

Principles for Meta-guideline - Guideline-for-Guidelines (GFG)

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Purpose & scope

This document 1) lists principles to follow for developing and maintaining a guideline, including meta-guidelines - guidelines for guidelines (GFG) - and 2) illustrates their implementation according to the roles and responsibilities of the responsible organization and various panels established by that organization. The identified panels are illustrative; not normative. They are the guideline 1) management panel, 2) drafting panel, 3) review panel and 4) publication panel. The use of multiple panels serves not only to distribute workload but also to assure the quality of a guideline. Panels may have overlapping members.

Principles

1. Transparency

- 1.1 Publish relevant information about 1) the responsible organization and 2) the group developing and maintaining the guideline; in such terms as type of organization, management structure, sources of funding, etc.
- 1.2 Allow input at all aspects and relevant stages of a guideline's development and maintenance ("guideline effort").
- 1.3 Describe, and publish information regarding guideline effort, including 1) relevant policies and procedures (P&P), 2) priority setting processes, and 3) guideline development and revision methods.
- 1.4 Conduct guideline effort according to published priorities, P&P, methods, criteria, etc.
- 1.5 Establish and publish guiding ethical principles and/or code of conduct for guideline panel members.
- 1.6 Make guideline available free-of-charge.

2. Need (for guideline)

- 2.1 Build on what exists; don't duplicate.
- 2.2 Use a structured process to identify or to establish the need or a rationale for a proposed guideline; includes, if applicable, a map of the domain in which the guidelines fits, evidence of what exists, and, consequently, the gap to be filled.
- 2.3 Describe the purpose, scope, and audience for a guideline.
- 2.4 Describe why the responsible organization 1) is appropriate for the task of developing and maintaining the proposed guideline and 2) has sufficient authority to promote and to facilitate its adoption.
- 2.5 Where applicable, develop a guideline in concert with other entities, eg, to increase the resultant guideline's "authority."

3. Openness

- 3.1 Establish appropriate structure for managing guideline effort; see following descriptions of illustrative roles and responsibilities.
- 3.2 For each panel (work group, task force, etc), create and publish a written charter, eg, to describe its purpose, role, membership, and ways of working.
- 3.3 Use, and publish, explicit criteria for identifying experts, establishing expertise, and selecting

- experts to panels; includes criteria for criteria.
- 3.4 Select members to panels using an explicit mechanism; publish a description of such mechanism. Panels may have separate or overlapping members. Members should serve for the duration of the project, or, if a continuing process, set terms that permit rotation of members.
 - 3.5 Define "expert" broadly to encompass all relevant perspectives.
 - 3.6 Ask members of panels to disclose their interests relevant to a guideline effort; the responsible organization should review these statements and identify potential conflicts.
 - 3.7 Publish guideline panel members 1) name and affiliations and 2) their "statements of interest" and the responsible organization's review of such statement.

4. Standardization

- 4.1 Use systematic, structured, rigorous processes.
- 4.2 Define all key concepts used in a guideline (except if used in accordance with a dictionary definition); prefer, and refer to, "standard" (generally-accepted) definitions; explain any need to define a concept in a specific way.
- 4.3 Where they exist, use "standard" methods to complete each guideline development step; cite standards used, eg, name, version, and version date (and link to relevant documentation).
 - 4.3.1 If a generally-accepted or available standard method is inappropriate for the task, explain why; describe what changes to a standard method were necessary for the purpose.
 - 4.3.2 If a standard method proves to be inadequate or insufficient, communicate the insufficiency or deficiency to the responsible organization.
- 4.4 Develop guidelines' elements based on whatever scientific evidence exists; if none exists, state rationale, assumptions, etc; publish evidence and/or rationale as part of a guideline (including any guide to use).
- 4.5 Don't include confidential, proprietary, or trade-secret information in a guideline.
- 4.6 Solicit feedback on a proposed guideline. Dispose of each comment received; publish results, including item-by-item dispositions.
- 4.7 Commit to reviewing periodically, and, if necessary revising (or, if no longer needed, retiring), each guideline developed.
- 4.8 Provide for "due process;" includes mechanisms to handle appeals of rejected comments, allegations of violations of P&P, processes, etc. Handle such appeals, allegations, etc expeditiously, according to published P&P.

5. Quality & safety

- 5.1 Develop a new guideline according to established standards, including GFG, to the extent possible; close any gap between GFG and the responsible organization's practices as quickly as possible.
- 5.2 Evolve any existing guideline to meet established standards, including GFG.
- 5.3 Consider explicitly expected benefits and risks of a guideline, including of its use in practice; publish resultant assessments as part of a guideline (including any guide to use).
- 5.4 Establish adequate quality assurance mechanisms.
- 5.5 Provide for continuous quality improvement; includes formal mechanisms to obtain feedback on 1) proposed guideline and its use in practice, 2) processes used to develop and to revise a guideline, 3) mechanisms to obtain feedback, 4) handling of appeals, allegations, etc.
- 5.6 Evaluate a guideline's utility to the intended audience and its impact within its domain, and, if applicable, more widely.



Roles & responsibilities

Assignment of roles and responsibilities to panels is only for purposes of illustration.

A. *Responsible organization*

- a. Establishes and publishes policies and procedures (P&P) and processes for the development, maintenance, and promotion of use of a guideline ("guideline effort").
- b. Supports guidelines effort; obtains funding, provides resources, etc.
- c. Manages mechanisms 1) to develop and to revise a guideline, 2) to obtain and to use feedback, and 3) to evaluate and to improve the responsible organization's guideline effort structure and processes.
- d. Adjudicates allegations regarding rejected comments, allegations of violations of P&P, processes, etc.
- e. Maintains and publishes "code of conduct" for panel members.
- f. Determines appeals of rulings on conflicts of interest.
- g. Establishes and monitors performance of guideline management panel; develops its charter.
- h. Acts as Secretariat for guideline effort, eg, to conduct literature reviews.
- i. Publishes guideline and any accompanying guide for use.
- j. Promotes use of guideline; includes implementing publication and marketing strategy, seeking endorsements for use of strategy, translating guideline into other languages, etc.
- k. Evaluates and reports guideline's effectiveness, in terms of its adoption, use in practice, and impact.

B. *Guideline management panel*

- a. Reviews and comments on the guideline panel charter.
- b. Manages development (or revision) of a guideline.
- c. Reviews evidence of need; decides if a proposed guideline is needed; specifies its purpose, scope, and audience.
- d. Develops the guideline development (or revision) management plan, templates, etc.
- e. Develops other guideline panels' charters.
- f. Establishes criteria for panel membership; describes identification and selection processes; selects experts meeting criteria to panels (including replacements). Panels may have overlapping memberships.
- g. Reviews statements of interest; decides if conflict exists.
- h. Adjudicates complaints, eg, that 1) panel members are not performing appropriately and 2) comments were not properly take into account.
- i. Monitors progress against plan; takes appropriate action to bring guideline effort on course (including, if appropriate, a recommendation to the responsible organization to abandon the effort).

C. *Guideline drafting panel (later, revision/ extension panel)*

- a. Reviews and comments on the drafting panel charter.
- b. For new guideline
 1. Reviews and comments on the guideline development management plan, templates, etc.
 2. Guides collection of information to start the guidelines development process; includes identification of existing guidelines, literature review, etc.
 3. Reviews 1) existing (and related) guidelines, 2) identified needs and concerns, and 3) other relevant information.

4. Produces an initial draft of a guideline; includes definitions of concepts.
- c. For guideline revisions/extensions
 1. Reviews and comments on the guidelines revision or extension plan, templates, etc.
 2. Guides collection of information; includes updated identification of existing guidelines, literature review, etc.
 3. Reviews 1) existing (and related) guidelines, 2) identified needs and concerns, and 3) other relevant information.
 4. Reviews feedback on and any evaluation data for current version of guideline.
 5. Produces an initial draft of a revision or extension of a guideline; includes definitions of concepts.

D. Guideline review panel

- a. Reviews and comments on the review panel charter
- b. Reviews, and, if necessary, revises drafting panel version of a guideline; may iterate versions.
- c. Describes and assesses potential benefits and risks of use of guidelines; adapts guidelines accordingly; describes benefits and risks, and potential mitigation strategies, eg, in accompanying guide for use.
- d. Drafts any necessary guide for use.
- e. Decides when version of a guideline is ready for "public" comment.

E. Guideline publication panel

- a. Reviews and comments on the publication panel charter
- b. Reviews comments and any other feedback received from the public.
- c. Finalizes guideline for pilot testing.
- d. Reviews results of pilot test; revises guideline accordingly.
- e. Finalizes any necessary guide for use.
- f. Determines when the guideline is ready for publication and use in practice.
- g. Decides when after publication a guideline should be reviewed (and, if necessary, revised).
- h. Develops guideline publication and marketing strategy.
- i. Develops guideline evaluation plan; includes measures of effectiveness, including those pertaining to 1) a guideline's adoption and use and 2) its impact.

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