Alternative Medicine Should Be More Tightly Regulated

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About Alternative Medicine

Complementary or alternative medicine (CAM) is defined as any health-based practice, product, or system focused on the healing properties of medicine that is not considered a conventional standard of care. CAM is comprised of practices including, but not limited to: Chinese herbal medicine, holistic nutrition, and chiropractic practices as well as natural health products (NHPs) such as homeopathic and herbal remedies. Alternative healing can be complementary or an alternative to conventional medicine administered by healthcare professionals such as doctors and nurses. It is a billion-dollar industry, with more than 70% of Canadians reporting regular use of CAM.[1] Many Canadians choose to use alternative medicine because it aligns with their personal philosophies and also provides a wider variety of treatment options.[2]

Recent controversy surrounding alternative medicine focuses on inconsistent regulations across Canada. Inconsistent regulations have a tendency to perpetuate a lack of knowledge amongst the growing CAM consumer base and result in variance in practitioner conduct. Regulations surrounding alternative medicine practices are fragmented and the associated regulatory bodies (i.e., Colleges) have been scrutinized for not monitoring practitioner conduct. Standardizing regulation will assist in integrating existing fragmented regulations and will clarify public understanding of the benefits and risks of alternative medicine. Due to an absence of consumer knowledge surrounding alternative medicine, regulations in the industry are necessary to enable consumers to make properly informed decisions. In addition, consumers may often overestimate the safety of NHPs, and this perception may result in uninformed purchases and/or product misuse. As such, alternative medicine should be more strictly regulated.

The Practice and Regulation of Complementary and Alternative Medicine (CAM)

A Canadian study in 2006 reported that 54% of Canadians used at least one CAM in the year prior to the survey.[3] As such, the main arguments for regulation through the licensing and certification of CAM practitioners include protecting public health, ensuring a trained and

competent workforce, and securing insurance coverage for individuals who use CAM. However, the regulations surrounding CAM are far from being standardized. The World Health Organization (WHO) contends that while CAM has grown in popularity, public understanding of the risks associated with it have not kept up with its demand.[4] Unequal regulation guidelines, misleading titles, and perpetuation of misinformation create an unsteady foundation for the legitimacy of CAM, which often translates to a perception of certain practices being illegitimate. Better understanding of the risks that poor quality regulations pose to the practice, as well as the safety of consumers' health, requires a comprehensive understanding of the current state of regulation.

In Canada, certain CAM professions are regulated provincially, meaning that health care legislation creates Colleges and regulatory bodies in each province to define the scope of practice, licensing practices, and requirements for licensing of CAM practitioners. In order to be eligible for regulation, CAM practitioners must fall within the definition of a 'health profession'. This often means that they must study a specific body of theory and practice, rather than broadly studying the human body.[5] For example, Chinese herbal medicine is only regulated within Ontario and British Columbia. This means that in these provinces, stringent criteria exists as to who can offer and advertise services in this field. A more regulated CAM practice is naturopathic medicine. The terms and profession are regulated and licensed in Alberta, British Columbia, Ontario, Saskatchewan, Manitoba, and Nova Scotia.[6] However, in any other province, these requirements do not exist. As such, in provinces without regulations, any individual that wants to practice CAM can do so. This raises concerns that clients of their services are receiving care from unequally trained service providers. Heather Boon, the Dean of the Leslie Dan Faculty of Pharmacy at the University of Toronto, recognizes the issue with inconsistent or lacking regulations. Boon cautioned that in unregulated provinces, a practicing naturopath may have received training at an accredited college or school, while others may have taken a weekend course, and others may have had no training at all. In addition, the credibility associated with certain CAM professions such as naturopaths mirrors that given to medical doctors, with the title of 'naturopathic doctor' often used to refer to naturopaths.[7] To consumers, this conveys the impression that all alternative medicine is always supported by empirical evidence and allows

this alternative health sector to hold some credibility based on these assumptions.[8] Differences in training and regulation create an inconsistent standard of care, often unbeknownst to the client.

Each regulated CAM profession has a code of conduct that outlines the profession's scope of practice; this includes details as to when a referral should be made (e.g., when a patient's life is at risk, or when comprehensively diagnosing or treating the condition is beyond the scope of practice). Unregulated CAM practitioners are not confined to the breadth of parameters that regulated practitioners (e.g., doctors, nurses, physiotherapists, etc.) must practice within. This means that unregulated practitioners are not institutionally obligated to make referrals in the same way that regulated practitioners are. Janet Blanchard of the Transitional Council of College of Homeopaths of Ontario expressed her concern about this; Blanchard noted that in addition to lacking scope, unregulated practitioners may make inappropriate claims about the effectiveness of their treatment without scientific evidence. Unfortunately, certain patients will take these claims as fact, and tailor the treatment according to their CAM practitioner's recommendations. Choosing holistic options without an evidence base over conventional recommendations, that are founded in research, can cause significant harm, particularly for individuals who are seeking treatment for acute and life-threatening conditions.

Lack of Adherence to Regulation Guidelines

The regulated CAM professions, such as: chiropractors, naturopaths, homeopaths, Chinese herbal medicine practitioners, and acupuncturists, are not exempt from the controversy surrounding CAM. The Colleges regulating practice are relatively new (e.g., the College of Naturopaths of Ontario was founded in June 2015). As such, empirical evidence does not exist to concretely suggest that the Colleges are satisfactorily regulating the profession as a whole. An example of this inconsistent regulation is in media advertising by naturopaths. For example, the College of Naturopaths of Ontario lists guidelines for unacceptable advertising, including, "unwarranted and unrealistic expectations about the effectiveness of a treatment, the use of endorsements or testimonials [...], or the use of misleading information".[9] However, an analysis done in 2016 by Carly Weeks of The Globe and Mail indicated that of the roughly 300 regulated and active naturopaths in Toronto that boast an online presence, approximately half appear to be in breach of the college's rules based on claims made online. These claims include that

naturopathic medicine can act as primary treatment for cancer, disproven homeopathic remedies for influenza, and advertisement of breast thermography as an alternative for mammograms, all of which have been contested by scientific research.[10] Despite the fact that the College has the authority to investigate and address these misleading and unscientific claims, they have not. If registered CAM practitioners are able to violate these rules, it is concerning to consider what effect this has on their patients.

Natural Health Products (NHPs)

Natural health products (NHPs) are defined as, "naturally occurring substances that are used to restore or maintain good health that are often made from plants".[11] NHPs, often called "complementary" or "alternative" medicines, include: vitamins and minerals, herbal remedies, homeopathic medicines, traditional medicines (e.g., traditional Chinese and East Indian medicines), probiotics, and other products like amino acids and essential fatty acids. NHPs are used and marketed for a number of health reasons, such as the prevention or treatment of an illness or condition, the reduction of health risks, or the maintenance of good health. Under Health Canada's Regulations (2016), NHPs must be safe for consideration as a nonprescription product, are available for self-care and self-selection, and do not require a prescription to be sold.[9]

An increasing number of Canadians are using NHPs. A 2005 Health Canada poll found that 71% of Canadians used NHPs, and that the most commonly used products were: vitamins (57%), echinacea (15%), and algal and fungal products (11%).[12] According to Health Canada, Canadian sales of NHPs were estimated to amount to about $4.3 billion and to number around 40,000 to 50,000 products in 2004.[13] The fact that a growing amount of people are using NHPs means more people are exposed to the potential adverse effects of these products, and is the main reason given by the Canadian government for broadening the regulatory framework of NHPs.

The Regulation of NHPs in Canada

The Natural and Non-Prescription Health Product Directorate (NNHPD) regulates NHPs under the Food and Drugs Act (FDA) and the Natural Health Product Regulations. The Natural Health Product Regulations, which came into force in 2004, covers pre-market product licensing requirements, site licensing, and post-market reporting requirements. Products authorized for

sale in Canada are issued a product license, which is a Natural Product Number (NPN) for a NHP or a Homeopathic Medicine Number (DIN-HM) for a homeopathic product. Health Canada has received over 78,000 license applications since 2004 and as of 2013, over 70,000 products and over 2,000 sites have been licensed in Canada.[14]

Health Canada's pre-market review of NHPs considers evidence that supports the safety, efficacy and quality of the product. Health Canada has two classifications when considering the evidence requirements needed to support the safety and efficacy of NHPs. The first is for products making modern health claims and the second is for products used as traditional medicine.[15] In general, the level of evidence (type and amount) required varies depending on the proposed health claims and the overall risk profile of the product or its ingredients.[16]

According to Health Canada's website, in order to apply for a general traditional health claim, versus one making a modern health claim, an applicant must provide two independent references that support the medicinal ingredient's use within the specified traditional paradigm. At least one of the references must support the product's extraction information and the recommended conditions of use (e.g., dose, duration, risk statements, etc.). As an example, three or more herbalists or Aboriginal elders can serve as a source of information. These references must indicate that the traditional use of the ingredient extends back to at least 50 years. While this type of evidence may indeed provide assurance that a product has been in use for a long period of time, it offers no validated evidence that the product is effective, yet this type of documentation is considered acceptable evidence of efficacy by Health Canada.

Consumer Confusion

As alternative healing becomes an increasingly popular choice for many people suffering from a myriad of medical conditions, it is evident how little knowledge many of these consumers possess about NHPs. In the past, alternative medicine has carried a common interpretation of illegitimacy; so much so, that patients were often afraid to ask their doctor about NHPs. This ideology about naturopathic medicine is changing with the implementation of the regulatory bodies and product approval from Health Canada.

The terminology "Natural Health Products" in itself is misleading. It is a common belief that the word natural is analogous to healthy or safe, however this is inaccurate.[17] In fact, Health Canada lists many possible risks to using NHPs such as manufacturing problems (e.g., contamination), unproven claims leading patients to use the wrong product or delay treatment for a serious condition, insufficient information for patients to make a properly informed decision and interaction with prescription drugs or unwanted side effects.[17] Many of these potential risks are detrimental to a patient's health and are even similar to the risks inherent of prescription drugs; the risks of prescription medication are often what patients are initially trying to avoid by using NHPs.

Consumer confusion is rooted in the inaccessibility of the language used by product manufacturers such as the misconception of traditional medicine being evidence based. Naturopathic medicine is supposed to create an alternative for patients where they are able to make informed choices and decisions on their treatments. NHPs can be categorized into traditional or modern medicine depending on the basis of the evidence of their effectiveness. The problem with this categorization is that it is not obvious to consumers whether the treatment or drug was approved based on traditional or scientific evidence. Many Canadians are unaware of this distinction.[18] To be sold in Canada, NHPs must "provide valid high-quality scientific and/or traditional evidence supporting any advertised health claims and demonstrate their safety and efficacy".[19] This creates confusion as the public is poorly educated in the difference of terminology, therefore it is an ineffective tool of distinction. There is no requirement that this product must be evidence based or even effective. By approving naturopathic products, Health Canada is also adding to the inaccurate validity of NHPs as many patients interpret this as government endorsement.[17]

NHPs are Not as Safe as We Think

Although NHP products are generally considered low risk, this perception should be questioned as there have been life-threatening adverse reactions that resulted in recalls (e.g., NHPs containing agents known to cause heart attacks and seizures).[20] Furthermore, there is limited safety and efficacy data from human clinical trials of NHPs, which may lead to unexpected adverse reactions in consumers.[21] However, the number of adverse reactions reported from NHPs

is low and it is unclear if this is a result of underreporting. Consumers who have informed healthcare professionals about adverse reactions to NHPs are encouraged to report to Health Canada.[22] In reality, reporting by both consumers and clinicians may not be common, and therefore it can be speculated that a number of adverse reactions are unreported. In a 2007 Canadian study, when patient participants were asked why they do not disclose complementary medicine use, they reported feeling that their health care providers will disapprove of the use of such products or that they would lose access to NHPs; it is crucial for doctors to know what treatments patients are using, conventional or otherwise.[25]

Similar to conventional drugs, when one takes more than the recommended dose of an NHP, the chance of adverse reactions increases.[23] As the consumer often assumes that NHPs do not carry real risks, they may not follow the recommended dosage as carefully as they would for a prescribed drug. In cancer, this is particularly problematic because herbs and vitamins have been found to interact with chemotherapy in about 25% of patients.[24] As such, it is crucial for consumers to take the recommended dosage for NHPs seriously, and for manufacturers to clearly state potential risks on their labels.

Too few consumers recognize that NHPs are researched less extensively, and therefore may be riskier than conventional drugs. Most consumers described these products with words such as "mild", "safe", and "natural".[25] In the same study, there was a consensus in consumer preference of labels with more information, meaning consumers prefer having additional information to make more educated decisions when purchasing and consuming NHPs. Manufacturers will likely comply in providing additional information on the labels, as this results in the product's assurance of being researched and reliable.[25]

Frustrations About NHP Labels

The Canadian government's stance on NHP regulation standardization is unclear. They have stated that providing NHPs with the same degree of regulations as conventional drugs is "too rigorous",[26] which contradicts their agreement with the standardization of regulations for NHPs being "beneficial" in decreasing confusion in the industry.[28] It is unlikely that regulation

advancements for NHPs will progress unless there is further consensus that it is advantageous for both the industry and consumers.

On the consumer side, there is frustration due to the difficulty in finding objective and reliable sources of information. There is no clear authority to turn to in order to ask about adverse interactions or effects of NHPs. It was noted that physicians lacked knowledge when answering questions about these products.[25] These problems can be mitigated with sufficient labeling on the NHPs as consumer knowledge can be limited surrounding many aspects of the product. The alternative medicine industry agrees that stricter label regulations will make NHP quality more consistent.[29]

Conclusion

This report concludes that alternative medicine should be more tightly regulated based on the analysis of current regulations and consumer safety. CAM practice regulations are inconsistent, which often makes it difficult for consumers to distinguish between qualified and unqualified professionals. Furthermore, where regulatory bodies do exist, the rules and regulations governing the profession are not well-enforced. On the consumer side, tighter regulations are necessary as consumers often have false perceptions of the safety of NHPs and may lack general knowledge regarding potential adverse drug interactions. Thus, stricter regulations in the CAM industry will improve public safety.

Recommendations

The first recommendation is that the CAM practice as a whole should be more strictly regulated. As discussed, the rules governing practitioners who are members of the regulated Colleges are not well-enforced. As such, there have been examples of practitioners working out of their scope of practice. The onus needs to be on the Colleges to enforce the rules in their practice, along with consequences for practitioners not adhering to these guidelines. Furthermore, the fact that regulation varies provincially can be misleading or confusing for the consumer. Stricter and national standardized regulation of the profession could help enhance CAM's legitimacy, which can be done through an organization such as a national certification board that licenses CAM professionals to practice consistently across Canada.

The current framework of Health Canada's NHP regulation does not offer a reliable assurance to consumers and health professionals that all approved NHPs are indeed "safe and effective". Consumers need to be able to access reliable information easily in order to make informed decisions about their treatment options. It's important for them to be wary of claims on NHP labels and realize that these claims are often not based on scientific evidence. As NHPs are becoming increasingly popular among Canadians, there needs to be a central location that facilitates a better dissemination of information regarding NHPs in order to educate the consumers. In this light, the second recommendation is for Health Canada's website to be more user-friendly and allow the general public to easily identify commonly taken NHPs along with their potential interactions with prescription drugs and treatments (e.g. chemotherapy). This information should also be clearly stated on NHP labels, and there should be more severe penalties for producers and manufacturers who do not adhere to labeling guidelines.

Finally, the third recommendation is to the Canadian public to act as catalysts for change by bringing this issue to the attention of the politicians with the power to enact these recommendations. In order to implement national regulation of CAM, the issue must be a priority of our Members of Parliament to improve public safety. Regarding the potential improvements to the Health Canada website and recommended label changes, it would be best to bring this to the attention of the Ministry of Health. Implementing these recommendations will allow for increased public health safety by bridging current gaps in regulation and consumer education.

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