HEALTHCARE INFECTION SOCIETY

GUIDELINE DEVELOPMENT MANUAL (V12)

HIS Guideline Development Manual prepared by members of the Scientific Development Committee for NICE Accreditation of HIS guidelines

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TABLE OF CONTENTS

1. Introduction

1.1 Guidelines and the Healthcare Infection Society

The Healthcare Infection Society (HIS) was established in 1980 as a specialist society to foster the advancement of knowledge in prevention and control of Healthcare acquired Infections (HCAI). HIS has become the leading UK association representing professionals in infection prevention and control (IPC) and is a well-established and highly respected organisation with national and international influence, committed to providing excellence in prevention and control of HCAI.

Among other activities, HIS acts as a national advisory body to professions and other organisations on all aspects of IPC and contributes representatives for international, national and local committees dealing with HCAI. In addition, HIS works to promote undergraduate, postgraduate and continuing medical education within IPC.

The current membership of the Society is around 670 across a wide range of healthcare professionals from the UK and worldwide. HIS has published the Journal of Hospital Infection (JHI) since 1980, which is subscribed worldwide. It has an impact factor of 3.126 in 2016.

HIS produced its first MRSA control guidelines in 1986, which were revised in 1990, 1998 and 2006 in collaboration with the Infection Control Nurses Association (ICNA) and the British Society for Antimicrobial Chemotherapy (BSAC), and which were published in the JHI. Since 2004, HIS has produced ten guidelines on the prevention and control of HCAI in collaboration with other stakeholders such as the Department of Health (DH), BSAC and the Health Protection Agency (HPA). A complete list of HIS guidelines can be found in Appendix 1.

HIS has a number of standing committees, one of which is the Scientific Development Committee (SDC). The SDC is responsible for recruiting members for each working party by whom evidence based guidelines are developed on different topics of IPC according to a process manual. Guideline development is based on the Scottish Intercollegiate Guidelines Network (SIGN) methodology (SIGN2015) and overseen by a methods expert (ME).

In previous guidelines, recommendations were categorised on the basis of existing scientific evidence, theoretical rationale, applicability and economic impact. HIS guidelines are supported by emerging evidence, which is based in IPC, predominantly on observational studies, and, to a lesser extent, on experimental randomised studies. Previous guidelines were based on the evidence appraisal of Thames Valley University (now University of West London), Health Care Infection Control Practices Advisory Committee (HICPAC) or SIGN gradings.

SIGN has used the 'ABCD' approach since 2000, which is based on the quality or strength of the evidence supporting a recommendation. In effect, the grade of a recommendation was strongly related to the types of study carried out on the topic, with randomized controlled trials (RCTs) scoring most highly. However, in some areas RCTs are unethical or impractical reasons. This historic SIGN approach gave, in these situations, precedence to case-control or cohort studies. In practice, there is a wide range of other possible study designs which may be more appropriate than either of these for addressing specific IPC issues. The 'ABCD' approach imposes a straightjacket within which it is increasingly difficult to find an appropriate fit for all the evidence.

The introduction of Grading of Recommendations Assessment, Development and Evaluation (GRADE; Guyatt *et al*., 2008) allows a balanced influence of observational studies onto the level of evidence. It requires users who are performing an assessment of the quality of evidence, to consider the impact of different factors on their confidence in the results. Authors of GRADE tables, grade the quality of evidence into four levels, on the basis of their confidence in the observed effect (a numerical value) being close to what the true effect is. The confidence value is based on judgements assigned in five different domains in a structured manner, which is applicable to observational studies. In the case of observational studies, the quality of evidence starts lower and may be up- or downgraded in the three domains: large effect, plausible confounding and dose response gradient. Strong or weak recommendations are made on the basis of further criteria:

- balance between desirable and undesirable effects (not considering cost);
- quality of the evidence;
- values and preferences; and
- costs (resource utilization).

The use of GRADE has been adopted by other national and international guideline development groups. However, this greater complexity results in the need to conduct full, detailed, systematic reviews for all questions. For small guideline organisations such as HIS, there are insufficient resources to do such reviews for all questions without extending the time required to develop a guideline. Thus SIGN has taken the decision to stop grading recommendations using the 'ABCD' method from 2013 onwards. An alternative approach based on the GRADE approach of making 'strong' or 'conditional' recommendations, using DECIDE Evidence to Decision frameworks (Alonso-Coello *et al.,* 2006 a & b), are is used in its place. This is the basis of the approach used by HIS for the presentation of recommendations in their guidelines, which are already based on the GRADE approach. A table showing the translation of evidence levels to SIGN's current grading system can be found in Appendix 2.

HIS attempts to harmonise its guidelines with other international IPC guideline development groups, whenever appropriate, to the UK healthcare system. The main target audience for the HIS guidelines are IPC practitioners seeking evidence based interventions to reduce HCAI. The key professional groups include: medical staff (consultant microbiologists, associate specialists, specialty doctors and specialty trainees), directors of infection prevention and control (DIPC), and nursing staff, especially infection control nurses.

1.2 Aims and structure of the guideline development manual

The main aims of this framework document are:

- to combine the range of improvements introduced into the guideline development process in recent years into a single document;
- to develop a reference tool for current and future co-authors of guidelines; and
- to summarise the guideline process for all users of the guideline but especially for members of HIS, stakeholders, patients and sister agencies.

Based on the Appraisal of Guidelines for Research and Evaluation (AGREEII; Brouwers *et al.,* 2010) Instrument, the subsequent sections of this document demonstrate that HIS guidelines

- Produced to promote IPC and reduce HCAI
- Produced by IPC specialists and other healthcare professionals using a transparent, consistent and reliable development process
- Designed to provide recommendations based and graded on the best available evidence
- Designed to provide recommendations – strong or weak – weighing up the cost, burden and benefits of treatment or intervention
- Designed to provide audit measures for the guideline recommendations

1.3 Review and update of the guideline development manual

It is planned that this manual will be updated every 12 months by the Research & Development manager with oversight by the SDC, subject to ratification by the HIS Council. This will ensure that the manual will remain aligned to the current SIGN and NICE methodology. Table 1.1 indicates how the HIS methodology aligns to SIGN methodology & NICE accreditation criteria.

169 Table 1.1 indicating where each criterion is addressed in the text.

170

Domain	Criteria	Section
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:**	
	1.1 The overall objective of the guidance	5.1
	1.2 The clinical, healthcare or social questions covered by the guidance	2.2, 4
	1.3 The population and/or target audience to whom the guidance applies	4.1, 4.3
	1.4 That the producer ensures guidance includes clear recommendations in reference to specific clinical, healthcare or social circumstances	4.4, Appendix 3
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).	**These criteria consider whether the guidance producer has a policy in place and adhered to that means it includes:**	
	2.1 Individuals from all relevant stakeholder groups including patients' groups in developing guidance	3.1, Appendix 3
	2.2 Patient and service user representatives and seeks patients' views and preferences in developing guidance	2.2, 3.1, 4.1
	2.3 Representative intended users in developing guidance	3.1

3. Rigour of development relates to the process used to gather and synthesise information and the methods used to formulate recommendations and update them.	**These criteria consider whether the guidance producer has a clear policy in place and adhered to that:**	
	3.1 Requires the guidance producer to use systematic methods to search for evidence and provide details of the search strategy	4.2, Appendix 6
	3.2 Requires the guidance producer to state the criteria and reasons for inclusion or exclusion of evidence identified by the evidence review	4.2, Appendix 2
	3.3 Describes the strengths and limitations of the body of evidence and acknowledges any areas of uncertainty	4.4
	3.4 Describes the method used to arrive at recommendations	4.5
	3.5 Requires the guidance producer to consider the health benefits, side effects and risks in formulating recommendations	4.5
	3.6 Describes the processes of external peer review	4.6
	3.7 Describes the process of updating guidance and maintaining and improving guidance quality	2.4
4. Clarity and presentation deals with the language and format of the guidance.	**These criteria consider whether the guidance producer ensures that:**	
	4.1 The recommendations are specific, unambiguous and clearly identifiable	4.1,4.3, 5
	4.2 The different options for management of the condition or options for intervention are clearly presented	5

	4.3 The date of search, the date of publication or last update and the proposed date for review are clearly stated	4.3, 4.6
	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	4.4, 5.1
5. Applicability deals with the likely organisational, behavioural and cost implications of applying the guidance.	**These criteria consider whether the guidance producer routinely considers:**	
	5.1 Publishing support tools to aid implementation of guidance	5, 6, Appendix 4
	5.2 Discussion of potential organisational and financial barriers in applying its recommendations	4.5, 6.2
	5.3 Reviewing criteria for monitoring and/or audit purposes within each product	4.5, 6.3
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.	**These criteria consider whether the guidance producer:**	
	6.1 Ensures editorial independence from the funding body	3
	6.2 Is transparent about the funding mechanisms for its guidance	4.2
	6.3 Records and states any potential conflicts of interest of individuals involved in developing the recommendations	2.5, Appendix 4
	6.4 Takes account of any potential for bias in the conclusions or recommendations of the guidance	4.5, 4.6

171

1.4 Medico-legal implications of Guidelines

Clinical guidelines are intended as an aid to clinical judgement not to replace it. Guidelines do not provide the answers to every clinical question, nor guarantee a successful outcome in every case. The ultimate decision about a particular clinical procedure or treatment will always depend on each individual patient's condition, circumstances and wishes, and the clinical judgement of the healthcare team. To clarify the legal position, all SIGN guidelines carry the following statement of intent:

> *"This guideline is not intended to be construed or to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. Adherence to guideline recommendations will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement must be made by the appropriate healthcare professional(s) responsible for clinical decisions regarding a particular clinical procedure or treatment plan. This judgement should only be arrived at following discussion of the options with the patient, covering the diagnostic and treatment choices available. It is advised, however, that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient's case notes at the time the relevant decision is taken."*

2. Selection and planning of guideline topics

2.1 Selection criteria for guideline topics

Topics for guidelines will be selected to cover all of the main areas of IPC. These topics are primarily proposed by the SDC. Additionally, topics identified by PHE, DH and NHS Scotland, as well as any future NHS quality standards may inform guideline topic areas.

In addition, any member of the Society can suggest a topic for a guideline to be formulated. This is submitted via an online proposal form and considered by the SDC, which in turn will propose relevant topics to HIS Council for approval. Approved topics for guidelines are published on the HIS website at www.his.org.uk.

In some instances, specialist areas of guidelines that require development in collaboration with other specialist societies undergo approval by the HIS Council before proceeding through the agreed process of guideline development and peer review of the lead organisation.

2.2 Drafting the scope of the guideline

The SDC will draft a scope for proposal to the HIS Council after searching

- related guidance from other IPC , infection societies , accredited developers policy and legislation
- key systematic reviews and epidemiological reviews and economic evaluations
- information on current practice, including costs and resource use and any safety concerns
- types of interventions that may be appropriate and their safety
- statistics (for example, on epidemiology), national prevalence data and data on the natural history of the condition
- information on the views and experiences of people using services, their family, members or carers, or the public.

The draft proposal for the guideline topic should:

- provide a brief description of the guideline topic (for example, a description of areas of infection control practice, the condition or disease or health or social care services)
- provide a brief overview of the context (current policy and practice) in which the guideline will be developed
- identify why the guideline is needed and where it will add value define the population to be covered
- describe what the guideline will consider and identify the key issues and list the key questions that will be considered
- provide a clear framework for the guideline by setting boundaries that ensure the work stays within the referral and informs any relevant quality standard set out the context in terms of the relationship between relevant commissioners and providers, to inform understanding of relevant outcomes and costs
- describe how the guideline will link to other recommendations and quality standards

- identify impacts on potential equality among groups sharing protected characteristics and set out how these will be considered
- identify health inequalities associated with socioeconomic factors and with inequities in access for certain groups to healthcare and social care, and identify opportunities to improve health.

This proposal for the guideline topic will be submitted to the HIS council for approval and then published on the HIS website. The HIS council will assess the guideline proposal according to the selection criteria listed in 4.1. The draft proposal will be published in an appendix of the final guidelines.

2.3 Timelines for development of guidelines

The dates of planned guidelines are published on the HIS website.

Dates covered by a preparatory literature search performed should be recorded in the introduction section of the guideline. The timeline for the completion of each guideline will be set by the SDC and this may vary between guidelines depending on their scope and complexity.

If a working party fails to complete its work within the specified period, the SDC will have the discretion to either extend the timeline or replace some or all of the members of the working party.

The first draft of the guideline is opened for consultation for one month on the HIS website, to invite comments from the public. After amending the guideline with comments from this public consultation phase, the revised guideline will be sent to infection related societies like BIA, BSAC to receive comments from peer reviewers within one month. It should be noted that all reviewers are invited to comment as individuals, not as representatives of any particular organisation or group. Comments from peer reviewers will not be considered unless an accompanying declaration of interests form has also been submitted.

Stakeholder organisations will be listed in the methodology section and comments from peer reviewers will be documented in an appendix. Each guideline may require in excess of six months for completion after the first draft is prepared, to allow one month for feedback from the public consultation, the preparation of the revised draft prior to expert peer review and final version to take account of feedback and endorsement of the final version by the SDC and HIS Council.

2.4 Updating Published Guidelines

Clinical practice is constantly developing and the introduction of new treatment options lead to guidelines becoming out-dated. For this reason, guidelines are reviewed constantly and updated as necessary (Alonso-Coello *et al*., 2011; Lyratzopoulos *et al.,* 2012; Martinez Garcia *et al.,* 2012; Schunemann *et al.,* 2014)

Following the SIGN system, a traffic light system will be used to indicate how current guidelines are.

Time since publication	Categorisation (symbol)
< 3 years	**Current (*)**
3 – 7 years	**Some recommendations may be out of date(#)**
> 7 years	**Use with caution(!)**
Over 10 years old/superseded	**Withdrawn (x)**

2.4.1 Process for updating an existing guidelines:

For existing guidelines, the date of completion of the current guideline is clearly displayed on the HIS website; if not already explicitly stated, the proposed date for updating the guideline, which will be usually every three to four years, will be determined by the SDC and stated on the website. In addition, the dates of the first and final drafts are recorded on the website in the archived PDF versions at the foot of the current guideline. Every two years the research objectives identified in the working party report would be reviewed for evidence of additional studies, contributing to resolving the objective.
A full review of a guideline after a fixed time period is not always appropriate as new evidence is published at different rates in different fields. At quarterly SDC meetings, the progress and status of each guideline is discussed with the working party representatives. Following factors will influence the decision whether and how to review a guideline on an unscheduled base:

- emergence of new evidence, that will change former recommendations
- identification of any error in the guidelines after publication
- emergence of any evidence of inequality in access to services between different social groups that can be addressed through guideline recommendations.
- emergence of any new technology or drugs or legislation, that will change former recommendations
- comments received to HIS about current guidelines

As a first step, the SDC commissions the standing working party on this topic, who will carry out an update search looking for evidence based guidelines, health technology assessments (HTAs) and systematic reviews produced since publication of the last version of a guideline. These searches are based on the key questions and search strategies used in the original guideline but also include an element of horizon scanning to see if there are new treatments or technologies that should be considered as part of the update. Results are presented in the form of summaries of the findings of the studies that have been identified. The search results are incorporated into a report that summarises the new evidence and looks at how it will

impact on the recommendations made in the existing guideline. This report will also note any new areas or key questions that have emerged since the previous publication and will be submitted to the SDC, who will decide (subject to ratification by the HIS Council), if the guideline, as it stands, will be revalidated or will undergo a complete or partial review or will be withdrawn. For guidelines, which were developed joint with partner organisations (e.g. BSAC ,PHE, BIA etc), a consultation with these organization will take place and members from these organization will be recruited in the working party to assess the need for review, and councils of the partner organisations will be involved in the decision.

2.5 Alternative update procedures

2.5.1 Selective updates

Updates may apply to individual sections or even individual recommendations of a guideline (Becker *et al.,* 2014). The methodology will be as described, although the focus of the sections will determine if all working party members are involved. A scoping meeting may not be required for selective updates, but the first draft of the changes will be made available on the HIS website for 1 month to enable public & peer consultation.

2.5.2 Living guidelines

Living guidelines undergo a rolling programme of regular update. This is largely dependent on the amount of new evidence that emerges, but these guidelines will be reviewed on an annual or biannual basis. Working party membership will remain consistent but sub-groups will be involved in the review process at any given time.

This process will be managed by a steering group and literature searches will be performed based on the existing questions. Updated drafts of the guideline will be made available on the HIS website for comment, & will be presented at HIS biannual meetings.

2.5.3 Monitoring and interim updates

HIS welcomes comments on published guidelines, and together with new evidence, the SDC will consider whether an immediate response is required or a more in-depth examination of the evidence is required when the guideline is reviewed.

A small change proposal form is available on the HIS website and SDC will consider an update to the guideline if the following criteria are met:

- new evidence substantially changes recommendations relating to less than 2 key questions

OR

- a specific issue such as a change in change in government policy gives rise to a new question

AND

- the nature of the update does not warrant the assembly of the complete working party

2.5.4 Withdrawal of guidelines

Guidelines may become superseded and therefore a proposal to withdraw the quideline may be made to the SDC.

To withdraw a guideline the following must have occurred:

- a more recent or comprehensive guideline has been published
- the guideline has become accepted practice (and there is evidence of this)
- the guideline has become irrelevant as new interventions have become available.

2.6 Overview of guideline production process

The following table summarises the steps involved in producing a guideline.

1.	Proposed title and scope approved by the SDC and agreed by the HIS Council.
2.	Lead author/chair and co-chair identified by SDC and working party members nominated by lead author and co-chair. Initial conflict of interest declaration is made.
3.	Initial meeting with methods expert (ME) to identify questions and to produce a scope, a search strategy and selection criteria. Allocation of sections/tasks to working party members. Timeline and date of second meeting agreed and checklist on guideline principles in appendix 3 distributed to all working party members.
4.	Scope and questions approved by the working party.
5.	Data extraction: ME performs literature search and identified titles and abstracts forwarded to relevant section authors.
6.	Authors, with the assistance of the ME, systematically sift and discard those that are irrelevant and scrutinize remaining papers to assess if they meet selection criteria. ME to document the selection process.
7.	Critical appraisal of the quality of remaining studies by members of the working party using the SIGN extraction forms (Appendix. 7)
8.	Section authors write draft review, concise guideline and identify potential audit points and educational tools.
9.	Second meeting to present a synthesis of data, review draft recommendations and establish consensus and implications for practice. Chair will summarize recommendations.
10.	Draft documents collated by authors and ME and finalised.
11.	Review by SDC chairman and ME using checklist found at Appendix 3. Comments are fed back to authors and amendments made.
12.	Publication on HIS website for public consultation and sent for external peer review.
13.	Third meeting: consideration of consultation feedback and redrafting, if necessary, in light of comments received.
14.	Review of checklist (Appendix 3) by SDC chair.
15	Redrafting in light of received comments if necessary.
16.	Review by HIS Council.
17.	Publication on HIS website and JHI or other journal, together with final conflict of interest statement.
18.	Periodic review: lead authors contacted by SDC prior to expiry of guidelines. Literature search re-run by methods expert. If needed, updated guideline subjected to usual peer review process. If no update needed, renew web-based document with new expiry date & comment that update not required (include information from searches)

3. Composition and responsibilities of the working parties

The chair of each working party, who is usually a member of SDC, is nominated by the SDC. They should be recognised as expert within the chosen field, will have no conflict of interest in the topic of the guideline and act as lead author for the guideline. The lead author has responsibility for timely preparation of the guideline. The ME will perform the literature search and oversee the evidence appraisal.

Prior to the working party meeting for the first time, a full declaration of interests in line with HIS policy, is sought from all prospective members of the working party and this is recorded.

The other members of the working party are then selected on the basis of their expertise and track record of interest in the sub-specialty area, as well as freedom from overt conflict of interest, by the chair and co-chair together with the SDC. If guidelines are developed in collaboration with other infection societies, representatives of these organisations will be selected for the working party according to their expertise, enthusiasm and time. The working party may also contain representatives from the nursing and other professional groups, where relevant. Training representatives from relevant medical and nursing professions will be invited by the chairman, upon application. All working parties should consider an open invitation to the membership of HIS to apply to join the working party if they have the relevant experience, enthusiasm and time (Grimshaw *et al.,* 1995, Qaseem *et al*., 2012).
Working Party membership will include academics, pharmacists, clinical scientists & representatives from primary, secondary & tertiary care, where appropriate. HIS will also ensure that each working party is representative of all of its members.

All members of the working party have an equal status and a key role of the lay representative is ensure the patient voice informs the working party's recommendations (Pagliari *et al.,* 2002).

During the preparation and publication of the guideline, the working party is responsible to the chair of the working party who in turn is responsible to the SDC and HIS Council.

3.1 Lay representation

Patients, carers & those in the voluntary sector whom represent or support patients should be engaged as lay representatives on each working party. Lay representation is key to the guideline development process and lay members may present different perspectives on healthcare processes, priorities & outcomes (Brouwers *et al*., 2010; van Wersch *et al.,* 2001). Guidelines should address their key concerns and highlight areas where patient perspective may differ from that of the healthcare professional.

Lay representative can do this by:

- examining the key question to make sure they reflect patient matters
- identify the outcome measures that are key for each question
- identify areas where patient preference & choice need to be acknowledged

A lay representative should have some of the following expertise:

- experience of the healthcare question being addressed
- an understanding of the experiences & needs of the wider patient group, & a willingness to share these experiences.
- time to commit to the working party
- some familiarity with medical & research terminology
- willingness to be objective
- good communication & team working skills

HIS will provide support to lay representatives by providing them with an induction, offering email & phone support via the Research & Development manager and providing clear guidance on the roles & responsibilities of the lay representative.

In addition, HIS will aid the working party chair to:

- make sure that the lay representative remains fully engaged with the working party,
- ensure the contribution of the lay representative is fully acknowledged
- be welcoming & encourage contributions.

3.2 Declaration of conflicts of interest

As part of its Conflict of Interests Policy, HIS requires that all trustees complete a declaration of interests. In addition, all members attending Council meetings are asked to declare any conflict of interests. All guidelines published in JHI should contain a full declaration of author(s)' conflicts of interests.

Since 2013, working party members are asked to complete a conflict of interest statement. A copy of the form is attached at Appendix 4. These statements will be reviewed by the HIS Research & Development Manager with oversight from the chair and vice chair of each working party. If there are any concerns, these will be referred to the SDC in the first instance. In the event of a potential conflict being identified, the working party ensures that the member should not contribute the section affected. In the case, that the chair of the working party has a conflict of interest in one section, the vice-chair or another member will take the lead for the relevant section.

3.3 Funding of guideline development

HIS guidelines are not funded by any commercial company. HIS covers the cost of assistance with gathering and grading evidence, meetings, incidental travel expenses and provides administrative support. No member receives any remuneration for participation in a working party. Only out-of-pocket expenses are paid (per the HIS Travel and Expenses Policy). Lay representatives are able to claim fully documented travel, subsistence & child care/carer expenses in accordance with the above policy.

4. Development process of the guidelines

HIS guidelines are developed using an explicit methodology based on five core principles:

- Development is carried out by nationally representative experts in the field of infection, who are free of overt conflicts of interest;
- The expert working party commissions a systematic review to identify and critically appraise the evidence;
- Recommendations using the SIGN system are explicitly linked to the supporting evidence;
- Recommendations take account of equality issues, financial and resource implications, and patient choice and lifestyle; and
- Recommendations are open to public review including members of HIS, stakeholders, patients and interested members of the public.

In order to ensure that these principles are adhered to, the chairman gives the checklist in appendix 3 to all working party members at outset.

4.1 Selection criteria of topics within guidelines

Each proposed new guideline is approved by the HIS Council prior to beginning the process of producing the guideline. Guideline topics selected for inclusion are chosen on the basis of the burden of disease, the existence of variation in practice, and the potential to reduce incidence of HCAI (Schunemann *et al.,* 2014). The following criteria are considered by HIS in selecting and prioritising topics for guideline development;

Areas of clinical uncertainty as evidenced by wide variation in practice or outcomes;

- Conditions where effective prevention and control of infection is proven and where mortality or morbidity can be reduced;
- Iatrogenic diseases or interventions carrying significant risks;
- Clinical priority areas for NHS: The strategic aims of NHS are also considered e.g. infection control targets; and
- The perceived need for the guideline, as indicated by a network of relevant stakeholders.

The definition of the target population and interventions is an essential component in the development of the guideline recommendations and in the published data which provides the supporting evidence for the recommendations. Application of these principles is readily achieved using the Patient or Population/ Intervention or Indicator/ Comparison or Control/ Outcome (**PICO)** framework (Counsell, 1997; Schardt *et al.,* 2007):

The **patients or population** of interest are patients, children and adults alike, in healthcare in hospital and community. The guideline is careful not to make recommendations which may prejudice clinical care based on gender, age, ethnicity or socio-economic status.

The **interventions** in the guideline on prevention and control of HCAI are identified in the literature to generate intervention-specific recommendations.

The **comparisons** in the guideline mainly involve comparison between different prevention strategies.

Hard **outcomes** such as incidence, transmission rates, mortality, morbidity, hospitalisation and complication rates are preferred in developing recommendations within HIS guidelines

4.2 Systematic literature review

HIS recognises that both its members and working party members provide their time and expertise free of charge and should be supported as much as possible. The SDC will therefore provide a methods expert to play a major role in performing the literature search and review and supporting the authors with appraisal of papers, grading of evidence and production of evidence tables. A job description of the methods expert can be found at Appendix 5.

The co-authors in each working party will have followed the literature in their field for many years prior to reviewing the evidence to prepare their guideline module. The chair of the working party will commission the guidelines co-ordinator to conduct a systematic search of the literature published in English. The dates covered by the systematic literature search should be stated clearly in the introduction of each guideline along with specific details of the search strategy and search terms used. This will involve, as a minimum, a search on PubMed, EMBASE and/or Medline using key search terms documenting the relevant literature for the search terms within the guideline topic agreed by the working party as well as a review of the Cochrane Library Database.

The period that the search should cover will depend on the nature of the clinical topic under consideration, and will be discussed with the guideline working party. For a rapidly developing field, a 5 or 10-year limit to the search may be appropriate, whereas in other areas a much longer time frame might be necessary.

As part of the question setting process, a set of inclusion and exclusion criteria should be drawn up and saved as part of the record of the review. This will provide guidance at a later stage when studies are being selected for review. Inclusion criteria will include definition of the topic and may include such as type of infection control intervention, risk groups and risk factors and clinical settings. Other factors include any geographic or language limits, the types of trials that will be accepted, and date range to be covered. Any equality groups that are expected to have specific needs in relation to the question being addressed should be specified. Exclusion criteria are likely to be more variable. They are, however, essential in that they help sift out irrelevant studies from the (often very large) initial search result.

Before any studies are acquired for evaluation, the search output is sifted to eliminate irrelevant material. Results are sifted in two stages. A preliminary sift of each search result is carried out by the Evidence and Information Scientist or Guideline Co-ordinator, normally by the individual that carried out the search. Studies that are clearly not relevant to the key questions or not the type of study being considered (e.g. observational studies when the focus is on controlled trials) are eliminated. Abstracts of remaining studies are then examined and any that clearly do not meet the agreed inclusion and exclusion criteria will also be eliminated at this stage. In cases of doubt, the Evidence and Information Scientist will leave abstracts in the output file at this stage.

A final full text sift is carried out by at least two independent individuals, comprised of at least one member of the working party and the ME. Clinical judgment will be applied to reject any

other studies that do not meet the pre-agreed criteria. These will include clinical criteria, but may also consider issues such as size of the study or relevance to practice in the UK.

HIS does not undertake hand searching of key journals for research articles as part of the literature review. It is accepted that this means some relevant trials may be missed, and introduces the possibility of a degree of bias in the process. However, given time and resource constraints, it is not feasible for this to form part of the process. Key systematic reviews are highlighted and the references checked against those retrieved by the literature searches.

A listing of the Medline search strategies used for the guideline, plus a list of excluded and included studies with the rationale for exclusions, is published as an appendix on the HIS website with the publication of the guideline.

Infection Prevention Science (IPS) is a rapidly evolving field and, therefore, developments often change practice rapidly. For this reason "grey" literature, namely conference presentations (as opposed to abstracts) from key international meetings, is considered and reviewed at the discretion of the working party. These include the annual Federation of Infection Societies (FIS) conferences, HIS international conferences, Public Health England (PHE), European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) and the Society of Healthcare Epidemiology of America (SHEA) and Healthcare Infection Control Practices Advisory Committee (HICPAC) meetings and conferences. These will be given less weight in consideration than peer-reviewed published work but should not be excluded from consideration in formulation of guidelines. Articles not available with an abstract in English will be excluded. The co-authors also review other IPS guidelines issued by other national and international societies such as PHE, British Infection Association (BIA), SHEA, HICPAC or guidelines relevant to the topic.

Legislation on this topic will be also reviewed in order to be considered in the recommendations.

All sifting is carried out by two people according to an agreed protocol setting out the criteria used to select papers for inclusion or elimination from the process. Disagreement over inclusion of studies will be resolved by discussion and rationales for exclusion of papers will be documented.

Different questions may be best answered by different databases, or may rely on different levels of evidence. Information officers take an iterative approach to the task, carrying out a search for high level evidence in the first instance. After the results of this search have been evaluated, the questions may be redefined and subsequent searches focused on the most appropriate sources and study types. This iterative process is illustrated in Appendix 6.

4.3 Addressing patient issues in the literature search

Incorporating the patient's perspective from the beginning of the development process is essential if it is to influence the coverage of the final guideline. One of the measures used to achieve this is to conduct a specific search on patient issues in advance of the first meeting of the working party.

This search is designed to cover both quantitative and qualitative evidence, and is not limited to specific study designs. It is carried out over the same range of databases and sources as the main literature review, but will normally include both nursing and psychological literature using databases such as CINAHL and PsychINFO, even where these are not seen as particularly relevant to the later searches of the medical literature.

4.4 Selection and evaluation of the evidence

The expert co-authors assess articles for relevance to the guideline topic, eligibility for inclusion in the evidence base for that guideline and methodological quality according to the methods described in the current version of SIGN50 (http://www.sign.ac.uk/assets/sign50_2015.pdf). Articles are considered of particular relevance if they are describing:

- Prospective randomised or quasi-randomised trials;
- Controlled trials;
- Meta-analyses of several trials;
- Cochrane systematic reviews;
- Systematic reviews; or
- Large cohort studies.
- Interrupted time series

In many areas of IPS the number of such high quality publications is, however, relatively low compared with other areas and much of the supporting evidence is based on observational studies. In general, co-authors do not exclude this evidence from the literature given that the SIGN system provides an informative and transparent means of providing strong or weak recommendations for best practice even if the available supporting evidence is limited to low level evidence such as observational and case–control studies or case reports.

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity (see appendix 2 for current SIGN evidence levels). The result of this assessment will affect the **level of evidence** allocated to the paper, which will in turn influence the **grade of recommendation** that it supports. The methodological assessment is based on a number of key questions that focus on those aspects of the study design that research has shown to have a significant influence on the validity of the results reported and conclusions drawn. These key questions differ between study types, and a range of checklists is used to bring a dree of consistency to the assessment process.

HIS has based its assessments on the Method for Evaluating Research and Guideline Evidence (MERGE; Liddle *et al.,* 1996) checklists (developed by the New South Wales Department of Health) and AMSTAR (Shea *et al.,* 2007) which have been listed and described by SIGN for different trial designs. These checklists were subjected to detailed evaluation and adaptation to meet requirements for a balance between methodological rigour and practicality of use. An example of such a checklist for systematic reviews is shown in Appendix 7. For assessing the trial design 'interrupted time series', Cochrane Effective Practice and Organisation (EPOC) resources will be used (available from http://epoc.cochrane.org/resources/epoc-resources-review-authors).

The assessment process inevitably involves a degree of subjective judgement. The extent to which a study meets a particular criterion – e.g. an acceptable level of loss to follow up – and, more importantly, the likely impact of this on the reported results from the study will depend on the clinical context. To minimise any potential bias resulting from this, each study must be evaluated independently by at least two individuals. Any differences in assessment should then be discussed by the full working party. Where differences cannot be resolved, an independent reviewer will arbitrate to reach an agreed quality assessment.

For many questions systematic reviews will already exist, and in these cases the guideline development parties are provided with a complete systematic review plus an evidence table summarising more recent studies. Where there are multiple existing reviews, an evidence table summarising the findings of all existing reviews, is provided. In these circumstances the quality of the studies included in the systematic review has already been established by the systematic reviewers, and, the working party can move on to consider its conclusions.

Consideration of the evidence in relation to different outcomes is considerably simplified if a summary of findings (SoF) table is available (Schűnemann *et al*., 2011). Any SoF produced as part of a systematic review should be included in the material submitted to the working party and published in an appendix.

4.5 Grading the guideline recommendations

The strength of the evidence is categorised by 5 SIGN levels (Appendix 2) according to the predictive power of the study designs from which this data was obtained. The type of study supporting a recommendation does not, for example, necessarily reflect the clinical importance of the topic. In some areas, RCTs are difficult or impossible to carry out for ethical or practical reasons. Diagnosis or surgery are examples of areas where RCTs are rare, but which are clearly important in clinical terms. A further issue is how non-RCT evidence is dealt with. In practice, there is a wide range of other possible study designs which may be more appropriate than either of these for addressing specific issues.

In contrast to the 'evidence focused traditional 'ABCD' approach, SIGN has moved to grading recommendations by using the Evidence to Decision (EtD) tool, which was developed as part of the DECIDE project (Alonso-Coello *et al.,* 2006a; Alonso-Coello *et al.,* 2006b) and is based on the work of the GRADE group as detailed in the SIGN50 guideline developer's handbook (http://www.sign.ac.uk/assets/sign50_2015.pdf). A recommendation is rated as either strong or weak via this method but in the SIGN implementation of GRADE, a weak recommendation is referred to as a 'conditional' recommendation).

A **strong recommendation for or against** is made where:

- the evidence is of high quality
- estimates of the effect of an intervention are precise (i.e. there is a high degree of certainty that effects (will be achieved in practice)
- there are few downsides of therapy
- there is a high degree of acceptance among patients.

A **conditional recommendation** is made where:

- there are weaknesses in the evidence base
- there is a degree of doubt about the size of the effect that can be expected in practice
- there is a need to balance the upsides and downsides of therapy
- there are likely to be varying degrees of acceptance among patients.

The three level grading system of recommendations has the merit of simplicity.

- A strong recommendation stipulates to do (or not do) something, where the benefits clearly outweigh the risks (or vice versa) for most, if not all patients.
- A conditional recommendation is issued, where the risks and benefits are more closely balanced or are more uncertain.
- "No recommendation/unresolved issue" for issues, which have not been sufficiently investigated.

Strong and conditional recommendations facilitate a clear interpretation of the implications of strong and weak recommendations by clinicians. Explicit recommendations are made on the basis of the trade-offs between the benefits on the one hand, and risks, burden, and costs on the other. The category "No recommendation/unresolved issue" is most commonly applied to situations where either the overall quality of the evidence base for a given intervention is low to very low or there is no published evidence on outcomes deemed critical to weighing the risks and benefits of a given intervention. If the latter is the case, those critical outcomes are noted at the end of the relevant evidence summary.

Factors determining the strength of a recommendation include:

- The overall quality of the evidence base for the given intervention or question (Appendix 2).
- the risks and benefits that result from weighing the critical outcomes
- assessing patients' preferences
- equity (taking into account the needs of equality groups)
- cost effectiveness

Fundamental to making any recommendation is the need to ensure that any benefit to the patient outweighs, preferably by a substantial margin, any risks or harms associated with the treatment. In order to make such judgments, the working party has to have a clear understanding of how substantial the expected benefits of an intervention are likely to be in practice. They also need to consider how substantial the downsides are. These may range from physical side effects to an increased risk of developing additional health problems. The evidence supporting benefits will often come from stronger study designs than that supporting harms. This makes judgments more difficult, but it is nonetheless essential to explicitly consider the size of effect for both sides of the balance. Once the size of all effects has been established, a judgment must be made as to whether the benefits outweigh the

harms. This is not just a clinical judgment but must take into account patient values, if a realistic assessment is to be achieved. A first step should be to consult patient representatives on the working party, and through them a wider body of patient opinion. If time and resources allow, a literature search can be carried out looking specifically for information on patient values in relation to the question being addressed.

Working parties are required by law, as well as good practice, to consider whether any recommendations they make will have a differential impact on any of equality groups (age, disability, gender reassignment, marriage and civil partnership, race, religion or belief, sex, sexual orientation).

There are two aspects to the consideration of costs and benefits in relation to guideline recommendations. The first relates to cost effectiveness of a single proposed intervention, and involves assessing the incremental cost of applying the new intervention compared to current practice and relating it to the net benefit of the intervention. The second issue relates to the resources required to implement a recommendation. This cost assessment may not influence specific recommendations directly, but should be produced along with the guideline to inform decision makers who need to allocate resources within individual health boards. If the potential cost is very high and may not be achievable in the short term, a 'next best' option may be recommended in the guideline. The guideline should, however, always identify the most cost-effective option, with the 'next best' as an interim option only.

If weighing the critical outcomes for a given intervention or question results in a "net benefit" or a "net harm", then a Strong Recommendation is formulated to strongly recommend for or against the given intervention respectively. If weighing the critical outcomes for a given intervention or question results in a "trade off" between benefits and harms, then a Conditional Recommendation is formulated to recommend that providers or institutions consider the intervention when deemed appropriate. If weighing the critical outcomes for a given intervention or question results in an "uncertain trade off" between benefits and harms, then 'No Recommendation' is formulated to reflect this uncertainty (See Table 4.1).

Table 4.1: Strength of recommendation

Judgement	Recommendation
Undesirable consequences clearly outweigh desirable consequences	Strong recommendation against
Undesirable consequences probably outweigh desirable consequences	Conditional recommendation against
Balance between desirable and undesirable consequences is closely balanced or uncertain	Recommendation for research *and possible conditional recommendation restricted to trials*
Desirable consequences probably outweigh undesirable consequences	Conditional recommendation for
Desirable consequences clearly outweigh undesirable consequences	Strong recommendation for

Recommendations are usually agreed by informal consensus and as each recommendations is linked to evidence, agreement is generally reached. When this is not possible independent review of the evidence may be sought & the Research & Development manager may seek advice from the Scientific Development committee or the HIS council. The outcomes of these discussions will be recorded in the supplementary information associated with the guideline.

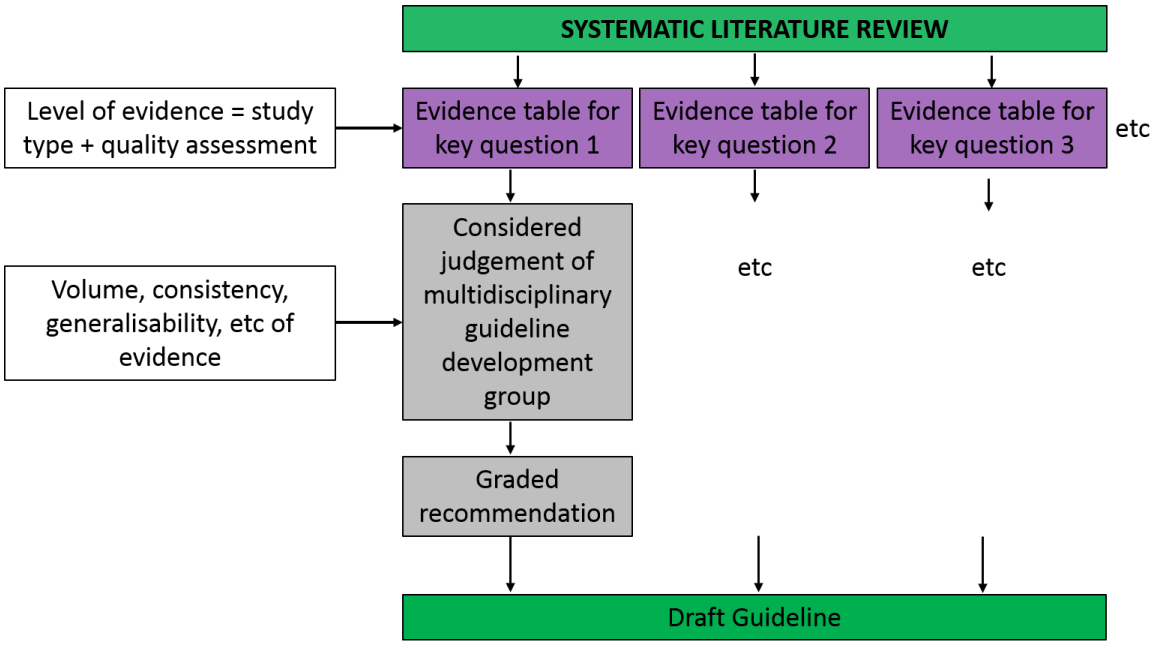
Regardless of the conclusion (& the steps taken to reach it), the published guideline &supporting documents will contain justification for each recommendation which will highlight the supporting evidence & factors that have been taken into account to reach the decision.

Good Practice Points (GPP) are intended to assist guideline users by providing short pieces of advice which may not have an evidence base, but which are seen as essential to good clinical practice. If the working party feels strongly that they want to make a recommendation even though there is no significant evidence, this should be done as a weak recommendation based on very low quality evidence. Note that there must be some evidence of opinion supporting the recommendation from outside the working party. If no such evidence exists, formal methods should be used to develop a consensus based recommendation which will be clearly identified as such within the guideline by a statement accompanying the recommendation. The method used to reach consensus will be detailed in an appendix or in the supplementary information for the guideline.

4.6. Consultation Process

On completion, these guidelines will be open for consultation by the stakeholders, and the comments made will be listed in an appendix of the guideline. The draft report will be placed on HIS website for 1 month. Views will be invited on format, content, local applicability, patient acceptability and recommendations. The Working Party consider and collate comments and agree revisions. As detailed in Section 2, reviewers are invited to comment as individuals and not as representatives of particular parties or organisations, and will be required to complete a conflict of interest declaration alongside their review.

4.7 Overview of process



5. Standard format of guidelines

5.1 Layout of guidelines

There is a standard format for all modules of HIS guidelines as follows:

- Title page;
- Contents page;
- Guideline development team including acknowledgements and co-authors' conflicts of interest
- Summary and lay summary
- Scope and purpose including publication and expiry dates
- Summary of all clinical practice recommendations;
- Implementation e.g. summary of audit measures;
- Methodology incl. search methods
- Rationale of each recommendation or group of recommendations followed by all of the references cited in the rationale;
- Appendix to publish the original working party documents, which are not relevant to the topic, but ensure that the development process was correct: e.g. scope, declarations of interest, review protocols, literature search strategy, clinical article selection, clinical evidence tables, excluded studies, research recommendations and peer reviewers' comments

5.2 Acknowledgements and declarations of interest

Significant contributions to the guideline from infection control practitioners, clinical scientists, patients and other stakeholders should be acknowledged. All authors will provide declarations of interest in accordance with the conflicts of interest policy of the association. Any conflicts of interests and source of funding will be published in this paragraph

5.3 Scope and purpose

The background and rationale for the development of the guideline and links to prior versions of the guideline and links with the guidelines of other international and national guideline development s should be described when appropriate. Each guideline should clearly indicate its overall objective, the clinical question(s) addressed, any particular patient groups included or excluded and the audience for which the guideline is intended. A publication date, an expiry and review date will be indicated in this section.

5.4 Summary of recommendations

A summary of the guideline recommendations is collated to provide a list of all recommendations for ease of review by the user. This section is readily available for printing separately from the full guideline and serves as a quick reference guide. This summary will be also given in lay people language and will be downloadable separately from the HIS website.

5.5 Implementation of guidelines

Each guideline contains a number of audit measures to assist with implementation of the guideline, promote an improvement in the quality of care and allow comparative audit. The audit measures should be measurable, achievable and serve as evidence-based criteria for continuing quality improvement. The barriers to implementation will be discussed.

5.6 Methodology

The search strategy with dates of search, search terminology and methods should be described in the introduction. Harmonisation with the recommendations from other international Infection control guidelines should be acknowledged to provide clarity to the guideline user. The method of grading the strength of recommendations and level of supporting evidence should be described. The review questions, the search terms and dates, the evidence tables and judgement reports can be added as appendix.

5.7 Supporting rationale and references for recommendations

This section provides the rationale and chain of logic for the guideline recommendations. The rationale and references are described separately after each recommendation or subgroup of recommendations to allow for ease of updating and editing. The rationale should provide support for the grading of the recommendations.

6. Dissemination and implementation of the guidelines

6.1 Notification of e-publication of the final version

HIS members will be notified when a final version of a clinical guideline is posted on the HIS website. Previous versions of the guideline are published electronically rather than in print.

A patient-friendly version of the guidelines will be produced in conjunction with the community for dissemination to service users and will be included as an annexe to the main guideline. This will be downloadable for free via the HIS website.

Current and guidelines under review are published on the HIS website:

- Planned guidelines are published on the guidelines on the HIS website
- Guidelines produced in collaboration with other associations are published at http://www.his.org.uk/resources-guidelines/guidelines-reports; and
- Historical HIS guidelines are archived at:

6.2 Use of audit measures for national audit by the SDC

Implementation of HIS guidelines is promoted by audit on performance measures related to key recommendations within the guideline. The co-authors of each guideline should identify several audit measures, in collaboration with SDC, to serve as evidence-based useful criteria for continuing quality improvement. A summary of all of the audit measures in each guideline is included before the rationale section of all of the recommendations

The audit measures may be used for local and regional audit by individual hospitals and institutions. Some of the audit measures are used as performance indicators in mandatory national surveillance schemes for hospital acquired infections. This approach helps ensure that implementation of all of the recommendations covered by national audit is high. Some of the established audit measures have been used as performance indicators by PHE for many years and are utilised to compare the performance of hospitals across the UK (e.g. SISS , MRSA BSI).

6.3 Dissemination and implementation initiatives

Several strategies and initiatives have been introduced to improve dissemination and implementation of HIS guidelines:

- Each guideline has a summary of recommendations before the section: supporting rationale and references for recommendation. This section of the guideline can be readily downloaded from the website as a concise summary of the recommendations without needing to read, download or print the entire guideline document;
- The HIS Council will liaise with the working party to produce educational CPD-accredited material to support the guidelines, including e-Learning material;
- All HIS guidelines published to date have been formatted as PDF files on its website providing printable copies of each guideline ready to download at no cost to any user;

- Liaison with the HIS Education Committee has ensured that presentations on new HIS guidelines at one of the HIS conferences have been used to launch and promote the awareness and uptake of guideline recommendations; and
- E-publication is planned on the HIS website and in JHI or other journal on completion of guidelines. The e-publications on the journal publisher's website will be cited by PubMed and Medline which should promote dissemination of the guideline.

Appendix 1 – HIS Guidelines

Listed below are guidelines produced by HIS working parties and in collaboration with other professional organisations.

Published Guidelines/Advice

- Surveillance of infection associated with external ventricular drains: proposed methodology and results from a pilot study [2017]*
- Decontamination of breast pump milk collection kits and related items at home and in hospital: guidance from a Joint Working Group of the Healthcare Infection Society and Infection Prevention Society [2016] *****
- Prevention and control of multi-drug-resistant Gram-negative bacteria: recommendations from a Joint Working Party [2016] *****
- Development of a sporicidal test method for Clostridium difficile [2015] *****
- epic3: National Evidence-Based Guidelines for Preventing HCAI in NHS Hospitals in England [2014] #
- Guidance on the use of respiratory and facial protection equipment [2013] #
- Guidelines on the facilities required for minor surgical procedures and minimal access interventions [2012] #
- Guidelines for prevention and control of group A streptococcal infection in acute healthcare and maternity settings in the UK [2012] #
- Guidelines for the management of norovirus outbreaks in acute and community health and social care settings [2012] #

Guidelines that have been withdrawn or superseded.

- Guidelines for the control and prevention of meticillin-resistant Staphylococcus aureus (MRSA) in healthcare facilities [2006] ¤Guidelines for the control of glycopeptide-resistant enterococci in hospitals [2006] ¤
- National Glycopeptide-Resistant Enterococcal Bacteraemia Surveillance Working Group Report to the Department of Health [2006] ¤
- National Clostridium difficile Standards Group: Report to the Department of Health [2004] ¤
- Behaviours and rituals in the operating theatre [HIS, 2002] ¤
- Microbiological commissioning and monitoring of operating theatre suites [2002] ¤
- Rinse water for heat labile endoscopy equipment [May 2002] ¤

Time since publication	Categorisation (symbol)
< 3 years	**Current (*)**
3 – 7 years	**Some recommendations may be out of date(#)**
> 7 years	**Use with caution(!)**
Over 10 years old/superseded	**Withdrawn (¤)**

All are available in PDF format on the HIS website at www.his.org.uk

UPDATES TO GUIDELINES

Guidelines for the facilities required for minor surgical procedures and minimal access interventions, 2012 – review conclusion.

The literature and evidence base underpinning these guidelines was reviewed in 2016 to determine if the guidelines, published in 2012, needed to be revised or updated. However, since being published there has been no additional significant evidence relating to measures or facilities to prevent infection arising from minor surgery or minimal access interventions. Consequently, the advice and recommendations in this document still stand and are current. The literature will again be reviewed in 2019 to determine if these guidelines need to be revised and updated.

Guidelines are in preparation by the following working parties

Burns
FMT
Rinse Water
MOMT
IMD
AED
WATER MANAGEMENT

Updates:
Guidelines for the control and prevention of meticillin-resistant Staphylococcus aureus (MRSA) in healthcare facilities [2006] ¤

MDRGN

Appendix 2 - Translation of evidence levels

Prior to SIGN 54, evidence was appraised using a different grading system. How the previous grading system has been translated to SIGN's current grading system is shown below:

Levels of evidence			
Previous grading system	**Description**	**Current Grading system**	**Description**
Ia	Evidence obtained from meta-analysis of RCTs	1 + +	High qualitymeta-analysis, systematic reviews of the RCTs, or RCTs with a very low risk of bias
Ib	Evidence obtained from at least one RCT	1 +	Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
IIa	Evidence obtained from at least one well designed controlled study without randomisation	2 +	Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
IIb	Evidence obtained from at least one other type of well-designed quasi-experimental study		
III	Evidence obtained from well-designed non-experimental descriptive studies such as comparative studies, correlation studies and case studies	3	Non-analytic studies
IV	Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authors	4	Expert opinion

951 **Appendix 3 - Checklist for all HIS guidelines**

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	Yes	No	Unsure	Comments
Is the overall objective clear?				
Are the recommendations specific, unambiguous and clearly identifiable?				
Is the population and/or target audience defined?				
Is the language appropriate for the specified target audience?				
Are the clinical, healthcare or social questions covered?				
Are the recommendations in reference to specific clinical, healthcare or social circumstances clear?				
Has there been adequate involvement of patient and stakeholder groups in development?				
Are the methods to search for evidence and data clearly defined and adequate?				
Are the criteria and reasons for inclusion or exclusion of evidence by documenting review methods clearly stated?				
Has the SIGN system been used to outline the strengths and limitations of the evidence and acknowledge any areas of uncertainty?				
Has the agreed methodology been used to arrive at recommendations including methods to reach consensus?				
Have the health benefits, side effects and risks been considered in formulating recommendations?				
Have the different options for management of the IPC issue been considered and stated?				
Are there auditable standards developed?				
Are any potential organisational and financial barriers considered?				

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Appendix 4 – Conflict of Interests disclosure form

Introduction

HIS requires that all members and co-opted members of guidelines working parties, as well as any external peer reviewers, must declare all interests and membership of other committees prior to serving on a working party or commenting in the consultation phase and this declaration is confirmed and repeated at the publication of each set of completed guidelines published.

The details given in this form will be retained on a register at the Society's Head Office and will be made available for publication, if required.

Instructions

1. Please report all relationships with pharmaceutical, diagnostic, or such similar companies involved in biomedical products in **[INSERT: year—year (CURRENT AND PRECEDING YEAR)]**. For the purposes of this disclosure, the term 'member' includes the BHIVA member and any spouse/partner/ family member.

2. Further information is likely to be requested if any positive responses are given in the sections below.

3. If undisclosed competing interest is later proven, BHIVA will follow Committee on Publication Ethics (COPE) guidelines.

4. If there is nothing to disclose, please so indicate.

5. This declaration covers the period **[INSERT: month/year—month/year (TO COVER 12 MONTHS RETROSPECTIVE TO START OF WORKING PARTY)]** for pecuniary and non-pecuniary interests.

6. A description is also included of the format for a competing interest in a presentation.

7. Please email your completed form by **[DEADLINE – INSERT AS APPROPRIATE]** to the HIS at gemma.marsden@his.org.uk. Signed originals should also be posted 162 King's Cross Road, London WC1X 9DH

Name			
Signature			
Date			
1. Pecuniary interests	**None**	**£0-999**	**£≥1,000**
Consultancy Work This refers to any paid retainer or agreement between the member and a company usually with a contract for a specific period and includes payment for attending Advisory Board meetings.	☐	☐	☐
Speaker fees This section mainly concerns fees (e.g. for lectures, commissioned articles, or other suchlike paid activity) received from a commercial sponsor and where the member has benefited personally.	☐	☐	☐
Company shares This section would include any shares held by the member in the biomedical industry (e.g., pharmaceutical, diagnostic, or such similar companies).	☐	☐	☐
Grant support This refers to fees and grants paid to the member which have been used for research, education, equipment, salaries (including Fellowships) in your department and for personal travel/hospitality for conferences meetings.	☐	☐	☐
Other paid income This refers to patents or royalties, serving as an expert witness, or performing other activities for an entity with a financial interest in this area undertaken by the member.	☐	☐	☐
Other relevant disclosure This refers to any other relationship which is financial or with an organisation that, if not disclosed by the member, could compromise the member or HIS as a charitable organisation.	☐	☐	☐
2. Non-pecuniary interests You are required to declare any trusteeships in other organisations, other committee memberships or directorships, which have conflicting or competing interests.			
Trusteeships Give full name of organisation(s) and information on term served to date and retirement date.			
Committee memberships Give full name of organisation(s) and indicate your role on any committees, giving details of term served to date and retirement date.			
Directorships			

Give full name of organisation(s) and information on term served to date and retirement date.

981

Appendix 5 – Job Description of HIS Guidelines methods expert

Responsibilities

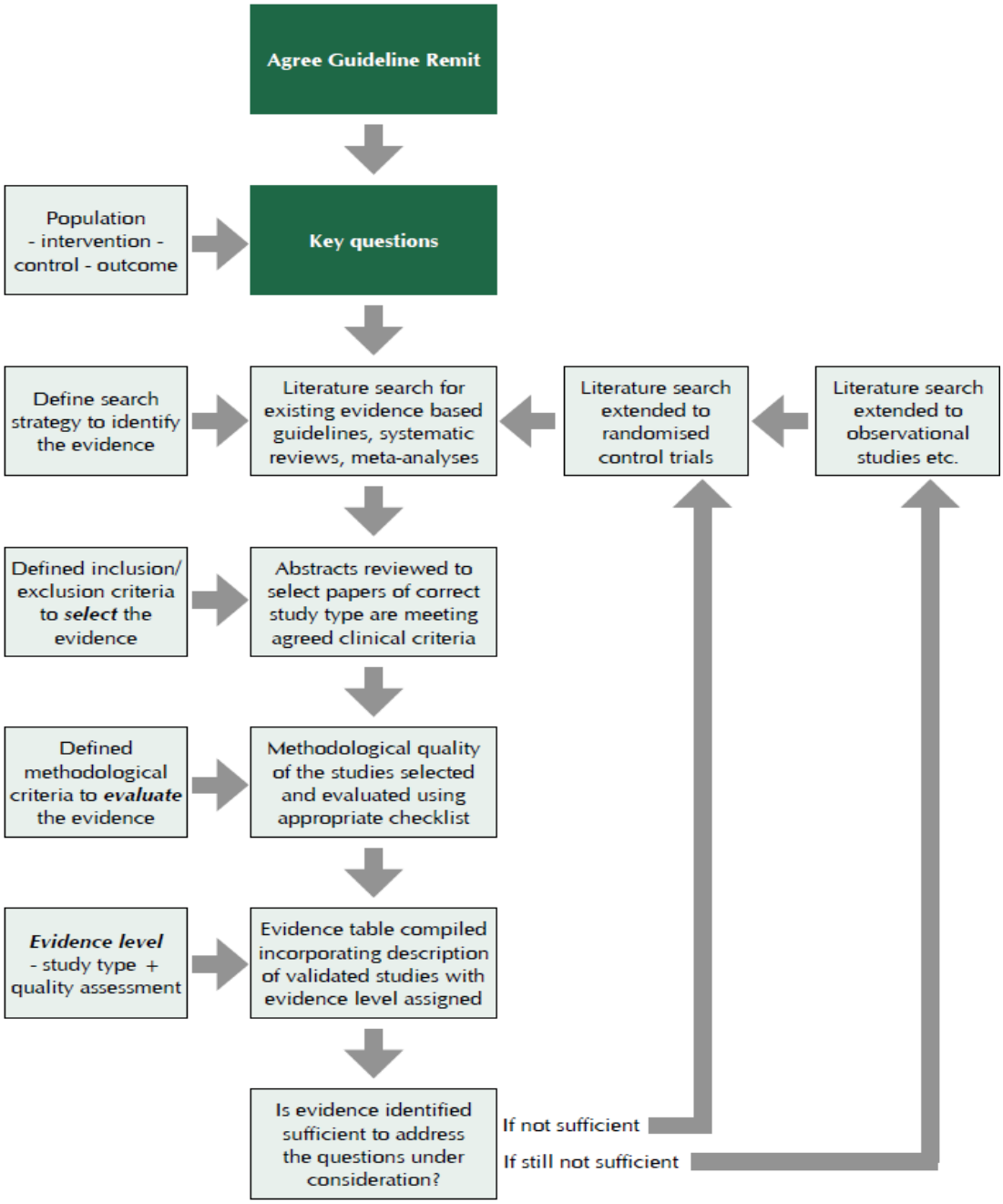
To lead in supporting systematic reviews, to inform guideline development and updating including performing literature searches, assessing scientific papers against set criteria, data extraction and analysis, as directed by the SDC and any working parties.

Person specification

- Experience of performing scientific literature searches, data extraction and analysis and preferably knowledge of the process of systematic reviews.
- Computer literate with accurate word processing skills and sound knowledge of Windows based applications, Word, Excel and Access.
- Excellent organisational skills.
- Ability to follow established procedures and policy.
- Ability to work as part of a team.
- Ability to work well under pressure, meet deadlines and pay accurate attention to detail.
- Ability to prioritise a range of tasks.
- Flexible.
- Knowledge of and interest in IPC desirable

Appendix 6 - Systematic Literature Review

Figure 10: Systematic literature review



1007 **Appendix 7 – Methodology Checklist : Systematic Reviews and Meta Analyses**

Methodology Checklist: Systematic Reviews and Meta-analyses HIS has based this checklist on the AMSTAR tool by *Shea, et al.,* Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. *BMC Medical Research Methodology 2007, **7**:10 doi:10.1186/1471-2288-7-10.*	
Study identification (*Include author, title, year of publication, journal title, pages*)	
Guideline topic:	Key Question No:
Before completing this checklist, consider: Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO, reject. IF YES, complete the checklist.	
Checklist completed by:	

1.1 Section 1: Internal validity

In a well conducted systematic review:		2 **Does this study do it?**
1.1	The research question is clearly defined and the inclusion/ exclusion criteria must be listed in the paper.	Yes ☐ No ☐ **If no reject**
1.2	A comprehensive literature search is carried out.	Yes ☐ No ☐ Not applicable ☐ **If no reject**
1.3	At least two people should have selected studies.	Yes ☐ No ☐ Can't say ☐
1.4	At least two people should have extracted data.	Yes ☐ No ☐ Can't say ☐
1.5	The status of publication was not used as an inclusion criterion.	Yes ☐ No ☐

1.6	The excluded studies are listed.	Yes ☐ No ☐
1.7	The relevant characteristics of the included studies are provided.	Yes ☐ No ☐
1.8	The scientific quality of the included studies was assessed and reported.	Yes ☐ No ☐
1.9	Was the scientific quality of the included studies used appropriately?	Yes ☐ No ☐
1.10	Appropriate methods are used to combine the individual study findings.	Yes ☐ No ☐ Can't say ☐ Not applicable ☐
1.11	The likelihood of publication bias was assessed appropriately.	Yes ☐ No ☐ Not applicable ☐
1.12	Conflicts of interest are declared.	Yes ☐ No ☐
SECTION 2: OVERALL ASSESSMENT OF THE STUDY		
2.1	What is your overall assessment of the methodological quality of this review?	High quality (++) ☐ Acceptable (+) ☐ Low quality (-) ☐ Unacceptable – reject 0 ☐

2.2	Are the results of this study directly applicable to the patient group targeted by this guideline?	Yes ☐ No ☐
2.3	**Notes:**	

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1010 **Notes on the Use of Methodology Checklist 1: Systematic Reviews and Meta-analyses**

Methodology Checklist 1: Systematic Reviews and Meta-analyses **Notes for completion of checklist**		
Must refers to a statement that has to be fulfilled for the question to receive a yes answer. Should statements are a mark of quality but not a necessity for a yes answer. These should be used to assess the overall quality of the paper.		
2.1 Section 1: Internal validity		
In a well conducted systematic review:		3 **Notes**
1.1	The research question is clearly defined and the inclusion/ exclusion criteria must be listed in the paper.	The PICO must be clear in the paper even if not directly referred to. The research question and inclusion criteria should be established before the review is conducted.
1.2	A comprehensive literature search is carried out.	At least two relevant electronic sources must be searched. The report must list the databases used (e.g., Central, EMBASE, and MEDLINE). (Cochrane register/Central counts as two sources; a grey literature search counts as supplementary). (PubMed and MEDLINE count as one database.) Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. Dates for the search should be provided. The paragraph above is the minimum requirement. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or/and experts in the particular field of study, and by reviewing the references in the studies found.

		The paragraph above is a quality criteria which affects the overall rating of the review. *Notes* This criterion will not apply in the case of prospective meta-analysis - this is where meta-analysis is based on pre-selected studies identified for inclusion before the results of those studies are known. Such reports must state that they are prospective.
1.3	At least two people should have selected studies.	At least two people should select papers. There should be a consensus process to resolve any differences
1.4	At least two people should have extracted data.	At least two people should extract data and should report that a consensus was agreed. One person checking the others data extraction is accurate is acceptable.
1.5	The status of publication was not used as an inclusion criterion.	The authors should state that they searched for reports regardless of their publication status. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status. If review indicates that there was a search for “grey literature” or “unpublished literature,” indicate “yes.” SIGLE database, dissertations, conference proceedings, and trial registries are all considered grey for this purpose. If searching a source that contains both grey and non-grey, must specify that they were searching for grey/unpublished lit.
1.6	The excluded studies are listed.	Limiting the excluded studies to references is acceptable.
1.7	The relevant characteristics of the included studies are provided.	In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions and outcomes. The ranges of characteristics in all the included studies e.g., age, race, sex, relevant socioeconomic data,

		disease status, duration, severity, or other diseases should be reported. (Note that a format other than a table is acceptable, as long as the information noted here is provided). Absence of this will make it impossible to form guideline recommendations. Mark as (-) original papers would need to be examined.
1.8	The scientific quality of the included studies was assessed and documented	It can include use of a quality scoring tool or checklist, e.g. risk of bias assessment, or a description of quality items, with some kind of result for EACH study ("low" or "high" is fine, as long as it is clear which studies scored "low" and which scored "high"; a summary score/range for all studies is not acceptable. Absence of this will make it impossible to form guideline recommendations. Mark as (-)
1.9	Was the scientific quality of the included studies used appropriately?	Examples include sensitivity analysis based on study quality, exclusion of poor quality studies, and statements such as 'the results should be interpreted with caution due to poor quality of included studies' The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations. Cannot score "yes" for this question if scored "no" for question 1.8.
1.10	Appropriate methods are used to combine the individual study findings.	Studies that are very clinically heterogeneous should not be combined in a meta-analysis. Look at the forest plot–do the results look similar across the studies? For the pooled result a test should be done to assess statistical heterogeneity i.e. Chi-squared (χ^2) test for homogeneity and/or I^2 test for inconsistency. If significant heterogeneity is apparent the authors should have explored possible explanations using methods such as sensitivity analysis or meta-regression. A random effects

		analysis may be used to take account of between-study variation but is not a 'fix' for heterogeneity. Planned subgroup analyses should be pre-specified and limited in number because conducting many subgroup analyses increases the probability of obtaining a statistically significant result by chance. Conclusions based on post-hoc subgroup analyses must be interpreted with caution. Cannot score "yes" for this question if scored "no" for question 1.8.
1.11	The likelihood of publication bias was assessed appropriately	The possibility of publication bias should be assessed where possible, commonly done by visual inspection of a funnel plot together with a statistical test for asymmetry (e.g., Egger regression test) although other statistical and modelling approaches may be reported. Absence of a funnel plot doesn't mean the likelihood of publication bias was not assessed appropriately (there are other methods); 10 studies is just a ball-park minimum number for a funnel plot and a plot is of little use when there are few studies.
1.12	Conflicts of interest are declared.	Potential sources of support should be clearly acknowledged in both the systematic review and the included studies.
SECTION 2: OVERALL ASSESSMENT OF THE STUDY		
2.1	What is your overall assessment of the methodological quality of this review?	Rate the overall methodological quality of the study, using the following as a guide: **High quality** (++): Majority of criteria met. Little or no risk of bias.. **Acceptable** (+): Most criteria met. Some flaws in the study with an associated risk of bias. **Low quality** (-): Either most criteria not met, or significant flaws relating to key aspects of study design. **Reject** (0): Poor quality study with significant flaws. Wrong study type. Not relevant to guideline.

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