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Ethical and Legal Obligations to Individuals Returning to Canada and the U.S. after Receiving Experimental Stem Cell Treatments Abroad

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Stem cell therapies, both embryonic and adult, have been the subject of significant debate in both the public forum and scientific literature; however, addressing coverage and care obligations to individuals after they have received these treatments has not been adequately discussed. Stem cell therapies have created a trend in individuals seeking treatments abroad because their country either (1) does not offer the treatment or (2) the cost is significantly reduced in a foreign country. These individuals then go abroad to receive the treatment and return to their home country. However, if there is a subsequent adverse event, the individual will typically receive treatment in their home country. The focus of this essay is to discuss what happens when individuals return to Canada and the U.S. after receiving stem cell treatments abroad and to argue that there needs to be a greater transparency about potential ramifications. Additionally, I will address legal and ethical arguments as to whether there is an obligation to provide insurance coverage for adverse events, ultimately concluding that there is an obligation.[1]

Medical Tourism and Adverse Events Due to Medical Treatment Abroad

Notably, the medical tourism industry is not isolated to those seeking stem cell treatments abroad. Estimates suggest that 52,000 Canadians sought medical treatments abroad in 2014 alone,[2] while in 2016 the CDC estimates that "up to 750,000 US residents travel abroad for care each year."[3] It is difficult to (1) determine what treatments were sought, and (2) which countries Canadians and Americans are travelling to. Importantly, these statistics do not specify the number of Canadians seeking care in the United States and Americans seeking care in Canada. Rationales for individuals who seek medical treatment abroad vary, but may include the reality that certain "treatments" are not permitted in the individual's home country, specialty care is not offered in their home country, cost avoidance,[4] or "jumping" wait times to receive care (though the latter does not apply for the present discussion). As might be expected there is a significant populace that not only is at risk for experiencing an adverse event during the procedures they have sought abroad, but is also at risk for needing long-term medical care as a result of the treatments sought abroad.

In 2016, the CDC warned that potential risks associated with receiving treatment abroad include poor communication, "unsafe injection practices," counterfeit

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medications, lack of adequate blood supply and "antibiotic resistance."[5] Additionally, many individuals who seek treatments abroad are not adequately vaccinated, resulting in risk of contracting disease (such as hepatitis B) unrelated to the procedure sought.[6] Specifically with stem cell treatments there is limited but growing data about severe adverse events connected with seeking these treatments.[7] The Mayo Clinic warns that potential side effects of stem cell treatments are "Graft-versus-host disease (allogenic transplant only); Stem cell (graft) failure; Organ damage; Infections; Cataracts; Infertility; New cancers; Death."[8] Moreover, there is concern that stem cells "could trigger an overzealous attack by the immune system."[9] One particularly tragic example was "a case in which a boy in Russia who was injected with fetal neural stem cells subsequently developed brain and spinal tumours."[10] Lastly, there is limited to no follow-up care with the individuals who provided the care abroad.[11] Given that there will be individuals who need follow-up care as a result of their stem cell therapies, there should be a clearer understanding of the ethical and legal reasons why care should be provided. Furthermore, there are various types of stem cell transplants—embryonic stem cell vs. adult stem cell (either allogenic or autologous)—and each has different risks and ethical questions associated with them that further complicate this discussion.

Legal Framework for Medical Coverage in Canada

The majority of medical care in Canada is paid for by a single-payer governmental system that provides insurance to Canadian residents.[12] The insurance is then implemented "by a series of thirteen interlocking provincial and territorial health insurance plans."[13] The general eligibility requirements are that an individual is either a citizen or resident of Canada, with each province and territory having specific residency requirements. Each province and territory may differ in benefits offered, but the following are required nationally: "hospital services provided to in-patients or out-patients, if the services are medically necessary for the purpose of maintaining health, preventing disease or diagnosing or treating an injury, illness, or disability; and medically required physician services rendered by medical practitioners."[14] This insurance has limited portability. When individuals seek treatment abroad "prior approval by [the] provincial/territorial health insurance plan may be required before coverage is extended for elective (non-emergency) health services."[15] As a result, when individuals seek elective treatment abroad, the majority of them are paying for these services out of pocket.

Legal Framework for Medical Coverage in the United States

Unlike the Canadian system, the United States has a multi-payer medical system. There are several different sources of medical insurance in the U.S. including: (1) employer-sponsored medical insurance; (2) Medicare; (3) Medicaid; (4) CHIP; (5) military-related insurance; (5) state provided insurance; and (6) privately procured insurance, some of which is available through healthcare exchanges.[16] However, the majority of health insurance is provided under employer-provided health insurance, Medicare, and Medicaid. Regardless of insurance coverage, due to the Emergency Medical Treatment and Active Labor Act, the public shall have "access to emergency services regardless of ability to pay."[17] This means that even if an individual who needs emergency medical service as a result of receiving experimental stem cell therapies cannot pay, they are still entitled to receive care. The unknown is whether the care will be covered in its entirety or only partially.

As the most common form of coverage in the U.S., employer-sponsored medical insurance can take one of two forms. The first is that the employer self-insures, meaning that they pay out-of-pocket for the medical needs of their employees. Often employers that self-insure outsource to an agency in order to facilitate the process. The other form of employer-provided medical insurance is that the employer purchases insurance from a medical insurance agency and provides it to their employees. Medicare generally covers eligible individuals over 65 years of age and certain individuals with special medical needs and disabilities, while Medicaid and CHIP (Children's Health Insurance Program) provides coverage to individuals (both adult and children) who have disabilities, are pregnant, or have limited financial means. Government programs have specific eligibility requirements, often including legal permanent residency or American citizenship.

Prior to the passage of the Affordable Care Act (ACA) there was significant variance in what and who health insurers were required to cover.[18] The ACA (with the exception of grandfathered plans)[19] requires medical insurance to cover essential health benefits. Essential health benefits include ten broad categories of benefits that medical insurance was required to cover: (1) ambulatory patient services; (2) emergency services; (3) hospitalization; (4) laboratory services; (5) maternity and newborn care; (6) mental health services and addiction treatment; (7) rehabilitative services and devices; (8) pediatric services; (9) prescription drugs; and (10) preventive and wellness services and chronic disease treatment.[20] Notably, it has been left up to the individual states to clarify what these categories mean.[21] Relevant to this discussion is that some states will cover certain stem cell transplants under essential health benefits while others have excluded them.[22] Of those that cover stem cell transplants under essential health benefits, typically they are limited to adult stem cell transplants involving bone marrow and some cancer treatments.[23]

Historically, experimental procedures were excluded from medical insurance coverage in the U.S.[24] Stem cell transplants, likewise, were considered experimental under certain insurance, though specific coverage depended upon the type of stem cell treatment. In addition to some states covering certain adult stem cell treatments under essential health benefits, the ACA has expanded

experimental coverage slightly for experimental research. As of January 2014, participants in approved clinical trials will be provided with coverage of "routine costs." These costs will cover "all aspects of care outside of the investigational drug, item or procedure itself."[25] However, it is important to note that "clinical trials must be approved or sponsored by the National Institutes of Health (NIH), the Center for Disease Control and Prevention (CDC), The Agency for Healthcare Research and Quality (AHRQ), [or] Centers for Medicare & Medicaid Services (CMS)."[26] As a result, at this time, stem cell research has very limited insurance coverage.

Generally, it can be concluded that insurance in both Canada and the United States is unlikely to pay for experimental stem cell services abroad. Some related costs may be covered, but each patient seeking treatment abroad would have to clarify whether and how much coverage they would be entitled to. Domestically, health insurers may decide on a case-by-case basis to provide coverage by considering factors such as stipulations in the insurance contract, whether the treatment is medically necessary, as well as its clinical trial status.[27] Additionally, it is ambiguous whether insurance policies would cover adverse events abroad if individuals have gone there for elective procedures.[28] However, there have been some discussions about private insurers providing private health insurance for individuals seeking treatments abroad. Notably, the Canadian government encourages individuals to purchase such health insurance based upon the understanding that medical tourism is growing.[29] However, it is unclear what these policies may provide coverage for; it is possible that they may provide coverage for emergency medical evacuation or some adverse events.

What is clear is that in Canada, if an individual returns and is experiencing events that fall under medically necessary care, they will be entitled to not only receive medical care, but that care will most likely be covered by the individual's provincial or territorial health insurance. In the U.S., unless the individual health insurance contract explicitly states revocation of coverage, it is also likely that medically necessary care would be covered. This conclusion is additionally based on the fact that the ACA prohibits discrimination based upon pre-existing conditions for most insurance contracts. However, there is less certainty in the United States compared to Canada, as there are many payers and many contracts providing health insurance coverage.

Ethical Obligations to Provide Health Insurance Coverage

Given that medical practitioners are required to provide care and that health insurers are likely required to cover the costs of such care, it should be questioned whether there is an *ethical obligation* to provide care. Interestingly, in a study conducted on Canadian physicians, "the majority of physician respondents agreed that it was their responsibility to provide follow-up care to medical travelers on return to Canada, although a substantial minority disagreed that they had such a responsibility."[30] Clearly, medical practitioners are in disagreement as to their duties regarding treatments sought abroad.

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I propose the following ethical reasons in favor of an obligation to provide care: (1) ethical notions of fairness; (2) duty to assist those that are medically needy; (3) individuals seeking these treatments abroad are already a vulnerable population and withholding medical treatment further disadvantages them; and (4) lack of informed consent should not further harm individuals. Note that throughout this section I am specifically addressing health insurance coverage to individuals when they return to Canada and the United States, with the presumption that care should be accessible regardless. I do not wish to argue that Canadian and American health insurers are required to provide health insurance coverage for stem cell treatments conducted abroad.

1. Ethical Notions of Fairness

Perhaps the most compelling reason why individuals should have accessibility to health insurance when they return from receiving stem cell treatments abroad is the notion of fairness. It is inconsistent to provide health insurance coverage for certain individuals and not others. During the passage of the ACA there was significant debate about providing coverage for preexisting conditions, especially coverage that was needed due to conditions that could be tied to certain lifestyle choices such as obesity and tobacco usage.[31] However, the ACA required that insurers provide health insurance because refusing coverage *unfairly classifies* people based upon medical conditions, even conditions associated with lifestyle choices. Part of the argument supporting providing health insurance to those who engage in medically risky activities is that many behaviors are impacted by societal influences, while recognizing that others may have avoided such behaviors simply because their personal circumstances were different. Similarly, in Canada not only is this notion tied to fairness, but it is also tied to notions of reciprocity, that all individuals should be covered simply because medical conditions can and will affect most individuals at some point during their life. Since it is difficult to determine what medical conditions individuals will become afflicted with it is most fair if we cover everyone who requires medically necessary care. Precluding individuals who have received stem cell therapies from Canadian or American health insurance coverage is too akin to prohibiting coverage based upon age, tobacco use or

obesity. Practically, without a "universal" system that provides medically necessary insurance coverage for individuals, individual judgment calls would have to be made about what is appropriately covered care, and this type of decision making runs the risk of being onerous and unfair to individuals who are designated decision makers.

Denying insurance coverage stems from the notion that individuals should understand the risks that they are undergoing. This is tied to the buyer-beware mentality—that individuals, if they want to partake in stem cell treatment abroad, should fully expect that there could be an adverse event and that they are financially responsible for care that is needed as a result. Additionally, in the situation of stem cell treatments that may be prohibited in Canada and the United States, prohibiting coverage of follow-up or long-term care may act as a deterrent for individuals who would otherwise seek these treatments abroad. While these are valid arguments, they are not compelling enough to suggest that individuals who engage in "riskier" behavior should be precluded from health insurance coverage. Aside from the noted lifestyle-related medical conditions mentioned above, individuals are granted health insurance coverage even though they engage in arguably unnecessary risky behavior. Some examples include those who agree to be live-organ donors and those that engage in medically risky sexual behaviors. Like any risky behavior it is difficult to determine long term outcomes. An individual may have an adverse event or long-term consequences, they may experience no change, or stem cell treatments may assist in the functioning of their lives. As a result, if fairness is a value that is to be upheld in the medical context, it is ethically impermissible to discriminate against individuals who have sought stem cell therapies abroad.

2. Duty to Assist Those that Are Medically Needy

It is important to remember that individuals who are seeking experimental stem cell treatments abroad are already members of a vulnerable population. They are generally individuals who have not had success treating their ailments with available medical care and as a result are seeking other alternatives. They are particularly vulnerable because not only are they seeking a cure or improvement of their ailment, their disease or disability may independently impact their capacity to make informed medical decisions. Issues of informed consent will be addressed later in this essay, but it is important to highlight that while the decision to seek experimental stem cell treatments abroad may be a decision impacted by an individual's emotions, many of these individuals are making an autonomous decision based upon their personal beliefs and values to seek experimental stem cell treatments.[32]

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If health insurers in both Canada and the United States were able to deny healthcare coverage for individuals after they sought stem cell treatments abroad, many individuals might decide not to seek alternative treatments. While many may argue that this is an appropriate deterrent mechanism, it also runs into contradiction with individuals being able to make autonomous decisions regarding their healthcare. With many medical decisions there can be tension between medical paternalism and individual autonomy, for example there are often circumstances in which doctors provide options for care in which some options are more medically effective, but the individual chooses a second less medically effective option. This often occurs with cancer patients, as patients may seek less aggressive alternatives to chemotherapy, but this does not preclude insurance coverage if the patient later wishes to seek chemotherapy. These patients have often exhausted all other alternative treatments before seeking more aggressive treatments. In comparison, physicians may administer chemotherapy treatment even if it is unlikely to be effective if a cancer patient wants to pursue aggressive treatment, and even if palliative care is more medically appropriate. As such, an individual who seeks treatment abroad, while possibly not the most medically appropriate treatment, should be provided health insurance coverage for their continued care.

3. Further Harming a Disadvantaged Population

As was mentioned in the above section, individuals who are seeking experimental stem cell therapies are already a part of a vulnerable group of individuals. Denying health insurance coverage harms these individuals because either these individuals will still seek medical care and not be able to afford it, or they will forego medical care due to concerns about cost. Neither option is beneficial from a public health perspective. Healthcare providers should be compensated for the care they provide, but in most situations they rely upon insurance to recover their costs. If individuals cannot pay for their medical costs, that imposes a strain upon medical care providers, not to mention the financial stress that places upon the individual. Individuals forgoing medical care due to cost often can lead to more costly needs in the future. Moreover, because individuals seeking stem cell treatments abroad tend to be ill individuals, they are foreseeable high-cost medical users, meaning that if they are denied health insurance coverage they are placed at a greater disadvantage comparatively to other "healthier" individuals.

Additionally, it is important to note that there is an immediacy concern when addressing an individual's ability to receive medical care after receiving experimental treatment abroad. The first is that while individuals may not experience an immediate adverse event in the short term, they may in the future. This has been evidenced by tumors and bone fragments forming later in patients who have received stem cell treatments.[33] Questions of whether insurance coverage should be revoked immediately if an individual seeks treatment abroad or whether certain procedures are denied coverage, either become too harsh or highly speculative. Why should health insurance coverage be denied if the stem cell recipient never experiences an adverse event; moreover, can medical practitioners conclusively determine that some adverse events were associated with such treatment? As a result, it may simply be too difficult to determine whether there will be an adverse event or the causation of such event, and denying coverage will foreseeably be detrimental to the health of the individual.

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Lastly, individuals who are seeking experimental stem cell treatments abroad may have misplaced hope in these experimental and often unregulated stem cell treatments.[34] While denying them health insurance coverage may act as a deterrent to seeking these treatments, the denial of coverage does not appropriately educate those seeking these treatments of the risks. There is significant confusion as to whether these treatments are effective and safe, which is further compounded by the involvement of a number of physicians assisting individuals to seek these treatments abroad, [35] physicians domestically engaging in these treatments,[36] and "predatory behavior" on the part of a number of clinics providing such services.[37]

4. General Lack of Informed Consent

Tied to the notions of fairness and justice is the reality that many individuals undergoing these experimental stem cell treatments may not truly understand the risks associated with the procedures, nor the long-term consequences of receiving these treatments,[38] not to mention that there is often ambiguity and confusion about medical insurance coverage to begin with. Individuals who are seeking treatments abroad may (1) not be aware about the potential insurance ramifications, (2) nor may it be something that they are thinking of when they are desperate enough to seek treatment abroad. Regarding the issue of awareness this may not absolve the responsibility of individuals seeking care, however, the opaqueness of what is covered and the educational level needed to understand benefits is often out of reach for many patients. In such cases where individuals go through appropriate channels for coverage approval, it is often difficult for individuals seeking such treatments to receive a concrete answer. Considering this, the default approach should be to provide medically necessary insurance coverage, not to revoke such coverage. Moreover, if health insurers were no longer to provide coverage, there would have to be greater mechanisms in place to fully disseminate such information.[39] Potential mechanisms include appropriately informed medical practitioners as well as having easily accessible information for the consumer. Increasing accessibility to resources is only one part of the equation when it comes to gaining true informed consent, however. Health insurers would also be obligated to make sure the consumer understood the potential insurance ramifications.

Counter-Arguments as to Not Provide Health Insurance Coverage

Despite the persuasiveness of the ethical arguments for requiring insurance companies to provide health insurance coverage to those that return to Canada and the United States after receiving stem cell treatments abroad, it is important to address relevant counter-arguments. The two most compelling arguments are (1) that individuals seeking treatment abroad should have knowledge of and be prepared to pay for events that are a direct result of their risky behavior, and (2) that providing care for these individuals is further burdening the Canadian and American healthcare system and as a result, insurers are not obligated to provide coverage.

1. Participants Should Bear Relevant Medical Costs:

As was mentioned earlier, one of the arguments in opposition to paying for medical care that results from seeking stem cell therapies abroad is that individuals that seek these therapies should expect to bear the cost of any relevant medical care. Generally, it is not argued that these individuals should not have access to relevant care, but instead arguments are focused on payment for such care.[40] This argument is based in the idea that individuals seeking therapy abroad should be responsible for the cost of their care. Some supporters of this argument suggest that individuals who have sought stem cell treatment abroad only have to pay for care that is a result of the treatment they sought abroad. For example, if tumors result from the stem cell injection, then the individual will be required to cover the relevant healthcare cost to remove the tumor(s). However, as discussed previously, it may be difficult, if not impossible, to determine if the stem cell treatment was the genesis

for the future medical need. There is also the consideration of the source of the stem cells, whether they are derived from embryos, whether they are from allogenic sources or whether they are from autologous sources. This may have an impact on whether insurance companies and governments are willing to provide coverage, as some of these sources may be unlawful and/or deemed unethical.

2. Further Burdening Canadian and American Healthcare Systems:

There is very little data on how much time, money, and resources are spent on care given to individuals returning to Canada and the United States as a result of seeking medical treatment abroad. However, estimates in Alberta, Canada suggest that patients receiving elective bariatric surgery add a conservative estimate of $560,000 a year to the province's direct medical costs.[41] Conceivably, the costs of individuals seeking treatments abroad and returning to Canada and the United States are significant. While burdens on healthcare systems should be considered, this argument is not persuasive enough to prohibit health insurance coverage. First, individuals who seek treatment abroad may experience improvement (both a physiological and/or psychological improvement) that may in fact lessen the amount of health resources spent on the individual back in Canada and the United States. Second, individuals who seek stem cell treatment abroad may never experience an adverse event. Third, as has been mentioned before, it may be difficult to determine whether the stem cell treatment was the genesis for the event. Lastly, while these adverse events may place a burden on health systems, there are many medical conditions that place burdens on healthcare systems, and the point of insurance is to attempt to mitigate the risk by spreading the cost through a larger pool of individuals.

Conclusion

The Canadian and American healthcare systems both have their advantages and disadvantages, but central to both systems is that individuals who need medically necessary care should not only be able to receive such care, but that insurance will cover the related costs. The most compelling reason for prohibiting health insurance coverage for individuals who seek stem cell treatments abroad and return to Canada and the United States is a cost-saving measure. While this may save both the Canadian and American healthcare system resources, it does not outweigh the ethical problems this policy would face. Individuals seeking this care abroad are members of a vulnerable population that arguably would not be seeking treatment abroad if (1) their current treatment was working or (2) it was offered domestically at a reasonable cost. Prohibiting health insurance coverage upon return to their country further disadvantages their health and autonomy as well as raising ethical concerns about resource allocation. As a result, better measures to prevent subsequent need for medical care include appropriately educating individuals about the risks of receiving unproven stem cell therapies as well as encouraging precautionary behavior when receiving these treatments. The onus is on health insurers, government bodies as well as medical practitioners to fully educate those contemplating stem cell treatments abroad.

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