

TRANSFORMING NURSING THROUGH KNOWLEDGE

Best Practices for Guideline Development,
Implementation Science, and Evaluation



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**GUIDELINE DEVELOPMENT:
FIRST PILLAR FOR SUCCESS**

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THE ANATOMY OF A RIGOROUS BEST PRACTICE GUIDELINE DEVELOPMENT PROCESS

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LEARNING OBJECTIVES

After reading this chapter, you will be able to:

- Understand the evolution of Best Practice Guidelines as useful knowledge tools in the delivery of evidence-based care
- Outline the qualities of an effective guideline, according to international guideline-development standards
- Describe the seven steps of RNAO's BPG development process and why each is important
- Discuss the elements of a systematic review that contribute to guideline rigor
- Determine the components of RNAO's BPG development process that serve to reduce bias
- Appreciate enhancements used and planned in the RNAO BPG development methodology, including application of GRADE frameworks

INTRODUCTION

This chapter describes the Registered Nurses' Association of Ontario's (RNAO) guideline development process, a pillar of the Best Practice Guideline (BPG) Program, which was introduced and described in Chapter 1. The process is delineated using RNAO's seven steps of rigorous guideline development, which adhere to international standards, and is depicted in Figure 2.1.

Included is a detailed overview of each step, with special emphasis on evidence synthesis through systematic reviews of peer-reviewed literature and the modified-Delphi consensus process used with the Expert Panel to refine evidence-based recommendations. The chapter outlines RNAO's emerging work in aligning methodologies with GRADE (Grading of Recommendations Assessment, Development and Evaluation), to evaluate the quality of evidence and strength of recommendations. RNAO's approach to ongoing process and outcome evaluation and continuous quality improvement with guideline development methods is also highlighted. The chapter provides answers to key challenges in guideline development such as timelines, resources, updating cycles, and engaging experts in effective and efficient processes to achieve maximum results.

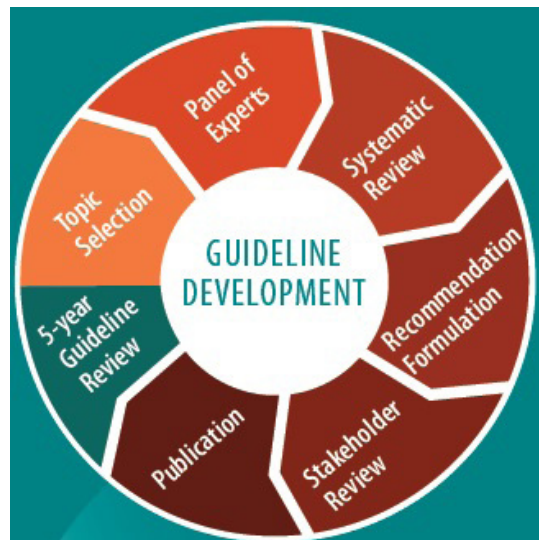


FIGURE 2.1 The guideline development pillar of the BPG Program showing steps in RNAO's BPG development process.

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BEST PRACTICE GUIDELINES: WHY?

The importance of robust evidence-based clinical practice guidelines cannot be overestimated. Globally, governments and clinicians are aiming to improve healthcare and optimize outcomes through initiatives that support evidence-based clinical care. Despite this laudable goal, variations in clinical practice first described by Wennberg and Gittelsohn (1973, 1982) continue, and so do the problematic results (Institute of Medicine [IOM], 2011; Grinspun, Melnyk, & Fineout-Overholt, 2014; Melnyk et al., 2012). Yet, patients trust and rely on healthcare providers for quality care and assume that those providers have the knowledge and expertise to make the best health-related decisions.

An important tool to respond to this challenge is the availability, uptake, and consistent utilization of clinical practice guidelines and rigorously developed evidence-based recommendations. These

guidelines aid healthcare providers, often faced with difficult decisions, overwhelming evidence, and considerable uncertainty, to make informed clinical decisions when treating patients. Best Practice Guidelines can aid clinicians and patients to determine the best options for a particular disease, condition, or health issue. Trustworthy guidelines are developed with the intent to improve healthcare quality while bolstering clinical, financial, and organization outcomes.

SCIENCE OF GUIDELINE DEVELOPMENT: SETTING THE STANDARDS

Previous approaches to guideline development focused on tradition (i.e., “we have always done it this way”) or authority (i.e., the most senior or well-respected physician) (AGREE Collaboration, 2003). Today, guidelines are based on an appraisal of current evidence, resulting in statements (derived by consensus) on best practices in healthcare. In 2011, the Institute of Medicine (IOM) reported that the Guidelines International Network database held more than 3,700 clinical practice guidelines from 39 countries, with an additional 2,700 guidelines in the National Guideline Clearinghouse (NGC), part of the Agency for Healthcare Research and Quality (AHRQ) (IOM, 2011a). The large number of available clinical practice guidelines challenges users, including practitioners, to determine which guidelines are of high quality. The positive or negative impact of implementing guidelines may vary significantly based on their quality. Guidelines developed using evidence on benefits and harms of treatments or interventions have the potential to improve healthcare and health outcomes and decrease morbidity and mortality (Grimshaw et al., 2004; Melnyk et al., 2012). Low-quality guidelines may cause harm to patients and should be carefully appraised for validity and reliability of their information and supporting evidence (Shekelle et al., 2000).

This increase in the number of guideline developers, the inconsistencies in the methodology, and the variable quality of recommendations made it apparent that a set of standards was needed to strengthen trust in the guideline development process, the guidelines developed, and the outcomes associated with their implementation. Guideline users needed a mechanism to identify high-quality, trustworthy clinical practice guidelines to support health-related decision-making that enhanced healthcare quality and outcomes. Thus, guideline-development standards would help developers to create reliable guidelines that improve decision-making, quality, and outcomes.

TRUSTWORTHY GUIDELINES

In 2008, the IOM entered into a contract with the Secretary of the Department of Health and Human Services to identify “the best methods used in developing clinical practice guidelines [in order] to ensure that organizations developing such guidelines have information on approaches that are objective, scientifically valid, and consistent” (Institute of Medicine, 2011b, p.1/para. 2). The resulting IOM (2011) report, *Clinical Practice Guidelines We Can Trust*, provided a revised definition of an evidence-based clinical practice guideline, including recommendations on what a guideline should entail, and eight standards for guideline development. The IOM recommendations for trustworthy guidelines included (2011a) that they should:

- Be based on a systematic review of the existing evidence
- Be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups
- Consider important patient subgroups and patient preferences, as appropriate
- Be based on an explicit and transparent process that minimizes distortions, biases, and conflicts of interest
- Provide a clear explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of recommendations and
- Be reconsidered and revised as appropriate when important new evidence warrants modification of recommendations

The eight standards for trustworthy guidelines proposed by the committee that were derived from these recommendations addressed the following (IOM, 2011a):

- Transparency
- Management of conflict of interest
- Guideline development group composition
- Clinical practice guideline–systematic review intersection
- Establishing evidence foundations for and rating strength of recommendations
- Articulation of recommendations
- External review
- Updating

More information on these standards is available from the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine (formerly the IOM), <http://www.nationalacademies.org/hmd/>.

GUIDELINES 2.0

The findings of the IOM resulting in the Standards for Trustworthy Guidelines (2011), as well as many other reviews of guideline development methods, highlighted the need for a systematic review and documentation of the diverse processes for guideline development available to organizations (Qaseem et al., 2012; Schünemann et al., 2007; Woolf et al., 2012). Although many manuals for single organizations are available as a complement to the eight IOM standards, a comprehensive list of items to consider related to each of the standards on an international scale was not available. The Guideline International Network (GIN) Working Group systematically compiled and made available a comprehensive checklist of items and a portal for related resources for guideline developers to consider for all stages of the guideline enterprise (Schünemann et al., 2013). The result of this work, entitled Guidelines 2.0, was a comprehensive, 18-point list of topics to consider during development of guidelines (AGREE Collaboration, 2003), outlined on the following page:

1. Organization, Budget, Planning, and Training
2. Priority Setting
3. Guideline Group Membership
4. Establishing Guideline Group Processes
5. Identifying Target Audience and Topic Selection
6. Consumer and Stakeholder Involvement
7. Conflict of Interest Considerations
8. (PICO) Question Generation
9. Considering Importance of Outcomes and Interventions, Values, Preferences and Utilities
10. Deciding What Evidence to Include and Searching for Evidence
11. Summarizing Evidence and Considering Additional Information
12. Judging Quality, Strength, or Certainty of a Body of Evidence
13. Developing Recommendations and Determining Their Strength
14. Wording of Recommendations and of Considerations of Implementation, Feasibility, and Equity
15. Reporting and Peer Review
16. Dissemination and Implementation
17. Evaluation and Use
18. Updating

Consideration of these 18 topics is crucial when developing trustworthy guidelines, as well as when such guidelines are being implemented and/or evaluated.

HOW TO KNOW WHICH GUIDELINES ARE TRUSTWORTHY: APPRAISAL OF GUIDELINES

This section outlines the various tools developed to help one determine whether the proposed guidelines are trustworthy or not. It covers the AGREE II and NEATS tools.

AGREE II

The AGREE (Appraisal of Guidelines Research and Evaluation) tool was published in 2003 by a group of international guideline developers and researchers, the AGREE Collaboration. The AGREE Collaboration (2003) defined quality of guidelines as the confidence that the potential biases of guideline development have been addressed adequately and that the recommendations are both internally and externally valid, and are feasible for practice. The guideline appraisal process to determine quality includes judgments about the methods used for developing the guidelines, the components of the final recommendations, and the factors associated with implementation.

Common to many new assessment tools, ongoing development was required to improve its measurement properties, usefulness to a range of stakeholders, and ease of usage. The original four-point response scale for each item of the AGREE instrument did not comply with methodological standards of health measurement design. This noncompliance threatened the performance and reliability of the instrument (National Guidelines Clearinghouse, n.d.). Data on the usefulness of the AGREE items were not systematically obtained from different groups of users. As a result of these shortfalls, the tool was subsequently revised and tested for reliability and validity. It now comprises 23 items organized into the original six quality domains (Brouwers et al., 2010), which are addressed more fully in following sections.

One of the most significant changes in the AGREE II appraisal tool is inclusion of the statement “strengths and limitations of the body of evidence are clearly described” (Brouwers et al., 2010, p. 2) as a measurement item in the rigour of development domain. The domain of editorial independence was strengthened to encourage that the content of the guideline not be influenced by funding sources. Conflict of interest (COI) must be recorded and clearly addressed during the guideline development process.

The 23-item tool comprises six guideline quality-related domains (Brouwers et al., 2010):

- **Domain 1**—Scope and Purpose is concerned with the overall aim of the guideline, the specific health questions, and the target population (items 1–3).
- **Domain 2**—Stakeholder Involvement focuses on the extent to which the guideline was developed by the appropriate stakeholders and represents the views of its intended users (items 4–6).
- **Domain 3**—Rigour of Development relates to the process used to gather and synthesize the evidence as well as the methods to formulate the recommendations and to update them (items 7–14).
- **Domain 4**—Clarity of Presentation deals with the language, structure, and format of the guideline (items 15–17).
- **Domain 5**—Applicability pertains to the likely barriers and facilitators to implementation, strategies to improve uptake, and resource implications of applying the guideline (items 18–21).
- **Domain 6**—Editorial Independence is concerned with the formulation of recommendations not unduly biased with competing interests (items 22–23).



What are some of the advantages of having and using international standards for guideline development, and why is this important?

Overall assessment includes the rating of the overall quality of the guideline and whether the guideline would be recommended for use in practice.

The AGREE II instrument is recognized as an international tool for the assessment of guidelines. A 10-year revision cycle was determined and updates were completed on September 2013; they did not result in further changes to the tool. Other AGREE appraisal tools and checklists have been created and will be discussed further in the section on aligning rigorous processes of evidence synthesis.

NEATS

The NGC has created a global repository for guidelines, and to ensure that only trustworthy and credible guidelines are housed within the repository, NGC aligned its inclusion criteria with IOM and GIN 2.0 standards. All submitted guidelines must include a systematic review published within the last 5 years. The guideline assessment results are posted on the NGC's website. For the purpose of assessing guidelines against the IOM standards, the NGC, in partnership with the AGREE Research Trust and others, created a new appraisal tool, the National Guideline Clearinghouse Extent Adherence to Trustworthy Standards (NEATS) Instrument. Each element of the eight standards and sub-standards is rated using a binary and five-point Likert scale ranging from lowest to highest adherence to the standard.

RNAO AND BEST PRACTICE GUIDELINES

RNAO Best Practice Guidelines (BPG) are systematically developed, evidence-based statements that include recommendations for nurses and the interprofessional clinical team, administrators, educators, policymakers, and patients and their families to improve outcomes on specific clinical, system, and healthy work environment topics. BPGs offer an evaluation of the quality of the relevant scientific literature and an assessment of the likely benefits and harms of a particular intervention, and present this information in specific recommendations for practitioners, organizations, educators, and policymakers. When appropriate, the BPG recommendations are targeted to be inclusive of and generalizable to all healthcare sectors (acute care, community, long-term care, complex continuing care, and rehabilitation). These recommendations enable healthcare providers to plan and deliver care for their patients based on best evidence, and aid those in education and organizational and health policy roles to use evidence in their curriculum and policy-related decision-making. BPGs should be used as a tool or template to enhance decision-making and support the provision of the best possible evidence-based care. Figure 2.2 graphically displays and explains the types of recommendations included in RNAO's clinical BPGs. These evidence-based recommendations influence practice at the individual and team level, as well as policy and education to ensure BPG uptake and sustained use.



FIGURE 2.2 Types of recommendations in RNAO clinical Best Practice Guidelines.
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Nurses, other healthcare professionals, and administrators who lead and facilitate practice changes say that RNAO's BPGs are invaluable resource tools for advancing evidence-based clinical practice, and for the development of policies, procedures, practice protocols, educational programs, assessment interventions, and documentation tools. Nurses who provide direct care say they benefit from reviewing the recommendations and seeing the evidence in support of the recommendations and the process that was used to develop the guidelines. As we discuss in Chapter 5, *Technology as an Enabler of Evidence-Based Practice*, RNAO's BPG recommendations for practice can be easily integrated into electronic health records. RNAO recommends that practice settings/environments adapt these guidelines in formats that are user-friendly for practitioners. There are currently 53 published guidelines, an Implementation Toolkit, and an Educator's Resource to support implementation. Additional new guidelines are being developed every year. The BPGs have been organized into themes representing key clinical areas of practice, and System and Healthy Work Environments, as shown in the circles in Figure 2.3 (RNAO Best Practice Guideline thematic organizing framework), with BPG covers from guidelines in that category as samples. To date, guidelines have been translated into French, Spanish, Italian, Chinese, German, and Japanese with a commitment to translating more materials on an ongoing basis.

REFLECTION

How do you think recommendations in the three areas identified—practice, education, and policy—impact BPG use by individuals and the organization and uptake at a systems level?



FIGURE 2.3 RNAO Best Practice Guideline thematic organizing framework.
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RNAO FUNDING

Funding granted to the RNAO by the Ontario Ministry of Health and Long-Term Care supports the BPG Program Managers, project co-coordinators, and nursing research associates and expenses related to guideline development projects (i.e., Expert Panel meetings, health services librarian, and document retrieval) and the costs of printing and disseminating published guidelines. Expert Panel members are not remunerated for their time. The RNAO does not provide financial support to Expert Panel members to attend or present RNAO BPG work at conferences. Any and all monies from sales of hardcopy versions of Best Practice Guidelines are directed back into the program.

The time required to develop an RNAO BPG is approximately 14 months, including the completion of systematic reviews. See Appendix A at the end of this chapter for a detailed account of the timelines, actions, and outcomes during the 14-month process.

RNAO'S SEVEN-STEP GUIDELINE DEVELOPMENT PROCESS

RNAO's process for BPG development has been used for almost two decades and has proven to be a user-friendly, effective, and efficient methodology. Over the years, each step has been altered as necessary to be consistent with current international guideline-development standards and our own quality-improvement processes. The seven steps include topic selection, use of an Expert Panel, systematic literature review, recommendation formulation, stakeholder review, publication, and a 5-year guideline review that produces the next editions of existing guidelines. Each step is described fully in this section.

TOPIC SELECTION

Topics for RNAO Clinical Nursing BPGs are selected using a priority-identification matrix. Appendix B at the end of this chapter provides an example of a priority-identification matrix. The process includes a set of criteria to guide the systematic assessment of a selected list of suggested topics and feedback from a range of stakeholders provided through focus groups. A completed assessment of each topic, carried out by a team of reviewers, leads to an overall suggestion for guideline development. Any group or individual may propose a guideline topic to the RNAO through a variety of methods such as:

1. "Submit an Idea" on the RNAO website at www.rnao.ca
2. Writing to RNAO's CEO or director/associate directors of the IABPG Centre
3. A rapid review or environmental scan (i.e., scoping search for trends, hot topics, practice concerns)
4. A survey requesting individuals to rank identified topics on a five-point Likert scale
5. Report sources (e.g., coroner's inquest, government or related agency)

RNAO selects topics for guideline development annually. All topics submitted are identified, and a maximum of three priority topics are chosen based on the following systematic assessment criteria.

- Key priority areas identified by the Ontario Ministry of Health and Long-Term Care (MOHLTC)
- Request from major public health agency
- Coroner's inquest
- Within the scope of nursing practice (RN, NP, RPN/LPN), and applicable in a range of practice settings
- A multidisciplinary approach would be appropriate for BPG development
- Builds on a previously developed guideline or general topic area
- Potential for partnerships in BPG development with other agencies (i.e., Heart & Stroke; Canada Health Infoway)
- Perceived need for the guideline, as identified by those submitting the topic for consideration
- Evidence to support the guideline recommendations is available
- No other good quality guideline exists on the topic area


REFLECTION

What are the best ways to determine topics for guideline development, what criteria would you set for such a selection process, and why?

Upon reviewing all submissions based on the above criteria, a report is created outlining the first, second, and third choice of topics. The results are shared with the BPG team. Consensus is achieved on priority topics, and results are shared and submitted for approval to the chief executive officer (CEO) of RNAO, who reports the selected topics to the MOHLTC.

When a topic is selected for potential new guideline development, the assigned RNAO Best Practice Guideline Development Team Lead assembles a focus group of subject matter experts (SMEs) and key opinion leaders to discuss relevant content and identify the scope and purpose of the guideline. SMEs may become potential RNAO Expert Panel members.

The objectives of the focus group are to identify:

- The scope of the proposed guideline
- Current tools and resources
- Current research
- Gaps in the current literature or guidelines pertaining to the proposed guideline topic area

These individuals come together during a series of teleconferences hosted by the RNAO and communication via email and telephone. Structured, open-ended questions are posed to the group, and the information they share is transcribed and referenced throughout the BPG development process.

EXPERT PANEL

Composition of the Expert Panel

Nurses (RN, NP, and RPN) make up 50% of the RNAO Expert Panel; the second half are other health professionals (social workers, registered dietitians, physicians, physiotherapists, etc.) and persons and family members with lived experience in the defined topic area. Expert Panel composition whenever possible represents: 1) expertise on the subject matter in direct and advanced clinical practice, research, education, administration, and policy; 2) rural and urban work settings; and 3) the spectrum of health services including public health, primary care, acute care, home healthcare, and long-term care as appropriate to the guideline topic. Invitations for panel membership are extended to the Ontario Nurses' Association (labour union for RNs) and the Registered Practical Nurses Association of Ontario (professional association for RPNs) to ensure equitable representation from all nursing perspectives. Representatives from First Nations, Inuit, people with lived experience, and students are routinely sought for inclusion on the panel. The aim is to have equal representation from each of the four major groups (patients, direct-care clinicians, researchers/educators, and system-level representatives). The RNAO requests a letter of intent and resume from the Expert Panel member with an indication of support from his/her organization to ensure commitment from the individual and organization. All individuals involved in developing the guideline are acknowledged in the published guideline.

Early in the panel selection process, two panel cochairs are identified by the RNAO Best Practice Guideline Development Team Lead, one of whom must be a PhD-prepared nurse with content expertise on the chosen topic. The second cochair can be from a discipline other than nursing or a lived experience representative. These individuals assist with expert-panel selection and support effective functioning of the panel in the development process respective of milestone timelines. The panel cochairs ensure that all members of the Expert Panel are engaged in the guideline development process and all voices are heard and respected. The RNAO Best Practice Guideline Development Team Lead assigned to each BPG works with the panel cochairs to facilitate group meetings and progress through the BPG development process.

Responsibilities of the Expert Panel

A terms of reference (TOR) document is developed for each RNAO Expert Panel (see Appendix C at the end of this chapter). The TOR outlines RNAO's mandate and the IABPG Centre structure, key RNAO stakeholders who will be involved in the guideline, and the approach and plan for guideline development including timelines and deliverables. The TOR document is distributed to all panel candidates prior to their acceptance to participate as a member of the RNAO Expert Panel. Expert Panel members are required to declare any conflicts of interest.

The lifespan of each guideline development Expert Panel is approximately 14 months with a commitment to meet twice in person and via teleconferences as needed. Generally, the Expert Panel members' responsibilities include development of:

- **Practice Recommendations**—Statements of best practice based on the best available evidence and expert consensus.
- **Education Recommendations**—Statements of educational requirements and educational approaches/strategies for clinicians for the introduction and implementation of the BPG.

- **Organization and Policy Recommendations**—Statements of conditions required for the successful implementation of the BPG by a health service practice setting or academic organization. The conditions for success are largely the responsibility of the organization and impact local policy and procedures, although they may have implications for policy at a broader level.
- **Evaluation Criteria**—Indicators used for evaluating the BPG in the practice setting. These indicators include structure, process, and outcome indicators for organizations, nurses, and clients, as well as measures for economic cost and resource utilization.
- **Implementation Tools**—User-oriented tools to facilitate the implementation of the BPG recommendations, which are appended to the guideline. Tools may target staff nurses, nursing students, or other healthcare professionals.
- **Health Education Fact Sheets**—Plain language hand-outs that highlight key information from the guideline and are used by nurses and other healthcare professionals for educating patients, their families, and members of the public (see Appendix D at the end of this chapter).
- **Research Gaps and Implications**—Identification of gaps in the current evidence and suggestion of areas for future research inquiry.

SYSTEMATIC LITERATURE REVIEW

The first RNAO guideline was issued in 2001. At the time, the guidelines were produced using comprehensive literature reviews. From 2012 and onward, RNAO BPGs have been based on systematic reviews of the evidence. This approach is intended to create guidelines grounded in rigorous, systematic reviews, and ensures that recommendations are based on empirical evidence as opposed to clinical judgment. There may be instances in the absence of scientific evidence where recommendations are based on Expert Panel consensus.

A systematic review working subgroup is identified from within the Expert Panel membership on the bases of skill and interest. This subgroup is responsible for assisting with the development and submission of a manuscript of the systematic review completed to develop the new guideline. Specific responsibilities of this subgroup include outlining the process used for the systematic review, literature search parameters, types of studies (i.e., study design), and the associated reference list of included studies and findings. Members of the systematic review working subgroup are listed as authors on the submitted manuscript, with the participating IABPG Centre members assigned to guideline development (e.g., RNAO Best Practice Guideline Development Team Lead, Nursing Research Associate). The published systematic reviews (Almost et al., 2016; Harripaul-Yhap, Dusek, Pearce, & Lloyd, 2015; Hirst et al., 2016; Legere et al., 2017; Recalla et al., 2013; Sharma, Bamford, & Dodman, 2016; Suva et al., 2015; Wilding & Wagner, 2012; Ye et al., 2017) are substantive evidence-based resources frequently accessed by nurses and other stakeholders related to the topic area.

Identify scope, search terms, and databases

At the first guideline development meeting (i.e., Expert Panel Launch), the Expert Panel reviews the purpose and scope of the guideline, including any suggestions from the focus group(s). The purpose and scope are refined to describe specific objectives, research questions addressed by the guideline, and target audiences. Inclusion and exclusion criteria, search terms and key words, and search data-

bases are identified during the first meeting to guide the literature search. A health sciences librarian is engaged to further develop the search strategy. Timelines for the guideline development and meeting schedule are finalized by the RNAO Best Practice Guideline Development Team Lead with the Expert Panel.

Use existing guidelines

Prior to the Expert Panel launch, the RNAO Best Practice Guideline Development Team Lead works with the Nursing Research Associates (NRA) to conduct a broad Internet search for existing guidelines on the defined topic area. An established list of evidence-based-practice websites and known guideline developers is searched using a set of preliminary search terms. This list of evidence-based-practice websites and known guideline developers is reviewed annually, and changes are made by the RNAO IABPG Centre based on recommendations by the RNAO Best Practice Guideline Development Team.

Retrieved guidelines are shortlisted using the established standard inclusion criteria, which include:

- Published in English language
- Developed within the timeframe identified by the Expert Panel
- Strictly on the topic area
- Evidence-based
- Available and accessible for retrieval

The guidelines are reviewed and independently appraised by two reviewers from the guideline development team using the Appraisal of Guidelines for Research and Evaluation Instrument (AGREE II) (www.agreetrust.org). The AGREE II Instrument evaluates the process of clinical practice guideline development and the quality of reporting. Guidelines of high quality are brought forward to the Expert Panel for consideration as evidence. Expert Panel members are instructed to:

1. Suggest any further guidelines not identified by the guideline development team
2. Review the guideline and consider the following questions:
 - a. Are there any guidelines that replicate the identified topic? If so, does the existing guideline(s) include the same specific questions that the Expert Panel is interested in?
 - b. If the guideline includes information that the Expert Panel is interested in but it seems outdated, should it be used but updated and/or expanded using findings from the literature search?
 - c. If a guideline exists and its content answers one or more of the specific questions the Expert Panel is interested in, and uses current, evidence-based information, should it be included or endorsed in the development of the RNAO guideline content or recommendations?
 - d. Given the content and questions asked in the existing guidelines being appraised, are there gaps that the RNAO guideline being developed can address? Gaps include: scope of questions, populations targeted, quality of evidence supporting the guideline, and whether the guideline includes recommendations specifically for nurses.

Guidelines selected for inclusion are used by the Expert Panel with the associated scientific literature and other resources as evidence for drafting guideline recommendations.

Frame clinical questions using PICO

Given the guidelines that exist and the knowledge gaps that remain, the Expert Panel develops specific research questions. Where appropriate, the research questions are structured using the PICO format (Fineout-Overholt & Johnston, 2005):

- Patients or population to which the question applies
- Intervention (or diagnostic test, exposure, risk factor, etc.) being considered in relation to these patients
- Comparison(s) to be made between those receiving the intervention and another group that does not receive the intervention
- Outcome(s) to be used to establish the size of any effect caused by the intervention

Identify and select evidence

A search strategy and a literature search is conducted by a health sciences librarian based on the research questions and the inclusion criteria provided by the RNAO Expert Panel. All references are downloaded into a reference management database. The search strategy is documented at the RNAO home office for the purpose of transparency and future referral. The Expert Panel is asked to submit any potentially relevant research studies as hand-search articles. Identified studies are forwarded to the RNAO Best Practice Guideline Development Team Lead who then cross references these studies with the librarian's search results, using the same predefined inclusion and exclusion criteria.

RNAO employs six full-time master's-prepared nursing research associates (NRA) trained in systematic reviews. Two NRAs begin the literature review, guided by the following process for identifying and selecting the evidence, which follows the standard steps of a rigorous systematic review process:

- Two NRAs (a lead reviewer and a second reviewer) independently review article titles and abstracts to decide whether they should be included or excluded when compared to the inclusion criteria.
- The NRAs' "title and abstract" screening results are compared. A third reviewer acts as a tie-breaker to resolve any discrepancy where reviewers differ in their decision regarding inclusion of study.
- Full-text articles for studies selected to be included are retrieved. Two NRAs independently review the full-text articles to determine if they are relevant to the clinical research question. This stage is referred to as "relevance review." Discrepancies are resolved by a third reviewer.
- During the screening process, the lead reviewer tracks decisions regarding each study's inclusion and exclusion status, and reasons for these decisions. Decisions and rationale for inclusion and exclusion are recorded to maintain an audit trail.

This process is repeated for each clinical research question, resulting in several systematic reviews per guideline.

Evaluate evidence

Inter-rater reliability (McHugh, 2012) must be determined between the two NRAs prior to the quality appraisal and data extraction of the articles. Inter-rater reliability refers to the consistency of agreement in the quality-appraisal scores between the two NRAs. Inter-rater reliability or the kappa calculation should be greater than or equal to 80%. When inter-rater reliability is established, the lead reviewer and second reviewer quality appraise the articles using standardized appraisal tools (see Appendix E at the end of this chapter). The quality ratings of each article are documented by the NRAs in an electronic template. A final data table of studies and corresponding quality ratings is forwarded to the RNAO Best Practice Guideline Development Team Lead.

Data extraction tables and final report

The NRAs develop data extraction tables for the research questions. These tables are used by the Guideline Development Lead to draft practice, education, and policy/organization recommendations for the guideline. The final report consists of narrative summaries and appendices of the data extraction tables, prepared by the NRAs. The systematic review manuscript incorporates the methodology of the review, written by the NRAs as the review progresses, in accordance with submission guidelines for the specific journal chosen by the working group.



REFLECTION

In what ways does a systematic review strengthen a BPG and give the user confidence in its recommendations? What are the disadvantages of incorporating a systematic review in the development process, if any?

FORMULATE GUIDELINE RECOMMENDATIONS

Levels of evidence

Each guideline recommendation is assigned a level of evidence based on the type of research study conducted that produced the recommendation (see Appendix F at the end of this chapter).

Consensus building for practice, education, and organization/policy recommendations

After the Guideline Development Lead drafts recommendations and evidence summaries, the Expert Panel will review the documents and reach consensus on the recommendations for inclusion in the guideline. RNAO has chosen to use the modified-Delphi technique to support consensus-building of recommendations for the guideline.

Modified-Delphi process

The Delphi technique has been in use in many fields including science and technology, war prevention, space progress, public policy, education, and health since the 1950s, and it was first officially published in 1963 (Dalkey & Helmer, 1963). The Delphi technique is a forecasting approach that is based on the outcomes of several sets of questions, the results of which are combined and shared in another iteration for response by a panel of experts until consensus is reached. However, there are a number of variations that occur, and in these cases the technique is referred to as the modified Delphi. The modified-Delphi approach has been used in healthcare to develop recommendations and guidelines as an alternative to conventional meetings, avoiding problems arising from powerful personalities, group pressures, and the effects of status.

The hierarchical structure of the health professions, where more junior practitioners may be reluctant to challenge the opinion of their seniors, has led to the Delphi technique being increasingly employed in nursing and similar research (Williams & Webb, 1994). The structure and sense of direction of the technique provides focus and avoids entropic and often counterproductive discussions and digressions common in face-to-face group discussions. A modified-Delphi approach is frequently used for recommendation development and other stakeholder-engagement activities. Through a collaborative review, individual feedback, and discussion of the draft recommendations, current evidence, and evidence gaps, the Expert Panel determines the final set of recommendations, as depicted in Figure 2.4.

Recommendation Build Process

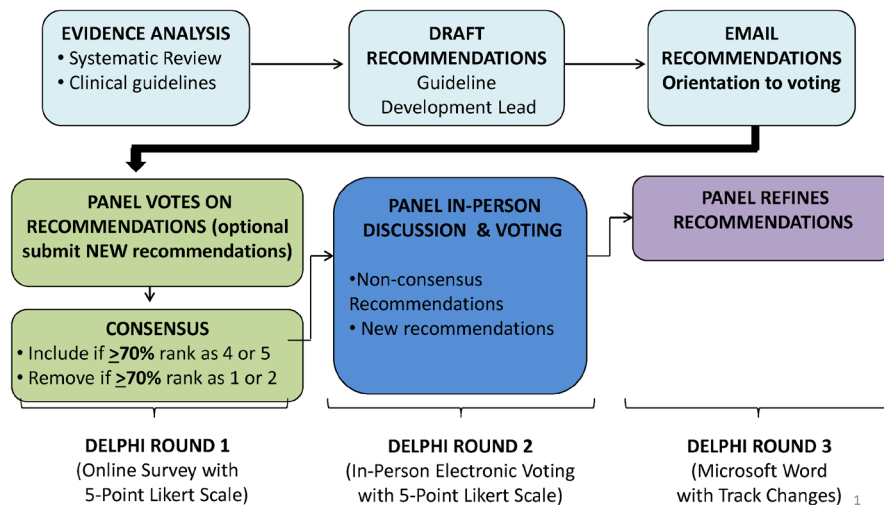


FIGURE 2.4 RNAO's BPG recommendation build process using the modified-Delphi technique.

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Research gaps and future implications

Guideline recommendations may be based on qualitative and quantitative research evidence and/or expert opinion. In the process of reviewing the evidence, the guideline development Expert Panel identifies gaps in the research literature pertinent to the guideline topic area. When considering the research gaps, the Expert Panel may identify priority research areas and list them in the BPG. The list, though not exhaustive, is an attempt to identify and prioritize some of the significant knowledge gaps in the area.

STAKEHOLDER REVIEW

As a component of the guideline development process, the RNAO is committed to obtaining feedback from healthcare providers in a wide range of practice settings, knowledgeable administrators, funders of healthcare services, and stakeholder associations throughout Canada and internationally. Once the recommendations are complete, the draft guideline is submitted to a set of external stakeholders for review and feedback. An acknowledgement of the reviewers is provided in every guideline.

Composition of stakeholders

Stakeholder reviewers may be individuals with expertise in the relevant area of the guideline or people involved in implementing the guidelines or affected by their implementation (e.g., direct-care nurses, nursing students, physicians, interprofessional team, nurse executives, etc.).

RNAO finds stakeholder reviewers in a variety of ways. RNAO Expert Panel members are asked to forward the contact information of colleagues, coworkers, and clients to the RNAO Best Practice Guideline Development Team Lead, and they are invited to be stakeholders; individuals can register to become stakeholder reviewers via an online sign-up form on the RNAO website; in addition, this online form may be promoted through social media or at RNAO events to solicit reviewers. The RNAO website provides a short description of the BPG and invites reviewers to provide their contact information to receive the BPG when it is ready for stakeholder review. The names of all interested stakeholder reviewers are compiled into a database and accessed when the BPG is ready for review. The goal is to enlist a minimum of 50 reviewers representing a range of practice settings from local, provincial, national, and international jurisdictions.

Timelines

Stakeholder reviewers have 2 weeks from the time they receive the guideline to respond. In general, stakeholder reviewers are asked to dedicate approximately 3 to 4 hours to review the guideline and to provide written feedback.

Stakeholder feedback

Feedback from external reviewers is collected by the RNAO Best Practice Guideline Development Team Lead using a brief questionnaire. Reviewers complete an online form; however, individuals also have the option to provide their feedback via mail or fax.

The questionnaire lists all the recommendations and asks the reviewer if the recommendation is clear (yes/no); if the reviewer agrees with the recommendation (yes/no); and if the evidence support is thorough (yes/no). A section for overall comments and general impressions is also provided by asking reviewers to consider the following three questions:

- Are there any significant gaps in the recommendations outlined that you believe should be addressed/included in this guideline? If so, please provide details of the gaps you have identified.
- Appendixes have been included in the draft guideline to support guideline implementation. Are they appropriate? Evidence-based? Are there any gaps in the content provided?
- Is there anything else you would like to comment on in order to strengthen this document? (e.g., Content: background context, research gaps, monitoring indicators. Format: flow, ease of readability, terminology/language, etc.); please feel free to comment in the space below.

The feedback from stakeholders is compiled by the RNAO Best Practice Guideline Development Team Lead and reviewed with the RNAO Expert Panel. Each point is addressed and discussed by the RNAO Expert Panel, and any changes to the guideline are noted. If no changes are made to the guideline as a result of the stakeholder review, the reason(s) are recorded. When all the comments have



How do stakeholder reviewers make an important contribution to the quality of BPGs and their uptake?

been addressed and the RNAO Expert Panel has come to consensus about the revisions, the document is ready for production through edit and design. Documentation of the stakeholder review process is maintained at the RNAO office for transparency and future reference.

PUBLICATION AND DISSEMINATION

Editing, design, and publication

Prior to publication, the guideline is professionally edited and then forwarded to a design company. Following final approval, the PDF document is posted to the RNAO website and printed. Hard copies are made available for purchase, and a free electronic version is made available for download from the RNAO website, www.RNAO.ca. Complimentary hard copies are distributed to all members of the Expert Panel and stakeholder reviewers, with a letter of appreciation and acknowledgement for their valuable contribution to the BPG development process. For dissemination of the guideline, it is sent to the NGC and GIN to be housed in their guideline databases. RNAO engages in a number of other dissemination and implementation activities that are discussed in other chapters.

Announcement of release of the new guideline

The announcement of a completed guideline is timed to coincide with other local, provincial, national, or international events of importance. Depending on the profile of the topic, RNAO considers the need to hold a stand-alone press conference, which at times is attended even by a minister of health or others (Di Costanzo, 2014). Other venues include a major conference where the BPG is introduced to live audiences. The announcement highlights the core elements of the guideline and directs the audience to the RNAO website: www.RNAO.ca. Expert Panel members are encouraged to share the new guideline within their organizations. Each new guideline enters RNAO's rich dissemination protocol, including: RNAO's *Registered Nurse Journal* and monthly *In the Loop*, the RNAO website, webinars, an app version of the guideline freely accessible online, health education fact sheets, and presentations at conferences to support uptake. All of these dissemination strategies are discussed in future chapters.

GUIDELINE UPDATING

RNAO has made a commitment to revise BPGs every 5 years following publication of the last edition as follows:

1. Each nursing BPG will be reviewed by a team of specialists (RNAO Expert Panel) in the topic area.
2. During the period between development and publication of a new edition, RNAO IABPG Centre staff will regularly monitor for new and relevant literature in the field.
3. Based on the results of this monitoring, RNAO IABPG Centre staff, in consultation with members of the original RNAO Expert Panel members and other specialists and experts in the field, may recommend the guideline be reviewed and revised earlier than the 5-year revision period.
4. Three months prior to the review milestone, the RNAO Best Practice Guideline Development Team Lead will commence the planning of the review process by developing a detailed work plan with target dates and deliverables for developing a new edition of the guideline.

GUIDELINE DEVELOPMENT ENHANCEMENTS

RNAO is continuing to improve its guideline development processes, making them as rigorous as possible. As discussed earlier in this chapter, changes have been made in the systematic review processes, Expert Panel composition, and recommendation build. Refining of the recommendation build using a modified Delphi process and incorporation of recommendation grading are two new processes that have been introduced to strengthen the recommendations. The Delphi process has been discussed earlier in this chapter, and this section will focus on guideline grading.

GUIDELINE GRADING

Grading recommendations was a process used by organizations with a defined focus on the level and quality of evidence or type of study used to support that evidence. Many organizations use formal systems to grade evidence, including consideration of various contextual factors and recommendations and why this is important for clinicians. As organizations utilized different methods to denote high-grade or strong recommendations, it became confusing and inconsistent for clinicians and others to determine why one guideline called a particular recommendation strong, while others, based on the same evidence, did not. This sparked the need for a structured approach to identify, evaluate, and implement a grading methodology for recommendations.

A methodology of rating recommendations based solely on the level of evidence supporting that recommendation should be used with caution, because limitations exist on the availability of Type 1 (RCT) evidence. For example, there are extensive observational findings that support hand washing to reduce infection rates; however, there are no randomized controlled trials showing similar results. Alternatively, there are strong data from Randomized Control Trials (RCTs) showcasing that alcohol-based hand sanitizer solution is better at reducing infection rates than the use of latex gloves. As such, the recommendation to wash hands, of the utmost importance in infection control, is based on weaker evidence (observational findings) as compared to the cleansing method (RCT). Most would agree it is more important that hands are washed regardless of the method chosen.

GRADE

Globally, guideline developers inconsistently rate quality of evidence and grade strength of recommendations, thus creating challenges for guideline users when interpreting the grading system and related content. To understand the methods, the GRADE (the Grading of Recommendations, Assessment, Development and Evaluation) system, first reported in 2004, is advantageous for the following reasons (Atkins et al., 2004):

- Developed by a widely representative group of international guideline developers
- Clear separation between quality of evidence and strength of recommendations
- Explicit evaluation of the importance of outcomes of alternative management strategies
- Comprehensive criteria for downgrading and upgrading quality-of-evidence ratings
- Transparency in the process of moving from evidence to recommendations
- A discussion of benefits, harms, values, and preferences

- Pragmatic interpretation of strong versus weak recommendations for clinicians, patients, and policymakers
- Applicability to systematic reviews and health technology assessments

In 2006, the *BMJ* requested in its “Instructions to Authors” on bmj.com that authors preferably use the GRADE framework when submitting a clinical guideline article following its publication (Guyatt et al., 2008). This highlights the importance of evidence frameworks that move beyond level or quality of evidence to clearly state the strength of a recommendation.

The strength of recommendations is based on the quality of supporting evidence, the degree of uncertainty about the balance between desirable and undesirable effects, the degree of uncertainty or variability in values and preferences, and the degree of uncertainty about whether the intervention represents a wise use of resources.

Strong recommendations imply that most individuals will be best served by the recommended course of action, in which the panel is confident that:

- Desirable effects of an intervention outweigh its undesirable effects (strong recommendation for an intervention), or
- Undesirable effects of an intervention outweigh its desirable effects (strong recommendation against an intervention)

Weak recommendations are those for which the panel believes the:

- Desirable effects *probably* outweigh the undesirable effects (weak recommendation for an intervention), or
- Undesirable effects *probably* outweigh the desirable effects (weak recommendation against an intervention) but appreciable uncertainty exists

The quality of evidence is graded as high, moderate, low, or very low, based on likelihood that further research would change our confidence in the estimate of effect. The GRADE approach is based on a sequential assessment of the quality of evidence, followed by judgment about the balance between desirable and undesirable effects, and subsequent decision about the strength of a recommendation. Separating the judgments regarding the quality of evidence from judgments about the strength of recommendations is a critical and defining feature of the GRADE framework. GRADE stresses the necessity to acknowledge the values and preferences underlying the recommendations and postulates a systematic approach to grading the recommendations that can minimize bias and aid interpretation.

Unlike other appraisals, the GRADE framework emphasizes that weak recommendations in the face of high-quality evidence are common because of factors other than the quality of evidence that influence the strength of a recommendation. For the same reason, it supports strong recommendations based on evidence from observational studies. The emergence of “real world evidence” or observational data, including qualitative research, is required to support identification of interventions that are effective and not amendable to RCT methodology. SIGN (Scottish Intercollegiate Guidelines Network) released a policy statement in 2013 when moving from its previous system of assigning

letter grades (ABCD) based mostly on the level of evidence (I–IV) to the GRADE methodology. Other guideline organizations, such as NICE (National Institute for Health and Care Excellence), have followed, and to date over 100 organizations from 19 countries have endorsed or use GRADE (GRADE working group, 2017). NICE is an independent public body that provides evidence-based national guidance and recommendations made by independent committees on a wide range of topics related to health and social care in England.

GRADE CERQual

The Confidence in the Evidence from Reviews of Qualitative Research (GRADE CERQual) is an approach developed in 2010 to facilitate a transparent and standard method for appraisal of qualitative literature. The World Health Organization (WHO) identified the need for the CERQual approach when attempting to develop a guideline that required qualitative evidence. Members of WHO and other international professionals formed a subcommittee of the GRADE working group to determine the components of the approach and conduct testing. CERQual requires review of qualitative evidence to determine confidence in *research findings*, defined as “data from primary studies that describe a phenomenon or aspect of a phenomenon” (Lewin et al., 2015, p. 3). The following four components are used to ascertain confidence in the research findings (Lewin et al., 2015):

1. **Methodological limitations**—Identify any issues in the design or conduct of the primary studies
2. **Relevance**—Assess the degree of consistency between the research findings for the body of evidence and the research question(s), specifically the population, phenomenon of interest, and setting
3. **Coherence**—Determine whether the patterns found in the data are adequately supported and explicated by the research findings
4. **Adequacy of data**—Evaluate the overall saturation, richness, and quantity of data available to corroborate the research findings

Confidence in the review findings, based on the four components, is ascribed one of four levels: high confidence, moderate confidence, low confidence, and very low confidence. Each of the levels represents varying degrees of confidence in the evidence ranging from “highly likely that review findings are a reasonable representation of the phenomenon of interest” to “not clear whether the review finding is a reasonable representation of the phenomenon of interest” (Lewin et al., 2015, p. 11). We anticipate that in the future, RNAO will incorporate the GRADE CERQual approach into the guideline development processes.

RNAO’s application of GRADE

The alignment of GRADE and GRADE CERQual frameworks with RNAO guideline development methodology has resulted in changes to current processes that were previously outlined. Prior to the systematic review, the development team now conducts a gap analysis to ascertain specific areas of focus for the purpose, scope, research questions, and outcomes of the guideline. Based on the findings, the Expert Panel further informs these areas and finalizes the direction of the guideline. The panel

votes on the PICO research questions and outcomes to ensure areas of highest priority are addressed in the guideline. The health science librarian continues to conduct the extensive literature search. When completed, two NRAs independently perform the title and abstract screening and relevance review.

The current evaluation of evidence, including the quality-appraisal tools (i.e., CASP, AMSTAR) is being replaced with the processes described in the GRADE and GRADE CERQual approaches. The data extraction tables are being transformed into the evidence profiles and summary of finding tables outlined by the GRADE and GRADE CERQual frameworks utilizing the GRADE pro software. The process of building recommendation statements has changed. The levels of evidence are eliminated. Instead, each new guideline as of 2018 and next editions of existing guidelines include GRADE and CERQual profiles and summaries, outlining the recommendations and strength of recommendations. The Expert Panel continues to reach consensus on the recommendations using the modified-Delphi technique. In 2017, RNAO pilot-tested this transition with two clinical and one healthy work environment guideline. This initial testing enabled the RNAO guideline development team to assess the processes and modify steps to ensure efficient integration of the GRADE and CERQual frameworks.

The topics relevant to nurse-led guidelines are diverse in subject matter, scope, population, and setting. This unique dynamic presents opportunities and challenges. We anticipate that systematic reviews will generate a multiplicity of study designs, including quantitative evidence amendable to meta-analysis, observational findings requiring narrative descriptions of GRADE criteria, and qualitative synthesis. Historically, when variability was found within one guideline topic area, future endeavours tend to generate similar results. As such, when quantitative and qualitative literature is used, the GRADE and CERQual evidence profiles are linked with the respective research question and its outcome to clearly and transparently demonstrate the basis for each recommendation statement.

REFLECTION

What are the advantages of using the GRADE methodology in RNAO's BPG development process? Do you see any disadvantages, and if so how could they be overcome?

Appraisal of graded recommendations

AGREE researchers developed and validated the AGREE REX: AGREE Recommendation EXcellence tool (AGREE, no date). This instrument is a “useful, reliable, and valid knowledge resource to complement the AGREE II, on the clinical credibility and implementability of practice guideline recommendations” (AGREE, n.d.). The AGREE-REX is comprised of 1) an Assessment Instrument, 2) a User’s Guide, and 3) a series of practical tools (Resource-Rex). Upon review of AGREE-REX and AGREE II, users may notice similarity with the NEATS tool created by NGC. The NEATS tool attempts to ascertain the clinical credibility, and feasibility of implementing recommendations with some of the other elements of guideline development methodology found in AGREE II.

RNAO'S EVOLUTION IN GUIDELINE DEVELOPMENT

This chapter has addressed all aspects of RNAO's rigorous BPG development process, along with the relevant background to guideline development in healthcare, as well as challenges and solutions. Included is our seven-step development process, use of emerging trends, new standards, and future

directions. As a developer of quality guidelines for international uptake, RNAO uses all study types in systematic reviews, including quantitative and qualitative research. This is necessary to best respond to questions that affect day-to-day patient care and capture interventions that can improve patients' clinical and quality-of-life outcomes. In addition, RNAO has focused on three domains that are critical to achieve results: 1) evidence-based clinical practice recommendations, 2) educational recommendations regarding the knowledge clinicians need to have to implement best practices, and 3) what the organizations and/or health system needs to do to create work environments that optimize best practices uptake.

RNAO's culture is that of a learning organization constantly using quality improvement. As such, its guideline development processes are not static. They evolve as needed to align with international standards. For example, RNAO has moved from panels of all nurses to 50% nurses to ensure a multidisciplinary approach. RNAO was amongst the first guideline developers to include patients and people with lived experiences in both the planning and development of guidelines as Expert Panel members. Furthermore, RNAO launched its Patient and Public Engagement Council (PPEC) in 2016, and is the first nursing professional association to do so. Through the PPEC, the concept of equity has been prioritized and will now be reflected in the evidence framework that RNAO is creating to denote a strong recommendation.

“Having tragically lost my son to a drug overdose, being a member of the supervised injection services BPG gives great meaning and voice to his life.”

—Cori Chapman, mother of Brad Chapman

RNAO guideline developers draft recommendations based upon the evidence from the systematic review and high-quality guidelines for the panel to examine, refine, and identify gaps. In addition, RNAO has implemented a robust consensus-building process, including the modified Delphi, to ensure all panel member voices are heard without undue influence from overbearing panel members. These last two processes provide a strong foundation for the implementation of GRADE. Over the course of 2017, RNAO has created its own nursing-led and -developed evidence framework to clarify and distinguish the level and quality of evidence with the strength of the recommendations. As of 2018, all new and next editions of existing guidelines include GRADE and CERQual profiles and summaries, outlining the recommendations and strength of recommendations.

In 1998, when RNAO embarked on the groundbreaking work of BPG development and shortly after implementation and evaluation, there were few other players in the field, and certainly no professional nursing organizations. Now nearly two decades later, RNAO is globally recognized for its leading-edge work in all aspects of evidence-based practice, and arguably is the “go to” organization when credible guidelines are necessary to address key clinical and healthy work environment issues that affect the practice of nurses and the public we serve.

RNAO has achieved these outcomes first and foremost by its dogged attention to guideline quality and capacity to continually improve its processes to be ever more rigorous and at the same time user-friendly. Guideline uptake and the differences these evidence-based tools make for patients as well as practitioners, organizations, and the system are the ultimate priorities.

KEY MESSAGES

- Quality guidelines that adhere to international development standards offer solutions to drive care quality, practice effectiveness, and improved health outcomes.
- RNAO's well-honed BPG development process is not static and continuously incorporates new international guideline standards.
- RNAO BPGs include top recommendations that influence practice, education, organizations, and the system. They also include evaluation indicators.
- RNAO BPG use and impact are facilitated by additional evidence-based resources including apps, quick summaries, online modules, and health education fact sheets.
- Guideline development processes continue to be advanced based on research and lived experiences.

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APPENDIX A: DETAILED TIMELINES FOR GUIDELINE DEVELOPMENT PROCESSES

Timeline Frame	Development Step	Development Phase	Activity
Month 1	Topic Selection	Identifying a topic	<ul style="list-style-type: none"> Decision for a new guideline or revision of existing guideline Topics for possible guideline development are reviewed from multiple sources Topics for guideline development are evaluated using a priority matrix RNAO Best Practice Guideline Development Team Lead initiates planning process Panel cochairs identified, one of whom is a PhD-prepared nurse
Month 1–3		Planning (as needed for new topics): Focus Groups Scoping review Refinement of purpose and scope	<ul style="list-style-type: none"> Recruitment of experts on topic for focus groups Development of premeeting questions for focus-group participants to gather information on current practice, resources, research, and gaps in information on selected topic for guideline development Information from focus groups gathered and transcribed into themes to assist RNAO Expert Panel in finalizing guideline purpose and scope
Month 1		Existing Guidelines Search	<ul style="list-style-type: none"> Search conducted for existing guidelines on topic selected for guideline development Assessment of existing guidelines with AGREE II Instrument High-quality existing guidelines identified for RNAO Expert Panel review at Panel Launch
Month 1	Expert Panel	Expert Panel Recruitment	<ul style="list-style-type: none"> Approximately 12–15 individuals are recruited to participate on the RNAO multidisciplinary Expert Panel Panel matrix is used to support identification of roughly one-quarter each of direct-care clinicians, researchers, education/policy/system level, and patient/persons with lived experience. This includes 50% nurses, at least one physician, and other disciplines from relevant sectors of the health-care system A terms of reference template (Appendix C) is developed for each guideline development Expert Panel and shared so each panel member understands his/her roles and the key deliverables and timelines for BPG development Panel chair is identified RNAO Expert Panel membership is finalized
Month 2	Expert Panel	RNAO Expert Panel Launch	<ul style="list-style-type: none"> Orientation to RNAO IABPG Centre guideline development program and methodology. Refine the guideline purpose and scope based on identified themes from focus groups Formulate Clinical Research Questions (CRQs) based on PICO Identify search terms and databases with librarian to create the search strategy

Timeline Frame	Development Step	Development Phase	Activity
			<ul style="list-style-type: none"> ■ Compile results of AGREE II assessments for Expert Panel to select guidelines that will inform guideline development ■ RNAO Expert Panel members sign up for one of the following subgroups to work on: Evaluation & Monitoring Indicators (including NQuIRE®), Manuscript, Health Education Fact Sheets, and Mobile Device version of guideline
Months 3–8	Systematic Reviews	Systematic Literature Reviews: Identify and Select Evidence	<ul style="list-style-type: none"> ■ A subgroup of the RNAO Expert Panel, panel chair, and RNAO IABPG Development Team Lead work with librarian on search strategy and systematic review processes ■ NRAs conduct relevance reviews for each CRQ ■ Two NRAs review article titles and abstracts independently to determine those for inclusion ■ Where there are differences related to inclusion, the RNAO Best Practice Guideline Development Team Lead becomes the third-party decision-maker
Months 3–8		Systematic Literature Reviews: Quality Appraisal to Evaluate Evidence	<ul style="list-style-type: none"> ■ Studies included accessed by two NRAs for quality ■ Inter-rater reliability is checked between the NRAs prior to completion of quality appraisal of all articles ■ Two NRAs critically appraise articles for quality using standardized tools
Months 3–8		Systematic Literature Review: Data Extraction and Final Report	<ul style="list-style-type: none"> ■ The two NRAs review the appraised included studies and extract data into tables specific to each research question ■ NRAs compile data extraction tables by research questions and compile a Narrative Summary of Themes report to present to Guideline Development Lead; this information is also made available to the Expert Panel as supplementary material
Month 8–9	Recommendation Development	Development of Draft Recommendations & Panel Consensus	<ul style="list-style-type: none"> ■ Guideline development lead reviews data tables and narrative summary to draft recommendation statements and supporting evidence summaries. Research gaps and indicators for evaluation and monitoring practices associated with topic are also identified. ■ Modified-Delphi technique utilized to build panel consensus on recommendations ■ Draft recommendations and evidence summaries are shared with panel for review and anonymous vote ■ Recommendations that reach consensus for inclusion are moved forward, for exclusion are removed ■ Nonconsensus recommendations are discussed at in-person meeting, refined, and voted upon until consensus achieved
Month 3–10		Development of draft guideline	<ul style="list-style-type: none"> ■ Sections of the draft guideline created by development lead include: purpose, scope, background information; guideline recommendations and supporting evidence; research gaps and future implications for research; implementation strategies; structure, process, and outcome indicators to support evaluation and monitoring of guideline implementation; and supporting tools for uptake in form of appendixes ■ Guideline draft is reviewed and edited by the RNAO Expert Panel ■ Permissions to reprint third-party content are requested and documented

continues

(Continued)

Timeline Frame	Development Step	Development Phase	Activity
Month 11	Stakeholder Review	External Stakeholder Review	<ul style="list-style-type: none"> ■ Reviewers (stakeholders, experts on topic of guideline) are identified through various methods—including open online application, social media recruitment, suggestions from the panel, and potential endorsers—to review guideline. Stakeholders represent individuals, organizations, and healthcare. Targeted recruitment is conducted to address any gaps, and a minimum of 50 stakeholders are invited to participate. ■ Stakeholder questionnaire developed and posted online in a survey tool for stakeholder review of draft guideline. Feedback submissions required within 2 weeks from stakeholders. ■ All feedback is compiled and reviewed by Guideline Development Lead and addressed and documented. ■ Items for discussion are brought to RNAO Expert Panel to determine adjustments to guideline draft. Decisions are documented.
Month 12		Final Guideline Draft	<ul style="list-style-type: none"> ■ All internal and external comments are addressed and reviewed by the panel. ■ Expert Panel reaches consensus on final version of the guideline.
Month 13	Guideline Publication	Final Draft production	<ul style="list-style-type: none"> ■ Final draft edited professionally ■ Edited draft designed and published for online and print ■ PDF version is posted on the RNAO website ■ Hard copies are available through online purchase
Month 14–15		Publication: Dissemination and Uptake Activities Mobile Device Version of BPG Health Education Fact Sheet (HEFS) Manuscript for Publication	<ul style="list-style-type: none"> ■ RNAO Expert Panel members who signed up for subgroup activities begin work on the following using templates: <ul style="list-style-type: none"> ■ Manuscript: to outline systematic review process on topic for guideline development ■ Health Education Fact Sheet: to outline key messages from guideline content to patients or healthcare providers ■ Mobile Device Version: key information required by clinicians for use on various mobile devices identified from design and proof for print draft version (following completion of final edit of guideline); RNAO BPG mobile app available for download ■ A draft summary of the content is completed according to the established templates ■ Manuscript submitted to journals until accepted ■ Health Education Fact Sheet put into HEF PDF template for upload to RNAO website after consensus reached on the content and health literacy review meets the Public Health Agency of Canada’s recommendation for reading level ■ Guideline is submitted to NGC and GIN for inclusion into their databases
Month 15		Celebration – Release of the Guideline	<ul style="list-style-type: none"> ■ The release of the guideline is linked to a conference, event, or webinar session ■ Guideline moves into dissemination and implementation through IABPG Centre’s guideline implementation activities

APPENDIX B: EXAMPLE OF PRIORITY-IDENTIFICATION MATRIX

The intent of this matrix is to assist in identifying priority areas for guideline development, based on a systematic approach to reviewing the short list of identified topics. The outcome of the review is to have all reviewers consider the topics identified, the results of the initial searches, and select a maximum of three priority topics. The compiled results will be used to establish the topic for guideline development. The following criteria have been identified as key to topic selection:

- Topic is relevant to one or more key priority areas, identified by the Ministry of Health and Long-Term Care (MOHLTC): gerontology; home healthcare; mental healthcare; emergency care; primary healthcare
- Topic is within the scope of nursing practice and will impact both RNs and RPNs in a range of practice settings
- A multidisciplinary approach would be appropriate for development
- Topic builds on a previously developed guideline, or general topic area
- Potential for partnerships in development, external to MOHLTC
- Perceived need for the guideline, as identified by those submitting the topic for consideration
- Evidence to support guideline recommendations is available
- Consideration of other known guideline work on the topic area

APPENDIX C: TERMS OF REFERENCE TEMPLATE

RNAO BEST PRACTICE GUIDELINE PANEL

The Registered Nurses' Association of Ontario (RNAO) is the professional association representing registered nurses, nurse practitioners, and nursing students in Ontario. Since 1925, RNAO has advocated for healthy public policy, promoted excellence in nursing practice, increased nurses' contribution to shaping the healthcare system, and influenced decisions that affect nurses and the public they serve.

TERMS OF REFERENCE AND TIMELINE

The International Affairs and Best Practice Guidelines (IABPG) Centre houses the Best Practice Guidelines (BPG) Program, a signature program of RNAO. The program mandate is the development, dissemination, implementation, and evaluation of clinical and Healthy Work Environment Best Practice Guidelines. To date, the program has published 42 clinical BPGs, 12 System and Healthy Work Environment BPGs, and various implementation resources (e.g., two "Toolkits," one for implementing clinical practice guidelines and the other an Educator Resource; e-Learning Programs; mobile versions of guidelines; and Health Information Fact Sheets). The BPGs and other resources can be accessed online at www.RNAO.ca/bpg.

BPG PURPOSE

The proposed purpose of this guideline will be to identify evidence-based best practices for nurses (in collaboration with the interprofessional teams that they work with), on [insert topic]. The guideline will have relevance to all areas of clinical practice including public health, primary care, hospital care, home care, rehabilitation, complex care, and long-term care.

The guideline will provide recommendations in three main areas: 1) practice recommendations, including assessment, planning, intervention and evaluation; 2) education recommendations; and 3) organization/policy/system recommendations. All recommendations will be developed in accordance with the systematic review literature and expert opinion.

RNAO team members involved with this BPG:

- RNAO Program Manager/Guideline Development Lead
- RNAO Project Coordinator
- Nursing research associates (NRA)
- Associate Director of Guideline Development
- Director of RNAO's IABPG Centre

PANEL MEMBERS

The Expert Panel will be comprised of a broad representation of experts from nursing practice, administration, education, research, and policy, as well as other health professions and patient representatives.

PANEL RESPONSIBILITIES

The responsibilities of the panel members are as follows:

- Attend face-to-face meetings and virtual meetings.
- Read preparatory materials sent by the Guideline Team.
- Participate in a consensus development process to finalize recommendations (i.e., anonymous voting process). All panel members will be expected to vote prior to the recommendation build session and attend the session in person to deliberate on the day.
- Provide feedback on various drafts of the guideline throughout the development process.
- Participate in the development of other implementation and evaluation resources (e.g., health education fact sheet, nursing order sets, and outcome indicators).
- Identify appropriate stakeholders to review the draft guideline prior to publication.
- Support dissemination and implementation of the guideline.

In addition to the panel responsibilities above, the role of the panel cochairs is to:

- Support the Program Manager to guide the panel and ensure activities are being completed and timeline is being met.
- Assist with setting meeting agendas.
- Facilitate the BPG panel meetings with the Program Manager (as needed).
- Participate in cochair meetings with the Program Manager and Project Coordinator on a monthly basis (or as needed).
- Colead dissemination activities (e.g., BPG webinar launch) and assist with promoting and disseminating the completed guideline.
- Support panel group process including conflict resolution.

TERM

The guideline development panel will carry out its work over the estimated timeframe of approximately 15 months from [Start date].

MEETINGS/COMMITMENT

There will be up to three in-person meetings in Toronto and three to four virtual meetings over the guideline development period. In addition, the panel will be expected to work independently to review pre-reading materials (e.g., systematic review data tables, narrative summaries). They will also be required to participate in small-group work between face-to-face and virtual meetings. RNAO will provide access to a teleconference line and other support as needed. See the timeline that follows for more details about expected dates.

EXPENSES

RNAO will reimburse the costs of economy travel, accommodation, and meals for all in-person meetings (details outlining allowable expenses are found on RNAO's expense form). Toll-free numbers will also be provided for all calls to RNAO for the purpose of virtual meetings.

This process of guideline development involves seven stages (see the diagram in Figure C.1). The panel will be most actively involved in recommendation formulation and review.

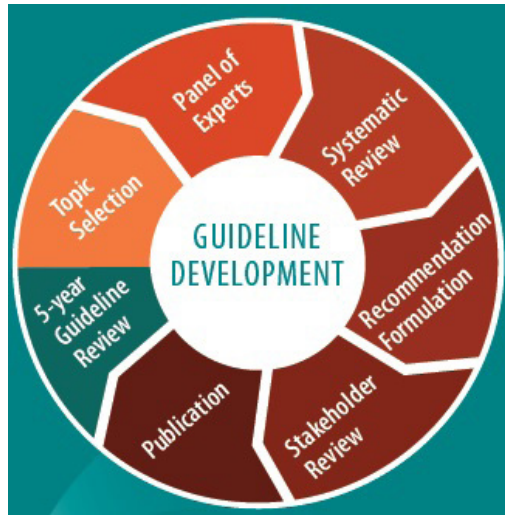


FIGURE C.1 Guideline development process diagram.
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APPENDIX D: RNAO HEALTH EDUCATION FACT SHEET



Delirium, dementia and depression: What is the difference?

Many older adults are affected by delirium, dementia and/or depression. These conditions are not part of normal aging. Delirium, dementia and depression are different from one another, but it can be hard to distinguish between them because their signs and symptoms may be alike. Sometimes a person has more than one of these conditions at the same time. Alert health-care staff if you or someone you know shows any of these signs or symptoms.



Delirium is a condition that **comes on quickly** (within hours or days) and affects the brain. It is usually temporary, lasting one-to-seven days, but should be treated right away. Most times delirium is caused by a combination of factors.

Delirium may be caused by:

- having an illness
- staying in bed too long
- being in a noisy or confusing environment
- having pain

People at highest risk for delirium include:

- older adults
- people with depression or dementia
- people who have broken their hip
- people who have had major surgery (e.g. heart surgery)

Signs of delirium

- poor concentration
- difficulty remembering things
- confusion about time and place
- seeing or hearing things that are not there
- being sleepy or slow to respond
- problems eating or sleeping
- changes in personality
- not showing interest in things

These signs can come and go. Tell a health-care provider right away if you notice any of these signs. Delirium is a serious illness and needs to be **treated right away**.

Dementia is a disorder of the brain that can affect learning, memory, mood and behaviour. Dementia **develops slowly**, over several months or years. Dementia affects different people in different ways. Aging does not cause dementia but it is more common among older adults. One of the most common types of dementia is Alzheimer's disease.

Continued on page 2

Signs of dementia

- difficulty performing familiar tasks (e.g. banking, driving, brushing teeth)
- difficulties with thinking, problem solving, or learning new information or language
- memory loss that affects day-to-day activities
- not being able to find things (e.g. thinking someone took or moved something)
- confusion about time and place
- changes in personality, mood or behaviour
- loss of initiative (e.g. needing to be told what to do)
- poor or decreased judgment

Keep in mind that just because a person has dementia does not mean they cannot continue to live well and have meaning in their lives.

Depression is a medical illness. Having depression does not mean someone is weak. Many people have depression throughout their lives, while others suffer from depression as a result of a major change in their life, including:

- death of a loved one
- loss of independence (e.g. moving to a long-term care home)
- developing dementia or an illness

Signs of depression

- sleeping more or less than usual
- loss of interest in usual hobbies or activities
- low energy levels
- eating more or less than usual
- difficulty concentrating
- aches and pains
- constipation
- being agitated or irritable
- feely guilty, worthless, hopeless, full of regret
- thoughts of not wanting to live or of ending one's life

Depression should be taken seriously. Talk to a health-care provider if you or someone you know shows signs of depression. There are many treatment options available.

Getting help

Talk to a health-care provider right away if you or someone you know shows signs of delirium, dementia or depression. They can arrange for a proper assessment and connect you to the care or treatment you need. Also, ask them where you can get more information or support. You can learn more about delirium from RNAO's fact sheet, *Delirium: How you can help*.

This fact sheet was developed to go with the RNAO best practice guideline (BPG) *Delirium, dementia, and depression: Assessment and care, Second Edition* (2016). It is intended to increase your knowledge, and help you take part in decisions about your health or the health of a family member. RNAO's BPGs are available for public viewing and free download at RNAO.ca/bestpractices

APPENDIX E: TOOLS FOR QUALITY APPRAISAL OF THE LITERATURE

Type of Study	Study Design	Quality-Appraisal Tool
Systematic Reviews	<ul style="list-style-type: none"> ■ Systematic Review ■ Meta-Analysis ■ Meta-Synthesis ■ Literature Review 	AMSTAR Appraisal Tool
Best Practice Guidelines	<ul style="list-style-type: none"> ■ Clinical Guideline 	AGREE II Tool
Experimental	<ul style="list-style-type: none"> ■ Randomized Controlled Trials <ul style="list-style-type: none"> –Double Blind –Single Blind –Non-Blind 	CASP RCT Appraisal Tool
Quasi-Experimental	<ul style="list-style-type: none"> Nonrandomized Trial Interrupted time series design Pre-Post Test with or without control group 	(Pre-Post Test with no control group) Controlled Clinical Trial Tool adopted from National Institutes of Health (Quasi-experimental study with a control group) Cochrane Public Health Quasi-Experimental Appraisal Tool [<i>Cochrane Public Health, n.d.</i>]
Non-Experimental	<ul style="list-style-type: none"> ■ Cohort Studies <ul style="list-style-type: none"> –Prospective Cohort –Retrospective Cohort –Time Series Study ■ Case Control Studies <ul style="list-style-type: none"> –Nested Case Control ■ Descriptive Studies <ul style="list-style-type: none"> –Cross Sectional Studies –Prevalence Studies 	CASP Cohort Appraisal Tool CASP Case Control Appraisal Tool CASP Cross Sectional Appraisal Tool
Qualitative Studies	<ul style="list-style-type: none"> ■ Phenomenology ■ Grounded Theory ■ Ethnography ■ Critical Social Theory 	CASP Qualitative Appraisal Tool
Mixed Method Studies	<ul style="list-style-type: none"> ■ Mixed Method 	Mixed Methods Appraisal Tool (Pluye et al., 2011)

APPENDIX F: RNAO STATEMENT ON LEVELS OF EVIDENCE USED IN SYSTEMATIC REVIEWS/GUIDELINES

The RNAO BPG development process uses the following Levels of Evidence:

Ia	Evidence obtained from <i>meta-analysis</i> of randomized controlled trials
Ib	Evidence obtained from at least one <i>randomized controlled trial</i>
IIa	Evidence obtained from at least one well-designed <i>controlled study without randomization</i>
IIb	Evidence obtained from at least one other type of well-designed <i>quasi- experimental study, without randomization</i>
III	Evidence obtained from <i>well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies</i>
IV	Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities

Adapted from the Scottish Intercollegiate Guidelines Network (2017) and Pati (2011).