Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

FEB 26 2021

ADMINISTRATIVE ORDER
No. 2021 - 0020

SUBJECT: Revised Guidelines on National Practice Guideline Development, Adoption and Dissemination

I. BACKGROUND

Practice guidelines are evidence-based recommendations used to optimize patient care by reducing inappropriate variations and ensuring efficient use of limited resources.

Standardizing the process of development, adoption, and dissemination is aimed at improving the overall availability of quality-assured practice guidelines.

The development of clinical care standards and the establishment of a mechanism for the development, adoption, and dissemination of practice guidelines are in line with the Department's mandate as the lead agency in ensuring the quality of health care through policy formulation, standards development, and regulations in accordance with Executive Order No. 102, s. 1999 and Sections 27.7 and 27.8 of Republic Act No. 11223, or the Universal Health Care Act.

The development of these guidelines, and the complementary Manual for National Practice Guideline (NPG) Development, were informed by a previous Advancing Health for Evidence Assisted Decision-making with Health Policy Systems Research project entitled, "Scoping of Current Practices in National Practice Guideline Development" in addition to operational issues encountered since the issuance of Administrative Order No. 2018-0019, "Guidelines on the Institutionalization and Implementation of the National Practice Guidelines Program."

II. OBJECTIVES

1. To set the operational framework for practice guideline development, adoption, and dissemination.
2. To update the standardized process of practice guideline prioritization, generation, appraisal and approval, dissemination, and monitoring and evaluation.

III. SCOPE OF APPLICATION

This Order shall apply to all DOH Central Office Bureaus and Services, DOH Centers for Health and Development, Ministry of Health-Bangsamoro Autonomous Region in

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Direct Line: 711-9502; 711-9503 Fax: 743-1829 • URL: http://www.doh.gov.ph; e-mail: fiduque@doh.gov.ph

Muslim Mindanao, DOH Hospitals and Treatment Rehabilitation Centers, DOH attached agencies, and all other public and private entities involved in practice guideline development including but not limited to health care providers, academe, researchers and research institutions, and professional societies.

IV. DEFINITION OF TERMS

The following terms are defined for the purpose of this Order:

A. Appraisal of Guidelines for Research & Evaluation II (AGREE II) - refers to an international tool used to assess the quality and reporting of practice guidelines

B. Appraisal of Guidelines for Research & Evaluation (AGREE) Reporting Checklist - refers to the reporting checklist to be complied with by Lead Practice Guideline (PG) Developers upon submission of their PGs for appraisal/review by the DOH

C. Conflict of Interest (COI) - refers to a set of situations that creates a risk that professional judgment or actions in relation to a primary interest are/may be unduly influenced by a secondary interest (IOM, 2011)

D. Grading of Recommendations, Assessment, Development and Evaluations (GRADE) - refers to "a transparent framework for developing and presenting summaries of evidence and provides a systematic approach for making clinical practice recommendations" (BMJ, 2020)

E. Health Technology Assessment (HTA) - refers to the systematic evaluation of properties, effects, or impact of health-related technologies, devices, medicines, vaccines, procedures, and all other health-related systems developed to solve a health problem, and improve the quality of lives and health outcomes, utilizing a multidisciplinary process to evaluate the clinical, economic, organizational, social, and ethical issues of a health intervention or health technology (RA 11223)

F. Interim National Practice Guidelines (Interim NPGs) - refer to DOH-endorsed National Practice Guidelines, standard treatment guidelines, evidence-based guidelines, or any equivalent standard that sets how individuals should be given care and meets the minimum requirement for the AGREE II domain of "Rigor of Development"

G. Manual for National Practice Guidelines Development - refers to handbook that sets the standards and prescribed methods set by the Department of Health on developing practice guidelines

H. National Practice Guideline Clearinghouse (NPG Clearinghouse) – an ad hoc panel or committee convened by the National Practice Guidelines Program to appraise a Practice Guideline and recommend on its endorsement by the DOH

I. National Practice Guidelines Program (NPGP) - previously referred to as the National Clinical Practice Guidelines Program

J. National Practice Guidelines (NPGs) - refer to DOH-endorsed National Practice Guidelines, standard treatment guidelines, evidence-based guidelines, or any equivalent standard that sets how individuals should be given care and that meets all quality requirements as stipulated in AGREE II

K. Practice guidelines (PGs) - refer to National Practice Guidelines, standard treatment guidelines, evidence-based guidelines, or any equivalent standard that sets how individuals should be given care, regardless of the care provider (ex. clinician or barangay health worker), the setting (clinical or community), or the care component being addressed (ex. screening, diagnosis, treatment, etc.). These consist of recommendations that are intended to optimize patient care, and are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options (IOM, 2011)

L. Rigor of Development - relates to the process used to gather and synthesize the evidence, the methods to formulate the recommendations, and to update them.

V. GENERAL GUIDELINES

A. To maximize the utility of PGs, the NPGP shall ensure that processes for PG development are responsive to the information needs of clinicians, other health care providers in non-clinical settings, DOH units, and PhilHealth while taking into consideration the patient's values and preferences in decision-making.

B. PGs for funding by the DOH shall be prioritized according to the needs of PhilHealth and the HTAU primarily in light of the need to expand PhilHealth benefit packages in support of Universal Health Care. Other criteria for prioritization shall be set by the NPGP as necessary in consultation with stakeholders, including DOH units and PhilHealth. These criteria shall be made known to the public for their guidance in applying for DOH funding.

C. PG generation shall adhere to the Manual for CPG Development (First Edition 2018) and its updates. In addition, apart from the full text/manuscript, pocket guides and laymanized versions of the PG shall also be developed by Lead PG Developers in collaboration with relevant units in the DOH.

D. PGs for endorsement by the Secretary of Health as NPGs must meet the quality standards as appraised by the National Practice Guideline Clearinghouse using AGREE II. PGs that do not meet all the quality standards but attain a minimum rating of "Satisfactory" for the domain "Rigor of Development" shall be endorsed as Interim National Practice Guidelines.

E. PGs that are endorsed as NPGs or Interim NPGs shall be used by healthcare providers, academe, and payers of healthcare (including the DOH and PhilHealth) to guide clinical practice, policy development, and benefit package development.

VI. SPECIFIC GUIDELINES

A. National Practice Guideline Governance Structure *(Refer to Annex I)*

1. The **National Practice Guideline Program** shall:

    a. be organized within the Disease Prevention and Control Bureau to oversee PG development in the Philippines, and to develop and periodically review and update the approaches, strategies, and processes to improve the quality, timeliness, or overall responsiveness of PG development (ex. adoption of 'living guidelines' approach, development of integrated care PGs, creation of additional committees or working groups as needed, etc.); and
    b. be the main coordinating body for PG development in the Philippines, and convene and provide administrative and technical support to the NPG Clearinghouse; engage, liaise with, or commission Lead PG Developers; and ensure involvement of relevant end-user units from the DOH and PhilHealth during the PG generation phase. This includes collaborating with the HTAU to ensure that information is shared between the two units and that outputs, evidence used, and recommendations are consistent.

2. The **National Practice Guideline Clearinghouse** shall:

    a. be convened by the NPGP for each PG that has been endorsed for the Clearinghouse's appraisal;
    b. ensure that PGs approved by the Secretary of Health meet the minimum quality standards using AGREE II; and
    c. be composed of one (1) DOH representative, two (2) content experts, and two (2) methodologists.

3. The **Lead PG Developer** shall:

    a. be the overall technical lead in PG development that convenes the working groups, namely the Consensus Panel and Evidence Review Experts;
    b. finalize the scope, research questions, and target users of the PG to be developed;
    c. preferably be trained and experienced in PG development and/or Evidence-Based Medicine;
    d. preferably be affiliated with an agency or institution that can provide adequate administrative and additional technical support;
    e. be a DOH Program Manager, content expert, methods expert, or any combination of the three, or representatives of medical societies or other stakeholder institutions;
    f. form a project team that has adequate project management, data management and analysis, and medical writing skills;
    g. be free from potential intellectual and financial COIs that are relevant to the content of the PG;
    h. provide administrative and technical support to the project team;
    i. engage additional content and technical experts as necessary; and
    j. collect, assess, and manage COIs.

4. The **Consensus Panel** shall:

    a. prioritize outcome measures, review evidence summaries, and draft and vote on recommendations; and
    b. be composed of 10-15 multi-sectoral representatives from health care providers (specialists, generalists, primary care providers); patients and/or patient advocates (at least 1); methodologists (at least 1) such as evidence-based practitioners, clinical epidemiologists, and economists; and other DOH representatives (at least 1) whose practice may be affected by the guidelines, who can influence the uptake of PG recommendations, or whose work would require information that can be obtained through the PG generation process (ex. costs of services for PhilHealth, service flow for HFDB).

5. The **Evidence Review Experts** shall:

    a. conduct the review of existing PGs, create evidence summaries, and formulate evidence-based draft recommendations; and
    b. include at least one (1) PG/GRADE methods expert, one (1) clinical epidemiologist or evidence-based practitioner, and one (1) biostatistician.

B. Management of Conflicts of Interest

1. Declaration and management of conflicts of interest shall be mandatory for all groups and persons involved in PG development, and shall primarily be led by Lead PG developers and overseen by the NPGP.
2. All stakeholders involved in PG development shall comply with the guidance provided in the Manual for National Practice Guideline Development (First Edition 2018) and its updates or forthcoming DOH guidelines on management of COIs.
3. All PGs submitted by Lead PG Developers shall undergo an assessment of COI as part of the PG appraisal process. PGs that are rated unfavorably for the domain "Editorial Independence" of AGREE II shall be recommended for disapproval and shall not be endorsed by the DOH.
4. To ensure a clear delineation between the PG generation and review processes, an individual that participates in the PG generation shall not participate in the review process (as a member of the NPG Clearinghouse) and vice versa.

C. Practice Guideline Appraisal and Approval

1. PG manuscripts submitted to the NPGP for documentary review shall adhere to the reporting criteria listed in the most updated version of the AGREE Reporting Checklist available at https://tinyurl.com/AGREEReportingChecklist prior to endorsement to the NPG Clearinghouse for appraisal. **(Annex II)**
    a. For consideration as National Practice Guidelines, submissions shall be 100% compliant with reporting requirements for all domains.
    b. For consideration as Interim National Practice Guidelines, submissions shall be 100% compliant with reporting requirements for Domain 3: Rigor of Development.

2. The NPG Clearinghouse shall appraise PG manuscripts with the AGREE II tool. PG approval requires 4 out of 5 favorable ratings by the NPGC. A minimum rating of 75% for all domains is required for an overall favorable rating.
3. DOH-endorsed PGs (whether Interim NPGs or NPGs) must at least maintain their favorable ratings to be continually recognized as DOH-endorsed PGs. Appraisals shall be done in accordance with the schedule/plan for updating of such PGs.
4. Updating requirements and specific guidelines on the appraisal, approval, and appeal processes shall be developed and specified by the NPGP.

D. Practice Guideline Dissemination

1. The NPGP shall ensure that there is a dissemination plan for DOH-endorsed PGs and shall keep a repository of DOH-endorsed PGs.
2. DOH-endorsed PGs shall be made publicly available and accessible through, but not limited to, DOH web-based platforms.
3. Apart from the PGs (full text, pocket guide, and laymanized versions), results of the appraisal by the NPGP shall be made publicly available for the guidance and information of end-users.

E. Monitoring and Evaluation

1. Monitoring and evaluation of PG development, adoption, and dissemination shall be led by the NPGP in collaboration with Lead PG Developers. Lead PG Developers shall identify key quality of care indicators to be monitored for each PG.
2. Monitoring and evaluation shall be done based on the logical framework to be developed by the NPGP in consultation with stakeholders.

VII. ROLES AND RESPONSIBILITIES

A. **Disease Prevention and Control Bureau** shall:

1. establish a functional NPGP with adequate technical and administrative support that is independent of other program management functions of the Bureau;
2. develop internal capacity for PG development among its Program Managers, apart from the NPGP, to encourage their participation as Lead PG Developers;
3. through the NPGP, ensure the development of the NPGP's logical framework and the operational guidelines for PG prioritization, reviews/appraisals, dissemination, and monitoring and evaluation; updating of the Manual for CPG Development; and the implementation of the NPGP's activities; and
4. secure financing for priority PGs for development.

B. **Health Policy Development and Planning Bureau** shall provide technical assistance to the NPGP as needed.

C. **Health Technology Assessment Unit, Health Facilities Development Bureau, and the Health Human Resource Development Bureau** shall:

1. participate in the PG prioritization and generation process;

2. utilize NPGs/Interim NPGs in health technology assessments, competency framework development, resource and service flow identification, and other program or policy development (ex. service package development, clinical pathway development, etc.);
3. contribute toward efforts at dissemination; ensuring utilization of PGs among non-DOH stakeholders; and monitoring and evaluation activities of the PG; and
4. provide supplemental funding for PG guideline development.

D. **Philippine Health Insurance Corporation** shall:

1. conduct their own prioritization of PGs that need to be developed in line with its plan for benefit package development that is aligned with the UHC Act;
2. participate in the PG prioritization and generation process;
3. use NPGs/Interim NPGs only in its benefit package development (including costing);
4. contribute toward efforts at dissemination; ensuring utilization of PGs among non-DOH stakeholders; and monitoring and evaluation activities of the PG; and
5. provide supplemental funding for PG guideline development.

E. **Lead PG Developers** shall:

1. comply with the requirements for PG appraisal as identified in the AGREE Reporting Checklist;
2. comply with COI policies stipulated in this issuance; and
3. develop internal capacity in their respective organizations/institutions/agencies for PG development.

VIII. REPEALING CLAUSE

This Order repeals Administrative Order No. 2018-0019, "Guidelines on the Institutionalization and Implementation of the National Practice Guidelines Program."

IX. SEPARABILITY CLAUSE

If any provision of this Order is declared unauthorized or rendered invalid by any court of law or competent authority, those provisions not affected thereby shall remain valid and effective.

X. EFFECTIVITY

This Order shall take effect fifteen (15) days after its publication in the Official Gazette or a newspaper of general circulation. Copies of this Order shall be filed with the U. P. Law Center - Office of the National Administrative Registrar.

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

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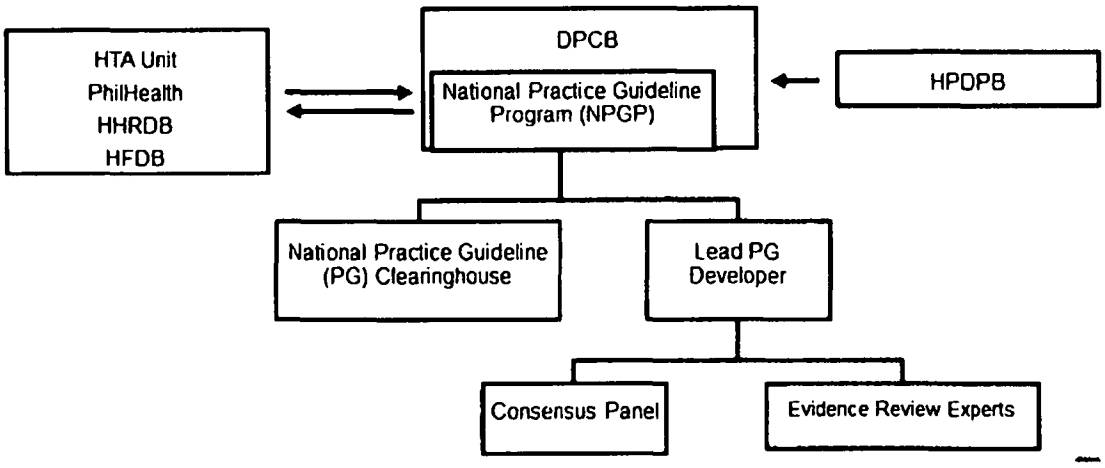
MAR 01 2021
CORAZON S. DELA CRUZ
KMITS - RECORDS SECTION
Department of Health

ANNEX I. Program Governance Structure and Responsibilities

Program Governance Structure and Responsibilities



ANNEX II. AGREE Reporting Checklist

AGREE

AGREE Reporting Checklist
2016

This checklist is intended to guide the reporting of clinical practice guidelines.

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
DOMAIN 1: SCOPE AND PURPOSE		
1. OBJECTIVES *Report the overall objective(s) of the guideline. The expected health benefits from the guideline are to be specific to the clinical problem or health topic.*	☐ Health intent(s) (i.e., prevention, screening, diagnosis, treatment, etc.) ☐ Expected benefit(s) or outcome(s) ☐ Target(s) (e.g., patient population, society)	
2. QUESTIONS *Report the health question(s) covered by the guideline, particularly for the key recommendations.*	☐ Target population ☐ Intervention(s) or exposure(s) ☐ Comparisons (if appropriate) ☐ Outcome(s) ☐ Health care setting or context	
3. POPULATION *Describe the population (i.e., patients, public, etc.) to whom the guideline is meant to apply.*	☐ Target population, sex and age ☐ Clinical condition (if relevant) ☐ Severity/stage of disease (if relevant) ☐ Comorbidities (if relevant) ☐ Excluded populations (if relevant)	
DOMAIN 2: STAKEHOLDER INVOLVEMENT		
4. GROUP MEMBERSHIP *Report all individuals who were involved in the development process. This may include members of the steering group, the research team involved in selecting and reviewing/rating the evidence and individuals involved in formulating the final recommendations.*	☐ Name of participant ☐ Discipline/content expertise (e.g., neurosurgeon, methodologist) ☐ Institution (e.g., St. Peter's hospital) ☐ Geographical location (e.g., Seattle, WA) ☐ A description of the member's role in the guideline development group	
5. TARGET POPULATION PREFERENCES AND VIEWS *Report how the views and preferences of the target population were sought/considered and what the resulting outcomes were.*	☐ Statement of type of strategy used to capture patients'/publics' views and preferences (e.g., participation in the guideline development group, literature review of values and preferences) ☐ Methods by which preferences and views were sought (e.g., evidence from literature, surveys, focus groups) ☐ Outcomes/information gathered on patient/public information ☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations	
6. TARGET USERS *Report the target (or intended) users of the guideline.*	☐ The intended guideline audience (e.g. specialists, family physicians, patients, clinical or institutional leaders/administrators) ☐ How the guideline may be used by its target audience (e.g., to inform clinical decisions, to inform policy, to inform standards of care)	

DOMAIN 3: RIGOUR OF DEVELOPMENT		
7. SEARCH METHODS *Report details of the strategy used to search for evidence.*	☐ Named electronic database(s) or evidence source(s) where the search was performed (e.g., MEDLINE, EMBASE, PsychINFO, CINAHL) ☐ Time periods searched (e.g., January 1, 2004 to March 31, 2008) ☐ Search terms used (e.g., text words, indexing terms, subheadings) ☐ Full search strategy included (e.g., possibly located in appendix)	
8. EVIDENCE SELECTION CRITERIA *Report the criteria used to select (i.e., include and exclude) the evidence. Provide rationale, where appropriate.*	☐ Target population (patient, public, etc.) characteristics ☐ Study design ☐ Comparisons (if relevant) ☐ Outcomes ☐ Language (if relevant) ☐ Context (if relevant)	
9. STRENGTHS & LIMITATIONS OF THE EVIDENCE *Describe the strengths and limitations of the evidence. Consider from the perspective of the individual studies and the body of evidence aggregated across all the studies. Tools exist that can facilitate the reporting of this concept.*	☐ Study design(s) included in body of evidence ☐ Study methodology limitations (sampling, blinding, allocation concealment, analytical methods) ☐ Appropriateness/relevance of primary and secondary outcomes considered ☐ Consistency of results across studies ☐ Direction of results across studies ☐ Magnitude of benefit versus magnitude of harm ☐ Applicability to practice context	
10. FORMULATION OF RECOMMENDATIONS *Describe the methods used to formulate the recommendations and how final decisions were reached. Specify any areas of disagreement and the methods used to resolve them.*	☐ Recommendation development process (e.g., steps used in modified Delphi technique, voting procedures that were considered) ☐ Outcomes of the recommendation development process (e.g., extent to which consensus was reached using modified Delphi technique, outcome of voting procedures) ☐ How the process influenced the recommendations (e.g., results of Delphi technique influence final recommendation, alignment with recommendations and the final vote)	
11. CONSIDERATION OF BENEFITS AND HARMS *Report the health benefits, side effects, and risks that were considered when formulating the recommendations.*	☐ Supporting data and report of benefits ☐ Supporting data and report of harms/side effects/risks ☐ Reporting of the balance/trade-off between benefits and harms/side effects/risks ☐ Recommendations reflect considerations of both benefits and harms/side effects/risks	
12. LINK BETWEEN RECOMMENDATIONS AND EVIDENCE *Describe the explicit link between the recommendations and the evidence on which they are based.*	☐ How the guideline development group linked and used the evidence to inform recommendations ☐ Link between each recommendation and key evidence (text description and/or reference list) ☐ Link between recommendations and evidence summaries and/or evidence tables in the results section of the guideline	

13. EXTERNAL REVIEW *Report the methodology used to conduct the external review.*	☐ Purpose and intent of the external review (e.g., to improve quality, gather feedback on draft recommendations, assess applicability and feasibility, disseminate evidence) ☐ Methods taken to undertake the external review (e.g., rating scale, open-ended questions) ☐ Description of the external reviewers (e.g., number, type of reviewers, affiliations) ☐ Outcomes/information gathered from the external review (e.g., summary of key findings) ☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations (e.g., guideline panel considered results of review in forming final recommendations)	
14. UPDATING PROCEDURE *Describe the procedure for updating the guideline.*	☐ A statement that the guideline will be updated ☐ Explicit time interval or explicit criteria to guide decisions about when an update will occur ☐ Methodology for the updating procedure	
DOMAIN 4: CLARITY OF PRESENTATION		
15. SPECIFIC AND UNAMBIGUOUS RECOMMENDATIONS *Describe which options are appropriate in which situations and in which population groups, as informed by the body of evidence.*	☐ A statement of the recommended action ☐ Intent or purpose of the recommended action (e.g., to improve quality of life, to decrease side effects) ☐ Relevant population (e.g., patients, public) ☐ Caveats or qualifying statements, if relevant (e.g., patients or conditions for whom the recommendations would not apply) ☐ If there is uncertainty about the best care option(s), the uncertainty should be stated in the guideline	
16. MANAGEMENT OPTIONS *Describe the different options for managing the condition or health issue.*	☐ Description of management options ☐ Population or clinical situation most appropriate to each option	
17. IDENTIFIABLE KEY RECOMMENDATIONS *Present the key recommendations so that they are easy to identify.*	☐ Recommendations in a summarized box, typed in bold, underlined, or presented as flow charts or algorithms ☐ Specific recommendations grouped together in one section	
DOMAIN 5: APPLICABILITY		
18. FACILITATORS AND BARRIERS TO APPLICATION *Describe the facilitators and barriers to the guideline's application.*	☐ Types of facilitators and barriers that were considered ☐ Methods by which information regarding the facilitators and barriers to implementing recommendations were sought (e.g., feedback from key stakeholders, pilot testing of guidelines before widespread implementation) ☐ Information/description of the types of facilitators and barriers that emerged from the inquiry (e.g., practitioners have the skills to deliver the recommended care, sufficient equipment is not available to ensure all eligible members of the	

	population receive mammography) ☐ How the information influenced the guideline development process and/or formation of the recommendations	
19. IMPLEMENTATION ADVICE/TOOLS *Provide advice and/or tools on how the recommendations can be applied in practice.*	☐ Additional materials to support the implementation of the guideline in practice. For example: o Guideline summary documents o Links to check lists, algorithms o Links to how-to manuals o Solutions linked to barrier analysis (see Item 18) o Tools to capitalize on guideline facilitators (see Item 18) o Outcome of pilot test and lessons learned	
20. RESOURCE IMPLICATIONS *Describe any potential resource implications of applying the recommendations.*	☐ Types of cost information that were considered (e.g., economic evaluations, drug acquisition costs) ☐ Methods by which the cost information was sought (e.g., a health economist was part of the guideline development panel, use of health technology assessments for specific drugs, etc.) ☐ Information/description of the cost information that emerged from the inquiry (e.g., specific drug acquisition costs per treatment course) ☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations	
21. MONITORING/ AUDITING CRITERIA *Provide monitoring and/or auditing criteria to measure the application of guideline recommendations.*	☐ Criteria to assess guideline implementation or adherence to recommendations ☐ Criteria for assessing impact of implementing the recommendations ☐ Advice on the frequency and interval of measurement ☐ Operational definitions of how the criteria should be measured	
DOMAIN 6: EDITORIAL INDEPENDENCE		
22. FUNDING BODY *Report the funding body's influence on the content of the guideline.*	☐ The name of the funding body or source of funding (or explicit statement of no funding) ☐ A statement that the funding body did not influence the content of the guideline	
23. COMPETING INTERESTS *Provide an explicit statement that all group members have declared whether they have any competing interests.*	☐ Types of competing interests considered ☐ Methods by which potential competing interests were sought ☐ A description of the competing interests ☐ How the competing interests influenced the guideline process and development of recommendations	

From:
Brouwers MC, Kerkvliet K, Spithoff K, on behalf of the AGREE Next Steps Consortium. The AGREE Reporting Checklist: a tool to improve reporting of clinical practice guidelines. *BMJ* 2016;352:i1152. doi: 10.1136/bmj.i1152.

For more information about the AGREE Reporting Checklist, please visit the AGREE Enterprise website at www.agreetrust.org.