

Navigating physicians' ethical and legal duties to patients seeking unproven interventions abroad

Jeremy Snyder PhD Krystyna Adams MPH Y.Y. Chen MSW Daniel Birch MD Timothy Caulfield LLM FRSC FCAHS
I. Glenn Cohen JD Valorie A. Crooks PhD Judy Illes PhD Amy Zarzeczny LLM

Medical tourism (MT), the practice of traveling to another country to access medical care that is paid for out of pocket, has received considerable attention in the Canadian news media. Stories depict Canadians traveling abroad for various elective or necessary medical procedures, such as hip and knee replacements, bariatric surgery, and dental treatments.^{1,2} Commonly cited safety concerns of MT focus on the quality of care abroad and differences in safety standards or protocols in different health care systems.³ Medical tourists might be unable to bring their records home, disrupting continuity of care and challenging physicians' abilities to provide appropriate follow-up care.⁴ Media and industry information sources, which are commonly accessed by medical tourists, might inadequately inform Canadians about MT safety concerns.^{5,6} As a result, there is concern among Canadian physicians and health and safety professionals that prospective medical tourists might not be well placed to make informed decisions about their care.⁷ As gatekeepers in the health care system and the first source of interaction between the health care system and patients, family physicians are well positioned to inform Canadians about these safety risks.⁸

Safety concerns with MT are particularly relevant for patients traveling for *unproven interventions*—that is, interventions that have not been tested using recognized methods and proven to be safe and effective. While it is not currently possible to know how many Canadians are traveling abroad or what procedures they are undergoing, anecdotal evidence suggests Canadian medical tourists are traveling abroad for unproven interventions including chronic cerebrospinal venous insufficiency treatment of multiple sclerosis, stem cell interventions for many ailments, and untested bariatric surgical procedures.^{9,10} Patients engaging in MT for unproven interventions might be exposed to additional safety risks owing to the unproven nature of the intervention, face high financial burdens for potentially ineffective interventions, and be disqualified from enrolment in legitimate (and free) clinical trials.¹¹ When patients are diagnosed with a progressive or chronic disease, their hope for improved quality of life has the possibility of being exploited by providers of unproven interventions to promote uptake, heightening concerns about inadequately informed decision making from medical tourists engaging in this type of intervention.¹² This is not to say that all promoters of unproven interventions are charlatans preying on the weak, but the risk is real and substantial. There are numerous challenges that family physicians face in supporting more informed decision making by Canadians who are considering traveling abroad for unproven interventions while also performing their legal and ethical duties to their patients. Physicians are constrained by trying to maintain a positive physician-patient relationship that honours patient autonomy and respects patients' hope for treatment from unproven interventions while protecting patient safety. In this commentary we outline family physicians' ethical and legal duties to these patients and discuss how the existing consensus on these duties does not adequately guide physicians' actions.

Duties to patients

In its code of ethics, the Canadian Medical Association lists 54 physician responsibilities to patients.¹³ Many of these responsibilities are particularly relevant in situations in which patients seek advice on accessing unproven interventions abroad.

- “Take all reasonable steps to prevent harm to patients” (responsibility no. 14).
- “Recognize your limitations and, when indicated, recommend or seek additional opinions and services” (responsibility no. 15).
- “Provide your patients with the information they need to make informed decisions about their medical care, and answer their questions to the best of your ability” (responsibility no. 21).
- “Recommend only those diagnostic and therapeutic services that you consider to be beneficial to your patient or to others” (responsibility no. 23).¹³

Together, these responsibilities focus on the role of the family physician in providing information and guidance to patients.

Patients seeking unproven interventions via MT can access ethical guidance specific to these procedures. The International Society for Stem Cell Research encourages physicians to answer their patients’ questions about unproven stem cell interventions abroad but advises that they actively discourage patients from seeking unproven stem cell interventions outside of clinical trials owing to the “potential physical, psychological, and financial harm” of these interventions.¹⁴ Based on Canadian patients’ trust in their family physicians and the role of these physicians in providing continuity of care, some have argued that physicians have a responsibility to educate about the limits and potential harms of these interventions.^{11,15} These sources suggest that physicians must respect their patients’ decisions whether or not to go abroad for this care; however, they should also inform their patients’ decision making, including potentially warning patients about the dangers of unproven interventions if doing so is consistent with their work-load, expertise, and best judgment.

Legal obligations

The doctrine of informed consent requires Canadian physicians to disclose treatment information that a reasonable patient would want in that context.¹⁶ Generally, this means that physicians must answer all questions posed by patients and share with patients all material information concerning the nature of the proposed intervention and alternative interventions, including benefits, risks, and likely outcomes.¹⁷ Although the informed consent standard applies when physicians are providing treatment, we think it is reasonable to suggest similar principles should also guide physicians’ conduct when patients are seeking information about unproven treatments, particularly when patients are considering pursuing such treatments as an alternative to conventional therapy offered by the physician. In this role, physicians act much as they do when they refer their patients to specialists within Canada. In such cases, patients require information to enable autonomous decisions regarding their treatment. Moreover, in this context patients entrust their health and safety to their family physicians, even if these physicians are not offering treatment themselves. For this reason, the duty of physicians to disclose material risks of an intervention is reinforced by the fiduciary nature of the physician-patient relationship, which demands physicians act in their patients’ best interests.^{18,19} Although courts have occasionally permitted physicians to withhold information when patients’ well-being might be seriously threatened as a result of disclosure, the scope of this privilege is highly circumscribed.¹⁷ Case law suggests that it is better for physicians to divulge the proper information to patients and then ameliorate any adverse consequences by comforting and reasoning with patients instead of avoiding the disclosure.²⁰

Although, to our knowledge, Canadian courts have not considered whether physicians are legally required proactively to inform patients of unproven therapies available in another country, American jurisprudence offers some clues about reasonable medical practice in such cases. Physicians’ duty to inform does not typically require proactive disclosure of interventions that are

unproven and unavailable locally. When expressly asked by patients about pursuing unproven interventions abroad or when it becomes clear a patient has decided to undergo such an intervention, family physicians are obliged to supply patients with relevant, evidence-based information, a standard that does not require the proactive disclosure of interventions that lack regulatory approval.^{21,22} For example, physicians ought to discuss the health and financial risks associated with MT in general, as well as the unproven intervention in question, and explain to patients how the risks, benefits, and uncertainties concerning the unproven intervention compare with those of conventional treatment so as to allow patients to make knowledgeable treatment decisions. Further, physicians should point out the challenges that patients might face when follow-up care is required in the home country. If the unproven intervention is known to cause serious harm, physicians' fiduciary responsibility might involve a fairly onerous duty of disclosure.²¹ This is not to say that physicians should coerce patients or attempt to undermine their autonomy, but that physicians should make their concerns with the intervention clear and make sure to effectively communicate material information so that patients can make informed decisions. Moreover, when parents have made the decision on behalf of pediatric patients to pursue unproven interventions abroad against medical advice, doctors might in extreme circumstances be required to report the situation to child welfare authorities, especially if the unproven intervention has clear risks and safer alternative treatment is available.²³

Navigating and clarifying obligations

There is considerable overlap between the ethical and legal obligations of family physicians of patients seeking unproven interventions abroad. Canadian family physicians should provide patients with requested information about these interventions to the best of their ability and should respect patient autonomy around decisions regarding their care. Physicians also have a responsibility to protect the welfare of their patients and should inform them about any concerns surrounding unproven interventions and discuss proven alternatives when they are available.

Several pressing questions remain unanswered.

- Given the lack of reliable information about unproven interventions, how active should physicians be in informing themselves about such interventions, particularly when the interventions are not available in Canada?
 - How can physicians maintain a positive physician-patient relationship and respect patients' hope for improved health while protecting patient safety?
 - Under what conditions, if any, may physicians refuse to offer follow-up care to their patients following treatment received abroad?
 - Should physicians be warning patients only about concerns with the effect of decisions on the patients themselves or should they also discuss the effects on third parties, including citizens in host countries for these interventions and the potential for undermining well designed research trials on new interventions?

We call for Canadian medical educators to challenge family physicians in training with questions such as these, encouraging them to grapple with the implications of MT for their clinical practice from the outset.

At present, Canadian family physicians face too much uncertainty in light of the growing trend of Canadians seeking unproven interventions via MT. They should face this challenge by informing themselves about relevant trends in travel abroad for unproven interventions, seeking to better understand the issues their patients are struggling with in this area, and give careful consideration to their ethical and legal obligations toward these patients. At the same time, physicians deserve clearer ethical and legal guidelines from professional colleges and associations around their roles in these cases so that they can execute their obligations without fear and confusion. The Canadian medical leadership is herein called upon to engage with legal, ethics, and policy scholars to actively work toward developing this guidance.

Dr Snyder is Associate Professor in the Faculty of Health Sciences at Simon Fraser University in Burnaby, BC.

Ms Adams is a doctoral candidate in the Faculty of Health Sciences at Simon Fraser University.

Mr Chen is a doctoral candidate in juridical science in the Faculty of Law at the University of Toronto in Ontario.

Dr Birch is Associate Professor in the Department of Surgery at the University of Alberta in Edmonton.

Professor Caulfield is Canada Research Chair in Health Law and Policy and Professor in the Faculty of Law and the School of Public Health at the University of Alberta.

Dr Cohen is Professor of Law at Harvard Law School in Cambridge, Mass.

Dr Crooks is Associate Professor in the Department of Geography at Simon Fraser University.

Dr Illes is Professor of Neurology and Canada Research Chair in Neuroethics at the University of British Columbia in Vancouver.

Professor Zarzeczny is Assistant Professor in the Johnson-Shoyama Graduate School of Public Policy at the University of Regina in Saskatchewan.

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