

# WHO recommended steps for development of evidence-based clinical practice and public health guidelines

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**Chair, WHO Guidelines Review Committee**  
**World Health Organization**

# Why Develop Guidelines?

## WHY DO WE DEVELOP GUIDELINES?



- To provide policy makers, practitioners and patients with clear guidance
- To guide decisions on an appropriate course of action (whether an intervention, practice, policy, medical device, diagnostic)
- Based on best available evidence that has been critically appraised
- Transparent consideration of other relevant information

## NEWS

# £5m wasted on 'needless' wisdom tooth surgery

By Celia Hall, Medical Editor

A TOTAL of £5 million a year is wasted on unnecessary surgery to remove wisdom teeth, according to a Government monitoring agency.

The National Institute of Clinical Excellence (Nice) said yesterday that a survey had found that 44 per cent of the operations to extract wisdom teeth had discovered no evidence of disease.

Nice, the organisation that advises on good practice, said that there was no reason to remove healthy teeth and that surgery exposed patients to needless risks and complications.

But the British Dental Association said that the institute was using old fig-

ures. It did not agree that £5 million would be saved and said that significantly smaller numbers of wisdom teeth were being removed than previously.

Nice said the risks to patients included nerve damage, damage to other teeth, bleeding and sometimes death.

It also said in its advice to the Department of Health: "After surgery to remove wisdom teeth patients may have swelling, pain and be unable to open their mouths fully."

But despite recommendations from dental surgeons three years ago, large numbers of adults were still

being referred for surgery. In 1998-99 50,000 operations to remove impacted wisdom teeth were carried out in England. Another 3,000 were conducted in Wales. The estimated cost to the National Health Service was £12 million.

Only patients with diseased wisdom teeth and other oral conditions should have the teeth removed, Nice said. The organisation is advising patients who are on waiting lists for surgery to seek their dentist's advice.

Andrew Dillon, the chief executive of Nice, said: "We have suggested to the NHS that patients who are waiting to have their wisdom teeth

removed are reviewed by their dentist or surgeon."

John Lowry, the chairman of the BDA committee for hospital dental services, said: "Nowadays dentists generally remove a wisdom tooth only when there is a problem so the Nice guidelines are only confirming current advice."

A spokesman for the BDA said in a statement: "It is interesting to note that Nice has chosen to use old figures especially when a survey — the largest of its kind in the UK — was published in 1998." He added that as most operations took place in NHS hospitals there was no financial advantage to dentists.

# Establishing WHO's Guidelines Review Committee



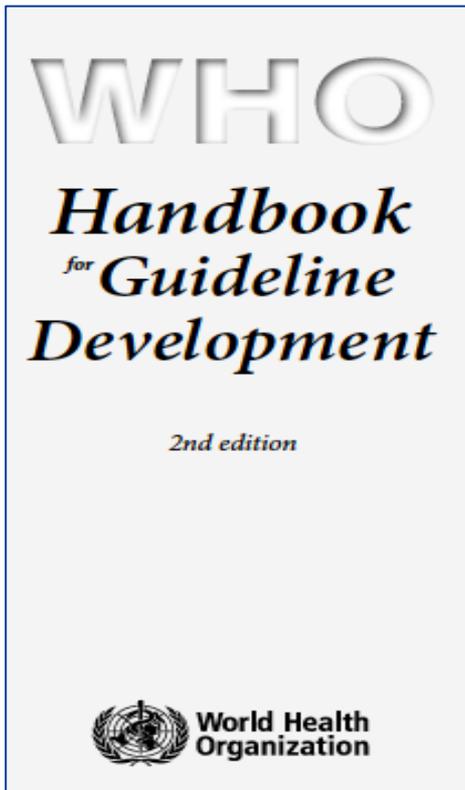
*Evidence not retrieved, appraised, synthesised, and interpreted using systematic and transparent methods.*

*Processes rely heavily on experts*

Oxman, *Lancet* 2007



# Guideline development principles



## Guideline development processes must be:

- Explicit and transparent
- Clear scope, objectives and target audience;
- Multidisciplinary: all relevant expertise and perspectives
- Detailed funding sources
- Adhere to WHO reporting standards

## Relevant contributors must:

- Disclose and manage relevant interests

## Recommendations should be:

- Actionable: clearly articulated and precise
- Informed by the best available evidence.
- Supported by a rationale, assessment of the certainty of the evidence, the strength of the recommendation

WHO GUIDELINE  
**RECOMMENDATIONS  
 ON DIGITAL  
 INTERVENTIONS  
 FOR HEALTH SYSTEM  
 STRENGTHENING**

EVIDENCE AND RECOMMENDATIONS



**INTERIM GUIDELINES**

**UPDATED RECOMMENDATIONS ON  
 FIRST-LINE AND SECOND-LINE  
 ANTIRETROVIRAL REGIMENS AND  
 POST-EXPOSURE PROPHYLAXIS  
 AND RECOMMENDATIONS ON EARLY  
 INFANT DIAGNOSIS OF HIV**

**SUPPLEMENT TO THE 2016 CONSOLIDATED GUIDELINES  
 ON THE USE OF ANTIRETROVIRAL DRUGS FOR TREATING  
 AND PREVENTING HIV INFECTION**

DECEMBER 2018

HIV TREATMENT

GUIDELINES ON  
**PHYSICAL ACTIVITY,  
 SEDENTARY BEHAVIOUR  
 AND SLEEP** FOR CHILDREN  
 UNDER 5 YEARS OF AGE



WHO  
**HOUSING  
 AND HEALTH  
 GUIDELINES**

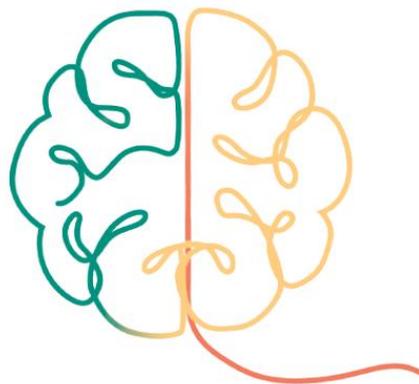


WHO  
 recommendations  
**non-clinical  
 interventions  
 to reduce  
 unnecessary  
 caesarean  
 sections**



**RISK REDUCTION  
 OF COGNITIVE DECLINE  
 AND DEMENTIA**

WHO GUIDELINES



**Child Maltreatment**



Worldwide,  
**1 in 4 adults** were  
 physically abused  
 as children.

**The Health Sector Responds**



WHO interim guidelines  
 for the treatment of  
 gambiense human African  
 trypanosomiasis

August 2019

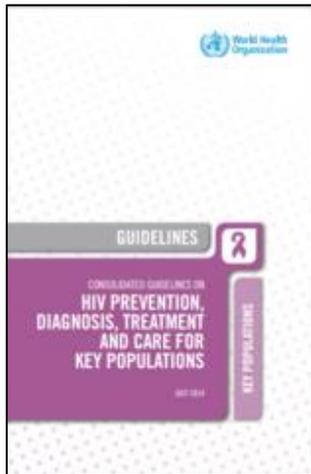


# Types of WHO guidelines

## Standard guideline

Full systematic review and guideline development process

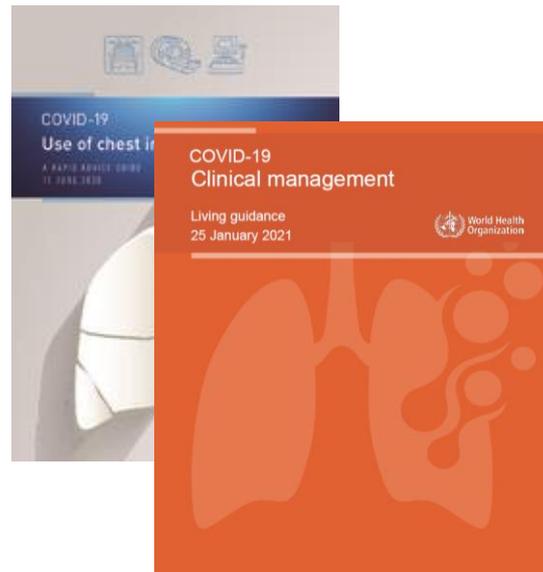
Timeframe: 6 months - 2 yrs



## Rapid advice guidelines

Compressed and abbreviated process in response to public health emergency

Timeframe: 1 - 3 months



## Emergency interim guidelines

Narrow scope, short shelf-life

Can be based on indirect evidence, existing WHO guidelines or expert opinion

Timeframe: days - weeks



# Guideline development process

Scope the guideline



Consider logic models

Consider all relevant evidence for decision-making

Set up guideline panel and external review group



Manage declarations of interest

Formulate questions and select outcomes

Approval - Proposal

Evidence retrieval, assessment, synthesis

Appraise certainty of the body of evidence

**GRADE**

**GRADE CERQual**

Formulate recommendations

Include explicit consideration of:

- Benefits and harms
- Resource use/feasibility
- Health equity/non-discrimination
- Human rights/sociocultural acceptability

Approval - guideline

Disseminate, implement

Evaluate impact

GRC Secretariat support



# Contributors to WHO guidelines

## WHO Steering Group

- **Support** development of recommendations by the GDG

## Guideline Development Group

- **Formulate** recommendations; approve the final guideline
- COI assessed and managed
- Participate as individuals; do not represent institutions
- Balanced in terms of gender, geographically, and perspective

## Guideline methodologists

- **Help** the GDG to develop recommendations

## Other

- Meeting Observers
- External review team
- Systematic review team



# Declaration of interests (Dols) of external contributors

## WHO revised policy in 2014

- Employment, consulting
- Research support
- Investment interests
- Intellectual property
- Intellectual interests
- Public statements and positions

## Public comment period

(biographies posted for 14 days)

Internet search (due diligence)

## Dols required from

- The Guideline Development Group
- The Methodologist
- The Evidence Review Team



# Evidence retrieval, assessment and synthesis and formulation of recommendations

*A common, sensible, transparent approach to establishing  
1) quality of evidence and 2) strength of recommendations.”*

The logo for GRADE (Grading of Recommendations Assessment, Development and Evaluation) consists of the word "GRADE" in a bold, red, sans-serif font, enclosed within a red rectangular border with rounded corners.

Welcome to the GRADE working group

From evidence to recommendations – transparent and sensible

# Certainty of evidence

Certainty of evidence based on assessment of:

1. limitations in detailed design and execution (*risk of bias criteria*)
2. Inconsistency (*or heterogeneity*)
3. Indirectness (*PICO and applicability*)
4. Imprecision (*number of events and confidence intervals*)
5. Publication bias

3 factors can increase quality

1. Large magnitude of effect
2. All plausible residual confounding may be working to reduce the demonstrated effect or increase the effect if no effect was observed
3. Dose-response gradient

# Strength of a recommendation

“The strength of a recommendation reflects the extent to which we can, across the range of patients for whom the recommendations are intended, be confident that desirable effects of a management strategy outweigh undesirable effects.”

**Strong recommendations:** the desired consequences of adherence most likely outweigh potential undesired ones.

**Conditional recommendations:** the panel is less confident with regard to their judgement.

# Implications

## Implications of a strong recommendation

Most people in the situation would want the recommended course of action and only a small proportion would not

## Implications of a conditional recommendation

The majority of people in your situation would want the recommended course of action, but many would not.  
Requires shared decision-making and involvement of stakeholders

# Factors affecting the strength of recommendations

- **Balance between benefits and harms**
  - The larger the relative benefit the more likely a strong recommendation
- **Certainty of the evidence**
  - Higher certainty (quality) evidence more likely to result in a strong recommendation
- **Values and preferences**
  - Decisions for which patient preferences or values are highly important or uncertain more likely to be graded as weak
- **Costs and resource allocation**
  - More costly/less cost-effective interventions less likely to receive a strong grade
- **Other factors**
  - Equity (how would recommendation impact equity)
  - Acceptability
  - Feasibility/ease of implementation

# Uptake of recommendations

## Adoption of recommendations across 44 guidelines in 20 countries

Strong: 82%  
Conditional: 61%



ELSEVIER

Journal of Clinical Epidemiology (2015)

Journal of  
Clinical  
Epidemiology

### BRIEF REPORT

#### Strength of recommendations in WHO guidelines using GRADE was associated with uptake in national policy

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#### Abstract

**Objective:** This study assesses the extent to which the strength of a recommendation in a World Health Organization (WHO) guideline affects uptake of the recommendation in national guidelines.

**Study Design and Setting:** The uptake of recommendations included in HIV and TB guidelines issued by WHO from 2009 to 2013 was assessed across guidelines from 20 low- and middle-income countries in Africa and Southeast Asia. Associations between characteristics of recommendations (strength, quality of the evidence, type) and uptake were assessed using logistic regression.

**Results:** Eight WHO guidelines consisting of 109 strong recommendations and 40 conditional recommendations were included, and uptake assessed across 44 national guidelines (1,255 recommendations) from 20 countries. Uptake of WHO recommendations in national guidelines was 82% for strong recommendations and 61% for conditional recommendations. The odds of uptake comparing strong recommendations and conditional recommendations was 1.9 (95% confidence interval: 1.4, 2.7), after adjustment for quality of evidence. Higher levels of evidence quality were associated with greater uptake, independent of recommendation strength.

**Conclusion:** Guideline developers should be confident that conditional recommendations are frequently adopted. The fact that strong recommendations are more frequently adopted than conditional recommendations underscores the importance of ensuring that such recommendations are justified. © 2015 Published by Elsevier Inc.

**Keywords:** GRADE; Guidelines; Quality; Strength; Uptake; World Health Organization

#### 1. Introduction

Guidelines issued by the World Health Organization (WHO) aim to help policy makers, health care providers, and patients make evidence-informed decisions [1].

Although global in intent, WHO guidelines are primarily focused on the needs and resources of low- and middle-income countries, where they are often used to develop national guidelines. The potential impact of WHO recommendations is far reaching, including influencing individual clinician practice, health service organization, the procurement policies of international donors, and potentially the global demand for health technologies.

WHO adopted the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) [2] system in January 2009 to support the formulation of evidence-based recommendations. Since that time, there has been a steady increase in the number of recommendations issued by WHO that are based on the GRADE approach [3–5].

Conflict of interest: S.M.U., P.C., and N.F. work for the World Health Organization. None of the authors have any conflict of interest to disclose.

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Disclaimer: Views expressed in this article are those of the authors and do not necessarily represent the views of the World Health Organization.

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0950-4230/2015 Published by Elsevier Inc.



# Rules of Procedure: Group decision making

## 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, Chair's discretion

# 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

## Implementation consideration

## Research priority

## Supported by:

### GRADE Evidence profile

Quality assessment of the body of evidence.

### Evidence to decision framework

Strength assessment of the recommendation.



# Summary: 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

