' are keywords or phrases that are used in search engines to identify articles which are relevant to the key questions. Appendix 2 gives an example of search terms used in a previous literature review. There are tools to help identify search terms for the literature review. It is useful to use one of these tools, e.g. the PICO, PICOS or PECOTS framework (P= population, I or E=interventions/indicator or exposure (if not an intervention under investigation, this can be substituted to make more applicable to the subject area, e.g. aetiology, disease frequency, diagnoses), C=comparators or controls (if applicable), O=outcomes, S=study designs, and T=timeframe, S=setting). Based on the key questions, one word should be provided for each of the subheadings. An example of a review question based on a PICO analysis is shown in Appendix 3.

For this search to be rapid, the methodological criteria should be shortened, restricted or limited as suggested in Table 1 (e.g. the search dates limited to publications produced in the previous five years, the search language restricted to English only, only one person to conduct literature review etc).

Once the literature search has been conducted using the appropriate search terms; the search results should be recorded. Articles should then be screened (also known as 'sifted' through), applying inclusion and exclusion criteria to identify and accept relevant papers. Screening involves reading the title, title and abstract or full article, depending on the review design and time available for this process. This may be carried out in one round or in several rounds (e.g. in the first round, articles accepted or rejected on the basis of the title only, in the second round, on the basis of the full article etc). The literature review may be carried be carried out by one or more reviewers, depending on time and resources available.

If time and resources allow, it may be useful to screen the reference lists of the accepted articles identified during the literature search. This may identify other relevant articles. This search strategy is also known as 'hand-searching', the 'paper-trail' technique, or the 'snowball technique'.

5.4.2 Collate and critically appraise results, formulate recommendations

Results from the literature review should be recorded and summarised in evidence tables (see an example in Appendix 4). Evidence tables should be constructed for each key question. Literature (including grey or peer-reviewed) identified by the targeted literature review should be formally critically appraised if time and resources are available. SIGN50 checklists can be used for this purpose, but there are other appraisal tools which may be useful such as NOS (Newcastle-Ottawa Scale for assessing the quality of nonrandomized studies in meta-analysis) and AMSTAR (for assessment of multiple systematic reviews).

A considered judgement table should be completed (see Appendix 5 for the SIGN considered judgement form). The considered judgement table should provide a link between the evidence and proposed recommendations and take into account the volume of evidence, applicability, generalisability, consistency, and clinical impact before making recommendations.

Key conclusions and recommendations should then be synthesised (i.e. finalised and written up). This should include justification and a description of how the recommendations have been reached based on the processes above. If there is not a consensus on recommendations, consensus approaches such as the Delphi method can be helpful in coming to an agreement. Appendix 6 provides a specific example of how key recommendations have been previously reported.

If time and other resources are lacking, these steps may be skipped and the individual or group writing the guidance, might go straight to the drafting stage.

5.5 *Drafting, consultation, approval and publication*

A draft document should be produced for consultation. Prior to external consultation, the intended audience of the document should be considered and the guidance shared with key stakeholders for an opportunity to comment. Once consultation comments have been incorporated, the document can be published on the HPS and the Scottish Health Protection Information Resource (SHPIR).

6. References

(1) Khangura S, Polisena J, Clifford TJ, Farrah K, Kamel C. Rapid review: an emerging approach to evidence synthesis in health technology assessment. International Journal of Technology Assessment in Health Care 2014 Jan;30(1):20-7.

(2) Tricco A, Antony J, Zarin W, Strifler L, Ghassemi M, Ivory J, et al. A scoping review of rapid review methods. BMC Medicine 2015;13(1):224.

(3) Watt A, Cameron A, Sturm L, Lathlean T, Babidge W, Blamey S, et al. Rapid reviews versus full systematic reviews: An inventory of current methods and practice in health technology assessment. International Journal of Technology Assessment in Health Care 2008;24(2):April.

Figure 1: Flowchart showing suggested protocol for rapid development of guidance

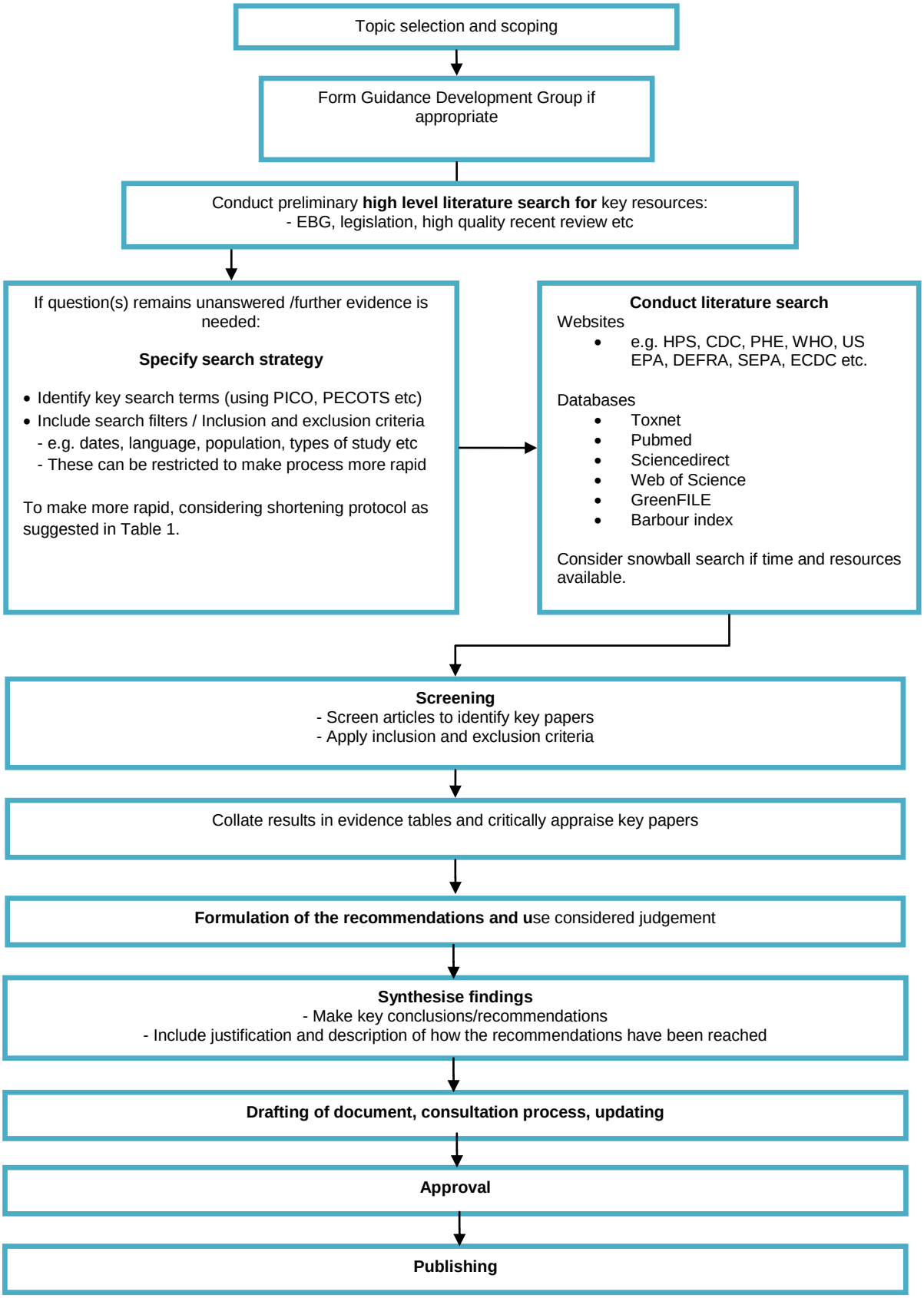
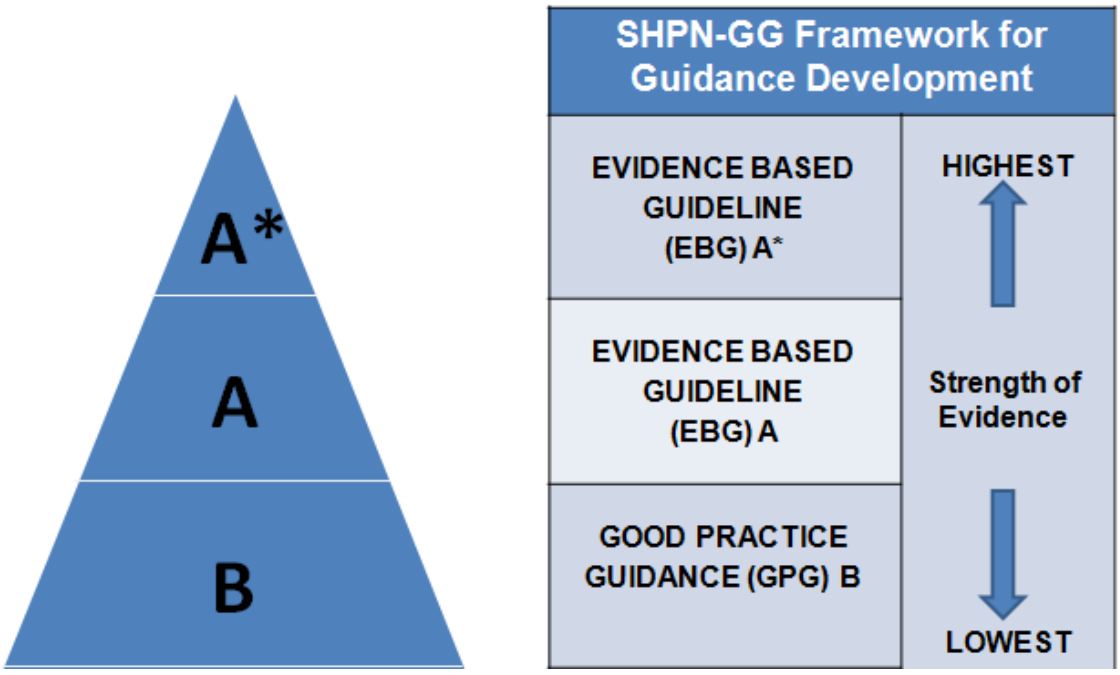


Figure 2: SHPN-GG Framework for Health Protection Guidance Development

The 'framework' ranks guidance documents based on the methods used to produce them, with, e.g. internally produced EBG at the top of the pyramid since it is considered the most robust.



Appendix 1: Example of table for recording results from preliminary rapid search & review of high level evidence

Date	Key questions/ recommendation	Search engine and Search terms
#	**Source / reference**	**Comment (usefulness, applicability, comparison with e.g. CDC guidance, WHO guidelines, ECDC guidance etc)**
1		
2		
3		
4		

Appendix 2: Example of Search Strategy

Example search from review of current evidence on maintenance of peripheral venous catheters.

Example: Database: Ovid MEDLINE(R) <1948 to April Week 3 2011>
Search Strategy:
---
1 Catheterization/ or exp Catheterization, Peripheral/ (37696)
2 peripheral venous catheter.mp. (79)
3 venflon.mp. (40)
4 1 or 2 or 3 (37751)
5 phlebitis.mp. (4605)
6 extravasation.mp. (11103)
7 exp Bacteremia/ or bacteraemia.mp. (18980)
8 blood stream infection$.mp. (346)
9 thrombophlebitis.mp. (22148)
10 5 or 6 or 7 or 8 or 9 (56084)
11 4 and 10 (1378)
12 limit 11 to (english language and humans and yr="2006 -Current") (215)
13 from 12 keep 1-212 (212)

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Appendix 3: PICO analysis for creating search terms

Q	Population	Intervention	Comparison	Outcome
1	Patients in Hospital settings	Removal of PVCs after 72 hours	Removal of PVCs on clinical indications	1.Infection rates 2.Outbreak evaluation 3.Complications
2	Children with VTEC	Treatment with antibiotics	No treatment with antibiotics	1. Development of HUS 2. Length of illness 3.Mortality

Appendix 4: Example of Evidence table

Evidence table: for recording information extracted from articles that have been identified during systematic literature reviews

The following grades were given to the papers included in this evidence table:

1++ High quality meta analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias;
1+ Well conducted meta analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1- Meta analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2++ High quality systematic reviews of case-control or cohort studies , High quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal.
2+ Well conducted case control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
2- Case control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3 Non-analytic studies, e.g. case reports, case series
4 Expert opinion

Key Question:
Search terms :
Date search conducted:

Study / Reference	Study Type	Evidence grade	Summary of information
Comment / Assessment of evidence:			
Comment / Assessment of evidence:			
Comment / Assessment of evidence:			

Appendix 5: Considered Judgement form from SIGN

Considered judgement

Key question:

A: Quality of evidence

1. How reliable are the studies in the body of evidence? (*see SIGN 50, section 5.3.1, 5.3.4*)
If there is insufficient evidence to answer the key question go to section 9.

Comment here on any issues concerning the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.	**Evidence level**

2. Are the studies consistent in their conclusions? (*see SIGN 50, section 5.3.2*)
Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence.

3. Are the studies relevant to our target population? (*see SIGN 50, section 5.3.3*)
For example, do the studies:

- *include similar target populations, interventions, comparators or outcomes to the key question under consideration?*
- *report on any comorbidities relevant to the target population?*
- *use indirect (surrogate) outcomes*
- *use indirect rather than direct comparison of outcomes*

4. Are there concerns about publication bias? (*see SIGN 50, section 5.3.5*)
Comment here on concerns about all studies coming from the same research group, funded by industry etc

B: Evidence to recommendations

5. Balancing benefits and harms (*see SIGN 50, section 6.2.2, 6.2.3*)
Comment here on the potential clinical impact of the intervention/action – eg magnitude of effect; balance of risk and benefit.

What benefit will the proposed intervention/action have?
Describe the benefits. Highlight specific outcomes if appropriate.

What harm might the proposed intervention/action do?
Describe the benefits. Highlight specific outcomes if appropriate.

6. Impact on patients (*see SIGN 50, section 6.2.4, 6.2.5*)
Is the intervention/action acceptable to patients and carers compared to comparison? Consider benefits vs harms, quality of life, other patient preferences (refer to patient issues search if appropriate).
Are there any common comorbidities that could have an impact on the efficacy of the intervention?

7. Feasibility (*see SIGN 50, section 6.2.6*)
Is the intervention/action implementable in the Scottish context? Consider existing SMC advice, cost effectiveness, financial, human and other resource implications.

8. Recommendation (*see SIGN 50, section 6.3*)
What recommendation(s) does the guideline development group agree are appropriate based on this evidence?
'Strong' recommendations should be made where there is confidence that, for the vast majority of people, the intervention/action will do more good than harm (or more harm than good). The recommendation should be clearly directive and include 'should/ should not' in the wording.
'Conditional' recommendations, should be made where the intervention/action will do more good than harm, for most patients, but may include caveats eg on the quality or size of the evidence base, or patient preferences. Conditional recommendations should include 'should be considered' in the wording.

	strong/conditional

Briefly justify the strength of the recommendation

9. Recommendations for research
List any aspects of the question that have not been answered and should therefore be highlighted as an area in need of further research.

Appendix 6: Specific example of identification of key recommendations
A review of HPS quality improvement tools on maintenance of peripheral venous catheters.

Recommendation for review	Strength of evidence	Health impact contribution (based on Healthcare Quality Strategy for NHSScotland)	Expert opinion / consultation & practical considerations	Yes	No	Is this a key recommendation (yes / no)
Check that a Peripheral venous catheter (PVC or venflon) is still required by the patient for care	**Category 1A**	**Safe:** **No harm is associated with checking a PVC is needed/removal of PVCs** **Effective:** **Evidence that the duration of PVC usage associated with increased incidence of infection and other complications e.g. reduction in incidence of catheter related blood stream infection (CRBSI) resulting from implementation. E.g. through locally produced run charts for SAB** **Efficient:** **If PVCs are not inserted unnecessarily this allows for releasing time for other aspects of care and a decrease in CRBSIs and other PVC associated complications, as well as positively managing avoidable NHS costs** **Equitable:** **All adults receiving care can have safer care supported by this bundle criterion. If PVCs are only inserted when needed this would result in positively managing avoidable NHS costs, beneficial to all** **Timely:** **Daily checking is required to fulfil the**	**Measurement and feedback:** **Potential for measurement through observation** **Feasibility and sustainability:** **Easily implemented within current culture and will improve the quality of care now** **Potential for consistent delivery** **Easily implemented based on reliably available resources /products/prompts** **Stealth integration into natural workflow/logical clarity of concept (see Cause & Effect Chart)** **Applicability and reach:** **Unambiguous** **Potential for applicability to a wide range of settings –** **Avoids unintended consequences/ perverse behaviour**	√ √ √ √ √ √ √		**YES**

Recommendation for review	Strength of evidence	Health impact contribution (based on Healthcare Quality Strategy for NHSScotland)	Expert opinion / consultation & practical considerations	Yes	No	Is this a key recommendation (yes / no)
		bundle and fits with other aspects of care required on a daily basis **Person Centred:** **Ensures regular checking and safe caring of a patient**	**Training and informing:** **Potential for congruency in design and meaning, with HCW, trainer and observer training and education**	√		