

# Good Practice Guidance (GPG) Methodology

Version 1.0

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Please note that this document should be used in tandem with the HSE Public Health: Health Protection – Consensus-Based Recommendations (CBR) Protocol and Framework for Health Protection Guidance Development in Ireland.

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Some content within this document has been informed by the *Framework for health protection guidance development (Public Health Scotland, July 2020).* 

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# **Contents**

List of Abbreviations	4
Summary	6
1.0 Background	7
Document aims	8
Definitions	8
Good practice in the context of health protection	8
General methodology	10
Stage 1: Topic selection and scoping	
Stage 2: Formation of multidisciplinary GDG	11
Stage 3: Identification and evaluation of evidence	
Formulation of key questions in GPG	12
Identification and evaluation of relevant types of evidence (scientific and non-scien	ntific) 12
Context and appraisal of all types of evidence	13
Stage 4: Formulation of recommendations and drafting	14
Informal approach to consensus	14
Formal consensus	15
Stage 5: Consultation	15
Stage 6: Editing, approval, and publication	16
Stage 7: Dissemination, uptake, and implementation	16
Monitoring and review	16
Bibliography	17
Appendix 1	18

# **List of Abbreviations**

AMRIC Antimicrobial Resistance and Infection Control

CBR Consensus Based Recommendations

**CPHMs** Consultants in Public Health Medicine

**DNHP** Director for National Health Protection

EBG Evidence Based Guideline

GIN Guideline International Network

**GPG** Good Practice Guidance

**HSE** Health Service Executive

**HP-SMT** Health Protection Senior Management Team

ICGP Irish College of GPs

KQs Key Questions

NCEC National Clinical Effectiveness Committee

NDPH National Director of Public Health

NHPO National Health Protection Office

NIAC National Immunisation Advisory Committee

NICE National Institute for Clinical Excellence

NIO National Immunisation Office

NSIO National Social Inclusion Office

RDPH Regional Director Public Health

**RGDU** Research and Guideline Development Unit

SIG Special Interest Group

SIGN Scottish Intercollegiate Guideline Network

SME Subject Matter Expert

**SME-TG** Subject Matter Expert Topic Group

WHO World Health Organization

# **Summary**

The Good Practice Guidance (GPG) Methodology provides a structured framework for developing health protection guidance within the HSE Public Health: National Health Protection Office (NHPO). It focuses on guidance that is primarily informed by expert opinion and non-scientific evidence—referred to as "colloquial evidence"—especially in contexts where scientific evidence is limited, ambiguous, or evolving.

The methodology outlines a seven-stage process adapted from evidence-based guideline (EBG) development, with specific attention to the appraisal and integration of non-scientific evidence. These stages include topic selection, formation of a multidisciplinary guideline development group (GDG), evidence identification and evaluation, recommendation formulation (using informal or formal consensus), consultation, editing and approval, and dissemination and implementation.

The document emphasises the importance of transparency, inclusivity, and contextual relevance in developing good practice recommendations. It also highlights the role of subject matter expert topic groups (SME-TGs) in ensuring credibility and balance in guidance development. The methodology complements the *Consensus-Based Recommendations* (CBR) Protocol and is intended to support consistent, quality-assured guidance for public health practitioners.

# 1.0 Background

There are several structured frameworks and methodologies, developed by leading national and international organisations, that help to inform public health guidance development within the National Health Protection Office (NHPO). These include:

- Guideline International Network (GIN)-McMaster Checklist,
- World Health Organization (WHO) handbook for guideline development,
- National Institute for Health and Care Excellence (NICE) Developing NICE
   Guidelines: the manual,
- National Clinical Effectiveness Committee (NCEC)

The HSE Public Health: National Health Protection Office - <u>Framework for Health</u>

<u>Protection Guidance Development in Ireland</u> outlines the methods employed by the RGDU, in informing the adaptation, adoption, and de novo development of guidance recommendations.

The RGDU has developed two methodology documents to promote and support consistent implementation of the Framework:

- Good Practice Guidance (GPG) Methodology
- Consensus Based Recommendations (CBR) Protocol

While the core principles of evidence-informed guidance development apply to both clinical and public health guidelines, public health guidelines often require a more nuanced and contextualised approach to address the complexities of population-level interventions and policies. As a consequence, in view of the hierarchy of evidence applied to clinical guidelines, this is frequently more challenging In the context of public health practice. Additionally, factors such as equity and economic impact are of less significance when considered from an individual patient perspective, yet these are critical factors where a public health perspective is concerned.

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#### **Document aims**

The aim of this document is to provide a generic approach for developing health protection guidance that is, primarily, based on good practice recommendations.

The RGDU acknowledge the need for quality assured evidence informed guidance, and much of the material used in everyday health protection practice will fall into this category. Good Practice Guidance Methodology may be applied where published evidence may be limited, weak or equivocal thus requiring reliance upon practitioner knowledge and experience. Guidance of this type can be used in tandem with a consensus-based recommendations methodology and will involve the use of both formal and informal consensus methods in the development of recommendations.

The process used to develop recommendations for this type of guidance will also involve a review of existing published evidence but will require relatively more emphasis on consensus-based approaches.

#### **Definitions**

#### Good practice in the context of health protection

For the purposes of this document, 'good practice' is succinctly defined as the recommended course of action aiming to achieve standards of excellence, as advised by a body of experts.<sup>3</sup>

We understand that experts, in the context of health protection, are those professionals who have acquired knowledge and skills through both academic qualification and practice, to the extent that his or her opinion is expected to be helpful in fact finding, problem solving, or understanding of a situation that matters to health protection functions. The RGDU establishes subject matter expert panels on the basis of several key principles, supported by the World Health Organization, to ensure that the panels provide credible, balanced, and relevant public health guidance. These include relevant subject matter expertise, clinical expertise and experience, relevant academic expertise, diversity of knowledge and experience, commitment and participation, and conflict of interest disclosure.<sup>4, 5</sup>

Good practice recommendations are based on colloquial evidence as defined in Conceptualizing and combining evidence for health system guidance<sup>6</sup> to include expert opinion and non-scientific evidence. This complements the available scientific evidence that aim to assist practitioners in effectively implementing health protection functions and public health interventions.

While developing guidance, under the NHPO, expert opinion is gathered from members of a Subject Matter Expert Topic Group (SME-TG).

Guidance that gives a considerable weight to good practice recommendations is known, within NHPO, as GPG. Its development follows the method outlined in this document.

# **General methodology**

The process to develop GPG, within NHPO, conforms to the seven main stages for EBG development which are modified as required. There are, however, specific aspects that need to be considered while developing GPG. These are summarised in Table 1 and further developed in this section, see also infographic in <u>Appendix 1</u>.

Table 1: Aspects to be considered while developing GPG

Stage	RGDU Guidance Development Stage	Steps that merit particular attention in the development of GPG
1	Topic selection and scoping	Establish what evidence (scientific and non-scientific) might be needed to address the issues identified within the agreed scope
2	Formation of the multidisciplinary GDG	Ensure GDG membership captures relevant subject matter expertise, clinical expertise and experience, relevant academic expertise, diversity of knowledge and experience, commitment and participation, and conflict of interest disclosure
3	Identification and evaluation of evidence	<ul> <li>Identify types of evidence (scientific and non-scientific), sources, and how they will be integrated with each other</li> <li>Document appraisals</li> <li>Identify and document where and how expert consensus is required</li> </ul>
4	Formulation of recommendations and drafting	<ul> <li>Identify and describe uncertainties</li> <li>Document approach for obtaining expert consensus</li> <li>Consider potential consequences of recommendations in context</li> </ul>
5	Consultation	<ul> <li>Agree list of organisations/groups for consultation</li> <li>Seek peer review from RGDU Core Stakeholders for Guidance Review</li> <li>Check consistency with relevant guidance and policies</li> </ul>
6	Editing and publication	<ul> <li>Identify the appropriate stakeholders to involve and consult with in review of the guidance to incorporate views of all those who may be impacted by the guidance.<sup>7</sup></li> </ul>
7	Dissemination, uptake and implementation	<ul> <li>Prepare an active dissemination plan with suitable approaches to enhance the adoption of the guidance.</li> <li>Agree appropriate list of organisations, groups, and routes for dissemination.</li> <li>Circulate approved guidance to RGDU Dissemination List for Guidance/Guidelines.</li> <li>Consider available resources, societal or cultural acceptability, and stakeholder participation.</li> </ul>

# Stage 1: Topic selection and scoping

A CPHM will propose the development of new guidance by submitting a request to the RGDU. This should provide a brief overview of the anticipated requirement for guidance, information on other relevant national/international guidance currently available and perceived gaps in the literature (**Form RGDU F004**).

At this stage, the criteria used to decide in favour of producing GPG are:

- it is expected that published scientific evidence will not be available, or sufficient, to support recommendations
- it is expected that recommendations will be based, primarily, on expert opinion (knowledge, experience, and expertise) from members of the SME-TG, who will consider all available evidence (scientific and non-scientific)

# Stage 2: Formation of multidisciplinary GDG

The RGDU, in conjunction with GDG, oversee the production of guidance and are responsible for ensuring conformance with the quality standards associated with that category of guidance, as specified in this document.

If the guidance request is approved by the Director of National Health Protection (DNHP), or deputy, a specific Subject Matter Expert Topic Group (SME-TG) will be set up to take on responsibility for producing the guidance document. The exact composition of the SME-TG should be tailored to the topic covered by the guidance. It should reflect the range of stakeholders and groups whose professional activities will be covered by the guidance.

All members will agree on terms of reference and will commit to their roles and responsibilities within the group. Defining the scope of the guidance (and what is out of the scope) will be the highest priority when the GDG first meet.

# Stage 3: Identification and evaluation of evidence

### Formulation of key questions in GPG

The process for formulating key questions (KQs) is common to any other guidance development process. However, special consideration should be given to the question format which, in the context of GPG, may not conform to the most common scientific models (i.e., PICO). A set of inclusion and exclusion criteria should also be drawn up at this stage.

The nature and type of KQs proposed by the SME-TG developing GPG might focus on different types of evidence, particularly non-scientific areas, such as communication channels between public health services, acceptability and accessibility of interventions, and experiences of practitioners or the public using services.

# Identification and evaluation of relevant types of evidence (scientific and non-scientific)

The validity of any guidance development process depends, predominantly, on an unbiased and comprehensive literature search. This is important also for developing GPG. The goal is to identify and use the best evidence from all relevant sources, producing a comprehensive body of evidence that will allow KQs to be answered. This exercise will highlight gaps in the scientific evidence base and identify other types of evidence that need to be considered.

In GPG, it is particularly important that the SME-TG members advise on how to identify best practice and colloquial evidence, in areas where contemporaneous evidence is ambiguous, limited, unavailable, or still evolving.

Colloquial evidence and other types of non-scientific evidence complement scientific evidence or provide additional information on context. The Developing NICE guidelines manual provides an overview. This can take several forms:

 Expert opinion from SME-TG members, or comments from stakeholders who contribute professional experience and practical considerations and the interests of specific groups. • Relevant sources of evidence such as legislation, reports, audits and standard operating procedures may be included, depending on the guidance topic; and 'grey literature' defined as the 'information produced at all levels of government, academia, business and industry not controlled by commercial publishing'. The latter may include conference abstracts, research reports, unpublished data, dissertations, policy documents, personal correspondence, electronic publications, and so on.9

GPG can be suitable in situations where expert opinion and other colloquial evidence complement scientific evidence: seeking consensus is, therefore, entirely appropriate, provided this basis is explicit and transparent.<sup>5</sup>

# Context and appraisal of all types of evidence

As in any other category of guidance, the literature selected as potential sources of evidence requires assessment to ensure its validity.

For scientific studies, the assessment applied is based on a number of criteria that focus on the study design, with a significant effect on the risk of bias in the results reported and conclusions drawn. These criteria differ between study types, and a range of checklists can be used to bring a degree of consistency to the assessment process.

Evaluating non-scientific evidence – colloquial and other types of evidence – on the other hand, is a complex task, as there is a huge variability in the quality of material available. Legislation, codes of practice, regulations and values, etc. are excluded from this rigorous stage of scrutiny.

The assessment of other colloquial evidence, however, is processed via collective professional judgement, in the context of the GDG.

Creating an overall synthesis of available evidence may help the SME-TG when formulating recommendations in the next stage (stage 4). It is to be noted, though, that in stage 4 of guidance development, the SME-TG will further generate colloquial evidence that also needs to be considered.

# Stage 4: Formulation of recommendations and drafting

The GDG will consider the selected evidence available, scientific and non-scientific, and assess this to adequately address the proposed guidance key questions. At this point, the GDG will consider how to formulate recommendations, either:

- · by adopting an informal approach to consensus; or
- by pursuing a more 'formal approach' to reach consensus (as outlined in the Consensus Based Recommendations Protocol)

The GDG will decide on adopting either a formal or an informal approach, depending on the nature of the available evidence (characteristics of studies), and on the pressing need for rigour in the decision-making process.

# Informal approach to consensus

An informal approach to consensus can be used as the default choice in the development of GPG. However, there are a number of significant drawbacks in the application of informal consensus methods in the context of developing health protection guidance.

Convening diverse panels of experts and reviewers introduces several challenges to the decision-making process. These include ensuring that every participant has the opportunity to contribute and engage in discussions, maintaining transparency, managing disagreements, achieving consensus, and addressing situations where consensus cannot be reached.

Expert panels frequently rely on informal processes to navigate these challenges. However, informal approaches are susceptible to the dynamics of group interaction. Factors like time constraints, fatigue, limited subject matter expertise, and the influence of individuals with strong personalities or reputations can undermine the integrity of the consensus reached.

An informal approach to consensus may be the (default) choice GDG members decide to pursue at this stage in the development of GPG.

The term 'deliberative' process has been used in the literature to coin the efforts among a body of experts, to discuss the interpretation and use of heterogeneous evidence, with the view to informally reach consensus.

A deliberative process, therefore, allows an informal approach to consensus but it is an active participatory platform for experts and stakeholders to engage face to face to assess all available evidence.

While applying the deliberative process, SME-TG members shall respect its identified core features, ensuring that they provide a channel to consider the colloquial and other types of non-scientific evidence, while acknowledging the wide range of knowledge, experience, expertise and views that professionals, stakeholders, potential users and beneficiaries of the guidance might bring. All of these are essential in the decision-making process, prior to the formulation of recommendations.

The SME-TG should document how they moved from the available evidence to each recommendation and should document the decision-making process. It is also recommended that the SME-TG document the quality of the considered evidence (if scientific or non-scientific), identified uncertainties, and other issues on context (e.g. resources, training needs) that impacted decision making.

#### Formal consensus

If a formal consensus method is the chosen approach to formulate recommendations, please refer to Consensus Based Recommendations (CBR) Protocol

# **Stage 5: Consultation**

Following the formulation of recommendations, either through an informal or formal approach, the SME-TG will have established draft recommendations that constitute the core of the GPG draft document.

When developed, an initial draft document will be circulated to the **RGDU Core Stakeholders for Guidance Review** (and any others as identified in the relevant request form).

 Core stakeholders include the SME-TG (where appropriate), Regional Directors of Public Health (RDPH), and other key consultees including Irish College of GPs (ICGP), Consultants in Public Health Medicine (CPHMs), National Health Protection Office (NHPO), Antimicrobial Resistance and Infection Control (AMRIC), National Director of Public Health (NDPH), National Social Inclusion Office (NSIO), Director Workplace Health and Wellbeing Unit, National Immunisation Office (NIO), National Immunisation Advisory Committee (NIAC), National Director of Nursing (Health Protection), Clinical Lead for Surveillance (National Health Protection).

# Stage 6: Editing, approval, and publication

The final draft GPG document is circulated within the GDG for final comments. The document should be updated appropriately. Before the final version can be published, final approval of the guidance document is obtained as follows:

The RGDU in conjunction with the SME-TG signs off for scientific and technical content and for quality assurance of the guidance development process. HPAC-ID will review the final working document prior to approval and sign off by DNHP.

# Stage 7: Dissemination, uptake, and implementation

When approved the document will be published on the HPSC website. A national alert to advise of publication shall be widely distributed by the DNHP, or deputy, to relevant stakeholders. **Refer to RGDU SOP003 Issuing Guidance Alerts for further information.** 

# Monitoring and review

Guidance documents will be regularly reviewed based upon emerging evidence at national and international levels and national policy decisions. In tandem with this, the guidance will be formally reviewed on a three-year cycle.

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# **Appendix 1**

# Infographic: Good Practice Guidance (GPG) Methodology

#### Stage 1: Topic Selection & Scoping

Define scope and identify evidence needs (scientific and colloquial).

#### Stage 2: Formation of GDG

Form a multidisciplinary group including SMEs, practitioners, and end users.

#### Stage 3: Evidence Identification & Evaluation

Formulate key questions and appraise all relevant evidence.

#### Stage 4: Recommendation Formulation

Use consensus methods to draft recommendations and document decisions.

#### Stage 5: Consultation

Engage stakeholders for feedback including SME-TG, ADPHs, and others.

#### Stage 6: Editing, Approval & Publication

Finalize content with RGDU and SMEs, then submit for DNHP approval.

#### Stage 7: Dissemination & Implementation

Publish guidance and issue alerts to stakeholders. Monitor and review periodically.