Health emergency interim guidelines: a WHO guideline development framework and toolkit
Acknowledgements

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Declaration of Interests

Mauricio Beller Ferri is a consultant to the Guidelines Review Committee secretariat and submitted the standard WHO Declaration of Interests to Susan L Norris who reviewed the declaration and determined there to be no conflicts of interest.

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Note about using this framework and toolkit

This information product can be used as a complement to the WHO Handbook for Guideline Development (2nd edition)\(^1\) when planning or developing Health Emergency Interim Guidelines or as a source of each of the standalone tools. The individual tools included in this information product can also be obtained directly from the WHO Guidelines Review Committee intranet website.
Table of Contents

Introduction ............................................................................................................................................ 6

Objectives ............................................................................................................................................... 8

Target audience ..................................................................................................................................... 8

What are health emergency interim guidelines? ............................................................................... 9

What set HEIGs apart from Standard guidelines? ............................................................................. 11

Development methods for the HEIG toolkit ..................................................................................... 14

Using lessons learned from previous emergencies .......................................................................... 14

Overview of the HEIG development process ...................................................................................... 17

8.1 Scoping and search for existing guidelines .................................................................................... 17

8.2 Coordination and prioritization form ............................................................................................... 19

8.3 Guideline template .......................................................................................................................... 20

8.3.1 Declaration of interests and management of conflicts ................................................................. 20

8.3.2 Guideline development methods ................................................................................................. 23

8.3.3 Formulating recommendations .................................................................................................... 24

Review checklist .................................................................................................................................... 27

References ............................................................................................................................................. 28

Annex 1. Summary of the evaluation the WHO Zika virus emergency guidelines ......................... 29

Annex 2. Templates for GDG member invitation and DOI ................................................................. 32

Annex 3. HEIG development tools ....................................................................................................... 41

Annex 4. Using GRADE for appraising the quality of the evidence and defining the strength of the recommendation in HEIG development ................................................................. 56
**Abbreviations**

**AGREE II** Appraisal of Guidelines Research and Evaluation Instrument

**COI** Conflicts of Interest

**CRE** The Office of Compliance, Risk Management and Ethics

**CV** *Curriculum Vitae*

**DOI** Declarations of Interest

**EtD** Evidence to Decision

**EVD** Ebola Virus Disease

**GDG** Guideline Development Group

**GRADE** Grading of Recommendations, Assessment, Development, and Evaluation

**GRC** Guidelines Review Committee

**HEIG** Health Emergency Interim Guideline

**MERS-CoV** Middle East Respiratory Syndrome Coronavirus

**PHEIC** Public Health Emergency of International Concern

**PICO** Population, Intervention, Comparator and Outcome

**RAG** Rapid Advice Guideline

**UN** United Nations

**WHE** World Health Organization Health Emergencies programme

**WHO** World Health Organization

**WHO CO** World Health Organization Country Offices

**WHO HQ** World Health Organization Headquarters

**WHO RO** World Health Organization Regional Offices
Introduction

As the United Nations agency for health, World Health Organization (WHO) plays a prominent role in public health emergencies supporting Member States to understand and manage risk, build resilience, and prepare for adequate emergency response and recovery actions. WHO’s mandate to minimize the health consequences of natural and technological disasters, disease outbreaks, conflict and other humanitarian crises demands multisectorial collaborations and a range of technical products and novel approaches. The recently constituted WHO Health Emergencies Programme (WHE) complements WHO’s traditional technical and normative role with a frontline operational arm, strengthening WHO’s role beyond producing high-quality information products through facilitating implementation in the front line and assuring a positive impact on health outcomes of the affected populations.

Guidelines are especially powerful tools to translate scientific evidence into concrete actions, either as public health policy or clinical management guidance. WHO broadly defines guidelines as any information product that contains a recommendation (i.e., action statement) aiming to optimize health outcomes of individuals or populations. Recommendations should be evidence-based and developed with explicit and transparent processes to assess the benefits and harms of the available options. Ideally, recommendations assist end-users to make informed decisions about the appropriateness of interventions in their context.¹

More than a decade ago, following harsh external criticism asserting that WHO guidelines were not evidence-based and did not take into consideration the needs of end-users, the WHO Guidelines Review Committee (GRC) was instituted to oversee the quality of the guideline portfolio. The specific roles of the GRC are to develop and implement guideline development methods and procedures to ensure that each WHO guideline meets the highest international standards of credibility, trustworthiness and relevance to end-users. In the past 10 years, the GRC has developed and implemented rigorous development processes that have resulted in marked improvement in the quality of WHO’s guidelines. However, some of the potential trade-offs of increasing methodologic rigour such as longer development time, increased resource requirements and a need for structured scientific evidence, make the application of these processes to emergency response guidelines potentially challenging. Populations affected by
natural and technological disasters, disease outbreaks, conflicts and other humanitarian crises often require technical guidance to be produced in condensed timelines, developed in an environment of uncertainty, with scarce structured scientific evidence at a time when WHO is most pressed for resources with multiple tasks being executed concurrently, highlighting this fundamental dilemma.

Guideline development methods and procedures specific to knowledge gaps in emergency response in condensed timelines are still in their infancy. Most organizations around the world, including WHO, still approach this problem with the same tools used for standard guidelines with \textit{ad hoc} modifications to fit the constraints of each situation. Until more robust development methods and procedures are available for emergency guidelines, it is important to provide a clear pathway for technical units developing guidelines in the context of an emergency.

The incorporation of rapid advice guidelines (RAG) into the \textit{WHO Handbook for Guideline Development (2nd edition)}\textsuperscript{1} in 2014 supported WHO technical units in developing guidelines within much shorter timelines than the standard WHO guideline process. The West Africa Ebola Virus Disease Outbreak (2014-16) highlighted the importance of this approach. However, technical units still encounter uncommon, but consequential situations when timely, high-quality guidelines must be produced in even shorter periods of time during public health emergencies. This was the main motivation for designing a clear and streamlined development framework containing a pathway and a toolkit to address this need.

This framework builds on the lessons learned with the recent emergency responses to infectious disease outbreaks, however the development pathway and tools apply to all types of emergencies with similar characteristics.
Objectives

The aim of this project was to provide an overarching framework to standardize the development of WHO guidelines in condensed timelines during public health emergencies. The specific objectives were to clarify the development pathway (i.e. methods and procedures) and to provide a pragmatic toolkit to enable transparent and efficient processes while minimizing bias, resulting in trustworthy and timely health emergency interim guidelines.

Target audience

The target audience for this information product is WHO technical units at headquarters, regional and country offices responsible for developing guidelines in the context of public health emergencies.
What are health emergency interim guidelines?

Health emergency interim guidelines (HEIGs) are information products focused on knowledge gaps identified during an emergency response for which no relevant up-to-date guidelines exist and the guidance is needed within a few days to several weeks (Box 1). Typically, WHO departments and programmes internally identify knowledge gaps that should be prioritized and addressed urgently, alternatively, Member States or partner organizations in the field request specific technical guidance during a public health emergency. The short time usually available for guideline development in this situation imposes difficult decisions about abbreviating, truncating, omitting or accelerating steps in the standard guideline development process, what could potentially jeopardize trustworthiness and accuracy of the resulting information product. In addition, the timeline provides challenges for WHO’s quality assurance measures that have been place since the institution of the GRC.

<table>
<thead>
<tr>
<th>Box 1. Health emergency interim guidelines (HEIGs): Key considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The processes and tools in this document are only applicable during public health emergencies.</td>
</tr>
<tr>
<td>2. HEIGs apply for development time ranging from a few days to 3-4 weeks.</td>
</tr>
<tr>
<td>3. HEIGs must be aligned with WHE emergency response priorities and needs.</td>
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<tr>
<td>4. HEIGs have the expectation of prompt implementation during the emergency response.</td>
</tr>
<tr>
<td>5. HEIGs have an expected short shelf life.</td>
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</tbody>
</table>

The high levels of uncertainty regarding the evidence, the context and the scarcity of structured scientific evidence add to the uniqueness of these guidelines. WHO technical units developing these information products usually rely on indirect scientific data (e.g., data from similar conditions), experiential epidemic information from early responders, and mechanistic and pathophysiologic reasoning to develop an initial set of recommendations as early as possible after the need is identified.

In practical terms, most acute health needs requiring technical guidance in emergency response can be anticipated and guidelines therefore planned and developed prior to an event as part of risk governance, resilience and preparedness priorities. In this ideal scenario, technical units use
established and trustworthy processes and methods such as for standard or rapid advice guidelines to produce high-quality documents (Figure 1). Occasionally during emergency response operations or recovery actions, field teams encounter situations that have not been anticipated and WHO needs to produce new technical guidance documents to deal with vital aspects of the health and well-being of affected populations at global, regional or local levels. Thus, despite the expected limited applicability of the HEIG toolkit, it is crucial in emergency responses that WHO has the capacity to develop trustworthy and impactful guidelines in short periods of time with explicit, transparent and credible processes.

Another important characteristic of HEIGs is the expectation of a short shelf-life. Technical units must anticipate early and frequent reviews with appropriate updating of the recommendations in the face of new evidence or changes in the conditions in the field. Experience during the Zika virus outbreak (2015-16) showed that it is common for HEIGs to have multiple updates during an emergency response, highlighting the importance of careful consideration of the challenges and resources necessary for producing updates throughout the response efforts and the need to manage the HEIG life-cycle tightly (Figure 2).

The term “guidelines” has been traditionally used in the field of emergency and crisis management encompassing a variety of information products such as field manuals, technical notes, clinical guidelines, policy advice and other types of documents broadly addressing technical guidance. Although many of these information products would also be categorized as WHO guidelines given their content, this framework and toolkit focus on WHO clinical and public health recommendations to be produced during the emergencies and are not intended to inform the development processes of other types of documents or other agencies. Any questions about the applicability of this toolkit to a specific project should be resolved early in the coordination phase of the development process involving the responsible technical units, the GRC secretariat and the WHE technical focal point.

Last, the processes and methods described in this document should not be applied to guidelines outside the context of public health emergencies and are no substitute for or a workaround to the standard WHO guideline development methods which apply in most situations (Figure 1).
**What set HEIGs apart from Standard guidelines?**

The unique production context for HEIGs imposes very specific challenges that set these guidelines apart from other types of WHO guidelines:

a. The urgent demand for guidance leads to abbreviated and accelerated methods to produce guidelines in condensed timelines. This approach may pose a significant threat to the quality and trustworthiness of guidelines and is particularly challenging in non-communicable diseases with a large evidence-base for peace-time situations, but no evidence or guidelines produced specifically for emergency situations.

b. The paucity of structured scientific data hinders evidence identification and assessment, especially early in the event timeline, leading to recommendations based on indirect data, epidemic experiential information and expert opinion. This scenario is common when emerging diseases are the focus of a public health emergency or when it is reasonable to assume that conditions present during the emergency situation are effect modifiers for an intervention and fundamentally change the balance between benefits and harms of its application.

c. Member States or regions facing complex emergencies have dynamic political and social contexts that can include fragile, illegitimate, absent or technically weak governments or Ministries of Health. This scenario applies to many conflicts and to most protracted emergencies with important implications for guideline development, adaptation and most importantly, implementation.

d. HEIGs are resource-intensive and are usually needed when WHO and the responsible technical teams have multiple concurrent tasks.
**Figure 1.** Matrix of WHO guideline types in the public health emergency continuum. A multi-hazard approach based on the priorities for action outlined in the Sendai Framework for Risk Reduction.

<table>
<thead>
<tr>
<th>Priorities for Action Sendai Framework</th>
<th>Examples of natural and technological disasters</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Understanding risk</strong></td>
<td>Epidemics</td>
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<tr>
<td>Vulnerability X Capacity</td>
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<tr>
<td>Exposure persons and assets</td>
<td></td>
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<tr>
<td>Hazards characteristics</td>
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<tr>
<td>Environment</td>
<td></td>
</tr>
<tr>
<td><strong>Risk governance</strong></td>
<td></td>
</tr>
<tr>
<td>Coherence local, national, global levels</td>
<td></td>
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<tr>
<td>Laws, regulations</td>
<td></td>
</tr>
<tr>
<td>Public policies</td>
<td></td>
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<tr>
<td>Partnerships</td>
<td></td>
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<tr>
<td><strong>Investing in resilience</strong></td>
<td></td>
</tr>
<tr>
<td>Structural and non-structural measures</td>
<td></td>
</tr>
<tr>
<td>Economic, social, health, cultural</td>
<td></td>
</tr>
<tr>
<td>Effective recovery and rehabilitation</td>
<td></td>
</tr>
<tr>
<td><strong>Preparedness for effective response</strong></td>
<td></td>
</tr>
<tr>
<td>Enhancing preparedness for all response phases</td>
<td></td>
</tr>
<tr>
<td><strong>Building back better</strong></td>
<td></td>
</tr>
<tr>
<td>Recovery, rehabilitation, reconstruction prepared ahead of disasters</td>
<td></td>
</tr>
</tbody>
</table>

**Legend.** The domains outlined in the rows pertain to the Sendai Framework for Disaster Risk Reduction priorities for action and the columns represent disaster typology. The intersections of Sendai priorities and disasters are populated with the types of WHO guidelines that are potentially useful to accomplish the actions in each priority. WHO, World Health Organization.
Figure 2. Development timeline for the WHO guideline on Infant Feeding in Areas of Zika Virus Transmission.⁵

Legend. Example of iterative guideline development process with a short timeline from the declaration of the Public Health Emergency of International Concern (PHEIC) to the first virtual Guideline Development Group (GDG) meeting and publication of the HEIG using an early version of the Health of the tools. While working on the HEIG, the technical team developed a review question and commissioned a systematic review in preparation for a second GDG meeting to develop a Rapid Advice Guideline (RAG). While waiting for approval from the Guidelines Review Committee (GRC), the technical team published the same content using the expedited process and templates as a HEIG update. This process illustrates successive improvement of the guideline starting with the timely HEIG and building up to a more robust product in the following weeks.
Development methods for the HEIG toolkit

The development of the methods and tools presented in this toolkit followed a set of conceptual pillars (Box 2) and was based on the WHO guideline development principles (Table 1).²

Box 2. Conceptual pillars for the development process of the HEIG toolkit

- The same standards for quality and trustworthiness for all WHO guidelines apply to HEIGs, although this may be difficult to operationalize. Transparency and explicit decision-making are key to enable end-users to make judgments about the quality of HEIGs and their applicability to the local context.
- HEIG tools must be simple and provide simultaneous guidance on methods, processes, documentation and reporting.
- Efficiency is paramount. All text required for tools will be used in the final document reaching the end-user.

Using lessons learned from previous emergencies

The tools in this document drew heavily on the lessons learned in recent WHO public health emergency responses. The GRC Secretariat undertook a comprehensive mixed-methods evaluation of guideline development for the following epidemics: Avian influenza A - H1N1 virus in 2009, Avian influenza A - H7N9 virus in 2013, Middle East Respiratory Syndrome Coronavirus (MERS-CoV) in 2013, and Ebola Virus Disease (EVD) in 2014 and 2015.³ This evaluation highlighted important points that were taken into consideration during the design phase of this toolkit: the negative impact of poor coordination amongst WHO teams on the efficiency of guideline development; lack of a standardized approach for emergency guideline development; and insufficient resources (both human and financial).

The first version of emergency guideline development tools was initially designed to assist WHO technical units at the beginning of the Zika virus outbreak in early 2016. The GRC Secretariat worked closely with the Pandemic and Epidemic Diseases unit and teams producing guidelines to understand how the tools were applied in real life and ensure that the tools were adding value to
the documents and were not hindering or delaying guideline development. The guidelines produced during the Zika response also demonstrated how to apply a streamlined and iterative process to address the challenges of developing HEIGs. A number of HEIGs produced during the Zika outbreak started with an expert opinion-based guideline produced within a few weeks and progressively improved in subsequent versions building on the work previously accomplished.\textsuperscript{4,5}

For example, one technical unit assembled a Guideline Development Group (GDG) and developed an expert opinion-based recommendation via a teleconference. This unit then refined the original review question and commissioned a systematic review to inform a rapid advice guideline process that was started shortly after the first iteration was published (Figure 2). Of course, the iterative nature of this process required continuing efforts and human and material resources to maintain up-to-date and accessible guidelines and accompanying documents (i.e. translations, implementation tools). In summary, the clear challenges introduced by the short shelf-life and the need for an iterative process with recurrent updates also brought the opportunity to incrementally improve the quality and trustworthiness of guidelines with each iteration, building on the previous achievements and taking advantage of the additional time and information available. In addition, this work was informed by an evaluation of Zika guidelines published in 2016 by WHO, conducted by the GRC Secretariat to gain insight into the potential effects of use of the tools on traditional indicators of guideline quality and trustworthiness (see summary of Zika Guidelines Assessment in Annex 1).

After the lessons learned with the evaluations and Zika field test were incorporated, the GRC Secretariat obtained structured feedback from a diverse group of stakeholders at WHO including GRC members, guideline methodologists, and staff in WHE and other technical units with experience in emergency guideline development.

Multiple HEIG development steps could potentially optimized, this multifaceted primary data generation approach led to the decision to choose the following for operationalize the conceptual pillars: (1) ensure an early definition of the scope, settings and target audience while enabling coordination and agreement among all stakeholders; (2) clarify the processes for declarations of Interests (DOI); (3) provide a structured, evidence-informed decision-making process using an adapted evidence-to-decision table (EtD) to for a multi-criteria discussion by the GDG; (4)
standardize the reporting of the final guideline and (5) facilitate a transparent external review process prior to publication.

**Legend.** WHO guideline development principles. Modified from *Clinical Practice Guidelines We Can Trust* from the United States Institute of Medicine (2011).²

**Table 1. Criteria for developing trustworthy guidelines.**

1. Guideline development processes must be explicit and transparent.
2. Guideline must have a well-described scope, objectives and target audience.
3. Guideline development processes and funding sources need to be detailed and accessible.
4. Contributors must disclose relevant interests and conflicts must be appropriately managed.
5. The guideline development group should be multidisciplinary and balanced, including relevant stakeholders and persons from the affected areas.
6. Recommendations should be informed by systematic evidence reviews.
7. Each recommendation should be accompanied by a rationale, an assessment of the certainty of the evidence, the strength of the recommendation, and any differences in opinion among the guideline development group.
8. Recommendations should be clearly articulated and precise.
9. External review should encompass all relevant stakeholders.
10. Plans for updating should be included and emerging data should be monitored.
11. Guidelines must adhere to WHO reporting standards
Overview of the HEIG development process

The HEIG development process resembles the one for standard and rapid advice guidelines (Figure 3) with some modifications to streamline, provide flexibility and optimize efficiency by focusing on the final product from the very start (e.g. all text produced will be part of the final guideline).

8.1 Scoping and search for existing guidelines

The initial steps for responsible technical unit is to clarify the knowledge gap and need and contact the WHE Incident Management Team or WHE technical focal point to plan the course of action. The next step is to search for existing guidelines on the WHO Institutional Repository for Information Sharing (IRIS) (http://apps.who.int/iris/) and the WHO database of emergency guidelines (Humanitarian health action: Technical guidance and guidance notes: http://www.who.int/hac/techguidance/guidelines/en/). Guidelines that are identified and potentially relevant must first be evaluated for applicability and quality including content validity, currency, and feasibility of immediate implementation of the recommended interventions (Box 3). If no suitable guidelines exist, the technical unit makes the preliminary decision to produce a new information product.

Box 3. Scoping and search for existing guidelines – Tips from the GRC Secretariat

1. Keep WHE technical focal point and the GRC Secretariat in the loop early on.
2. The AGREE II tool is useful for assessing the quality of existing guidelines and may be applied before making the final decision to use an existing guideline. Assess also for applicability, currency, feasibility of immediate implementation and other EtD criteria.
3. Contact all relevant WHO technical units to scan the knowledge environment.
**Figure 3.** Health Emergency Interim Guideline (HEIG) development and updating process

*Legend.* Blue boxes represent development steps. Green boxes represent decisions and tools. Red rims indicate steps with direct GRC secretariat involvement. WHE, WHO Health Emergencies program; COI, conflicts of interest; CRE, Office of Compliance, Risk Management and Ethics at WHO; GRC, Guidelines Review Committee; DOI, Declaration of Interests; GDG, Guideline Development Group.
8.2 Coordination and prioritization form

The responsible technical unit should assess existing WHO guidelines to determine if a new product is necessary and whether it should to be a HEIG. Completing the Coordination Form requires a succinct description of the problem including the epidemiology and pathophysiology, geopolitical aspects and background information to describe the scale and perceived priority of the issue within the emergency scenario. In addition, to structure and document this decision-making process, the technical unit must define the scope, the settings and target audience early in the development process, improving efficiency and avoiding a scope that is too ambitious to be finalized in the available timeline with the available resources. Another important information required is the rationale for developing a HEIG. this is key for priority setting and coordination among multiple WHO teams (Box 4).

Box 4. Coordination and prioritization form – Tips from the GRC Secretariat

1. Describe the settings, perspective, affected populations and end-users of the guideline.
2. Define the scope (refine the question) to prioritize the most pressing issues first.
3. Refine the questions using the PICO format (population, intervention, comparator, outcomes). This helps focusing the scope and is a good feasibility gauge. A broad scope facilitates the search for existing guidelines and systematic reviews, but increases the development time.
4. Define the target audience.
5. In the rationale section, articulate why it is necessary to develop a HEIG given the methods challenges. Indicate that there is immediate readiness for implementation and synergy with other aspects of the emergency response.
6. Engage with pertinent WHO technical units early on.
8.3 Guideline template

The guideline template has two main functions: (1) to standardized the reporting structure of the final guideline and (2) to provide a quality assurance framework as it outlines the required development steps and sections of the final guideline. Technical units can tailor the template and add items that are important for their target audience and cover other technical aspects not anticipated in this toolkit. This template does not impose any specific approach (i.e. textbook or recommendations) and flexibility is embedded and encouraged for implementation success and relevance of the final product to the end-users and affected populations.

8.3.1 Declaration of interests and management of conflicts

One of the hallmarks of a trustworthy guideline contained in the guideline template is the section for disclosure of secondary interests and management of any conflicts of interest (COI) that may be identified (Box 5). The WHO Office of Compliance, Risk Management and Ethics (CRE) issued a revised Guideline for Declaration of Interests (WHO Experts) and an updated process for Declaration of Interests (DOI) for WHO Experts in 2014. CRE mandates full application of DOI guidelines in emergency guideline development settings with some adaptations given the compressed timelines as described in Figure 4 and Box 5. This requirement poses significant challenges, nonetheless this policy is essential to ensure WHO HEIGs are unbiased, trustworthy and credible. Technical units must engage departmental senior leadership to assess DOI and consult with CRE when necessary to make decisions about inclusion or exclusion of prospective GDG members.

Considering the typical constraints that define HEIGs, some DOI steps such as online publication of prospective GDG members biographies (Figure 4, step 4) may not be feasible without adaptation. In this example, it is acceptable to invite the prospective GDG members based on the assessment of their DOI and their Curriculum Vitae. However, CRE requires that the biographies be available online for at least 14 days for public comment, even if this period extends after the first GDG meeting. If concerns about COI arise in response to the posting of biographies, these must be assessed on a case-by-case basis by the director of the technical unit developing the guideline, in
consultation with CRE as needed. For full implementation details, refer to the CRE (https://intranet.who.int/homes/cre/about/) and GRC (http://intranet.who.int/homes/ker/grc/) websites. Annex 2 of this document includes templates of the invitation letters, an example of prospective GDG members’ biographies for online publication, a note for the record and links to DOI, Confidentiality Undertaking and the Code of Conduct for WHO experts.

**Figure 4.** Declarations of interests and management of conflicts of interest for Health Emergency Interim Guidelines.

![Diagram of process flow](image)

*COI*: When COI is identified (step 7b - red circle in the process flow), the technical unit is responsible for managing COI in accordance to CRE guideline and WHO Handbook for Guideline Development (2nd edition). Total or partial exclusion of potential contributors are the possible actions. As soon as the decision is made notify prospective GDG member and make a Note for the Record. Redo steps 2 to 6 until GDG composition is adequate.

**Legend.** Process flow for obtaining the declarations of interest and other information relevant to assess and manage conflicts of interest of GDG members participating in HEIG development. DOI, declarations of interest; COI, conflicts of interest; GRC, Guidelines Review Committee; CV, Curriculum vitae; WHO, World Health Organization, CRE, WHO Office of Compliance, Risk Management and Ethics; GDG, guideline development group; MoA, Memorandum of Agreement; HEIG, health emergency interim guidelines.
Box 5. Declaration of interests and management of conflicts

Every effort should be made to adhere to all the components of CRE DOI guidelines.

1. Identify prospective GDG members.
2. Collect Declarations of Interest following standard CRE guidelines.
3. Collect a Curriculum vitae and 250-300-word biography from prospective GDG members.
4. Perform a focused internet search using the approach suggested by the GRC Secretariat as soon as the DOI and Curriculum vitae are received (Annex 2).
5. Publish online the names and biographies of prospective members for public consultation for at least 14 days even if this period extends beyond the first GDG meeting.
6. Assess the Declarations of Interests and determine if any conflicts of interest are present.
7. Manage conflicts of interest as per CRE guidelines. If concerns regarding COI are raised during the public consultation, the RTO, the technical unit director and the guideline steering group, in consultation with the Office of CRE, will evaluate and formulate a management plan, focusing on risk of bias and potential for lowered credibility.
8. Send a standard invitation letter, the WHO Memorandum of Agreement for Temporary Advisers, the Confidentiality Undertaking and the Code of Conduct for WHO Experts to prospective guideline development members without significant COI who approved to participate (Templates on Annex 2). Collect signed copies of these documents.
9. Plan for pre-meeting (all meetings including teleconferences) disclosures and updates by all external contributors.
10. Prepare a summary statement in the guideline about disclosure, conflicts and management decisions.
11. Prepare an online, publicly available annex encompassing a summary of all the declarations of interests and the assessment and management of any conflicts of interest.
12. Produce a Note for the Record for each GDG meeting at which recommendations are formulated (including virtual meetings), documenting any declared interests and the assessment and management of any conflicts of interest. Submit to CRE.
The use of scientific evidence to inform recommendations is an established hallmark of quality and trustworthiness. Even in an expert opinion-based guideline it is important to perform and report on the evidence search and retrieval strategy. It is paramount to list the databases searched and the restrictions of language, date of publication and geography. Note that restrictions are invariably required in HEIGs with compressed timelines, however, these difficult decisions must be strategic, transparent and carefully considered in face of the potential downside of leaving information out. For example, it is important to report if the process was iterative starting with a review of reviews, then systematic reviews, then selected individual studies. For each step, describe the findings and the decision-making process. Indicate if the included evidence was guided primarily by the GDG members.

In HEIGs, it is crucial to take advantage of the knowledge and evidence base brought in by the external experts to navigate a landscape of scarce structured scientific data or difficult to find mechanistic or basic research. Reference lists provided by experts should be used and noted. Another potential source of information comes from reports of front-line workers; experiential knowledge in the actual situation is invaluable and the technical unit must make all efforts to include it (e.g. the use of standardized case report forms and preliminary non-published scientific reports). The same is true for epidemiologic reports, risk assessment reports and other WHE information products that could inform the decision-making. Including this information in the final guideline will contribute to transparency and trustworthiness, especially when the first HEIG is
followed by a more rigorous guideline (i.e., standard or rapid advice) that builds on the original HEIG and includes a systematic review.

8.3.3 Formulating recommendations

Evidence-to-decision (EtD) tables are used to provide structure and guide the group discussions ensuring that the GDG decision-making process takes into consideration all relevant criteria in a thorough and focused debate, and has access to a summary of the best available evidence (Box 7). They are established components of the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach to develop evidence-based recommendations.8,9

It is important for GDG members to seek information, assess and make judgments about the characteristics of the crisis and its current and near-future impact on the needs and conditions for implementation. Natural disasters, poverty, regional political and social instability, conflict and violence, and other factors and events external to the will of the countries may further weaken institutions or worsen already fragmented and disorganized states (so-called distressed states) and are potential determinants of state fragility. In this context of unpredictability with a rapidly changing landscape, a realistic understanding of the context is critical to the success of implementation of any recommendation, be it a public health policy or clinical.10 EtDs in HEIGs also facilitate important discussions about flexibility, diverse options, the concrete possibility of failure or error and other pragmatic decisions that are relevant in any guideline, but fundamental in this context.

Following the processes provided in this toolkit should allow for most technical units developing HEIGs to formulate recommendations and provide an assessment of the quality (certainty) of the evidence and the strength of each recommendation following the typical GRADE approach described in the WHO Handbook for Guideline Development (2nd Edition)1. A summary of the considerations to apply GRADE as body of the evidence appraisal approach in the context of HEIG development is provided on Annex 4. For some HEIGs, such formal assessments may not be possible, but responsible technical units should strive to apply a transparent and explicit approach to appraise the body of the evidence.
Recommendations included in a HEIG should be readily implementable. It is part of the formulation process to consider all relevant aspects to facilitate local adaptation or adoption with minimal time and resources. It is important for HEIG developers to think about and provide implementation tools and other resources to support end-users in affected areas where the conditions will certainly be more challenging.

**Box 7. Typical evidence-to-decision criteria (Full list on Annex 3)**

- What is the balance between benefits and harms
- What are the resources requirements?
- What is the impact on equity?
- Is the intervention/option acceptable to all stakeholders?
- Is the intervention/option feasible to immediate implementation?
- Additional considerations for diagnostic tests.

**Box 8. Formulating recommendations**

1. GDGs should strive for unanimous consensus. It conveys strength that a diverse group could agree on a recommendation.
2. When consensus is not possible, describe the controversies for the end-users to understand the rationale for the recommendation.
3. Each recommendation should be accompanied by an assessment of the quality (certainty) of the evidence and the strength of each recommendation according to the GRADE approach. For some HEIGs, such formal assessments may not be possible,
4. Whenever possible include implementation tools such as algorithms, wall-charts, decision trees, visual tools and any resources aimed directly at frontline end-users.
Box 9. Formulating recommendations – Tips from the GRC Secretariat

1. Design and tailor EtD that fit the guideline project. The template provided in this document is modular and does not cover all potential criteria.

2. Fill in the EtD with evidence and other information sources ahead of the GDG meeting as much as possible without belaboring it.

Ensuring flexibility in HEIG recommendations

3. Document and report GDG perceptions about important variation in the evidence (e.g. effectiveness, acceptability or implementability) across different countries or settings for which the guideline is intended. Important variation is defined as a difference that is large enough that it might lead to different decisions or recommendations in different settings.

4. Document and report plausible consequences for which no evidence was found (e.g. logical reasons for anticipating a potential reduction in inequities) or plausible reasons for anticipating that the intervention might not be acceptable to key stakeholders or might be difficult to implement. Reporting the rationale for each recommendation will help end-users in the field decide if the recommendation applies to their situation.

5. Explicitly outline and report assumptions and judgments and the basis for decisions when there is uncertainty and the evidence base is scarce or indirect.

6. Consider the multiple implementing actors in the field (government and non-governmental agencies) with different resources, capabilities and agendas.
**Review checklist**

The main purpose of this simple tool is to guide the technical units on the required guideline components and reporting items, and facilitate the external review process by the GRC Secretariat and peer reviewers. For each section of the guideline, there is a separate field for the GRC or peer reviewer to comment and suggest improvements.

Currently, the GRC does not have a formal set of standards and procedures for HEIGs and GRC approval is not required for publication. Nevertheless, the GRC secretariat and the GRC chair have committed to a 24-hour turn-around time for reviewing all HEIGs. The goal of this step is to add value by improving the clarity of the message, transparency of the development methods and processes, and to optimize the presentation of recommendations.

---

**Box 10. Review checklist – Tips from the GRC Secretariat**

1. Thorough reporting is required for end-users to assess the methods and procedures that were used. Poor reporting reduces guideline trustworthiness and may impede the implementation of the recommendations.

2. Set up a system to track and periodically assess the need to update each HEIG, including those still valid at the end of an emergency response.

3. If no new information is available, there is no need to update but each recommendation needs to be revalidated at regular intervals.

4. In protracted emergencies, plan to develop standard guidelines to replace the HEIG as soon as possible.
References

Annex 1. Summary of the evaluation the WHO Zika virus emergency guidelines

Purpose
The purpose of this evaluation was to describe and assess WHO Zika virus outbreak guidelines to inform the development of WHO guidelines for future public health emergencies.

Background
In May 2015, Brazil confirmed that the Zika virus was circulating in the country and in the following months reported a potential association between Zika virus infection and Guillain-Barré syndrome and microcephaly. By the end of 2015, other countries had also reported cases of Zika virus infection and its complications. In 1 February 2016 WHO declared that the association of Zika infection with clusters of microcephaly and other neurological disorders constituted a Public Health Emergency of International Concern. Currently, Zika virus infection and its consequences continue to be a significant global public health issue, however, the evolution of the situation led WHO to declare the end of the Public Health Emergency of International Concern in November 2016, directing the focus to an enduring long-term response programme.

Health Emergency Interim Guidelines
Most of the need for technical guidance in public health emergencies can be addressed with standard guidelines developed in advance of the event with robust and explicit methods. However, novel and unanticipated situations may arise which require innovative approaches, including HEIGs.

HEIGs:
- Abbreviated and accelerated methods needed to produce guidelines in condensed timelines pose a significant threat to validity and potentially affecting trustworthiness.
- The paucity of structured scientific data on emerging diseases, especially early in the event timeline, poses significant challenges for guideline development.
- Member States or regions facing complex emergencies have dynamic contexts that can include fragile, illegitimate, absent or technically weak governments or Ministries of Health, with important implications for guideline development, adaptation and implementation.

Key findings
- 21 guidelines were identified: 13 de novo (developed for the first time) and 8 updates (Table).
- Zika guidelines were all available in IRIS and all but one of the current versions were available on the WHO webpage dedicated to the Zika outbreak response.
- There were high rates of adherence to WHO publication requirements.
- Most guidelines involved external contributors and reported collecting declaration of interests and managing conflicts of interest.
- Non-English translations (including Portuguese and Spanish) were available for most documents.
- The iterative guideline development model used by four groups was feasible: ultra-fast production of an initial document based on expert opinion and subsequent updates that increasingly incorporated quality elements such as a systematic review.

<table>
<thead>
<tr>
<th>Guideline characteristics</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(total n=21)</td>
<td></td>
</tr>
<tr>
<td>Contained WHO logo and disclaimer</td>
<td>21 (100)</td>
</tr>
</tbody>
</table>
Remaining challenges for WHO guidelines in health emergencies

- Timely translation of updates. Only 7 of the 13 current, English versions were available in other languages, leading to thousands of downloads of outdated documents in non-English versions. The Zika webpage did not inform end-users that the translations were outdated.
- Reporting of key development steps in de novo and updated guidelines. Some updated guidelines reported steps undertaken in previous versions without clarifying changes (if any) in the update.
- Quality control procedures including Guidelines Review Committee (GRC) approval. Guidelines were rarely submitted to the GRC; other forms of quality control such as peer review and informal review by the GRC were more frequent.

Next Steps for the GRC secretariat

- The GRC Secretariat is currently developing a toolkit for producing new guidelines and for updating existing ones within short time periods based on the experience with Zika guidelines. Tools for appraising the quality and relevance of existing guidelines are also under development.
- The GRC Secretariat is working to facilitate a direct link between the GRC and WHE to provide expertise in methods and procedures for the development of guidelines, highlighting the need for coordinated efforts.
and resources within WHO.

**For further information:** Please contact Susan L Norris (HIS/IER/REK) at norriss@who.int.
Annex 2. Templates for GDG member invitation and DOI

Template 1

Letter to prospective GDG members requesting completion of a declaration of interests and submission of a *curriculum vitae*.

Tel. direct: +41 22 791
Fax direct: +41 22 791
E-mail:

In reply please refer to:

Your reference:

Dear [insert name],

Subject: [insert title of the guideline under development]

The World Health Organization (WHO) is considering to invite you to participate in its Guideline Development Group for [insert title].

*A description of the guideline to be developed, its scope, the Terms of Reference of the GDG, and the planned meetings is attached for your information. The working language of the GDG will be ...*

In order to allow WHO to assess whether it can extend such an invitation, we would be grateful if you could complete and sign the attached Declaration of Interests form. In this regard, kindly note that your participation in the above mentioned Guideline Development Group is inter alia contingent upon WHO determining that there is no significant conflict of interest, or that any such conflict can be appropriately managed.

Please also submit an up-to-date *curriculum vitae* along with the signed Declaration of Interests form. Submit both of these items to us by [date].

In order to enhance its management of conflicts of interest as well as strengthen public trust and transparency in connection with WHO meetings and activities involving the provision of technical/normative advice, the names and brief biographies of individuals (“Published Information”) being considered for participation in a WHO-convened Guideline Development Group are disclosed for public notice and comment. Therefore at a later date, we may request a brief biography from you for this purpose.
Comments brought to the attention of WHO through this process are an integral component of WHO’s conflict of interest assessment process and are carefully reviewed and evaluated in order to take appropriate management action in accordance with WHO policies. The comments received by WHO through the public notice and comment process are treated confidentially, however WHO will generally share information received through this process with you, disclosing also the name and affiliation of the provider of such information to you. In exceptional circumstances where WHO considers that such disclosure might potentially adversely affect the individual providing the comments, the name and affiliation will be withheld.

The list of participants in the Guideline Development Group, summary of relevant interests disclosed by such experts, and any appropriate mitigation measures taken by WHO relating to the management of conflicts of interests, will be reported publically in accordance with WHO policies.

We look forward to hearing from you. Please contact me if you have any questions.

Yours sincerely,

[signature]

[name] ....................

[title] .........................
Template 2

Biographies of prospective Guideline Development Group members which will be posted on the internet.

Surname, first name(s) and initial [as commonly used in professional work]

Institutional affiliation(s) [current and in the prior four years]

Academic degrees

City and country of primary residence

Biography [Provide a brief summary of education, skills, experience as it relates to the guideline under development; maximum 200 words].]

[Alongside the publication of the biographies, the following disclaimer should be posted.]

Disclaimer:

In order to enhance its management of conflicts of interest as well as strengthen public trust and transparency in connection with WHO meetings and activities involving the provision of technical/normative advice, the names and brief biographies of individuals (“Published Information”) being considered for participation in a WHO-convened Guideline Development Group are disclosed for public notice and comment.

The Published Information is provided by the experts themselves and is the sole responsibility of the individuals concerned. WHO is not responsible for the accuracy, veracity and completeness of the Published Information provided. Furthermore, in no event will WHO be responsible or liable for damages in relation to the use of, and reliance upon, the Published Information.

The comments received by WHO through the public notice and comment process are treated confidentially and their receipt will be acknowledged through a generic email notification to the sender. Comments brought to the attention of WHO through this process are an integral component of WHO’s conflict of interest assessment process and are carefully reviewed. WHO reserves the right to discuss information received through this process with the relevant expert and disclose to this expert the name and affiliation of the provider of such information. Upon review and assessment of the information received through this process, WHO, in its sole discretion, may take appropriate management action in accordance with its policies.

Guideline Development Groups provide technical and/or normative advice and recommendations to WHO. Participation in a Guideline Development Group convened by WHO does not necessarily mean that the views expressed by the expert concerned are shared by WHO and/or represent the decisions or stated policy of WHO.
The list of participating experts, a summary of relevant interests disclosed by such experts, and any appropriate mitigation measures taken by WHO relating to the management of conflicts of interests, will be reported publically in accordance with WHO policies.

Annex:

1. Declaration of Interests for WHO Experts

Template 3

Invitation letter to WHO Temporary Advisors (GDG members)

This template for a letter can be used to formally invite individuals to be a member of a Guideline Development Group once their Declaration of Interests, curriculum vitae, the results of the internet search and any comments received from the publication of their biographies have been fully assessed and an appropriate management plan developed in collaboration with the Office of CRE. Modify the text related to travel and other arrangements as appropriate to the planned guideline and meeting.

Tel. direct: +41 22 791
Fax direct: +41 22 791
E-mail :

In reply please refer to:

Your reference:

Dear [insert name],

Subject: [insert title of the guideline under development]

I have the pleasure of inviting you to participate in the development of above mentioned document as a member of the Guideline Development Group as a Temporary Adviser to the World Health Organization (WHO).

A description of the guideline to be developed, its scope, the Terms of Reference of the GDG, and the planned meetings is attached for your information. The working language of the GDG will be ...
I attach a Memorandum of Agreement (Attachment 1, with one annex) containing the terms and conditions to which your assignment as a Temporary Adviser will be subject. Please carefully read and return a counter-signed copy of this letter and a signed copy of the Memorandum of Agreement (Attachment 1), with its annex, to WHO, together with the signed Confidentiality Undertaking (Attachment 2). Kindly note that the invitation for you to act as a Temporary Adviser is subject to WHO receiving from you the signed Memorandum of Agreement and Confidentiality Undertaking. Attachment 3 is the Declaration of Interest (DOI) form which you have already completed and sent to us. Please note that consistent with the declaration you have made in the DOI, you should promptly notify WHO of any changes in the information provided by you and complete a new DOI form that describes these changes. This includes any change that occur before or during your membership of the Guideline Development Group up to the publication of the guideline in question.

We kindly request that you complete and return the forms to the Secretariat (Attn: Responsible Officer, Title, Name of Programme) as soon as possible. In addition, please also find a “Code of Conduct for WHO Experts” (Attachment 4).

After we receive the counter-signed invitation letter, signed Memorandum of Agreement and signed Confidentiality Undertaking form, a travel authorization will be sent to you. Flight reservations to attend the Guideline Development Group meeting should be made through the following agency. Please inform us of your planned itinerary as soon as possible.

[Name, address and telephone number of the appropriate agency]

Please note that your ticket[s] will be provided by WHO through this agency only. Any request to purchase your own ticket for reimbursement must receive prior approval by WHO, which will be given in exceptional circumstances only.

[A single room has been provisionally reserved in your name at the Hotel … (give address, telephone number, fax number, email address) from … to … inclusive. The rate is …. per night [inclusive of breakfast]. If you wish to secure this reservation, please send your credit card details directly to the hotel [or to this office (……)]. Without your credit card confirmation, the room will be held only until …. Please let us know if you intend to arrive after … or if you would like to make changes to the reservation, so that we may inform the hotel. Payment of the hotel is your responsibility.

Please note that it is your responsibility to obtain any vaccinations and visas which may be necessary for this travel.

In this regard, upon receipt of this letter, please verify with the nearest Swiss Embassy or consulate whether you are required to have a visa to enter Switzerland. If so, kindly let us know by sending an e-mail or
fax to (…………………………) and provide us with your email address/fax number and personal information (i.e., family, first and middle names as they appear in passport, title (Mr, Mrs, Ms etc…), date of birth, nationality, passport number, dates of issue and expiry of passport). Following receipt of your communication, and provided that we receive it in a timely manner, WHO will provide you with a visa support letter, either by fax or e-mail, which you should present to the competent Swiss representation when applying for a visa. WHO has been informed that visa procedures may take up to 21 days. You are therefore urged to apply for a visa well in advance of your planned departure date. It is understood that the decision whether or not to issue a visa to any applicant rests with the competent Swiss authorities.

I look forward to hearing from you.

Yours sincerely,

[signature]

[name] ....................

[title] ...................

I agree to the conditions contained in this letter and its Attachment 1, both of which are duly executed. I have also duly completed and signed the enclosed Confidentiality Undertaking (Attachment 2) and the Declaration of Interests for WHO Experts if I wish to make any new declarations or revise existing ones (Attachment 3).

Name: __________________________________________________________

Signature: ________________________________ Date: ________________________

Attachments

1. Memorandum of Agreement: Terms and Conditions for Temporary Advisers
2. Confidentiality Undertaking
3. Declaration of Interests for WHO Experts
4. Code of Conduct for WHO Experts
WHO staff can obtain Attachments 2, 3 and 4 at the URL indicated below or from the Office of CRE (http://intranet.who.int/homes/cre/ethics/doiexperts/).

Confidentiality Undertaking
http://intranet.who.int/homes/leg/documents/updated_generic_conf_undertaking.docx

Declaration of Interests for WHO Experts

Code of Conduct for WHO Experts

Template 4

An example of a Note for the Record

The information featured in this template is presented as an example: the names and scenarios are fictional.

Note for the record: Meeting on the Role of Antibiotic Resistance in the ability of pathogenic bacteria to cause infection

FINAL

Date: (of the final Note for the Record)

Final number of participating experts:

Final number of experts with declared interests:

The Control for Antimicrobial Resistance unit is hosting a meeting on the Role of Antibiotic Resistance in the ability of pathogenic bacteria to cause infection, from 24-26 June 2015. 10 experts from various areas of expertise have been invited to attend. All the experts have duly completed and submitted their Declaration of Interest (DOI) and Confidentiality Undertaking forms. On review of the completed DOIs, the following two experts declared interests that required further consideration and discussion with the Office of Compliance, Risk Management and Ethics (CRE):

- Professor John Doe: received private funding for a research project
- Dr Jane Sandler: received research funding and is a patent holder
Further to a meeting with CRE, the technical unit sought additional information from the two experts regarding their respective disclosed interests:

**Professor John Doe**

Professor John Doe is the Head of John Hopkins Research Unit whose focus is Antimicrobial Resistance research. In his DOI, he noted that his Research Unit received funding in the amount of 100,000 USD from a private donor. After an initial screening of the DOI and consultation with CRE, the technical unit requested further information on the private donor funding, specifically the name and background of the donor. Professor Doe advised that the funding came from the Bill & Melinda Gates Foundation. This information was shared with the Office of Compliance Risk Management and Ethics.

**Conclusion**

Upon receipt and review of the additional information, it was determined that this interest did not present a conflict in respect of the meeting and Professor Doe could participate as an expert. (The request for additional information and response has been attached to the original DOI.)

**Dr Jane Sandler**

Dr Jane Sandler is the founder of Antimicrobials Research Group which investigates the mechanisms of action of and resistance to antibiotics, as well as exploring the role of antibiotic resistance in the ability of pathogenic bacteria to cause infection. Dr Sandler declared that she had received a number of research grants from various funding sources; she is also a holder of an antibiotic patent. After an initial screening of her DOI and consultation with CRE, additional information was requested with respect to the research grants and the patent. Dr Sandler advised that her Group has received two grants of 150,000USD each from the Bill & Melinda Gates Foundation and the US National Institutes of Health, as well as one 20,000 USD grant from Merck Pharmaceuticals. In respect of the patent, Dr Sandler advised that it was for the antibacterial drug Macrolides. This drug is going to be discussed at the meeting. This information was shared with the Office of Compliance Risk Management and Ethics.

**Conclusion**

Upon receipt and review of the additional information, it was determined that Dr Sandler has a significant interest (Merck funding and the patent) in respect of the objective of the meeting. It was thereby decided that Dr Sandler be excluded from participating in the meeting. (The request for additional information and response has been attached to the original DOI.)

**Signature:**

**Technical Officer**

**Director/Coordinator**

(Copy of the final Note for the Record to be share with the Office of Compliance Risk Management and Ethics.)
Annex 3. HEIG development tools

For each item in the templates below, hover the cursor over the text to open a pop-up window.

### 1. Coordination Form

Add name of health emergency and year if applicable.

<table>
<thead>
<tr>
<th>Title</th>
<th>WHO reference number</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responsible officer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Description of problem</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scope</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Settings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target audience</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rationale for HEIG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coordination</td>
<td>Informed affected WHO RO/CO?</td>
<td>□ Yes □ No</td>
</tr>
<tr>
<td></td>
<td>Informed GRC secretariat?</td>
<td>□ Yes □ No</td>
</tr>
<tr>
<td></td>
<td>Informed relevant WHO HQ units?</td>
<td>□ Yes □ No</td>
</tr>
<tr>
<td></td>
<td>List of WHO staff selected for Steering Group:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>List of external collaborating organizations:</td>
<td></td>
</tr>
<tr>
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<td>List of languages to translate:</td>
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</tr>
<tr>
<td></td>
<td>Notes</td>
<td></td>
</tr>
<tr>
<td>WHE technical focal point (this section is for WHE use only)</td>
<td>WHE approval date:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Deliver-by date (within weeks):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reason for non-approval: □ Not priority □ Other (add in comments)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>List of technical units to be contacted:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Comments</td>
<td></td>
</tr>
</tbody>
</table>

**Email form to:**

Add name - @who.int – WHE technical focal point
Add name - @who.int – GRC secretariat
2. Evidence to decision table – HEIG

Add name of health emergency and year

<table>
<thead>
<tr>
<th>Title</th>
<th></th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO reference number</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Responsible officer</td>
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<tr>
<td>External experts</td>
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<tr>
<td>Scope</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target audience</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Question:**

**Perspective**

**Population**

**Subgroups**

**Settings**

**Intervention/Option**

**Comparator/Alternative**

**Main outcomes**

1. Select the criteria that are relevant to your guideline, tailor the module and add right after the row with main outcomes. The EtD criteria should be discussed in the sequence they appear in the list (a complete list with the additional question for emergencies is provided in the end of this document). The modular approach allows for flexibility and tailoring according to the needs of each guideline.
2. Copy and paste the questions following the format of the template below.

**List of major criteria.**

1. Priority of the problem and intervention
2. Balance between benefits and harms
3. Resource requirements
4. Impact on equity
5. Acceptability
6. Visibility
7. Diagnostic tests

EtD criteria module template

1. Main criteria?
   • Detailed questions in sequence?

Evidence summary

<table>
<thead>
<tr>
<th>No studies included</th>
<th>Very low</th>
<th>Low</th>
<th>Moderate</th>
<th>High</th>
</tr>
</thead>
<tbody>
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<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Additional considerations about the evidence base:

Discussion

<table>
<thead>
<tr>
<th>Judgement</th>
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</thead>
<tbody>
<tr>
<td>Don’t know</td>
</tr>
<tr>
<td>☐</td>
</tr>
</tbody>
</table>

After adding the modules and tailoring the EtD, add the summary section below to complete the tool. This information will be copied and pasted in the guideline template.

Recommendation:
*Add the strength of the recommendation and quality of the evidence according to GRADE.

Rationale (justification of decision-making):

Remarks (implementation considerations, priority and other conditions including capacity building in emergency settings):

Subgroup considerations:

Considerations about adaptability and flexibility in emergency settings:

Updating considerations:
Criteria and detailed question list

Adaptation of evidence to decision criteria for HEIGs: a pragmatic approach

1. Is the problem a priority?
- Are the consequences of the problem serious?
- Is the problem urgent?
- Is it a recognized priority (e.g. based on a political or policy decision)?

Considerations for HEIG development

The priority of the problem is usually established prior to the guideline meeting and it is mostly irrelevant to this stage of the development process of HEIGs (see the Coordination form section about description of the problem).

Alternatively, it might be relevant to document the panel’s opinion on how much the affected populations and end-users consider the option/intervention (solution) a priority for immediate implementation during the emergency response.

- Is problem a priority for the immediate emergency response?
- Are there considerations regarding the priority of components of multifaceted intervention/options or multiple interventions may be needed with limited resources at the same time (important for flexibility)?

2. Balance between benefits and harms
- How substantial are the desirable anticipated effects (benefits)?
- How substantial are the undesirable anticipated effects (harms, adverse effects, unintended consequences)?
- Is there important uncertainty about or variability in how much people value the main outcomes?
- What is the overall certainty (quality of the evidence) of the evidence of effects in support of the recommendation?
- How much less people value outcomes that are in the future compared to outcomes that occur now (their discount rates)?
- People’s attitudes towards undesirable effects (how risk averse they are).
- People’s attitudes towards desirable effects (how risk seeking they are).

Considerations for HEIG development

Document and report all sources of information utilized during the decision-making process. For example, was it based on guideline development group members’ opinion? If so, was it unanimous consensus? Any divergent views? Any concerns with the safety of the option/intervention? Are reports from the operational field available? Field manuals or epidemiologic reports? Text books? Guidelines from other organizations?
For HEIGs, the term “people” in the questions above refers to both affected populations and end-users (target audience).

3. Resources requirements

How large are the resource requirements (costs)?
- How large is the difference in each item of resource use for which more resources are required?
- How large is the difference in each item of resource for which fewer resources are required?

What is the certainty (quality) of the evidence of resource requirements (costs)?
- Have all important items of resource use that may differ between the options being considered been identified?
- How certain is the cost of the items of resource use that differ between the options being considered?
- Is there important variability in the cost of the items of resource use that differ between the options being considered?

*For cost-effectiveness considerations use the questions in the evidence-to-decision templates from DECIDE (available for download on the GRC intranet page).

Considerations for HEIG development

What is the anticipated impact of the current public health emergency on resources requirements?

Are the resources required to implement the intervention/option large in the affected areas? Please consider all items (preferably focused on information from the affected areas):
- Comparative costs between options/interventions
- Acquisition costs of medications
- Capital costs of new equipment
- Capital costs of new infrastructure
- Human resources
- Capacity building
- Other operational expenses (i.e., maintenance)

What is overall budget impact (estimated) of this option/intervention?

Document and report all sources of information utilized during the decision-making process.
4. Impact on equity

What would be the impact on health equity?

Are there groups or settings that might be disadvantaged in relation to the problem or options/interventions that are considered?

Are there plausible reasons for anticipating differences in the relative effectiveness of the option for disadvantaged groups or settings?

Are there different baseline conditions across groups or settings that affect the absolute effectiveness of the option or the importance of the problem for disadvantaged groups or settings?

Are there important considerations that should be made when implementing the option/intervention in order to ensure that inequities are reduced, if possible, and that they are not increased?

Considerations for HEIG development

Identify differential access to the intervention/option of affected subpopulations (gender, age, ethnicity and geographic region).

Identify impact of the intervention/option differential access to general health products and services of affected subpopulations (gender, age, ethnicity and geographic region).

Identify other vulnerable groups, communities or populations based on differential exposure to social determinants of health impacted by the public health emergency.

Consider potential impact on right-to-health and other basic human rights?

5. Acceptability

Is the intervention acceptable to key stakeholders?

Are there key stakeholders that would not accept the distribution of the benefits, harms and costs?

Are there key stakeholders that would not accept the costs or undesirable effects in the short term for desirable effects (benefits) in the future?

Would the intervention (option) adversely affect people’s autonomy?

Are there key stakeholders that would disapprove of the intervention (option) morally, for reasons other than its effects on people’s autonomy (i.e. in relationship to ethical principles such as non-maleficence, beneficence or justice)?
Considerations for HEIG development

Identify a list of key stakeholders (include and identify groups represented and not represented in the guideline development group).

Is the intervention/option acceptable to all stakeholders? What are the potential barriers to acceptability?

Is the intervention/option compatible with cultural expectations of end-users?
Is the intervention/option compatible with cultural expectations of the affected population?

Is the intervention/option a departure from local current practices? If so, what is the plan to address the difficulties?

Have states (or state-like actors) in the area taken similar actions in the past?

Some concepts from the considerations about equity may help with decision-making of “Acceptability”.

6. Feasibility

Is the intervention feasible to implement?

Is the intervention (option) sustainable?
Are there important barriers that are likely to limit the feasibility of implementing the intervention (option) or require consideration when implementing it?
Is it feasible to ensure appropriate use for approved indications?
Is inappropriate use (indications that are not approved) an important concern?
Is access to the intervention an important concern?
Are there important legal or bureaucratic constraints that make it difficult or impossible to implement the option/intervention?

Considerations for HEIG development

Identify all the key stakeholders and implementing healthcare actors (governmental and non-governmental) considered in the decision-making?
Is the intervention/option feasible for **immediate** implementation in the affected areas? Consider the time to availability of the following:

- Infrastructure (built and equipment)
- Human resources (health and non-health workforces)
- Pre-implementation capacity-building
- Other technical resources relevant to the recommendation

Consider the potential impact of implementing this option/intervention on other areas of health services delivery such as:

- Basic services for high-burden (morbidity and mortality) conditions during public health emergencies
- Geographic areas where the state (or state-like actors) will not have the technical resources to implement the intervention/option
- Fit with system-wide initiatives
- Fit with past decisions about related components of the health system

Consider the need to adapt and adjust the option/intervention to be flexible and allow implementation in different scenarios:

- Which components (if multiple components) are crucial for effectiveness and require high-fidelity on implementation?
- Which components (if any) can be adapted and adjusted to local conditions?

**Additional Module: Diagnostic tests**

**Test accuracy**

How accurate is the test?

What is the overall certainty of the evidence of test accuracy?

What is the overall certainty of the evidence for any critical or important direct benefits, adverse effects or burden of the test?

How certain is the link between test results and management decisions?

What is the overall certainty of the evidence of effects of the management that is guided by the test results?
3. Guideline template

Add title

Health Emergency Interim Guidelines

Add name of health emergency, month and year

WHO reference number

1. Introduction

1.1 Background

1.2 Scope and objectives

1.3 Perspective and healthcare settings

1.4 Target audience

2. Technical content

a. Narrative review of the topic

Narrative reviews are textbook-style sections summarizing key relevant points for the end-user. Usual topics are epidemiology, case definitions, pathophysiology, clinical presentation and, exceptionally, interventions can be included here if they are proven best practices with no uncertainty in the field about the correct clinical or public health action in this context.

2.2 Recommendations

Recommendations are action statements designed to help end-users decide what are the best options for clinical or public health uncertainties in the field during a health emergency. They should be based on the available evidence and contextualized by a group of experts to fit the specific purposes of the target audience within the stated perspective, healthcare settings and scope.

3. Guideline development

3.1 Acknowledgements

3.1.1 WHO steering group

3.1.2 Guideline development group (GDG)

3.1.3 Peer reviewers

3.1.4 Others (Technical advisors, evidence review team)

3.1.5 Any organizations (if applicable)

3.2 Declaration of interests (DOI)

Only include here overall statements about the DOI procedures and conflicts of interest if members remained in the group. If not conflicted were declared, please state that DOI was collected and no conflicts identified. All DOI information should be included in a separate online annex that will be available to the public in the same website section.
as the guideline. Please check the GRC/CRE DOI requirements in HEIG development.

3.3 Funding sources

The funding source had no influence on the content of this guideline.

3.4 Guideline development methods

3.4.1 Evidence identification, retrieval and synthesis

3.4.2 Group decision-making processes

3.4.3 Evidence-to-decision criteria

Please include a link to the evidence-to-decision table (as online Annex).

3.4.4 Peer review processes

3.4 Review date

These recommendations have been produced under emergency response procedures and will remain valid until (add date 6 months in future). The Department of (add responsible department) at WHO headquarters in Geneva will be responsible for reviewing this guideline at that time, and updating it as appropriate.

3.5 Contact information

4. References
4. Health emergency interim guidelines review checklist

<table>
<thead>
<tr>
<th>Add name of health emergency and year (if applicable)</th>
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<tbody>
<tr>
<td><strong>Title</strong></td>
</tr>
<tr>
<td>WHO reference number and date</td>
</tr>
<tr>
<td>Responsible officer</td>
</tr>
<tr>
<td>Reviewer</td>
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<tr>
<td><strong>List of attached documents</strong></td>
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<td><strong>Comments by GRC secretariat or peer reviewer:</strong></td>
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<td><strong>1. Introduction</strong></td>
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<td><strong>3. Guideline development</strong></td>
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<td>4. Declaration and management of conflicts of interest</td>
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<tr>
<td>☐ Approach to collect and assess DOI from all non-WHO contributors</td>
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<td>☐ List of all declarations of interest (annex)</td>
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<tr>
<td>☐ Approach for managing relevant conflicts of interest</td>
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<tr>
<td>☐ List of all conflicts of interest and how they were managed (annex)</td>
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**Comments by GRC secretariat or peer reviewer:**

<table>
<thead>
<tr>
<th>5. Evidence use (identification, retrieval, and synthesis)</th>
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<tr>
<td>☐ Methods and procedures to inform narrative review</td>
</tr>
<tr>
<td>☐ Methods and procedures to inform recommendations</td>
</tr>
<tr>
<td>☐ Was a systematic or rapid review done?</td>
</tr>
<tr>
<td>☐ Was the use of evidence described (type, quality)?</td>
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**Comments by GRC secretariat or peer reviewer:**

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<th>6. Group decision-making</th>
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<td>☐ Consideration for the balance of benefits and harms of interventions</td>
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<tr>
<td>☐ Consideration for other decision criteria (EtD)</td>
</tr>
<tr>
<td>☐ Definition of consensus for formulating recommendations</td>
</tr>
<tr>
<td>☐ Group decision-making approach to resolve disagreements</td>
</tr>
</tbody>
</table>

**Comments by GRC secretariat or peer reviewer:**

| 8. External review |
Comments by GRC secretariat or peer reviewer:

9. References

10. General comments and suggestions
Annex 4. Using GRADE for appraising the quality of the evidence and defining the strength of the recommendation in HEIG development

The WHO Handbook for Guideline Development 2nd ed. suggests the use of GRADE as a formal approach to standardize the rating of the quality of the evidence (table 1) and the evidence-to-decision process to define the strength of the recommendation (table 2). The terminology proposed by GRADE was not developed for guidelines produced in response to public health emergencies and thus its application and interpretation in this context may be difficult and require adaptation. Nonetheless, the use of the widely-accepted GRADE approach and terminology, even if modified, adds clarity, transparency and facilitates translation and communication of the messages contained in HEIGs. The GRC Secretariat strongly encourages the application of GRADE whenever the resources and conditions available allow. Recognizing that emergency guideline development is a recent concern to the guideline methods community and most questions remain unanswered, all GRADE modifications and pragmatic adaptations utilized during the HEIG development process should be fully outlined by the technical team, discussed with the GRC secretariat prior to implementation and reported in the final guideline.

Table 1. Standard terminology for rating the quality of the body of evidence to support recommendations.

<table>
<thead>
<tr>
<th>RATINGS</th>
<th>MEANING</th>
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<tr>
<td>✭✭✭✭</td>
<td>The GDG is very confident that the true effect of the intervention is close to the estimate of the effect presented to the group. Evidence with this quality rating provides a very good basis to support a decision for a recommendation.</td>
</tr>
<tr>
<td>✭✭✭</td>
<td>The GDG is moderately confident that the true effect of the intervention is close to the estimate of the effect presented to the group. The true effect is likely close, but it could be substantially different. Evidence with this quality rating provides a good basis to support a decision for a recommendation.</td>
</tr>
<tr>
<td>✭✭</td>
<td>The GDG has limited confidence that the true effect of the intervention is close to the estimate of the effect presented to the group. The true effect may be substantially different.</td>
</tr>
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</table>
The GDG has very little confidence that the true effect of the intervention is close to the estimate of the effect presented to the group.

**Legend.** The rating can be represented in the guideline by the symbols, the text or both. GDG, Guideline Development Group.

**Table 2.** Standard terminology for describing the meaning of strength of a recommendation.

<table>
<thead>
<tr>
<th><strong>STRONG RECOMMENDATIONS</strong></th>
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<td>The GDG is highly confident that the balance between desirable and undesirable effects or consequences of adherence to the recommendation outweigh the undesirable effects. This means that in most situations the recommendation can be adopted as policy.</td>
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<tr>
<th><strong>CONDITIONAL RECOMMENDATIONS</strong></th>
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<td>These are made when there is greater uncertainty about the criteria above (table 1) or if local adaptation must account for a greater variety in values, or when resource use makes the intervention suitable for some, but not for other locations. This means that there is a need for substantial debate and involvement of stakeholders before this recommendation can be adopted locally as policy.</td>
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**Legend.** The strength of the recommendation is determined by the GDG using the evidence-to-decision table provided in this toolkit (Annex 3 – Tool 3. GDG, Guideline Development Group.

The GRADE approach does not mandate a specific relation between the quality of the evidence and the strength of the recommendation. However, strong recommendations are usually not justified when the quality of the evidence (confidence in the estimates of effect) is low or very low. There are exceptional paradigmatic circumstances that may justify strong recommendations even with low or very-low quality of the evidence and that may have an application for HEIG development (table 3).