

2012

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Recommended Citation

Arnold J. Rosoff *The Role of Clinical Practice Guidelines in Healthcare Reform: An Update*, 21 *Annals Health L.* 21 (2012).
Available at: <http://lawcommons.luc.edu/annals/vol21/iss1/5>

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The Role of Clinical Practice Guidelines in Healthcare Reform: An Update

*Arnold J. Rosoff**

I. INTRODUCTION

Moving the U.S. healthcare system toward greater emphasis on evidence-based medicine (“EBM”) is an essential part of the nation’s healthcare reform strategy. The use of clinical practice guidelines (“CPGs”) is one of the main ways that EBM can be implemented. Much has been written about CPGs, pointing up their potentials and pitfalls. This update steps off from that foundational and definitional body of work and highlights some key developments and issues in the CPG movement over the past two decades. It concludes with a look at the recent work of the Institute of Medicine (“IOM”), which has long played a leading role in the promotion of CPGs. The IOM recently concluded a pair of yearlong initiatives to refine the methodologies by which medical evidence is systematically reviewed; these reviews will, in turn, provide the data needed to develop trustworthy and reliable CPGs.

II. THE IMPERATIVE AND PURSUIT OF COST CONTAINMENT AND THE ROLE OF CPGS IN THAT QUEST

As President Obama and many others have observed, to have the kind of inclusive health care system we want in the United States we have to “bend the cost curve,” in other words, halt the seemingly inexorable tendency of U.S. healthcare expenditures to rise faster than the rate of GDP growth and, thus, to consume an increasingly large share of our national resources. We cannot hope to achieve and sustain universal health care (“UHC”), a national regime where all have adequate access to quality health care, unless and until we can control the runaway costs of care. Moving the U.S. healthcare system toward wise and responsible cost containment requires a multi-step process. First we have to figure out what works in medical care,

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which we do by outcomes research through “systematic review” of the medical evidence, the core component of EBM. Then, where there are multiple ways to approach a health care need, we engage in “comparative effectiveness research” (“CER”) to figure out which way(s) works best. Next, we do an economic analysis, plugging in the cost component to determine which approach provides the best value for the money a process known as “cost-effectiveness analysis” (“CEA”).¹ Finally, when this analysis is complete, we take the resulting insights and convert them into CPGs to help practitioners implement in their day-to-day actions what has been learned. As defined by the IOM in its seminal 1990 report, *Clinical Practice Guidelines: Directions for a New Program*,² CPGs are “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.” CPGs are, then, one of the principal mechanisms through which the results of outcomes research are put into practice, in pursuit of the important goal of advancing EBM.

III. IMPEDIMENTS TO THE ADOPTION AND SUPPORT OF CPGs

Although CPGs have played an increasingly prominent role in health care for more than a quarter century, there continue to be significant impediments to their development, adoption and use. The concept of CPGs is still not universally accepted and supported. Clearly, if they are to achieve their potential they must be trusted. To be trusted they must be “trustworthy;” thus, one of the two IOM committees established to work on this was called the “Committee on Standards for Developing Trustworthy Clinical Practice Guidelines.” I served on that committee and my insights presented here are largely drawn from that experience.

A. *We Must Have Good CPGs*

Obviously, if CPGs are to achieve what they are meant to, they must be of good quality. At the least, there must be assurance that they meet a minimum standard of quality. But, despite their having been around and in use for many years, there are not clearly defined and universally accepted standards and measures of what a quality CPG is. So, “Job One” is to

1. See, e.g., Ray Robinson, *Cost-Effectiveness Analysis*, 307 BRIT. MED. J. 793 (1993), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1696433/pdf/bmj00040-0053.pdf>; Uwe E. Reinhardt, ‘*Cost-Effectiveness Analysis*’ and U.S. Health Care, N.Y. TIMES BLOG (Mar. 13, 2009, 6:45 AM) <http://economix.blogs.nytimes.com/2009/03/13/cost-effectiveness-analysis-and-us-health-care/>.

2. INST. OF MED., *CLINICAL PRACTICE GUIDELINES: DIRECTIONS FOR A NEW PROGRAM* 8 (Marilyn J. Field & Kathleen N. Lohr eds., Nat’l Acad. Press 1990), available at http://www.nap.edu/catalog.php?record_id=1626 [hereinafter *DIRECTIONS FOR A NEW PROGRAM*].

define and disseminate quality standards that will be generally accepted and followed.

In undertaking this, we do not start from scratch; much of the valuable foundational work has been done over the past quarter century. The federal Agency for Health Care Policy and Research (“AHCPR”) was created in 1989 largely to help develop, refine and disseminate the methodology for creating CPGs. Renewed and renamed in 1999 as the Agency for Healthcare Research and Quality (“AHRQ”)³, this arm of the U.S. Department of Health and Human Services continues to support outcomes research, evidence-based practice, and the development and use of CPGs. It also conducts a variety of activities to enable citizens to be knowledgeable consumers of healthcare services. The AHRQ maintains the National Guidelines Clearinghouse (“NGC”)⁴, and the AHRQ funded the IOM committees introduced above and discussed below. On the international front, the Cochrane Collaboration⁵ and the Guidelines International Network⁶ have been active proponents and supporters of outcomes research, systematic reviews, and the development, dissemination, and use of CPGs. These are just the most prominent and visible contributors to the EBM-CPG movement; there are many others.

Although the proliferation of guideline-generating organizations and their CPG products has helped to propel the movement, this embarrassment of riches poses a problem. With so many players in the game and no clear rules or controlling organizational structure, a “Tower of Babel” situation is inevitable. It commonly happens that numerous guidelines exist for a particular condition or treatment. Some may say essentially the same thing, but in different ways, so it is difficult to recognize the consensus. Others may contain significant differences not apparent at a casual reading or even upon a close reading. Some may be based upon robust evidence and be the product of careful, skillful analysis, and synthesis; others may be built on a shaky scientific foundation and may include misinformation, or deliberate “disinformation.” Some may proceed from an auspice, such as a drug company with a product to push, that has a bias or ulterior motive, and

3. The AHCPR was created through the Omnibus Budget Reconciliation Act of 1989, Pub. L. 101-239. See Bradford H. Gray et al., *AHCPR and the Changing Politics of Health Services Research: Lessons from the Falling and Rising Political Fortunes of the Nation's Leading Health Services Research Agency*, HEALTH AFFAIRS, June 25, 2003, <http://content.healthaffairs.org/content/suppl/2003/12/09/hlthaff.w3.283v1.DC1> (detailing the stormy, politically perilous history of the AHCPR).

4. Agency for Healthcare Research & Quality, National Guideline Clearinghouse (2010), <http://www.guidelines.gov/> (maintained through a contract with the Emergency Care Research Institute).

5. The Cochrane Collaboration (2011), <http://www.cochrane.org/>.

6. Guidelines International Network, Welcome to G-I-N (Sept. 15, 2011), <http://www.g-i-n.net/>.

compounding this problem, there are various ways that a CPG's true auspice can be concealed. Unless those wishing to use CPGs – whether providers, payors, or consumers of health services and products – can readily and reliably assess the legitimacy and quality of guidelines, the CPGs' worth is severely compromised and the guidelines movement is seriously hampered.

B. Providers Must Accept and Follow Them

Assuming that we can have reliable access to good CPGs, a big assumption at this point in time, they will not necessarily be universally adopted and followed. Notwithstanding how helpful CPGs can be in enabling physicians to stay up-to-date with evolving medical knowledge and practices and in helping them make treatment decisions – the obvious *raison d'être* of guidelines – some physicians are suspicious of guidelines and reluctant to follow them and/or participate in their development. Physicians may question the evidence underlying CPGs, or the methodology used to generate them, or the competence, objectivity, and/or motivation of the persons or organizations behind them. In too many cases, guidelines are presented without sufficient information to enable prospective users to address these concerns; adequate documentation and transparency are essential if guidelines are to be accepted as credible. Moreover, even when a particular guideline is seen as sound, a physician may not regard it as applicable to a particular patient, or to their patient population generally. For these reasons, physicians do not uniformly adhere to guidelines.

Guidelines give general guidance; clearly there will be cases, perhaps many, where a “one size fits all” approach is not appropriate. A key challenge, then, is how to identify the exceptional situations and allow sufficient latitude for individual judgment and for deviation from the guidelines. Where deviation from the general approach is thought to be warranted, how should the need for exception be confirmed and documented? Should physicians have wide latitude to deviate from guidelines provided they can offer a justification after the fact for the deviation? Or, if prior approval of a deviation is to be required, what mechanism(s) or procedure(s) can be devised to make it feasible, and not overly burdensome, given the exigencies and time pressures of daily practice?

Another factor complicating the task of convincing physicians to use CPGs is the natural resistance of professionals to accept standardization of practice. Physicians pay dearly to acquire their expertise and the recognition of it; they are understandably reluctant to give up the latitude that has traditionally been accorded them to exercise their clinical judgment

as they see fit. When we have limited knowledge of what works and what does not in medical care, we must trust the discretion of professionals in the field and cut them a good deal of slack for making judgment calls, even when those calls turn out to be wrong. But as the EBM movement advances our knowledge and medicine increasingly morphs from an art into a science, society will have less tolerance for medical judgments that are not rigorously supported by the accumulating evidence. The same advances that facilitate clinicians' decision-making will constrain that decision-making, and no one welcomes constraints, especially not those who have invested so heavily in their autonomy.⁷

Another challenge, then, harking back to what was said above, is to design guidelines that are no more constraining than they have to be – so that they do not pinch like an ill-fitting corset – and to involve guideline users in their development so that they see them as reflecting and embodying their own judgment rather than being imposed by external forces.

C. *Guidelines Must Not Unduly Impede Medical Advance*

Not surprisingly, EBM (and the standardization of medical practice that it fosters) has the potential to slow medical advance. If we increasingly require carefully studied evidence that proves an approach to treatment is effective before adopting it, clinical innovation will necessarily be limited.⁸ To put this into real-world terms, if a health plan will only cover treatments that are proven effective and cost-efficient, especially if the bar for this proof is set high, new approaches will be harder to introduce. To achieve an optimal balance between necessary cost containment and desirable medical progress there must be adequate opportunities built into the system for trying new drugs, devices, techniques, and other innovative medical technologies. Innovation must continue, but it must be managed and measured. “Life on the (healthcare) frontier” where anything goes is a thing of the past, not a blueprint for the future.

D. *The Law Must Embrace Them*

How the law understands and treats CPGs will surely affect their acceptance and support by the medical community. There is an inherent

7. See STEPHAN TIMMERMANS & MARC BERG, *THE GOLD STANDARD: THE CHALLENGE OF EVIDENCE-BASED MEDICINE AND STANDARDIZATION IN HEALTH CARE* (Temple Univ. Press 2003).

8. Complicating this matter is the difficulty of distinguishing between “clinical innovation” and “medical experimentation,” the latter being subject to significantly higher constraints and regulatory requirements. See, e.g., *Brook v. St. John’s Hickey Mem. Hosp.*, 380 N.E.2d 72 (Ind. 1978).

tension between EBM approaches and the way the law has traditionally measured whether care rendered was of adequate quality. Deeply imbedded in the law is the principle that the standard of care is fixed by customary medical professional practice; a physician is deemed to act properly if he or she treats a patient as other physicians customarily would in the same situation.⁹ To the extent that customary practice incorporates elements that are not justified by the scientific evidence – e.g., wasteful use of resources, such as unnecessary testing and procedures, days of hospitalization, etc. – physicians who practice according to EBM dictates, and thus deviate from customary practice, might put themselves at risk of legal liability if something goes wrong. To put the matter more starkly, if one of the principal purposes of promoting EBM is to move physicians away from customary approaches and toward demonstrably more efficient and effective approaches, but the law continues to use customary practice to define what is legally required, physicians who practice EBM might find themselves caught between Scylla and Charybdis.

If CPGs are to aid rather than confound courts' quest for justice in health care litigation, the law needs to (a) recognize that customary practice is not always good practice and (b) be willing to admit EBM evidence as proof of what healthcare providers should do. The first part of this, (a), is not entirely new. There are court opinions dating back more than a quarter century, which hold that customary practice is not always the right measure of what should be done.¹⁰ The second part, (b), is somewhat more in question; courts are nowhere near consensus on whether CPGs should be admitted as evidence, on what basis, and with what limitations. On the face of it, CPGs could be inadmissible as hearsay, since they are statements made outside of court by people, the guideline developers, who were not under oath at the time the statements were made, and are not present in court to allow cross-examination or observation of their demeanor.¹¹ However, despite being "technical" hearsay, CPGs could be admitted through one of the recognized exceptions to the hearsay rule, such as the

9. To make decisions based on customary medical practice, courts must be able to determine what customary practice is. That is not so easy. Courts typically look to expert witnesses to inform them of the "standard of practice," but that is a time-consuming, expensive, cumbersome, and ultimately not very reliable process. CPGs have the potential to move the fact-finding process past this difficulty and streamline courts' decision-making in quality of care and coverage of benefits litigation. *See, e.g., Arnold Rosoff, Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines*, 26 J. HEALTH POL. POL'Y & L. 327 (2001).

10. *See, e.g., Burton v. Brooklyn Doctors Hosp.*, 452 N.Y.S.2d 875 (N.Y. App. Div. 1982); *Helling v. Carey*, 519 P.2d 981 (Wash. 1974).

11. *See, e.g., Hinlicky v. Dreyfuss*, 848 N.E.2d 1285, 1289 (N.Y. 2006). *See also Michelle M. Mello, Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 663 (2001).

“learned treatise” exception, the “professional reliability” exception, or on the grounds that they are not hearsay at all because they are not being offered to prove the truth of what was said outside of court.¹²

In *Hinlicky v. Dreyfuss*, the New York Court of Appeals approved admission of a guideline issued by the American Heart Association and the American College of Cardiology despite hearsay objections. The court’s rationale was that the guideline was offered not for the truth of the matter asserted and not to establish a *per se* standard of care but, rather, for the non-hearsay purpose of illustrating a physician’s decision-making methodology.¹³ Beyond that, there is the question of whether a CPG can be used by one party in a malpractice or insurance coverage suit to counter expert witness testimony by the other party, and if so, whether the CPG and expert testimony evidence should be given equal probative weight. That question would presumably turn on a court’s ability to assess the relative merit of different CPGs based upon their underlying scientific evidence, the reputation of their generators, and/or other factors.¹⁴

The ability to distinguish “good” from “poor” CPGs, and the gradients in between, must be developed, not just for courts, but for other users as well. How this can best be done is addressed later in this paper. There is also the question of whether patient-plaintiffs and healthcare providers should stand on equal footing in their ability to use CPGs in litigation. A Maine law on the books for approximately twelve years, from 1990 through 2002, allowed physicians participating in an experimental program to use state-approved CPGs as a “shield” (exculpatory use) against malpractice suits while denying patient-plaintiffs their use as a “sword” (inculpatory use).¹⁵ In other words, a physician could point to his or her compliance with an approved guideline as proof that they gave good care, but a patient could not use the physician’s non-compliance with a guideline as evidence that they did not. This lop-sided allowance of scientific evidence arguably violated the equal protection and due process clauses of the Fourteenth

12. Hinlicky, *supra* note 11, at 1289-90.

13. Michael T. Loffredo, Court of Appeals Holds Clinical Practice Guidelines Setting Forth Standards of Care Are Admissible as Demonstrative Evidence (Aug. 2006), http://www.clausen.com/index.cfm/fa/firm_pub.article/article/4bae4aba-f089-4169-b790-cec297459f7e/.

14. For discussion of federal judges’ responsibility to evaluate what scientific evidence would be helpful to a jury’s deliberations and, thus, is admissible, see *Daubert v. Merrell-Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

15. ME. REV. STAT. ANN. tit. 24, §§ 2971-2978 (repealed 1999). For a thorough discussion of the pros and cons of using guidelines for inculpatory as opposed to exculpatory purposes and an empirical analysis of the relative use in reported cases, see Andrew L. Hyams et al., *Medical Practice Guidelines in Malpractice Litigation: An Early Retrospective?* 21 J. HEALTH POL. POL’Y & L. 289 (1996); Rosoff, *supra* note 9, at 341.

Amendment and corresponding sections of the Maine Constitution,¹⁶ but the constitutional infirmity was never challenged or resolved in the courts. In fact, during the decade when the experiment was in effect it yielded not a single court case, so there was never an occasion for judicial resolution of the constitutional issue. Other states followed Maine's lead and its lopsided approach,¹⁷ designed to gain physicians' support for CPGs by neutralizing their fear of the legal risks. This approach was also incorporated into a number of healthcare reform bills, none of which ever became law.¹⁸

Successful implementation of EBM through the use of CPGs will require a clarification of how the law should treat CPGs. To summarize the foregoing overview, the key issues the law must resolve are: Should CPGs be allowed as evidence? If so, should both plaintiffs and defendants be allowed to use them? (Political considerations aside, this seems a "no brainer;" certainly both sides should be able to use them.) What weight should CPG evidence be given and, as a part of that question, how should courts go about differentiating between "good" and "bad," "better" and "best" CPGs? This brings us back to the main thrust of this update, the recent work of the IOM committees to refine and strengthen EBM and the CPG development process.

IV. INSTITUTE OF MEDICINE COMMITTEES WORK TO STRENGTHEN EBM AND CPGs

The Medicare Improvements for Patients and Providers Act of 2008¹⁹ called for the creation of two committees to study ways of improving systematic reviews of medical evidence: the Committee on Standards for Systematic Reviews of Comparative Effectiveness Research²⁰ and the Committee on Standards for Developing Trustworthy Clinical Practice Guidelines.²¹ Federal funds, channeled through AHRQ, supported the IOM

16. Jennifer Begel, *Maine Physician Practice Guidelines: Implications for Medical Malpractice Litigation*, 47 ME. L. REV. 69, 93, 98-99 (1995) (explaining that such an allowance is also a violation of Article I, Section 6-A of the Maine Constitution); but see Mello, *supra* note 11, at 704-708.

17. FL. STAT. ANN. § 408.02 (repealed 2004); Minn. Stat. 62J.34(3)(a) (repealed 1995).

18. Health Security Act, H.R. 3600, 103rd Cong. (1993); Medical Injury Compensation Fairness Act of 1993, H.R. 1989, 103rd Cong. (1993); Medical Malpractice Liability Reform Act of 1993, H.R. 1625, 103rd Cong. (1993); Medical Injury Compensation Fairness Act, S. 1232, 102nd Cong. (1991).

19. Medicare Improvements For Patients And Providers Act of 2008, Pub.L. 110-275, § 304 (2008).

20. See Inst. of Med., Standards for Systematic Reviews of Comparative Effectiveness Research (Apr. 13, 2011), <http://www.iom.edu/Activities/Quality/SystemReviewCER.aspx>.

21. See Inst. of Med., Standards for Developing Trustworthy Clinical Practice Guidelines (Mar. 3, 2011), <http://www.iom.edu/Activities/Quality/ClinicPracGuide.aspx>.

to do this work. The committees were convened in the fall of 2009 and met throughout 2010. They worked on parallel tracks, with close collaboration facilitated by interchange among the members, coordinated meetings, and close interaction between the IOM staff supporting each committee. Their work was interlinked in that systematic reviews yield the EBM content that gets embodied in CPGs; thus, in concept, the CPG committee was “downstream” of the systematic review committee. The committees concluded their work in early 2011, submitted their reports to Congress, and released them to the public in March 2011. The two reports are titled *Finding What Works in Health Care: Standards for Systematic Reviews* and *Clinical Practice Guidelines We Can Trust*. To facilitate dissemination of the committees’ deliberations, findings and recommendations, both reports are available free of charge from the National Academies Press.²²

The IOM committees’ work and output are closely related to the broader healthcare reform effort currently underway in the U.S. Reflecting this paper’s opening comments about the need to “bend the cost curve,” the federal healthcare reform legislation passed in March 2010, the Patient Protection and Affordable Care Act (PPACA or, as it is often called, the “ACA”) puts emphasis on “finding what works in health care,” the title of the first IOM report. The ACA creates a nonprofit, public-private body, the Patient-Centered Outcomes Research Institute, (“PCORI”) tasked with “setting methodological standards for clinical effectiveness research, including systematic reviews of research findings.”²³ The IOM committees’ work will afford guidance and direction to PCORI’s efforts toward setting and maintaining high standards for deriving the evidence that will power the EBM movement. Explaining the need for such standards, Dr. Harvey Fineberg, IOM’s president, said, “[w]hen conducted well, a systematic review identifies, appraises, and synthesizes the available body of evidence for a specific clinical question. However, not all of these reviews meet the appropriate standards of quality and methodology.”²⁴

The chairs of the Systematic Reviews (“SR”) committee continued the explanation in their report’s preface, “[t]here are many competing systems for evaluating and synthesizing evidence, and there are no internationally agreed-upon standards for how to conduct an SR or create a CPG.”²⁵ They

22. Inst. of Med., *Clinical Practice Guidelines We Can Trust* (2011), <http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx>; Nat’l Acad. Press, *Finding What Works in Health Care: Standards for Systematic Reviews* (2011), http://www.nap.edu/catalog.php?record_id=13059.

23. INST. OF MED., *FINDING WHAT WORK IN HEALTH CARE: STANDARDS FOR SYSTEMATIC REVIEWS* ix (Jill Eden et al., eds, Nat’l Acad. Press 2011), *available at* http://www.nap.edu/catalog.php?record_id=13059.

24. *Id.*

25. *Id.* at xi.

acknowledged that their committee's standards "set a high bar that will be difficult to achieve for many SRs, yet the evidence and experience are not reassuring that it is safe to cut corners if resources are limited. The standards will be especially valuable for SRs of high-stakes clinical questions with broad population impact, where the use of public funds to get the right answer justifies careful attention to the rigor with which the SR is conducted."²⁶ Getting healthcare providers to do the right thing is not just a matter of figuring out what that is, it also entails devising and implementing payment and incentive mechanisms that reward appropriate actions. Pay for performance – value-based purchasing or "P4P," as it is widely referred to²⁷ – will increasingly be the order of the day in both governmental and private insurance plans alike. To make this work, there must be readily accessible, reliable, and accepted measures of clinical performance. The CPGs fashioned from properly conducted SRs are key to this initiative. They will provide the clinical performance measures that are used to implement P4P.

A. *Strengthening What Goes into CPG Development*

The standards articulated by the SR committee are in fact quite rigorous, as are those set out in the CPG committee report. Both put strong emphasis on the identification, disclosure and management of bias and conflicts of interest ("COI"). Bias and COI can affect both the SR and CPG-development phases and can arise in a number of ways. Clinicians who are known for their knowledge and skill in treating particular ailments or for using and/or perfecting particular treatment approaches and techniques are the most obvious and likely candidates to be asked to participate in systematic reviews and in guidelines development related to those activities. They bring knowledge, expertise and credibility to the process, but they also potentially bring bias and COI. They may have too strong of an investment – intellectual, financial and/or institutional – in a particular drug, device, clinical approach, or treatment technique. The challenge, then, is to take full advantage of the good elements without undermining the objectivity or the credibility (perceived objectivity) of the process and the resulting CPG. The CPG committee's standards call for full disclosure by prospective panel members of their bias and COI, divestiture of financial interests that they or close family members might hold, and prohibition of a member's participation in advisory boards or marketing activities related to companies with a stake in the subject guideline(s). Chairs and co-chairs of guideline-generating committees must not have any COI and members with

26. *Id.* at xii.

27. *See, e.g.*, Agency for Healthcare Research & Quality, Pay for Performance (P4P): AHRQ Resources (Mar. 2006), <http://www.ahrq.gov/qual/pay4per.htm>.

conflicts must be in the minority on a committee. Funders of a guideline development activity can play no role in it. These are strict standards, but as the British medical journal, *The Lancet*, puts it, “. . . tough talk from the IOM — but much needed talk.”²⁸

In addition to putting rigorous constraints on who can participate in guideline development and in what way, the CPG committee report provides guidance on the process that committees should follow in assembling and analyzing the available evidence, in formulating their recommendations, and in vetting them before presentation to the relevant professional community(ies) and the general public. Stakeholders should be identified and given adequate opportunity to have their say, not just about the scientific validity of a guideline, but also about the impact it is likely to have when implemented.

B. And What Comes Out: Clarity, Transparency and Harmonization of CPGs

The guideline development process inherently involves group dynamics and politics. Differences of view around how to phrase conclusions and recommendations are inevitable. Should a guideline’s recommendation(s) be framed in absolute or near-absolute terms? When a recommendation is stated as “must” how different is that from “should” or “should consider” or “should generally”? The variety of language used in CPGs makes for ambiguity that complicates or frustrates accurate, reliable translation into action. The committee pushed for greater standardization in language, advocating the adoption of terms that are consistently used and readily comprehensible. The strength of a recommendation should be expressed in a way that the user can readily understand and use to compare two or more CPGs. The strength of evidence underlying a CPG should, likewise, be phrased in a way that assures correct understanding and facilitates comparisons. When a CPG is applicable only to a particular subgroup of the population – or where the applicability to certain subgroups has not been adequately tested or established – that should be clearly stated. The thought process that the guideline developers went through in formulating the CPG should be evident as part of the guideline. It should not be distilled down into a form where users have to guess at it. The goal is transparency. Users of guidelines should be able to access, examine and understand what went into them. Only then can they properly and confidently decide whether, when and how to use them.

In a world where so many are engaged in guideline development there will inevitably be overlapping guidelines that are similar in some respects

28. Editorial, *Guiding the Guidelines*, 377 LANCET 1125, 1125 (2011).

and different in others. The differences may be subtle and comparability may be made difficult by variability in language and modes of expression. The NGC and other mechanisms help by assembling guidelines in a given subject area and making it possible to display them against each other for easier comparison. Prospective users can “shop” the guidelines and decide which best suit their needs or the particular case or occasion. But even when such comparison is facilitated, it can be confusing to have a multiplicity of similar guidelines. “Harmonization” – the weeding out, distilling down, and consolidation of related guidelines – can bring some order to this chaos; so there needs to be a process for periodically compiling and surveying the guidelines in a particular area and “harmonizing,” or reconciling them. Where two or more guidelines are essentially saying the same thing, but in different ways, they should be combined. When there are significant differences that are not readily apparent because of the language or mode of expression, those differences should be flagged so they are visible to prospective users. This can be a difficult, politically sensitive, process. When attempting to fold two or more guidelines into one, the egos of the developers, both individual and institutional, must be taken into account and dealt with appropriately. The challenge of standardization of practice, touched on above, comes into play here as well.

V. CONCLUSION

With the issuance of its report, *Clinical Practice Guidelines: Directions for a New Program*, in 1990, the Institute of Medicine helped to shine a health policy spotlight on EBM and CPGs. Its definition of CPGs as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances”²⁹ has been widely disseminated and adopted. For some two decades that IOM report has provided guidance to move the EBM/CPG movement forward. Now, with its latest work and reports, the IOM has taken that movement another big step into the future. It is no longer enough to simply embrace CPGs. To live up to their full potential, clinical practice guidelines must be “trustworthy.” Building upon extensive fact-finding, consultation, and deliberations by its two committees, the IOM offers new, more extensive direction for systematic reviews of medical evidence and the generation of CPGs. It also offers a new definition and prescription to achieve that end:

Clinical Practice Guidelines are statements that include recommendations intended to optimize patient care. They are informed by a systematic review of evidence and an assessment of the benefits and harms of

29. DIRECTIONS FOR A NEW PROGRAM, *supra* note 2, at 8.

alternative care options. To be *trustworthy* [emphasis supplied], guidelines 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 modifications of recommendations.³⁰

Here's hoping that the IOM's new formulation will be even more helpful than the original one was in moving us toward accessible, high quality, cost-effective health care. To bend the cost curve by focusing our healthcare resources on doing what works, we will need all the help we can get.

30. INST. OF MED., CLINICAL PRACTICE GUIDELINES WE CAN TRUST 25-26 (Nat'l Acad. Press 2011), available at http://www.nap.edu/catalog.php?record_id=13058.