PREAMBLE

The CPSO has initiated a preliminary consultation process on the existing CAM policy, last revised in 2011. This consultation process is open to the public until May 6, 2019.

Integrative physicians practicing in Ontario wish to provide the college with an organized collection of feedback summarized in a single document. The Ontario Medical Association Complementary and Integrative Medicine Medical Interest Group (OMA CIM MIG) and several individual physician members have therefore prepared the following list of recommendations regarding CAM policy modifications as part of the preliminary consultation process.

These recommendations are made to better reflect practice structures for the developing field of integrative medicine and are made in consideration with the college's mandate to achieve "right touch regulation" for all physician specialties and practices. The goals of the policy are to protect patients and the public as well as physicians who practice CIM while undergoing college investigation as this policy often serves as a guide for physician peer assessment.

GENERAL COMMENTS

1. Do you think the College policy provides physicians with useful guidance?

Yes, however there are several general issues:

- There are several unprofessional statements to physicians in the policy requiring removal or modification.
- Some parts of the policy are incomplete and require elaboration.
- There should be increased latitude to apply concepts of evidence-informed medicine and use of clinical judgment when recommending therapies, and to monitor responses to therapy based on patient outcomes, while doing so in a safe manner and employing acceptable informed patient consent.

2. What about the policy do you find helpful? Please explain.

- Structure is clear.
- Good resource for physicians, especially those practicing integrative medicine.
- Defines different circumstances for:
    - 1) Conventional physicians exposed to patients who practice CAM
    - 2) Physicians who practice integrative medicine and advise patients themselves on complementary therapies.
- Outlines physician expectations regarding assessments, treatment selection, and informed consent.

3. Can you think of any resources that would help you implement this policy more easily in your practice? If so, please explain.

- A basic one sheet bold, highlighted version for physician self-reference.
- Handout that uniformly explains to patients that a physician complies with CAM policy.

- Recommendations on how to appropriately obtain and document informed consent at a level acceptable to college standards.
- Clarify conflicts of interest regarding associated fees for
    - non-OHIP covered additional patient assessments or treatments,
    - non-OHIP covered investigations or testing,
    - sales of products within the clinic.
- Document summarizing physician rights when under college investigation: i.e. to be evaluated by true physician peer(s), to have integrative physicians on ICRC boards used to judge consequences for integrative physicians, requirement to be judged not on choice of therapy but on overall care provided to patient (i.e. considering communication, integrity, and patient outcomes) as consistent with the Monte Kwinter law (Medicine Act 5.1, 1991).

Note: Resource guides for physicians addressing the above concerns are in production by physician members of the OMA CIM MIG

SUMMARY OF RECOMMENDED CHANGES

TITLE Change policy title to "Complementary and Integrative Medicine"

Rationale: The terminology of Complementary and Integrative Medicine reflects a general change including at the level of the National Institute of Health (NIH) that the goals and use of most therapies is to complement conventional therapies, not to imply them as alternatives.

KEY WORDS: Autonomy; Beneficence; Altruism; Exploitation; Conflict of Interest; Informed Consent; Trustworthiness

Remove – Trustworthiness, Exploitation.
Rationale: Unnecessarily condescending terminology. These words apply to all physicians and are not be specific to the CAM policy. These concepts would be better addressed in a broader CPSO policy on professionalism, if they must be specified at all.

Suggested Additions – Integrity, Integrative, Complementary.
Rationale: More appropriate terminology than above. Includes integrative and complementary as search terms.

INTRODUCTION

1) Apply bold font and create a separate paragraph for the following phrase, including a reference to its source: Medicine Act 5.1, 1991.

> ***Physicians shall not be found guilty of professional misconduct or incompetence solely on the basis that they practice a therapy that is non-traditional or that departs from the prevailing medical practice***
>
> Bill 2, Medicine Amendment Act, 1991.

2) Add reasons for why patients may seek complementary/integrative therapies, i.e.

- health conditions have not responded to or are not optimally managed by conventional therapy
- personal preference for pursuit of other therapies in accordance with patient values and preferences.
- health optimization and preventive health practices

3) Add rationale for existence of the current policy:

"There is a need for physicians with appropriate knowledge of complementary and integrative therapies to help provide patients with science-based information including safety and efficacy, and to guide patients on the appropriate uses of such therapies."

4) Add that the practice of complementary/integrative medicine be

"evidence-informed using best research evidence, clinical expertise and judgment and patient values, preferences and autonomy"

TERMINOLOGY

1) Conventional Medicine

- Remove sentence referring to conventional medicine being "traditional" and "science based"
- Conventional medicine may also be referred to as "allopathic medicine"

Rationale: "traditional" medicine is more appropriately applied to Ayurveda, Traditional Chinese Medicine, indigenous health practices, and other cultural traditions. The use of the words "conventional" or "allopathic" are simply the most appropriate words.

2) Complementary/Alternative Medicine

- Remove reference that these practices are "non-traditional" for the same reasons outlined above.

3) ADD: Integrative Medicine

- Add a definition for integrative medicine.
- "Refers to a blend of conventional with complementary medicine practices that are based on best available research evidence, clinical expertise and judgment and patient values, preferences and autonomy. This practice includes a holistic patient-oriented approach to health and wellness that emphasizes lifestyle changes and engages the patient in their health care management."

Define integrative medicine treatment modalities for reference.
The National Centre for Complementary and Integrative Health (NCCIH) broadly classifies complementary and integrative health treatment modalities into the following 3 categories:

i) Natural Products including:
   a. Herbals or botanicals and their extracts, isolates or derivatives.
   b. Dietary supplements, amino acids, vitamins and minerals.
   c. Bio-identical hormone replacement therapies
   d. Probiotics and other naturally occurring substances.

ii) Mind and Body practices including:

a. Mind practices including mindfulness, meditation, yoga, relaxation techniques, hypnotherapy, guided imagery, breathing exercises, tai chi, qi gong, and others.
b. Body therapy practices such as: Osteopathy, chiropractic, acupuncture, various biofeedback and neurofeedback techniques and others.

iii) Other complementary health approaches including:

a. Adjunct heath systems such as environmental medicine, functional medicine etc
b. Alternative or traditional health systems such as Traditional Chinese Medicine (TCM), Ayurveda, Indigenous healing practices, homeopathy, and other traditional or alternate health systems.
c. Physical and energetic modalities such as hyperthermia, oxygen/ozone therapies, laser, pulsed electromagnetic field therapy and others.
d. Other therapies including chelation etc.

4) ADD: "Evidence-Informed Medicine"

"This term reflects the most accurate and intended use of the original concept of evidence-based medicine. Evidence-informed medicine seeks to incorporate a trio of concepts including: 1) Evidence and science, weighing the best available evidence and the nature of that evidence, 2) clinical expertise including clinical experience and judgment, and 3) patient expectations, goals and values. Evidence-informed medicine does not imply that the only therapies that can be offered to patients must be based on high-grade evidence, as this is at odds with the limitations of research trial structure and funding, does not allow for clinician experience or judgment and is at odds with a patient's right to autonomy. The goal of evidence-informed medicine is to weigh these three concepts appropriately when selecting and guiding patients on appropriate therapies. "

Rationale: "Evidence based medicine" is a central concept in the practice of medicine, yet is sometimes interpreted as "evidence-dictated medicine" rather than "evidence-informed". Since this is an important concept in the practice of medicine and especially integrative medicine we believe it should be articulated.

PRINCIPLES

• Good – no changes.

SCOPE

The scope may require some rewording based on recommended modifications to section structure outlined below.

POLICY

A. General Expectations for Physician Conduct

i) Act in Patients' Best Interests

Good – no changes.

ii) Respect Patient Autonomy

Good – no changes.

iii) Refrain from Exploitation

Remove this section.
Rationale: The wording implies the assumption that physicians are inclined to exploit patients and promotes an attitude of distrust. This material would be better included in a general CPSO policy on professionalism, not the current policy.

Suggestion: Reword this section as "Patient-Centered Care", and include content such as:
- Discuss concepts of altruism, compassion, and acting in the best interests of the patient.
- Communicating accurate information on the risk/benefit ratios of conventional and CIM therapies.
- Promoting trust by abiding with the section on conflict of interest.
- Referring to the CPSO policy on professionalism.

iv) Conflicts of Interest

- Add that this section applies to "all" physicians
- Expand: "Physicians who have financial relationships to any aspect of patient care or prescription of therapies should refer to the CPSO policy on Conflict of Interest and ensure that any financial conflict of interest is appropriately declared to patients."
- Expand at: Physicians must also refrain from charging excessive fees for services provided "… in accordance with the CPSO Policy on Uninsured services."

B. Specific Expectations: Physicians who care for patients who pursue CIM therapies

Note: We recommend re-ordering of the two main sections on specific expectations, placing this section first as it flows more logically from the section on general expectations.

i) Patient Use of CAM and Documentation

Good – no changes.

ii) Discussing CAM

- Suggest include examples of "referring patients to other health care practitioners" i.e. "with greater familiarity of the treatment modalities in question, such as physicians actively practicing CIM. Enabling patients to obtain appropriate information on the CAM therapies they are using is in the best interests of the patient and will support informed decision making as well as optimize patient safety."

- Add at the end: “Physicians should refrain from negative judgments and commentary on therapies they are unfamiliar with or not trained in and must never condemn patients for pursuing CIM therapies. These actions erode communication and trust in the patient-doctor relationship and reduce the likelihood of patients discussing use of other therapies in the future.”

iii) Implications for Conventional Medical Care

- Add: Physicians must never discharge or threaten to discharge patients from their care simply because they chose to use CIM therapies or seek care from physicians who practice CIM or other non-physician health care practitioners.

Rationale: This phrase is recommended for the protection of the public because in the experience of many CIM physicians, this has happened previously.

C. Specific Expectations: Physicians who practice/provide CIM

1. Practicing CAM

i) Clinical Competence: Knowledge, Skill and Judgment

- Add material at beginning of this section to comment on (lack of) certification in Canada:
- “Integrative medicine is not an officially recognized specialty in Canada, however it is recognized by the American Board of Physician Specialties (ABPS). To maintain high quality patient care, physicians who declare focused interest in CIM in Ontario must always act…”

ii) Clinical Assessment and Diagnosis

Shorten first phrase to: “All patient assessments and diagnoses must be consistent with the standards of conventional medicine.”

Rationale: There is no need to state that conventional assessments and diagnoses are based on evidence and science. This simpler statement will suffice.

Clinical assessments

Minor modification to 2nd paragraph:

- “Any clinical assessment of a patient must involve taking an appropriate patient history and obtaining any additional other necessary information relevant to and assessment of the patient’s condition. This may include: appropriate physical examination, ordering of blood tests or other investigations or obtaining specialist reports.”

ADD SECTION: "Investigations"

"Some physicians chose to incorporate specific tests or other investigations that are not considered conventional medical practices as part of their patient assessment. Such tests are permissible provided the following expectations are met:

1) the test has a reasonable expectation of improving care for that patient,
2) the test is used in conjunction with and does not replace conventional patient assessments
3) the physician obtains appropriate informed consent prior to use of the test, and
4) the physician discloses any relevant financial interests as per the section above on conflict of interest.

Rationale: There are a variety of tests and investigations at different stages of acceptance within conventional medicine. Patients should be allowed to access such tests through their physician, provided there is appropriate consent, transparency on financial conflict of interest and consideration for safe and appropriate use.

Diagnosis

- Add to first phrase: ", whenever possible. In cases where patients present with undifferentiated symptoms where it is difficult to apply a clear conventional diagnosis, consideration of appropriate differential diagnoses or symptoms "not yet diagnosed" may be the most appropriate action. Physicians should use their best clinical judgment when choosing to offer any diagnosis for their patient's condition."

Rationale: Many patients present with undifferentiated symptoms, as is commonplace in primary care and any kind of general medical practice. It is not good medicine to assume that a conventional diagnosis MUST be given to every ailment when occasionally the most appropriate diagnosis is "symptom NYD". This approach is very frequently used in generalist practices including family medicine and emergency medicine. Sometimes the most accurate description of a patient's symptoms is no clear diagnosis.

- Remove last phrase. Change to:
  "Acceptable CIM diagnoses should use terminology that would be considered reasonable to other CIM physicians to facilitate peer to peer communication. Patients must also be appropriately informed when they are given a CIM diagnosis."

Therapeutic Options

- Modify first sentence:
- "… must abide by the principles of evidence-informed medicine. Use of therapies for which there are limited clinical data must:"

- Bullet point #1: Change to:

"…logical connection to the patient's presentation or concerns"

Reasoning: In some cases of undifferentiated illness there may not be a clear diagnosis. Also, CAM therapies are occasionally used for health and wellness promotion, where there is no diagnosis.

- Bullet point #2: Remain as-is.

- Bullet point #3 separated into the following points:
    - Have a favorable risk/benefit ratio regarding safety vs. efficacy relative to other convectional or CIM therapies.
    - Be offered with consideration for patient safety including side effects, potential interactions with other active treatments, or any other relevant considerations.

- Remove last phrase: "Physicians must never recommend therapeutic options proven ineffective through scientific study"
Reasoning: Research never "proves" therapies to be effective or ineffective. Research simply supports the use of that therapy, or does not support its use. This phrase, if necessary, belongs in a broader CPSO policy relevant to the practice of all physicians, however, notably there are many practices in conventional medicine that are no longer considered effective yet are still employed by some physicians.

- Add a new concluding phrase on the concept of the "n of 1 trial":
"Whenever possible, physicians should use a rational prescribing approach regarding prescription and supervision of specific CIM therapies. This includes consideration of the above points as well as acceptance of the use of certain therapies as an "n of 1 trial" for efficacy. This approach would include considerations for safe use of the employed therapy, previous use of other successful or unsuccessful therapies, appropriate patient consent, appropriate follow-up or reassessments to review the efficacy of that therapy and continuing or modifying treatment in a shared decision-making process based on the patient's response."

Informed Consent and Communication

Background on rationale for changes: The consent process as listed in the policy is quite onerous and held to a higher and unequal standard than that of a typical consent discussion in conventional medicine. In CPSO assessments, the current consent process is time consuming and onerous on documentation standards and physicians frequently fail to supply "adequate documentation" of patient consent as specified in this current policy without an elaborate written consent form for every single therapy implemented.
We request that the requirements for patient consent for be modified to reflect consent obtained by conventional therapies and that the extent of the consent discussion required be proportionate to the risk/benefit ratio of that therapy.

- Remove bullet point #1: this information is incorporated in the section on "diagnosis"
- Bullet points #2 and #3 could be combined into a single point: "The rationale for recommending the therapeutic option in question including reasonable expectations about its efficacy"
- Bullet point #4: Change to: "The extent to which the use of that therapy is evidence-informed or supported by other practitioners such as conventional or other integrative physicians"
- Remove bullet point #5: *Rationale*: Accurate information cannot be given since head-to-head comparisons between conventional and CIM therapies are rare in the literature.

- Bullet point #6: Add at the beginning: “Accurate information on or comparison with conventional…” and at the end: “if applicable.” *Rationale*: many patients seeking CAM therapies have 1) already pursued many conventional therapies, or 2) conventional therapies may be out of the scope of the CIM practitioner (i.e. for multiple sclerosis, lupus etc.), or 3) conventional therapies may not be well defined or offered for certain diagnoses (chronic fatigue syndrome, multiple chemical sensitivities)

- Change the phrase below bullet points to: “The details of the consent process must be documented in the patients medical record in accordance with the CPSO policy on Medical Records.”
- Add the following phrase:

“The extent of the consent discussion required for the use of different therapies should be tailored to its specific efficacy/safety profile. Therapies that are invasive or that pose a higher side effect risk profile should involve a more extensive consent discussion relative to non-invasive therapies or therapies with few side effects.”

For the last 2 paragraphs:

- Combine the first and last phrases of these paragraphs as this makes an appropriate conclusion to this section: “In order for patient consent to be informed, physicians must always provide patients with accurate and objective information about the available therapeutic options supported by sound clinical judgment and informed by evidence and science. Clinical concerns must always be highlighted.”
- Remove the middle phrase: “Physicians must never inflate or exaggerate the potential therapeutic outcome that can be achieved, misrepresent or malign the proven benefits of conventional or CAM treatment, or make claims regarding therapeutic efficacy that are not substantiated by evidence.” *Rationale*: This phrase is disrespectful of physicians. The concepts of accurate communication regarding appropriateness of therapy should apply to the practices of all physicians. If it still needs to be stated explicitly, it belongs in a broader CPSO policy on professionalism or in the Practice Guide.

3. Professional Affiliations

Remove this section entirely. Content of this section should be covered within the umbrella of “conflict of interest”.

Rationale: Physical proximity or co-location to other health care practices does not by nature “endorse” every single aspect of that practice.

ADD

D. Resources on CIM therapies

For more information on the use of CIM therapies, consider consulting with any of the following external resources. These resources are provided simply for reference and are not specifically endorsed by the CPSO, neither do they consist of a complete list of the resources available on CIM.

Practitioners

- Any physician with a focused interest in CIM
- Appropriately licensed or trained experienced CAM providers in the community including but not limited to: Naturopaths, Chiropractors, Osteopaths, Homeopaths, or other practitioners.

Textbooks

- Integrative Medicine – 4th edition. By David Rakel.
- Nutritional Medicine – 2nd edition. By Alan Gaby.

Websites

- Natural Medicines database – one of the most comprehensive resources providing reviews of natural products and supplements, usually available by subscription through a formal educational institution. Available at https://naturalmedicines.therapeuticresearch.com/
- National Centre for Complementary and Integrative Health (NCCIH) health Info reference sheets "from A to Z", providing basic information on CIM treatments targeted to patients. Available at https://nccih.nih.gov/health/atoz.htm
- TAP Integrative, a general resource on CIM therapies and practices targeted towards practitioners. Available at https://tapintegrative.org/
- Examine, a new non-industry funded database on CIM therapies. Therapies and their potential indications are graded by the level of evidence supporting use - https://examine.com/

Evidence-Informed Medicine

- Montori VM, Guyatt GH. Progress in evidence-based medicine. JAMA. 2008 Oct 15;300(15):1814-6.
- Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't 1996. Clin Orthop Relat Res. 2007 Feb;455:3-5.
- Masic I, Miokovic M, Muhamedagic B. Evidence based medicine - new approaches and challenges. Acta Inform Med. 2008;16(4):219-25.
- Dobrow MJ1, Goel V, Upshur RE. Evidence-based health policy: context and utilisation. Soc Sci Med. 2004 Jan;58(1):207-17.

Health and Medicine acts

- *Monte Kwinter Law*: Medicine Amendment Act, 1991.