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

Standard Operating Procedure (SOP014) for Rapid Health Protection Guidance Development

Version 1.0

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V 1.0	10/02/2026	Draft procedure developed	HPAC-ID

1.0 Purpose

This Standard Operating Procedure (SOP) establishes the official, mandatory process for developing and deploying rapid health protection guidance. It is designed for use in urgent situations where timely recommendations are critical to protect public health. The procedure ensures a structured approach that balances the need for speed with a firm commitment to transparency and scientific rigour.

The standard development timeline for comprehensive health protection guidelines typically spans one to three years. This rapid guidance process is specifically engineered for critical scenarios where such a lengthy process is not feasible. It provides a condensed, yet robust, framework for delivering evidence-informed recommendations under compressed timelines.

This document details the scope, principles, roles, and step-by-step methodology that govern the application of this rapid process.

2.0 Scope of this document

This SOP defines the procedural boundaries for the rapid development of health protection guidance. It applies to all activities and personnel within the Research and Guideline Development Unit (RGDU), as well as associated expert panel members, involved in the initiation, development, approval, and updating of rapid guidance documents.

The procedures outlined herein are specifically applicable to scenarios requiring the issuance of interim, temporary, or emergency guidance. This includes situations where data may be incomplete due to the novelty of a public health threat, such as high impact emerging infectious diseases, a new intervention, or a sudden environmental exposure.

The following sections detail the core principles that underpin this process and the specific triggers that activate its use.

3.0 Guiding Principles and Activation Triggers

The strategic integrity of the rapid guidance process depends on clear principles and well-defined activation triggers. These elements ensure that this expedited procedure is initiated only when appropriate and is executed in a manner that preserves the essential, evidence-based elements of standard guideline development, even under the pressure of an urgent response.

3.1 Guiding Principles

The methodology for developing rapid guidance is founded on the following core principles, which must be upheld throughout the lifecycle of the project:

- **Preservation of Rigour:** A steadfast commitment to maintaining scientific validity and methodological soundness, even when utilising abbreviated methods to meet time constraints.
- **Commitment to Transparency:** An obligation to ensure the development process is clear, justifiable, and well-documented, allowing stakeholders to understand the basis for each recommendation.
- **Prioritisation of Urgency:** A clear acknowledgment of the critical need for timely recommendations to inform immediate public health action and decision-making.

3.2 Activation Triggers

The decision to apply this rapid procedure is not arbitrary; it is prompted by specific conditions that demand an accelerated response. The following table outlines the official triggers for activating the rapid guidance development process.

Table 1: Triggers for Applying the Rapid Guidance Approach(1)

Situation / Trigger	Example(s)
Public health emergencies	Epidemics, pandemics, disasters
Emergent/potentially dangerous situations requiring coordinated international response	Chemical/radiological spills, outbreaks
Urgent stakeholder or policy need	Requests from governments, WHO, etc.
Interim guidance needed	While awaiting full guideline development
New, impactful evidence	New drug efficacy/safety data

Having established when and why this procedure is activated, the next section defines the roles and responsibilities of the team assembled to execute it.

4.0 Roles and Responsibilities

A clearly defined team structure is essential for executing a complex process within a compressed timeframe. In a rapid-response environment, the standard Guideline Development Group (GDG) is replaced by a more targeted and agile panel specifically constituted to meet the demands of an urgent public health need.

4.1 Team Composition

The rapid guidance panel is a targeted group of experts assembled to provide the necessary knowledge and skills for the specific topic. The panel must include the following roles:

- **Content Experts:** Subject matter experts (SMEs) with relevant, direct experience and a diversity of expertise related to the guidance topic. They are responsible for providing the core knowledge base.
- **Technical Experts (Methodologists):** Specialists with demonstrable prior experience in developing rapid guidance or guidelines. They ensure the methodological integrity of the process is maintained.
- **Research and Guideline Development Team:** The core operational team from the RGDU responsible for coordinating and facilitating the entire development lifecycle.

4.2 Governance

The rapid guidance team operates under a streamlined governance framework to ensure accountability and efficiency.

1. **Terms of Reference (ToR):** A formal ToR document is established for the team, adapted from standard templates to reflect the specific needs, scope, and expedited timeline of the rapid guidance project.
2. **Declarations of Interest:** The process for managing conflicts of interest is streamlined to accommodate the rapid recruitment and onboarding of panel members while ensuring all potential conflicts are declared and managed appropriately.

With the team and governance structure in place, the panel can proceed with the formal development lifecycle.

5.0 Procedure: Rapid Guidance Development Lifecycle

This section outlines the end-to-end lifecycle for developing rapid guidance, from initial topic selection to final sign-off. The entire process is designed to be completed within a timeframe of **up to 90 days**. While the stages mirror those of standard guidance development, this procedure allows for expedited or parallel steps to be conducted to prioritise the most critical recommendations.

5.1 Step 1: Initiation and Topic Selection

1. Topics and associated development timelines are formally established in coordination with the Director of National Health Protection (DNHP).
2. Upon initiation, the target audience must be alerted that new rapid guidance will be published shortly to encourage engagement and adoption.

5.2 Step 2: Main Stages of Development(2)

This step comprises the core technical work of creating the guidance document, from defining the key questions to drafting the final recommendations.

5.2.1 Scoping

The scope must be narrowly defined to ensure the project remains focused and achievable within the rapid timeframe. The scope document is drafted by Subject Matter Experts (SMEs) and the RGDU.

- **Required Components:**
    - Key Questions to be addressed
    - PICOs (Population, Intervention, Comparison, Outcome)
    - Exclusion Criteria
    - Target Audience
- The final scope document requires formal sign-off by the relevant Consultant in Public Health Medicine, in consultation with the SME group, before proceeding to the next stage

5.2.2 Identifying the Evidence

Evidence gathering is a **focused and targeted** activity.

i. The team will conduct targeted literature searches, prioritising high-level evidence sources, including **WHO, ECDC, NICE, and UKHSA**.

ii. Where possible, the process should be based on existing systematic reviews. Indirect evidence may be used if direct evidence is unavailable.
iii. SMEs play a critical role in this stage by providing supplementary information and helping to pinpoint relevant primary research studies that may not be captured in broad searches.

5.2.3 Selecting and Reviewing the Evidence

Evidence is critically appraised to ensure its quality and relevance.

i. The quality of the evidence is formally assessed using the **AGREE II** tool.(3)
ii. Health economic evidence is rarely sought in this rapid process due to time constraints.
iii. To support the efficient formulation and comprehension of recommendations, all evidence must be presented in a **decision log adapted for this purpose**.

5.2.4 Writing the Guideline

Recommendations are the final, actionable output of the guidance.

i. Recommendations must be based on the reviewed evidence. If evidence is insufficient, recommendations may be based on expert opinion, but the rationale must be clearly and explicitly documented.
ii. The strength of each recommendation is assessed by the subject matter experts during a facilitated nominal group technique meeting. This will enable a judgment of how confident the group is that implementing the recommendation will lead to more benefits than harms.
iii. The final guidance document must be clearly labelled to indicate that it was developed using the rapid guidance process, thereby distinguishing it from standard guidance.

5.2.5 Approvals Process

The final guidance document must receive formal approval before publication.

i. Final approvals are conducted as per the procedures outlined in **RGDU SOP001: Section 6.5 Approvals Process**.

a. A final working draft will then be reviewed by the RGDU, in conjunction with the SMEs for scientific and technical content (where required), and for quality assurance of the rapid guidance development process.
b. HPAC-ID will review the final working document prior to approval and sign off by DNHP.
c. The RGDU Document Control Register is updated in accordance with SOP001.
d. A guidance alert is issued to relevant stakeholders as outlined in **SOP003 Issuing Guidance Alerts.**

ii. The DNHP may be requested to consider expedited approval, at the final approval stage, depending on the topic and context.

iii. Following sign-off, the guidance is published, but the lifecycle continues with post-publication surveillance.

6.0 Post-Publication Surveillance and Updating

Post-publication vigilance is critically important for rapid guidance, which is often based on incomplete or rapidly emerging data. An active surveillance process ensures the guidance remains valid and reliable over time.

The RGDU team must implement a process of frequent evidence screening to monitor for new information that could impact the recommendations. This allows for rapid updates to be initiated as soon as significant new evidence becomes available. Furthermore, the team must determine if an expedited review process can be incorporated into the guidance lifecycle plan to maintain its currency and protect public health.

This commitment to ongoing surveillance ensures that rapid guidance serves as a living document, responsive to the evolving evidence base.

7.0 Monitoring, Audit and Evaluation

The CPHM Lead in Evidence Based Medicine, Research & Quality Improvement or RGDU Coordinator deputising, will evaluate this SOP annually, or sooner if changes occur.

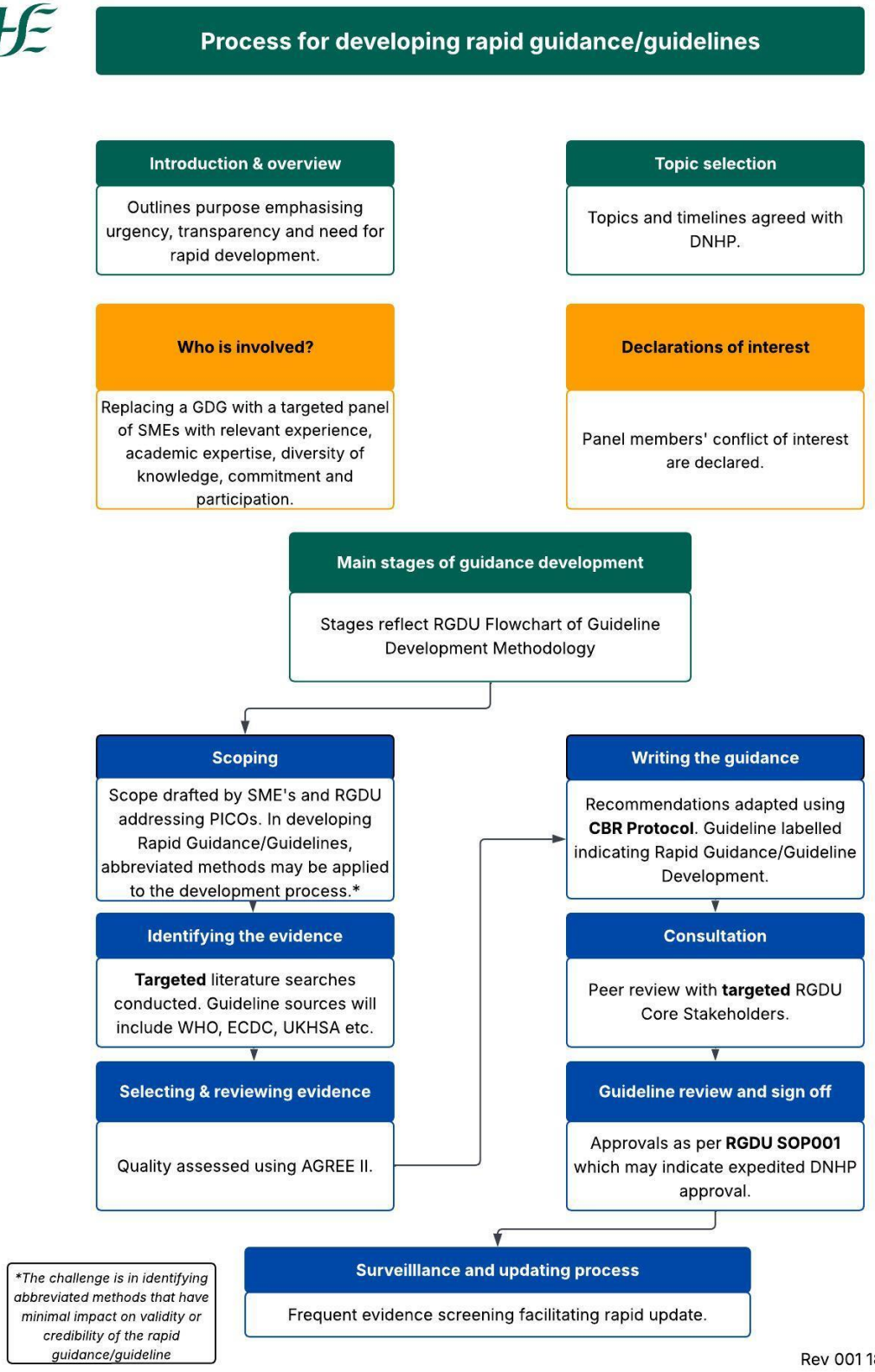
8.0 References

1. Morgan RL, Florez I, Falavigna M, Kowalski S, Akl EA, Thayer KA, et al. Development of rapid guidelines: 3. GIN-McMaster Guideline Development Checklist extension for rapid recommendations. Health Res Policy Syst. 2018;16(1).

2. Klugar M, Lotfi T, Darzi AJ, Reinap M, Klugarová J, Kantorová L, et al. GRADE guidance 39: using GRADE-ADOLOPMENT to adopt, adapt or create contextualized recommendations from source guidelines and evidence syntheses. J Clin Epidemiol. 2024;174:111494.

3. Brouwers MC, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, et al. AGREE II: advancing guideline development, reporting and evaluation in health care. CMAJ. 2010;182(18):E839-42.

Appendix 1


Process for developing rapid guidance/guidelines
Introduction & overview
Outlines purpose emphasising urgency, transparency and need for rapid development.
Topic selection
Topics and timelines agreed with DNHP.
Who is involved?
Replacing a GDG with a targeted panel of SMEs with relevant experience, academic expertise, diversity of knowledge, commitment and participation.
Declarations of interest
Panel members' conflict of interest are declared.
Main stages of guidance development
Stages reflect RGDU Flowchart of Guideline Development Methodology
Scoping
Scope drafted by SME's and RGDU addressing PICOs. In developing Rapid Guidance/Guidelines, abbreviated methods may be applied to the development process.*
Identifying the evidence
Targeted literature searches conducted. Guideline sources will include WHO, ECDC, UKHSA etc.
Selecting & reviewing evidence
Quality assessed using AGREE II.
Writing the guidance
Recommendations adapted using CBR Protocol. Guideline labelled indicating Rapid Guidance/Guideline Development.
Consultation
Peer review with targeted RGDU Core Stakeholders.
Guideline review and sign off
Approvals as per RGDU SOP001 which may indicate expedited DNHP approval.
Surveilllance and updating process
Frequent evidence screening facilitating rapid update.
*The challenge is in identifying abbreviated methods that have minimal impact on validity or credibility of the rapid guidance/guideline
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