Clinical Practice Guidelines: Critical Appraisal is the Key

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The unbridled enthusiasm for guidelines, and the unrealistic expectations about what they will accomplish, frequently betrays inexperience and unfamiliarity with their limitations and potential hazards. Naive consumers of guidelines accept official recommendations on face value, especially when they carry the imprimatur of prominent professional groups or government bodies.—S H Woolf and others[1]

As front-line health-care providers and information managers, pharmacists use the pharmaceutical care model and evidence-based medicine to integrate the best evidence from the literature, the individual characteristics of the patient, and clinical expertise into their decision-making processes to optimize drug therapy for patients.[2] Although systematic reviews and randomized controlled trials represent the highest level of evidence, a "good" study design does not guarantee quality of conduct or accuracy of reporting.[2] Pharmacists understand the importance of critical appraisal and use published user's guides, checklists, and appraisal tools to assess the validity of the published evidence.[3] Unfortunately, the mere existence of high-level evidence does not guarantee changes in practice, which often lag far behind the publication of pivotal trials.[4] The development and dissemination of high-quality, evidence-based clinical practice guidelines (CPGs) represents a potential strategy to bridge this practice gap and may improve the quality of care and clinically relevant health outcomes.

CPGs are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances".[5] As the scope of pharmacy practice evolves, pharmacists are accepting more responsibility and assuming more authority to optimize medication management for patients and are increasingly reliant on CPGs to guide their management decisions.[6] Although rigorous approaches to CPG development have been advocated, serious methodological limitations still plague many CPGs, and critical appraisal of CPGs is therefore essential before any guideline recommendations are adopted into practice.[7]

Poorly developed CPGs can perpetuate medical myths, disseminate unproven beliefs, inappropriately justify poor prescribing practices, and pose risks to the health care system, health care professionals, and patients. CPGs are often subject to external influence and bias because they are not independent from their respective funding bodies or because they do not identify the role of sponsors in their development and reporting.[8] There is considerable interaction between the authors of CPGs and the pharmaceutical industry; therefore, failure to develop and adhere to conflict-of-interest guidelines and to disclose potential, perceived, and actual conflict-of-interest relationships threatens the external validity of guidelines.[9]

The authors of CPGs may not adhere to methodological standards during development of the guidelines.[10] They may fail to describe the scope and purpose of the CPGs and may not provide adequate information on the rationale for development, specific clinical questions, target population, and intended setting of the guideline. They may not address stakeholder development, including multidisciplinary involvement of

professional groups, explicit descriptions of how patient values and preferences were integrated into the development of recommendations, and delineation of target users. CPGs may be subject to selection bias if the literature search is not systematic, comprehensive, and reproducible, including disclosure of literature sources searched; search terms used; language, date, or publication status restrictions; and study selection criteria. CPGs may not state the methods used for formulating recommendations, and the recommendations may use vague and qualitative descriptions, rather than quantitative descriptions, of the benefits and risks of an intervention. Authors of CPGs may not rank the quality of the evidence and may neglect to cite high-quality evidence.[11] CPGs are not necessarily evidence-driven, but rather may be necessity-driven, and even if they are based on the best available evidence, that may only be expert opinion. CPGs may not include an adequate description of the grading of recommendations, and authors may not justify specific recommendations by linking them with their evidentiary support. Ideally, guidelines should be specific and unambiguous, should provide options for management, and should have easily identifiable key recommendations.

The application of CPG recommendations into clinical practice is the "art" of evidence-based medicine. Clinicians consider the absolute risk of disease in a given patient, the relative and absolute benefits and the risks of the intervention, the cost implications of the intervention, the resource or system limitations that threaten applicability across different clinical settings, and the discrepancies in values between the recommendation and the clinician or patient. CPGs should recommend effective strategies to disseminate and implement their recommendations and should identify potential organizational barriers to implementation.[11-14] CPGs should also outline quality indicators to measure adherence to guidelines and the impact of practice change on clinically relevant health care outcomes. Standardization does not always mean quality. Although adherence to guidelines is a performance indicator, it does not ensure better health outcomes. Quality improvement programs and remuneration decisions based on adherence to weak guideline recommendations or unproven surrogate markers may be inappropriate, may threaten patient safety, may increase the costs of care, and may delay confirmatory research. The assumption that adherence to CPG recommendations will always translate into benefits for health outcomes is flawed. It is analogous to assuming that merely understanding the mechanism of action of a drug can predict its effect on health outcomes in a clinical trial. The ultimate success of a CPG must be judged by its impact on clinically relevant health outcomes.

Although CPGs have methodological limitations, they serve an important purpose and will continue to be published and used by health care professionals, professional organizations, policy-makers, payers, and patients to guide drug therapy decisions. To practice autonomously and to advance their professional practice, pharmacists should try to increase their participation in CPG development and to use CPGs appropriately in their individual practices. Pharmacists can locate relevant CPGs by comprehensively searching computerized databases, Internet resources, and the resources of international health care agencies and professional associations involved in guideline development. Pharmacists should use user's guides, checklists, and validated appraisal instruments to critically appraise CPG methodology and thus to determine their quality of conduct, accuracy of reporting, and validity.[7,15] They should also use a systematic and logical approach to appropriately apply CPG recommendations and facilitate implementation by collaboratively developing clinical pathways, treatment algorithms, and drug therapy protocols. Finally, pharmacists must continue to promote the dissemination of high-quality, evidence-based CPGs and must conduct more research to identify barriers to guideline adherence and strategies to influence prescribing behaviour. Ultimately, practice-based research by pharmacists is required to evaluate the impact of CPG treatment recommendations on quality of care and clinically relevant health outcomes.

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