Guidelines for medical practice: 1. The reasons why

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Various external special interest groups are promoting attempts to better measure and control the performance of the medical profession, primarily to restrain costs. We can neither afford to ignore the rising costs nor reject efforts by provincial licensing authorities to improve supervision of the quality of care. Furthermore, there is increasing public interest in the outcome of medical treatment and a suspicion that some care may be unnecessary or inappropriate. Much of what physicians do is not based on impeccable or complete scientific evidence, and we have not established a method whereby science can consistently be translated into practice. Optimal practice patterns must be defined to improve the quality of care and to maximize the efficiency with which scarce resources are used. Careful scientific evaluation of data is particularly necessary with the arrival of new drugs and technology. Sensible, flexible guidelines produced by appropriate panels will help promote improved practice. Rigid standards must be avoided to allow for individual consideration and scientific innovation. The recognized difficulties of influencing clinical practice by precept or education and the problems imposed by rapidly changing scientific knowledge are two hurdles to be overcome. Licensing bodies must identify and enforce minimal standards, but optimal practice patterns are better devised by a broader segment of the profession. Intervention by third-party payers, as is prevalent in the United States, intrudes upon physician autonomy and reduces access to care. Physicians must support the development of guidelines for optimal medical practice based on the best existing data and focused on improving the quality of care.

Plusieurs groupes d'intérêts spéciaux préconisent des moyens de mieux déterminer et régir la manière dont notre profession s'acquitte de sa tâche, surtout afin de diminuer la dépense. Il ne nous est loisible ni de fermer les yeux devant l'escalade des coûts, ni de nous opposer aux efforts que font les collèges provinciaux qui régissent l'attribution des licences pour améliorer la surveillance de la qualité des soins. D'autre part, le grand public s'intéresse de plus en plus à l'issue des traitements médicaux et soupçonne certains d'entre eux d'être inutiles ou intempestifs. Beaucoup de nos actes médicaux ne reposent pas sur des preuves scientifiques impeccables ou complètes. Nous n'avons pas établi de méthode permettant de faire passer de façon constante la science dans la pratique. Il faut définir pour celle-ci les qualités qui lui permettront d'assurer les meilleurs soins et d'utiliser de la manière la plus efficace possible des ressources limitées. Les acquisitions récentes en pharmacie et en technologie doivent faire l'objet d'un examen rigoureux des données scientifiques qui les sous-tendent. Pour améliorer l'exercice de la médecine on a besoin de principes directeurs raisonnables et souples, élaborés par des comités idoines. On évitera les règles trop rigides, afin de laisser libre cours au choix personnel et à l'esprit d'innovation scientifique. Nos deux plus grands obstacles à surmonter sont la difficulté, que personne ne conteste, de modifier par des

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préceptes ou par l'éducation les comportements cliniques et la rapidité avec laquelle les acquisitions scientifiques se succèdent. Les collèges régissant l'attribution des licences de la médecine doivent fixer et appliquer les normes minimales, mais il faut compter sur un secteur plus important de la profession pour définir la pratique médicale à son meilleur. L'intervention de tiers payants, comme aux États-Unis, nuirait à l'accessibilité des soins et à l'autonomie du médecin. Celui-ci devrait accueillir des normes d'exercice fondées sur les données actuelles les plus fiables et axées sur l'amélioration des soins.

The development of guidelines for medical practice is a controversial and complicated issue compounded by the emotive vocabulary used by various interest groups — "standards" by the government to indicate enforcement, "parameters" by the College of Physicians and Surgeons of Ontario (CPSO) to indicate a limit or boundary. There are, however, compelling reasons why physicians must now act decisively to generate and disseminate sensible clinical policies. In most developed countries the tension imposed by increasing health care costs, amplified by consumer forces, has led to calls for increased accountability and the identification of efficient practice patterns by the profession. In some countries, particularly the United States, organizations outside the profession are rapidly developing standards for medical practice to be enforced by government or third-party payers in the hope of controlling costs.[1] Delineating its own guidelines would allow the medical profession to increase the quality of health care and delay the need to ration it through improved efficiency. The penalty will be high if this initiative is taken from us.

Why are guidelines necessary?

The rapidly increasing pressure to establish parameters is being applied by governments, medical licensing bodies, insurers of health care and various other special interest groups. The Ontario minister of health has talked frequently about the need for closer supervision of the medical profession and intends to implement an "outcome-based peer review system by which the efficacy of procedures done by doctors would be monitored".[2] Performance would be evaluated against a "list of standards", the results eventually affecting resource allocation decisions. However this might develop, physicians cannot ignore the fact that health care costs account for one-third of Ontario's government expenditures and cannot evade the burden of accountability. Although likely motivated by financial constraint the minister is justified in attempting to ensure that increasingly expensive medical services are provided efficiently and that scarce resources are not wasted on inappropriate services.

The CPSO has recently restated its intention to develop and promulgate "practice parameters" to better serve its mission of protecting the public. The college claims support for this from a membership survey, although only 500 of 5000 physicians replied (Brian Dingle: personal communication, 1989). About 70% of the respondents favoured the development of guidelines in general but did not want them under CPSO control. Pressure from the college continues, and the argument is about who should be in charge of generating clinical practice parameters.

Hospitals and health care insurers in Canada are searching for structures by which to identify their need for funds, increase their efficiency and assess the relative values of programs or services competing for resources. Without accepted criteria of practice these goals are elusive. As government attempts to devolve financial responsibility to local hospital boards and other bodies these organizations increasingly need to be able to define efficient medical practices and to use this information in their management processes. Without such justification individual decisions to reduce, constrain or refuse to develop services will be susceptible to many external pressures.

As Canadian hospitals try to cope with annual budgets insufficient even to maintain existing services they will encounter increasing conflict with medical staff. Caps on expenditure or imposed reductions in service volume will meet with opposition, which will often be magnified by local press coverage. Before this happens hospital boards will rightly wish to measure their hospital's efficiency against accepted parameters and to remove unnecessary or inappropriate services. Hospitals are actively pursuing ways of identifying departments, units or physicians whose practices differ significantly from the norm in terms of quality, cost and risk.

This drive to develop professional standards embraced by the government, the CPSO, hospitals and insurers is supported by societal and legal trends that promote disclosure and public debate on such matters. There is heightened public interest in the nature and outcome of medical treatment as well as increasing suspicion that at least some medical care may be wasteful. This suspicion has been fostered by the demonstration in most developed countries of significant variations in the rates of provision of medical and surgical services. These variations are also evident when contiguous small geographic areas are examined.[3] These findings have been quoted as evidence that significant amounts of medical care

are inappropriate and therefore the opportunity exists for cost saving without reduction in accessibility or quality of care.

The legal implications of generating guidelines warrant close examination. Physicians naturally fear any extension of the perceived risk of litigation, and at first glance the definition of recommended practices might seem to create this. The risk will be reduced if guidelines remain flexible, defining only the limits of acceptable practice. Furthermore, physicians under the present arrangements are probably already at risk, for cases may be decided almost at random after dispute between two or more "experts" in a given field. Under these circumstances practitioners are often uncertain about the standards they might be expected to meet. The definition of the limits of acceptable practice may therefore become a defence rather than a hazard.[4]

Advantages of guidelines for the medical profession

Of more importance than these external compulsions are the benefits that will accrue if the profession can deal with this contentious issue sensibly and expeditiously. The stimulus for enthusiastic participation must come from the need to improve both the quality and the efficiency of care. Guidelines produced by the profession should never address cost factors alone or define limits to the provision of care except on clinical and humane grounds.

Although our knowledge of basic science and the pathophysiology of disease has advanced rapidly we have not established a method of consistently translating science into practice. In many cases academic standards for medical practice are not yet based on well-tested medical science. We have no structure, minimal resources and few people trained to design clinical studies, collect reliable data, analyse outcomes and devise the best way to integrate new drugs or procedures into routine clinical practice. Thus, we still have many clinical procedures for which the indications are uncertain and the outcomes unknown. Further study of the variations in the rates of provision of services confirms this: conditions for which there is no debate over diagnosis or treatment show very little rate variation, but most medical and surgical causes of hospital admission demonstrate significant variation because of differing practice styles.[5] The absence of defined and scientifically supported practice patterns prevents us from identifying whether these variations represent underservicing or overservicing.[3] We must acknowledge that there is much to learn about the effects of complex drugs and techniques in infinitely complicated human disease. Many people are looking to medicine as a self-governing profession that will act quickly to improve the situation.

Some will contend that we already have clinical policies developed by traditional methods but in many cases their genesis and quality are suspect. Physicians like to believe that they make logical clinical decisions based on analysis of known data, but this is often not the case. It is unusual for us to be able to base such decisions on solid scientific outcome data. Clinical policies have been developed on an ad hoc basis from the considerations and decisions of hundreds of physicians acting individually. Textbooks and medical journals publish this fragmentary information, and other contributions to clinical decision-making come from continuing medical education, institutional policies, the example of influential physicians and the often biased information provided by pharmaceutical detailing. We should now recognize that, for reasons of clinical accuracy, there is an urgent need to expand and improve the information base upon which we make clinical decisions. Moreover, huge sums of money are possibly being wasted on investigative or therapeutic procedures that may be of marginal benefit or even harmful.

A few simple examples underline this critical point. Again using studies of comparable areas in which rates for various procedures differed significantly, US researchers have identified significant levels of inappropriate use of procedures; for example, even with the use of very broad criteria 28% of instances of coronary angiography were found to be inappropriate, as were almost 20% of instances of upper gastrointestinal tract endoscopy.[6] However, some of the data are questionable, often derived from studies done some years ago and in very specific areas. Although fragmentary evidence suggests that rate variation does occur in Canada we have as yet little evidence of extensive misuse of health care services. Nevertheless, the existing evidence should direct our attention to this issue.

Even if most procedures in Canada are done appropriately many of our important management decisions are clearly made under conditions of oversimplification and empiricism because information is lacking. For example, even in an apparently simple disease such as essential hypertension major clinical and economic commitments are made on very questionable grounds. One would wish to base therapeutic decisions on a knowledge of how treatment affects the outcome. But outcome depends on many factors, some not quantified; these include age-specific and sex-specific illness and death, natural history of the disease, patient compliance, salt intake, smoking and alcohol intake, other risk factors, drug side effects and drug interactions. Despite the absence of scientific data to guide us we are in

the midst of a shift from relatively cheap drugs to more expensive and intellectually seductive ones. Experience and anecdotal evidence tell us that diuretics and β-blockers are effective antihypertensive agents, but their known side effects are maximized in the promotional material for new drugs. We often forget that patient tolerance of the older drugs has been good, adverse reactions and toxic effects have been relatively minor, blood pressure control has usually been effective, and cost has been acceptable. For the new drugs many of these things are still unknown, yet in most Western countries marked increases in the cost of treating hypertension are occurring without scientific evidence of improved outcome.[8]

An even more dramatic example of our failure to develop clinical policies is emerging in the case of benign prostatic hypertrophy (BPH). Routine treatment of BPH has been surgical, the only real debate centring on whether surgery should be a preventive measure or only for symptom relief. Wennberg and associates[8] have revealed that surgery for BPH slightly reduces life expectancy, although it does alleviate symptoms. The choice, therefore, depends on the patient's intolerance of symptoms and attitude toward risk; "watchful waiting" may become a reasonable option. It is not even the apparent severity of symptoms that determines the appropriate treatment decision but, rather, the patient's perception of the discomfort produced.[9] In addition, these studies have underlined the need for guidelines to be not only carefully developed but also continually updated: new approaches to BPH include prostatic shrinkage with drugs or microwaves, as well as simple incision and balloon dilatation.

Honest self-examination will suggest to most of us that our databases and our analytic abilities are strained even by apparently trivial clinical problems. In almost all cases the number of possible actions, the wide range of outcomes, the need to deal with probability estimation and the variabilities introduced by other diseases, age and sex add up to a computation beyond the capacity of most of us.[10] If that argument does not make the case for medical practice guidelines, a consideration of the questions posed by new advances should.

The avalanche of undigested scientific and clinical data in the medical literature, persuasive advertising and increased patient demand conspire to leave the physician in a quandary. Recent examples include the rapid emergence of drugs that are said to lyse clots in coronary arteries. The literature has been flooded with multiple studies of varying size and scientific content. Few physicians indeed could have synthesized from these studies a sensible management scheme for the use of thrombolytic agents. Thus, the Ontario Medical Association (OMA) sponsored a group of cardiologists, internists and clinical epidemiologists to generate appropriate guidelines on the basis of the best scientific evidence then available. Particular care was taken to ensure that the guidelines were flexible enough to allow the best decision for each patient. The guidelines provided a hierarchical list of factors that should influence the decision for or against treatment.[11] The recommendations were disseminated and had a significant impact on practice patterns, if only because they affected the government's funding decision.[12] Similarly, no individual physician could possibly have evaluated the mass of data emerging on the detection and treatment of asymptomatic hypercholesterolemia. The production of guidelines on this issue has provoked much discussion and highlighted many of the problems intrinsic to it.[13]

We contend, therefore, that the medical profession must support the generation of guidelines for clinical practice in order to improve the quality of care. Our participation would benefit principally the patient, but there would be other beneficiaries. Appropriate action based on the information gained from improved data collection and analysis would help to avoid unnecessary tests, procedures and drug prescription. Inappropriate care would be decreased and the efficiency of the whole system increased; thus, resources for new and expanding services would become available. From time to time scientifically evaluated guidelines would likely identify real needs for more funds, which would be difficult for governments to refuse. Peer review and audit would be enhanced, and the review process would become more fair. The ability of hospitals and governments to determine priorities for funding would be improved. Finally, the medical profession would benefit greatly. If we seize this responsibility we shall avoid the hazards of having standards imposed by external agencies. The autonomy of the medical profession will be protected, and we shall have contributed to maintaining the quality of care we provide.

The argument against guidelines

Physicians generally prefer individual consideration to following predetermined algorithms, and most remain satisfied with the care they provide. The epithet "cookbook" is very readily applied to practice directed by rules. The risks of this can be reduced by ensuring that we do not write standards defining exactly what must be done but instead develop guidelines defining the range of options for a given problem that is acceptable yet adaptable to individual consideration. We must aim to define what will and will not work in order to assist and improve the decision-making process.

Some will contend that it is simply not possible to develop meaningful guidelines or that the difficulties in doing so are compounded by the rapid rate of change in scientific knowledge and technology development. This argument is often bolstered by the accurate observation that it is difficult to influence physicians' clinical practice by precept or education. Also, acceptable standards may differ between rural and urban settings. These observations, however, identify the major hurdles rather than the reasons for not trying.

Perhaps the most critical objection, at least for the profession itself, is the risk that guidelines will be misused. The principal risk lies in their use as standards by organizations outside the profession. In the United States, for example, at least a hundred organizations, including government and almost every private insurance company involved in the field, are producing guidelines, standards or parameters for virtually all aspects of medical care. There is clearly a risk that government will use the standards to affect its payments to physicians and all other aspects of the funding of health care. Third-party payers in the United States will use their standards to expand authorization programs, and inspection and control of treatments may be increased by the availability of parameters against which such treatments can be measured. Computerized monitoring of adherence to guidelines will become possible, as will the publication of comparative data on outcomes of health care provided by individuals and by hospitals.[1] These risks must never be forgotten when methods of developing guidelines are debated.

Who should write the guidelines?

Guidelines must emanate from a credible and acceptable source. Governments do not qualify on either ground, for whatever they do physicians will believe that cost containment is their primary objective, allied to an attempt to inveigle the profession into some responsibility for rationing of health care. Inevitably the real intellectual debates surrounding any proposed consensus would be inflamed and embittered by political concerns. The same reservations apply to any body whose independence from government is not clearly established.

The second group of nonmedical organizations that might attempt to impose standards includes third-party payers, insurance groups and, perhaps, hospital administrative organizations. This has occurred extensively in the United States, where intrusive monitoring, supervision and control are commonly imposed by paying agencies. The interference with physician autonomy and the reduction of access to needed care have been severe, and the administrative costs have been very high.[14] In Ontario the change from the Ontario Health Insurance Plan to a payroll tax to help fund health care places employers in the situation of third-party payers, who may well soon want a voice in the system and its cost control.

The CPSO continues to insist that it should establish practice parameters and quotes the legislation that charges it with the responsibility for protecting the public.[15] We contend that designating the CPSO to produce the type of medical practice guidelines that we advocate would be undesirable. Since the CPSO is the licensing and disciplinary body for the profession there is a significant risk that its parameters might be used to constrain the provision of health care, reducing both accessibility and quality. Because of the CPSO's official position any guidelines it produced would likely be regarded by the courts as minimum acceptable standards. Finally, the legal status of the college would impose upon it an absolute but unfeasible responsibility to ensure that all its standards of practice reflect optimal care at all times — a goal it simply could not achieve.

The present dispute between medical associations and provincial licensing bodies may be largely a semantic one: the CPSO has a clear duty to define and enforce minimum standards of acceptable practice both for licensure and in continuing practice. The medical profession needs to develop optimal practice patterns not only to maintain present levels but to improve the quality of care and increase the efficiency of our system.

There is probably no absolute dividing line between minimal "standards" and optimal "guidelines". If there is complete agreement on what constitutes acceptable medical practice, based on impeccable scientific evidence, the recommended practice pattern can be definitive, permitting little deviation. In this situation the optimal practice pattern would also be the minimal standard, defined and enforced by the CPSO. Such circumstances, however, are rare except in so far as they deal with facilities standards, staffing recommendations, levels of training or physical standards such as radiation control. These, too, are appropriately dealt with by the CPSO. In contrast, most clinical practices cannot be so exactly defined: the greater the scientific uncertainty, the more flexible and permissive the guidelines must be. In some cases it will be possible only to designate what is acceptable practice, and we must ensure that innovation and research are never hobbled by poorly constructed recommendations on practice patterns.

There has been substantial agreement that the medical profession is the only body capable of successfully generating the guidelines. It is likely the only group that could produce guidelines generally acceptable to physicians and the one most likely to focus on quality and efficiency of care. Some exter-

nal observers question the objectivity of physicians, but surely a system can be found to balance professional bias? Within the medical profession there are many contenders for the role: the medical schools, the Royal College of Physicians and Surgeons of Canada, specialist societies, national or provincial medical associations and various special interest groups, as well as the CPSO. A collaborative arrangement involving all these bodies is attractive. Evaluation of existing practice will challenge the profession to meet the highest standards of self-regulation. We shall succeed only if the guidelines we develop are fair, flexible, scientific and open to public debate. They must be rooted in the formal science of medicine and avoid purely fiscal concerns. Only then shall we be defining what is best for the patient.

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In the next issue the authors will outline a possible strategy for generating guidelines.

Conferences

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Nov. 1-2, 1990: 1990 Gairdner Foundation International Awards Lectures
University of Toronto, main auditorium
Sally-Anne Hrica, executive director, Gairdner Foundation, 220-255 Yorkland Blvd., Willowdale, Ont. M2J 1S3; (416) 493-3101, FAX (416) 493-8158

Nov. 1-4, 1990: Quebec Association of Urologists 15th Annual Meeting
Four Seasons Hotel, Montreal
Ms. Jacqueline Deschênes, Quebec Association of Urologists, 2 Complexe Desjardins (East Tower), Door 3000, PO Box 216, Stn. Desjardins, Montreal, PQ H5B 1G8; (514) 844-9523

Nov. 2, 1990: 12th Annual Social Work Clinic Day — Listen to My Story: Literature and Personal Narratives in Clinical Practice
Joseph E. and Minnie Wagman Centre, North York, Ont.
Sybil Gilinsky, Education Department, Baycrest Centre for Geriatric Care, 3560 Bathurst St., North York, Ont. M6A 2E1; (416) 789-5131, ext. 2365

Nov. 8-10, 1990: Symposium on Palliative Care: Focus on the Family
Inn on 7th, Edmonton
Marge Berg, conference coordinator, Misericordia Hospital, 16940-87th Ave., Edmonton, Alta. T5R 4H5; (403) 486-8913

Nov. 9, 1990: Neurotoxins: Impacts on Public Health
Mount Sinai Hospital Auditorium, Toronto
Canadian Neurological Coalition, 126-100 College St., Toronto, Ont. M5G 1L5; (416) 596-7043, FAX (416) 964-2165

Nov. 11-13, 1990: Canadian Hospital Association National Conference on Waste Management for Health Care Facilities
Radisson Hotel, Ottawa
Conferences, Canadian Hospital Association, 100-17 York St., Ottawa, Ont. K1N 9J6; (613) 238-8005, FAX (613) 238-6924

Le 15-16 nov. 1990: Colloque international — Biotechnologies et environnement: Gérer les risques
Hôtel Delta Montréal
Mme. Denyse Pronovost, Centre de recherche en évaluation sociale des technologies, Université du Québec à Montréal, CP 8888, succursale A, Montréal, PQ H3C 3P8; (514) 987-7944, télécopieur (514) 987-4166

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