PARADOX, PROCESS AND PERCEPTION: THE ROLE OF ORGANIZATIONS IN CLINICAL PRACTICE GUIDELINES DEVELOPMENT

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Abstract • Résumé

The role of organizations in the development of clinical practice guidelines (CPGs) has received virtually no analytic attention. In a strictly rational and disinterested world, CPGs would be assessed on the basis of the supporting evidence and applicability to practice. However, factors that have more to do with medical sociology play a key role in CPG acceptance and, in some cases, development. The entire concept of CPGs entails troubling paradoxes, many of which turn on the distinction between scientific evidence and the sociologic determinants of validation and implementation. At the root of the question of organizational roles is the issue of values: Whose values should be at the table? What values are legitimate? From what perspectives should the utility of a procedure or technology be addressed? The Canadian health care system is a largely public creature, and CPG development is part of the public policy process. In this context, decisions about organizational roles must be sensitive to conflict of interest and a diversity of values. A provisional model for participation in CPG processes would minimize the role of organizations per se, although individual participants would no doubt reflect the legitimate interests of their affiliations without representing them formally.

Le rôle des organisations dans l'élaboration des guides de pratique clinique (GPC) n'a à peu près pas été analysé. Dans un monde strictement rationnel et désintéressé, les GPC seraient évalués en fonction des preuves à l'appui et de leur applicabilité dans la pratique. Des facteurs liés davantage à la sociologie médicale jouent toutefois un rôle clé dans l'acceptation des GPC et, dans certains cas, dans leur élaboration. Tout le concept des GPC entraîne des paradoxes troublants dont beaucoup pivotent sur la distinction entre les données scientifiques probantes et les déterminants sociologiques de la validation et de la mise en oeuvre. L'enjeu des valeurs se trouve au coeur même de la question des rôles organisationnels : Quelles valeurs devraient faire l'objet de négociations? Quelles valeurs sont légitimes? Dans quelle optique faudrait-il évaluer l'utilité d'une intervention ou d'une technologie? Le système de soins de santé du Canada est une entité en grande mesure publique et l'élaboration des GPC fait partie du processus d'élaboration de politiques publiques. Dans ce contexte, les décisions relatives aux rôles des organisations doivent tenir compte des conflits d'intérêts et de tout un éventail de valeurs. Un modèle provisoire de participation aux mécanismes relatifs aux GPC réduirait au minimum le rôle des organisations en soi, même si chaque participant refléterait sans aucun doute les intérêts légitimes de son organisation sans la représenter officiellement.

Clinical practice guidelines (CPGs) constitute a branch of scientific review, summation and prescription refracted through the prism of health care practice. CPG production generally pursues or claims to pursue a classic scientific model: accumulation of evidence, transparency of method and replicability. Whereas science governs CPG production, medical sociology (group attitudes and behaviours, value-laden assessments of research and CPG feasibility) governs their fate. Production being the easy part,[1] we produce and produce. The CPG inventory has apparently passed 4000; we at the Health Services Utilization and Research Commission of the Province of Saskatchewan participate in, among other things, its enlargement.

There are effective processes for correcting and superseding faulty science, but faulty practice is more durable. One wonders how many CPGs would have seen the light of day had their development required approval through rigorous peer review that included potential impact as a principal assessment criterion.

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The fact that we need to discuss who can and should be involved in CPG development reveals cracks in the pedestal to which we have elevated the randomized controlled trial (RCT). In a world devoid of clans and interests it would not matter who produced, disseminated or endorsed guidelines. CPGs would be assessed entirely on the strength of the supporting scientific evidence and applicability to practice. We would still admire a Hamlet produced by innumerable monkeys randomly banging on keyboards. However, practitioners may resist CPGs produced by the "wrong" experts or promoted by a group considered remote from or unsympathetic to the practice of medicine.[2] Come to think of it, CPGs produced by monkeys might be better received if the simians were local opinion leaders.

This paper does not conclude with a fixed blueprint for ideal organizational roles in CPG development. It focuses on the distinction between and interaction among scientific inquiry and validation using the laboratory model and the sociologic aspects of guidelines. Values and interests, often unarticulated, greatly influence CPG acceptance and, in some cases, development. Rating the quality of scientific evidence is a welcome trend in contemporary medicine; yet we tend to take the values and interests that influence how people receive CPGs as unrankable and legitimate "givens." Those who resist CPGs play trump cards: "We cannot do that here"; "Algorithms dehumanize medicine"; "RCTs are meaningless at the bedside"; and "Population-based evidence cannot rule clinical decision making." Are the cards truly trumps? And do we even know the rules of the game?

The purposes of CPGs

The answer to who should be involved at what stages of CPG development and implementation depends on what the CPGs are supposed to achieve. Their purposes include

- limiting variations in practice that may signal problems in the quality of service;
- eliminating or reducing unnecessary costs associated with variations in practice;
- influencing health care practice in a scientific direction (i.e., contributing to the development of a "culture of evidence") by providing concise guides to practise based on the consensus of experts;
- providing up-to-date summaries of evidence-based "best practices" accessible to practitioners in a format they find usable; and
- providing a basis for educating the public on the value, risks and benefits of diagnostic and therapeutic procedures.

Each goal is not equally important to all prospective CPG audiences, whose responses will be conditioned by their own rank ordering. For example, practitioners may not be at all interested in cutting costs (especially their own incomes), whereas paying agencies would be.

Should CPGs work? Some troubling paradoxes

The philosophy of CPGs is strictly utilitarian: guidelines exist to be useful. The corollary is that someone must use them. From these observations emerge some troubling paradoxes.

The paradox of need

Guidelines should influence precisely those at greatest risk of practising (or consuming) as outliers, whose actions would result in either poor quality or unnecessary utilization. However, the influence of CPGs may be greatest among those who need them least: the "ideal type" clinician-scientists, who participate in research, think critically and concern themselves with effectiveness and efficiency. The high-needs groups are more likely to be active or passive resisters, often on principle — "No one's going to tell me how to practise medicine."

The radical paradox

Good CPGs are in the scientific mainstream and encapsulate the best accumulated evidence, but they are usually radical in relation to established practices. Otherwise, why produce them at all? There must be at least an implicit assumption that the evidence is unread or undigested, that there is too much variation in practice or that CPGs do more than merely sum up. The "value added" is the attempt to refine decision making and to narrow practice variation *to a degree unlikely to be achieved "naturally" by the target audience(s)*. The intent is, therefore, remedial. Achieving voluntary compliance with inherently radical and remedial measures is difficult under the best of circumstances. The corollary is that radical prescriptions without policies to ensure compliance are destined to remain prescriptions.

The paradox of representation

Considerable cachet attaches to guidelines prefaced by the word "consensus." In a perfectly rational and disinterested world any group following a prescribed method would assess the evidence and agree on many, if not most, aspects of practice under various conditions. The world, however, is imperfect, and there are honourable disagreements about science and practice. Indeed, one reason to establish an inclusive process of

CPG development is to incorporate different valuations and interpretations of the clinical scientific evidence. The corollary is that the broader the panel (including, for example, researchers, academic clinicians, rural and urban practitioners, consumers and other disciplines) the less prominent a role purely scientific evidence will play in the final, negotiated product. Similarly, the probability of producing courageous and evidence-focused guidelines may be higher in small, local groups than in national consensus-seeking panels, unless the latter comprise members who are selected to minimize rather than reflect diversity. Departure from conclusions based solely on the expert analysis of evidence may not be a bad thing but we should at least be clear about the values inherent in attitudes toward evidence and consensus-oriented conclusions.

The paradox of inefficiency

Science aims for objectivity and universal application. Logically, national and even international guidelines would seem to be both feasible and efficient. However, other things being equal, physicians respond more readily to the counsel of their peers and local opinion leaders.[2-4] Effective CPGs almost invariably have a local champion with credibility and clout in the community or institution. The paradox is that maximum impact may require inefficient (redundant) production, which may result in a series of similar, and in some cases identical, guidelines.

The temporal paradox

CPGs produced today are designed to influence behaviour in the future. Given the short half-life of medical knowledge and the laborious processes of CPG production, dissemination and implementation, science and "best practices" may change before the ink is dry (or the software written). Particularly for new and developing technologies and procedures, the science behind a CPG may have a very short and tentative period of validity. (Shelf life will vary with technologic stability: quite long, for example, for electrocardiography and quite short for ultrasonography.) These realities evidently convinced Sweden to abandon its process of national guidelines development, and this in a relatively homogeneous country of 8 million people, geographically smaller than half of Canada's provinces.[5]

The sociology of CPGs: uncharted territory

Given the growth in the CPG industry and the unpredictability of its impact, it is perplexing that the organizational aspects have been so little studied. There are no articles on the subject of this paper. There is some excellent evaluative work on compliance,[5,3] self-reported versus actual behavioural change,[6,7] impact on utilization[8] and compliance-enhancing interventions,[9,10] but there appear to be no comparative reports of the products, acceptance and impact of CPGs produced under different organizational circumstances.[11] If Hayward's findings are generalizable,[2] physicians clearly rank CPGs on the basis of who has been involved in the process even when the guidelines are identical and funded by the same source.

The practicalities of everyday medical practice and the propensities of practitioner audiences strongly affect CPG reception and implementation.[12] It seems crucial to learn more about how physicians learn and adapt. Traditional didactic continuing medical education, unassisted by reinforcing mechanisms, does little to change perspectives or behaviour.[13] The convergence of evidence and sociology in CPG production and implementation is an inherently volatile mix that requires explicit strategic attention. At the forefront is the question of values: Do we seek participation from those (individuals or groups) likely to derive conclusions from RCT-type evidence, or from those likely to challenge the sanctity of the population-based model with its marginal utility perspective? Do we include them because we think they think like us, or because they don't?

All producers claim that their CPGs are scientific; to do otherwise would be to undermine their legitimacy. Yet practitioner audiences frequently declare with pride that medicine is only partly a science, the remainder being the province of inspired judgement, hunch and the application of skill and knowledge under conditions of uncertainty. Physicians are pulled in both epistemologic directions, and their practices reflect these influences. CPG processes that do not address these realities risk dismissal. If unable to articulate precisely when even high-quality evidence is an incomplete guide to practice, we will continue to be confronted by the opposing tendencies of algorithm and intuition, explicit assent and implicit scepticism.

Getting the rules straight

There may be no single organizational best practice for developing CPGs about best practice. Before outlining options for improving the process, we need to come to grips with some important questions.

- If we find that organizational roles are pivotal, with science only an equal or even subordinate partner to ultimate acceptance and implementation, is this *prima facie* evidence of a potential problem or merely the not especially troublesome "facts of life"?
- To what extent are variations in guidelines accept-

able, particularly when there is a large body of high-quality evidence suggestive of best practices? If local acceptance is crucial but goes wholly or partially against the grain of a national or provincial panel, is the implementation glass half empty or half full? Should arguments that a CPG would be impractical in a jurisdiction be subject to standards of cogency and evidence-based justification?

- Are there more effective ways to improve practice than the piecemeal, incremental approach inherent in CPGs? Should we focus more on changing patterns of learning and thinking (the processes of inquiry and judgement) and less on the specific products of evidence and consensus (CPGs)? The rationale would be that critically trained practitioners would, by virtue of their reasoning processes, adhere substantially to CPG algorithms, but in a more comprehensive, flexible and lasting manner, without the problems of format, scope, number, timeliness, shelf life, etc.

Organizational roles and public policy

The Canadian health care system is (still) a largely public creature. Directly in some cases and indirectly in others, CPGs are part of the discourse about health and health care that contributes to Canada's public policy fabric. Certain trends in the political landscape may be relevant to a discussion of organizational roles in CPG development.

First, self-regulation and exclusive domain are on the verge of becoming obsolete. Process and product are interdependent: the legitimacy of the latter depends on the perceived legitimacy of the former. Professional bodies now include public representatives, often by law. The "stovepipe" model of health professional role assignment (fragmented and rigid scope of practice sanctioned by law or regulation) frustrates the public, government, managers and providers. In the short term, CPGs produced exclusively by a specialty society or a single profession may be acceptable. However, if CPGs extend in influence and affect resource allocation and other public policy decisions, there will be pressures to open the process of development and, particularly, the terms of reference to a host of other stakeholders with complementary or competing value systems.

The survey of organizations in the CPG field, described by Carter and colleagues in the previous issue of *CMAJ*,[14] shows rather remarkable consensus (albeit from a limited range of respondents) on the central role of specialty societies in CPG priority setting and development. The specialty societies themselves consider only their own participation to be essential in most CPG-related activities. There is startling indifference to the role of consumers, and most respondents would consign government to a funding role. Most would reserve virtually all key roles for medicine itself. These responses do not accord with the notion that CPG development is part of the public policy process. CPG development by the elite may, among other consequences, constrain the nature of the questions asked in CPG development. The less inclusive the process the more likely the central question will be, Is this procedure effective? A more inclusive process, reflecting a diversity of public policy perspectives and issues, would tend to pose three additional questions: Is this procedure efficient? Does it produce greater health status gains than the alternatives? Does it deserve a place in the publicly insured health care system? Different questions lead to different answers.

Second, even the merest whiff of self-interest is enough to discredit a process or recommendation in today's political climate. Herein may lie a challenge to the prevailing sociology of guidelines. Ownership of any public policy process is unlikely to be conferred on any group or association, *pace* the survey respondents. If physicians will adhere only to CPGs whose development process they have "owned," and governing boards and governments prefer more broadly based ownership, the potential for conflict is obvious. There will be quite enough unavoidable head-butting over scientific and clinical uncertainty without constituency-based wrangling over motive and legitimacy.

To forestall such unhappy distractions it seems highly desirable for the main constituencies in the health care system to agree on the general rules of the game. The basic prerequisites here are likely to include a multiparty process, whereby scientific and clinical expertise is deliberated transparently in the presence of other audiences; terms of reference that assess a technology or procedure in a broader context (population health perspective, cost–benefit analyses, explicit discussion of underlying philosophy of health and health care); and agreement on the nature and standards of evidence acceptable in the CPG development and validation processes.

Third, societal sensors are highly tuned to signals of conflict of interest. No organization, however well intentioned, is considered immune. In this environment it may be prudent for organizations to consider appearances as well as realities as they think about their roles in CPG development. Organizations often find it difficult to serve both their members' and the public's interests. CPGs can affect incomes; hence, medical associations may be at risk of either alienating some of their members or opposing a well-constructed, evidence-based CPG because of conflict of interest. Even the failure to endorse may be a fatal silence. Organized medicine might

increase the influence of CPGs on practice more subtly and effectively by sharing ownership broadly or even keeping some distance from the development process.

Fourth, progress requires an articulation of the sociologic factors affecting CPG processes and particularly the values that deserve a legitimate place at the table — and those that do not. In eight CPG exercises (relating to electrocardiography, thyroid function testing, cataract surgery, obstetric ultrasonography, cholesterol and lipid-lowering medications, cervical cancer screening, chest radiography and prostate-specific antigen testing) the Health Services Utilization and Research Commission has found that the terms of reference and their implicit values and perspectives create as much debate as does the examination of evidence. The approach and context are hugely important, and diversity in the working groups tends to ensure that the wider questions remain in the forefront.

Fifth, let us learn from CPG failures, which are surely legion and potentially instructive. Positive reporting bias afflicts the CPG literature. Reality is more sobering. This paper is theoretical and speculative because we know so little about the impact of organizational roles on CPG success. Because there are no blueprints we have an opportunity to observe a natural experiment in which participation should be a useful analytic variable.

The model provisionally advanced here is CPG development with restrictions on baggage. CPG developers will naturally bring with them the values and perspectives of their environments and their affiliations. Good CPGs are products of clinical expertise, rigorous scientific review and context-sensitive judgement. These are hard enough to consolidate into a usable guideline without the need to balance a wide variety of competing interests and loyalties.

Not all organizations have the perspective or expertise to contribute to the culture of evidence at the heart of CPG development. Some have earned scientific and clinical credibility; others are adept at social marketing. Some have mandates that highlight scientific inquiry in the service of the public; others have mandates that go well beyond the pursuit of evidence-based practice.

The ultimate customers for CPGs are not providers but, rather, the public, which is interested in the validity of CPGs and not their origins. The public doubtless wants guidelines produced by credible people, but its interests are served best when others' interests are set aside. It would be informative to ask the public about organizational roles in CPG development. Would the citizens' views affirm those of the respondents in Carter and associates' survey? Would they want formal organizational representation at the CPG table? After all, the citizens are the "organization" to which we are all accountable, and surely their interests should trump ours?

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