
VI. THE REGULATION OF
COMPLEMENTARY AND
ALTERNATIVE HEALTH CARE
PRACTITIONERS :
POLICY CONSIDERATIONS

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The views expressed in this paper are those of the authors and do not necessarily represent the views of the Health Systems Division, Health Canada

I. INTRODUCTION

The following is one in a collection of background papers prepared for Health Canada to assist users, practitioners, and policy makers to understand and explore issues emerging with the development of complementary and alternative health care (CAHC) in Canada. While it may touch some of the other aspects of CAHC development being explored elsewhere in other Health Canada papers, this background paper focuses on the regulation of CAHC practitioners. In that regard, it is an early introduction, literally a "think piece," intended to assist with the preliminary task of how major stakeholders might identify and explore the many questions, issues and challenges that arise when one considers the topic. Given the introductory nature of this report, it is intended to serve as a catalyst for further analysis of the many important policy issues in this area.

The provinces and the territories have the constitutional jurisdiction to regulate health care professionals, including CAHC practitioners. While Health Canada does not have a direct role in regulating health professionals, the significant impact of CAHC on the health system has necessitated policy analysis in this area. As has been previously stated:

"The role of the Health Systems Division, with respect to CAHC, is to consider the impact of the CAHC on the health system and the implications of CAHC for the renewal of the health system." (de Bruyn, p.2)

Health Canada's intent with this paper is to produce a beginning conceptual framework that the provinces and territories, professional bodies, CAHC practitioners, consumer groups, and other stakeholders might use as a reference in considering the policy implications related to the regulation of CAHC practitioners.

It is beyond the scope of this paper to debate what CAHC is and is not and would be duplicative of other Health Canada initiatives.¹ For the purpose of this paper we adopt the definition accepted by the United States Office of Alternative Medicine.

Complementary and alternative medicine (CAM) is a broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period. CAM includes all such practices and ideas self-defined by their users as preventing or treating illness or promoting health and well-being. Boundaries within CAM and between the CAM domain and the domain of the dominant system are not always sharp or fixed. (as referenced in Achilles, 2000).

The term "CAHC practitioners" in this report refers to individuals who practice complementary and/or alternative health care, as defined above.

II. METHODOLOGY

This report builds on related work already done by Health Canada, including but not limited to:

1. *Complementary and Alternative Health Practices and Therapies: A Canadian Overview* by York University Centre for Health Studies (August 1999). The purpose of this extensive report was to provide an overview of the knowledge, opinion and practice of CAHC in Canada and to provide a useful basis for future research. (This report is referred to later as "YCHS, 1999")
2. *Defining Complementary and Alternative Health Care* by Rona Achilles (April 2000). The purpose of this report was to review the issues related to defining complementary and alternative health care.
3. *Taking Stock: Policy Dimensions Associated with Complementary and Alternative Health Care* by Theodore de Bruyn (March 2000). The purpose of this report was to synthesize the broad range of available information on CAHC and identify the primary policy issues.
4. *Towards an Integrative Health System* (July 2000). This is a discussion paper undertaken by the Advisory Group on Complementary and Alternative Health Care. The purpose of the report was to examine implications of the growth in utilization of complementary and alternative therapies and practices and to initiate discussions on integrating "mainstream" and "complementary and alternative" approaches.
5. *Status Report and Analysis of Health Professional Regulations in Canada* by James T. Casey (March 1999) prepared for the Federal/ Provincial/ Territorial Advisory Committee on Health Human Resources. The purpose of this report was to survey developments in health professional regulation across Canada and to identify regulatory structures which may impede or facilitate health care reform. While the

report does not focus specifically on CAHC practitioners, it provides an overview of the various mechanisms used to regulate health professionals generally in Canada.

The approach to data collection and information gathering for this paper was shaped by three objectives:

1. To identify the policy objectives and context of decisions to regulate or not regulate CAHC practitioners;
2. To identify the various approaches to regulating health practitioners in Canada; and,
3. To discuss the value of utilizing a "controlled acts" methodology in assessing whether certain CAHC practitioners should be regulated.

A focused search of the literature and the Internet² as well as an extensive review of relevant policy documents and printed materials were the two principal methods of gathering of information. In addition to the collection and review of printed or published works, 19 key informant interviews were conducted. Appendix A identifies the respondents to the interviews, who represent practitioners, policy makers, and regulators at the national and provincial levels in Canada, with the addition of two from the United States. Appendix B outlines the interview template used to collect "top of mind" thoughts regarding the regulation of CAHC practitioners. The interviews with the key informants focused on the current environment for the regulation of CAHC generally and on issues, concerns and policy options with respect to the regulation of CAHC practitioners.

Finally, the authors have brought their professional expertise and experience to the analysis and discussion of both the context and options for regulating CAHC practitioners in Canada. (See Appendix C for a description of the authors' background and experience.)

III. THE REGULATION OF HEALTH PROFESSIONALS IN CANADA

An analysis of the policy issues concerning the potential regulation of CAHC practitioners requires an assessment of whether the regulatory structures currently used in Canada for the conventional health professions are either appropriate or inappropriate for a particular group of CAHC practitioners. This in turn requires an understanding of the current health professional regulatory structures in use. It is beyond the scope of this report to describe in detail the current regulatory structures; readers seeking further information can review *Status Report and Analysis of Health Professional Regulations in Canada* or one of the standard texts in the area such as *A Complete Guide to the Regulated Health Professions Act* by Richard Steinecke (1995) or *The Regulation of Professions in Canada* by James T. Casey (1994), or *Health Care Practitioners: An Ontario Case Study in Policy Making*, by Patricia O'Reilly, 2000. However, we will briefly summarize the main features of the current regulatory structures in order to provide the context for our analysis.

The provinces and territories are granted the jurisdiction by the Constitution to regulate professions. The provinces and territories have passed legislation for many professions which delegates authority for the regulation of a particular profession from the province or territory to an organization comprised of members of the particular profession. These professional organizations are largely self-governing within the boundaries of their statutory authority and have been granted the privilege of self-governance in order to protect and promote the public interest.

Some of the earliest self-governing organizations for physicians and dentists date back to the time of Confederation or earlier. There was a gradual increase in the number of self-regulated professions as health care developed in Canada. There was explosive growth in the 1960s and 1970s in the number of health professions as different sub-specialties emerged. Increasing numbers of informal groups of professionals sought self-regulation through legislation. Today there are over 35 different health professions regulated in Canada. There is a core

group of professions (medicine, dentistry, registered nursing, optometry, and pharmacy) which are regulated in all of the Canadian jurisdictions but for the balance of the professions there is a significant divergence among the jurisdictions as to whether a particular profession is formally regulated. For example, massage therapy is only formally regulated in British Columbia and Ontario but is practised across the country.

The predominant mode of regulation for health professions in Canada is self-regulation. Historically, this has been legislatively achieved after certain acceptance or recognition by the political and economic players and institutions in the health sector. Regulatory precursors to such self-regulation include direct government regulation through mechanisms such as the Acupuncture Committee in Alberta. Legislation in Canada has established three primary regulatory structures for the self-regulation of health professions. We have adopted the definitions of the three systems from a *Status Report and Analysis of Health Professional Regulations in Canada* (page 2).

1. *Exclusive scope of practice*: members of a profession are granted by the legislation the exclusive right to provide a particular service to the public. (However, it should be noted that there are often exceptions in the legislation permitting other professions to perform certain services which would be within the scope of the practice.)
2. *Right to title*: both members of the profession and non-members can provide services to the public but only members may use a protected title or hold themselves out as being registered.
3. *Controlled acts system*: a model under which specific tasks or activities are regulated. Rather than regulating an entire field of practice, legislation provides that certain activities can only be performed by a specific regulated health professions. For example, an exclusive scope of practice model would provide that only a physician can provide services that fall within

the scope of the practice of medicine. A controlled act model would provide, for example, that setting a fracture can only be performed by a member of one or more specified health professions.

The terminology used across Canada to describe these three systems is inconsistent. For example, "exclusive scope" is sometimes referred to as a "licensure" system; "right to title" as a "certification" system; and "controlled acts" as a "restricted activities" or "reserved acts" system. It must also be appreciated that some legislative structures do not fit neatly into the categorization of the three systems and that in some cases a combination of systems is used. For example, a controlled acts system might also utilize a right to title structure. The *Status Report and Analysis of Health Professional Regulations in Canada* (page 18) concludes that exclusive scopes of practice remained the predominant form of professional regulation but that there is a very strong trend towards controlled acts systems.

Self-governing professions generally operate within one of the three systems described above and perform four other critically important regulatory functions.

1. They act as "gate-keepers" to the profession by typically establishing and enforcing entrance standards for the profession.
2. They establish standards of practice for the profession providing guidance to members of the profession on the performance of their duties.
3. They establish continuing education or continuing competence requirements members must follow to maintain their competence throughout their career.
4. They administer a professional disciplinary process designed to protect the public from incompetent or unethical professionals. Members of the profession found to have

engaged in unprofessional conduct or unskilled practice can face a range of sanctions from a directive to take remedial training to the expulsion from the profession in extremely serious cases.

Some CAHC practitioners are self-regulating in Canada through conventional professional regulatory models. Options for various regulatory models are reviewed later in this report. Although reliable statistics are difficult to obtain, it is our assessment that the vast majority of CAHC practitioners are not self-regulating through the three conventional professional regulatory models mentioned above.

The literature review, key informant interviews and our own analysis all confirm that the issue of whether CAHC practitioners should be regulated is a central policy challenge to the continuing development of CAHC in Canada. However, we are acutely aware that the potential regulation of CAHC practitioners cannot be considered only within the paradigm of the regulation of conventional health professionals. The analysis of the regulation of CAHC practitioners needs to take place within the broader regulatory environment for CAHC, which includes a consideration of a number of factors including:

1. reasons for increased utilization of CAHC;
2. consumer-driven demand for CAHC;
3. relationship of CAHC to modern science;
4. the need for a "systems approach" to assessing the CAHC quality assurance environment; and
5. challenges for the regulation of CAHC practitioners.

Each of these factors will be reviewed below in the context of their impact on the potential regulation of CAHC practitioners.

IV. REGULATORY ENVIRONMENT FOR COMPLEMENTARY AND ALTERNATIVE HEALTH CARE

A. Reasons for the Increased Utilization of Complementary and Alternative Health Care

The literature (Boozang, 1998; Eskinazi, 1998; Shenfield, 1998) and key informants report reasons for the rise in utilization of CAHC. It is interesting that there is not much attention to or concern for professional regulation on the part of consumers. The most frequently referenced reasons for the increased utilization areas follows.

- Dissatisfaction with the shortcomings of the conventional healthcare system. Several key informants were quick to add that the restructuring of health care in the 80s and 90s was not a factor. Rather, the emphasis was on the limitations of the biomedical model, particularly in the areas of pain, chronic illness, health promotion, and healing along with, or in lieu of cure; which is increasingly more unattainable, given the predominance of chronic illness (CBC, 2000).
- Aversion to the reliance of conventional medicine on highly invasive (e.g., surgery) or high risk treatments (e.g., drugs with serious adverse effects).
- Satisfaction in particular with the more holistic, open and partnership-based approach to professional services used by CAHC providers, which many refer to as a consumer perspective that is attentive to and respectful of the patient as a consumer (Government of Canada, 1998; Eskinazi, 1998).
- The access to information made available through the "information highway", and freedom of information supports, especially in the public health system.
- Globalization, and in particular exposure to large established cultures where the dominant health care system is traditionally and/or folk medicine based (Drew and Myers, 1997).

A notable number of respondents commented that, demographically, the CAHC utilization trend is a manifestation of the "baby boomer" generation's insistence on choice, as well as its financial ability and willingness to explore all alternatives in any service area. As one respondent clearly expressed, reflecting many others' views, "Akin to this is an intellectual movement away from hard science, toward the intuitive, insightful, and indeed the spiritual." Others suggested that advertising, the media and word of mouth have also contributed to the exponential increase in the use of CAHC services in the 1990s.

Different, yet not contradictory, reasons are seen for the uptake of training, education and service provision by CAHC practitioners.

- Patients/consumers are asking for alternatives.
- A shared dissatisfaction with consumers about the biomedical model and mainstream health care system, particularly with the focus on surgery and drugs, and lack of support for services that treat the patient as a whole person, rather than as a disease. Practitioners find particular satisfaction in being able to assume and facilitate the informed consumer, respectfully disclose the limitations of the biomedical model and alternative therapies in the areas of chronic illness, pain management and health promotion, and approach the patient/practitioner relationship like a partnership.
- Practitioner hope that other modalities may help when they do not see their patients getting better with conventional approaches.
- Practitioner curiosity about this growing sector of the health system.
- Economic opportunity – the field is growing and there is "a lucrative market out there," especially for the merchant and service provider.

- Continuing education and training are increasingly available to mainstream or conventional providers who wish to add CAHC skills and services as a modality within their existing practice repertoire, and new basic programs are increasingly available for those entering the field solely as CAHC practitioners. (Ruedy and Kaufman, 1999)

Most key informants did not see the necessity to differentiate between complementary and alternative health care at this time and some advised against it. Many observed that the lack of boundaries between CAHC and conventional therapies or among CAHC services is not problematic for consumers. Based on professional and personal experience, alternative therapies are seen to exist outside of the conventional system and to be used instead of conventional or mainstream services. They are seen to not arise out of or support the modern science framework embraced by conventional medicine and in particular to be holistic by nature (e.g., chelation therapy, touch for health, prayer). Complementary services are those characterized as adding to or increasing the benefit of conventional or mainstream services, as they are used along with these other services, either to enhance their benefit or reduce the effects of mainstream interventions (e.g., acupuncture to reduce the negative side effects of radiation therapy for cancer patients, music therapy used preoperatively in cardiac units). Complementary services are seen to be more akin to or more compatible with the modern science model embraced by conventional medicine.

There is consensus that patients should have access to and be able to benefit from both complementary and alternative health care, as well as conventional services. There is also strongly divided opinion on whether differentiating between complementary and alternative services would support such a goal (Bonn, 1999; CBC, 2000; Druss and Rosenheck, 1999). Some key informants suggested that it would be highly inappropriate to support complementary over alternative services out of support for the continued dominance of conventional medicine. As O'Reilly points out in describing the Ontario experience in health professions regulation, "The door has been opened, if only a crack, for the possibility of a less restricted definition of health care expertise. But it would

likely still be a scientific interpretation of expertise which would prevail." (O'Reilly, 2000, p.1380). For this very reason, concern is expressed that a move to integrate complementary and alternative or CAHC and conventional services may "fly in the face of " a truly integrated system, where patients can benefit from both the medical model and a more holistic approach to health and healing.

B. Consumer-Driven Demand

The literature search and key informant interviews yielded an unsolicited consensus that the uptake of CAHC is a consumer-driven phenomenon and reality, and that it will likely continue to increase exponentially. (*The Berger Monitor*, 1999; Boozang, 1998; Eisenberg, 1998; Fisher and Ward, 1994) There is also consensus (with a significantly varied range of concern) that the utilization trend with CAHC has been led by demand rather than evidence (Zollman and Vickers, 1999). The perception (or fact) that consumers have driven the utilization of CAHC without the usual protective mechanisms of professional regulation or established consumer protections emerges as a strong concern, particularly for professionals. For regulators and policy makers, it is a compelling curiosity to perhaps be more seriously explored when considering regulatory options for the regulation of CAHC practitioners (Fisher and Ward, 1994, Geddes and Henry, 1997).

C. Relationship of Complementary and Alternative Health Care To Modern Science

While CAHC is increasingly recognized to have been consumer-led, it is as frequently and even more generally recognized not to be evidenced-based. The assertion is that the value of all modalities may not have been proven using modern scientific methods. The questionable scientific status of CAHC predictably further reduces its chances of acceptance or recognition not only in the political and economic but also judicial processes of today (Cohen, 1998; O'Reilly, 2000). Historically, "The claim for scientific expertise was used with effect first by medical practitioners, then by other practitioners to argue for a more protectionist role by the state [for the professions] than is commonly held in Western society." As O'Reilly further points out, for health professions to advance in Canada, i.e., to obtain recognition by

the dominant political, economic and judicial structures, they must demonstrate commitment to the public welfare, and be associated with or supported by science. (O'Reilly, p. 17)

Some conventional health professional organizations and commentators have taken the position that CAHC practitioners should not be given sanction by the state in the form of self-regulation unless and until they can demonstrate that their particular CAHC modality is evidence-based. (See generally the discussion of the issue in Boozang, 1998; CBC 2000; Lewith et al, 2000; O'Reilly, 2000; Stone, 1996). The evidence-based "issue" is a major force primarily in practitioner-based discussions of CAHC. Along with discussions of the placebo effect, it looms largely at the centre of discrediting CAHC, (CBC 2000; Hodgkin, 1996; King 1998) and is fundamental in the barriers to recognition and acceptance of CAHC by conventional practitioners and their governing bodies. (Zollman and Vickers, 1999)

The weak or inapparent link of CAHC to modern science is further compounded by the lack of formal bureaucratic organizational status, a characteristic that also fosters credibility with the dominant structures of the day. Ironically, concern about the modern scientific basis of CAHC has been noticeably absent among the public, which has generally accepted CAHC, probably the most important "recognition" for CAHC so far. (Cooper and Stofflet, 1996)

An extensive discussion of the "evidence-based" issue is beyond the scope of this report. However, we note that both the literature and key informants reflect a concern that different criteria are perhaps being applied to CAHC professions than to conventional health professions for regulation. It is generally recognized that evidence-based status has not previously been required for conventional health professions to achieve recognition through regulation. The concern expressed is that to require CAHC practitioners to provide a rigorous evidence-based case before they will be accepted for regulation may be setting the bar at a level which conventional health professions have not been required to meet themselves, and may only partially meet today, if at all.

While evidence-based is not yet generally established as the "school of standard" (Studdert et al, 1998, p.1614), regulatory bodies are beginning

to employ levels of validation that arise out of this expectation in policy instruments used as practice guides in the regulation of CAHC. (Kentucky Board of Medical Licensure, 1999) Some regulatory bodies in Canada are only now beginning to attempt to utilize a more complete evidence-based approach to set practice standards. Other regulatory bodies in Canada have not made any significant attempt to establish evidence-based practice standards. Obviously the evidence-based issue needs to be considered in the debate as to whether and how to regulate CAHC practitioners. Given the historical context of this issue we conclude that the lack of a strict evidence-based approach for some CAHC modalities should not in and of itself be a barrier to regulation of CAHC practitioners if there exists sufficient social value from such regulation. We further suggest that the modern scientific basis of CAHC may be more appropriately understood as a recognition challenge, rather than a regulatory matter.

D. A "Systems Approach" to Assessing the Environment for Complementary and Alternative Health Care Quality Assurance

The environment for the regulation of CAHC participants is broader and more complex than any regulatory structure that may be established to regulate CAHC practitioners. In any analysis of the advantages and disadvantages of professional regulation, there is a tendency to focus only on the impact on quality assurance from the presence or absence of a self-governing structure. However, such an exclusive focus is misleading; there are numerous factors in the health care system which affect the quality of health services including educational programs, employer supervision, employer practices and policies, accreditation of health care facilities, tort law, dispute resolution mechanisms, third party insurers, consumer demands, consumer protection laws, food and drug labeling regulations, and access to information access. The potential for professional regulation of CAHC practitioners cannot be considered in isolation. All factors affecting the quality of a CAHC service need to be considered when analyzing whether the regulation of CAHC practitioners is either necessary or desirable.

For example, suppose that a jurisdiction is considering whether to regulate practitioners who

sell natural health products in locations other than pharmacies. Concern has been expressed that unregulated practitioners in this area could be a risk to the public as they might not have a satisfactory knowledge of potentially negative interactions between some natural health products and medications. Regulation of the practitioners is being considered because a regulatory body could establish both educational requirements for entrance to the profession and standards of practice.

While the regulation of the CAHC practitioners in this hypothetical example may be a positive force for quality assurance, it would be an error to consider this option in isolation of other factors in the environment that could affect quality of the product and service. For example, labeling regulations passed by the federal government could serve to provide the necessary information to consumers. Further, federal and provincial regulation on drugs and prescribing will already place some limits on the types of products that can be sold by the practitioners. Practitioners may voluntarily belong to an active non-statutory organization that sponsors continuing education programs and consumers may choose to only patronize establishments where the practitioners are knowledgeable about the products they sell. We do not use this simplified example to support whether regulation of the CAHC practitioners in this context is appropriate. We utilize the example to underscore the point that a failure to consider all quality assurance mechanisms in a particular environment may lead to inappropriate decisions regarding CAHC practitioner regulation and potential over-regulation, especially in an era of informed and empowered consumers.

E. Challenges for the Regulation of Complementary and Alternative Health Care Practitioners

Recognizing the heterogeneous nature of CAHC (Zollman and Vickers, 1998) and the need for a pluralistic approach to the development of a regulatory regime (Fisher and Ward, 1994; Geddes and Henry 1997) both the literature and key informants suggested the following challenges face the regulation of CAHC practitioners in Canada.

- There may be hostility from conventional health professions to CAHC practitioners providing services to individuals who might otherwise have sought services from conventional health professionals.
- There may be conflict between groups of existing CAHC providers with respect to which group should most "appropriately" provide a particular service.
- The practitioners are not organized, and where they are, the groups are often small and struggling financially.
- CAHC practitioners are as a group very heterogeneous and difficult to standardize as far as entry requirements and continued competence are concerned.
- There is pressure from professional organizations of conventional practitioners to discourage self-regulation for these groups, especially using evidence-based practice, as a "gatekeeping" barrier.
- There is a need to reconcile the apparent lack of level playing field for the education of CAHC practitioners compared to physician education for example, which is significantly subsidized by the provinces. A similar sense of unfairness characterizes the research dollars spent by government and granting bodies on conventional versus CAHC clinical research.
- A need to understand the responsibilities as well as rights of consumers with respect to CAHC.
- It appears that some third party insurers are reluctant to provide benefit coverage for services offered by CAHC practitioners unless those practitioners are granted recognition by being regulated in the same way that conventional health care practitioners are regulated. Some respondents commented that private funding should not influence regulation, nor should regulation be a requirement for private funding or third party coverage. A number also predicted that third party coverage will probably increase regardless of regulatory status, especially if targeted to certain problems for which CAHC services are deemed to be more effective and efficacious than conventional treatments (e.g., chronic pain management).

V. POLICY OBJECTIVES FOR THE POTENTIAL REGULATION OF COMPLEMENTARY AND ALTERNATIVE HEALTH CARE PRACTITIONERS

There is consensus in the literature and in the comments from the key informants that the predominant purpose of any potential regulation of CAHC practitioners is to protect the public from unsafe and unethical practice and to reduce unacceptable levels of risk. The great challenge is to identify accurately and assess the degree of risk and then match regulatory mechanisms that reduce the risk. As noted by the Manitoba Law Reform Commission, in order to produce a benefit "the regulatory regime must be meaningfully related to the causes of improper performance of the service." (p. 33)

Professional regulatory mechanisms which are generally considered to reduce risk are standard education requirements for entry to the profession, mandatory registration, practice standards, codes of ethics, mandatory continuing competence, and full disclosure requirements to the public, including any potential for conflict of interest on the part of the practitioner.

However, it must not be automatically assumed that there is a sufficient degree of risk which would require conventional professional regulation of CAHC. Some key informants noted that there is currently a dearth of evidence regarding harm done by CAHC practitioners and as a result were concerned that it may be premature to consider regulation. Other key informants emphasized that knowledgeable and empowered consumers may reduce the need for regulation. As noted by the Manitoba Law Reform Commission, "So long as consumers have the knowledge necessary to make an informed judgement as to their need for the service, the form of the service they need, and the ability and ethics of the practitioner, they are able to protect themselves from incompetence and from unethical practices." (p. 13)

Policy analysis of professional regulation has historically focused on reducing incompetent and unethical services. However, it should be appreciated that professional regulation serves a

broader sociological function in society related to the recognition of the profession by the dominant political forces in a society. The fact that a particular modality is regulated serves to "legitimize" the particular health profession to many consumers, governments, organizations, third-party insurers and other health care professionals. Achieving self-regulation can assist a profession in communicating the value of its services and to integrate into "mainstream" health care. While it remains contentious whether CAHC should integrate with conventional health care, policy makers need to be cognizant that proper regulation can be a tool not only to reduce risk but which could also serve to promote a particular CAHC modality.

After synthesizing the literature and the comments of the key informants, we would suggest that the following policy objectives inform decisions concerning the potential regulation of CAHC practitioners.

1. Regulation of CAHC practitioners should generally only be considered where there exists an unacceptable level of risk and be designed to meaningfully reduce that risk. The exception would be where there may not be an unacceptable level of risk but jurisdictions decide to "promote" or integrate CAHC by providing certain CAHC practitioners with the sanction of state regulation.
2. The cost-effectiveness of the regulatory scheme must be carefully considered, recognizing that there are both societal benefits and societal costs to all regulation of professionals. One of the potential benefits of self-regulation is decreased risk of harm to consumers through the quality assurance mechanisms of entrance standards, practice standards, code of ethics, and continuing education requirements. The costs of regulation include not only the direct costs of administering the regulatory regime but also the potential social costs of reduced competition and higher prices which may occur when

entrance to a profession is restricted and the cost of obtaining a license to practice is significant. (Manitoba Law Reform Commission, 1994, Chapter 2)

3. The regulatory structures should maximize informed consumer choice and access. Exclusive scopes of practice regimes, in particular, reduce access and choice. Access may be affected because exclusive scopes of practice tend to reduce the number of practitioners working in an area since only those who meet the entry and practice standards of the profession are legally allowed to offer the service to the public. Access can also be reduced if an exclusive scope of practice regime causes prices to rise beyond the reach of certain groups of consumers. Exclusive scopes of practice also have a dramatic negative effect on consumer choice. In an exclusive scope of practice regime, consumers, even if knowledgeable and fully informed, are prohibited from obtaining services from anyone other than a licensed member of the profession. Right to title and controlled acts systems restrict consumer access to a much lesser degree. It would be problematic to adopt regulatory regimes that significantly limit consumer choice and access to CAHC given that CAHC has
4. The regulatory structures should not stifle development of CAHC provided public safety is not jeopardized. Even in conventional health professions, there is always a tension between conventional norms of practice and innovative but unproven methods of treatment. The conventional health professions have historically considered it to be appropriate to utilize standards of practice and the disciplinary process to prevent their members from offering 'unscientific' or unproven treatments to patients. However, a too vigorous application of standards of practice and the disciplinary process can undermine the development of new health treatments. There are many widely accepted health treatments today that were vigorously opposed by certain conventional health professional organizations at the time the treatment first began to be introduced. Given that CAHC is largely not evidence-based, care must be taken to ensure that any integration of CAHC with conventional health care does not stifle the development of CAHC.

VI. POLICY OPTIONS FOR THE POTENTIAL REGULATION OF COMPLEMENTARY AND ALTERNATIVE HEALTH CARE PRACTITIONERS

This section of the paper is not intended to be a survey of the steps in Canada which have already been taken to regulate certain groups of CAHC practitioners (For an overview, see de Bruyn, 2000, p.15-20; YCHS, 1999, Part III; and Casey, 1999, Appendix B.) Rather, this section identifies some of the primary options for the regulation of CAHC practitioners available to policy makers.

1. No Regulation

While professional regulation has been one of the predominant organizational forces in health care in the past century, it must not be automatically assumed that CAHC practitioners should be regulated. Nor should it be automatically assumed that the organizational forms that have worked reasonably well for conventional health professions

are necessarily the best structure for CAHC practitioners. It is now recognized that professional regulation has both societal benefits and societal costs (See the analysis in the Manitoba Law Reform Commission, 1994, Chapter 2.) Regulation of a particular group of CAHC practitioners should not be undertaken unless the societal benefits outweigh the societal costs broadly defined.

It is our assessment that most CAHC practitioners are not currently regulated. For example, practitioners of traditional Chinese medicine have not been regulated anywhere in Canada although the Province of British Columbia has announced that it will establish a College of Traditional Chinese Medicine and Acupuncture. In some cases there may be an express policy choice made not to extend conventional regulatory structures to CAHC practitioners. For example, in 1993 the Office des professions du Quebec recommended that a professional corporation not be created in the domain of alternative medicine and that the mechanisms under their Code not extend to the practice of massage, naturopathy, phytotherapy and energetic therapies. (YCHS, 1999, page 94)

2. Voluntary Professional Associations

Many CAHC practitioners belong to non-statutory, voluntary professional organizations with membership comprised of individuals practicing in the same field even where the "profession" is not recognized by legislation. Development of strong voluntary professional organizations may be seen as part of the natural evolution of CAHC professions. Professional organizations in conventional health care typically evolved from voluntary professional organizations that sought self-governing status through legislation once the organizations became sufficiently well-organized, financially sound, and politically influential. In other words, this occurred once they were recognized by the dominant policy structures in the health sector. Voluntary professional organizations undertake many of the same types of activities as professional organizations established by legislation, such as:

- setting education standards which must be met to join the organization;
- promoting continuing competence activities by its members;

- adopting a Code of Ethics; and
- disciplining members who demonstrate unethical or incompetent behaviour.

Given that there is no legislative recognition of these groups, they are unable to establish an exclusive scope of practice, controlled acts or protected titles. Policy makers should consider whether some of the societal goals of potential regulation can be achieved by encouraging and nurturing non-statutory organizations of CAHC practitioners. Numerous non-statutory organizations of health care providers exist across Canada. For example, the Association of Massage Therapists and Wholistic Practitioners (AMTWP) has a large membership in many jurisdictions across Canada and carries on functions similar to conventional professional organizations, although membership in the AMTWP is voluntary and the organization is not recognized or created by legislation.

3. Encouraging The Development of Educational Programs

One of the primary ways in which self-governing professions promote competent practice is through entrance standards. Individuals are not permitted to enter the profession unless they have graduated from a recognized educational program and perhaps have completed a period of training or internship. Entrance standards are useful in promoting competence where the educational program teaches the technical knowledge and attributes necessary for the successful delivery of the professional service. However, excessive or improperly designed entrance standards can also serve to restrict access to the profession unduly.

CAHC education is developing through a wide variety of both formal and informal initiatives. (See YCHS, 1999, pp.229- 242.) For example, Douglas College in New Westminister, British Columbia offers a wide variety of programs and certificates in Natural Health and Healing Alternatives; the Michener Institute for Applied Health Sciences in Toronto offers a wide variety of programs in CAHC at both entry and post-graduate level. (YCHS 1999, pp. 235 and 238) Some of the advantages of statutory entrance standards can be achieved even where there is no

formal regulation if CAHC practitioners voluntarily take appropriate educational programs. Therefore, policy makers may wish to consider whether they should actively encourage the development by educational institutions of appropriate educational and training programs for CAHC practitioners.

4. Establish Exclusive Scopes of Practice For Complementary and Alternative Health Care Practitioners

An "exclusive scope of practice" exists where only those individuals who are members of a legislatively recognized professional organization may engage in the practice of a particular profession. The "practice" of a profession is often described in the legislation in broad and somewhat vague terms.

Exclusive scope of practice has historically been the predominant form of professional regulation in the health care sector in Canada. (Casey, 1999, p.19) A detailed analysis of the relative strengths and weaknesses of this model is beyond the scope of this paper. However, it should be noted that in the last decade there has been a strong movement away from the exclusive scope model to either "right to title" or "controlled acts" models in the conventional health care professions. In the CAHC area (and increasingly for many health professions), concern has been expressed that exclusive scope models may not be the best choice because the model is insufficiently risk sensitive, restricts the supply of CAHC practitioners, and limits consumer choice and freedom. Exclusive scopes of practice are also static and politically difficult to change once granted.

In our assessment it is rare for jurisdictions to grant exclusive scopes of practice to CAHC practitioners. However, naturopathic physicians in British Columbia and Saskatchewan are two examples. (Casey, 1999, Appendix B)

5. Establish Right to Title Models for Complementary and Alternative Health Care Practitioners

Under a "right to title" model, both members of the profession and non-members can provide services to the public. However, only members of a

legislatively recognized professional organization can use the titles identified in the legislation or hold themselves out as being registered.

The use of the protected title is intended to be a "quality signal" to consumers that the individual has a certain level of education and training and is subject to the regulatory control of their professional organization. The right to title model allows a greater degree of consumer choice since the consumer can theoretically make an informed choice by selecting either a member of the professional organization or a non-member. One disadvantage of the right to title model is that it may not adequately protect consumers where there is a serious risk of harm if the service is performed inadequately. (See the analysis in Casey, 1999, pp. 25-26.) One example of a right to title regime is the profession of midwives in Alberta regulated under the Health Disciplines Act.

6. Establish a Controlled Act Model for Complementary and Alternative Health Care

Under a controlled acts model, only specific tasks or activities are regulated. The legislation provides that certain discrete, clearly defined tasks can only be performed by members of identified regulated health professions. The controlled acts model seeks to identify those activities which pose the greatest risk to the public if incompetently performed and then to ensure that these activities are performed only by those health professions with adequate education and training to safely perform the activity. The controlled acts model differs from the exclusive scope model in that the latter regulates an entire field of practice, whereas the former regulates only particular activities. For example, an exclusive scope of practice model might provide that only a physician can practice medicine. If a particular task is not on the list of "controlled acts" then it can be performed by any of the health professions or by a member of the public. A controlled acts model is often combined with a right to title regime.

A number of jurisdictions across Canada have moved away from exclusive scopes of practice and are considering adopting, or have adopted, the controlled acts model for some or all of their conventional health care professions. (See the

survey in Casey, 1999, pp.11-12). The potential value of a restricted activities analysis is further discussed in Part VII of this report.

Examples of a controlled act structure include massage therapy in Ontario and British Columbia and midwives in Ontario. Once the *Health Professions Act* is proclaimed in Alberta the following CAHC professions will be regulated under a controlled act regime coupled with a right to title: midwives, naturopaths, chiropractors, acupuncturists.

7. Regulation of Complementary and Alternative Health Care By Existing Self-Governing Professions

There has been a significant growth in the practice of CAHC by members of "conventional" health care professions. (YCHS, 1999, pp. 199-229) This has provoked a variety of responses from the conventional health care professional organizations ranging from overt hostility to neutrality to encouragement. Some professional organizations have developed education and practice standards for those of its members who also want to practice CAHC. Other organizations have taken steps to integrate elements of CAHC into parts of the profession's regular practice. Some organizations have adopted treatment protocols for CAHC focusing on maximizing informed consumer choice while ensuring safety. For example, the Alberta Association of Registered Nurses has approved standards for registered nurses in the areas of alternative and complementary therapy in nursing practice, and the College of Physical Therapists of Alberta has adopted practice standards for physical

therapists who want to incorporate acupuncture into their practice.

In some cases legislation has been adopted to ensure that conventional health care professional organizations do not completely prohibit their members from practicing CAHC. For example, in Alberta the *Medical Profession Act* was amended to provide that a physician cannot be found guilty of unbecoming conduct or be found to be unfit to practice medicine solely on the basis that the physician employs a therapy that is non-conventional or departs from the prevailing medical practices, unless it can be demonstrated that the therapy has a safety risk for that patient unreasonably greater than the prevailing treatment. A number of states in the U.S. have passed controversial "Medical Freedom Acts" to protect health care professionals who wish to practice CAHC and to prevent the professional licensing bodies from using the disciplinary process against professionals for choosing to use alternative and complementary therapies. (Cohen, 1998, pp.92-95)

Conclusion on Options

In assessing the various regulatory options for Complementary and Alternative Health Care practitioners, it must be appreciated that there is no one "right" model. The most appropriate model or combinations of models will depend on the type of CAHC under consideration, the environment in a particular jurisdiction, and most important, the degree of risk of a particular CAHC modality. A conceptual framework for assessing the degree of risk is discussed in the next section.

VII. A CONTROLLED ACTS ANALYSIS IN THE COMPLEMENTARY AND ALTERNATIVE HEALTH CARE AREA

The literature, the responses from the key informant interviews, and our own analysis all conclude that an assessment of risk related to the complementary and alternative health care activity/modality is central to any decisions with respect to the potential regulation of CAHC practitioners. As noted earlier, one of the key challenges is to identify risks and match the regulatory regime in order to reduce the risk in a meaningful way provided that the advantages of the reduced risk are greater than the broadly defined cost of the regulation.

While there is near consensus that an assessment of risk is central to regulatory decisions for complementary and alternative health care practitioners, no comprehensive analytical framework has been proposed to facilitate the risk analysis by policy makers. We suggest that the analytical framework for controlled acts might be useful to assess risk in the CAHC area. There are a number of potential advantages to using the controlled acts analytical framework.

1. The controlled acts framework is intended to identify and assess the degree of risk to the public from the improper performance of the service.
2. A significant number of Canadian jurisdictions have experience with utilizing the controlled acts analytical framework given the legislative trend away from exclusive scopes of practice to a controlled acts model for the conventional health care professions.
3. A controlled act system requires a rigorous analysis of the correlation between the "inputs" (education, training, experience, and other qualities) and the desired "outputs," the safe and effective performance of the service. (Casey, 1999, p.26)

There are also a number of potential disadvantages to controlled act systems. It is difficult to identify and articulate the precise attributes needed to be

able to perform a task safely. The controlled act system is also somewhat artificial in that the complex process of providing a health service is broken down into a series of discrete, compartmentalized tasks. Finally, the controlled acts system is reasonably new in Canada coming into use in Ontario in 1993 so there is not a great deal of research into its effectiveness. However, on balance we are of the view that the controlled act analytical structure is a very useful tool for policy makers considering the potential regulation of Complementary and Alternative Health Care practitioners.

In conducting the controlled acts analysis, a number of fundamental questions must be addressed.

1. What are the Complementary and Alternative Health Care modalities being provided in a particular jurisdiction?
2. What are the component tasks of each complementary and alternative health care modality being provided in the jurisdiction?
3. Is there a risk of harm to the public which may arise from the improper provision of each task?
4. Can these risks be managed or reduced through methods other than regulating the complementary and alternative health care practitioners performing these tasks? Are there other quality assurance mechanisms in the system which reduce the risk to an acceptable level?
5. What is the benefit to the public of having the task performed by a regulated complementary and alternative health care practitioner as opposed to a non-regulated practitioner?
6. If a significant degree of risk is identified for a particular complementary and alternative health care task, what are the attributes (education,

training, experience, other qualities, and environmental factors) which will reduce the risk to an acceptable level?

7. Which types of complementary and alternative health care practitioners possess the necessary attributes to safely perform the tasks identified with a significant degree of risk?

It should be noted that while we see the value in a controlled activity analytical framework to assess the issue of potential regulation of CAHC practitioners, we do not assume that it will necessarily be appropriate to establish in legislation a controlled activity model for CAHC practitioners. The controlled activity framework is

used to assist in identifying and assessing the degree of risk. However, the analysis may determine that the risk is so slight for a particular CAHC activity that no regulation is necessary. For other CAHC activities a right to title model might be appropriate, or a right to title model coupled with a restricted activities model might be the best solution. We propose the controlled activity analytical framework not necessarily as the "right" solution but rather as a methodology to ask the right questions.

For further discussion of the controlled act model see Government of Ontario (1989), Government of Alberta (1997), and Government of British Columbia (1998).

VIII. SOME THOUGHTS ON THE ROLES OF THE FEDERAL , PROVINCIAL , AND TERRITORIAL GOVERNMENTS

Complementary and alternative health care has developed in Canada largely without official government support or sanction. This leads one to consider the role that governments should adopt now that CAHC has emerged as a major part of health care in Canada. Based on our interviews with key informants and our assessment of the literature, we would propose that the following broad roles for governments are appropriate:

- An overall leadership and guidance role enacted through processes and initiatives that allow respectful exploration, shed insight and promote inclusiveness of all CAHC stakeholders.
- A continued nurturing of the understanding of CAHC, its overall link to the rest of the health care system (e.g., significant overlap with health promotion), and the policy reasons for the focus on consumer protection.
- Exploring the context and backdrop against which CAHC practitioners would be regulated in the provinces and territories. In particular, governments should bring an emphasis on informed consumer protection mechanisms and reinforce the need for any regulation to be "appropriate, rigorous, and relevant". (This phrase

is taken from the report by the Advisory Group on Complementary and Alternative Health Care, 2000, p. 6.)

- Funding CAHC information initiatives for consumers.
- Championing the notion that contemporary regulation will require information-based, open systems that exist to facilitate and protect the informed and empowered consumer, and the vulnerable patient, and support fairness for the practitioner.
- Given the federal government's jurisdictional involvement with complementary and alternative health products, signaling that health professionals who sell or distribute these products should be expected to meet regulatory requirements for safety whether or not they practice CAHC services.
- Given that CAHC services are largely privately funded, encouraging a level playing field between conventional and CAHC practitioners, so that there is fairness between them in the marketplace.

Four primary messages to government have emerged from our work on this report.

1. In exploring potential regulatory mechanisms, it will be important for government to remain cognizant of the consumer driven nature of complementary and alternative health care . The potential lack of an "evidence-based" approach should not necessarily be a barrier to regulation.
2. Consideration of potential regulatory mechanisms should focus primarily on the identification of risk and the meaningful reduction of risk.
3. Consider carefully the implications of championing complementary over alternative health care, or over-emphasizing the concept of integration of Complementary and Alternative

Health Care with conventional health care. Many CAHC practitioners worry that complete integration of Complementary and Alternative Health Care with conventional health care would lead to an undermining of the holistic nature of CAHC which is perceived by consumers to be of great value.

4. Consider the pace and extent to which governments consider regulating CAHC practitioners, given the dearth of evidence about harm done to the public because of the level of current professional regulation. Government should advocate for *appropriate regulation*, rather than overregulation or underregulation. In some cases no regulation of practitioners of certain CAHC modalities may be appropriate. Where some form of regulation is necessary, it cannot be assumed that the same type of regulation is necessary for all CAHC modalities.

IX. AREAS FOR FUTURE ANALYSIS , POLICY DEVELOPMENT AND RESEARCH

A suggested emerging policy goal is to develop a regulatory regime that will be risk- focused, assume the informed and empowered consumer, and practical for major stakeholders. Four priorities have been identified for future analysis, policy development, and research.

1. The information needs and rights of consumers need attention if we are to respect them as informed and empowered to judge the safety and ethics of Complementary and Alternative Health Care.
2. The identification, frequency and distribution of harm done through complementary and alternative health care which could be reduced through regulation of CAHC practitioners.
3. The further development of the key elements and regulatory mechanisms for a conceptual framework that regulators might consider to guide risk-based, consumer sensitive regulation of complementary and alternative health care practitioners in Canada. In particular, the

advantages and disadvantages of different regulatory models in the CAHC context needs to be further developed.

4. The impact of the current regulatory structures for conventional health professions on the development of complementary and alternative health care in Canada.

Conclusion

Canada, along with many other nations, is grappling with the policy issues relating to the safety, efficacy, cost-effectiveness, informed choice and due access of complementary and alternative health care services (de Bruyn, p. 9). The policy choices that will be made with respect to the recognition and regulation of complementary and alternative health care practitioners will have a profound impact on the continuing development of complementary and alternative health care in Canada. It is our hope that this report will serve as a catalyst for the further analysis of this important issue.

ENDNOTES

¹ For a further review of the definition of CAHC, the reader is referred to Achilles (2000) and Zollman and Vickers (1999) for such discussion. Variations on many themes or approaches to defining CAHC still abound (Achilles 2000). Some of these focus on the substantive nature of the practice framework involved (Eskinazi, 1998); others (especially those for public policy purposes) focus on relationship to the dominant political and economic attributes of the culture at a certain point in time. The authors acknowledge the Cochrane Collaboration definition (Zollman and Vickers, 1999, p.2)

² The Internet search of mostly alternative medicine and alternative healthcare related keywords was conducted using the Netscape and Lycos search engines. The literature search was conducted using HealthSTAR (1975 to present) and ERIC (Educational Research Information Clearinghouse) (1985 to present), online database facilities at the University of Alberta. Several combinations of key words were searched using the Boolean operator "and," to combine concepts/topics to narrow the search. We also used the online archive facilities at the British

Medical Journal (www.bmj.com) Canadian Medical Association Journal (www.cma.ca) Journal of the American Medical Association (www.jama.com) and the Medical Journal of Australia (www.mja.com.au).

Keywords searched included:

- complementary medicine
- alternative medicine
- complementary and alternative medicine
- complementary and alternative health care

The yield from the above terms were combined through the Boolean operator "and", with the following terms:

- regulation
- regulatory
- legislation
- government
- policy
- licensing
- licensing body
- professional association
- college

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APPENDIX A

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APPENDIX B COMPLEMENTARY AND ALTERNATIVE HEALTH CARE (CAHC) IN CANADA

INTERVIEW TEMPLATE

Backdrop

1. What do you think is behind the rapidly increasing use of CAHC by consumers in Canada?
2. What do you think is behind the growth of new modalities in the CAHC area, and the expanded use of these modalities by stand alone and conventional professionals?
3. What do you see as the role of government in CAHC at this time?
4. Is it important to differentiate between complementary and alternative health care? If so, how?

Current Environment for the Regulation of CAHC in Canada

5. Who are the major players?
6. What are major trends or directions?
7. What issues or challenges exist?
8. How do education, organization, funding, and private insurance coverage of health services influence the regulation of CAHC, and vice versa?

Options for Regulating Practitioners of CAHC in Canada

9. Should CAHC practitioners be regulated?
10. What purposes/policy goals should regulation serve?

11. Should CAHC practitioners be regulated in the same manner that conventional practitioners are?

12. Should regulation of CAHC practitioners be integrated with or parallel to that of conventional practitioners?

13. Of the three models regulating conventional practitioners, which do you think would best suit the regulation of CAHC practitioners?

a. Exclusive Scope of Practice or Licensure Model: Members of the profession are granted the exclusive right to provide a particular service to the public (exceptions may be allowed with the permission of the profession having exclusive scope).

b. Right to Title or Certification Approach: both members of the profession and non-members can provide the services to the public but only members may use a protected title or hold themselves out as being registered.

c. Controlled Acts: (also known as Reserved Acts or Restricted Activities Model). Rather than regulating an entire field of practice, legislation provides that certain activities can only be performed by specific regulated health professions, thus regulating specific acts or activities which many, but only authorized professions may perform.

Additional Comments