

Legislation – quality improvement – the regulatory process

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Legislation governing the health professions has traditionally been drafted with differing regulations and provisions in statute for each profession. This legislation has often been the consequence of seniority or political lobbying, resulting in a disjointed regulatory system, where many professions performed similar procedures. Growing health care awareness by consumers has prompted a greater accountability by the professions. In Ontario, the government addressed this concern by formulating a Health Professions Legislation Review. The review, based upon a new structure to legislate the health professions, required submissions and input from over 200 different groups, including health professions and consumers. The goal was to establish guidelines for the delivery of health care that considered the interests of the public rather than the professions. This impacted directly upon authorized acts, professional self-regulation, shared authority and standards of practice. The ultimate goal being quality assurance. This required attention not only to the methods of delivering health care, but more importantly to measuring its outcome. Chiropractors must recognize that other stakeholders are demanding that their standards be explicitly formulated and be open to public criticism and debate. Standards based upon the "usual and customary practice" are inadequate. (JCCA 1991; 35(4):221-228)

KEY WORDS: chiropractic, manipulation, standards.

Introduction

Legislation governing the health professions has traditionally been drafted with differing regulations and provisions in statute for each profession. In Ontario, "five professions are regulated under the Drugless Practitioners Act, six under the Health

La législation régissant les professions de la santé a traditionnellement été rédigée avec des dispositions et des règlements différents dans les codes de chaque profession. Cette législation a souvent été la conséquence de sollicitations de groupes de pression politiques ou de doyens de la profession, résultant en un système de réglementation incohérent, où de nombreuses professions exécutent des procédures similaires. L'opinion publique, de plus en plus consciente des questions touchant aux soins de la santé, a poussé les professions médicales à mieux prendre leurs responsabilités. En Ontario, le gouvernement a abordé cette question en effectuant la « Révision de la législation en matière de professions médicales ». La révision, fondée sur de nouvelles structures pour légiférer les professions de la santé, a consulté plus de 200 groupes, parmi lesquels des associations de consommateurs et de professionnels de la santé, et leur a demandé de soumettre leurs propositions et conseils. Le but de cette démarche était d'établir un code de déontologie médicale qui prenne en considération les intérêts du public plutôt que ceux de la profession. Ceci a eu des répercussions directes sur les actes autorisés, l'autorégulation professionnelle, le partage de l'autorité et les normes de pratique. Le but ultime étant l'assurance de la qualité. Pour ce faire, il faut accorder une attention particulière non seulement aux façons de prodiguer les soins de santé, mais surtout à la mesure des résultats. Les chiropraticiens doivent être conscients du fait que les autres parties intéressées veulent des normes explicitement formulées et ouvertes à la critique publique et au débat. Les normes fondées sur « la pratique courante et habituelle » sont inadéquates. (JCCA 1991; 35(4):221-228)

MOTS-CLÉS : chiropratique, manipulation, normes.

Disciplines Act, six are regulated by individual statutes"¹ and seven professions proposed to be regulated are currently unregulated.

The senior professions or those politically astute have generally exhibited greater influence on the decision makers and often were successful in maintaining a hierarchical system, at the expense of the smaller emerging professions. The end result of this traditional process is a disjointed regulatory system, inequitable to say the least, wherein each profession functions independent-

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ly of the others in what has been purported to be a health care regulatory system which provides the health care consumer with the best quality care.

Many professionals perform identical procedures in the course of exercising their scope of practice, and all the professions are struggling with approaches to developing standards. It may be counter-productive to expect each profession to develop its own standards or quality improvement measures for the performance of the same procedure in the anticipation that the standard will be the same.

We must examine the traditional isolationist approaches and current thinking of the profession in light of the imminent changes that other stakeholders in chiropractic and changing health care policy demand. The stakeholders, those who pay for or consume health care services, are demanding objective evidence upon which to base their decisions with respect to health care providers and the relative value of the services performed. It is essential to the discussion of quality assurance and standards of practice that we explore the overlapping scopes of the professions and the views of health care professionals and other stakeholders in the regulatory process as it now functions.

There are many interests in chiropractic, including consumers, insurance companies, protective funds, educators, governments, other professions, lawyers and researchers. Implicit standards, those based on the "usual and customary practice", immune to public criticism and debate, are no longer sufficient. Implicit standards, exclude the interests of all but the profession. In light of the changing health care system, we must re-evaluate our focus and recognize that standards must be explicitly formulated, open to the scrutiny of all. They must also be based upon explicitly formulated scientific studies, which validate not only the process and structure of chiropractic practice, but measure the profession's performance against the outcomes (i.e. the effectiveness of what we do).

How health professionals view legislation

Legislation from the perspective of health professionals most commonly elicits concern with respect to the definition of scope of practice. Legislative review or revision of scope of practice is often viewed as a threat to the profession and what it currently "has". Alternatively, it may be viewed as an opportunity to expand the scope of practice of the profession, a chance to "gain turf".

For health professionals, it is unpleasant to contemplate the possibility of one's profession or livelihood being challenged. Most commonly, the "laundry list" approach to defining scope of practice has been the chosen approach. It is an attempt to ensure that everything a professional does is specified in the "list". Professionals fear that elements of scope relevant to practice may be left off the "list", and this is a typical concern. This approach to defining scope provides each profession with an opportunity to hold, gain or lose its turf in the face of changing legislation.

When one examines what is permitted by legislative provi-

sions in various jurisdictions, it would appear that the scope of practice of the chiropractic profession varies greatly. In fact, there is often little resemblance when one jurisdiction is compared with another. The results of a survey of 60 chiropractic licensing Boards,² reinforces the 1989 opinion of the Inspector General. The Inspector General found that "a therapeutic measure quite legitimate in one state may well constitute a criminal offence and grounds for board discipline, if carried out by the same chiropractor a few miles away across the state line".³

The chiropractic profession has no fixed national, state, provincial nor international identity. The "laundry list" approach has clearly been inadequate to define chiropractic scope of practice and the lack of consistency in the definitions, requires that standards and quality assurance measures must vary from one jurisdiction to another.

How other stakeholders in health care view legislation

Interested observers of the present day approach to regulation have not overlooked, nor failed to point out, that the purpose of regulating the professions is to serve the interests of the public. If this is so, the traditional approach to legislation from their perspective has failed to achieve the mark.

There are various pressures for changes in the way health professionals are regulated. The public, a major stakeholder, is seeking a more open and responsive regulatory system. They are dissatisfied with the complaints investigation and disciplinary process of all the professions. They have had little if any opportunity to impact upon the policy direction of the professional regulatory bodies whose mandate is to protect their interests. They are also frustrated with the existing system because of the restrictions it places on their ability to utilize health care providers efficiently.

The health care consumer, be it the patient, insurance company, corporate business or otherwise, demands a "standardization" of health care. One concern is that any and all procedures performed by the professions meet one standard, where quality of care is assured not only within the practice of one profession, but that same procedure meet "one standard of the professions".

A new approach

In 1982, the Minister of Health of Ontario, the Honorable Larry Grossman, recognized that the traditional approach to regulating health professionals failed to meet either the concerns of the professions or the concerns of the public. He announced the creation of the Health Professions Legislation Review. In effect, rather than wanting to know how best to define and regulate a specific profession, the Minister wanted to know what is the best approach to legislation and regulation of health care professionals within a health care system.

The review team, co-ordinated by Toronto lawyer Mr. Alan Schwartz, was mandated with "devising a new structure for all legislation governing the health professions".¹

The Review, performed an exhaustive examination of the

health care legislation across Canada, the United States and Europe.

Realizing that none of the reviewed jurisdictions had an effective model that could be used, a new process evolved, no longer relying only on the professions as the only source of expertise, but including all the stakeholders in health care. The result was an extensive process that involved submissions from more than 200 different groups, including submissions from approximately 75 health professions represented by governing bodies, public interest groups, advocacy organizations and health care institutions and unions.

The purpose of professional regulation

Schwartz defined the purpose of professional regulation as one "aimed at advancing the public interest, not the interests of the profession".¹ He proposed that this could be accomplished in four ways:

- 1 By protecting the public from unqualified and incompetent and unfit providers;
- 2 By developing mechanisms that encourage (the provision of) quality care;
- 3 By allowing the public to exercise their freedom of choice of health care providers within a range of safe options;
- 4 By promoting the roles played by individual professions and individual professionals so that health services may be delivered with maximum efficiency.

This highly consultative process unfolded, demanding that the professions consult and address many contentious issues. In September, 1983, the Review circulated to participants a first Topics Paper inviting responses to questions pertaining to all areas of professional regulation. Each respondent was required to justify and support their replies with due consideration to often differing opinions of related groups.

The responses of each participant were subject to the scrutiny of the others in the process. The professions, the public stakeholders and the Review team consulted openly.

The professions quickly realized that the Review was taking a different approach to the regulation of health care. Many modified their positions, setting priorities and surrendering contentious issues. On the other hand, a minority of professional groups refused to compromise and were prepared to rival all opponents.

With respect to scope of practice issues, it became apparent to many that the Review was primarily interested in the potentially harmful aspects of the practice of the professions. *Any element of a professions scope which was considered harmless was no longer considered to be distinctive to that profession.*

The existing system, in which a small number of health professions are "licenced" (their members have an exclusive licence or monopoly over the provision of services that fall within their scope of practice) and others are "registered" (their members have the exclusive right to use certain titles), does not effectively protect the public from unqualified health care providers.

With the new system, each self-regulating profession will be required to assure safe competent and effective health care. Thus the purpose of granting self-regulation to a profession is not to enhance its status or to increase the earning power of its members by giving the profession a monopoly over the delivery of particular health services; but to protect the public.

In this system, every Professional Act will contain a general statement describing – but not licencing – the profession's scope of practice. *It describes areas where, entry requirements and standards of practice must be established and delineates* for consumers, members of the profession, employers, and courts the proper range of the profession's scope of practice. It will also serve to guide educators in the designing and updating of curricula. Of particular importance, the new model stresses more equal sharing of authority between professions as opposed to a monopoly by a few licenced professions.

The impact of the new system on standards and quality assurance

Examination of table 1 and table 2 outlining the permitted areas of chiropractic scope of practice in various jurisdictions of the USA, illustrates the variances in statutory provisions. It is striking to note that the "laundry list" model of table 1 and table 2 for the practice of the chiropractic profession is more detailed than that outlined for all "authorized" areas of practice for 24 different self-regulating health professions. (See table 3)

The new regulatory model will *require authorization for the performance of all* potentially harmful acts and procedures. There are 13 categories listed as "authorized acts" (see table 3). Not all the professions will perform "authorized acts". The Medicine Act for example includes all thirteen, while the Acts of six self-regulating professions list no authorized acts, and the remaining Professional Acts contain one or more authorized acts.

Aside from the 13 potentially harmful "authorized acts", there are no strictly written definitions of what a profession does or how it does it. Thus, it is the general statement that identifies what is distinct about the profession.

The intention of this open ended approach to scope provides greater accessibility to health care professionals by the public and flexibility as technology and quality assurance measures unfold. Technologies will not be dealt with in a profession specific fashion; rather a multi-disciplinary body will assess emerging technologies and be responsible for establishing explicit guidelines for all professions.

The manner in which this proposed legislation deals with scope will in my view impact the way we must deal with standards. Potentially harmful procedures will be strictly regulated, and the demand for standards and quality assurance will be provided for in statutes. It is inconsistent with the philosophy of this "new system" to anticipate that each profession will have its own standard and quality assurance measures with respect to potentially harmful acts or procedures.

This new model demands that there be an open consultative

Table 1* DIAGNOSTIC PROCEDURES

[illegible]

Response Key: + = Yes; 0 = No; - = No response; ? = Qualified or questionable response; # = By certification; @ = Can order; z = If taught in a chiropractic college

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process within the health care system, including stakeholders who are not professionals, to validate the procedures, the parameters of performance, quality assurance and measurement of outcome.

Impending changes in legislative proposals have not overlooked the interests of other stakeholders. There are provisions to ensure quality care, from a perspective which is broader than

the self interest of the professions. This poses a complex and difficult task for the governing body of the profession, who must reconcile the statutes, defining the mandate to assure standards and quality care. This must be achieved in consideration of the interests of other stakeholders in chiropractic, and those in the profession committed to the implicit; "the usual and customary practice" of the profession.

Table 3 PROHIBITIONS

Controlled acts restricted	<p>26.—(1) No person shall perform a controlled act set out in subsection (2) in the course of providing health care services to an individual unless,</p> <ul style="list-style-type: none"> (a) the person is a member authorized by a health profession Act to perform the controlled act; or (b) the performance of the controlled act has been delegated in accordance with section 27 to the person by a member described in clause (a).
Controlled acts	<p>(2) A "controlled act" is any one of the following done with respect to an individual:</p> <ol style="list-style-type: none"> 1. Communicating to the individual or his or her personal representative a conclusion identifying a disease, disorder or dysfunction as the cause of symptoms of the individual in circumstances in which it is reasonably foreseeable that the individual or his or her personal representative will rely on the conclusion. 2. Performing a procedure on tissue below the dermis, below the surface of a mucous membrane, in or below the surface of the cornea, or in or below the surfaces of the teeth, including the scaling of teeth. 3. Setting or casting a fracture of a bone or a dislocation of a joint. 4. Moving the joints of the spine beyond the individual's usual physiological range of motion using a fast, low amplitude thrust. 5. Administering a substance by injection or inhalation. 6. Putting an instrument, hand or finger, <ol style="list-style-type: none"> i. beyond the external ear canal, ii. beyond the opening of the nostrils, iii. beyond the larynx, iv. beyond the opening of the urethra, v. beyond the labia majora, vi. beyond the anal verge, or vii. into an artificial opening into the body. 7. Applying or ordering the application of a form of energy prescribed by the regulations under this Act. 8. Prescribing, dispensing, selling or compounding a drug as defined in clause 113 (1) (d) of the <i>Drug and Pharmacies Regulation Act</i>, or supervising the part of a pharmacy where such drugs are kept. 9. Prescribing or dispensing, for vision or eye problems, subnormal vision devices, contact lenses or eye glasses other than simple magnifiers. 10. Prescribing a hearing aid for a hearing impaired person. 11. Fitting or dispensing a dental prosthesis, orthodontic appliance or a device inside the mouth to protect teeth from abnormal functioning. 12. Managing labour or conducting the delivery of a baby. 13. Allergy challenge testing of a kind in which a positive result of the test is a significant allergic response.
Exemptions	<p>(3) An act by a person is not a contravention of subsection (1) if the person is exempted by the regulation under this Act or if the act is done in the course of an activity exempted by the regulations under this Act.</p>

There is concern however, about the use of the "usual and customary practice" as a basis for standards and quality assurance. There is no guarantee that it reflects current research evidence about efficacy or effectiveness, and it may perpetuate a dependency on criteria which could well be proven wrong".

What the courts have said

The Canadian Physiotherapy Association established guidelines of practice and guidelines of care which were agreed upon by 90% of the profession. Following a formal disciplinary proceeding, the governing body of Physiotherapy (The Board of Directors of Physiotherapy), found a registrant guilty of violating the standards accepted by the profession. She was suspended from practice, and subsequently the registrant appealed to the courts. The appellant court stated that:

"The court supports a finding of guilty where a physiotherapist... has done something with regard to the profession which would be reasonably regarded as disgraceful or dishonorable, by his professional brethren of good repute and competency. Where the alleged misconduct, however, relates to the methods or techniques of the member in performing the very function of the profession, then a different test must be applied.

In my view, (the court), the member cannot be found guilty on the basis that the vast majority of the profession feel the conduct or judgement of the member was wrong - if there exists a responsible and competent body of professional opinion that supports that conduct or judgement."⁴

In this instance, evidence was led by health professionals other than a physiotherapist, that the standard of the accused was an acceptable practice in other professions but that the standard agreed to by the physiotherapy profession are not appropriate. Despite all efforts to enforce the standards agreed upon by 90% of the profession, the court in essence instructed the governing body to approach the issue of standards in a different fashion. Although the governing body may have the power to remove a professional's livelihood, they will be permitted to do so only if the standards apply to more interests than their own. They must also consider the opinion of other responsible stakeholders.

Based on the precedent set by the courts and the changing elements of professional regulation, the question that the professions must address is, can we afford to accept the premise of standards based only on the views of the profession? May we exclude the consensus of the stakeholders in the health care delivery system and anticipate that our standards will not be challenged?

Standards are important, but approaching the task the proper way is equally important. In my view the value of the professions commitment must necessarily be measured by other stakeholders. On this basis, it would appear that we must reassess our thinking and our approach to the fundamental issue of

standards. The profession may "set" guidelines or standards for informed consent - clinical examination - documentation - record keeping - practice management - continuing education - advertising - x-ray - therapeutic and diagnostic instrumentation - frequency and duration of care - modes of management and may find we have done little to address the real issue.

The challenge is to establish what the standard of the profession is today. Not based on what we think it is or wish it to be, but simply, what the standard of practice and care of the chiropractic profession is in a given jurisdiction.

Learning from others

In November, 1990, the Ontario Task Force on the Use and Provision of Medical Services reported to the Minister of Health, including recommendations on the guidelines development process.⁵ The Task Force recommended that the process used to develop guidelines should:

- utilize outcomes measures from clinical research studies and consider how they will impact upon the resources of the health care system;
- be voluntary and permissive;
- be sensitive to social concerns; and
- be open to public, professional and private industry input and debate.

With respect to establishing guidelines and standards, it is clear from these recommendations that expectations of major stakeholders include a process which must be expanded beyond the experience and expertise of the profession. It is fundamental that quality improvement not be identified with punitive measures and should not be restricted to pointing fingers or assigning blame. Rather, guidelines and standards should be targeted at quality improvement of the profession and not focus on the individual practitioner.

The complaints and disciplinary provisions of the regulatory process is the appropriate mechanism to deal with the "bad apples" and weed them out of the system. Discipline is a necessary part of the regulatory process, but it is scarcely more than an *ad hoc* analysis of what went wrong. Dealing with a complaint about a practitioner does not assume nor improve the quality of care of the profession. It just uncovers a problem that's always been there.

Those who view standards as a mechanism to "control quality", "police the profession", to ensure that there is a minimum standard of practice and care, must reconcile the outcome of such a process to the alternative which is "quality assurance". This alternative involves everyone but blames no one.

Quality assurance, is more than quality assessment, it "is the measurement of health care activity, and the outcomes of activity, in order to identify whether the expected objectives of the activity are being achieved and, when this is not the case, to respond with effective action to reduce the deviations from objectives".⁶

Improving the quality of care of a profession must relate structure and processes, to the outcomes of "what we do". This

concept is difficult for professionals to accept, yet impossible for other stakeholders to ignore. Simply stated, in the eyes of some, it may be of little value to perform with excellence, an examination, diagnosis and treatment of a patient, if the outcome of patient care is not measured.

Therefore, we must establish what the standard of the profession is today, so we may determine the necessary steps to improve the performance of the profession tomorrow. The chiropractic profession has a responsibility to demonstrate the improvement of the profession as a health care delivery instrument.

The task force recommendations provide a template of how we should approach this task. We must recognize that other stakeholders are demanding that our standards be explicitly formulated and open to public criticism and debate. We must recognize that standards based on the "usual and customary practice" and what you and I think is appropriate is adequate. We must demonstrate that the standards of the chiropractic profession are validated, up-to-date, and explicit, for it is only through explicit standards that we may demonstrate that the objectives and assumptions of our health care delivery process are truly accountable.

Health care policy

The report of the Premier's (of Ontario) Council on Health Strategy in March, 1991, provides insight into public policy initiatives which must be considered:

"Many people still think health gains are possible only through expenditures on the formal health care system. But the medical treatment system has a limited role to play in improving overall health of the population. International and Canadian research data show that other factors are more important determinants of health than the formal health care system."⁷

In a report, "Achieving The Vision: Health Human Resources", the committee addresses "efficient and effective health services":

"Our aim is to deliver quality service with maximum productivity in the system. This requires use of the most appropriate skill sets, at the least cost, to achieve better patient outcomes. It also means that substitution of skill sets will occur between and within health professional and provider group."⁸

Stakeholders are challenging the professions to get together and explicitly formulate measures of quality assurance, that they may understand and scrutinize as well. They don't want to be left out - they want their voices to be heard.

Impact on the professions

Contrary to the rigidly controlled "licenced acts", many health professionals will be performing procedures which are no longer "listed" as part of any profession's scope because they are not

considered to pose a significant risk of harm and are open for anyone to perform. This category of procedures or acts is referred to as "the public domain".

Such categorization will not alter the practice of the professions because the public domain may be practiced by all. Those Acts, however, which are potentially dangerous must necessarily meet rigid standards which transcend the traditional borders of any one profession's scope of practice. Similarly, those elements of chiropractic practice which are common to other professions will ultimately meet the same challenge.

The new structure demands "THE STANDARD" for any procedure be objective, explicit and verifiably formulated. There must be involvement of the scientific community, other providers, the public and chiropractors, if we are to explicitly challenge what we are doing and why we are doing it.

Paralleling these conclusions were those reached at the International Conference on Quality Assurance and Effectiveness in Health Care, in November, 1989. Called by Canada's First Ministers to address specific challenges facing Canada's health care system, it reiterated that assuring quality health care "requires a strategy for changing what is wrong, deficient, excessive, uneven, or ineffective".⁷

Conclusion

In conclusion, explicitly formulated standards need to be validated by what the profession is actually doing and related to the outcomes of care. On this foundation we may establish goals to "continuously improve" the quality of care of the profession.

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