



Healthcare Infection Society

Guideline Development Manual (V14)

This Guideline Development Manual was originally prepared by members of the Scientific Development Committee for NICE Accreditation of HIS guidelines (original document dated 26.10.2015)

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1. Introduction

1.1 About 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). The Society 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 1150 across a wide range of healthcare professionals from the UK and worldwide. Healthcare Infection Society has published the Journal of Hospital Infection (JHI) since 1980, which is subscribed worldwide. It has an impact factor of 3.704 in 2018. Since March 2019, HIS also publishes an open access journal Infection Prevention in Practice (IPIP).

The Society 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 sixteen 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). Of these, four were NICE accredited. Further eleven are currently under development, of which eight are expected to be NICE accredited. A complete list of HIS guidelines can be found in Appendix 1 and on the HIS website (<https://www.his.org.uk/resources-guidelines/his-guidelines-and-guidance/>). Since 2015, when HIS received its accreditation, all HIS guidelines are produced using NICE approved methodology. The guides which were in development before the NICE accreditation are published as 'guidance' document without a NICE logo.

1.2 Development of guidelines at HIS

The Society has several standing committees, one of which is the Guideline Committee. The Guideline Committee is responsible for recruiting members for each Guideline Development Group (GDG) by whom evidence-based guidelines are developed on different topics of IPC according to the guideline development manual. This document is based on NICE guideline methodology and is overseen by the HIS research team.

In previous guidelines, recommendations were categorised based on existing scientific evidence, theoretical rationale, applicability and economic impact. These guidelines were supported by

emerging evidence, which in IPC is based 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. The introduction of Grading of Recommendations Assessment, Development and Evaluation (GRADE; Guyatt *et al.*, 2008) has allowed 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 the GRADE tables rate the quality of evidence into four levels, based on 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 based on further criteria:

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

The use of GRADE has been adopted by other national and international GDG. This requires a conduct of full, detailed, systematic reviews for all questions. The method based on the GRADE approach of making 'strong' or 'conditional' recommendations, using DECIDE Evidence to Decision frameworks (Alonso-Coello *et al.*, 2006 a and b) is used. This is the basis of the approach used by HIS for the presentation of recommendations in the guidelines

The Society attempts to harmonise its guidelines with other international IPC GDGs in relevance 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.

1.3 Aims and structure of the guideline development manual

The main aims of this guideline development manual 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 the guidelines
- to summarise the development 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 Instrument (AGREEII; Brouwers *et al.*, 2010), the subsequent sections of this document demonstrate that HIS guidelines are:

- 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 research recommendations based on gaps in literature identified during the guideline development
- Designed to provide audit measures for the guideline recommendations

The Society develops guidelines according to the following core principles:

- Guideline is based on the best available evidence of what works, what it costs and how feasible it is to conduct in the clinical setting.
- Guideline is developed by independent and unbiased committees of experts (known as GDG).
- All GDG include at least two lay members, who represent people with personal experience of using health or care services who could potentially be affected by the guideline.
- Stakeholders and individuals have an opportunity to comment on HIS recommendations before the guidelines are published. This is achieved via the consultation process.
- Once published, all guidelines are regularly checked and updated in the light of new evidence or intelligence if necessary.
- All GDG members are committed to advancing equality of opportunity and ensuring that the social value judgements made reflect the values of the society.
- Guideline processes, methods and policies are regularly updated to ensure they remain up to date.

1.4 Review and update of the guideline development manual

This manual is checked and updated every 12-24 months by the HIS Research and Development Manager (RDM) with an oversight by the Guideline Committee, subject to ratification by the HIS Council. This practice ensures that the manual remains aligned to the current NICE methodology. Table 1.1 indicates how the HIS methodology aligns with NICE methodology and accreditation criteria.

1.5 Medico-legal implications of HIS guidelines

Clinical guidelines are intended as an aid to clinical judgement but do not aim 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 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, HIS 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.”

Table 1.1 The list of NICE accreditation criteria with the description of where these criteria are addressed in this document

Domain	Criteria	Section
1. Scope and purpose is concerned with the overall aim of the guideline, the specific health questions and the target population.	1.1 The overall objective of the guideline	5.1
	1.2 The clinical, healthcare or social questions covered by the guideline	2.2, 4
	1.3 The population and/or target audience to whom the guideline applies	4.1, 4.3
	1.4 That the producer ensures guideline 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 guideline represents the views of its intended users and those affected by the guideline (patients and service users).	2.1 Individuals from all relevant stakeholder groups including patients' groups in developing guideline	3.1, Appendix 3
	2.2 Patient and service user representatives and seeks patients' views and preferences in developing guideline	2.2, 3.1, 4.1
	2.3 Representative intended users in developing guideline	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.	3.1 Requires the guideline producer to use systematic methods to search for evidence and provide details of the search strategy	4.2, Appendix 6
	3.2 Requires the guideline 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 guideline 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 guideline and maintaining and improving guideline quality	2.4
4. Clarity and presentation deals with the language and format of the guideline.	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 guideline 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 guideline.	5.1 Publishing support tools to aid implementation of guideline	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 guideline in general and their recommendations in particular.	6.1 Ensures editorial independence from the funding body	3
	6.2 Is transparent about the funding mechanisms for its guideline	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 guideline	4.5, 4.6

2. Selection and planning of HIS guidelines

2.1 Selection criteria for guideline topics

Topics for guidelines are selected to cover all the main areas of IPC. These topics are primarily proposed by the Guideline Committee. Additionally, topics identified by PHE, DH and NHS Scotland, as well as any 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 (Appendix 2) and considered by the Guideline Committee, which in turn proposes relevant topics to HIS Council for approval. Other organisations, such as other Societies (e.g. BSAC, BIA or IPS), can also approach HIS with a proposal for collaboration on newly identified guideline topic. In these 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. Approved topics for guidelines are published on the HIS website at <https://www.his.org.uk/about/structure-and-governance/working-parties>.

2.2 Drafting the scope of the guideline

The Guideline Committee drafts a scope for proposal to the HIS Council after searching:

- related guideline from other societies, accredited developers' policy and legislation
- key systematic reviews and epidemiological reviews and economic evaluations
- information on current practice, including cost 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 includes:

- 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)
- a brief overview of the context (current policy and practice) in which the guideline is to be developed
- rationale on why the guideline is needed and where it is likely to add value to the current best practice
- definition of the population to be covered
- information on what the guideline should consider, the key issues to be covered and the list of the key questions that are to be considered by the GDG
- a clear framework for the guideline, which sets 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

- description of how the guidelines link to other recommendations and quality standards
- information about the areas where evidence is likely to be lacking
- considerations of the impact of the guidelines on potential equality among groups sharing protected characteristics
- information on health inequalities associated with socioeconomic factors and with inequities in access for certain groups to healthcare and social care, and the identified opportunities to improve health.

This proposal for the guideline topic is submitted to the HIS council for approval and then published on the HIS website. The HIS council assesses the guideline proposal according to the selection criteria listed in section 4.3. The draft proposal is published in an appendix of the final guidelines.

2.3 Timelines for development of HIS guidelines

The dates of planned guidelines are published on the HIS website. Dates covered by a preparatory literature search performed are recorded in the introduction section of the guideline. The timeline for the completion of each guideline is set by the Guideline Committee and varies between guidelines depending on their scope and complexity. The expectation is that a guideline takes between 18 and 36 months to complete. If a GDG fails to complete its work within the specified period, the Guideline Committee has the discretion to either extend the timeline or replace some or all the members of the GDG.

The first draft of the guideline is opened for consultation for one month on the HIS website, to invite comments from the public and other stakeholders. After amending the guideline with comments from this public consultation phase, the revised guideline is sent to HIS council. All reviewers are invited to comment as individuals, not as representatives of any organisation or group. Comments from peer reviewers are not considered unless an accompanying declaration of interest form has also been submitted. Stakeholder organisations and individuals are listed in the appendix alongside their comments. 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 final version that considers the feedback from the stakeholders and the endorsement of the final version by the Guideline Committee 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 regularly and updated as necessary (Alonso-Coello *et al.*, 2011; Lyratzopoulos *et al.*, 2012; Martinez Garcia *et al.*, 2012; Schunemann *et al.*, 2014). Adapting the SIGN framework, HIS uses a traffic light system to indicate how current the existing guidelines are (Figure 2.1). Considering that the median lifespan of the

guideline is 60 months (Alderson *et al.*, 2014), the HIS system ensures that all guidelines are checked every three to four years, so the updates are produced in a timely manner.




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 (*)

Figure 2.1: The traffic light system used by HIS to indicate whether the existing guidelines are current.

2.4.1 Process for updating an existing guideline

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 is usually every three to four years, is determined by the Guideline Committee and stated on the website. Every three to four years, the research objectives identified in the GDG report are reviewed for the 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 Guideline Committee meetings, the progress and status of each guideline is discussed with the GDG representatives. The following factors influence the decision whether and how to review a guideline on an unscheduled basis:

- emergence of new evidence, that can 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, drugs, policy or legislation, that can change former recommendations
- emergence of another guidance that contradicts recommendations
- withdrawal of a drug/technology or an emergence of a significant drug safety update

- comments received to HIS about current guidelines

As a first step, the Guideline Committee commissions authors of the previous guideline on this topic to 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 conducted with the support of the HIS team and are based on the key questions and search strategies used in the original guideline. The searches also include an element of horizon scanning to see if there are any 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 can impact on the recommendations made in the existing guideline. This report also highlights any new areas or key questions that have emerged since the previous publication and is submitted to the Guideline Committee, who decides (subject to ratification by the HIS Council), whether the guideline as it stands needs to be revalidated, undergo a complete/partial review or needs to be withdrawn. For guidelines which were developed jointly with partner organisations (e.g. BSAC, PHE, BIA etc), a consultation with these organization takes place and members from these organization are recruited in the GDG to assess the need for review. The councils of the partner organisations are involved in this decision.

2.4.2 Alternative update procedures

(i) Selective updates

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

(ii) 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 are reviewed on an annual or biannual basis. GDG membership remains consistent but sub-groups are involved in the review process at any given time as needed. This process is managed by a steering group and HIS team conducts literature searches based on the existing questions. Updated drafts of the guideline are made available on the HIS website for comment and are presented at HIS biennial meetings.

(iii) Monitoring and interim updates

The Society welcomes comments on published guidelines, and together with new evidence, the Guideline Committee considers whether an immediate response 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 Guideline Committee considers an update to the guideline if the following criteria are met:

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

- a specific issue such as a change in government policy gives rise to a new question and the nature of the update does not warrant the assembly of the complete GDG

2.4.3 Withdrawal of guidelines

Guidelines may become superseded and therefore a proposal to withdraw the guideline may be made to the Guideline Committee.

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.

2.4.4 Overview of guideline production process

Table 2.1 summarises the steps involved in producing a new guideline. These steps are undertaken when new guidelines are commissioned or when the existing guidelines are updated.

Table 2.1: Steps involved in HIS guideline production.

1.	Proposed title and scope approval by the Guideline Committee and agreed by the HIS Council. (If joint guideline, agreement made with other societies)
2.	Lead author/chair and co-chair identified by Guideline Committee; GDG members nominated by lead author and co-chair. Initial conflict of interest declarations made.
3.	Initial meeting with all relevant stakeholders to identify questions, produce scope, allocate sections to GDG members, agree timelines/meeting dates. Checklist on guideline principles distributed to GDG members.
4.	Search strategy, scope and questions approved by the GDG. GDG members asked to identify studies of interest
5.	HIS team perform systematic reviews with an oversight from GDG.
6.	HIS team present evidence reviews. GDG consider the evidence, statements and recommendations and research recommendations made. Guidelines written to the format required. GDG identify potential audit points, educational tools and other outputs relevant to the guidelines.
7.	Further meetings to continue to present synthesis of data, review draft recommendations and establish consensus and implications for practice. Chair summarizes all recommendations.
8.	Draft documents collated and finalised.
9.	Review by Guideline Committee chair. Comments fed back to authors and amendments made.
10.	Publication available on HIS website and sent out to stakeholders for public consultation/external review.
11.	Meeting: consideration of consultation feedback and redrafting considering the comments received.
12.	Review of checklist by Guideline Committee chair, redrafting if necessary.
13.	Review by Guideline Committee and HIS Council (and other Councils if joint guideline)
14.	Publication on HIS website and JHI or other journal, together with final conflict of interest statement.
15.	Periodic review: lead authors contacted by Guideline Committee prior to expiry of the guidelines. Guidelines updates if required, if no update needed, the web-based document renewed with a new expiry date and comment that update was not required (information from searches is included).

3. The Guideline Development Group

3.1 Responsibilities of the Guideline Development Group

The role of the group is to:

- agree on the research questions to be addressed by the evidence reviews (for example, when topic-specific input is needed to further define outcomes or specify appropriate comparators) as defined in the scope
- advise on developing the review protocol and alternative analyses
- consider the evidence
- develop the recommendations for practice and research
- consider the likely cost and savings associated with implementing the recommendations
- consider factors that may help or hinder implementation ('levers and barriers')
- advise on implementation support that may be needed.

3.2 Composition of the Guideline Development Group

The GDG are formed to work on specific topics and guidelines. Therefore, the group is multidisciplinary and includes practitioners, professionals, providers, commissioners, researchers (specialists and generalists) and lay members (people using services, family members and carers, and members of the public and community or voluntary sector with the relevant experience). The chair of the GDG, who is a recognised expert within the chosen field, is nominated by the Guideline Committee. The chair must have no conflict of interest in the topic of the guideline and act as lead author for the guideline. The lead author has a responsibility for timely preparation of the guideline. The Society assigns two researchers who are responsible for performing the literature searches and the evidence appraisal as well as ensuring they developed using the NICE principles.

The chair and the co-chair select other members of the GDG based on their expertise and track record of interest in the sub-specialty area, as well as a freedom from overt conflict of interest. If guidelines are developed in collaboration with other infection societies, representatives of these organisations are selected for the GDG according to their expertise, enthusiasm and time. The GDG may also include representatives from other professional groups, where these are considered relevant. All group members are recruited in accordance with the society's policy and procedure for recruitment and selection. Positions are advertised on the HIS website, in membership newsletter and other appropriate places (for example on social media), and relevant stakeholders are notified. Candidates are required to submit the curriculum vitae (CV) and a covering letter. The Society puts a call out to its Trainee members for their representation on the GDG. Training representatives are invited by the chair, upon receiving their CV and covering letter. All GDG chairs are encouraged to open an invitation to the members of HIS to apply to join the GDG if they have the relevant experience, enthusiasm and time (Grimshaw *et al.*, 1995, Qaseem *et al.*, 2012). The application process is the same as that described above.

All members of the GDG have an equal status, including the lay representatives who are selected to ensure that the patient voice informs the guideline recommendations (Pagliari *et al.*, 2002). During the preparation and publication of the guideline, the GDG is responsible to the chair, who in turn is responsible to the Guideline Committee and HIS Council.

The group may also be supported by co-opted members and expert witnesses who are invited to contribute to formulating recommendations in a specific part of the guideline only. They take part fully in discussions, but do not have voting rights or count towards quorum. Expert witnesses may also be invited to some group meetings to provide additional evidence. The resulting group reflects, as far as practically possible, the range of stakeholders and groups whose activities, services or care are covered by the guideline. Depending on the size of the group, GDG can be divided into a steering group and writing group, with secretariat and project management provided by the HIS team.

3.2.1 Number of members

The number of members depends on the scope of the guidelines. The GDG aims to recruit healthcare professionals, commissioners and providers from different fields to ensure that the GDG have a broad range of experience and knowledge and represent all important stakeholder groups. Thus, the extent of the topic and number of representations from the professional bodies influence this decision. In accordance with NICE principles, at least 13 members are selected to join the GDG, but if the topic is particularly broad, more members are recruited.

3.2.2 Support staff

Each GDG is supported by at least two HIS researchers who work together to identify, review and summarise the evidence. They provide project management, oversight of the development process and the quality assurance. The researchers ensure that the development processes are followed appropriately, and that all methods are clear and transparent, during and after guideline production.

3.2.3 Lay representation

Two lay members who represent or support patients or carers or those in the voluntary sector are engaged on each GDG. Lay representation is key to the guideline development process as the lay members present different perspectives on healthcare processes, priorities and outcomes (Brouwers *et al.*, 2010; van Wersch *et al.*, 2001). By involving the lay members, HIS ensures that the guidelines address the key concerns and highlight areas where patient perspective is different from that of the healthcare professional.

Lay representatives do this by:

- examining the research questions to make sure they reflect patient matters
- identifying the outcome measures related to research questions that are important to patients
- identifying areas where patient preference and choice need to be acknowledged

A lay representative is chosen based on the following expertise:

- experience of the healthcare situation being addressed
- an understanding of the experiences and needs of the wider patient group, and a willingness to share these experiences.
- time to commit to the GDG
- some familiarity with medical and research terminology (or a willingness to ask for clarification)
- willingness to be objective
- good communication and team working skills

HIS supports the lay representatives by providing them with an induction, offering email and phone support from HIS RDM and supplying them with a clear guideline on the roles and responsibilities of the lay representative.

In addition, HIS supports the GDG chair to:

- make sure that the lay representative remains fully engaged with the GDG
- ensure the contribution of the lay representative is fully acknowledged
- ensure the GDG members use appropriate language to make the discussions understandable
- be welcoming and make sure their voice is heard

3.3 Declaration of conflicts of interest

Since 2013, as part of its Conflict of Interests Policy, HIS requires that prior to the GDG meeting for the first time, a full declaration of interests is sought from all prospective members of the GDG (Appendix 3). These statements are reviewed by the HIS RDM with oversight from the chair and vice chair of each GDG. If there are any concerns, these are referred to the Guideline Committee in the first instance. Records are retained by HIS for the duration of the guideline development on the understanding that HIS are informed if the member's circumstances change during this time. To further reinforce this policy, the chair asks about the changes to the conflict of interest each time the meeting is held. In the event of a potential conflict being identified, the GDG ensures that the member does not contribute to the section affected. In the case where the chair of the GDG has a conflict of interest in one section, the vice-chair or another member take the lead for the relevant section. All published guidelines contain a full declaration of authors' conflicts of interests.

3.4 Identifying and meeting training needs of GDG members

As a part of HIS commitment to develop the guidelines according to NICE methodology, HIS researchers ensure that the principles for developing the guidelines are highlighted to the GDG members at the first meeting. The principles cover the topics such as the importance of NICE accreditations, the process of guideline development and the essential elements that ensure quality standards are met, composition of the GDG and the responsibilities of the GDG members. The members are further supported in developing research questions, reviewing evidence and forming/wording the recommendations; these are instituted at the stages when these skills are required. Other aspects of NICE principles such as the declaration of interests, social value judgements and equality policy are included in the Terms of Reference form (Appendix 3), which,

together with the copy of the HIS guidelines methodology manual, is distributed to the GDG members following the first meeting. All members of GDG are required to sign the document before any subsequent meetings. If the need for systematic reviewing/guideline development training is required for GDG members, these are sponsored or provided by HIS. Specific training for GDG chair or lay members is also offered if needed.

3.5 Funding of guideline development

The guidelines developed by HIS are not funded by any commercial company. The Society covers the cost of guideline development such as library cost for study retrieval, venues/refreshments for the meetings, travel expenses, and cost of administrative support. No member receives any remuneration for participation in a GDG. Only out-of-pocket expenses are paid as stated in the HIS Travel and Expenses Policy. In addition to the above, lay representatives can claim fully documented subsistence and childcare/carer expenses in accordance with HIS policy.

4. Guideline development process

The guidelines produced by HIS are developed using an explicit methodology based on the following core principles:

- Development is carried out by nationally representative, independent experts in the field of infection who are free of overt conflicts of interest (sections 3.2.1 and 3.3)
- Apart from the independent experts, each GDG includes at least two lay members (section 3.2.3)
- The GDG commissions the conduct of a systematic review to identify and critically appraise the literature. Recommendations using the GRADE system are linked to the supporting evidence and their wording reflects the strength of each of the recommendations. Each guideline is based on the best available evidence which considers what works and at what cost.
- Besides the financial and resource implications, all recommendations take account of equality issues and patient choice and lifestyle to ensure the guidelines reflect the values of the entire society.
- Recommendations are open to public review including members of HIS, stakeholders, patients and interested members of the public.
- Guidelines are regularly checked and updated as required.
- The guideline development processes, methods and policies are regularly updated.

In order to ensure that these principles are adhered to, the chair of GDG gives the checklist (Appendix 4) to all members at outset.

4.1 Meetings

All GDG members are experts who bring with them different beliefs, values and experience and it is important that all these perspectives are valued and considered. It is GDG chair's and HIS team's responsibility that all members of the group are engaged in the meetings and that each member has an equal opportunity to contribute to the development of the guideline. The Society also recognises that to be able to express these perspectives, some members may need additional support. For this reason, it is the chair's and HIS team's responsibility to ensure that the terminology used is understood by all group members and is clarified if needed. The chair also ensures that during the discussions all possible approaches are considered, while maintaining the focus on the guideline scope and ensuring the project is completed within the agreed timescale.

(i) Meeting documentation

Meeting documentation is prepared by HIS team, agreed with the chair and distributed within the GDG members to arrive at least five working days before a group meeting. A member of the HIS team takes formal minutes during the meetings and these are reviewed and approved at the next meeting. The minutes of each meeting are publicly available on the HIS website. The document includes the information on when and where the meeting took place, who attended, any declarations of interest and the list of subjects discussed. The details of the next meeting are posted on the website as soon as they become available.

(ii) Initial and development meetings

During the initial meeting(s), HIS encourages the GDG to establish a framework that clarifies the objectives of the group, the role of each member during the guideline development and the draft timetable with the milestones. Initial meetings are used to plan the evidence reviews and potential outputs and define the responsibilities of each member.

If the guideline is an update, drafts and completed evidence reviews from the previous guidelines are included in the meetings along with other materials, e.g. other relevant guidelines and HTM reports. The review questions and protocols from the previous guidelines are reviewed and updated in necessary, new review questions are developed by HIS team and the protocols are presented to the group for comment. The group is asked whether the planned evidence reviews are likely to cover all topics outlined in the scope and whether the review questions match the proposed reviews. The group members are asked to suggest any amendments or improvements, for example, to further define outcomes, specify appropriate comparators or suggest keywords for search strategies. The group are also asked whether the proposed evidence reviews can be completed within the agreed timeframe and whether there are any areas that might benefit from expert testimony. If the expert testimony is required, the group are asked to suggest people who can provide it.

Evidence reviews are presented to the group throughout the development of the guideline. Each member is sent the relevant documents in advance and the meetings are used to discuss the findings and consider the evidence for the relevant questions. Any additional evidence (e.g., expert testimony, views of lay members and the group members' experience) is also considered. The group discusses how the evidence answers the review questions and summarises each area. If subgroups are used, the meetings and proposed decisions are made within each sub-group and these are discussed and agreed when the whole GDG meets. The GDG discusses the wording of any draft recommendations and the rationale for the recommendations is recorded in the meeting notes and are reflected in the evidence statements. At this stage, HIS staff give presentations and/or provide information to explain their roles to the group. Group members may be asked to volunteer to work on additional guideline outputs such as e-learning packages, key messaging or pocket guidelines.

(iii) Final meetings

Following the guideline consultation, the group meets to discuss the comments, make any required changes and to agree the final wording of the draft guideline.

4.2 Making group decisions and reaching consensus

Any decisions made throughout the guideline development, e.g. review questions, evidence review protocols or developing recommendations are done so by the entire GDG. The role of the GDG chair in reaching consensus is to ensure that everyone has an opportunity to present their views, all perspectives are debated and that the discussions are open and constructive. The chair and HIS team also ensure that these are concluded in the timely manner and that all GDG members agree with the stated recommendations. If the group cannot come to consensus, the reasons are documented and reflected in the guidance document. The group consensus is usually reached through group discussion, but in case when this has not happened, this is resolved by the following methods:

- *Formal consensus within the group using voting procedure:* this is recorded in the minutes of the meeting and the guideline document, together with the statement made about the factors that have been considered to reach this decision. This method is generally used when the GDG members cannot reach the consensus via discussions.
- *Formal consensus outside the group using Delphi technique or the nominal-group technique:* this involves seeking to explore the views of the stakeholders outside of the GDG group with the decision agreed by the Guideline Committee who in such circumstances provide the quality assurance for the guideline. This is recorded in the minutes as well as documented in the minutes and the relevant meeting and the guideline document with the statement made about how these views were sought. This method is generally used when the literature searches identified no evidence and the recommendation is based on an expert opinion.

4.3 Selection criteria of topics of guidelines

Each new guideline or guideline update is proposed by the HIS Guideline Committee and approved by the HIS Council prior to beginning the process of guideline development. The guideline topics are chosen based on the burden of disease, the existence of variation in practice, and the potential to reduce the incidence of HCAI (Schunemann *et al.*, 2014). The following criteria are considered 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 the NHS and the strategic aims of NHS e.g. infection control targets
- The perceived need for the guideline, as indicated by a network of relevant stakeholders.

4.4 Developing review questions and the search strategy.

Review questions guide the search for evidence and the type of evidence used depends on the type of question. The number of the questions depends on the scope and the complexity of the topic covered. The Stakeholder meeting questions are amended into review questions by GDG and HIS team. Typically, these are initially drafted by the HIS team based on the discussions of the initial meetings. They are further refined and agreed with the group members at the subsequent meetings. The proposed review questions are reviewed by the external stakeholders via the process of scoping consultation. This ensures that the potential important topics are considered for inclusion by the GDG. Following this process, HIS requires that any changes to the protocols are agreed with the chair and HIS team (subject to HIS council approval) and that they are reported in the review protocols and the guideline document. The review questions cover at least one of the following issues:

- extent and nature of the issue as described in the scope

- mechanisms for disease development, associations between factors/variables and the outcome of interest, the epidemiology or aetiology of a disease or condition
- interventions that work best in ideal circumstances and are expected to be effective in specific circumstances/settings
- tests/technologies that are best to diagnose certain diseases or conditions
- programme theory, theory of change, or mechanisms of action which explain behaviour or effects
- views and experiences of service users and those who may be affected by the recommendation
- people's values and preferences that influence the uptake of an intervention
- views and experiences of providers and practitioners, including barriers and facilitators to the implementation of the intervention
- cost and resource use
- adverse events or unintended consequences.

The review questions are based on the PICO framework (Counsell, 1997; Schardt *et al.*, 2007), which provides a structured approach to identify the essential components of the question and later assist in design of the literature search strategies. The PICO define the following components:

- The **(P)atients or (P)opulation** of interest are individuals in relevant setting and/or with or at risk of relevant conditions. The GDG is careful not to make recommendations which may prejudice clinical care based on gender, age, ethnicity or socio-economic status, hence sub-groups of different populations are considered if required.
- The **(I)nterventions** define which strategies to prevention and control of HCAI are proposed to be assessed
- The **(C)omparisons** are those that are used to allow comparison between different prevention strategies. These may include standard care, no intervention, placebo or other interventions
- The **(O)utcomes** define how the interventions are working, including the benefits and harms. The relevant outcomes usually include incidence of the infection, transmission rates, mortality, morbidity, hospitalisation and complication rates. These are known as 'hard' outcomes and are preferred in developing recommendations within HIS guidelines, however other outcomes are considered if they are identified as important for the service users. The outcome sets are defined using COMET database.

The letter 'S' for **(S)tudy design** is also added to the PICO question. More information about the selection of studies based on the study design is included in section 4.5.2(i).

(i) Different question types

The evidence reviews conducted to assist the development of the HIS guidelines include different types of review questions depending on a scope. Typically, they include the following types:

- Questions about the effectiveness of the interventions: these compare different interventions (including standard care, placebo or no intervention) and measure them against the defined outcomes
- Questions that consider implementation: these identify factors that either enable or hinder the implementation of the interventions
- Questions that consider cost effectiveness: these determine whether the costs of implementing the intervention are balanced by the potential benefits, e.g. reducing costs by preventing the disease
- Questions about diagnostic accuracy: these determine how well a test performs in diagnosing a condition compared to a routinely used reference standard
- Questions about prognosis: these describe how specific characteristics of the individuals predict the occurrence of particular outcome
- Questions about clinical prediction models for prognosis or diagnosis: these help to estimate the probability that the specific disease is present or will occur in the future
- Questions about the views and experiences of the service users: these describe the views and experiences of the interventions, which may be important to the individuals affected by them, such as those who use the services, their family members/carers or the public. To ensure that the quality criteria are included in all guidelines, HIS encourages the GDG to use PROGRESS-Plus criteria when developing review questions
- Questions about service delivery: these describe how services are delivered and how these could be improved
- Questions about epidemiology: those that describe the incidence or prevalence of the condition

4.5 Systematic literature review

The Society recognises that both, its members and the GDG provide their time and expertise free of charge and should be supported as much as possible. Therefore, HIS has a dedicated team of staff who support the GDG in performing the literature searches, appraising the quality of the evidence, producing evidence tables and providing the GDG with completed systematic review reports. The process of conducting the systematic reviews used at HIS is based on the methodology described in the Cochrane handbook for systematic reviews (<https://training.cochrane.org/handbook/current>). After the development of the PICO questions the following steps are used to gather the evidence: conducting a systematic search, selection and evaluation of the studies and presenting and summarizing the evidence.

4.5.1 Systematic search

(i) Sources of evidence

The systematic search involves, as a minimum, a search of Embase (Cochrane Database of Systematic Reviews is included in this database), MEDLINE and CINAHL databases but if required, other databases such as PsychInfo, Cochrane Central Register of Controlled Trials or Medicines and Healthcare products Regulatory Agency can also be used. This is agreed with the whole GDG during the development of PICO questions.

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 GDG. 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 group (HICPAC) meetings and conferences. If these are agreed to be included by the GDG, they are given less weight in consideration than peer-reviewed published work and this is clearly signposted in the guideline document. Articles not available with an abstract in English are excluded. The GDG also review other relevant guidelines issued by other national and international societies such as PHE, British Infection Association (BIA), SHEA or HICPAC. Sources of grey literature include CORE, OpenGrey and The Canadian Agency for Drugs and Technology in Health (CADTH) Gray Matters.

(ii) Search Protocols

Search protocols are developed by the HIS team with an input from the group. The protocol includes the initial terms to be used, the sources to be searched, the limits to be applied and any supplementary search techniques to be used. The finalised review protocol is published on the HIS website and in the Prospero database.

The HIS team conduct a systematic search of the literature. The search strategy is built based on the review question which helps to identify additional search terms related to each element of the PICO framework. Following this, the initial search is performed to identify additional keywords and search terms used in the relevant publications. Once the search strategy is designed, this is first peer-reviewed by another HIS team member and then sent to be checked by GDG to ensure that there are no errors and that all relevant search terms are included.

(iii) Search terms, limits and filters

Search strategies are designed to incorporate subject headings (such as MeSH in Medline and Emtree in Embase) and free text. The group members identify synonyms, acronyms, generic and brand names and medical terminology. Tools such as PubReMiner and Medline Ranker are also used to flag terms of high value.

The period that the search covers depends on the nature of the clinical topic under consideration. This is discussed with the GDG at the time of protocol development. 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. For the updated guidelines, the period typically covers the time since the last search was conducted.

As part of the question setting process, a set of inclusion and exclusion criteria is drawn up and saved as part of the record of the review. This provides guidance at a later stage when studies are being selected for review. Inclusion criteria are based on the definition of the topic and may include limits such as type of infection control intervention, risk groups and risk factors and clinical settings. Other factors include geographic or language limits and the types of trials. These are decided by GDG before searches begin. Exclusion criteria are variable depending on the topic. A listing of the 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.

(iv) Citation searching

The team at HIS use a search technique known as pearl growing. The references of all relevant papers e.g. those meeting inclusion criteria and the key systematic reviews are checked, and any citations not identified by the literature searches are included (back searching). A further step is undertaken to search any articles which cited the identified articles (forward searching).

(v) Stepped searching

Different questions may be best answered by different databases or may rely on different levels of evidence. If required, an iterative approach to the literature searching is undertaken, carrying out a search for high level evidence in the first instance. After the results of this search are evaluated, and the questions need to be redefined, the subsequent searches focus on the most appropriate sources and study types.

(vi) Existing reviews and guidelines

For many review questions, previous guidelines or relevant systematic reviews already exist. If these are available and appropriately conducted, the GDG is 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 GDG can move on to consider its conclusions. Legislation relating to the guideline topic is also reviewed and is considered when making recommendations.

(vii) Addressing patient issues in the literature search

Incorporating the patients' perspectives 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 GDG. 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 typically includes 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. To ensure that the quality criteria are included in the guidelines, HIS encourages the GDG to use PROGRESS-Plus criteria for developing each review question.

4.5.2 Selection and evaluation of the evidence

(i) Evidence sifting

Before any studies are acquired for evaluation, the search output is sifted to eliminate irrelevant material. Results are sifted in two stages based on the selection criteria described by PICO and previously agreed and included in the research protocol. A preliminary sift of each search result is carried out. 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 are also eliminated at this stage. Following this process, selected studies are retrieved, and the full text is screened against the inclusion criteria. Priority screening is not used for selecting studies to be included in HIS guidelines.

All sifting is carried out by one researcher, with the double sifting carried out on a minimum 10% of the literature (with an agreed level of inter-rater reliability of 90%). The percentage of the records sifted by a second reviewer is agreed with the GDG. Disagreement over inclusion of the studies is resolved by discussion and rationale for exclusion of papers is documented. Where disagreement continues, studies are retained. Clinical judgment is sometimes applied to reject any studies that may meet the pre-agreed criteria but are not relevant to the guidelines. If this happens, this decision is made by a medically qualified GDG member. These may include clinical criteria but may also consider issues such as the relevance of practice in the UK or the availability of product on the UK market.

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 the NICE guideline development manual. Articles are considered of relevance if they describe:

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

In many areas of infection prevention and control, 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 GRADE 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. When these studies are selected, this is included in the evidence statements together with the description of how the GDG decided to make a recommendation. The process is also evidenced in the final guideline document. A table with the list of studies excluded during the sifting is included in the appendix of the evidence review. The table lists the studies as well as the reasons why they were excluded.

(ii) Quality appraisal

Once the studies are selected as potential sources of evidence, they are screened for quality to ensure their validity. The result of this assessment affects the level of evidence allocated to the study, which in turn influences the grade of recommendation that it supports. The methodological assessment is based on several 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 degree of consistency to the assessment process. The checklists used at HIS are those recommended by NICE. Full list of checklists is available in the Appendix 5.

Since the assessment process involves a degree of subjective judgement and therefore may impact the grade of recommendation, each study is evaluated independently by at least two individuals. Any differences in assessment are discussed by the reviewers. Where disagreement cannot be resolved, another independent reviewer arbitrates to reach an agreed quality assessment. A pictorial or tabular summary of the quality assessments of all studies is included in the evidence review reports and is described narratively in the evidence statements.

(iii) Data extraction

Characteristics of the studies and any relevant data are extracted using standardised templates developed by HIS (Appendix 6). These are typically included in the Appendix of the evidence review reports, although relevant data are also presented in the results section of the report. For the guidelines, HIS aims to conduct the meta-analysis whenever possible (i.e. when more than one study reporting the same outcome was identified, Higgins and Green, 2011). Meta-analysis is conducted regardless whether other analyses are available and is accompanied by the Forrest plot. When meta-analysis is conducted, the data are analysed using Cochrane software for conducting systematic reviews (RevMan®). If more than two competing options are compared, these are analysed using the network meta-analysis. Considering the current limitations of this approach, if network meta-analysis is conducted, this is described in the final guideline document using the PRISMA-NMA checklist (Hutton et al, 2015) and the diagram showing the number of direct and indirect treatment comparisons is included in the appendices. For diagnostic accuracy studies, data are analysed using diagnostic module in the RevMan® software and the analysis is accompanied by the ROC curves.

Similarly, if the data synthesis from qualitative studies is possible, this is done by using meta-themes and assessed using GRADE-CERQual approach. If meta-analyses or meta-syntheses are not possible, the extracted data are described narratively or using tables and diagrams.

(iv) Ensuring the inclusivity of the evidence review criteria

To ensure the equality and diversity concerns are addressed, any data relevant to the equalities criteria (as specified in a protocol) are included in the data extraction and evidence tables. These are further discussed at the GDG meeting with the results of these discussions and description of how they influenced the recommendations being described in the evidence statements.

(v) Including economic evaluation

Cost-effectiveness of interventions can help the GDG to consider whether their implementation would be beneficial. Economic evaluations do not only estimate how much the intervention costs, but also consider the potential benefits of the interventions (e.g. cost effectiveness, patients' quality of life). This may be particularly important if the resources are limited in particular settings. Thus, while the cost impact is not the most important factor in the decision-making process, it is considered by GDG when making recommendations. This ensures that the recommendation does not introduce the financial pressure on the institutions unless the GDG has confidence that the benefits and cost effectiveness are balanced. The Society aims to include the economic analysis in all relevant review questions.

4.5.3 Presenting and summarising the evidence

(i) Evidence review report

The evidence review report is prepared by HIS team with an input from GDG members. Each report contains the following information:

- An introduction section describing the background and the aim of the review
- Methods section describing how the evidence was identified, appraised and analysed/synthesised
- Summary of the evidence identified, which includes the narrative description as well as tables, diagrams and the outputs from meta-analyses/syntheses
- Suggested evidence statements based on the evidence
- Appendices with the following information: evidence tables, any additional data not presented in the main body, excluded study table, GRADE/GRADE-CERQual profiles

The evidence review is distributed within the entire GDG and discussed at the meeting. The group review the recommendations and consider other factors that may have not been fully considered e.g. personal views and experiences of the lay members, barriers not captured by the literature but experienced in clinical practice, equality issues not discussed in the literature. Recommendations from existing guidelines and other sources are also considered. At this point, GRADEing tables are introduced, these summarize the evidence from the previous guidelines, describe the evidence

included in the evidence review and describe any considerations discussed during the meeting. These include the evidence statements which were re-drafted at the meeting using the GRADE/GRADE-CERQual approach.

(ii) Evidence tables

Evidence tables are produced using the standard template developed by HIS (Appendix 7) and include the following information from the quantitative studies:

- Citation
- Aim
- Design
- Population
- Intervention and comparator
- Outcomes and key findings (including confidence intervals, p-values and any other information). If possible, data are back calculated into the format required for the evidence review
- Results of quality assessment
- Authors' conclusions
- Comments from the reviewer (including funding details, full description of intervention and comparator, method of allocation, inappropriately reported or missing data, any concerns regarding authors' conclusions)

For qualitative studies, the following information is extracted:

- Citation
- Aim
- Design
- Population
- Theoretical perspective used
- Objectives, methods of data collection and synthesis
- Key themes/findings, including relevant quotes
- Results of quality assessment
- Authors' conclusions

- Comments from the reviewer (including funding details, methods, gaps/limitations and any concerns about authors' conclusions)

(iii) Certainty/confidence in findings

The draft recommendations are prepared following the discussion of the evidence using the Evidence to Decision (EtD) framework, with attention to outcomes, harms and benefits of each of the recommendations. For each outcome of the review question the certainty/confidence in the findings is established by drafting a GRADE/GRADE-CERQual table. The evidence is considered and judged using the following ratings: **high**, **moderate**, **low** and **very low**, based on the characteristics of the included studies (Table 4.1). The wording of the evidence statements and the recommendations (sections iv and v below) reflects the strength of the evidence and its classification.

(iv) Structure of evidence statements

For each review question, the GDG provides an explanation and clinical context of the problem being discussed. Literature, which is relevant to this background but not necessarily included in the research question (e.g. describing the prevalence of the problem) is presented. Evidence statements are then prepared for each outcome of the review question. If the question is complex and has subsidiary questions (e.g. examines different types of populations/settings, different interventions or a range of outcomes), more than one evidence statement may be used. Each evidence statement clearly summarizes the key information which was used to make decisions when wording the recommendations. Each statement includes the following information:

- Details of the intervention and comparison, including information on where, how these were conducted and how the effectiveness was measured
- Population, including information on how many people were analysed and important information about the setting (e.g. which hospital unit or which country)
- Outcomes, the direction of effect and the size of the effect
- Strength of evidence
- Applicability to the people likely to be affected by the guideline

Other information such as whether the intervention was delivered as intended or whether there are factors that affect its implementation are also included. If no evidence was found, the evidence statement is still included.

The standardised terms are used for describing the strength of the evidence of quantitative studies:

- '**No evidence** was found from the studies published since...'
- '**There was weak evidence** from ...'
- '**There was moderate evidence** from...'

- ‘There was strong evidence from...’
- ‘The quality of the evidence is mixed’ OR ‘There was inconsistent evidence from...’

The example of the evidence statement below was taken from the MRSA guidelines currently in a process of an update. The review question investigated the effect of antibacterial surfaces in hospital environment on the incidence of MRSA infection:

“There was weak evidence of the benefit from one Randomised Controlled Trial¹⁴ which investigated the incidence of MRSA infections in patients admitted to isolation rooms with copper surfaces (n=36) as compared to standard surfaces (n=34). The study found lower, but insignificant incidence of MRSA infection in patients admitted to isolation rooms with copper surfaces (2/36, 5.5%) as compared to standard surfaces (3/34, 8.8%; OR 0.63 [95% CI 0.10-4.00], p=0.6240).”

Table 4.1 Assessing the certainty and classification of the evidence.

Assessing evidence	
GRADE (quantitative studies)	GRADE-CERQual (qualitative studies)
Study limitations (internal validity)	Methodological limitations (internal validity)
Inconsistency (heterogeneity)	Relevance (applicability to the context)
Indirectness	Coherence
Imprecision	Adequacy of data
Other considerations (e.g. publication bias)	
Classification of the evidence	
High	Further research unlikely to change recommendation
Moderate	Further research likely to impact recommendation and may change its strength
Low	Further research very likely to impact recommendation and change its strength
Very low	Estimate very uncertain, further research will likely change recommendation

The evidence statements for qualitative evidence are structured using similar approach, but instead of numerical data they summarize the evidence using the information about the context, quality of studies, consistency of the findings and the themes across the studies.

(v) Making recommendations

When writing the recommendations, the following are considered:

- The target group that should act on these recommendations
- The potential harms and benefits of the intervention and any unintended consequences
- The efficacy and the effectiveness of each intervention
- The consequences of stopping another intervention because it has been superseded by the new recommendation
- The potential effect on health inequalities
- Cost-effectiveness along with effectiveness of the intervention (e.g. implications of cost, resources and economic concerns)

- The feasibility of implementing the recommended interventions into practice (any information that can help implement the intervention or any barriers that can prevent the intervention to be implemented are included).
- If indirect evidence is used or the results are extrapolated to other settings or context, any differences and similarities in population, staffing, facilities, resources and limitations.

The quality and quantity of the evidence as well as the above considerations are reflected in the strength and the wording chosen. The following wording is used to write the recommendations (Table 4.2 provides examples of how the recommendations were worded in the updated MRSA guidelines):

- **'offer', 'measure', 'advise', 'refer', 'use'** or similar wording is used if GDG believes that most practitioners/commissioners/service users would choose an intervention if they were presented with the same evidence; this usually means that the benefits outweigh harms and that the intervention is cost-effective. This reflects a strong recommendation for the intervention. If there is a legal duty or if not following a recommendation may have serious consequences, the word **'must'** is used.
- **'do not offer'** or similar wording is used if GDG believes that harms outweigh the benefits or if an intervention is not likely to be cost-effective. If the recommendation is weaker, the recommendation can be for certain people or under specific circumstances. This reflects a strong recommendation against the intervention. If there is a legal duty or if not following a recommendation may have serious consequences, the word **'must not'** is used.
- **'consider'** is used if GDG believes that the evidence does not support the strong recommendation, but that the intervention may be beneficial in some circumstances. This reflects a conditional recommendation for the intervention.
- **'do not offer, unless...'** recommendation is made if GDG believes that the evidence does not support the strong recommendation, and that the intervention is likely not beneficial, but may be used in some circumstances e.g. no other options are available. This reflects a conditional recommendation against the intervention.

If the evidence is not sufficient or inconsistent (quality of the studies or the conclusions are mixed), the following options are used:

- **'consider'** recommendation is made
- **'no recommendation'** is made, and more research is advised
- **'use only in the context of research'** recommendation is made
- **'not to offer'** recommendation is made

The following elements are also included in the recommendations:

- **Good Practice Points (GPP)** to assist guideline users by providing short pieces of advice which may not have an evidence base, but which are considered essential to good clinical practice
- **Recommendations for research** that are likely to influence the decision making in the future. These are initially identified by the GDG during writing the evidence statements (step 1). Upon

the agreement with the group, they are subsequently limited to five per guideline using the following process:

- Step 2 – identifying the most important uncertainties and prioritising them
- Step 3 – translating the prioritised uncertainties into research recommendations
- Step 4 – assigning ‘key priority’ status to the most important research recommendations
- Step 5 – consultation and finalising research recommendations
- Step 6 – disseminating research recommendations
- Step 7 – reviewing research recommendations

Table 4.2: Examples of different types of recommendations used in HIS guidelines

Type of recommendation	Example
Legal requirement	<i>Patient MRSA screening must be performed and must be linked to a specific point of action such as decolonization or isolation (or both).</i>
Strong recommendation for	<i>Continue to use mupirocin for nasal decolonisation, either selectively, or universally in high-risk patients</i>
Conditional recommendation for	<i>If the patient underwent decolonization therapy, consider repeat MRSA screening to determine whether decolonization therapy was successful</i>
Strong recommendation against	<i>Do not perform repeat MRSA screening for patients who screen positive at admission unless the patient underwent decolonization therapy</i>
Conditional recommendation against	<i>Consider using chlorhexidine in neonates only if there is no alternative and there is no broken skin present</i>
No evidence	<i>If there was a significant MRSA exposure risk, consider re-screening the patient to determine whether MRSA was acquired</i>

(vi) Linking to other guidelines

During the scoping phase of the guidelines, the existing NICE guidelines as well as the guidance on Health Technology (HT) and Interventional Procedures (IP), which are related to the topic are identified. These are reviewed to determine whether proposed review questions link to published recommendations and whether these recommendations are current and appropriate. If these are identified, the action is decided by GDG based on the following criteria:

- The review question proposed by the GDG is similar to the question addressed in the published guideline
- The evidence used to decide on the recommendation is not likely to have changed since the recommendation was made
- The evidence review for this question is relevant and appropriate to the guideline in development (e.g. covers a similar setting)

The committee can decide to:

- Exclude the review question from scope: if this decision is made, the guideline explains why this review question was not covered

- Link to the recommendation in the published guideline: if this decision is made, the GDG agrees to accept the exact wording of the current as well as future recommendations (e.g. in updated guidelines). The link to the published guideline is made available in a final document.
- Use the evidence from the published guidelines to make a new recommendation: if this decision is made, the evidence reviews and the process leading to making the new recommendation are described in the guideline
- Conduct a new evidence review

Any guidelines produced by organisations not accredited by NICE may also be included as a potential source of evidence. These are appraised for quality using AGREE II instrument and are included only if they meet the following criteria:

- The appropriate methodology was used for their development and they are considered as being of sufficient quality
- They used GRADE/GRADE-CERQual or evidence statement/evidence tables
- Considered to be up to date

5. Consultation Process

Following the completion and approval by the HIS Guideline Committee, the guidelines are open for consultation by the stakeholders. The draft report is placed on HIS website for six weeks. The society informs the stakeholders that the draft is available via email and social media channels and invites them to comment on format, content, local applicability, patient acceptability and recommendations. Frequent reminders are sent to ensure a good response rate. As detailed in section 2.3, reviewers are invited to comment as individuals and not as representatives of their organisations. All reviewers are required to complete a conflict of interest declaration for their review to be considered. The reviews received from individuals with declared conflict of interest or those who did not provide a declaration are excluded from the GDG response along with any other reviews which are submitted late or are considered inappropriate or intentionally hostile. Following the open consultation, the GDG consider and collate the received comments and agree revisions. The following principles are observed when responding to the stakeholder comments:

- Each comment is acknowledged and answered clearly with as much information given as possible
- The GDG discusses and agrees whether any changes to the guideline are needed as a result of the stakeholder comments
- The response to the comments advises whether suggested changes have been made and if not, explains the reasons why this has not been done
- The GDG keep an audit trail for all changes made. The stakeholder comments, responses and the changes made are listed in an appendix of the final guideline document.

Following the response to the stakeholders' comments and any amendments made to the guideline document, HIS does not usually initiate a second consultation. In exceptional circumstances, the decision may be made to open another consultation. This happens when following the consultation process, substantial changes have been made to a guideline document or the recommendations have changed significantly. The HIS Guideline Committee is responsible for quality assurance of each guideline developed by HIS. All registered stakeholders are sent the copy of the finalised guidelines two weeks before the publication. This stage is intended to inform the stakeholders rather than seek their comments or approval for the guidelines to be published.

6. Format of HIS guidelines

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

- *Title page*: this section includes a title which clearly states that this document is a guideline. The title also includes information about which organisations have been involved in the guideline development.
- *Contents page*
- *Guideline development group*: this section includes information about all individuals involved in the guideline development, including their conflicts of interest as declared by HIS policy. Source of funding (typically HIS but may include other organisation if the guideline is developed in collaboration) is stated. Any significant contributions to the guideline from IPC practitioners, clinical scientists, patients and other stakeholders are acknowledged and included in this section.
- *Summary*: this section provides an overview of the guidelines including the reason for development/update
- *Lay summary*: this section provides similar information to the one above, but is written by the lay members of the GDG
- *Scope and purpose*: this section provides an information about the background and rationale for the development of the guideline, and links to prior versions as well as other relevant guidelines as appropriate. The overall objective, clinical questions addressed, as well as the information about patient groups included or excluded and the audience for which the guideline is intended are included. A publication date, an expiry and review dates are also provided in this section.
- *Summary of all clinical practice recommendations*: a summary of the guideline recommendations is provided, so that they are easily accessible to review by the users. This section is readily available for printing separately from the full guideline and serves as a quick reference guide. This summary is also available written in lay people terms and is available to download from the HIS website.
- *Implementation*: this section provides a summary of audit measures which can be used to assist the users with implementation of the guideline, promote an improvement in the quality of care and allow comparative audit. The audit measures are considered carefully to ensure that they are achievable and measurable, and that they serve as evidence-based criteria for continuing quality improvement. Any potential barriers to implementation which have been identified by GDG are discussed in this section.
- *Methodology*: this section includes an information about how the evidence was gathered (e.g. search protocols, dates, terminology and inclusion/exclusion criteria), appraised and synthesised, as well as how the decisions were made to make the recommendations included in the guideline. If recommendations from other guidelines are incorporated into the guideline, this is clearly

signposted in this section. A more detailed description of methods used is also provided in the appendices.

- *Rationale of recommendation/group of recommendations*: this section provides a chain of logic that led the GDG to make the recommendations. This includes background information, the evidence statements (with references to all relevant studies) and other factors (e.g. concerns about the implementation, lay members' opinion) which influenced the decision.
- *Appendices*: this section includes all original GDG documents which are not relevant to the topic, but ensure that the guidelines were developed according to NICE principles: e.g. scope, declarations of interest, review protocols, literature search strategies, study selection, evidence tables, excluded studies tables, research recommendations and responses to the stakeholders' comments.

7. Dissemination and implementation of the guidelines

7.1 Notification of e-publication of the final version

Members of Healthcare Infection Society and the public are notified when a final version of a clinical guideline is posted on the HIS website. Previous versions of the guideline are available in an electronic form until the new version is available. The members receive the email newsletter with the link to the guidelines while the public are generally informed via Twitter and other social media. A patient-friendly version of the guidelines is produced with the help of the lay representatives and other members of the public. This is included in the appendix of the final guideline and is available to download free of charge from the HIS website.

Current guidelines developed by HIS are published on the HIS website and, if developed in collaboration, on the websites of collaborating organisations. If any of the existing guidelines are in a process of being updated, it is mentioned on the website together with the details of the GDG and the progress the group has made so far. The existing guideline remains available on the website until it is replaced by the updated version. Similarly, the details of the progress of the new guidelines under development are also available. Historical HIS guidelines are archived and can be accessed via HIS website.

7.2 Use of audit measures for national audit by the Guideline Committee

Implementation of HIS guidelines is promoted by audit on performance measures related to key recommendations within the guideline. The co-authors of each guideline, in collaboration with Guideline Committee, identify several audit measures to serve as evidence-based criteria for continuing quality improvement. A summary of the audit measures in each guideline is included before the rationale section. The audit measures are intended to be used for local and regional audit as well as 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 to ensure that the recommendations are implemented. 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).

7.3 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 at the beginning of the document. This section of the guideline is also available for downloading from the website as a concise summary of the recommendations without needing to read, download or print the entire guideline document.
- The HIS Council liaise with the GDG to produce educational CPD-accredited material to support the guidelines, including e-Learning material.

- All HIS guidelines published to date are formatted as PDF files, providing printable copies of each guideline ready to download free of charge.
- Liaison with the HIS Education group 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.
- E-publication is planned on the HIS website and in JHI or other journal on completion of the guidelines. The e-publications on the journal publisher's website are cited by PubMed and Medline which further promotes dissemination of the guideline.
- Additional guideline outputs such as e-learning packages, key messaging or pocket guidelines, patient leaflets, relevant flowcharts and other related materials are considered and published in the appendices.

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Appendices

List of appendices

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Appendix 1: HIS guidelines and guidance

Published Guidelines/Advice

- The use of faecal microbiota transplant as treatment for recurrent or refractory *Clostridium difficile* infection and other potential indications, 2018 (joint BSG and HIS guidelines), **NICE accredited guidelines**
- Guidance for the decontamination of intracavity medical devices, 2018 **Expert guidance**
- Treatment of infections caused by multidrug-resistant Gram-negative bacteria, 2018 (joint BSAC/HIS/BIA guidelines), **NICE accredited guidelines**
- Surveillance of infection associated with external ventricular drains: proposed methodology and results from a pilot study, 2017 **Expert methodology**
- Decontamination of breast pump milk collection kits and related items at home and in hospital, 2016 (joint HIS/IPS guidelines) **Expert guidance**
- Prevention and control of multi-drug-resistant Gram-negative bacteria, 2016 (joint BSAC/HIS/BIA guidelines), **NICE accredited guidelines**
- Development of a sporicidal test method for *Clostridium difficile*, 2015 **Expert methodology**
- epic3: National Evidence-Based Guidelines for Preventing HCAI in NHS Hospitals in England, 2014 (joint IPS/HIS/BIA guidelines), **NICE accredited guidelines**
- Guideline on the use of respiratory and facial protection equipment, 2013 **Expert guidance**
- Guidelines on the facilities required for minor surgical procedures and minimal access interventions, 2012 (this guidance was reviewed in 2016 and decision was made that these recommendations are still current) **Expert guidance**
- Guidelines for prevention and control of group A streptococcal infection in acute healthcare and maternity settings in the UK, 2012 **Expert guidance**
- Guidelines for the management of norovirus outbreaks in acute and community health and social care settings, 2012 (joint multi-agency guidance) **Expert guidance**

Guidelines that have been withdrawn or superseded.

- Guidelines for the control and prevention of methicillin-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, 2002
- Microbiological commissioning and monitoring of operating theatre suites, 2002
- Rinse water for heat labile endoscopy equipment [May 2002][†]

All guidelines and guidance are available at: <https://www.his.org.uk/resources-guidelines/his-guidelines-and-guidance>

Guidelines in development

- Guidelines for prevention and control of group A streptococcal infection in acute healthcare and maternity settings in the UK
- Guidelines for the management of norovirus outbreaks in acute and community health and social care settings
- Guidelines for the control and prevention of meticillin-resistant Staphylococcus aureus (MRSA) in healthcare facilities
- Behaviours and rituals in the operating theatre
- Microbiological commissioning and monitoring of operating theatre suites
- Guideline on the use of respiratory and facial protection equipment
- Final rinse water for endoscope washer disinfectors
- Automated Room Decontamination Devices
- The prevention and Control of Infection in Burns Units
- Water Management for Healthcare Microbiologists
- Prevention of fungal infection

Appendix 2: Proposal form for new guideline topic

I understand that this proposal will be retained by HIS and be made available on the HIS website for time period that the proposal is being considered. Only proposals with a completed Declaration of Interests for the principal proposer will be considered	
Accredited guideline	<input type="checkbox"/>
Advisory guidance	<input type="checkbox"/>
1.	What is the problem/need for a guideline/clinical scenario?
2.	Burden of the condition
	Mortality
	Incidence
	Prevalence
3.	Variations
	In practice in the UK & Ireland (& Europe)
	In health outcomes in the UK & Ireland (& Europe)
4.	Areas of uncertainty to be covered
	Key question 1
	Key question 2
	Key question 3
5.	Areas that will not be covered
6.	Aspects of the proposed clinical topic that are key areas of concern for patients, carers and/or the organisations that represent them
7.	Population
	Included
	Not included
8.	Healthcare setting
	Included
	Not included
9.	Potential
	Potential to improve current practice
	Potential impact on important health outcomes (name measureable indicators)
	Potential impact on resources

	(name measurable indicators)
1.0	What evidence based guidance is currently available?
	None
	Out-of-date (list)
	Current (list)
11.	Relevance to current Government policies
12.	Who is this guidance for?
13.	Implementation
	Links with existing audit programmes
	Existing educational initiatives
	Strategies for monitoring implementation
14.	Primary contact for topic proposal
15.	Group(s) or institution(s) supporting the proposal

This document is available at <https://www.his.org.uk/resources-guidelines/resources-in-preparation/>

Appendix 3: Terms of reference and declaration of interest form

Terms of Reference for Guideline Working Party members

The Healthcare Infection Society (HIS) believes that good science underpins good clinical practice and views the development of clinical guidelines and advice documents as key to the Society's strategic plan. By creating this document, HIS aims to ensure that guidelines are developed according to HIS principles.

Responsibilities of the Working Party member:

During the preparation and publication of the guideline, the Working Party member is accountable to the chair of the Working Party who in turn is accountable to the Guideline Committee and HIS council. All Working Party members have an equal status. Each Working Party member agrees to:

- Attend a minimum of 60% of group meetings and participate in teleconferences.
- Contribute to all stages of guideline development.
- Complete actions as agreed at meetings.
- Provide a response to any stakeholder comments.
- Undertake to contribute to updates to the guideline if significant new evidence emerges prior to a formal review of the guideline. The members may become aware of new evidence through their own knowledge of current research or by communication from other colleagues.
- Provide comment on any documentation circulated, particularly when they are absent from a meeting.
- Ensure the guidelines are completed according the agreed timeline.
- Abide by the principle of collective responsibility, stand by the recommendations of the Committee and not speak against them in public.
- Refrain from submitting comments as stakeholders during the consultation on the draft guideline. If a Committee member is involved with another stakeholder organisation, they should not submit comments during the consultation on behalf of that organisation – someone else in the organisation should draft and submit the comments.
- Publish any outputs arising from the guideline development (e.g. systematic reviews) only after the official publication of the guidelines and after a formal agreement with HIS and the rest of the Working Party.

Working Party management and collaborations with other organisations:

- The HIS Research and Development Manager is available to aid the management of working parties and should be involved in all discussions regarding the Working Party, including the preparation of the outputs and publication in the *Journal of Hospital Infection* or *Infection Prevention in Practice*.
- 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. These are retained for the duration of the guideline development.

- The Research and Development Manager should be notified of the intention to invite any new Working Party members in order to manage the conflict of interest process and budget.
- Following the scoping phase, any changes to the protocols, search strategies and outputs must be agreed by HIS. The request should be submitted to the Research and Development Manager, and the advice will be sought from all the stakeholders as well as the Guideline Committee.
- Authorship of the guideline will follow the Committee on Publication Ethics (COPE) guidelines and will include all Working Party members and staff who have worked on the guideline.
- Many guidelines are produced in association with other societies and organisations. If a member is invited to represent HIS on a Working Party by another organisation, he/she is responsible for informing HIS, so the Society can enter a discussion and form an agreement with the other organisation about joint working and publication.

Data protection:

- All information held by HIS is retained and used in accordance with the General Data Protection Regulations (GDPR).
- The Society does not share the Working Party members' data outside the Society and when possible uses a mailing list for communication with the Working Party members.
- At times when the above is not possible, it is assumed that the member agrees to share their name and email address with all other Working Party members for the sole purpose of Working Party activities.

NICE accreditation:

- The Society is accredited by NICE to produce the clinical guidelines. The accreditation means that guidelines produced adhere to the methods outlined in the NICE methodology document. By joining the Working Party, whether with or without the collaboration with another organisation, it is assumed that the member agrees to follow this methodology.

Honoraria and expenses:

- The Society does not provide an honorarium for contribution to the Working Party, but Working Party members are entitled to reimbursement for reasonable expenses when attending the Working Party meetings organised by HIS. These must be in line with the Society's policy, which is available at: <https://www.his.org.uk/about-his/travel-policy/>.
- Any expenses claimed must be agreed in advance and submitted through the Research and Development Manager.
- Where interim in-person meetings are arranged between Working Party members, the Research and Development Manager must be notified in order to authorise any subsequent travel expense claims.
- Where Working Party members have been invited to represent HIS to disseminate Working Party outputs, expenses will be covered as per the policy above.

Terms of Reference for Guideline Working Party members agreement form

By signing this document, the Working Party member agrees to the above Terms of Reference

Full name

Signature

Date

Conflict of interest form

The Healthcare Infection Society (HIS) requires that all members and co-opted members of Working Party, 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. 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. Conflicts of interest are defined as any interest that may affect or reasonably be perceived to affect the expert's objectivity and independence. Whether a potential conflict of interest is deemed of relevance depends on the role taken on within the Working Party and, consequently, the disclosure of a conflict of interest does not automatically disqualify or limit participation in these activities. It should be noted that if the nature of an interest or the amount or value, where relevant, is not indicated, the conflict of interest will be assumed to be significant.

Instructions

1. All relationships with pharmaceutical, diagnostic, cleaning equipment suppliers (and their agents) or such similar companies involved in biomedical products in the last four years must be reported. For the purposes of this disclosure, the term 'member' includes the HIS Working Party member and any spouse/partner/ family member.
2. If there is nothing to disclose, this needs to be indicated. The declaration is made by double clicking the appropriate box and selecting 'checked' in the value box.
3. Further information is likely to be requested if any positive responses are given in the form.
4. If an undisclosed competing interest is later proven, HIS will follow the Committee on Publication Ethics (COPE) guidelines.
5. The completed form can be submitted to HIS by emailing the Research and Development Manager.
6. This declaration covers the period during which the guidelines are under development; any subsequent updates will require a new form. If the member's circumstances change, the member is responsible for completing a new form. If the member is involved in more than one Working Party, he/she is required to complete the form for each group.
7. At every meeting of the Working Party, members will be expected to declare conflicts of interest if new conflicts have arisen since the last meeting, or if a new item being discussed by the Working Party introduces a new conflict. The Chair at each meeting should provide this opportunity at the start of each meeting.

1. Member's details					
Name:					
Primary employer and other paid positions:					
Email:					
Signature:			Date:		
HIS member <input type="checkbox"/>					
Other HIS Working Party memberships (Role and dates):					
2. Pecuniary interests (amounts in GBP)	None	≤2500	≥2,500 - 5000	≥5000- 25000	≥25000
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Please provide further details					
Speaker fees This section mainly concerns fees (e.g. for lectures, commissioned articles, or other similar paid activity) received from a commercial sponsor and where the member has benefited personally.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Please provide further details					
Company shares This section includes any shares held by the member in the biomedical industry (e.g., pharmaceutical, diagnostic, or similar companies).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Please provide further details					

<p>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.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Please provide further details					
<p>Other relevant disclosures This refers to any other relationships which are financial or with an organisation that, if not disclosed by the member, could compromise the member or HIS as a charitable organisation.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Please provide further details					
3. Non-pecuniary interests					
<p>You are required to declare any trusteeships in other organisations, other committee memberships or directorships, which have conflicting or competing interests.</p>					
Trusteeships					
<p>Give full name(s) of organisation(s) and information on term served to date and retirement date.</p>					
Committee memberships					
<p>Give full name of organisation(s) and indicate your role on any committees, giving details of term served to date and retirement date.</p>					
<p>Are you:</p>					
<ul style="list-style-type: none"> • a member of an executive committee (or board) of another international organization (e.g. society, federation, association)? • a member of the programme committee of another international congress? • an editor-in-chief, senior editor or (associate) editor with any journal in the fields of CM/ID/IC? • a member of an advisory board of a company involved in the medical field? • taking up any other functions in an international organization? 					
Directorships					
<p>Give full name(s) of organisation(s) and information on term served to date and retirement date.</p>					
4. Please indicate any potential future conflicts of interest.					

Appendix 4: Checklist for HIS guidelines

	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?				

Appendix 5: Quality checklists

Randomised Controlled trials: Cochrane RoB tool (2.0)



RoB_2.0 for RCT.docx

Non-randomised trails, controlled before-after studies and cohort studies: Cochrane ROBINS-I tool



ROBINS for non
RCTs and cohort stud

Case control studies: CASP tool



CASP for case
control studies.pdf

Interrupted time series: EPOC RoB tool



EPOC RoB for ITS.pdf

Cross-sectional studies: JBI checklist for cross-sectional studies



JBI checklist for cross
sectional studies.pdf

Diagnostic accuracy studies: QUADAS-2 tool



QUADAS-2 for
diagnostic accuracy s

Qualitative studies: CASP tool for qualitative studies



CASP for qualitative
studies.pdf

Appendix 6: Templates for data extraction

Description of the included studies

Author, Year	Study Design	Country	Setting	Study duration	Population	Intervention	Comparator	Outcomes

Incidence/prevalence/transmission rates

Author, Year	Outcome measure	No of participants		Colonisation/Transmission rates			Reviewer's comments
		Intervention	Comparator	Intervention	Comparator	significance	

Cost (if economic evaluations not available) or use of resources (e.g. staff time)

Author, Year	Outcome definition	No of participants		Cost/resources		Reviewer's comments
		Intervention	Comparator	Intervention	Comparator	

Diagnostic accuracy

Author, Year	No. of samples	No. of patients	test + / index +	test + / index -	test - / index +	test - / index -	Inconclusive Results (%)*	Sensitivity [95% CI]	Specificity [95% CI]	PPV [95% CI]	NPV [95% CI]

Turn around time (for diagnostic tests)

Author, Year	Number of participants	Time			
		Measurement	Test	Index	significance

Adverse events

Author, Year	Agent	No of participants		Events				Reviewer's comments
		Intervention	Control	Type	Intervention	Control	Significance	

Excluded studies table

Citation	Reason for exclusion

Appendix 7: Template for evidence tables

Study reference								
Study type	Study quality	Intervention	Comparator	Method of allocation	Setting	Number of participants	Participant characteristics	
Outcome measure	Assessment of outcome	Statistical analysis	Length of follow-up	Results Intervention	Results comparator	Significance	Attrition - Intervention	Attrition - Comparator
Author conclusions								
Additional comments								
Summary of findings								