STATEMENT

Rethinking the Role of Clinical Practice Guidelines in Pharmacy Education

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Clinical practice guidelines (CPGs) play a major role in pharmacy education. Students learn to locate, retrieve, and apply CPGs in didactic coursework and practice experiences. However, they often memorize and quote recommendations without critical analysis, which tends to undermine their clinical growth. Students should become genuine drug experts, based on strong critical-thinking skills and the ability to assimilate extensive clinical and scientific knowledge. Clinical practice guidelines improve health care, and students should be familiar with them, but there are legitimate criticisms of CPGs, stemming largely from potential conflicts of interest and limitations in the quality and scope of available evidence. Despite such flaws, CPGs can be used to facilitate the clinical growth of students if the emphasis is placed on critically analyzing and evaluating CPG recommendations, as opposed to blindly accepting them. From that perspective, the role that CPGs have come to play in education may need to be reconsidered.

INTRODUCTION

Clinical practice guidelines not only play a pivotal role in health care practice, but also are ingrained in medical education.¹ In clinical didactic coursework, pharmacy students are trained to locate, retrieve, and apply CPGs for a variety of medical conditions. During practice experiences, they are often expected to quote an applicable CPG as justification for their clinical decisions. Pharmacy students tend to be well versed in the latest guidelines for common disease states, such as diabetes and hypertension.

On the surface, CPGs appear to provide the same type of straightforward guidance to students as to practicing clinicians. But beneath the surface, at the level of cognitive processing within a clinical context, the ready-made clinical recommendations of CPGs may enable students to circumvent formulating their own therapeutic plans. Some students may choose to learn excerpts from CPGs without developing an in-depth understanding of the scientific basis or clinical evidence behind the recommendations. Although no faculty member would intentionally promote such a practice, it is a reasonably expected offshoot of the memorization-oriented academic culture that plagues many pharmacy schools today.² Not all students fall victim to this “bulimic” study pattern, but for those prone to

superficial learning methods, CPGs can undermine clinical growth by providing a tempting academic short-cut: memorizing clinical facts rather than learning clinical principles. The possibility that a subset of pharmacy students might manifest such paradoxical outcomes warrants consideration by the academy.

HISTORY AND DEVELOPMENT OF CPGS

The essence of CPGs is to provide predetermined evidence-based clinical recommendations to influence decisions relating to a specific health intervention.¹ They address the need to reduce high-cost or high-risk variables in patient care based on current clinical evidence. They reflect the realization that it is increasingly difficult for individual clinicians to remain abreast of the latest therapeutic information. As the cost and complexity of new therapies continue to expand, there is an ever-increasing potential of practitioners being influenced by market-driven forces, leading to unwarranted use of the latest novel therapeutic alternative.³

The CPG is a fairly recent phenomenon. The first diabetes guidelines from the American Diabetes Association were published in 1988.⁴ In December 1989, Congress established the Agency for Health Care Policy and Research (AHCPR) to enhance the quality, appropriateness, and effectiveness of health care services.⁵ One of the primary responsibilities of AHCPR was to initiate the development, dissemination, and evaluation of practice guidelines. To that end, AHCPR partnered with the

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Institute of Medicine (IOM), and together they defined practice guidelines as, “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.”

The two agencies determined that guidelines should demonstrate validity, reliability/reproducibility, clinical applicability, clinical flexibility, clarity, multidisciplinary development, scheduled review and updating, and meticulous documentation. Despite setting high standards, they acknowledged that regardless of the quality of research and the impartiality of the participants, experts may come to different conclusions about the same evidence.⁵

Between 1992 and 1996, AHPRC published 19 CPGs, none of which are still in use. The agency, which was renamed the Agency for Healthcare Research and Quality (AHRQ) in 1999, turned its attention to overseeing the development of CPGs by other institutions and organizations.^{6,7} It established the National Guideline Clearinghouse (NGC) to set standards for CPG development and provide a repository for collecting, comparing, and disseminating CPGs.⁸ The website, which is updated weekly, now contains thousands of searchable guidelines organized by categories.⁹

In 2011, IOM released a report establishing new standards for CPGs, which led to a new set of inclusion criteria that were implemented by the NGC in 2014, along with a new definition: “CPGs are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.”^{10,11} The institute’s efforts to refine CPG criteria reflect the natural tension that stems from the need to use evidence-based analysis to standardize care, while affording practitioners the flexibility to exercise their own clinical judgment.¹ That tension is the source of ongoing controversy.

IMPACT OF CPGS IN PRACTICE

With randomized clinical trials serving as the fuel, CPGs are intended to function as the primary vehicle for actualizing evidenced-based health care. Kiser wrote a concise review of CPGs, emphasizing that they have resulted in improvements in patient care by guiding rational decisions and fostering collaboration among clinicians.¹² Pyon also concluded that when appropriately developed, CPGs are valuable tools that provide practitioners with evidence-based information on which to base quality medical care.¹⁰

To be of optimal value, CPGs should be accountable and credible, with evidenced-based clinical data given priority over the opinions of expert panels.¹² An assessment of the evidence used to develop recommendations

should be included. If empiric evidence is lacking, or if recommendations contradict the evidence, the rationale behind recommendations should be made explicitly clear.¹² Unfortunately, these characteristics are not always met, and legitimate concerns about the processes involved in developing CPGs have been raised.¹³

Guidelines often reflect evidence drawn from studies with narrow inclusion criteria, despite being applied to a broader population of patients.¹² Some patients will deviate from study subjects, and patient comorbidities might cloud the interpretation of CPG recommendations.¹³ The “standard of practice” nature of CPGs, based on the use of consensus expert panels to derive recommendations, might coerce clinicians to follow the recommendations, even when patient-specific considerations suggest that a different therapeutic course of action is preferable.¹⁴ Moreover, CPGs sometimes promote defensive medical practices, as clinicians seek to minimize the risk of malpractice litigation by complying with published guidelines.^{1,14} There is also concern over consensus reports being used to establish benchmarks by which to define the quality of practitioner performance.¹³ Even insurance coverages and third-party reimbursement policies can be influenced by CPGs.

One of the more obvious limitations of CPGs is the potential that bias might influence the decisions of consensus panels when formulating recommendations if some members hold a strong advocacy position for or against a particular practice.¹ Although the intent is for experts to base their recommendations purely on the evidence, CPGs are not just summaries or compilations of clinical evidence. They include interpretations of evidence that reflect personal and organizational preferences based on value judgments.^{3,15} Mendelson et al examined 17 CPGs developed by the American College of Cardiology (ACC) and the American Heart Association (AHA) as of 2008.¹⁶ Of the 498 individuals who participated in the CPG process, 56% reported a conflict of interest, such as being the recipient of a research grant or speaker honorarium, owning company stock, or serving as a paid consultant or board member. Implications of conflicts are exacerbated by a lack of transparency, in that panel deliberations are often kept confidential, and preliminary versions of CPGs are not posted for comment.^{15,17}

Another issue that may call into question the validity of some CPGs relates to the quality of available evidence on which recommendations are based. Tricoci et al examined all CPGs developed by ACC and AHA from 1984 to 2008, which included 53 guidelines with a total of 7196 recommendations.³ The level of evidence was reported for 16 current CPGs containing 2711 recommendations. Only 11% of the recommendations were based on level A

evidence (ie, from multiple randomized trials or meta-analyses), and 48% were based on level C evidence (ie, from expert opinion, case studies, or standards of care). It was further noted that only 19% of Class I recommendations (there is evidence and/or general agreement that a given procedure or treatment is useful and effective) were based on level A evidence. The authors concluded that most recommendations contained in CPGs developed by ACC and AHA were based on low-level evidence or expert opinion.³

Lee and Vielmeyer evaluated the strength of 4218 recommendations and the quality of evidence found in 41 CPGs developed by the Infectious Diseases Society of America (IDSA) between January 1994 and May 2010.¹⁸ They determined that only 14% of the recommendations were based on at least 1 randomized controlled trial, compared to 55% that were based on expert opinion alone. Similar issues relating to low levels of evidence were documented in a comprehensive study of National Comprehensive Cancer Network CPGs.¹⁹ A related editorial emphasized that most recommendations in CPGs appear to be based not on clinical certainty but on clinical probability, and although the quality of evidence is reported, it is not always clear how the evidence factored into the development of specific recommendations.¹⁵

Imperfect as they are, CPGs can serve as valuable clinical tools, provided that practitioners understand and appreciate their limitations. The availability of evidence-based CPGs does not preclude the need for clinicians to evaluate pertinent literature and exercise clinical judgment, even when such decisions are contrary to published recommendations. The importance of conducting an individualized clinical analysis for every patient, and not blindly accepting CPG recommendations, should be carefully considered when developing instructional strategies for teaching pharmacotherapy.

IMPACT OF CPGS IN EDUCATION

In his book on revisioning professional education, Zlatic described the vital role of critical thinking as students learn to practice as professionals.²⁰ He emphasized that students must go beyond the acquisition of knowledge and the application of conventional wisdom to develop the cognitive capacity to formulate alternative ideas and strategies. Critical thinking is what enables students to analyze and evaluate information and form logical conclusions as they learn to design individualized therapeutic plans.

But for many, the process is not intuitive. It must be cultivated by repetitive practice and experience in making clinical decisions over the duration of a doctor of pharmacy (PharmD) curriculum. If faculty members place undue emphasis on knowing specific CPG recommendations, they may be inadvertently enabling students to project the

outward appearance of being clinically knowledgeable, while masking the fact that they lack a fundamental understanding of the scientific basis and clinical evidence behind the recommendations they so capably recite. Although the issue is mentioned in medical literature, greater attention is warranted.

Kiser made reference to the educational aspect of CPGs, but from the perspective of increased awareness among practitioners through continuing education.¹² He suggested that CPGs could provide a basis for discussion of patient care management in both clinical and didactic academic settings, but provided no documentation or elaboration to clarify that viewpoint. Berg et al suggested that medical students and residents should be trained to evaluate CPGs based on a critical analysis of the process and the outcomes produced.¹ They also discussed the potential hazards associated with teaching students to accept and apply CPGs uncritically, regardless of the source or appropriateness of the recommendation. Uncritical acceptance undermines an educational process that is predicated on developing sound clinical judgment and rational decision-making skills. According to Berg et al, "Failure to equip trainees with the skills necessary to evaluate and apply clinical practice guidelines will leave them with a serious disability as guidelines become the norm for practice. Students and residents untrained in the new methods will not be able to intelligently negotiate their way; they will tend to be overly deferential to authority, and unable to critically evaluate clinical practice guidelines promulgated by various health care organizations. They will lose autonomy, forced to follow poorly constructed guidelines that subject their patients to substandard care without a strong scientific base."¹

Kothari posited that there may be unintended deleterious effects of using CPGs in medical education, stating, "Bombarding students with guidelines for all scenarios in seminars, textbooks, and journals is like providing them with the printout of the destination without showing them the roadmap. It may seem more efficient in the short-term but does little to enhance discriminatory skills and numbs the facility for critical thinking."²¹ Shaneyfelt and Centor acknowledged an "interesting concern" about the unintended detrimental aspects of CPGs on trainees.²² They suggested that with proper guidance, CPGs could be used to enhance students' clinical reasoning skills. However, that would necessitate the use of strategic exercises in which students must analyze and evaluate CPGs in a variety of clinical scenarios. It would require an intentional process of deconstructing a CPG so students gain an appreciation of how available evidence and foundational science might have shaped the recommendations.

The importance of how pharmacy students approach CPGs during their education extends beyond graduation. If the clinical expertise of new graduates is largely based on being adept at recalling the latest guidelines, they are relying on skills that could eventually be replaced by technology. Algorithmic sequences, pathways, and protocols can be readily adapted to a computer program or smart phone app. A pharmacist's therapeutic knowledge must exceed the specifics of CPGs. In fact, knowing the elements of CPGs is not listed among the learning outcomes enumerated in the Center for the Advancement of Pharmacy (CAPE) 2013 Educational Outcomes.²³ The only mention of guidelines is found in 2.2.6 (medication use systems management), which refers to applying best-practice standards in relation to the safe and effective use of medications and in 2.4 (population-based care), which indicates that students should understand how patient-centered care influences the development of practice guidelines.

There are no references to CPGs in the 2016 Accreditation Standards and Key Elements for the Professional Program Leading to the Doctor of Pharmacy Degree, the Joint Commission of Pharmacy Practitioners 2014 Pharmacists' Patient Care Process, or the American College of Clinical Pharmacy's 2014 Standards of Practice for Clinical Pharmacists.²⁴⁻²⁶ This is not to suggest that CPGs should not play a role in pharmacy education. To the contrary, students need to be familiar with major treatment guidelines. A working knowledge of major CPGs is advantageous for students or pharmacists interacting with other health care practitioners in a collaborative patient care setting and for pharmacists pursuing board certification who need to be aware of the CPGs pertinent to their respective areas of practice. Nevertheless, there is cause for concern when students quote CPG recommendations without having a firm grasp of the clinical implications. Therein lies the challenge for clinical instructors.

PROPER ROLE OF CPGS IN PHARMACY EDUCATION

A commentary in *AJPE* metaphorically illustrated that the responsibility of faculty members is not to give students fish, but to help students learn to catch fish on their own.² Pharmacy students must be guided by faculty members to develop the ability to form clinical judgments and make patient care decisions, which necessitates educational processes deeply rooted in critical thinking—in diametric contradiction to superficial memorization and recitation. From that perspective, the impact of CPGs in pharmacy education is not an inherent property of the guidelines themselves; they simply contain information. The issue relates to how students interact with the information in a CPG. Although some students might be

inclined to memorize parts of a CPG verbatim, their learning can be enhanced significantly by analyzing and critiquing the relevance and validity of the CPG, or by assimilating its recommendations into other clinical findings. A practice tool, no matter how effective, can function differently when used as an instructional tool. By defining specific learning outcomes that emphasize analysis over memorization, faculty members can strategically maximize the benefits and minimize the risks of using CPGs for educational purposes.

In didactic coursework, whether disciplinary coverage is integrated into the same pharmacotherapy course or separated into distinct science and clinical courses, instructors should engage students in critical-thinking, problem-solving, and decision-making activities that force them to explore the science and evidence behind important CPG recommendations. For example, in the 2014 Evidence-Based Guidelines for the Management of High Blood Pressure in Adults (JNC 8), recommendation 8 states, "In the population aged 18 years or older with CKD (chronic kidney disease) and hypertension, initial (or add-on) antihypertensive treatment should include an ACEI (angiotensin converting enzyme inhibitor) or ARB (angiotensin receptor blocker) to improve kidney outcomes."²⁷ That singular fact is relatively easy to memorize and recite.

But for students to understand the rationale behind the recommendation, they should answer a variety of relevant questions. What are the mechanisms by which ACEIs and ARBs exert their pharmacologic effects? How does the pathophysiology of CKD relate to that of hypertension, and how do those pathologies correspond to the pharmacology and medicinal chemistry of ACEIs and ARBs? What clinical trials have been published on the therapeutic applications of ACEIs and ARBs in adult patients with CKD and/or hypertension? What were the findings of those studies, and how reliable is the evidence? Some of these questions address the "why" of the CPG recommendation, some address the "how" of CPG application, and others involve a critique of the quality of the CPG. All extend beyond simply knowing that CKD patients with hypertension should be treated with an ACEI or ARB. All promote the type of critical thinking that leads to deep, substantive learning.

Following the same example, but from the perspective of a pharmacy preceptor instructing a student or resident during a practice experience, the questioning shifts in focus to include the assimilation of patient-specific information, as the benefits and risks of various therapeutic options are contemplated. What other disease states or medical conditions does the patient have, and how are they impacted by ACEI or ARB therapy? How should

one monitor and manage the adverse effects of ACEIs or ARBs? What other medications does the patient take and to what extent might they interact (and by what mechanisms) with ACEIs or ARBs? If ACEI or ARB therapy is not effective at controlling the patient's blood pressure, should the dosing be changed or other therapeutic alternatives considered? These are but a subset of the questions that should be running through the minds of trainees as they form clinical judgments based on recommendation 8 of JNC 8.

It is by answering such questions and justifying the answers that students and residents will develop a level of clinical skill commensurate with the type of patient care roles that pharmacists should be prepared to assume. When faculty members and preceptors consistently pose such questions, trainees will gradually gain an appreciation of the relevance and importance of clinically-oriented critical thinking. It would be prudent to discourage students from immediately seeking out a CPG when asked to resolve a clinical dilemma. The initial approach should be to define the problem, examine all related information, and formulate a rational conclusion of their own. Thereafter, as a means of confirmation and further analysis, it would be appropriate to consult a CPG.

There are no legitimate shortcuts when it comes to learning the intricacies of clinical practice. As trainees draw upon their scientific and clinical knowledge and scrutinize available evidence, CPGs can function as catalysts of deep learning, rather than substitutes for it. Ultimately, it is the manner in which an instructor directs students to engage CPGs that determines whether the process will augment or subvert their clinical growth.

CONCLUSION

Those who teach pharmacy, whether didactically or experientially, should be cognizant of the academic ramifications of CPGs. This is particularly true in light of the ongoing challenge that pharmacists face in trying to gain recognition as patient care providers, which essentially hinges on the health care community's perception of pharmacists as being genuine drug experts. Gourmet chefs—ie culinary experts—do not rely on cookbook recipes. Their deeper expertise enables them to cook masterful meals. Likewise, for pharmacists to create masterful pharmacotherapeutic plans, they must possess a deeper expertise, a level of mastery that enables them to function beyond the “cookbook” recommendations of CPGs. The pharmacy academy needs to ensure that it produces drug experts of the highest caliber, practitioners who excel at thinking critically and making sound clinical decisions. With this goal in mind, it is time to rethink and perhaps redefine the role of CPGs in the educational process.

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