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

Standard Operating Procedure (SOP) for Health Protection Guidance Development

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V 1.0	13/02/2025	Procedure developed	EOM
V1.1	19/06/2025	Procedure updated to include links related to OOH Handbook	EOM

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1. Introduction and Purpose

Health protection is a critical component of public health, aimed at preventing and controlling infectious diseases, environmental hazards, and other threats to the health of the population. In Ireland, the development of Health Protection Guidance is essential to ensure a coordinated and effective response to these challenges.

The purpose of this document is to provide a structured framework for the development, and review of Health Protection Guidance, and where applicable, implementation of guidance into practice. This framework is designed to promote high standards of practice, ensure consistency, and facilitate the use of evidence-based approaches in health protection activities.

The guidance development process involves a multidisciplinary approach, incorporating input from experts, practitioners, and stakeholders across various sectors. This collaborative effort ensures that the guidance is comprehensive, practical, and tailored to the specific needs of the Irish context.

This document outlines the roles and responsibilities of the various groups involved in the guidance development process, the methodologies used, and the principles underpinning the framework. It also provides a classification of different types of practice guidance for Health Protection and the standards required for their development and approval. By adhering to this standard operating procedure (SOP), health protection practitioners in Ireland can access high-quality, reliable guidance that supports their efforts to protect and improve public health.

The SOP also describes the roles and responsibilities of the component parts of the RGDU, HSE Public Health: National Health Protection Office guidance development system; some basic principles underpinning Health Protection Guidance development; the categories of guidance and includes an option for approval of externally produced (i.e. without input from RGDU, HSE Public Health: National Health Protection) guidance.

The RGDU oversees the process for ensuring the quality of Health Protection Guidance produced by the relevant public health experts and wider stakeholders to support HSE Public Health: NHPO. The principal role of the RGDU is to encourage consistent high standards of

Health Protection practice by promoting a multidisciplinary approach to the development of quality assured Health Protection Guidance.

Ideally all Health Protection Guidance should be evidence-based. An evidence-based output 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 Health Protection Guidance for situations where the published evidence is inadequate or where it is not possible to comply with the full standards required of an evidence-based output.

The role of the RDGU is to recommend evidence-based guidelines and good practice guidance for Health Protection (i.e. Health Protection Guidance) to the Director of National Health Protection (DNHP), for a list of Clinical Effectiveness Outputs in Health Protection, see Appendix A. In this work, the DNHP will be informed and supported by expert advisory groups within the National Health Protection Office e.g. via the Health Protection Advisory Committee – Infectious Diseases (HPAC-ID)[1], or within wider HSE e.g. Antimicrobial Resistance and Infection Control (AMRIC), or by appropriate *ad hoc* advisory groups established in response to emergent threats or issues (e.g. National Incident Management Team (N-IMT)). Advice provided by such groups should usually also go to HPAC-ID for discussion and ratification unless urgent need requires action in a timeline which precludes that option when the DNHP may take executive action. Such guidance, once approved by the DNHP, will become HSE Public Health: National Health Protection Office approved for use within Health Protection in Ireland. The RGDU does this by:

- Prioritising clinical effectiveness outputs for Health Protection that are important to support key objectives of protecting health and preventing harm in line with statutory. strategic and operational needs;
- Supporting National Incident/Outbreak Management Teams in assessing the need for clinical effectiveness outputs for Health Protection to support the management of that incident or outbreak response;
- Provision of framework and checklist for Subject Matter Expert Topic Group(s) (SME-TG(s)/Special Interest Group(s) SIG(s) in assessing clinical effectiveness outputs for Health Protection against criteria to judge that they have been developed in the best possible way. This assures that all outputs are based on best available evidence, have

1 New Health Protection Advisory Committees may be formed in the future e.g. HPAC-Environ, HPAC-Rad etc. to reflect work in wider hazards.

involved key people, including patient(s)/advocacy group(s), in their development and have considered resource issues for smooth implementation; and

- In exceptional circumstances, where interim public health guidance is required on an emergency basis (e.g. public health emergencies, hazards and emerging infectious threats requiring urgent actions), this guidance should be developed by the relevant SME-TG (which could be convened by a **National Incident Management Team)**,(N-IMT) based on the best available evidence. If sustained as guidance following the initial emergency, this interim guidance can be further developed using current pathways.

The **RGDU has limited resources to support Health Protection Guidance development projects**. To ensure that we effectively meet the needs of Health Protection, the RGDU must prioritise available expertise and resources. This prioritisation will be informed by a triage process to determine the relative priority of each individual piece of work. As a result, the number of clinical effectiveness outputs for Health Protection that can be officially supported in any given year will be constrained by resource availability. This includes both the initial document development and the regular review process. Therefore, it is unlikely that RGDU will be able to support all proposals for Health Protection Guidance documents made by the SME-TG(s)/SIG(s).

2. Roles & Responsibilities for Developing Health Protection Guidance

Research and Guideline Development Unit (RGDU)

The RGDU provides overall governance to produce Health Protection Guidance sponsored by HSE Public Health: National Health Protection Office. The RGDU focuses on defining frameworks and setting standards to promote a consistent quality of guidance development. RGDU does not provide detailed oversight of the content of individual guidance documents; this responsibility lies with the respective SME-TG(s)/SIG(s).

RGDU Role Encompasses:

- Provide strategic leadership for the national Health Protection Guidance in Health Protection agenda;
- Contribute to national Health Protection quality improvement agenda;
- Publish Standards for Clinical Practice Guidance in Health Protection;
- Prioritise and quality-assure Health Protection Guidance in Health Protection;

- Report periodically on the implementation and impact of Health Protection Guidance;
- Support SME-TG(s)/SIG(s) Health Protection Guidance work-streams;
- Support National Incident/Outbreak Management Team(s) around development of evolving Health Protection incidents in addition to development of Health Protection Guidance;
- Through collaborative partnership, shared resources and expertise, facilitate the development and implementation of evidence informed health protection research; and
- Produce reports on activity as required by the Director, National Health Protection.

Subject Matter Expert Topic Group (SME-TG)/Specialist Interest Group (SIG)

SME-TG/SIG agree their priorities for Health Protection Guidance development within their topic area, based on a consensus approach and in line with operational and strategic priorities of the HSE Public Health: National Health Protection Office. SIGs can also have a range of other functions, for further details please see here.

SME-TG/SIG Criteria for Potential Shortlisting:

- The topic aligns with HSE Public Health: National Health Protection Office priorities or has been previously identified as high priority;
- The topic relates to:
    - a response to an emergent public health threat led by an NIMT.
    - a significant burden of care and/or illness.
    - premature mortality.
    - reduced quality of life.
- There is no current or up-to-date guidance on the topic;
- There is no relevant guidance from external organisations that might be adapted for use in Ireland; and
- There is capacity to support development of guidance by RGDU.

The SME-TG(s)/SIG(s) identify potential topics that require HSE Public Health: National Health Protection Office supported guidance and screen these to determine which type of guidance would best meet the health protection need. Following this process, a **proposal should be sent to the RGDU via a completed request form** with the intention. The RGDU will determine whether topics proposed by the SME-TG(s)/SIG(s) fulfil the requirement for a RGDU Health Protection Guidance. If RGDU 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 Health Protection Guidance development work programme.

If there are more candidate topics for Health Protection Guidance than available resources, the list of potential candidates across all the health protection topic groups will be referred to the Director for National Health Protection (or designate) supported by the CPHM Lead for RGDU for prioritisation. Also, where potential candidate topics span several topic groups or are of general relevance to Health Protection practice in Ireland, decisions on prioritisation will be referred to the Director for National Health Protection (or designate) supported by the CPHM Lead for RGDU.

SME-TG/SIG Role Encompasses:

- Oversee the production of the Health Protection Guidance and are responsible for ensuring conformance with the quality standards associated to that category of clinical excellence output in Health Protection, as specified in this document.
- Will normally set up a specific Guideline Development Group (GDG) to take on responsibility for producing the Health Protection Guidance document.[2] Exceptionally the SME-TG/SIG may fulfil this function itself to develop interim high-priority Health Protection Guidance;[3] however, the RGDU recommends that formation of a GDG is preferred.
- Will be 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.

Final Approval of the Health Protection Guidance will be obtained from:

- **Step 1:** The SME-TG/SIG for scientific and technical content;
- **Step 2:** The RGDU's SOP for Health Protection Guidance Development for quality assurance of the Health Protection Guidance development process; and culminating with

[2] A GDG should consist of an appropriate 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.
[3] The SME-TG should be multidisciplinary and consist of an appropriate number of individuals with specific technical and content expertise on the subject in question together with a cross section of representation from experienced practitioners, and potential end users of the guidance.

- **Step 3:** The HPAC-ID or other relevant group for non-infectious hazards for in respect of scientific and technical content when the topic and content is in relation to health protection in Ireland.
- **Step 4:** Recommendation to the DNHP for review and approval for final sign-off.

A final draft document will be submitted to HPAC-ID (or relevant group for non-infectious hazards) for review, with a statement verifying conformance to the appropriate RGDU quality standards as outlined in this SOP. Checklists for scientific and quality assurance sign-off are provided in the detailed Health Protection Guidance development protocols (see **Appendix A**). Where any of the appropriate quality standards are not met, these will need to be identified and reasons given for the non-conformance.

The HPAC-ID group (or relevant group for non-infectious hazards) will review the final draft and supporting documentation to determine whether it fulfils the RGDU requirements in respect of quality assurance.

At the regular planned reviews, SME-TG(s)/SIG(s)s should consider if there is a need to retain the Health Protection Guidance document for the specific subject; whether the topic is no longer a priority or whether it is completely redundant.[4] If Health Protection 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 formats. Where the SME-TG(s)/SIG(s) decides to update an existing Health Protection Guidance document, it is recommended that this should be carried out by a reformed GDG.

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 Health Protection Guidance document, then the relevant Health Protection Guidance may be reviewed earlier.

The stages of the Health Protection Guidance process are outlined in **Appendix C**, and outlines the process for RGDU-supported and SME-TG/SIG-lead Health Protection Guidance.

[4] A review period of three years is recommended for all Clinical Effectiveness output(s), with options for an earlier review depending on the pace at which important new knowledge becomes available rendering the output as outdated. Exception to this three-year rule will be the seasonal respiratory Clinical Effectiveness outputs, will be updated on an annual basis.

Either option requires the same adherence to core components that form the basis for high quality evidence-based Health Protection Guidance outputs.

3. Adopt a Multidisciplinary Approach

A multidisciplinary approach is essential for the development of effective Health Protection Guidance. This approach ensures that the output is comprehensive, practical, and reflective of diverse perspectives and expertise. Here are the key elements to consider:

1. **Formation of SME-TG/SIG Groups:**
   - **Composition**: Include experts from various fields such as epidemiology, public health, clinical practice, environmental health, and social sciences. This diversity ensures that all relevant aspects of health protection are considered.
   - **Stakeholder Involvement**: Engage stakeholders, including healthcare providers, policymakers, community representatives, and patients/service users, to incorporate their insights and experiences. In developing guidance for specific settings or communities, it is important to have appropriate representation to inform the work of the group. This is particularly important to address issues of health equity and inclusion.
2. **Collaborative Development Process:**
   - **Consensus Building**: Use formal and informal consensus methods to develop recommendations, especially when evidence is limited. Techniques such as Delphi panels can help achieve agreement among experts.
   - **Regular Meetings**: Schedule regular meetings to discuss progress, address challenges, and ensure alignment among group members.
3. **Integration of Evidence and Expertise:**
   - **Systematic Evidence Review**: Conduct thorough literature reviews and critical appraisals to gather the best available evidence. This process should be supported by healthcare scientists and librarians.
   - **Expert Opinion**: When evidence is lacking, rely on the collective expertise and experience of the group (and their professional networks) to formulate practical and applicable guidance.
4. **Quality Assurance and Approval:**
   - **Drafting and Consultation**: Develop draft Health Protection Guidance documents and seek feedback from all group members and external reviewers. This step ensures the output is robust and widely accepted.

- **Final Approval**: Obtain final approval from relevant governance bodies, ensuring that the guidance meets established quality standards and is ready for dissemination and implementation.

By adopting a multidisciplinary approach, Health Protection Guidance in Ireland will be well-rounded, evidence-based, and more likely to be effective in addressing public health challenges.

4. Classification of Health Protection Guidance

In the development of Health Protection Guidance, it is essential to classify the types of outputs to ensure clarity, quality, and appropriate application. The classification helps practitioners understand the level of evidence and rigor involved in the development process, thereby guiding their use in various health protection scenarios.

Ideally all health protection practice guidance would be evidence-based. An Evidence Based Guideline (EBG) incorporating systematic reviews and critical appraisal 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 RGDU has developed a framework defining the diverse types of health protection guidance that are recognised by NHPO as being suited to different practice situations (available here) and summarised in Appendix D.

5. Standardise Development Methodologies

To ensure consistency, quality, and effectiveness in the development of Health Protection Guidance, it is essential to standardize the methodologies used. The following table outlines the key components and steps involved in the standardised development process:

COMPONENT	DESCRIPTION
1. Purpose and Scope	
Purpose	Clearly define the objective of the Health Protection Guidance.
Scope	Specify the health protection areas, target population, and settings covered.

2. Governance and Roles	
Governance Model	Establish formal governance arrangements at local, regional, and national levels.
Roles and Responsibilities	Define roles for Health Protection Guidance development, approval, dissemination, and review.
3. Development Process	
Topic Selection	Criteria for selecting Health Protection Guidance topics.
Multidisciplinary Group	Form a group with relevant stakeholders and experts.
Evidence Review	Conduct systematic literature reviews and critical appraisals.
Drafting and Consultation	Draft guidance and seek feedback from stakeholders.
4. Methodology	
Evidence-Based Approach	Use systematic methods to gather and appraise evidence.
Consensus Building	Employ formal or informal consensus methods when evidence is lacking.
5. Implementation and Monitoring	
Implementation Plan	Develop a plan with timelines, responsible persons, and integration into service planning.
Training and Support	Provide education and resources for staff.
Monitoring and Review	Establish processes for regular review, audit, and updates.
6. Communication	
Communication Plan	Ensure effective communication with all stakeholders.
Dissemination	Outline procedures for disseminating the Health Protection Guidance.

By adhering to these standardised methodologies, Health Protection Guidance can be developed in a structured, transparent, and efficient manner, ensuring high-quality outcomes and consistent application across various health protection scenarios.

6. Regular Review and Updates

Regular review and updates are crucial to ensure that Health Protection Guidance remains current, relevant, and effective. This process involves systematic evaluation and revision of Clinical Effectiveness Outputs documents to incorporate new evidence, address emerging health threats, and reflect changes in best practices. The following steps outline the approach to regular review and updates:

Review Cycle:

- **Frequency:** Health Protection Guidance documents should be reviewed at regular intervals, **typically every three years**. However, **reviews may be conducted sooner if significant new evidence or changes in the health protection landscape emerge.**
- **Triggers for Early Review:** Important new knowledge, changes in legislation, or the publication of new guidelines by other authoritative bodies may necessitate an earlier review.

Review Process:

- **Initial Assessment:** The relevant topic group (e.g., HSE Public Health: National Health Protection Office -Topic Group) conducts an initial assessment to determine if the guidance document remains relevant and accurate.
- **Stakeholder Consultation:** Engage stakeholders, including practitioners, experts, and users of the guidance, to gather feedback on the current document and identify areas for improvement.
- **Evidence Update:** Conduct a systematic review of the latest evidence to identify new research, data, and best practices that should be incorporated into the guidance.

Revision and Approval:

- **Drafting Revisions:** Based on the review and stakeholder feedback, draft revisions to the guidance document. This may involve updating recommendations, adding new sections, or modifying existing content.
- **Quality Assurance:** Ensure that the revised document meets the established quality standards. This includes verifying the accuracy of the evidence, ensuring clarity and consistency, and confirming that the guidance aligns with current best practices.
- **Final Approval:** Obtain final approval from the relevant governance bodies, such as the HSE Public Health: National Health Protection Office - Guidance Group, to ensure that the revised guidance is ready for dissemination.

Dissemination and Implementation:

- **Communication Plan:** Develop a communication plan to inform all relevant stakeholders about the updated guidance. This may include publishing the document on official websites, distributing it through professional networks, and conducting training sessions.
- **Quality Assurance*:*** To review the quality of the guidance, a mechanism is in place, to gather feedback from Stakeholders, immediately after the guidance development process and at an appropriate interval after publication.

- **Monitoring and Evaluation:** Implement mechanisms to monitor the uptake and impact of the updated guidance. This includes tracking its use in practice, evaluating its effectiveness, and identifying any further areas for improvement.
- **Out-of-Hours (OOH) Operational Relevance Check:** As part of the guidance development and review process, regional and national public health teams should assess whether the guidance has implications for Out-of-Hours (OOH) public health actions. Where relevant:
    - The OOH Handbook should be reviewed for consistency with the new or updated guidance.
    - Links to the OOH Handbook should be included in the guidance document where appropriate.
    - If concerns or inconsistencies are identified, these should be escalated to HPAC-ID to ensure formal multi-stakeholder review and incorporation into future updates of the OOH Handbook.
    - This step should be documented in the guidance development checklist and reviewed during final sign-off.

By adhering to a structured process for regular review and updates, health protection guidance can remain a valuable resource for practitioners, ensuring that public health responses are based on the most current and reliable information available.

7. Conclusion

The development of Health Protection Guidance in Ireland is a critical endeavour that ensures the safety and well-being of the population. By adopting a structured framework, we can produce high-quality, evidence-based guidance that is both practical and effective. This framework emphasises the importance of a multidisciplinary approach, the classification of guidance types, standardized development methodologies, and regular review and updates.

Implementing these principles will help maintain high standards of health protection practice, ensuring that guidance remains current and relevant in the face of evolving public health challenges. By fostering collaboration among experts, practitioners, and stakeholders, and by committing to continuous improvement, we can enhance the effectiveness of health protection measures and ultimately improve public health outcomes in Ireland.

Appendix A

Types of Clinical Effectiveness Outputs in Health Protection

GUIDANCE DETAILS	EXPLANATIONS
Health Protection Guidance	This is defined as systematically developed statements or processes to assist clinician and patient/population decisions about appropriate health care for specific clinical circumstances, with the type of Health Protection Guidance determined by evidence-based criteria and clinical requirements. Such clinical effectiveness outputs include algorithms, policies, procedures, protocols and guidelines.
Health Protection Guideline	This is a compilation of systematically developed statements, based on a thorough evaluation of the evidence, to assist clinician and patient/population decisions about appropriate health care for specific Health Protection circumstances, across the entire clinical spectrum.
Health Protection Audit	This is a cyclical process that aims to improve patient/population care and outcomes by systematic, structured review and evaluation of clinical care against explicit clinical standards.
Health Protection Policy	This is a written operational statement of intent which helps staff to make appropriate decisions and take actions, consistent with the aims of the service provider and in the best interests of service users.
Health Protection Procedure	This is a written set of instructions that describes the approved and recommended steps for a particular act or sequence of events.
Health Protection Protocol	This is an agreed statement about a specific clinical issue, with a precise sequence of activities to be adhered to, with little scope for variation. Protocols are usually based on guidelines and/or organisational consensus.
Health Protection Algorithm	This is an evidence-based step-by-step visual interpretation of the decision making and/or associated actions relating to a particular guidance area. Notably the steps within an algorithm are more narrowly defined than in a guideline.
Clinician	A clinician refers to a health professional involved in Public Health or allied medical specialities.
Standard	A standard is a definable measure against which existing structures, processes or outcomes can be compared.

Appendix B

Standard Letter for Health Protection Guidance

Link to standalone version of letter template

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

TO: Chair, Health Protection Advisory Committee – Infectious Diseases (HPAC-ID)

FROM: [INSERT DETAILS]

RE: ***Standards for submitted Health Protection Guidance***

DATE: [INSERT DATE]

Please find enclosed standards for submitted Health Protection Guidance.

[**INSERT NAME OF OUTPUT FOR REVIEW**]

Clarity of scope and purpose

QUESTION(s)	YES	NO
The decision-making approach relating to type of output required (policy, procedure, protocol, guideline), coverage of the output (national, regional, local) and applicable settings are described.	☐	☐
The overall objective(s) of the output are specifically described.	☐	☐
The clinical question(s) covered by the output are specifically described.	☐	☐
The target users and the population/patient group to whom the output is meant to apply are specifically described.	☐	☐
The potential for improved health is described (e.g. clinical effectiveness, patient safety, quality improvement, health outcomes, quality of life, quality of care).	☐	☐
The scope of the output is clearly described, specifying what is included and what lies outside the scope of the output.	☐	☐

Governance model

QUESTION(s)	YES	NO
Formal governance arrangements for clinical practice guidance at local, regional and national level are established and documented.	☐	☐
Conflict of interest statements from all members of the guidance development group are documented, with a description of mitigating actions if relevant.	☐	☐
The guidance has been reviewed by independent experts prior to publication. (as required, complex CPGs).	☐	☐

Communications

QUESTION(s)	YES	NO
A communication plan is developed to ensure effective communication and collaboration with all stakeholders throughout all stages.	☐	☐
Plan and procedure for dissemination of the CPG is described.	☐	☐

Service user and stakeholder involvement

QUESTION(s)	YES	NO
Stakeholder identification and involvement: The EAG/GDG/SIG includes individuals from all relevant stakeholders, staff and professional groups.	☐	☐
Output is informed by the identified needs and priorities of service users and stakeholders.	☐	☐
The views and preferences of the target population have been sought and taken into consideration (as required).	☐	☐
There is service user/lay representation on EAG/GDG/SIG (as required).	☐	☐

Evidence-based

QUESTION(s)	YES	NO
Systematic methods used to search for evidence are documented (for output(s) which are adapted/adopted from international guidance, their methodology is appraised and documented).	☐	☐
Critical appraisal/analysis of evidence using validated tools is documented (the strengths, limitations and methodological quality of the body of evidence are clearly described).	☐	☐
The health benefits, side effects and risks have been considered and documented in formulating the output.	☐	☐
There is an explicit link between the output and the supporting evidence.	☐	☐
The guidance/recommendations are specific and unambiguous.	☐	☐
A systematic literature review and Health Technology Assessment (HTA) has been undertaken (as required, complex outputs).	☐	☐

Knowledge management

QUESTION(s)	YES	NO
The output will be easily accessible by all users e.g. CPG repository.	☐	☐
Documented process for version control is provided.	☐	☐
Copyright and permissions are sought and documented.	☐	☐

Resource implications

QUESTION(s)	YES	NO
The potential resource implications of developing and implementing the output are identified e.g. equipment, education & training, staff time and research.	☐	☐
Synergies are maximised across departments/organisations to avoid duplication and to optimise value for money and use of staff time and expertise.	☐	☐
Budget impact analysis is documented (as required, complex outputs).	☐	☐
Literature review of cost effectiveness is documented (as required, complex outputs).	☐	☐

Planning and implementation

QUESTION(s)	YES	NO
Written implementation plan is provided with timelines, identification of responsible persons/ units and integration into service planning process.	☐	☐
Barriers and facilitators for implementation are identified and aligned with implementation levers.	☐	☐
Information and support are available for staff on the development of evidence-based output.	☐	☐
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated patient care.	☐	☐
Education and training are provided for staff on the development and implementation of evidence-based output (as required, complex outputs).	☐	☐

Audit, monitoring, review & evaluation process

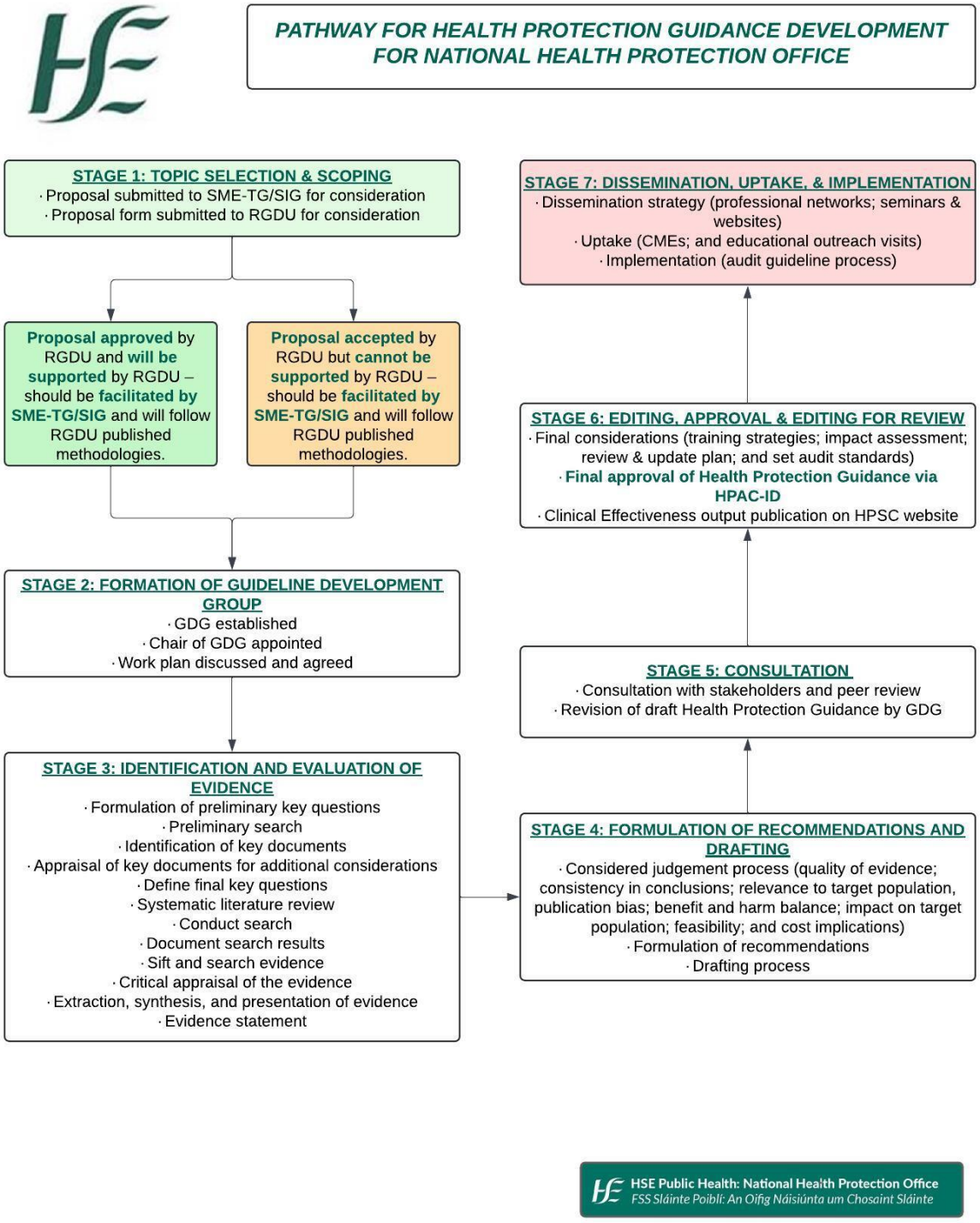
QUESTION(s)	YES	NO
Process for monitoring and continuous improvement is documented.	☐	☐
Process for evaluation of implementation and clinical effectiveness is specified.	☐	☐
Audit criteria and audit process/plan are specified.	☐	☐
Documented process for revisions/updating and review, including timeframe is provided.	☐	☐

Yours sincerely,
Chair, Expert Advisory Group (EAG)/Guideline Development Group (GDG)/Special Interest Group (SIG)

Appendix C

Health Protection Guidance Pathway

[Link to standalone version of pathway]



Appendix D

Classification of Health Protection Guidance

1. Evidence-Based Guidelines (EBG)

Definition: EBGs represent the highest standard of guidance, developed using rigorous methodologies and systematic literature reviews. They are based predominantly on published peer-reviewed evidence.

Types:

- **EBG Type A***: Requires a minimum of two independent reviewers for the evidence review and appraisal stages.
- **EBG Type A**: Requires only one reviewer for the evidence review and appraisal stages.

Criteria for Use:

- Suitable for topics with a robust evidence base.
- Developed through a multidisciplinary GDG.
- Reviewed every three years or sooner if new evidence emerges.

2. Good Practice Guidance (GPG)

Definition: GPGs are quality-assured guidance documents developed using less rigorous methods than EBGs. They rely more on expert opinion and consensus, making them suitable for situations where published evidence is limited or conflicting.

Criteria for Use:

- Appropriate when a higher standard of EBG is not available.
- Used when published evidence is lacking but there is sufficient practice-based knowledge and experience.
- Developed through consensus approaches, either formal or informal.

Methods and Quality Assurance:

- Should be produced to an accepted standard of professional practice.
- Reviewed at least every three years, with the option for earlier review if new knowledge becomes available.

Using GPG when there are limited resources in RGDU

In scenarios where resources are limited, such as during the rapid development of Health Protection Guidance, Good Practice Guidance (GPG) becomes particularly valuable. The following points outline how GPG can be effectively utilized in such situations:

Rapid Development:

- **Protocol for Rapid Development**: Utilise the RGDU Protocol for the Rapid Development of Guidance to produce high-quality guidance quickly. This involves a more targeted and less systematic approach to evidence retrieval and assessment.
- **Short Lifespan**: Recognise that rapidly developed guidance may have a shorter lifespan and may need to be reviewed or replaced by more formal guidance in the longer term.

Consensus-Based Recommendations:

- **Expert Input**: Rely on the knowledge and expertise of experienced practitioners to develop consensus-based recommendations. This approach is essential when there is a lack of published evidence.
- **Formal and Informal Methods**: Use both formal methods (e.g., Delphi panels) and informal consensus processes to agree on the content and recommendations.

Quality Assurance:

- **Professional Standards**: Ensure that GPGs are produced to an accepted standard of professional practice, consistent with peer group expectations.
- **Regular Review**: Implement a regular review cycle to update the guidance as new evidence or knowledge becomes available.

By classifying Clinical Effectiveness Output types and strategically using GPG when resources are limited, health protection practitioners can maintain high standards of practice and ensure timely and effective responses to public health challenges.

Standards for Clinical Effectiveness Outputs in Health Protection - Rationale

Types of Health Protection Guidelines will vary in complexity and scope, with the choice of output model determined by evidence-based criteria and clinical requirements. Not all outputs require the same pathway of development. However, regardless of the variation in scope and focus, it is important that the development of any output is underpinned by an evidence-based approach and quality assurance measures to assist clinician and patient decisions about appropriate healthcare for specific clinical circumstances.

RGDU Development Methodologies

The RGDU has produced methodology documents to promote and support consistent implementation of this:

- Consensus based recommendations protocols;
- Flowchart for guidance development;
- Good practice guidance methodology;
- GRADE adolopment of guideline recommendations; and
- Working draft framework for Health Protection Guidance Development.

Additional documents have also been developed by the RGDU:

- Prioritisation process for the development of Health Protection Guidelines; and
- Scoring matrix for assessment of topics for prioritisation process for the development Health Protection Guidelines.

Language Use

The use of verbs to indicate the level of action required is Health Protection Guidance requires close attention.

- The word '**should**' is used for actions/responsibilities/recommendations, what one thinks is best for the concerned subject. The word '**must**' is used for actions/responsibilities, that are required and considered compulsory/necessary. Consequently, the following meanings must be considered carefully when formulating recommendations in developing Public Health Guidance:
    - '**Shall**', '**Must**', and '**Will**': indicates a requirement.
    - '**Should**': indicates a recommendation.
    - '**May**': indicates a permission.
    - '**Can**': indicates a possibility or capacity.