REPORT 3 OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS (A-18)

Medical Tourism

(Reference Committee on Amendments to Constitution and Bylaws)

EXECUTIVE SUMMARY

Every year, a growing number of "medical tourists" cross borders to receive treatments and procedures, including elective cosmetic services that are less costly than in their home countries; "medically necessary" care that is available at lower cost or in a more timely fashion; for access to nonvalidated therapies or other services that for ethical or legal reasons are not available in the health care system where the patient resides. Sometimes patients travel at the recommendation of their own physicians or under the auspices of programs initiated by their health plans or employers; sometimes patients travel on their own initiative, with or without consulting their physician, and with or without utilizing the services of commercial medical tourism companies.

Many aspects of medical tourism confound core ethical expectations regarding patients' rights—to informed consent, continuity of care and access to their medical records (E-1.1.3)—and physicians' responsibilities—to promote quality of care (E-1.1.6) and patient safety (E-8.6), to be prudent stewards of health care resources.

Physicians need to be aware of the implications of medical tourism for individual patients and the community. Collectively, the profession should support access to outcomes data about medical tourism and advocate for appropriate education for health care professionals as well as for appropriate oversight of medical tourism.

Individually, physicians should familiarize themselves with issues in medical tourism, including risks and possible benefits, to help support informed decision making when patients approach them about seeking care abroad and offer professional guidance as they would for any decision about care. They should advise patients who consult them in advance whether they are or are not willing to provide follow up care. Physicians should respond compassionately when patients who did not discuss traveling for care return seeking nonemergent follow-up services. Before declining to provide such care, physicians should consider carefully the nature and duration of their relationship with the patient, the likely impact on the patient's well-being, the burden declining to provide care may impose on fellow professionals, and the likely impact on the health and resources of the community.

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 3-A-18

Subject: Medical Tourism

Presented by: Dennis S. Agliano, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws

(Peter H. Rheinstein, MD, JD, MS, Chair)

Policy H-460.896(a), "Stem Cell Tourism," adopted at the 2016 Annual meeting, calls on the American Medical Association (AMA) to encourage study of "appropriate guidance for physicians to use when advising patients who seek to engage in stem cell tourism and how to guide them in risk assessment."

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In keeping with this policy, the Council on Ethical and Judicial Affairs (CEJA) was asked to develop ethics guidance for physicians in this area. Based on its review of relevant literature and its deliberations, the council concluded that guidance focusing on the broader phenomenon of medical tourism, of which stem cell tourism is only one example, would better serve the profession. The following report and recommendations thus provide broad guidance for physicians who interact with patients who seek or have received medical care outside the U.S.

EMERGENCE OF MEDICAL TOURISM

Every year, a growing number of "medical tourists" cross borders to receive treatments and procedures, often treatments that are unaffordable or unavailable to them at home [1]. In its broadest sense, "medical tourism" refers to any occasion on which patients travel outside their home geographic area to receive medical care elsewhere—for example, traveling to a center of excellence in another city or state. As most commonly used today, however, medical tourism refers to traveling to a foreign country to receive care. It encompasses international travel by wealthy patients from lower wage countries to medical centers in higher wage countries, notably the U.S. [2]. Increasingly, however, medical tourism is understood as travel in the opposite direction, from higher wage countries to less affluent countries where medical services are available at lower cost [2,3].

Estimations of how many patients travel abroad for care vary considerably, but appear to exceed one million [4,5]. In some instances, patients travel abroad for care at the recommendation of their own physicians or under the auspices of programs initiated by their health plans or employers [2,6,7]. In others, patients travel on their own initiative, with or without consulting their physician, and with or without utilizing the services of commercial medical tourism companies [2].

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MEDICAL SERVICES OFFERED

Medical tourists travel to address what they deem to be unmet personal medical needs [8], prompted by issues of cost, timely access to services, higher quality of care or perceived superior services, or to access services that are not available in their country of residence [9,10]. Patients may also go outside their usual health care system to achieve other goals, for example, to preserve anonymity [11]; immigrant patients may return to their country of origin to receive care in culturally familiar settings [9]. The care medical tourists seek may be elective procedures; medically necessary standard care; or care that is unapproved or legally or ethically prohibited in their home system [12].

Elective Procedures: "Cosmetic Tourism"

A significant and expanding portion of the medical tourism industry is comprised of individuals who seek cosmetic procedures that are available in their home country but are offered at often considerably lower cost elsewhere [11,13,14]. For example, 2011 data indicate that breast implants that would have cost approximately \$6,000 in the U.S. were available for about 43 percent of that cost in Thailand (approximately \$2,600) and less than 25 percent (approximately \$1,248) in Cuba [11]. Because cosmetic procedures are generally not covered by insurance plans and patients must pay out of pocket, going abroad for a desired procedure can be an attractive option. However, as Australian researchers noted, "[t]he model of care by which these services are delivered limits preoperative assessment and follow up to a few days to a week" [14].

Medically Necessary Care: "Transplant Tourism"

Medical tourism also encompasses care that would be deemed "medically necessary," such as cardiac care (coronary artery bypass grafts, heart valve replacements, angioplasty) and orthopedic surgery (hip and knee replacement, hip resurfacing, spinal fusion) [15]. Patients from publicly funded health care systems, such as Canada, Australia, or the U.K., cite long wait times at home as a primary reason for seeking care abroad [16], although they could receive needed care in their home system. Uninsured or underinsured patients in predominantly private health care systems, such as the U.S., travel to access needed care that would otherwise not be available to them [3].

 Over the past decade "transplant tourism" has emerged as a particularly problematic form of medical tourism. As one critique noted, many of the patients who go abroad for an organ transplant are "middle-income Americans evading impoverishment by expensive, medically necessary operations" [17]. Self-insured employers may encourage transplant tourism in an effort to contain health care costs [18]. A study of transplant tourists who presented for follow-up care at one U.S. facility found that these patients "had a substantially lower mean dialysis time before transplantation" compared with patients who underwent transplant at the institution [19]. By one estimate, as of 2007 some 10 percent of transplants worldwide involved commercial sales of organs [20]. Organ trafficking and the exploitation of vulnerable donors in resource poor countries associated with transplant tourism led the international transplant community in 2008 to adopt principles intended to curb unethical transplant practices [20].

Unapproved/Investigational Therapies: "Stem Cell Tourism"

Other than therapies for blood disorders, there is no evidence that stem-cell-based interventions are efficacious. Yet the market in stem cell tourism continues to grow—by 2012 some 700 clinics worldwide offered stem cell therapy for spinal cord injury, cardiovascular disease, Parkinson's and

a host of other conditions [21]. For the most part, these therapies are unapproved and unregulated [21,22].

 A recent case highlights the dangers of stem cell therapy. Richard Gass, a retired attorney in the U.S., suffered a stroke that left one arm paralyzed and one leg with weakness. Although he was able to live independently, he encountered a story about the miraculous physical recovery of a professional athlete who had traveled to Russia for stem cell treatments following a serious injury. Convinced of the promise stem cell treatments could bring, and undeterred by his family's concerns about the dangers of these therapies, he traveled to Mexico to receive stem-cell injections. Despite improvement in his mobility early on, within months Gass became paralyzed from the neck down. When he sought follow-up care from his U.S. health care team, they discovered that a large, rapidly growing tumor along his spine derived from foreign cells that could not be completely removed [23].

 In 2013, the International Society for Stem Cell Research called on governments and professional organizations to discourage commercial provision of (autologous) stem cell interventions outside of clinical trials [24]. Governments are moving to strengthen or more stringently enforce legal regulations where they exist [25]. For example, the U.S. Food and Drug Administration has issued draft guides that increase clarity and suggest that the U.S. Food and Drug Administration is preparing to take increased regulatory action in response to stem cell interventions offered domestically [26].

Proscribed Therapies: "Reproductive Tourism" ("Fertility Exile")

 As another area of medical tourism, travel for reproductive services highlights in particular issues involving access to services that for legal or ethical reasons are not available in the health care system where the patient(s) reside, or that are denied to certain categories of patients [27,28]. Hence the suggestion that such travel might better be described as "fertility exile" [29]. As reproductive tourists, patients may cross borders to receive services that are not legally available in their home health care system (e.g., pre-implantation genetic diagnosis); services for which they do not qualify in their home system by reason of age or marital status (e.g., in vitro fertilization); or services denied by their home health care institutions or health systems based on social rather than clinical considerations (e.g., gestational surrogacy for male same-sex couples) [28]. By one estimate, some 5,000 cross-border IVF treatment cycles were performed in 25 countries in 2008 [30].

Like transplant tourism, reproductive tourism raises concerns about the exploitation of vulnerable populations and the commercialization of human biological materials, as well as about discrimination against classes of patients [28,30,31]. Travel for unapproved or prohibited services can also exploit medical tourists themselves, of course, when it trades on false hope [12].

IMPLICATIONS FOR PATIENTS, PHYSICIANS & HEALTH CARE SYSTEMS

Many medical tourists receive excellent care, but data suggest that issues of safety and quality can loom large. Substandard surgical care, poor infection control, inadequately screening of blood products, and falsified or outdated medications in lower income settings of care can pose greater risks than patients would face at home [32,33]. Patients who develop complications may need extensive follow-up care when they return home; for those who return with infections, the differential diagnosis is often broader than in their home country, further complicating follow-up care [33]. The often short recovery periods following treatment abroad also mean medical tourists

can face greater risk for deep vein thrombosis, pulmonary embolism, or other travel-related complications [5,14,33].

seven were prescribed more than five different classes of antibiotics [13].

For example, in 2013, the Maryland Department of Health and Mental Hygiene dealt with the repercussions of medical tourists traveling outside the U.S. for cosmetic surgery. Public health officials, working with the CDC, identified 21 patients from six states who had traveled to the Dominican Republic for cosmetic procedures (liposuction, abdominoplasty, buttocks augmentation, breast augmentation, and breast reduction); 18 were confirmed to have rapidly growing *Mycobactenam abscessus* (RGM), likely because of poor sterilization procedures during their surgeries [13]. All patients were successfully treated, but their course of care was complicated. Among the nine patients for whom chart data were available, median onset of illness was 24 days after their surgical procedure. Of the five from whom RGM culture was positive, median time to laboratory confirmation was 79 days after their first presentation for care in the U.S. Eight were hospitalized in the U.S., five of them on more than two occasions. All nine underwent at least one therapeutic surgical procedure; seven required courses of antibiotics for three months or longer;

 Cost of post-surgical care can also be a concern. Of the patients who responded to requests for information about cost, 13 used medical insurance, although four indicated that their insurer had declined to cover some costs. Ten patients indicated the illness had caused financial problems; two reported that indirect costs, such as inability to work, compounded their financial difficulty [13]. A review of data for patients hospitalized at London's Royal Free Hospital between 2015 and 2017 following plastic surgery outside the U.K. found that among 21 patients, complications led to 18 in-patient admissions and 46 surgical procedures overall. The total cost of follow up care was £282,000 (U.S. \$368,600); cost per patient averaged £13,500 (slightly less than U.S. \$18,000) [34]. Chart review at Gold Coast University Hospital in Queensland, Australia, similarly found that between 2012 and 2013, the facility treated 12 patients for complications following cosmetic

surgery abroad—including not only infection, but also pulmonary embolism—at a cost of

facilities [5].

Medical tourism carries implications for patients' home communities as well. For example, the financial costs of needed follow-up care fall on health care institutions and health insurers [10,12,32], which may be especially problematic in publicly funded health care systems [10,14]. Medical travel poses public health risks, providing means for moving bacteria and resistant genes globally [33]. The fact that patients may return to multiple home institutions from a single destination treatment center underscores the need for tracking medical travel and outcomes that currently is not being met [14,33].

AU\$151,172.52 (approximately \$115,800 U.S.) [14]. Similar additional costs are reported by U.S.

Additionally, medical tourism carries implications for destination communities and health care systems. It can foster dual systems of care, one catering to medical tourists, and one for the local population, a situation that risks exacerbating health inequity [10,32,35]. Development of commercial health care institutions to serve medical tourists risks creating, in the words of one author, "islands of medical excellence in a sea of medical neglect" [31]. Transplant and reproductive tourism in particular pose significant risk that vulnerable local populations will be exploited as donors of biological materials that benefit foreign patients [20,31].

GUIDANCE FROM PROFESSIONAL ORGANIZATIONS

In 2008, the American Medical Association adopted H-450.937, "Medical Care outside the United States," which advocates that entities that "facilitate or incentivize" medical care outside the U.S.

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ensure that such care is voluntary, take care that financial incentives neither limit the alternatives offered to patients nor restrict treatment or referral, and refer patients only to internationally accredited institutions. Policy further urges that local follow-up care and financing be coordinated prior to travel and that coverage include costs of necessary follow-up care in the U.S. Patients should be informed about their rights and legal recourse and should have access to information about the foreign facility and health care professionals, the potential risks of combining surgical procedures with travel, and outcomes data for the procedure(s) they will undergo. Transfer of medical records to and from facilities outside the U.S. should adhere to HIPAA requirements. Policy also supports reporting and tracking safety and quality data for procedures performed outside the U.S. Substantially similar guidelines were published by the American Society for Metabolic and Bariatric Surgery.

 Also in 2008, the Transplantation Society and the International Society of Nephrology jointly developed the Declaration of Istanbul on Organ Trafficking and Transplant Tourism to promote and uphold ethical practice in organ transplantation internationally [20]. The following year, the American College of Surgeons issued a position statement on medical and surgical tourism that supports patients' right to choose where and from whom they receive care and encourages College Fellows to support informed decision making. The statement advises patients to consider not only medical, but also "social, cultural and legal implications of seeking treatment abroad," as well as to seek care at an accredited institution and to obtain a complete copy of their medical records before returning to the U.S [36]. In 2013, the International Society for Stem Cell Research similarly issued a critique of commercial stem cell therapy and called for adherence to ethical standards regarding interventions whose clinical value has not yet been demonstrated [24].

Several professional medical organizations have published cautionary information for patients about medical tourism, including the American Academy of Facial and Plastic Surgery [37], the American Society of Hematology [38], the American Society of Plastic Surgery [39], and the American Society for Metabolic and Bariatric Surgery [40].

ETHICAL CHALLENGES OF MEDICAL TOURISM

 Medical tourism can leave home country physicians in problematic positions: Faced with the reality that medical tourists often need follow-up when they return, even if only to monitor the course of an uneventful recovery; confronted with the fact that returning medical tourists often don't have records of the procedures they underwent and the medications they received, or contact information for the foreign health care professionals who provided services; asked to make right what went wrong when patients experience complications as a result of medical travel, often having not been informed about, let alone part of the patient's decision to seek health care abroad [41].

Many aspects of medical tourism confound core ethical expectations regarding patients' rights—to informed consent, continuity of care and access to their medical records (E-1.1.3)—and physicians' responsibilities—to promote quality of care (E-1.1.6) and patient safety (E-8.6), to be prudent stewards of health care resources (E-11.1.2). Patients' decisions to seek medical care abroad may also threaten trust [41] and the integrity of patient-physician relationships. These challenges are fundamentally systemic, yet patients often expect individual physicians to find ways to address them.

Informed Decision Making

Ensuring that patients make informed decisions about seeking care abroad is not possible unless patients let physicians know they are considering doing so. Expecting physicians to routinely screen patients for possible interest in becoming a medical tourist is not realistic, but when a patient expresses concern about access to certain services, or a desire to receive care that is generally not available in the community, physicians should recognize the possibility that the patient is contemplating going outside the local system of care and explore the patient's concerns and wishes more fully.

When patients' responses indicate interest in medical tourism, it is reasonable to expect physicians will help ensure that patients have the information they need to make well-considered decisions. Physicians might do so by addressing the pros and cons of medical tourism themselves when they have relevant knowledge, by referring the patient to a specialist who has relevant expertise, or by directing the patient to other resources on medical tourism for the procedure, such as specialty society or government information pages.

Continuity of Care

Arguably, the extent of individual physicians' ethical responsibility to provide after care for patients who have undergone a medical procedure abroad as a medical tourist will vary with the circumstances. Physicians have a responsibility to provide urgently needed care, or refer the patient appropriately (Principle VI), and to provide or refer for needed follow-up care when a current patient has received emergency medical care abroad. They are likewise expected to honor contractual obligations to provide care (E-1.1.2).

In other circumstances, however, physicians' ethical responsibility may be less stringent, particularly when patients have traveled for elective procedures. Physicians have stronger obligations to patients with whom they have a patient-physician relationship, especially one of long standing (E-1.1.7) [8]. Beyond carefully considering the likely effect on the individual patient's welfare, physicians should take into account whether they have the resources to provide the needed care safely and the likely effects providing care or declining to do so will have on their ability to meet the needs of other patients in their practice (E-1.1.2). Physicians have a further responsibility to reflect on the burden declining to provide follow-up care may impose on fellow professionals (cp. E-1.1.7), and on the likely impact on the health and resources of the community (E-11.1.2).

Preserving Trust

Patients may be hesitant to discuss medical tourism, fearing their physician's reaction [41]. Physicians have a responsibility to offer their best professional guidance about a patient's decision to become a medical tourist, just as they would any other decision about care. This includes being candid when they deem a decision to obtain specific care abroad not to be in the patient's best interests and helping the patient understand why they believe that to be the case. To protect the trust on which an effective therapeutic relationship is grounded, physicians should acknowledge the patient's goal for seeking care. As patient advocates, they should help ensure that the patient has exhausted options for getting the desired care within their home health care system [42]. This includes encouraging patients who propose to travel for an unapproved therapy to enroll in appropriate clinical trials.

When patients inform them before they travel, physicians should advise the patient about the level of care they will or will not be able or willing to provide when the patient returns (cp. E-1.1.7).

When a patient who did not inform the physician in advance returns seeking follow-up care for treatment received abroad, physicians must decide whether to provide that care. The obligation of compassion does not automatically translate into a duty to treat except in an emergency. However, before declining to provide needed after care to a medical tourist, physicians should carefully consider the effect that decision is likely to have on the patient's welfare, other health care professionals, and the community.

Oversight

The European Union has established formal guidelines for cross-border care among member countries [43], and entities such as the Joint Commission International and Accreditation Canada accredit international health care facilities [32], but at present, medical tourism is otherwise regulated only to the extent that medical practice in individual countries is regulated. Medical tourism companies as such are not regulated at all. Nor do medical tourism agents receive specific training or certification [32]. The absence of systematic collection and reporting of data about outcomes leaves patients, physicians, and health care systems in the dark, impeding informed decision making about medical tourism and obscuring potential risks to public health. Physicians have firsthand knowledge of the experience of individual patients who have become medical tourists and are well positioned to advocate for standards to improve quality of care and protect the interests of patients who seek care abroad.

RECOMMENDATION

In view of these considerations, the Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report filed:

Medical tourists travel to address what they deem to be unmet personal medical needs, prompted by issues of cost, timely access to services, higher quality of care or perceived superior services, or to access services that are not available in their country of residence. In many instances, patients travel on their own initiative, with or without consulting their physician, and with or without utilizing the services of commercial medical tourism companies. The care medical tourists seek may be elective procedures, medically necessary standard care, or care that is unapproved or legally or ethically prohibited in their home system.

Many medical tourists receive excellent care, but issues of safety and quality can loom large. Substandard surgical care, poor infection control, inadequately screening of blood products, and falsified or outdated medications in lower income settings of care can pose greater risks than patients would face at home. Medical tourists also face heightened travel-related risks. Patients who develop complications may need extensive follow-up care when they return home. They may pose public health risks to their home communities as well.

 Medical tourism can leave home country physicians in problematic positions: Faced with the reality that medical tourists often need follow-up when they return, even if only to monitor the course of an uneventful recovery; confronted with the fact that returning medical tourists often do not have records of the procedures they underwent and the medications they received, or contact information for the foreign health care professionals who provided services, asked to make right what went wrong when patients experience complications as a result of medical travel, often having not been informed about, let alone part of the patient's decision to seek health care abroad.

1 2 3	•	Physicians need to be aware of the implications of medical tourism for individual patients and the community.	
4 5 6		llectively, through their specialty societies and other professional organizations, physicians ould:	
7 8 9	(a)	Support collection of and access to outcomes data from medical tourists to enhance informed decision making.	
10 11	(b)	Advocate for education for health care professionals about medical tourism.	
12 13 14	(c)	Advocate for appropriate oversight of medical tourism and companies that facilitate it to protect patient safety and promote high quality care.	
15 16 17	(d)	Advocate against policies that would require patients to accept care abroad as a condition of access to needed services.	
18 19	Ind	ividually, physicians should:	
20 21 22	(e)	Be alert to indications that a patient may be contemplating seeking care abroad and explore with the patient the individual's concerns and wishes about care.	
23 24 25	(f)	Seek to familiarize themselves with issues in medical tourism to enable them to support informed decision making when patients approach them about getting care abroad.	
26 27 28 29	(g)	Help patients understand the special nature of risk and limited likelihood of benefit when they desire an unapproved therapy. Physicians should help patients frame realistic goals for care and encourage a plan of care based on scientifically recognized interventions.	
30 31 32 33	(h)	Advise patients who inform them in advance of a decision to seek care abroad whether the physician is or is not willing to provide follow-up care for the procedure(s), and refer the patient to other options for care.	
34 35 36 37 38 39	(i)	Offer their best professional guidance about a patient's decision to become a medical tourist, just as they would any other decision about care. This includes being candid when they deem a decision to obtain specific care abroad not to be in the patient's best interests. Physicians should encourage patients who seek unapproved therapy to enroll in an appropriate clinical trial.	
40 41 42 43	(j)	Physicians should respond compassionately when a patient who has undergone treatment abroad without the physician's prior knowledge seeks nonemergent follow-up care. Those who are reluctant to provide such care should carefully consider	
44 45		(i) the nature and duration of the patient-physician relationship;	
46 47		(ii) the likely impact on the individual patient's well-being;	
48 49		(iii) the burden declining to provide follow-up care may impose on fellow professionals;	
50		(iv) the likely impact on the health and resources of the community.	

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- Physicians who are unable or unwilling to provide care in these circumstances have a responsibility to refer the patient to appropriate services.
- 1 2

(NEW HOD/CEJA POLICY)

Fiscal Note: Less than \$500.

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