What Is Complementary/Alternative Health Care?

Complementary/alternative health care is also referred to as complementary and alternative medicine or CAM. CAM includes all health systems and therapies based on theories about the causes and treatment of ill health that are different from “conventional” medicine: examples include Ayurvedic medicine, Traditional Chinese Medicine, and some Aboriginal healing traditions, which rest on different systems of belief and understanding about illness and health.

CAM also includes therapies that may work in a fashion that can be explained by basic principles of conventional medicine, but which haven’t been validated by conventional scientific methods. For example, if a given herbal mixture or natural substance is used to treat cancer, the chemical effects of the substance could be described, but perhaps conventional science either can’t explain how the substance could help in treating cancer, or perhaps the evidence doesn’t show that the substance is effective.

Because CAM includes a wide range of therapies and health systems, it’s important to avoid generalizations. As with conventional medicine, some CAM has been shown to be safe and effective for some purposes, while some therapies or practices are known to be harmful and/or ineffective. For many, there isn’t enough evidence to make any firm evaluation of safety or effectiveness.

Categories of CAM

The National Center for Complementary and Alternative Medicine at the US National Institutes of Health has identified five categories for classifying CAM:

• alternative medical systems (eg, traditional Chinese medicine, Ayurveda, Aboriginal systems, homeopathy, naturopathy);
• mind–body interventions (eg, meditation, hypnosis, art therapy, prayer, and mental healing);
• biologically based therapies (eg, herbal therapies, special diet therapies, animal substances);
• manipulative and body-based methods (eg, chiropractic, osteopathic manipulation, massage therapy); and
• energy therapies (Qi gong, reiki, therapeutic touch).

Some say these categories are artificial, or irrelevant to a “holistic” perspective that underlies many CAM therapies, and that such a breakdown is rooted in a “biomedical” understanding of illness and health.
Use of CAM by Canadians
Research has shown that a significant and rapidly increasing number of Canadians have used CAM. The most recent, comprehensive information available comes from a study undertaken in 1997 (Ramsey et al., 1999). It shows that 73% of Canadians had used some form of CAM at least once, and 50% had used CAM in the past year. The researchers estimated that in 1997 Canadians spent about $1.8 billion on visits to CAM providers and another $2 billion on products such as herbal medicines, vitamins, diet programs, and related books.

Use of CAM by People with HIV/AIDS
There are only a few studies into the use of CAM by people with HIV/AIDS in Canada. Some conclusions can be drawn: (1) There is a high variation in overall use of CAM among people with HIV/AIDS. Studies done in BC and Ontario showed rates of roughly 40% and 80%, respectively; (2) It appears that women living with HIV use CAM more frequently than men; (3) People with HIV/AIDS most commonly use massage, acupuncture, vitamins, supplements, and herbal products; (4) Overall, many people with HIV/AIDS say that using CAM has made them feel better.

As with Canadians in general, there are many reasons why people with HIV/AIDS use CAM. Studies show that most use CAM in addition to their conventional medical treatment, rather than as an alternative. Some of the most common reasons include: taking active control over one’s own health care; boosting immune function; lowering viral load and preventing, delaying, or treating symptoms of HIV disease progression or opportunistic infections; helping with side effects of conventional therapy; helping relieve stress, depression, and fatigue, thereby improving general well-being; and taking a more “holistic” approach to their health.

One small study looked in more detail at the attitudes of people with HIV/AIDS toward CAM (Pawluch et al., 1998). Women mentioned additional reasons for using CAM, such as keeping themselves healthy to look after family; feeling that conventional medicine was neglecting their needs; and feeling that CAM was “more natural” and “less toxic.”

Aboriginal People & Traditional Healing
Many Aboriginal healing practices that non-Aboriginal people may consider “alternative” or “unconventional” are conventional or traditional from their perspective. Unlike “Western medicine,” which often involves specific practices to treat symptoms or disease, traditional Aboriginal healing practices generally see many dimensions to “health,” and aim at restoring balance between mind, body, emotion, and spirit.

There is little documented research on the experiences of Aboriginal people with HIV/AIDS and their approaches to health care. One pressing need identified by the Royal Commission on Aboriginal Peoples is for “people who can apply Aboriginal knowledge to current health problems and combine traditional health and healing practices with mainstream approaches to build distinctive Aboriginal healing systems.”

Conclusions & Recommendations
(1) Many Canadians use CAM as part of their health care. There is a need for research and for patient and provider education. We also need to consider how to regulate the field of CAM to properly balance patients’ right to make informed decisions about their health care, the use of public money for health care, and the protection of consumers’ health.

(2) There is a need for research in areas such as: the use of CAM by people with HIV/AIDS; the safety and effectiveness of those therapies; where and how people with HIV/AIDS get their information about CAM; how to make reliable treatment information accessible; the interface between how people with HIV/AIDS use conventional medicine and CAM; and the barriers (such as cost) that people with HIV/AIDS face in accessing CAM.

(3) Research with and within Aboriginal communities must respect principles of community ownership and control over, and access to, research methods and results, including enforceable legal protections for traditional knowledge.
Applying Four Ethical Principles to Regulating CAM

Four basic ethical principles are helpful in considering the ethical questions raised in regulating CAM. The principle of non-maleficence guides us to “do no harm” when our actions can affect others. The principle of beneficence directs us to bring about the good of others, whenever possible. The principle of respect for personal autonomy requires us to respect the choices and actions of people when they act voluntarily and with adequately understood information. Principles of justice require a fair distribution of resources or of opportunities to access resources, as well as fair compensation for harms and wrongs.

Non-Maleficence

As with conventional medicines, CAM may carry both risks and benefits to users. Some CAM may cause direct physical harm. A natural substance could be intrinsically harmful to health; it could be contaminated with some toxin; it could be unknown how much is safe to use; it may provoke an allergic reaction; or people could be harmed by interactions between herbal products and conventional medications.

There may also be indirect physical harm as a result of delaying or avoiding the use of a conventional treatment known to be effective. Harm may also come from financial or emotional exploitation. Financial exploitation can happen if an unethical practitioner or manufacturer takes financial advantage of patients by misleading them about a therapy’s safety or effectiveness. People whose expectations are misleadingly built up, only to go unmet when therapy fails, are also harmed by emotional exploitation.

Ethical implications: (1) Both conventional and CAM health-care practitioners have an ethical duty to obtain information from their patients about their use of CAM and of conventional therapies. They need to become familiar with these therapies and their possible interactions, so they can help patients make informed decisions and avoid harm. (2) Given the widespread use of CAM, safety research into the most widely used CAM therapies is ethically required. Priority should be given to researching those CAM therapies most widely used by people with HIV/AIDS, or for which there is evidence of known or potential negative effects. (3) Quality control, which is lacking for many CAM therapies, is ethically required to protect users from harm. This includes measures such as “good manufacturing practices” for natural health products, and labeling guidelines. It may require standard-setting for CAM practitioners who are currently not regulated.

Ethical Issues and the Use of CAM

This info sheet reviews four basic ethical principles (non-maleficence, beneficence, respect for personal autonomy, and justice) in the context of the use of CAM, and discusses implications for research, education/training, and regulation.

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**Beneficence**

Ethical health-care practice (whether conventional or CAM) requires that patients benefit, or that there be a reasonable prospect they will benefit, from a given therapy. Are the risks adequately balanced by known benefits or those that can reasonably be expected?

Assessment is often difficult in the case of CAM for at least two reasons. First, there is reliable evidence of benefit in some cases of CAM, but in many cases it is not available. Second, there are differences between CAM therapies and conventional treatments that in some cases make it difficult to assess the effectiveness of CAM therapies using conventional scientific research methods. For example, it may be impossible to do a randomized, placebo-controlled trial for some kinds of CAM, but it may well be possible to develop scientifically rigorous research into other forms of CAM. And research focusing on patient outcomes may still be useful, even if it does not provide a fully “scientific” explanation for how a therapy works.

**Ethical implications:** Given that ethical practice requires benefits to patients, there is an ethical duty to research the effectiveness of CAM therapies. Without reliable data, practitioners lack an adequate basis for treatment suggestions, in which case patients cannot exercise their right to informed decision-making.

In evaluating any treatment, it is prudent to adopt a more cautious stance toward risk/benefit analysis and to err on the side of caution. But there should not be a double-standard: many conventional medical treatments are not based on clear results from clinical trials, and it would not be in patients’ best interests to withhold access to at least relatively safe therapies until all the scientific evidence is in.

**Respect for Personal Autonomy**

Some argue that the unrestricted use of CAM should be permitted because the worry over risks and questionable benefits of many CAM therapies (as with experimental conventional medications) should not much matter, provided that people with HIV/AIDS make competent, voluntary decisions.

But this is precisely the problem. If we are to respect personal autonomy, efforts must be made to ensure that people have reliable information about the risks and benefits of alternative therapies. Any claim to unconstrained access to a therapy based on respecting the individual’s autonomy is weakened where that person’s autonomy is weakened because they lack the information needed to make an informed choice.

**Ethical implications:** (1) Information about the risks and benefits of CAM must be given directly to people, through measures such as adequate labeling of natural health products or requiring practitioners to discuss what evidence exists for the safety and effectiveness of a given therapy. (2) Health-care practitioners need to become aware of at least basic information about CAM, so they can comply with their ethical duty to support the personal autonomy of patients by providing them with information about risks and benefits.

**Justice**

*Distributive justice* requires a fair distribution of burdens and benefits in society. It requires, for example, that people with HIV/AIDS don’t disproportionately bear the burden of health-care expenses by being denied public health insurance coverage of medically necessary care. This raises the complicated issue of which CAM therapies should be considered “medically necessary” and under what circumstances.

Similarly, distributive justice requires that funds for health-care research be distributed so that they stand the best chance of equitably benefiting those in need of care and treatment. Research funding should be biased in favour of research concerning treatments that address the real health-care needs and wants of patients/consumers. A bias by funding agencies against research into CAM per se is unethical.

*Compensatory justice* requires that people be compensated for the wrongs done to them, and that providers of health-care products and practices be accountable to patients/consumers. Producers must demonstrate that their products meet quality control standards, are safe, and (if health claims are made or insurance coverage of the products is sought) are effective. The state must ensure mechanisms are in place to guarantee the accountability of producers. Similar requirements apply to CAM practitioners.
What Are Natural Health Products? How Are They Regulated?

Until recently, natural health products were legally classified as either “foods” or “drugs” under the federal *Food and Drugs Act*. How a product was classified determined what kinds of health claims could be made for it. It also determined how carefully the product was examined before being sold and monitored after being sold. Drugs are more restricted, and because they make health claims, are more carefully evaluated than foods.

But it’s been recognized that this classification system often created inappropriate and inconsistent results, so a new, third category of “natural health products” (NHPs) is now being created in Canadian law. Health Canada’s new Office of Natural Health Products (ONHP) is responsible for developing and implementing a new regulatory framework to govern NHPs.

The ONHP has conducted country-wide consultations about issues such as the legal definition of NHPs and what kinds of regulations should apply. These regulations will cover things such as: the kind of evidence necessary for getting approval to sell something in Canada as an NHP and to make certain kinds of claims about its health benefits; how NHPs should be labeled; what “good manufacturing practices” should be followed by makers of NHPs, etc. The final regulations should be available toward the end of 2001 and become law soon after.

The definition of “natural health products” will likely include things such as: herbs on a list prepared by the ONHP; homeopathic preparations; substances used as a “traditional medicine” (including in traditional Chinese, Ayurvedic, or North American Aboriginal medicine); and minerals, vitamins, amino acids, essential fatty acids, and other “botanical, animal or micro-organism derived substances.”

Product Licensing: Degree of Risk and Nature of Health Claims

As a basic principle, the regulation of NHPs should be based on the known or reasonably foreseeable risks of harm they pose. This should apply both at the stage of review before the government licenses a product for sale in Canada (“pre-marketing review”) and in the approach to monitoring the product’s safety after it goes on the market (“post-marketing surveillance”). In addition, the strictness of pre-marketing review should partly depend on the claims being made about the product’s health benefits. Claims that are supported by evidence should be allowed. The stronger the claim, the
stronger the evidence must be. Otherwise, only generalized claims should be permitted.

**Labeling Requirements**

As with drugs, labeling requirements for NHPs are key to helping avoid harm to the consumer and promoting informed decision-making in using NHPs. A group of organizations working in HIV/AIDS have recommended that the federal government require that all labels of NHPs sold in Canada:

- be in a standardized format using plain language and including key information about the safe and recommended use of the product;
- list the quantities of all contents (and if a product is labeled as a product, it must contain minimum amounts of that product that are specified by law);
- indicate whether the product is synthetic or natural, including whether it uses animal sources, and whether it incorporates genetically modified organisms;
- include directions for use, recommended dosage, warnings and, where known, possible interactions with drugs or other NHPs;
- advise consumers to tell their health-care provider that they are using the product, even if it may not seem relevant at the time;
- include a toll-free number and website for information on how consumers can report a bad reaction to the product.

In some cases the physical packaging of a product does not allow these things to be included in or on the package itself. In such cases, a vendor of the product should be required to have a product “monograph” (ie, a written description of the product, its proper use, and the evidence for its health claims) with this information available for consumers where they purchase the product.

**Monitoring Safety: Post-Marketing Surveillance of NHPs**

A system for reporting “adverse events” (ie, negative effects) linked to the use of NHPs would allow consumers and health-care practitioners to provide input regarding their observations and experiences using such products. It would also ensure that consumers have easy access to information regarding known adverse reactions (eg, access through a toll-free number) in addition to the disclosure of such confirmed information on product labels (including package inserts).

Under existing law, manufacturers of products classified as “drugs” have specific obligations to report adverse events to Health Canada, so that health authorities can take necessary steps (which could include removing the drug from the market) to protect the public’s health. The ONHP and others have proposed a similar reporting scheme for NHPs.

The ONHP should establish a post-marketing surveillance system for NHPs that, through different mechanisms, collects information about (1) adverse events of varying degrees; (2) short-term side effects and long-term cumulative effects of NHPs; and (3) data regarding consumer use of NHPs.

As part of that system, those licensed to sell NHPs in Canada should be legally required to report any “serious adverse event” regarding their product they know about, whether inside or outside Canada, and whether it was anticipated or “unexpected.” In addition, health-care practitioners should be legally required to report to the ONHP any serious adverse event in a patient under their care that relates to the use of an NHP (whether or not the product is legally sold in Canada).

In addition, the ONHP and pharmacists’ professional associations and regulatory bodies should, with the input of consumer groups, collaborate in developing a standard protocol for pharmacists to encourage patients to voluntarily disclose serious adverse events with NHPs and non-prescription medications they are using. This information should be kept confidential, but should be tracked by pharmacies to identify possible interactions or safety concerns about the use of product. Such a tracking system would allow pharmacists to systematically provide this information to patients/consumers and, where appropriate, draw concerns to the attention of Health Canada for further investigation.
Regulating CAM Practices and Practitioners

Standards of practice are one important way to protect the health of patients who use the services of health care providers. This info sheet considers the direct regulation of health care practitioners through legislation and professional codes. It also looks at how the law indirectly regulates conduct by holding practitioners liable in case of malpractice. Both of these issues are considered as they relate to practice in the field of CAM.

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Statutory Regulation of Health-Care Practitioners

In Canada, the regulation of occupations and professions (including health-care practitioners) is a provincial/territorial matter. However, governments have largely delegated this responsibility to health-care professions themselves. Usually a “college” or “board” has the legal power to set standards of practice and codes of conduct, and to discipline members.

Historically, there are three principal forms of regulation. Under a licensure (or “exclusive scope of practice”) model, only licensed members of a profession can do things considered to be within that profession’s scope of practice. For example, only licensed physicians can practise “medicine.” Practitioners are usually subject to ongoing professional regulation, and to discipline if they fail to meet professional standards.

Under a less restrictive certification (or “right to title”) model, only practitioners who meet certain training requirements are allowed to use a given professional title (eg, “registered massage therapist”). Other practitioners may offer the same services, but are not allowed to use the title. This signals to the consumer/patient that the practitioner has (or lacks) certain qualifications. A certification system does not generally involve possible discipline for misconduct.

Least restrictive is the registration model, which requires practitioners who provide a certain type of service to register on some sort of official registry. There are no particular training standards or other qualification requirements, and no legally binding standards of professional conduct.

In the last decade, several provinces/territories have moved to what is called a “controlled acts” model. Rather than establish exclusive areas of practice (eg, “medicine”) reserved to only certain professionals (eg, physicians), this model focuses on identifying certain acts or practices that pose a risk of harm to patients. These acts are then “controlled” by authorizing only certain practitioners to provide or perform them, based on the level of specialized skill and expertise the acts require. So some procedures can be done not only by physicians, but also by nurses, osteopaths, chiropractors, etc. As in traditional approaches, a “controlled acts” model usually restricts who can use certain professional titles.

Should CAM Practitioners Be Regulated? How?

Some practitioners (eg, chiropractors in most jurisdictions) already have the experience of both the
benefits and drawbacks of being regulated by law. Others, such as naturopaths, massage therapists, etc, are at different stages.

Opinions vary among CAM practitioners about formal professional regulation. There is a history of conflict between conventional health professions and CAM practitioners, who have sometimes been dismissed as “quacks.” Some CAM providers are concerned that conventional professionals will use regulation to restrict CAM practices.

Governments have also historically violated the rights of Aboriginal peoples, and even sometimes outlawed traditional practices. Some healers and communities feel that governments cannot be trusted with the regulation of traditional Aboriginal healers.

But many see regulation as an important step in achieving legitimacy, and as a way to maintain professional standards, discipline incompetent practitioners, and protect their profession’s reputation. Regulation could also lead to better integration with other health-care professionals, and increase the chance of insurance coverage.

For CAM practitioners not already regulated by law, voluntary self-regulation may be a first step. Voluntarily grouping together to establish standards for training and for competent, ethical practice, and enforcing those standards among members, could be the basis for getting legal recognition as a self-regulating health profession.

**Regulating Conventional Practitioners**

Some conventional health professionals incorporate CAM therapies into their practices, but are also subject to the rules set out in statutes or by their professional bodies, some of which have adopted policies on “complementary medicine.”

For example, professional rules governing physicians in Québec or British Columbia are strictly worded. Physicians using many kinds of CAM run the risk of professional discipline. The policy of the BC College of Physicians & Surgeons even prohibits the “ethical” physician from associating with alternative practitioners who recommend “unproven” therapies, and states that physicians must not expose a patient to any degree of risk from a CAM therapy of no proven benefit. This arguably goes too far.

Less restrictive approaches are possible. Legislation has been adopted in BC, Alberta, and Ontario that says that a physician cannot be found guilty of professional misconduct or incompetence merely for using a “non-traditional” or “complementary” therapy unless it poses a greater risk to the patient than the prevailing medical practice.

**Aboriginal Healers**

Aboriginal communities are discussing how to deal with individuals who claim to be traditional healers but who are not aware of, or who do not follow, proper teachings. Traditional healers are generally seen as accountable to the people they assist, but mechanisms or processes for accountability are not as formally defined as a system of professional regulatory bodies.

Accountability is more diffuse, and not based on legal measures such as disciplinary proceedings. In some provinces, legislation governing health professionals states that it does not apply to Aboriginal healers providing traditional healing services.

**Practitioners’ Liability for Malpractice**

CAM practitioners have a legal duty to use reasonable care and skill, both in obtaining patients’ informed consent and in “diagnosing” and “treating” the patient. Legally, the practitioner must act as would a “prudent and diligent” practitioner “in the same circumstances.” And a specialist must exercise the skill and knowledge of an “average specialist” in the field.

Legally, CAM practitioners belonging to an identifiable profession or “school of practice” should generally be held to the standards of their own school, rather than to standards set by some other school, but in some cases it may be hard to identify a coherent school with generally accepted protocols or practices.

In the case of conventional professionals using CAM who are sued for malpractice, the appropriate legal standard may not be clear, but courts are likely to hold them to the regulatory standards set by their conventional professional body.

While the issue of malpractice and professional standards for some practitioners using CAM remains uncertain, there is no doubt of the importance of all practitioners’ ethical and legal duty to ensure patients’ informed consent to treatment.

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Complementary/Alternative Health Care: Key Resources

There is a vast literature on complementary/alternative health care. This info sheet provides information about a number of selected, essential resources – articles, books, reports, and websites that provide crucial information on CAM, its use (including by people with HIV/AIDS), research into CAM, and ethical and regulatory issues.

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CAM: General Documents & Resources for Research


Use of CAM


Research into CAM


CAM and Aboriginal Peoples


Use of CAM: Ethical Issues


Natural Health Products


Regulatory Issues: Legal & Ethical Issues


Health Care Providers and CAM


Useful Websites

Canadian AIDS Treatment Information Exchange

www.catie.ca

CATIE is a Canadian national, non-profit organization providing HIV/AIDS treatment information. It operates a comprehensive website, electronic mailing lists, several print publications, and a bilingual, toll-free service (1-800-263-1638). It also produces info sheets on complementary/alternative therapies and “practical guides” on complementary therapies and herbal products.

CAMline

http://camline.org

A Canadian-based database on CAM that includes information on various therapies, a list of “best practices” from institutions, and a mechanism for reporting adverse reactions.
A web-based source of information funded by Health Canada and created in partnership with the Tzu-Chi Institute for Complementary and Alternative Medicine in Vancouver (www.tzu-chi.bc.ca) and the Toronto Public Library.

Canadian HIV/AIDS Legal Network
www.aidslaw.ca

Centre for Complementary Health Studies,
University of Exeter
www.ex.ac.uk/chs
This leading centre’s website includes general information about complementary and alternative medicine in the UK and Europe. The Centre publishes the journal FACT – Focus on Alternative and Complementary Therapies: An evidence-based approach.

Foundation for Integrated Medicine
www.fimed.org
This United Kingdom foundation produces policy documents relating to the integration of conventional and complementary/alternative medicine, and includes website news updates.

National Center for Complementary and Alternative Medicine
US National Institutes of Health
The NCCAM Clearinghouse disseminates information to the public and healthcare providers about the Center’s program and research findings through fact sheets, information packages, publications and a quarterly newsletter distributed to public subscribers. See also the Combined Health Information Database (CHID) (http://chid.nih.gov) for a variety of materials regarding CAM that are not publicly available elsewhere.

CAM on PubMed
A partnership between NCCAM and the US National Library of Medicine, CAM on PubMed allows users free access to a database of journal citations on complementary/alternative medicine.

Direct Access Alternative Information Resources
www.daair.org
A members-only, not-for-profit buyers club promoting “self-empowered healing” to help manage illness through the use of scientifically researched nutrients, therapies, and practices.

Research Council on Complementary Medicine
www.rccm.org.uk/
This UK charitable organization supports CAM research. The website has information on recent research, a database with thousands of references on published and unpublished research in complementary medicine (searchable for a fee), and a list of publications on CAM research.

Rosenthal Center for CAM, Columbia University
http://cpmcnet.columbia.edu/dept/rosenthal
Includes links to complementary medicine Internet resources, factsheets and databases, as well as information about the Center for CAM Research in Women’s Health.

Health Canada’s Office of Natural Health Products
www.hc-sc.gc.ca/hpb/ohnp
Responsible for overseeing the regulation of natural health products in Canada.

White House Commission on Complementary and Alternative Medicine Policy
www.whccamp.hhs.gov
Charged with reporting to the US President on policy issues relating to CAM.

The information in this series of info sheets is based on a report prepared by Crouch, Elliott, Lemmens, and Charland for the Canadian HIV/AIDS Legal Network: Complementary/Alternative Health Care and HIV/AIDS: Legal, Ethical and Policy Issues in Regulation. Additional reading can be found in info sheet 5. Copies of the report and info sheets are available at www.aidslaw.ca/Maincontent/issues/care-treatment.htm or through the Canadian HIV/AIDS Clearinghouse (email: aids/sida@cpha.ca). Reproduction is encouraged, but copies may not be sold, and the Canadian HIV/AIDS Legal Network must be cited as the source of this information. For further information, contact the Network at info@aidslaw.ca. Ce feuillet d’information est également disponible en français.

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