Quality in health care and globalization of health services: accreditation and regulatory oversight of medical tourism companies

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Abstract

Patients are crossing national borders in search of affordable and timely health care. Many medical tourism companies are now involved in organizing cross-border health services. Despite the rapid expansion of the medical tourism industry, few standards exist to ensure that these businesses organize high-quality, competent international health care. Addressing the regulatory vacuum, 10 standards are proposed as a framework for regulating the medical tourism industry. Medical tourism companies should have to undergo accreditation review. Care should be arranged only at accredited international health-care facilities. Standards should be established to ensure that clients of medical tourism companies make informed choices. Continuity of care needs to become an integral feature of cross-border care. Restrictions should be placed on the use of waiver of liability forms by medical tourism companies. Medical tourism companies must ensure that they conform to relevant legislation governing privacy and confidentiality of patient information. Restrictions must be placed on the types of health services marketed by medical tourism companies. Representatives of medical tourism agencies should have to undergo training and certification. Medical travel insurance and medical complications insurance should be included in the health-care plans of patients traveling for care. To protect clients from financial losses, medical tourism companies should be mandated to contribute to compensation funds. Establishing high standards for the operation of medical tourism companies should reduce risks facing patients when they travel abroad for health care.

Keywords: accreditation, medical travel, globalization, regulation and oversight, legal standards

Introduction

Increasing numbers of individuals are leaving their local communities and crossing national borders in search of affordable, timely medical care [1, 2]. Such countries as India, Malaysia, Singapore, Thailand and the Philippines are common destinations in Asia [3, 4]. In North America, many citizens of the USA and, to a lesser extent, holidaying ‘snowbirds’ from Canada, arrange care in Mexican hospitals and clinics located along the Mexico–US border [5, 6]. Other Canadians and Americans arrange medical procedures—cosmetic surgery in particular—in Argentina, Brazil, Costa Rica and the Dominican Republic [7]. In Europe, patients seeking inexpensive care commonly travel from Western European nations to such countries as Czech Republic, Hungary and Poland. The search for affordable dental care is an important driver of health-related travel in Europe [8, 9]. Many countries are both departure and destination points for medical travelers. For example, while some US citizens travel abroad for treatment, citizens from other countries arrange care at such well-known US medical facilities as the Cleveland Clinic, Mayo Clinic and University of Pittsburgh Medical Center [10].

Why patients travel abroad for medical care

There are many reasons why patients travel abroad for care. In some nations, delays in obtaining access to care in local health-care facilities prompt patients to travel to regions where they can receive immediate treatment. For example, some patients wait-listed for treatment in Canada and the UK fly to India and arrange prompt access to hip and knee replacements [11]. In other countries, the high cost of local health care is a major factor in prompting patients to seek
treatment elsewhere. In the USA, over 47 million Americans lack health insurance [12]. These individuals, along with ‘underinsured’ Americans, often cannot obtain affordable care at local hospitals and clinics [13]. To find affordable care they must travel to such countries as Mexico and India. Some immigrants decide to travel abroad because they want to return home to their countries of origin and receive care within health-care systems with which they are familiar [14]. Similarly, former ‘expats’ sometimes return to countries in which they once lived and arrange care in facilities offering what they regard as high-quality, comparatively low-cost, consumer-oriented treatment. Some patients travel abroad for medical interventions that are not approved in their home country. For example, many patients obtain stem cell injections of unknown therapeutic effect and degree of risk by traveling to clinics situated in such countries as China, India and Ukraine [15, 16]. Other patients travel for procedures that are illegal in their home country. In particular, some patients suffering from renal failure arrange commercial organ transplants in countries where it is possible to buy and sell kidneys [17, 18]. In short, there are many reasons why patients cross borders and obtain medical care outside the countries in which they are domiciled. Economic gradients—traveling from higher-to-lower cost health-care settings—are important but patient movement is not driven solely by cost-savings. Labels used to describe patients traveling abroad for care include ‘medical tourists’, ‘medical travelers’ and ‘medical refugees’.

Medical complications

Though there are limited data on clinical outcomes associated with medical travel, some patients presumably travel abroad and receive professional, timely, affordable and high-quality medical care. No country has a monopoly on the ‘best health-care providers’ and ‘top medical facilities’ in the world. Also, it is an error to assume that inexpensive health care is necessarily inferior to higher cost health services. However, a growing body of scholarship indicates that some patients suffer serious medical complications and require costly treatment as a result of traveling abroad and purchasing health services [19–21]. Current evidence suggests that poor outcomes are attributable to substandard surgical care, infections that in at least some circumstances are a result of inadequate infection control measures in surgical settings, deep vein thrombosis and pulmonary embolisms following long-distance travel shortly before or after surgery, and inadequate post-operative care following departure from the treating facility [22–28]. These outcomes, in addition to causing considerable anxiety and suffering for patients, are often quite costly for individuals requiring extensive care after receiving treatment abroad, the hospitals providing emergency treatment after complications occur, and, in some countries, public health insurance plans covering the cost of post-operative care required following purchase of inexpensive treatment abroad.

Need for regulation and oversight of medical tourism companies

Recognizing that there are many excellent health-care facilities around the world, and that it is possible to cross national borders and obtain high-quality care at international hospitals and clinics, lack of oversight and regulation of the medical tourism industry presumably increases the risks facing medical tourists. Not all patients use medical tourism agencies or brokerages to make arrangements when they obtain medical care outside their local communities. Some patients coordinate care directly with physicians and hospitals in destination nations. However, many individuals now turn to medical tourism companies for assistance when planning to obtain health-care abroad [29, 30]. In Australia, Canada, the UK, the USA and elsewhere, these businesses proliferated over the last decade. In contrast to medical clinics and hospitals as well as travel agencies and tourism organizations, they are subject to little oversight and are not obliged to undergo accreditation.

Medical tourism companies must be held to high standards of practice if they are to be permitted to facilitate cross-border travel for health services. Medical tourism companies should not be permitted to operate in a regulatory vacuum. Rather, these businesses must conform to legal standards governing informed consent, privacy and confidentiality of patient information and medical records, fair advertising practices and patient care. Without attempting to provide an exhaustive description of the quality standards to which medical tourism companies must be held, I propose 10 standards that ought to govern what are typically identified as medical tourism companies, agencies or brokerages (Table 1). More encompassing standards need to take into consideration relevant legislation, case law, regulations and cultural norms in particular jurisdictions. State, provincial and federal standards will need to be considerably more detailed and exacting than the brief list of standards described here. These standards are offered as a basis for promoting public debate about how to better evaluate and regulate the rapidly expanding medical tourism industry.

Accreditation of medical tourism companies

Legislative bodies such as federal and provincial or state governments need to regulate the operation of medical tourism companies. Just as legislation is used to ensure accreditation of hospitals and clinics, licensing of health-care professionals and accreditation of travel agencies, legislation needs to be crafted to regulate the practices of businesses that integrate features of both travel agencies and health-care facilities. Medical tourism companies arrange travel to other nations, but they are also involved in coordinating provision of health services. Given their role in organizing health services for patients, medical tourism companies should be subject to external evaluation and accreditation. Medical tourism
Table 1 Summary of recommended standards for accreditation and regulatory oversight of medical tourism companies

1. Medical tourism companies must undergo accreditation review. Given their role in organizing health services for patients, medical tourism companies should be subject to external evaluation and accreditation.

2. Care organized by medical tourism companies must be arranged only at accredited international medical facilities. When establishing international networks of health-care providers, medical tourism companies should be restricted to arranging health services at hospitals and clinics that have undergone accreditation by ISQua in Health-Care-accredited organizations.

3. Standards must be established to ensure that clients of medical tourism companies make informed choices. Medical tourism companies must have a legal obligation to promote informed patient choices. Informed consent is a key ethical and legal standard and it is imperative that potential clients of medical tourism companies have comprehensive discussions about risks and benefits of medical procedures before deciding whether to obtain treatment abroad.

4. Continuity of care needs to become an integral feature of international medical travel. Medical tourism companies must be held accountable for ensuring that their clients have access to health-care providers before travel abroad and upon return from international health-care destinations. Pre-travel assessment and care, monitoring of patient care while clients are abroad and provision of post-operative care must be recognized as crucial components of international medical travel.

5. Restrictions should be placed on medical tourism companies’ use of waiver of liability forms. Waiver of liability forms must be standardized and their scope restricted. Patients should be informed that they retain the right to take legal action against medical tourism agencies if patients are harmed as a result of receiving care in medical facilities that lack international accreditation, if they are treated by health-care providers who are not licensed to provide medical care, or if medical tourism companies make inaccurate, misleading or false claims about the effectiveness and safety of particular forms of care.

6. Medical tourism companies must conform to relevant legal standards governing privacy and confidentiality of patient information. Since medical tourism companies acquire health-related information and sometimes provide teleconferencing, international teleradiology, and international telecommunication of medical records, they must meet ethical and legal standards governing privacy and confidentiality of medical records and patient information.

7. Restrictions must be placed on the types of health services marketed and arranged by medical tourism companies. Medical tourism companies must be legally responsible for ensuring that their clients receive treatment that falls within the professional standard of care of the jurisdiction within which medical tourism agencies are located. Companies should not be allowed to market interventions that are unsafe and ineffective or whose safety and effectiveness is unknown.

8. Representatives of medical tourism agencies should have to undergo training and certification. Coordinators, agents or medical facilitators arranging international health services should have to undergo approved training programs that enable them to discharge this task in a competent and professional manner.

9. Medical travel insurance and medical complications insurance should be included in the health-care plans of patients traveling for care. All clients arranging international health care with the assistance of medical tourism companies should be required to obtain both travel medical insurance and medical complications and errors insurance in case they suffer unintended medical outcomes or are victims of negligent medical care while receiving treatment abroad.

10. Medical tourism companies should be compelled to contribute to compensation funds. Medical tourism companies, like travel agencies in some jurisdictions, must make annual contributions to compensation funds. These funds would exist to compensate clients for losses incurred when medical tourism companies fail to meet their contractual obligations.

Medical tourism companies should have to undergo accreditation before receiving state or provincial licenses to market international health services packages to clients. Accreditation should not be based simply on paying a business registration fee but on meeting or exceeding transparent, appropriate, well-defined standards of practice. Most health-related international accreditation organizations currently accredit hospitals, medical clinics and laboratories. New accreditation standards will need to be developed for critical assessment of medical tourism agencies.

**International accreditation of destination health-care facilities**

When establishing international networks of health-care providers, medical tourism companies should be restricted to arranging health services at hospitals and medical clinics that have undergone international accreditation by International Society for Quality (ISQua) in Health-Care-accredited organizations. ISQua, the ‘accreditor of accreditors’, accredits such international accreditation organizations as Joint Commission International, Accreditation Canada and Malaysian Society for Quality in Health. Precisely what constitutes reasonable and sufficient ‘international accreditation’ standards for hospitals, clinics, blood services and laboratories will become increasingly significant as growing numbers of patients cross borders in search of health care. Recognizing the numerous organizations involved in national and international accreditation, marketing and provision of global health services by medical tourism companies should be restricted to facilities accredited by recognized international accreditation bodies. Medical tourism companies that arrange care at unaccredited international health-care facilities should have their licenses...
revoked. Hospitals and clinics seeking to attract international patients should undergo international accreditation review before joining the global health-care networks established by medical tourism companies. As health care becomes increasingly global, regulatory standards will also have to become transnational in scope.

**Informed patient choice**

At present, there are no studies describing what information medical tourism companies provide to prospective clients before their customers make financial arrangements for provision of medical procedures. Informed consent is a key ethical and legal standard and it is important that potential clients of medical tourism companies have sustained exchanges about medical procedures before deciding whether or not to obtain treatment abroad. Information disclosure and discussions related to informed choice should occur before customers of medical tourism companies sign contracts and pay for health-related services. Before clients of medical tourism companies decide whether to arrange cross-border health care, prospective patients must understand risks of treatment, anticipated benefits of treatment, alternatives to treatment and consequences of non-treatment. Discussions related to anticipated risks and benefits of treatment should also occur at treating facilities prior to surgery and other medical interventions. Health-care providers employed by medical tourism companies will need to be familiar with and follow laws governing information disclosure and informed patient choice. Because medical tourism companies profit from arranging medical procedures, there is risk of a framing effect in which benefits of treatment are highlighted and risks of treatment are minimized. Accreditors and regulatory bodies need to ensure that medical tourism companies promote informed patient choices. In particular, risks of treatment must be disclosed in discussions with prospective clients.

**Continuity of care**

All patients having international care arranged by a medical tourism company should first be seen by a licensed physician before organizing international medical travel. Medical tourism companies should have to demonstrate that their clients had access to local health-care providers before journeying abroad for care. Local health-care providers should be responsible for examining and evaluating patients prior to travel, ensuring they are in sufficiently good health to travel and undergo medical treatment, discussing risks and benefits of treatment, facilitating cross-border telecommunication while patients are abroad, and coordinating follow-up care when patients return from international health-care destinations to their local communities. Medical tourism companies need to be held accountable for ensuring access to health-care providers both before travel abroad and upon return from international health-care destinations. Follow-up appointments and post-operative treatment plans should be established before patients travel abroad for medical care. Organization of pre-travel assessment, monitoring of patient care during stays at international health-care facilities, and post-operative care should be seen as crucial components of arranging cross-border health services. Some of the risks associated with obtaining health care at international facilities could likely be reduced by better coordinating post-operative care following return of patients to their home communities. Continuity of care needs to be recognized as a key feature of arranging international health care.

**Addressing waiver of liability forms**

Restrictions must be placed upon the waiver of liability forms used by many medical tourism companies. These documents typically assert that customers of medical tourism companies cannot sue these businesses if patients are harmed while receiving care abroad. Clients of medical tourism companies should not be requested to waive their legal rights as a condition of establishing contracts with medical tourism agencies. Patients should retain the right to take legal action against medical tourism operators if patients are harmed as a result of receiving care in health-care facilities that lack international accreditation, if they are treated by health-care providers who are not licensed to provide medical care, if medical tourism companies make misleading or false claims about the effectiveness and safety of particular forms of care, and other circumstances in which patients make decisions on the basis of inaccurate, incomplete, false, or misleading information provided by medical tourism agencies. Medical tourism companies play a significant role in organizing cross-border health care. They need to be held accountable for their role in coordinating international health care. Defining responsibilities of medical tourism companies should help ensure that patients experience a high standard of care when they travel abroad for treatment.

**Privacy and confidentiality of patient information**

Medical tourism companies must conform to national and provincial or state legislation governing privacy and confidentiality of medical records and patient information. They should be bound by federal and provincial or state laws of jurisdictions in which they are located. A US-based medical tourism company, for example, should have to conform to Health Insurance Portability and Accountability Act legislation governing privacy of medical records. Since medical tourism companies sometimes arrange teleconferencing, international teleradiology and international telecommunication of medical records, they will often need to conform to confidentiality and privacy of medical records legislation in both source and destination nations.

How effectively medical tourism companies preserve confidentiality and privacy of medical records and patient
information is at present unknown. Medical tourism agencies are privately held companies and currently there are no studies describing how they manage patient records and transmit across national borders confidential information about patients. It is unclear, for example, whether photographs and names of patients identified on some medical tourism company websites are used with the consent of clients. During accreditation review medical tourism companies should have to demonstrate what processes and structures they have in place to conform to relevant legislation governing privacy and confidentiality of patient information.

Professional standard of care and health services eligible for marketing

Medical tourism companies should be responsible for ensuring that their customers receive treatment that falls within the professional standard of care of the jurisdiction within which medical tourism agencies are located. Medical tourism companies should be prohibited from advertising and organizing treatment that is outside the professional standard of care and has not received federal approval by appropriate regulatory bodies in the countries within which medical tourism companies are located. For example, when stem cell ‘treatments’ have not been approved by the Food and Drug Administration in the USA, medical tourism companies located in the US should not be allowed to market and coordinate stem cell injections in China, India, the Ukraine or elsewhere. Federal and state or provincial legislation should be used to reduce the likelihood that customers of medical tourism companies are exposed to interventions that have no demonstrable medical benefits, are costly, and often have significant risk of harm. Arrangement of international health services should be based on evidence-based medicine, limited to approved procedures, medications and medical devices, and held to a professional standard of care. Maintaining this standard reduces the risk that patients will be exposed to substandard health care when they travel abroad for treatment.

Training and certification of medical tourism agents

Coordinators, agents, brokers or medical facilitators arranging health services in another country should have recognized training that enables them to discharge this task in a competent manner. They should be familiar with relevant legislation, case law and professional standards both in the country in which the medical tourism company is located and in countries where health services are offered. Medical tourism companies and employees of such businesses should have to conform to detailed regulatory standards intended to protect the health and financial interests of consumers. Standards for certification of medical tourism agents should be set through provincial, state or federal legislation. Medical tourism companies and medical tourism business associations should not be permitted to establish their own certification mechanisms. Rather, medical tourism company representatives need to be evaluated by agencies with proper authority to evaluate training and provide certification. Only certified representatives should be allowed to coordinate international health-care plans with clients of medical tourism companies. Accreditation review should in part involve ensuring that employees of medical tourism companies have undergone proper training and certification. There are, at present, few barriers to entering the medical tourism industry and establishing a medical tourism company. Insisting that representatives of medical tourism companies have undergone training and certification might help improve standards and reduce risks facing clients of medical tourism companies.

Medical travel insurance and medical complications insurance

All patients arranging care abroad with the assistance of medical tourism companies should be required to obtain both travel medical insurance and medical complications and errors insurance in case they suffer unintended medical outcomes or are victims of negligent medical care while receiving treatment abroad. Medical travel insurance should include coverage of extended stay care in the event of unanticipated health problems following medical care abroad. Medical travel insurance should also include provision for medical evacuation flights in the event customers require prompt medical evacuation to health-care facilities located in their home communities. In addition, customers of medical tourism companies should be required to purchase medical complications insurance that will serve as a financial safety net if they experience harm as a result of the health care they receive at international medical facilities. Many researchers note that international patients will often experience considerable difficulty establishing medical negligence when they travel abroad and are harmed while receiving medical care. Insurance products should be used to reduce financial risks patients face if they receive negligent care and are harmed while receiving treatment at international health-care facilities.

Contributions to compensation funds

State, provincial or federal legislation should mandate that medical tourism companies, much like travel agencies in many jurisdictions, must make annual contributions to compensation funds. These funds would exist to compensate clients for losses incurred when medical tourism companies fail to meet their contractual obligations. Contributing to compensation funds should be a condition of licensure and accreditation. Compensation funds should be established to compensate clients stranded abroad when medical tourism companies cease operating or when customers fail to receive other contracted services.
Conclusion

Individuals have the right to travel, and, acknowledging various restrictions, liberal democratic nations permit citizens to cross national borders. Increasing numbers of patients are traveling in search of health care, and patients are free to travel abroad if they wish to obtain health care outside their local community. However, there are risks associated with cross-border medical care. Government ministries need to use legislative powers to manage and reduce these risks. Accreditation bodies can help ensure medical tourism agencies meet reasonable, prudent standards of practice. Government agencies in nations from which patients depart for care abroad can work with regulatory authorities in other countries but ultimately they cannot control licensing of health-care providers, accreditation of health-care facilities and legislation governing malpractice and liability in other nations. They can, however, use legislative powers, accreditation, regulation and oversight mechanisms to impose standards on local businesses that arrange medical procedures at international health-care facilities. To ensure that ‘medical tourists’ receive competent care abroad as well as proper follow-up care upon their return, medical tourism companies must be held to high standards of practice. Such an arrangement would differ from current circumstances, in which most medical tourism companies operate in a regulatory vacuum, use waiver of liability documents in an effort to avoid legal and financial responsibility when their customers receive negligent medical care or suffer serious post-operative complications and organize both medical services and travel arrangements while not being held to the standards of either health-care facilities or travel agencies. To protect patients engaging in cross-border health care, medical tourism companies must be held to demanding standards of practice. Quality in health care is often addressed in relation to hospitals, health-care systems and health-care professionals. As health care increasingly crosses national borders, efforts to improve quality in health care must also attend to the proliferation of medical tourism companies and the role of these businesses in promoting globalization of health services.

References

