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Consensus Based Recommendations (CBR) Protocol

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Please note that this document should be used in tandem with the HSE Public Health: Health Protection - *Framework for health protection guidance development in Ireland, October 2025.*

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List of Abbreviations

CBR	**Consensus-Based Recommendations**
CP	**Consensus Panel**
ECDC	**European Centre for Disease Prevention and Control**
GDG	**Guideline Development Group**
GPG	**Good Practice Guidance**
NGT	**Nominal Group Technique**
NHPO	**National Health Protection Office**
RGDU	**Research and Guideline Development Unit**
SME	**Subject Matter Expert**
SME-TGs	**Subject Matter Expert Topic Groups**
ToR	**Terms of Reference**
UKHSA	**United Kingdom Health Security Agency**
WHO	**World Health Organization**

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Summary

Evidence is required for producing public health guidance. Evidence resulting from systematic literature reviews is generally preferred to assist in the decision-making process. However, for certain topics, literature reviews may return insufficient or provide low-quality evidence.

This protocol provides a structured approach for developing public health recommendations in Ireland when high-quality or sufficient evidence is lacking or conflicting. It is used by the National Health Protection Office's Research and Guideline Development Unit and supports both evidence-informed guidelines and good practice guidance.

The protocol emphasises the importance of integrating research evidence, clinical expertise, patient input, and local context, and describes both informal and formal consensus methods. Formal methods, such as the Delphi method and Nominal Group Technique, are preferred for their transparency and ability to minimise bias. The process involves multidisciplinary groups, clear documentation, conflict of interest management, and iterative rounds of feedback to reach consensus. The protocol aims to ensure that public health guidance is credible, transparent, and based on the best available evidence and expert opinion, even when scientific data is limited or ambiguous.

If HSE Public Health: Health Protection guidance does make use of a consensus approach to developing recommendations, it is expected that this protocol will be used.

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1.0 Background

Developing evidence-informed guidance is a core function of the National Health Protection Office (NHPO) within Ireland's Health Service Executive. The purpose is to enhance health outcomes for patients, diminish variation in practice, and support and improve the quality of clinical decision-making. This is delivered through the work of the NHPO's Research and Guideline Development Unit (RGDU) which leads on the development of evidence informed health protection guidance.

Guidance can be produced internally by the RGDU, or externally by recognised public health organisations outside Ireland, for example the UK Health Security Agency (UKHSA), the European Centre for Disease Prevention and Control (ECDC), the World Health Organization (WHO) etc. and approved for use by the RGDU within HSE Public Health: National Health Protection Office.

The HSE Public Health: Health Protection - **Framework for health protection guidance development in Ireland** outlines the categorisation and methods employed by the RGDU, encompassing:

- the development of new guidance
- reviewing and updating existing HSE Public Health: National Health Protection Office guidance
- reviewing guidance produced externally to HSE Public Health: National Health Protection Office, for acceptability of use in Ireland

Within this framework, the RGDU has outlined two categories of health protection guidance for ensuring the quality of decision-making to support health protection practice in Ireland:

- **Consensus-Based Recommendations (CBR)**
- **Good Practice Guidance (GPG)**

A consensus-based recommendations protocol provides an alternative way to facilitate guidance development, especially in circumstances where contemporaneous evidence is ambiguous, limited, unavailable, or still evolving.[1] It focuses specifically on the advancement of consensus-based recommendations in the context of public health guidance development. This approach harnesses the expertise of key subject matter experts (SME) and enables consensus on generating recommendations. Membership OF SME panels is established on the basis of a number of key principles, supported by the World Health Organization, to

ensure the panels provide credible, balanced, and relevant public health guidance.[2] These include relevant subject matter clinical expertise and experience; relevant academic expertise; diversity of knowledge and experience; commitment and participation; and conflict of interest disclosure. Although participation bias is to some extent inevitable in populating SME panels, this is mitigated by recruiting panel members from a broad range of backgrounds, specialties, and experiences to ensure no single group dominates the discussions.[3]

Within a consensus-based recommendations approach, Terms of Reference (ToR) are ratified by the guidance development group (GDG) and these delineate the role of the Chair; responsibilities of group members; and responsibilities of the RGDU. ToR also outline principles for working together that include openness, respect, transparency and confidentiality. The GDG is chaired by a subject matter expert with methodological expertise provided by the RGDU. The GDG is comprised of multidisciplinary membership and constancy among group members is important throughout the lifetime of a guidance development project. This ensures continuity, cohesion and high-quality decision making, particularly with reference to consensus panels (CP).[4] The rationale for the number of panel members on a GDG is to ensure an optimum group size to achieve topic appropriate balance of expertise, and adequate representation on the GDG and Subject Matter Expert-Topic Groups (SME-TGs).

The RGDU provides methodological oversight and project management support throughout the guidance development process. 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.

The SME-TG should comprise evidence review experts, all with training in the analysis of data and evidence-based medicine. They perform systematic searches, appraisal and synthesis of evidence for specific content. An SME-TG lead supervises group members who develop evidence summaries and recommendations and present these to the consensus panel. Roles and functions are outlined in Table 1.

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Table 1: Roles and functions of the guidance development panels

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 Reviewing the evidence and develop recommendations for practice. Stakeholder consultation (both internal and external). Ongoing evaluation and review of the guidance Liaise with the Health Protection Advisory Committee for Infectious Diseases (HPAC-ID) regarding publication and dissemination of the guidance.
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 guidance. Develop and present the recommendations and evidence to the consensus panel.
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 guidance to ensure it is comprehensive, clear, and applicable to public health practice.

1.1 Conflict of interest

In order to adequately moderate potential conflicts of interest, and to uphold standards of integrity, conduct and concern for the public interest, all GDG members are required to complete a conflict-of-interest declaration form as a prerequisite step to effective participation. The Chair and the RGDU screen and review submissions by panel nominees for potential conflicts of interest. A policy for the management of conflicts of interest is established in accordance with HSE Code of Governance 2021.[5]

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2.0 Key principles

- The core principles of evidence-based guideline development apply to both clinical and public health guidelines.
- Evidence is required to inform guidance development.
- 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.[6]
- Public health guidelines often require a more nuanced and contextualised approach to address the complexities of population-level interventions and policies.
- In view of the hierarchy of evidence applied to clinical guidelines, this is frequently more challenging in the context of public health practice.
- Public Health Guidelines require an integration of research evidence, clinical experience, patient experiences and information from local contexts to ensure an inclusive and balanced evidence base.

Table 2: Evidence-based vs Evidence-informed

EVIDENCE-BASED	EVIDENCE-INFORMED
Focuses on decisions that are solely or predominantly based on the best available research evidence	A broader approach that considers research evidence as one of several factors in decision-making.
Research evidence is the primary driver of decision-making.	Includes research evidence but also takes into account local context, values, public opinion, equity, and feasibility.
Often applied in clinical settings, where controlled trials and systematic reviews dominate.	Often applied in public health, where policy decisions must balance scientific findings with societal needs and limitations.
Example: Using clinical guidelines based strictly on randomised controlled trials (RCTs).	Example: Developing a public health policy that integrates scientific research with community input and local resource considerations.

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- A systematic literature review and critical appraisal of the literature is the gold standard in considering evidence for guidance development; however, this process is generally very resource intensive and sometimes results in insufficient (or even contradictory) information.
- Consensus protocols, where experts come to an agreement on recommendations, provide an alternative approach to develop guidance where scientific evidence is either insufficient or conflicting.
- The most common (formal) approaches to consensus development that have been used in healthcare and clinical related areas are the:
    - Delphi method
    - nominal group technique (NGT)
- The above methods are appropriate in the context of HSE Public Health: National Health Protection Office guidance development.
- The protocol outlined here, and the approaches detailed, are flexible, so that they can be modified to meet the needs of a given situation.
- **The approach used should always be clearly stated in the guidance documentation, should a consensus-based protocol become part of the development of guidance.**

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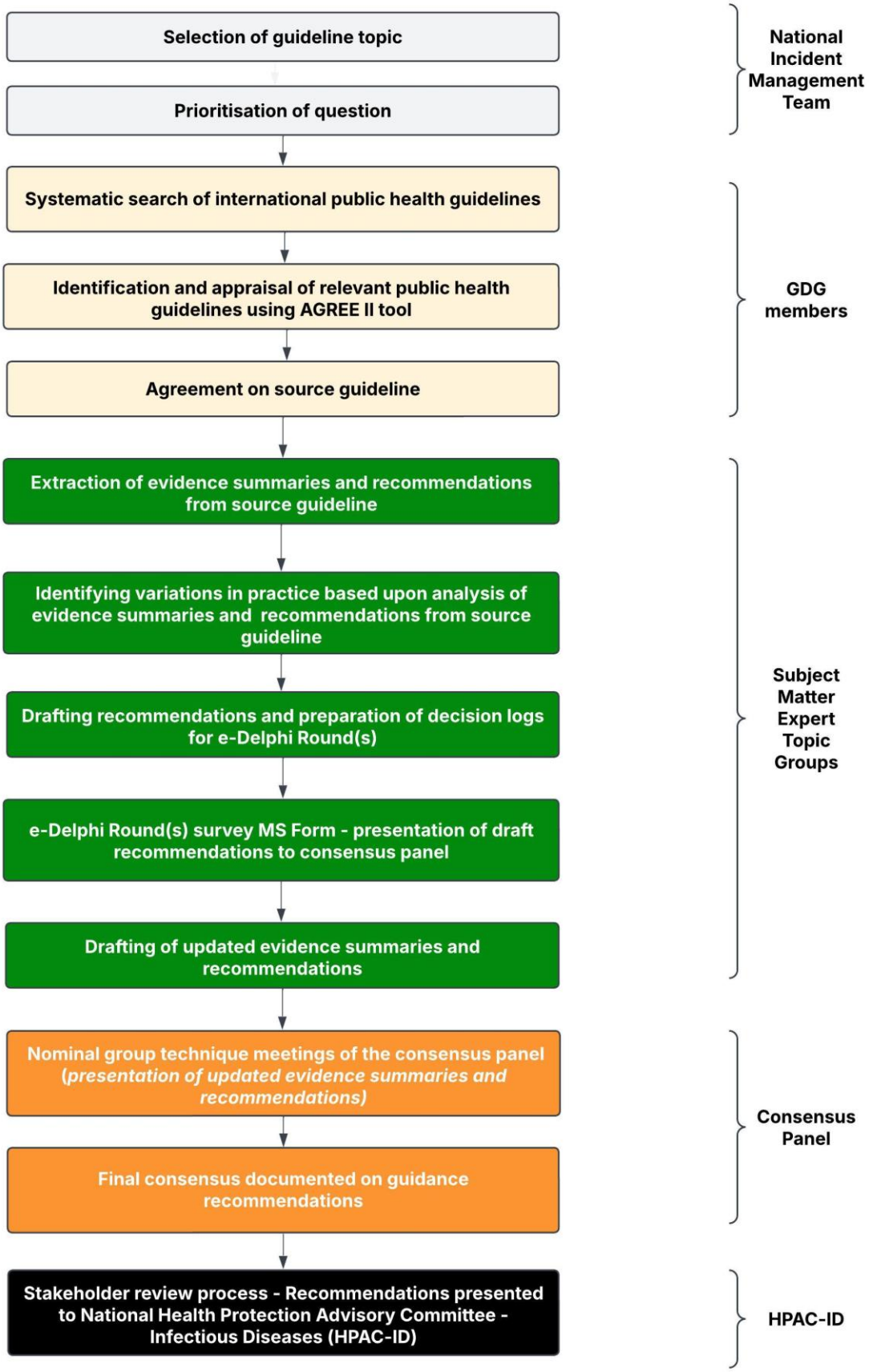
Flowchart of guideline development methodology - CBR Protocol



3.0 Definition of Consensus Decision-Making

It has been previously espoused that there is no requirement to characterise consensus as unanimity among all GDG members.[7] To that end, many organisations have purposely formulated, a priori, definitive rules that aggregate results thus indicating the strength of agreement. The RGDU adopts the meaning of consensus purported by the World Health Organization (2014):[8]

"In guideline development groups, consensus decision-making is a process whereby the consent of all committee members is pursued. When consensus has been reached, it generally means that every committee member finds the proposed resolution acceptable – or at least lends it support, even if less than wholeheartedly".

Siwiec et al (2019) emphasise the role of negotiation as an instrument for agreement via formal consensus.[9] Rather than pursuing concessions from panel members, it is argued that the purpose of consensus is recognising solutions that are acceptable to all involved.

4.0 Consensus-based approaches

The approaches outlined below are only intended to highlight methods and combinations that might be considered while developing public health guidance, particularly in circumstances where scientific evidence is ambiguous, limited, unavailable, or still evolving[1], and where reaching expert consensus is needed.

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 GDG members, the RGDU views formal consensus methods as a suitable approach.[10] Formal consensus methods can address the aforementioned complexities, and support the adaptation and adoption of public health guidelines in Ireland, when situated within a structured and transparent framework.[11]

In tandem with the best available scientific evidence, formal consensus methods incorporate rigorous and explicit processes that fuse the knowledge, experiences and perspectives of stakeholders representing multiple clinical specialties, patient and public forums, and

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additional SMEs. This facilitates the production of recommendations and guidelines that are more credible and considered.

In various studies[10, 12] researchers have used a combination of formal consensus methods that usually includes both the Delphi Method and the Nominal Group Technique. This should enable guidance developers to exploit the perceived benefits of both mechanisms. If applied properly, this combination has been demonstrated to maximise judgement among GDG members resulting in optimum reliability of outcomes.[13]

The underlying premise for utilising these methods is that group decision making among SMEs offers considerable benefits such as consolidating expert knowledge, perspectives and experiences on a wide range of topic areas. If applied methodically, these methods should also enhance participant anonymity, group participation, controlled feedback, and statistical group consensus.[14]

4.1 Informal approach to consensus

An informal approach to consensus can be used as the default choice in the development of GPG (as outlined **HSE Public Health: National Health Protection Office** **Good Practice Guidance Methodology**). However, there are several 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. Consequently, where possible, the RGDU advocates the application of formal consensus methods to enhance the credibility of public health guideline development in Ireland. As such, the steps outlined in **Figure 2** should be adhered to as far as possible.[15]

4.2 Formal approach to consensus

If formal consensus is the chosen approach to formulate recommendations, the GDG should consider which method would be the most appropriate to follow to meet the needs of the topic of the guidance or the situation that is being addressed Two of the most commonly used methods for social and health-related topics are the Delphi method and the nominal group technique (NGT). The selection of method is influenced by the nature of the question, the time available, and any technical constraints or feasibility considerations.[16]

A number of recent academic articles[10] [11, 17] [18, 19] have also been pivotal to informing the RGDU position on consensus methods. The Delphi method and Nominal Group Technique are proposed as the most appropriate methods to use by the RGDU. However, other methods may be used if considered appropriate.

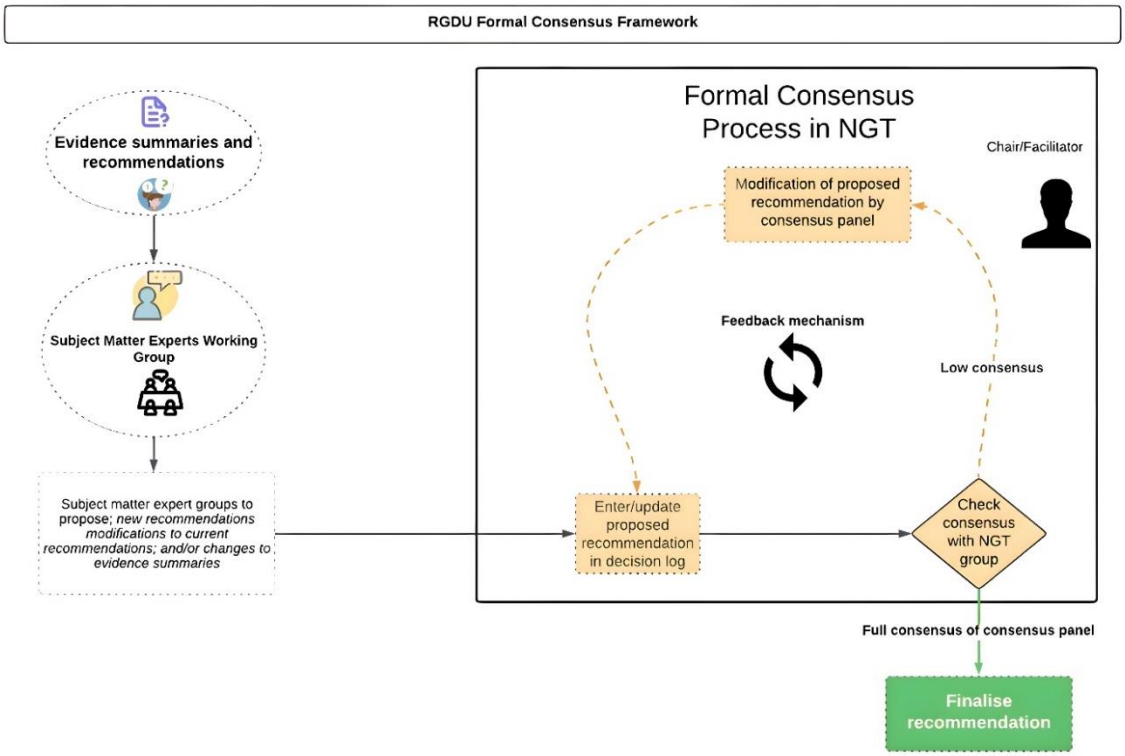

Figure 2: RGDU Formal Consensus Framework

4.2.1 Delphi method

4.2.1.1 Background

The Delphi Method was developed in the post-World War II era by the RAND Corporation as a mechanism for convening experts in order to predict potential attacks during the Cold War.[20] Since then it has been widely applied by health scientists and more pertinently to elicit consensus on guideline recommendations. It can provide guidance developers with a structured method of soliciting opinions from a panel of experts by virtue of a questionnaire designed specifically for this purpose. Expression of opinion is facilitated anonymously, via the questionnaire, enabling guidance developers to collate the information and engage in an iterative process, via multiple rounds of evaluating and refining submissions provided. In support of this approach, Rowe and Wright (1999) suggest that the four main tenets of the Delphi method are focused upon anonymity, iteration, controlled feedback and statistical aggregation of group response.[17, 21] The ultimate aim is to achieve expert consensus and advance the formulation of recommendations.[22] It has been previously suggested[20] that many Delphi studies do not adequately define criteria for achievement of consensus and that even when consensus has been defined, it is not always clear whether the prespecified criteria for consensus have been a factor in deciding when to stop the Delphi process.

Falzarano and Pinto Zipp[23] describe the Delphi method as a valid way of seeking and organising judgements where there is little or no existing, conflicting and/or heterogeneous evidence.

Essentially, the Delphi method offers a structured process where a series of questionnaires or ‘rounds’ are used to gather information from experts (GDG). Each subsequent round is informed by the discussions and conclusions from the previous round. Participants are asked to reconsider their responses considering the previous round’s results. The rounds continue until an appropriate level of consensus is reached. This process is further described in *The Delphi technique - the Delphi technique in nursing and health research*[24].

In the Delphi method, a first questionnaire survey allows the GDG members to privately express their opinion on a particular key question. These opinions are then summarised and organised in a limited set of statements, which are then circulated to allow participants to rank their agreement with the statements in the questionnaire. The results are summarised again and circulated to all participants with a repeat version of the questionnaire for a second round of rankings.

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As this is an iterative process (Figure 3), the recommendations can be refined by re-phrasing questions in subsequent questionnaires, and the process may be repeated several times. This, however, may be time-consuming and lead to a delay in producing the final recommendations for the guidance document. A maximum of three rounds is preferred for producing draft recommendations.

The final rankings are summarised and assessed for degree of consensus and the participants receive feedback. The opinions of participants can be weighted depending on the expertise of a participant.

The coordination of this iterative process (summarising and circulating surveys) should be carried out by the Facilitator/Chair of the GDG in association with the RGDU project manager. Traditionally, the Delphi method is carried out without the participants physically meeting or interacting directly. This can allow a wider pool of experts across a wide geographical area to be involved. The GDG may decide, however, to meet later in the process to debate findings or finalise and sign-off recommendations.

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4.2.1.2 Strengths of the Delphi method[25]

- **Anonymity of Responses**
  Panel members provide feedback anonymously, which reduces the influence of dominant personalities and minimises bias in group decision-making.
- **Iterative Feedback and Refinement**
  The process involves multiple rounds of rating and feedback, allowing participants to reconsider and refine their opinions based on the collective input of the group.
- **Structured Collection of Expert Opinion**
  The Delphi method uses carefully designed questionnaires to systematically gather expert views, ensuring that all relevant aspects of the topic are addressed.
- **Controlled Feedback**
  Participants receive controlled feedback between rounds, which helps clarify points of disagreement and guides the group towards consensus.
- **Statistical Aggregation of Group Response**
  Results are collated and analysed statistically, providing a clear measure of the level of agreement and helping to identify areas needing further discussion.
- **Facilitates Consensus on Complex Issues**

Particularly useful when evidence is limited or ambiguous, the Delphi process enables experts to reach consensus on recommendations that require nuanced judgement.

- **Reduces Risk of Groupthink**
  By separating individual responses and providing structured feedback, the Delphi process helps prevent premature convergence on a single viewpoint.
- **Transparency and Documentation**
  The process is well-documented, with decision logs and feedback recorded at each stage, supporting transparency and reproducibility.

4.2.1.3 Limitations of the Delphi method[25]

- **Ambiguity in Defining Consensus**
  Many Delphi studies do not adequately define what constitutes consensus, and even when criteria are set, it is not always clear if these criteria are used to determine when to stop the process.
- **Potential for Participant Fatigue**
  Multiple rounds of questionnaires and feedback can lead to participant burnout and reduced engagement, especially in later rounds.
- **Limited Opportunity for Discussion**
  The process relies on written feedback and does not allow for real-time discussion or clarification, which can limit the depth of understanding and resolution of disagreements.
- **Risk of Superficial Responses**
  Anonymity and lack of direct interaction may result in less detailed or thoughtful responses from some participants.
- **Challenges in Integrating Diverse Perspectives**
  While the process is designed to gather a wide range of expert opinions, the lack of face-to-face interaction can make it harder to fully integrate and reconcile differing viewpoints.
- **Dependence on Questionnaire Design**
  The quality of the outcomes is highly dependent on the clarity and relevance of the questionnaires used. Poorly designed questions can lead to confusion or misinterpretation.

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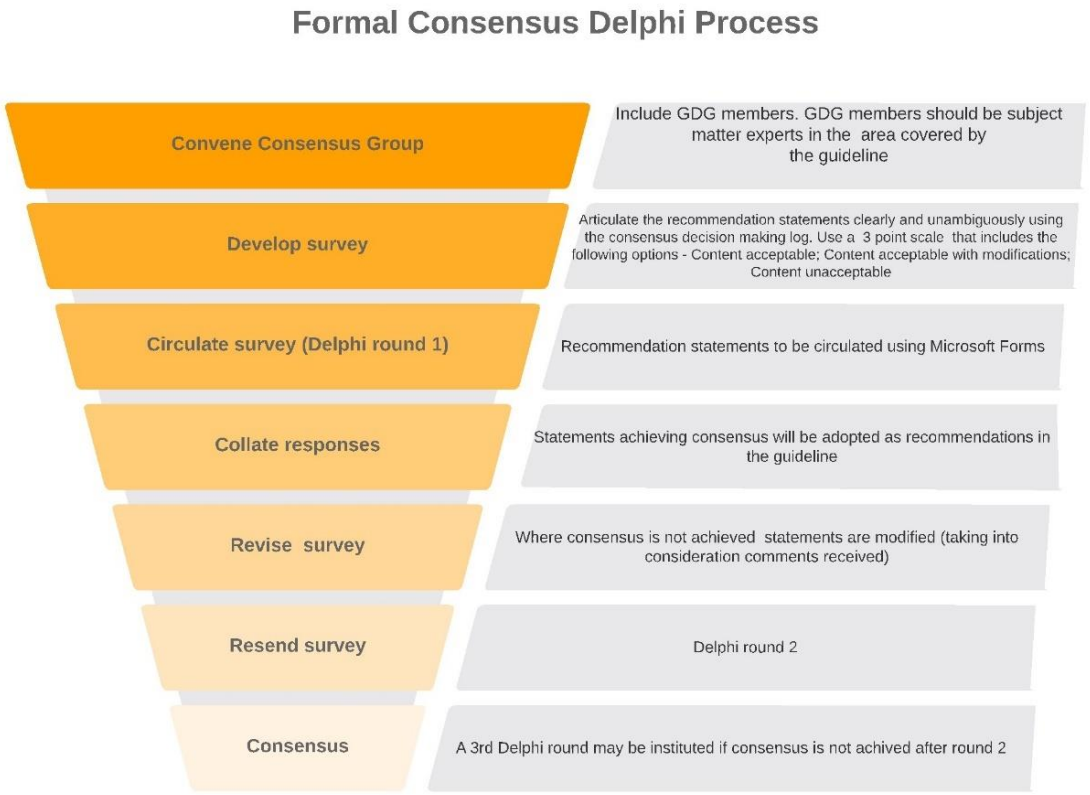

Figure 3. Formal Consensus Delphi Process

4.2.2 NGT

4.2.2.1 Background

The NGT is a facilitated group interaction that empowers group members to have their voices heard and opinions considered by fellow members.[26] Originally designed by Delbecq and Van de Ven[26] it comprises four to five key stages although these are open to adaptation when employed alongside additional consensus methods. When used in conjunction with the Delphi Method, NGT meetings generally follow the initial Delphi round(s) and are guided by an experienced facilitator.

It is crucial that the criteria for the selection of panel experts, the group size, the procedure and the principles for reaching consensus are transparent and the entire process recorded, including how and when consensus was realised.[27] The NGT approach is conducive to extracting relevant and trustworthy qualitative information from a panel of experts. It is suggested that the attributes of the NGT, specifically the focus on collaboration, enhance

ownership of the items under discussion and thus increase the potential for positive outcomes.[20]

Methods of formal consensus in classification/diagnostic criteria and guideline development[7] describes NGT as a method to give priority to questions to be discussed. It consists of face-to-face structured group meetings where groups of panellists are led by a moderator. The session begins with ideas generation. There is then a round robin where ideas are shared, then privately and independently ranked. The highest-ranking ideas are kept, others discarded. There is no definitive guidance as to what ranking would be considered as acceptable; however, this should be predefined. A facilitator is needed to support the process.

NGT could be modified by generating the initial responses via email, using the Delphi technique. It has been suggested that in an NGT, each person is more likely to generate ideas uninhibited by other participants. By avoiding elaboration during the idea's generation phase, this should reduce the risk of focusing on one particular suggestion. Moreover, this method allows everyone to contribute, avoiding dominance of the group by one or two stronger personalities.

Using the nominal group technique[7, 28] effectively describes a five-stage process:

1. **Ideas stage**: Each panellist is asked to generate ideas to specific questions and record privately based on the key questions posed.
2. **Round robin stage**: participants are asked to provide each of their ideas which are listed and visible to the entire group. This should be facilitated by a non-participating individual.
3. **Clarification/discussion stage**: a serial brief discussion is led by the moderator; the goal of the discussion is clarification of the ideas or statements. Duplicate ideas are brought together, and the individual ideas are numbered.
4. **Voting stage**: from the ideas which are numbered, the group needs to rank them based on an agreed voting system. Each idea is privately ranked or rated. The highest-ranking solutions will be kept while the remaining solutions are discarded.
5. **Action stage**: the group discusses the outcome of the voting stage with the intent of reaching agreement and produces recommendations to address the key questions.

   It is important to remember that there can be a number of variations of this process.

4.2.2.2 Strengths of NGT[25]

- **Structured and Transparent Process**
  NGT provides a systematic framework for group decision-making, ensuring that every step is documented and transparent. This increases the credibility and reproducibility of recommendations.
- **Equal Participation**
  The technique is designed to give all panel members an equal opportunity to contribute, discuss, and vote. This helps to mitigate the risk of dominance by any single individual or subgroup, promoting balanced input from a diverse range of experts.
- **Reduction of Bias**
  By facilitating anonymous feedback (in combination with Delphi rounds) and structured group discussion, NGT helps to counteract potential biases that can arise in informal consensus methods.
- **Facilitates Consensus on Complex Issues**
  NGT is particularly effective for resolving areas of disagreement or uncertainty. The iterative process allows for clarification, modification, and re-rating of recommendations until consensus is achieved.
- **Enhanced Stakeholder Confidence**
  The transparency and rigour of the NGT process increase stakeholder trust in the final recommendations, as the rationale for decisions is clearly documented.
- **Adaptability**
  NGT can be adapted and combined with other consensus methods (such as Delphi) to suit the needs of different guidance development contexts.
- **Comprehensive and Contextualised Outcomes**
  The technique enables the integration of diverse perspectives, ensuring that recommendations are both scientifically robust and practically applicable to the local context.
- **Mitigation of Arbitrary Decisions**
  The structured approach ensures that decisions are based on collective expert judgement rather than arbitrary or subjective opinions

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4.2.2.3 Limitations of NGT[25]

- **Challenges Integrating Diverse Perspectives**
  While NGT aims to ensure equal participation, the lack of patient involvement and potential for limited perspectives can affect the breadth of consensus discussions.
- **Dependence on Skilled Facilitation**
  The quality of NGT outcomes relies heavily on the expertise of the facilitator to ensure balanced participation and effective moderation of discussions.
- **Risk of Limited Scope**
  NGT meetings may focus primarily on areas of disagreement, potentially overlooking broader issues or perspectives that could be relevant to guidance development.
- **Technical and Logistical Barriers**
  The process requires clear documentation, structured decision logs, and iterative feedback, which can be resource-intensive and complex to manage.

The Delphi Method and Nominal Group Technique (NGT) are frequently combined in a hybrid formal consensus approach towards guidance development.[13, 25]

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4.2.3 Summary of formal consensus methods

A formal approach to consensus in guidance development, as outlined in the protocol, centres on structured, transparent methods that minimise bias and enhance credibility. The two primary methods recommended are the Delphi Method and the Nominal Group Technique (NGT).

The Delphi Method involves iterative rounds of anonymous questionnaires to gather and refine expert opinions, with controlled feedback and statistical aggregation to reach consensus. This process reduces the influence of dominant personalities and allows for the integration of diverse perspectives, though it can be time-consuming and may lead to participant fatigue.

The NGT is a facilitated, face-to-face group process where participants generate ideas, discuss them, and then privately rank or vote on the most important ones. This method ensures equal participation, reduces bias, and is particularly effective for resolving disagreements or uncertainty. Often, a hybrid approach combining Delphi and NGT is used to maximise the strengths of both.

Throughout, the process is documented, criteria for consensus are predefined, and the involvement of multidisciplinary experts is emphasised to ensure recommendations are both scientifically robust and contextually relevant.

For further information on how the RGDU apply formal consensus methods for the purpose of Health Protection and Public Health Guideline Development, please refer to:

Parlour R, Gilbourne C, Williams M, Quintyne K, O'Moore É. *Applying Formal Consensus Methods To Enhance The Credibility Of Public Health Guideline Development – A Case Study*. **Open Public Health J, 2025; 18:e18749445415283.**
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Appendices

Appendix 1. Consensus Decision-making Log

Disease/ Health Threat	GDG Meeting Date	Chapter/Section	Original question	Question for consensus review (*e.g. amended question)*	Sources/Evidence reviewed (*e.g. evidence to support new amended recommendation*)	Suggested modifications	Consensus achieved