



## **Scottish Health Protection Network Guidance Group (SHPN-GG)**

(Version 5.0 Final)

# **Framework for Health Protection Guidance Development**

## 1. Summary

SHPN-GG oversees the process for ensuring the quality of guidance produced by the Network to support Health Protection practice in Scotland. The principal role of the group is to encourage consistent high standards of Health Protection practice by promoting a multidisciplinary approach to the development of quality assured guidance.

Ideally all Health Protection practice guidance would be evidence-based. An Evidence Based Guideline (EBG) is the preferred standard of guidance where possible and is generally considered to represent the *gold standard* for practice guidance. However, there is also a need for Health Protection practitioners to have access to quality assured guidance for situations where the published evidence is inadequate or where it is not possible to comply with the full standards required of an EBG. The purpose of this document is therefore to set out a framework defining the different types of Health Protection guidance that are recognised by SHPN as being suited to different practice situations.

This framework aims to classify guidance types based on the process used to derive the guidance, relative to that used to develop an EBG. The categories are defined in terms of the quality standards used in the relevant guidance development methodology. The intention in having these standards is to provide reassurance to guidance users on the quality of the guidance.

The framework sets out a hierarchy of health protection guidance types with the respective quality standards required to meet SHPN-GG approved status. More detailed supporting protocols provide further advice regarding the process for developing each type of guidance document.

The framework also describes the roles and responsibilities of the component parts of the SHPN guidance development system; some basic principles underpinning SHPN guidance development; the categories of SHPN guidance and includes an option for approval of externally produced (non-SHPN) guidance.

## 2. Background

A methodology for evidence based Health Protection guideline development was originally developed in Scotland by the former Health Protection Network (HPN). This was modelled on existing well developed approaches to guideline development used in clinical practice. There are a number of recognised standards for reviewing evidence and producing guidelines developed by leading organisations involved in the development of public health guidance (e.g. the Cochrane Collaboration Reviews, National Institute for Clinical Excellence [NICE], Scottish Intercollegiate Guideline Network [SIGN]). This original HPN guideline methodology has been further refined to provide a standardised approach to SHPN guidance development, including EBG, involving a seven stage process:

- agreement on the topic selection and scope
- the formation of a multidisciplinary guideline development group
- identification and evaluation of evidence including planning and execution of a systematic literature search, followed by systematic evidence appraisal
- formulating recommendations and drafting
- consultation
- editing, approval and publication (including assessment of needs for training to support implementation)
- dissemination, uptake and implementation

The process for EBG in particular is (necessarily) resource intensive and sometimes relatively lengthy. This, combined with the limited resource available to support the process, especially systematic literature reviewing involving twin reviewers, limits the range of topics that can be addressed by an EBG in any given year.

To complement the (gold standard) EBG development process, SHPN-GG recognised the need to provide Health Protection practitioners with a wider range of quality assured guidance, produced more quickly and requiring less intensive resource use. SHPN-GG therefore agreed on the need to define a wider range of guidance types for use by Health Protection professionals in Scotland, suited to a range of practical scenarios.

A framework was therefore developed to address these issues, based on the EBG 7 stage model, which maintains the same basic approach to developing all the SHPN guidance types, modified as required to balance the availability of good quality published evidence with alternatives including expert opinion.

### **3. Roles of SHPN-GG & SHPN-Topic Groups**

The SHPN-GG provides overall governance for the production of guidance sponsored by SHPN. SHPN-GG focuses on defining frameworks and setting standards to promote a consistent quality of guidance development. SHPN-GG does not provide detailed oversight of the content of individual guidance documents; this responsibility lies with the respective SHPN-Topic Group (SHPN-TG).

SHPN-TGs agree their priorities for guidance development within their topic area, based on a consensus approach. The following are suggested as criteria to help guide the selection of subjects suitable for SHPN sponsored guidance:

Potential new guidance shortlist criteria:

- the topic aligns with national priorities or has been previously identified as high priority;
- the topic relates to:
  - a significant burden of care and/or illness
  - premature mortality;
  - reduced quality of life
- there is no current SHPN guidance on the topic
- there is no relevant guidance from external organisations that might be adapted for use in Scotland
- there is capacity to support development of guidance

SHPN-TGs identify potential topics that require SHPN supported guidance and screen these to determine which type of guidance would best meet the health protection need. Following this stage, a proposal is sent to SHPN-GG for consideration. SHPN-GG will determine whether topics proposed by the SHPN-TGs fulfil the requirement for an SHPN-GG guidance document. If SHPN-GG agrees that the topic is appropriate, it will determine what resources will be required to produce the document and will allocate resources, based on a planned guidance development work programme.

If there are more candidate topics for guidance development than available resources, the list of potential guidance requirements across all the health protection topic groups will be referred to the SHPN-Coordination Group (CG) for prioritisation. Also, where potential guidance subjects span a number of topic groups or are of general relevance to Health Protection practice in Scotland, decisions on prioritisation will be referred to the SHPN-CG.

SHPN-TGs oversee the production of the guidance and are responsible for ensuring conformance with the quality standards associated to that particular category of guidance, as specified in this document.

The SHPN-TG will normally set up a specific Guidance Development Group (GDG) to take on responsibility for producing the guidance document. Exceptionally the SHPN-TG may fulfil this function itself; however, SHPN-GG recommends that formation of a GDG is preferred.

A GDG should consist of a number of individuals with specific knowledge and expertise of the subject in question together with a cross section of representation from experienced practitioners, potential users and beneficiaries of the guidance.

A healthcare scientist (HCS) will provide support and expert assistance to the GDG during the guidance development process. This will include conducting literature reviews, critical appraisals, and formulation of proposals for recommendations to be considered by the GDG members. The healthcare scientist support will be provided either from within the SHPN-GG support team or alternatively (e.g. when this is not possible) from within the SHPN-TG (or associated HPS team).

Final approval of the guidance document will be obtained from:

- the SHPN-TG for scientific and technical content,
- the SHPN-GG for quality assurance of the guidance development process, and
- the SHPN-Coordination group in respect of scientific and technical content when the topic and content spans several SHPN TGs, in relation to health protection in Scotland.

A final draft document will be submitted to SHPN-GG for review, with a statement verifying conformance to the appropriate SHPN-GG quality standards. Checklists for scientific and quality assurance sign-off are provided in the detailed guidance development protocols. Where any of the appropriate quality standards are not met, these will need to be identified and reasons given for the non-conformance.

The SHPN-GG will review the final draft and supporting documentation to determine whether it fulfils the SHPN requirements in respect of quality assurance.

SHPN-GG has a limited resource to support guidance development projects. The number of guidance documents that can be officially supported in any year will be limited by resource availability, both for the initial document development and for the regular review process. It is therefore unlikely that SHPN-GG will be able to support all proposals for guidance documents made by the SHPN-TGs. Where a guidance topic does not meet the criteria for sponsorship by SHPN-GG, information, advice or guidance may still be provided by an SHPN-TG in another format (e.g. in the form of a briefing note or SBAR).

The relevant SHPN-TGs responsible for a guidance document will also be responsible for reviewing it at regular intervals; this will normally be a three year review cycle, with an option to review sooner if required. Please see the '*SHPN Guidance Review and Update Methodology*' for further information.

At the regular planned reviews, SHPN-TGs should consider if there is a need to retain the guidance document for the specific subject; whether the topic is no longer a priority or whether it is completely redundant. If guidance is considered still to be required on the subject, the existing document should be reviewed or consideration should be given as to whether the subject could be addressed by other mechanisms, using alternative guidance. Where the SHPN-TG decides to update an existing

guidance document, it is recommended that this should be carried out by a reformed GDG. The full process is outlined in the '*SHPN Guidance Review and Update Methodology*' document.

If, at any point, important new knowledge becomes available on a topic, or if another agency produces guidance on the same subject that impacts on the recommendations of an existing SHPN-document, then the relevant SHPN guidance document may be reviewed earlier.

#### **4. Principles Underpinning the SHPN Framework for Health Protection Guidance Development**

Based on a review of definitions set out by SIGN and NICE, SHPN-GG has agreed to adopt the term *guidance* as the generic term to describe the range of work to be addressed by the group and covered by this framework. The term *evidence based guideline* (EBG) is reserved to describe the highest standard of SHPN guidance document.

SHPN-GG has adopted the following definitions to define its scope, adapted from the above sources:

##### Guidance

- *Guidance* is the umbrella term used to describe the full range of materials supported by SHPN Guidance Group that aim to provide information and considered advice on aspects of health protection practice in Scotland.

*Guidance documents incorporate recommendations based on the best available evidence, which may include expert opinion where published evidence is lacking, and which are used to guide decisions in a particular area of health protection practice in Scotland.*

*This is the standard used to define SHPN-Good Practice Guidance.*

##### Guideline:

- *Guideline* is the term reserved for guidance documents that incorporate predominantly evidence-based recommendations derived mainly from published peer-reviewed literature, which are intended to improve the quality and consistency of health protection practice in Scotland.

*This is the standard used to define SHPN-Evidence Based Guidelines.*

Further to the above, there are circumstances when externally generated guidance will be considered by SHPN for approval in respect of acceptability of use in Scotland. This is discussed in section 7.

The *SHPN Framework for Health Protection Guidance Development* therefore:

- specifies the types of guidance and descriptive terms to be used;
- defines standard categories of guidance to be produced either by SHPN sponsored groups or sourced from external agencies;
- Outlines the methods and standards to be used in developing guidance in each category.

All guidance sponsored by SHPN requires a form of collective agreement as outlined in the detailed methodologies. Therefore, guidance in the form of individual professional opinion falls outside the scope and remit of the SHPN-GG.

## **5. Categories of SHPN sponsored Guidance**

There will be two basic categories of guidance sponsored by SHPN: evidence based guidelines (EBG) and good practice guidance (GPG). These categories indicate the relative strength of each type of guidance in terms of the recommendations made (Annex A1). The different categories also indicate the relative reliability of the evidence on which the recommendations have been based. These designations are intended to provide users with reassurance that the relevant quality standards have been applied to their development and to signal the degree of confidence that users may have in applying the guidance recommendations.

Although EBG and GPG are distinct categories, some of the processes used to develop the final guidance documents are common to both.

### **A) Evidence-Based Guideline (EBG)**

EBGs are the highest level of guidance document produced by the SHPN and will be developed using the methodology summarised in Annex B and described in detail in a separate SHPN EBG protocol (see *SHPN Evidence Based Guideline Methodology*). This standard of guidance requires the most rigorous development process and the greatest supporting resource. EBG therefore represents the gold standard SHPN guidance category. However, not all topics will be suitable for or will merit development of an EBG, particularly where there is a relative lack of published scientific evidence to provide the basis for recommendations.

When the evidence review and appraisal process for developing a guideline relies on only a single reviewer, the guideline will be classed as an EBG type A.

When the literature review and critical appraisal process involves (at least) two independent reviewers, the guideline will be classed as an EBG type A\*.

A review period of three years is recommended for all EBGs, with the option for an earlier review depending on the pace at which important new knowledge becomes available rendering the guideline as outdated (see *SHPN Guidance Review and Update Methodology*).

### **B) Good Practice Guidance (GPG)**

SHPN-GG acknowledged the need for guidance that although it does not meet the criteria for an EBG; it is nonetheless quality assured. It is likely that much of the material used in everyday health protection practice will fall into this category, where published evidence may be scarce requiring a heavy reliance to be placed on practitioner knowledge and experience. Guidance of this type is thought likely to predominate in Health Protection practice and will involve the use of more informal methods of recommendation development than for an EBG.

The process used to derive recommendations for this category of guidance will also involve a review of existing published evidence but will require relatively more emphasis on consensus based approaches involving the GDG (consisting of topic experts and practitioners) using

either a formal or informal consensus development methodology (see *SHPN Good Practice Guidance Methodology*).

GPG documents should be reviewed at a minimum of every three years, with the option for earlier review if relevant new knowledge becomes available sooner (see '*SHPN- Guidance Review and Update Methodology*').

## 6. Guidance Development Methodologies

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

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

Two protocols have also been produced by the SHPN:

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

All SHPN methodology and protocol documents shall be published on the HPS website and the SHPN microsite to be readily available to a range of HP practitioner and wider professional audiences.

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

### A) Protocol for the Rapid Development of Guidance

There are situations in health protection practice where there is a need to address an urgent or newly emerging issue for which there is no suitable existing guidance. High quality guidance is then required that needs to be developed more rapidly than is possible for a conventional EBG or GPG. Different clinical teams within HPS developed processes to produce such guidance quickly, using rapid evidence appraisal methods. These methods involved modifying the evidence retrieval stage of the original (HPN) EBG method to provide a more targeted, less fully systematic approach, with a simplified evidence assessment stage. Guidance of this type may be considered less rigorous than an equivalent EBG. It is however, only intended to be applied in a narrowly defined situation and may be of relatively short lifespan. Such guidance was referred to as *rapidly developed guidance*.

Formerly, SHPN-GG designated *Rapidly Developed Guidance (RDG)* as a specific type of guidance. However, it was subsequently recognised that the timescale associated with producing this type of guidance precludes SHPN-GG from being able to consider it formally. SHPN therefore concluded that defining this as a separate category was not appropriate.

The *SHPN Protocol for the Rapid Development of Guidance*, based on the original HPS models, has however been retained for SHPN use as a guidance development protocol. SHPN recommends that

this protocol should be used by SHPN-TGs or others to develop *Rapidly Developed Guidance* when this is required. RDG documents however will not be eligible for formal approval by SHPN-GG.

If developed by an SHPN-TG, following completion of such rapidly developed guidance, the TG should consider reviewing whether there is a need for more formal guidance on the particular subject in the longer term, in the form of an EBG or a GPG.

### *Protocol for the Development of Consensus Based Recommendations (CBR)*

Formerly, SHPN-GG differentiated a specific type of guidance designated as *Consensus Based Guidance (CBG)*. However, it was subsequently recognised by SHPN-GG that consensus development is intrinsic to all forms of officially sponsored SHPN guidance. *Consensus Based Guidance* is therefore no longer defined as a separate SHPN guidance category.

All forms of guidance developed by a group, including EBG, are likely to use some form of consensus approach to agree their content and recommendations. However, situations arise in Health Protection practice where there is either a lack of published evidence available to address an issue, or the available evidence is scientifically inadequate. Much greater reliance may then have to be placed on developing an agreed consensus view, which will have to be based mainly on the knowledge and expertise of a group of experienced practitioners, rather than on published evidence.

Consensus based recommendations may be developed using formal consensus methods (e.g. Delphi) involving systematic input from experienced practitioners with specialist knowledge of the topic. Alternatively, informal consensus development processes may be used.

Guidance on the use of consensus development processes, as part of guidance development generally, has been retained in the form of an SHPN recommended protocol (see *SHPN Protocol for the Development of Consensus Based Recommendations*).

## **7. Externally produced, SHPN-approved guidance**

Adopting or adapting guidelines that are produced by recognised public health/health protection organisations outside Scotland is one practical way to expand the range of quality assured guidance available for use in Scottish Health Protection practice (e.g. Public Health England, European Centre for Disease Control, US Center for Disease Control, World Health Organisation).

SHPN-GG has adopted the following definition to define the scope of externally produced guidance that it will consider:

### *External guidance:*

- *SHPN-GG will only consider the approval of documents which are considered to be equivalent to SHPN-Good Practice Guidance or SHPN-Evidence Based Guidelines (see SHPN Framework for Guidance Development).*

Externally produced guidance will require assessment to determine it is appropriate for use in Scotland either without modification or with minor amendments. Assessment is also important to ensure that externally produced documents fulfil the criteria for SHPN-produced EBG or GPG as outlined in Tables A-B in Annex A1. Approval of acceptability for use in Scotland will be obtained from:

- the SHPN-TG for scientific and technical content,
- the SHPN-GG for quality assurance, and
- the SHPN-Coordination group in respect of scientific and technical content when the content spans common SHPN-TG remits in relation to health protection in Scotland.

As with SHPN-produced guidance documents, a three year minimum review period for externally produced guidance is recommended, with the option to review sooner if required (see *SHPN-Guidance Review and Update Methodology*).

If an external guideline does not meet SHPN-GG standards for approval it may nonetheless be eligible for inclusion on SHPIR if no other document is available, pending identification of an alternative.

## **8. SHPN-GG Guidance Framework**

Annex A1 provides a description of the framework used for categorising the main types of guidance specified above. Tables (A and B) set out: the title for each guidance type; a description of each type; the criteria for use; the methods and quality assurance standards. These are in outline form only and are supported by more detailed documentation.

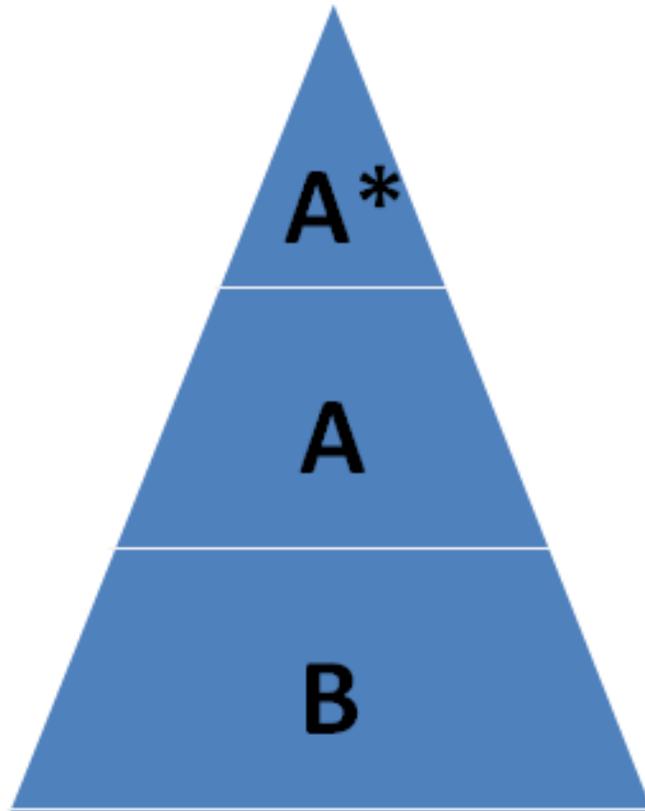
Annex A2, Figure 1 illustrates the relationship between the different types of guidance in terms of the relative strength of each guidance category. EBG (type A\*) sits at the top of the pyramid having the strongest evidence base and being the highest quality of SHPN guidance produced.

**Annex A1:****SHPN Framework for Health Protection Guidance Development****Tables A-B**

<b>A</b>	<b>GUIDANCE TYPE</b>	<b>DESCRIPTION</b>	<b>CRITERIA FOR USE</b>	<b>METHODS AND QUALITY ASSURANCE STANDARDS</b>
	<b>Evidence Based Guideline (EBG)</b>  <b>EBG Type A*</b>  <b>EBG Type A</b>	<ul style="list-style-type: none"> <li>• A guideline developed using the full <i>SHPN Evidence Based Guideline Methodology</i>, sponsored by the relevant SHPN-Topic group and the SHPN-GG</li> <li>• EBG Type A* requires use of a minimum of two independent reviewers for the evidence review and appraisal stages of development.</li> <li>• EBG Type A requires only one reviewer for the evidence review and appraisal stages of development.</li> </ul>	<ul style="list-style-type: none"> <li>• Topic meets SHPN-GG criteria for EBG development</li> <li>• A suitable evidence base exists to allow use of the full EBG development methodology (see Annex B).</li> <li>• Development is coordinated by the relevant SHPN-Topic group via a suitably constituted guideline development group</li> </ul>	<ul style="list-style-type: none"> <li>• Full SHPN EBG development in line with the <i>SHPN Evidence Based Guideline Methodology</i></li> <li>• Full systematic literature review</li> <li>• Developed via a multi-disciplinary guideline development group</li> <li>• Reviewed on a 3 year cycle (see <i>SHPN Guidance Review and Update Methodology</i>.)</li> </ul>

<b>B</b>	<b>GUIDANCE TYPE</b>	<b>DESCRIPTION</b>	<b>CRITERIA FOR USE</b>	<b>METHODS AND QUALITY ASSURANCE STANDARDS</b>
	<b>Good Practice Guidance (GPG)</b>	<ul style="list-style-type: none"> <li>Advice produced by a group of health protection practitioners using predominantly personal expertise and experience with or without additional expert knowledge but not following specific SHPN sponsored methods for EBG, RDG or CBR</li> </ul>	<ul style="list-style-type: none"> <li>Where a higher standard of EBG is not readily available.</li> <li>Where published evidence is lacking (or conflicting) but where there is practice based knowledge, experience and expertise on the topic to support a formal or informal consensus approach.</li> <li>Suitability is based on collective professional judgement.</li> </ul>	<ul style="list-style-type: none"> <li>Should be produced to an accepted standard of professional practice, consistent with peer group expectations and in line with <i>SHPN Good Practice Guidance Methodology</i>.</li> </ul>

**Annex A2: SHPN Framework for Health Protection Guidance Development**



<b>SHPN-GG Framework for Guidance Development</b>	
<b>EVIDENCE BASED GUIDELINE (EBG) A*</b>	<b>HIGHEST</b> ↑
<b>EVIDENCE BASED GUIDELINE (EBG) A</b>	<b>Strength of Evidence</b>
<b>GOOD PRACTICE GUIDANCE (GPG) B</b>	↓ <b>LOWEST</b>

# Annex B: SHPN Evidence Based Guideline Flowchart

