World Health Organization

WHO Guideline development process

23 September 2020

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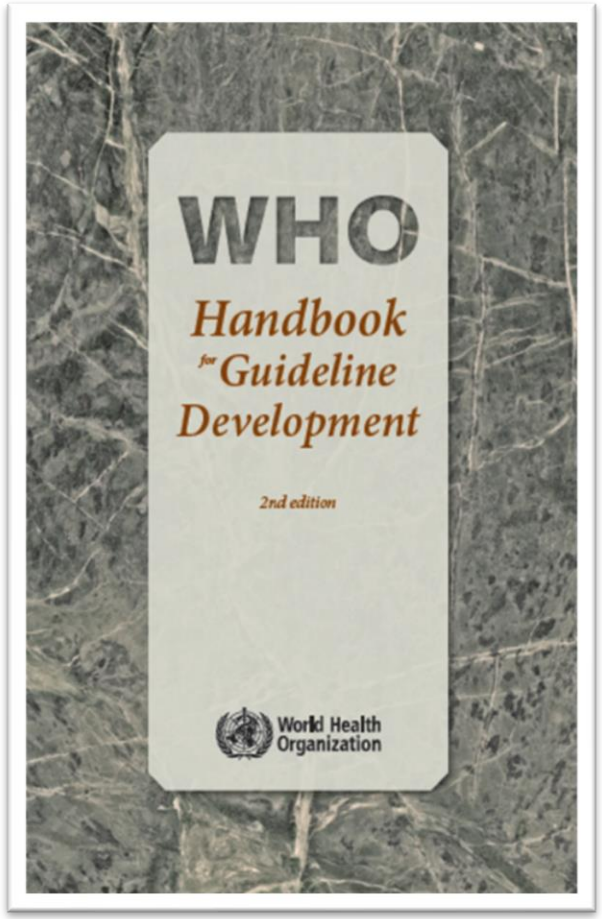

Procedures and standards for WHO guidelines

- Evidence-informed
- Transparent

Guidelines Review Committee Secretariat

Peer review feedback

Quality assurance process

What is a WHO guideline?

WHO guideline

- is any document, whatever its title, that contains WHO recommendations about health interventions, whether they be clinical, public health or policy

WHO recommendation

- Provides information about what policy-makers, health-care providers or patients should **do**.
- It implies a choice between different interventions that have an impact on health and that have ramifications for the use of resources.

What is not a WHO guideline?

- Documents that state established principles (e.g. human rights)
- WHO Secretariat reports and other papers submitted to the Governing Bodies (e.g. WHA resolutions)
- Information documents that report facts, describe evidence, or document or review existing practices and interventions
- Documents containing standards for manufacturing health technologies, such as pharmaceuticals and vaccines
- Documents that describe standard operating procedures for organizations or systems
- “How to” documents such as operational manuals or implementation guides or tools based on GRC-approved guidelines.

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Request

Request guidance on a topic

- WHO Member State
- WHO Country Office
- Prioritization exercise

Planning

WHO Technical unit

- Confirm sufficient resources; determine the timeline
- Draft a well-defined scope and target audience
- Convene the WHO Steering group

WHO Steering group

- Identify potential broad and representative GDG and ERG members
- Obtain disclosure and manage all secondary interests (COI)
- Submit Planning Proposal to the Guideline Review Committee

Guideline Development Group

- A priori development of key question(s) for the systematic review, usually in population, intervention, comparator and outcome (PICO) format
- Prioritize outcomes

Development

Systematic review team

- Perform the systematic and comprehensive evidence retrieval and synthesis for each key question
- Assess the certainty of the body of evidence for each critical outcome using GRADE as appropriate

Guideline Development Group

- Formulate recommendations based on the evidence and other explicit considerations

Approval

WHO Steering Group

- Draft the guideline document; should be usable: relevant, applicable and user-friendly
- Conduct external peer review
- Finalize guideline
- Submit to the Guideline Review Committee

WHO Technical unit

- Publish
- Disseminate, adapt, implement and evaluate
- Update

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Required elements

- **Scope/planning**
  - Well-defined scope and target audience
  - Broad and representative guideline development group
  - Disclosure and management of all secondary interests (COI)
- **Evidence identification and synthesis**
  - A priori development of key question for systematic reviews
  - Systematic and comprehensive evidence retrieval, synthesis
  - Assessment of certainty of the body of evidence for each question
- **Formulation of recommendations**
  - based on the evidence and other explicit considerations
- **Adherence to WHO reporting standards**
- **Usable document: relevant, applicable, user-friendly**

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Contributors

Contributors

Contributors and their roles in guideline development

	Primary responsibility	Main functions
WHO Steering group	Oversee the guideline development process	Administration; draft the scope; identify members of the GDG and ERG; oversee the conduct of the systematic review; draft the final guideline
GDG	Formulate recommendations; the general scope and content of the guideline	Provide input into the scope and key questions; attend GDG meetings; formulate recommendations; critically review the final guideline document
ERG	Provide diverse and real-world perspective	Peer review the draft final guideline; may provide input into the scope and key questions

Contributors

Contributors and their roles in guideline development

	Primary responsibility	Main functions
SR Team	Provide a comprehensive, objective synthesis of the evidence to inform each recommendation	Provide input into the key questions; perform systematic reviews on evidence; assess the quality of the body of evidence and develop GRADE evidence profiles
Methodologist	Oversee the process of developing recommendations based on evidence	Review GRADE evidence profiles developed by the SRT; attend the GDG meeting and assist the group in developing recommendations using the GRADE framework
Observer	Observe	Ensure the transparency of the processes; engage partners; facilitate implementation

Confidentiality

Confidentiality undertaking

The World Health Organization (WHO), acting through its Departments of Maternal, Newborn, Child and Adolescent Health, and Nutrition for Health and Development,

has access to certain information relating to [wasting],

which information WHO considers to be proprietary to itself or to parties collaborating with it (hereinafter referred to as "the Information").

Evidence retrieval, assessment and synthesis and formulation of recommendations

Evidence retrieval, assessment and synthesis and formulation of recommendations

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To “reach agreement on a **common, sensible** approach to grading 1) quality of evidence and 2) strength of recommendations.”

Formulate question

Select outcomes

Rate importance

Outcomes across studies

Create evidence profile with GRADEpro

Rate certainty of evidence for each outcome

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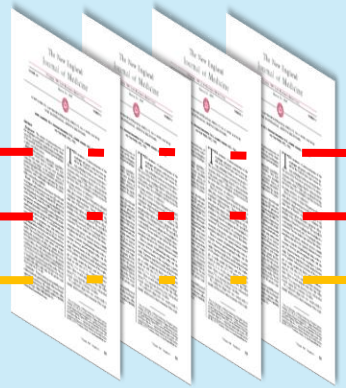
P
I
C
O

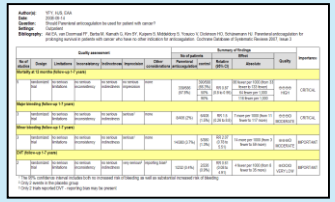
Outcome Critical

Outcome Critical

Outcome Important

Outcome Not important





Summary of findings & estimate of effect for each outcome

High
Moderate
Low
Very low

Grade down

1. Risk of bias
2. Inconsistency
3. Indirectness
4. Imprecision
5. Publication bias

Grade up

1. Large effect
2. Dose response
3. Opposing bias & Confounders

Systematic review

Guideline development

Guideline Development Group

GRADE overall certainty of evidence across outcomes based on lowest quality of *critical* outcomes

GRADE recommendations
- For or Against (Direction) ↓↑
- Strong or Conditional (Strength)

By considering balance of:

- ❑ Certainty of evidence
- ❑ Balance of benefits/harms
- ❑ Values and preferences
- ❑ Resource utilization
- ❑ Equity and Human rights
- ❑ Acceptability/Feasibility

GUIDELINE

Formulate Recommendations
- "The GDG recommend using…"
- "The GDG suggest using…"
- "The GDG suggest not using…
- "The GDG recommend not using…"

What makes GRADE special?

- Sequential assessment of
  1. Certainty (quality) of evidence
  2. Judgement about the balance between desirable and undesirable effects
  3. Decision about the strength of the recommendation
- Separating the judgements regarding the certainty of evidence from judgements about the strength of recommendations is a critical and defining feature of the GRADE system

Consider all relevant evidence and factors for decision-making (WHO-INTEGRATE)

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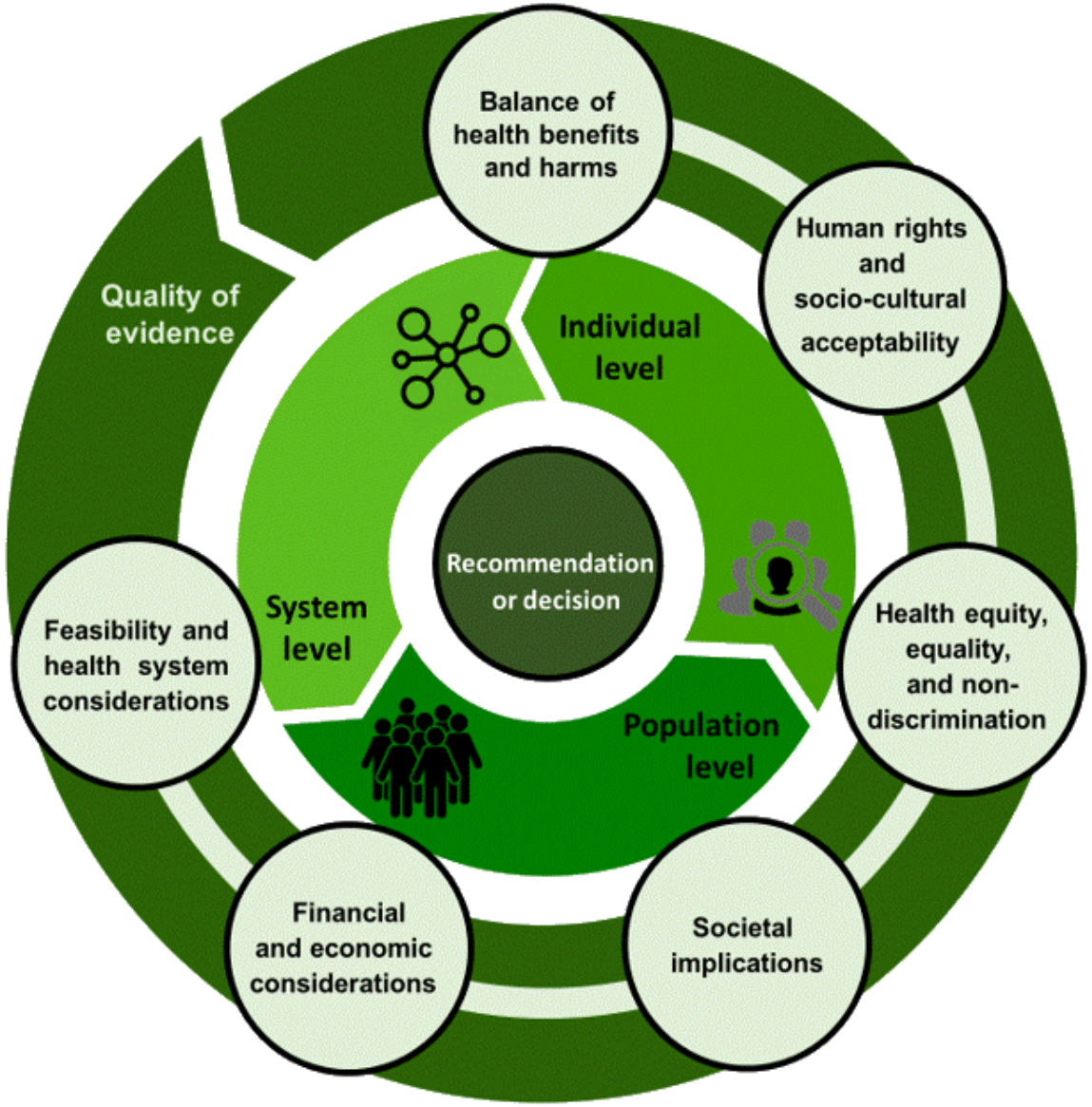
Clinical /population health (2004)	Clinical /population health	WHO – INTEGRATE framework
	Problem	
Benefits	Desirable effects	
Harms	Undesirable effects	
	Certainty of evidence	
Values and preferences	Values	
	Balance of effects	Balance of health benefits and harms
Resource considerations	Resources required	Financial and economic considerations
	Cost effectiveness	
	Equity	Health equity, **equality, non-discrimination**
	Acceptability	**Human rights and** socio-cultural acceptability
	Feasibility	Feasibility **and health system considerations**
		Societal impact

GRADE DECIDE

GRADE DECIDE

Rehfuess & Stratil

WHO-INTEGRATE Framework



Rehfuess EA, Stratil JM, Scheel IB, *et al*. The WHOINTEGRATE evidence to decision framework version 1.0: integrating WHO norms and values and a complexity perspective. *BMJ Glob Health* 2019;4:e000844. doi:10.1136/ bmjgh-2018-000844

Recommendations

Group decision making

WHO recommendations should be based on consensus

WHO recommendations should be based on consensus

- Defined as general agreement among the decision makers
- Minor disagreements can be addressed in the Remarks Section of the guideline
- Voting can be used as a tool to achieve consensus

If consensus cannot be reached, voting can be used

- 2/3 majority, anonymous or hand-raising, Chairs' discretion

Recommendations

Interpretation of strong and conditional recommendations

Audience	Strong recommendation	Conditional recommendation
Patients	Most individuals in this situation would want the recommended course of action; only a small proportion would not.	Most individuals in this situation would want the suggested course of action, but many would not.
Clinicians	Most individuals should receive the intervention.	Different choices will be appropriate for individual patients, who will require assistance in arriving at a management decision consistent with his or her values and preferences.
Policy-makers	The recommendation can be adopted as policy in most situations.	Policy-making will require substantial debate and involvement of various stakeholders.

Recommendation format

Recommendation

- “At primary health-care facilities, health workers should provide general nutrition counselling to caregivers of overweight children aged less than 5 years (strength of recommendation: conditional; very low quality evidence).”

Justification remarks

GRADE Evidence profile

- Quality assessment of the body of evidence.

Evidence to decision framework

- Strength assessment of the recommendation.

Implementation consideration

Research priority

Guideline: Assessing and managing children at primary health-care facilities to prevent overweight and obesity in the context of the double burden of malnutrition - 2017

WHO Guidelines…

Meet the highest quality standards for evidence-based guidelines

Focus on UN Member States' and end-users' needs

- Address the right questions
- Optimize usability
- Diverse stakeholder input into key development steps

Are based on high-quality systematic reviews of all relevant evidence

Use GRADE, which provides an explicit approach to:

- Assessing the quality of the evidence across studies and outcomes
- Translating evidence to recommendations

Incorporate multiple processes to minimize bias

All judgments and decision-making are transparent and explicit

Thank you

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