HSE Public Health: National Health Protection Office
FSS Sláinte Poiblí: An Oifig Náisiúnta um Chosaint Sláinte

Framework for Health Protection Guidance Development in Ireland

Version 1.1

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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 Good Practice Guidance.*

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List of Abbreviations

AMRIC	**Antimicrobial Resistance and Infection Control**
CBR	**Consensus-Based Recommendations**
CP	**Consensus Panel**
CPHM	**Consultant in Public Health Medicine**
DNHP	**Director of National Health Protection**
EBPH	**Evidence-based Public Health**
ECDC	**European Centre for Disease Prevention and Control**
EIPH	**Evidence-informed Public Health**
GDG	**Guideline Development Group**
GIN	**Guideline International Network**
GPG	**Good Practice Guidance**
GRADE	**Grading of Recommendations, Assessment, Development and Evaluation**
HPAC-ID	**Health Protection Advisory Committee for Infectious Diseases**
ICGP	**Irish College of General Practitioners**
NCEC	**National Clinical Effectiveness Committee**
NDPH	**National Director of Public Health**
NGT	**Nominal Group Technique**
NHPO	**National Health Protection Office**
NIAC	**National Immunisation Advisory Committee**
NICE	**National Institute for Health and Care Excellence**
NIO	**National Immunisation Office**

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NSIO	**National Social Inclusion Office**
RDPH	**Regional Directors of Public Health**
RGDU	**Research and Guideline Development Unit**
SME	**Subject Matter Expert**
SME-TGs	**Subject Matter Expert Topic Groups**
WHO	**World Health Organisation**

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Summary

This framework, developed by the **Research and Guideline Development Unit (RGDU),** describes the structured process for creating evidence-informed health protection guidance in Ireland. It draws on methodologies from organisations such as Guideline International Network (GIN) – McMaster, World Health Organization (WHO), and National Clinical Effectiveness Committee (NCEC), emphasizing adaptation, adoption, and de novo development of recommendations tailored to the Irish context. The framework describes the roles and responsibilities of the component parts of the National Health Protection Office (NHPO) guidance development system; some basic principles underpinning NHPO guidance development and the categories of NHPO guidance.

The process involves prioritising topics, reviewing evidence, consulting stakeholders, and building consensus through multidisciplinary groups and panels. The framework distinguishes between evidence-based and evidence-informed public health, advocating for the use of best available evidence while considering local context, values, equity, and feasibility.

Two main methodologies are outlined: **Consensus-Based Recommendations (CBR) Protocol**, which uses formal consensus methods when evidence is limited or evolving, and **Good Practice Guidance (GPG) Methodology**, which relies more on practitioner expertise and consensus when published evidence is weak. Governance is provided by the Director for National Health Protection (DNHP), and guidance documents are reviewed at least every three years, with rapid updates possible if new evidence emerges. This document also includes references to supporting materials and methodologies from leading health organisations.

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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)**

Guidance methodology employed by the Research and Guideline Development Unit (RGDU) is informed by explicit processes associated with adaptation, adoption, and de novo development of guideline recommendations. This has been previously outlined via the "GRADE-ADOLOPMENT" approach.[1] With reference to GRADE, adaptation comprises the contextualisation and modification of source recommendations or evidence summaries; adoption constitutes contextualisation without any requirement for further amendment.[1] In the context of public health guideline development in Ireland, the contextualisation process facilitates an examination of established guidelines and supportive evidence with a potential positive impact upon resources typically associated with this approach.

While the core principles of evidence-based guideline 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.[2, 3] 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.[4]

The RGDU guidance development process typically involves the stages outlined in **Figure 1**.

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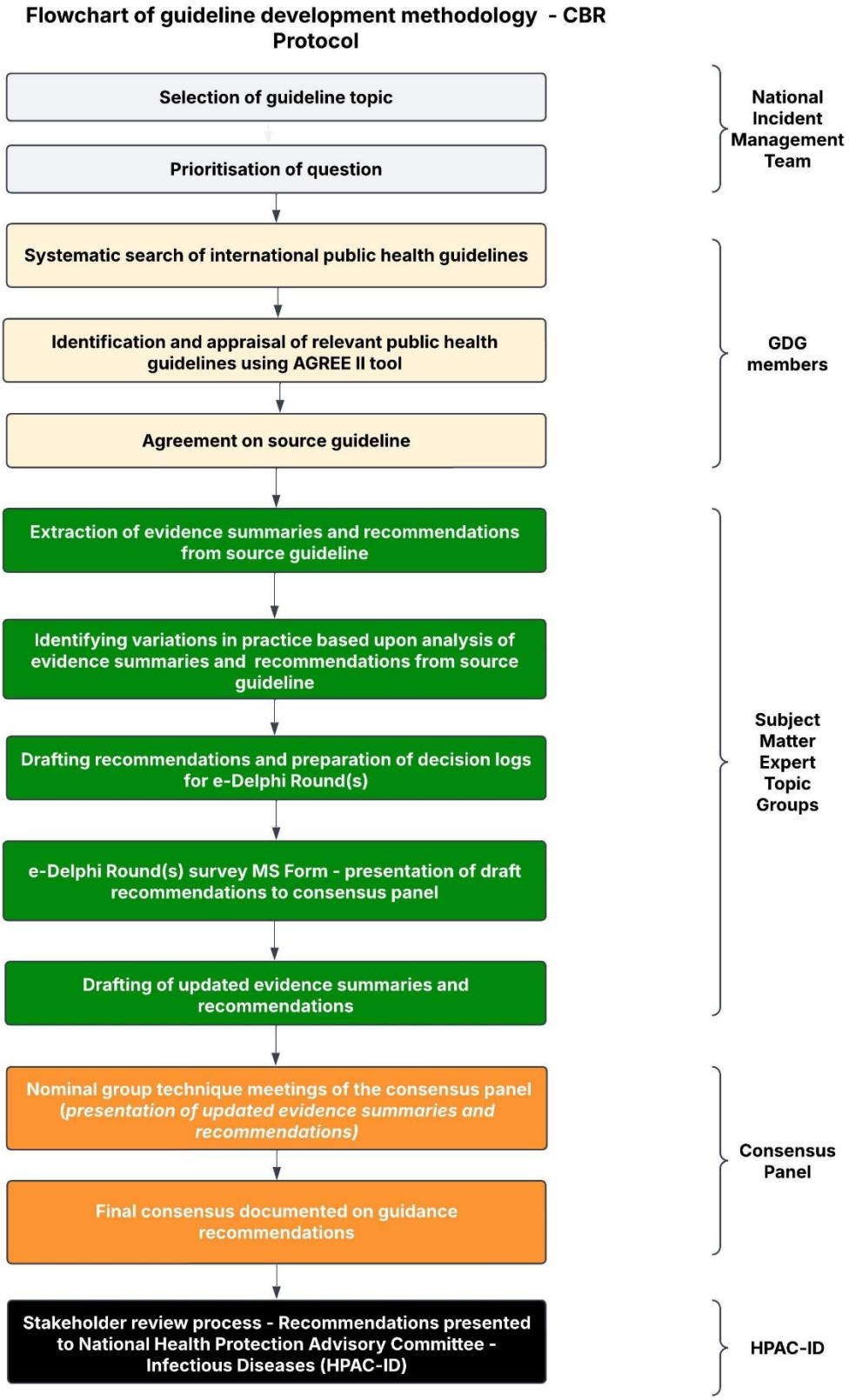

Figure 1: Flowchart of RGDU guideline development methodology

When considering the evidence base for public health guideline development, it has previously been contested Rycroft-Malone (2001) that the most important factor is that the evidence derives from the most relevant source to address the question being proposed.[5] This is consistent with advances in the complex sphere of evidence-informed practice where there has been recognition of the requirement for integration of research evidence, clinical experience, patient experiences and information from local contexts to ensure an inclusive and balanced evidence base for public health practice.[5] The challenge for public health guidance developers is to blend these evidence sources whilst ensuring transparency in the process and the application of comprehensive, systematic methods.

2.0 Roles of the RGDU & the Subject Matter Expert (SME) Topic Groups

As a core function of the National Health Protection Office (NHPO) within Ireland, the Research and Guideline Development Unit (RGDU) develops evidence informed health protection guidance that enhances health outcomes for patients, diminishes variation in practice and supports and improves the quality of clinical decisions.

The Director for National Health Protection (DNHP) provides overall governance for the development of health protection guidance produced by the RGDU. The RGDU provides project management support and methodological expertise throughout the guidance development process. The RGDU facilitates detailed oversight of the content of individual guidance documents, although this responsibility lies with the respective Guidance Development Groups (GDGs). The GDG is comprised of multidisciplinary content experts who provide unique knowledge and insight for the purpose of developing robust evidence informed guidance updates. The group reflects those whose professional activities will be covered by the guidance. In addition, the GDG will ideally comprise representation from the target audience, patients and carers, frontline clinicians, content experts and methodology experts.

Subject Matter Expert Topic Groups (SME-TGs) are formed to work on specific sections of the guidance as appropriate. The SME-TG comprises evidence review experts, all with training in the analysis of data and evidence-based medicine and with extensive knowledge in their field. The SME-TGs will review evidence summaries and actions focused on

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modifying proposed recommendations where necessary. These modified recommendations are presented to the consensus panel for review, discussion and consensus.

Consensus Panels are derived from GDG membership and play a significant role in developing the guidance through agreement on recommendations based upon the summaries of evidence. Roles and functions are outlined in Table 1.

Table 1: Roles and functions of guidance development group members

Group	Composition	Role description
Guideline Development Group (GDG)	Multidisciplinary stakeholders with diverse experience and expertise	• Define the scope and purpose of the guideline. • Constitute SME-TGs and Consensus Panel • Review the evidence and develop recommendations for practice. • Stakeholder consultation (both internal and external). • Ongoing evaluation and review of the guideline • Liaise with the Health Protection Advisory Committee for Infectious Diseases (HPAC-ID) regarding publication and dissemination of the guideline.
Subject Matter Expert Topic Groups (SME-TGs)	Experts with previous knowledge of evidence-based medicine and evidence synthesis	• Synthesise evidence and expert opinions to formulate recommendations for public health practice. • Identify variations in practice upon analysis of the evidence summaries and recommendations from the source guideline. • Developed and presented the recommendations and evidence to the CP.
Consensus panel (CP)	Multidisciplinary stakeholders with diverse experience and expertise	• Participate in iterative rounds of voting to reach consensus on recommendations. • Address areas of practice where variation may exist, and rigorous evidence may be inadequate. • Appraise draft guidelines to ensure they are comprehensive, clear, and applicable to public health practice.

To ensure that the RGDU addresses the guidance development priorities of the NHPO, a triage process is undertaken to determine the relative priority of each individual topic. The following are suggested as criteria to help guide the prioritisation of topics suitable for NHPO guidance;

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Potential new guidance shortlist criteria:

- the topic aligns with current national priorities
- the topic relates to:
    - a significant burden of care and/or illness adding to health service demand
    - premature mortality
    - reduced quality of life
    - wider societal impact, including economic impact
- there is no current NHPO guidance on the topic
- there is no relevant national/international guidance that might be adopted/adapted for use in Ireland

and

- there is capacity to support guidance development

In the event of challenges regarding prioritisation of resources, the Director of National Health Protection (DNHP) will make the final decision on which projects are supported.

A **Request for new RGDU Guidance Document (RGF004)** is completed, approved by the relevant Consultant in Public Health Medicine (CPHM) and is sent to the RGDU for consideration. If the request for guidance is approved (and prioritised where necessary), the RGDU will determine what resources will be required to produce the document and will allocate resources, **Refer to *SOP002 for Managing Requests for RGDU Guidance documents.***

When developed, an initial draft document will be circulated to the health protection core membership group for review (and any others as identified in the relevant request form). Core membership includes 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).

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A final working draft will be reviewed by the RGDU, in conjunction with the SME-TG for scientific and technical content (where required), for quality assurance of the guidance development process. The Health Protection Advisory Committee for Infectious Diseases (HPAC-ID) will review the final working document prior to approval and sign off by DNHP.

A review of guidance produced by the RGDU will be undertaken no more than three years after publication as part of the routine cycle of guidance review. At these planned reviews, the RGDU in conjunction with the GDG should consider if there is a need to retain the guidance document for the specific subject or whether the document requires updating. A review of guidance will be undertaken no more than three years after publication by the RGDU as part of the routine cycle of guidance review. The RGDU will also request an internal evaluation of the guideline development process from all GDG members and additional information to determine the effectiveness of the guideline following implementation. The RGDU may undertake a more rapid update of specific chapters within guidance if new and relevant evidence is published according to need.

3.0 Principles Underpinning the RGDU Framework for Health Protection Guidance Development in Ireland

Consistent with NICE the RGDU has adopted the term **guidance** as the generic term to describe the range of work to be addressed by the unit and covered by this framework.[6] Public Health Guidance makes recommendations for populations and individuals on activities, policies and strategies that can help prevent disease or improve health. The guidance may focus on a particular topic (such as smoking), a particular population (such as schoolchildren) or a particular setting (such as the workplace).

The RGDU has adopted the following definition:

Evidence-based Public Health (EBPH) is defined as *the conscientious, explicit, and judicious use of the current best evidence in making decisions about the care of communities and populations in the domain of health protection, disease prevention, health maintenance and improvement (health promotion). It is the process of systematically finding, appraising, and using contemporaneous research findings as the basis for decisions in public health.*[7]

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Evidence informed public health (EIPH) involves a broader approach that considers research evidence as one of several factors in decision- making. It also takes into account local context, values, public opinion, equity, and feasibility and is applied in public health, where policy decisions must balance scientific findings with societal needs and limitations.[8]

The methods used may differ, especially between those for the identification of problems and those for the identification of effective measures. Evidence is not scientifically valid by virtue of the fact that it is derived from a randomised controlled trial but that it comes from the most appropriate source for the question being posed.[5]

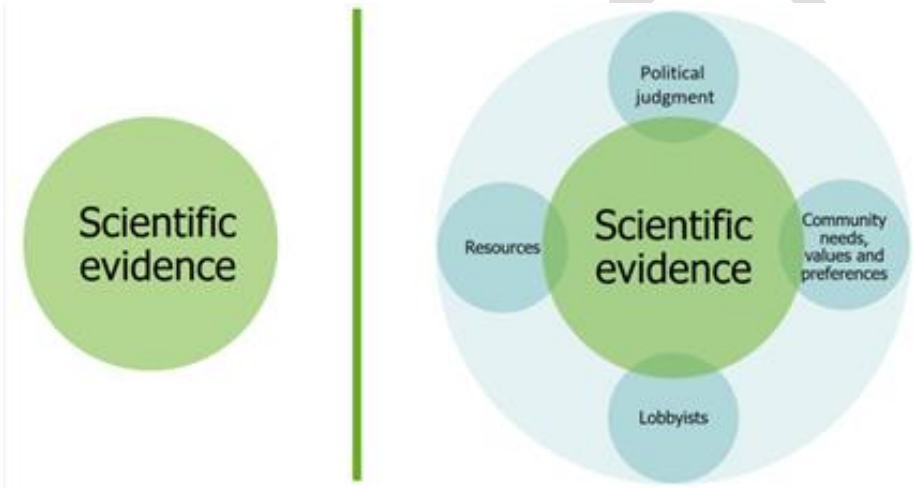

Figure 2: EBPH vs. EIPH[8]

4.0 Guidance Development Methodologies

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

1. **Good Practice Guidance Methodology**
2. **Consensus Based Recommendations Protocol**

All RGDU methodology and protocol documents will be published on the HPSC website and the **RGDU homepage**.

4.1 Consensus Based Recommendations (CBR) Protocol

Situations arise in health protection practice where contemporaneous evidence is ambiguous, limited, unavailable, or still evolving. Historically, within the healthcare context, consensus methods have been applied as a means of enhancing clinical decision-making and in advancing health policy.[9] Evidence suggests that there are potentially significant shortcomings with informal consensus methods, applied to decision-making within guideline development, and most notably these concern: power imbalance of individuals within the consensus panel resulting in dominance over discourse and subsequent recommendations; a lack of transparency on complex issues as a result of unstructured processes.[10] In addition, it is considered that informal consensus methods are more likely to be founded upon both insufficient criteria and arrangements for explicit consensus. As a consequence, guidance that is developed using this approach is frequently subjective and inadequately defined.[5]

Recognising the limitations of informal consensus methods, and in an effort to: establish systematic and transparent support for consensus group decision making; diminish the impact of potential biases; and enable equal opportunities for engagement across all group members, formal consensus methods have been promoted.[11]

Formal consensus methods are viewed by the RGDU as a suitable approach to address the aforementioned complexities, and to support the adaptation and adoption of public health guidelines, when situated within a structured and transparent framework. When applied, it is strongly recommended that a formal consensus approach is situated within an evidence based framework.[12] The RGDU have adopted Grade (Grading of Recommendations Assessment, Development and Evaluation) methodology for this purpose and this framework is endorsed by organisations including the WHO, ECDC (European Centre for Disease Prevention and Control) and NICE.

For further details on implementation, please refer to the **Consensus Based Recommendations (CBR) Protocol.**

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4.2 Good Practice Guidance (GPG) Methodology

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. 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.

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5.0 Bibliography

1. Schünemann HJ, Wiercioch W, Brozek J, et al. GRADE Evidence to Decision (EtD) frameworks for adoption, adaptation, and de novo development of trustworthy recommendations: GRADE-ADOLOPMENT. *J Clin Epidemiol* 2017; 81: 101-110. 20161003. DOI: 10.1016/j.jclinepi.2016.09.009.
2. National Health and Medical Research Council (NHMRC). Australia National Health and Medical Research Council. A guide to the development, implementation and evaluation of clinical practice guidelines. 1999.
3. World Health Organization (WHO). Enhancing WHO's standard guideline development methods. Available at: https://www.who.int/news/item/28-01-2019-enhancing-who-s-standard-guideline-development-methods. 2019.
4. Schünemann HJ, Reinap M, Piggott T, et al. The ecosystem of health decision making: from fragmentation to synergy. *Lancet Public Health* 2022; 7: e378-e390. DOI: 10.1016/s2468-2667(22)00057-3.
5. Rycroft-Malone J. Formal consensus: the development of a national clinical guideline. *Qual Health Care* 2001; 10: 238-244. DOI: 10.1136/qhc.0100238..
6. National Institute for Health and Care Excellence (NICE). Talking about NICE | NICE style guide | Guidance | NICE [Internet]. www.nice.org.uk.2024. Available from: https://www.nice.org.uk/corporate/ecd1/chapter/talking-about-nice#:~:text=NICE%20guidance%20refers%20to%20all. 2024.
7. Jenicek M. Epidemiology, Evidenced-Based Medicine, and Evidence-Based Public Health. *Journal of Epidemiology* 1997; 7: 187-197. DOI: 10.2188/jea.7.187.
8. European Centre for Disease Prevention and Control (ECDC). EU health security workshop strengthens regional skills in evidence-based public health. [Available at]: https://www.ecdc.europa.eu/en/news-events/eu-health-security-workshop-strengthens-regional-skills-evidence-based-public-health. 2025.
9. Parlour R, Gilbourne C, Williams M, et al. Applying Formal Consensus Methods To Enhance The Credibility Of Public Health Guideline Development – A Case Study. *Open Public Health J,* 2025; 18: e18749445415283.
10. Arakawa N and Bader LR. Consensus development methods: Considerations for national and global frameworks and policy development. *Res Social Adm Pharm* 2022; 18: 2222-2229. 20210630. DOI: 10.1016/j.sapharm.2021.06.024.
11. Carter P, O'Donoghue KJM, Dworzynski K, et al. A demonstration of using formal consensus methods within guideline development; a case study. *BMC Medical Research Methodology* 2021; 21: 73. DOI: 10.1186/s12874-021-01267-0.

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12. Waggoner J, Carline JD and Durning SJ. Is There a Consensus on Consensus Methodology? Descriptions and Recommendations for Future Consensus Research. *Acad Med* 2016; 91: 663-668. DOI: 10.1097/acm.0000000000001092.

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