International Accreditation of Ambulatory Surgical Centers and Medical Tourism

Michael F. McGuire, MD[a,b,*]

KEYWORDS

• Accreditation • Ambulatory surgical centers • Outpatient surgery • International accreditation • Plastic surgery • Outpatient facilities • Medical tourism • Patient safety

KEY POINTS

- The two forces that have driven the increase in accreditation of outpatient ambulatory surgery centers (ASC's) in the United States are reimbursement of facility fees by Medicare and commercial insurance companies, which requires either accreditation, Medicare certification, or state licensure, and state laws which mandate one of these three options.
- Accreditation of ASC's internationally has been driven by national requirements and by the competitive forces of "medical tourism." The three American accrediting organizations have all developed international programs to meet this increasing demand outside of the United States.

INTRODUCTION

Over the past decade, there has been an increasing interest on the part of many aspects of American medicine to become more involved with international colleagues, from the interest of the Accreditation Council on Graduate Medical Education and the American Board of Medical Specialties in exploring opportunities in international residency training and board certification to the development by many medical specialty organizations of increased relationships with international counterparts. Simultaneously, the growth of medical tourism has been driven by commercial insurance payers and corporations as well as by individuals to obtain medical care abroad at cheaper rates or to obtain procedures or drugs not yet available in the United States. This situation has also spurred domestic interest in foreign medicine and surgery.

There is a long history of the international involvement of American physicians in medical missions, medical education, international medical organizations, fellowship study abroad, and rich collegial interactions, but more recently there has been a realization that there is increased quality and sophistication in medicine around the world, as well as a growing desire both in the United States and in many other countries to increase professional interaction for mutually beneficial goals. These newer initiatives have been based on recognition of the similarity of challenges confronting physicians in all parts of the world, and the value of sharing experiences and solutions. In some areas, the United States has had successes in solving problems, or has developed programs that may be of value to our international colleagues; in many other areas, various other countries have had greater successes in dealing with challenges or developed a more innovative

[a] Department of Surgery, Division of Plastic Surgery, University of Southern California, 1520 San Pablo Street, Los Angeles, CA 90033 USA; [b] Department of Surgery, Division of Plastic Surgery, University of California, Los Angeles, 757 Westwood Plaza, Los Angeles, CA 90095, USA
* 1301 20th Street, Suite 460, Santa Monica, CA 90404, USA.
E-mail address: mmcguire@UCLA.edu

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approach that we can benefit from in the United States. Unlike many older relationships, in which the United States tended to dominate and control the activities and focus of an international exchange, the more recent approach has been more collegial, more equal, and more focused on mutual benefit.

THE INCREASE OF MANDATORY ACCREDITATION OF AMBULATORY SURGICAL CENTERS

In the United States, the accreditation of outpatient surgical facilities, especially those not part of an acute care hospital, has slowly become important, and, in many cases, mandatory, for several reasons.

Federal Medicare Program

The federal Medicare program began to certify out-of-hospital ambulatory surgical centers (ASCs) and reimburse them for facility fees in 1982 after developing and publishing the conditions for coverage (CfCs) in the Federal Register. These requirements form the fundamentals for determining which facilities can participate as a supplier under the Medicare program.[1] These CfCs have undergone numerous revisions and refinements over the ensuing years.

Three National Accrediting Organizations

Beginning in 1996, the Centers for Medicare and Medicaid Services (CMS, then called the Healthcare Financing Authority) began to allow the 3 national accrediting organizations to deem compliance with the CfCs for ASCs by an approved inspection process. This system was separate from the state agency process, which had been the only option to achieve Medicare certification before that time.[2]

The 3 organizations (the American Association for the Accreditation of Ambulatory Surgery Facilities [AAAASF], the Joint Commission, and the Accreditation Association for Ambulatory Health Care [AAAHC]) had to be approved by CMS as a deeming agency by showing that their standards and processes met or exceeded the CfCs for ASCs. That approval must be renewed by CMS every 6 years.

Outcomes of Compliance Process

This new process of deeming compliance dramatically improved the inspection system for ASCs seeking to participate in the Medicare program and made the requirements more uniform across all the states. The lengthy and variable delays in arranging site inspections under the state programs were virtually eliminated, and the number of certified facilities steadily increased. In 2011, the last year of available data, there were 5368 Medicare-certified ASCs, with continued growth over the last 3 years despite the economic slowdown.

The ASC payment system underwent a substantial revision in 2008, most significantly increasing the number of surgical procedures that would be covered.

More than 3500 surgical procedures are covered by the Medicare system in certified ASCs. However, payments from Medicare are not a substantial source of revenue for most ASCs. A study by the Medical Group Management Association in 2009, for example, showed that only 17% of ASC revenue was from Medicare, on average.[3] Commercial insurance reimbursement was the greatest source of revenue, but in many states Medicare certification is required to collect facility fees from commercial insurers.

Effect of State Laws on Accredited Surgical Facilities

The other factor that has increased the number of accredited surgical facilities has been the gradual increase in state laws requiring that all outpatient surgical centers be accredited by 1 of the 3 national organizations, certified by Medicare, or licensed by the state. This movement began in California in 1995, when the state began to evaluate the need for some oversight of the burgeoning ambulatory surgery industry, which had no requirements for operating until that time.

Unlike the situation in acute care hospitals, which have long had extensive requirements covering all aspects of patient care, including safety, sterility, personnel, physical plant, and so forth, the outpatient center could start caring for patients, administering general anesthesia, and performing major surgery without anyone inspecting the facility or certifying compliance with even basic requirements.

The new law went into effect in July, 1996 in California,[4] and has been followed by laws in 21 states that mandate either state licensure, accreditation by 1 of the 3 national organizations, or certification by Medicare. However, this situation means that there are still no requirements for these outpatient surgical centers in 28 states: no oversight, no inspection process, no standards to comply with, no control over what is performed in these facilities. In several states, laws have been proposed, and rejected by the regulatory agencies as unnecessary because there have

been no reported deaths or serious complications as yet from these centers. Although elective surgery on generally healthy patients is inherently safe, as the types of procedures that are performed on an outpatient basis increase, and the health requirements for patients who qualify for surgery in ASCs decrease, it is inevitable that untoward outcomes will occur without some basic standards in place. Numerous studies have shown the safety of even major surgery performed in accredited facilities,[5–8] but without external oversight, the risks can increase to a dangerous level. The reluctance to act until a crisis occurs has meant that most states still have no protections in place to assure their citizens that basic requirements have been met when they have surgery and anesthesia in an outpatient surgical center.

The 2 major forces that have driven the requirement for accreditation of outpatient ambulatory surgery centers in the United States are:

1. Reimbursement of facility fees by Medicare and commercial insurance companies, which requires either accreditation, Medicare certification, or state licensure
2. State laws that mandate 1 of those 3 options for all centers

Impact of Professional Plastic Surgery Societies on Accredited Surgical Facilities

An additional strong incentive for plastic surgeons to operate only in accredited, Medicare-certified, or state-licensed facilities is the requirement for membership in the 2 largest national plastic surgery societies, the American Society of Plastic Surgeons, and the American Society for Aesthetic Plastic Surgery, that all outpatient surgery other than those performed under just local anesthesia is performed only in such facilities.[9,10] The American Board of Plastic Surgery (ABPS) now also requires compliance with this requirement as a part of the Maintenance of Certification program, which is mandatory for all diplomates certified after 1995. As a result, virtually all plastic surgeons certified by the ABPS operate only in these inspected surgery centers, whether or not their state requires it, and whether or not Medicare or commercial insurance cover the procedures that they are performing. This situation adds a measure of reassurance to patients considering elective surgery procedures, especially aesthetic surgery, in that they now know that not only is the surgeon performing the procedure appropriately trained and ABPS Board certified to perform it safely but the facility where it is being done is also certified as meeting national standards for patient safety and quality care.

International Facility Accreditation

None of these forces acting to require some degree of external oversight of the functions of an ASC exists internationally. Although some nations have imposed mandatory compliance with national standards, including France, the United Kingdom, Brazil, Australia, and Germany, most nations have no requirements in place. A recent effort to develop an ASC accreditation requirement in the European Union (based largely on the AAAASF model) has yet to materialize, caught up in the political turmoil that limits that group's efforts in so many areas. With so many more serious issues to confront in most nations, regulating ambulatory surgery centers is not even being considered. The Swiss Society of Plastic, Reconstructive, and Aesthetic Surgery recently mandated that surgery performed by its members outside of licensed hospitals must be done in ambulatory surgical facilities that have been inspected and accredited by the international affiliate of AAAASF, known as AAAASF-I.

THE MOVEMENT TOWARD AN OUTREACH ABROAD TO ACCREDIT SURGERY CENTERS

Recognizing the lack of any established programs to accredit hospitals and surgery centers internationally, the Joint Commission made the first venture into international accreditation in 1994, when it formed the Joint Commission International (JCI). Their program includes separate standards for multiple types of international health care organizations: ambulatory care, clinical laboratory, home care, hospital, long-term care, medical transport, primary care centers, and the Certification for Clinical Care Program (CCPC) which is focused on recognizing excellence in the integration and coordination of care for the treatment of specific diseases. There is no accreditation specifically for ambulatory surgery centers. Instead, all ambulatory care centers are grouped together, and the ambulatory care standards are applicable to a wide variety of organizations, including freestanding medical, surgical, and dental facilities, dialysis facilities, diagnostic radiology centers, chronic care management facilities. As a result, the standards are generic, with little detail regarding requirements for performing surgery or dental surgery in an ambulatory setting.

The JCI has now accredited or certified more than 400 organizations in 50 countries. However, most of these facilities are in the hospital category, and many of the accredited ambulatory facilities are nonsurgical. The number of accredited hospitals and other facilities in various countries can be directly related to the country's prominence in

seeking to attract international patients for medical and surgical treatments, as is the number of CCPC certificates in those specialties with a special attraction for international patients. Countries such as India, Korea, Singapore, Thailand, Indonesia, and the United Arab Emirates have many JCI-accredited facilities and certified specialties. In some cases, the national governments are involved in encouraging hospitals and other facilities to obtain JCI accreditation as a part of their initiatives to encourage foreign medical tourists for economic benefits.[11]

In 2005, AAAASF recognized the potential of an international accreditation program for ambulatory surgical facilities. At the time, it was perceived that an organization with American in its name might not be welcomed in many nations, for political and economic reasons. Because there was also a need to keep the international program legally separate from the domestic activity of AAAASF, a subsidiary organization was formed similar to JCI. Surgery Facilities Resources was incorporated in 2005. The existing domestic standards for accreditation were modified to accommodate international cultural and social differences and maintain the high bar set by AAAASF, which has given it a reputation as the gold standard in accreditation. In 2009, as the program gained international recognition, and the value of accreditation by an American organization to facilities interested in attracting American patients for dental or surgical care became important, the name of the organization was changed to AAAASF International (AAAASF-I). The number of accredited dental and surgical facilities has grown steadily over the past 5 years, especially in Central and South America, as a result of intense competition to attract foreign patients as well as encouragement or requirement for accreditation by some national governments. There are now more than 115 ambulatory surgery and dental facilities accredited by AAAASF-I in 12 countries around the world, including the United States; the value of an international accreditation is recognized for marketing purposes, both domestically and internationally. The program has been endorsed by the International Society for Aesthetic Plastic Surgery and has trained inspectors to perform accrediting surveys in many countries.

More recently, AAAHC has formed an international subsidiary, and has just started to accredit facilities in Costa Rica and Peru. This increase in international accreditation has been motivated by several factors: the desire on the part of individual facilities as well as governments to attract foreign patients and the increasing demand for quality and safety in ambulatory surgery, both by international patients as well as by international governments, similar to the situation in the United States.

MEDICAL TOURISM

The concept of traveling abroad to obtain medical or surgical care, commonly termed medical tourism, dates back to the ancient Greeks, who traveled to seek the help of the god of medicine, Asclepius. Historically, medical travel was most often associated with wealthy citizens of less-developed countries going to more developed nations, because of the greater safety and quality of care in those nations. The United States and the United Kingdom were the destination of much of this medical travel, and Brazil has also long attracted patients desiring aesthetic plastic surgery, because of the quality of the surgeons. More recently, the travel patterns have been reversed, with many patients leaving the United States and the United Kingdom to receive surgery in many less-developed countries around the world.

Newer devices or drugs may not be available in the United States because of the lengthy approval process of the US Food and Drug Administration. Commercial insurers or Medicare may not cover newer techniques, such as stem cell therapies, because they are considered experimental, and they are often available abroad sooner.

Cost Factor

Cost, rather than quality, has been the principal motivation for this more recent travel. Also, in some cases, surgical procedures still considered experimental in the United States (and therefore not yet covered by commercial health insurers or Medicare) are only available abroad. In countries such as Canada and the United Kingdom, with national health systems, the long waiting lists that exist for less urgent surgery have also been a major motivation for seeking care abroad.

Although aesthetic surgery has been a significant part of the medical travel industry, increasingly, medically necessary surgery has been the more important component. Interest in procedures such as coronary bypass, hip and knee replacement, and organ transplant surgery covered by Medicare and third-party insurers has come from those in the United States who lose their employer-sponsored coverage from job loss or insurance coverage discontinuation by their employer. The millions of Americans without insurance coverage seek care internationally because the cost of these major surgeries abroad is estimated to be one-tenth or less of the cost in the United States, including round-trip air fare and postoperative recovery in a hotel or resort.[12]

Commercial Insurer-Driven Procedures Abroad

Some commercial insurers have developed programs to encourage their subscribers to go abroad to have their covered procedures performed, because of the cost savings to the company. Often, the insurers waive copayments and deductibles if surgery is performed abroad, and sometimes they even pay for travel expenses and companion travel. Blue Shield of California started Access Baja in 2000, directing patients to several hospitals in Mexico, and in 2007, Blue Cross/Blue Shield of South Carolina teamed up with hospitals in multiple foreign countries to provide care for subscribers. Some large employers who are self-insured have also developed programs to encourage their employees to seek surgery abroad, and this has been a major element in the development of the medical tourism industry.

Several individuals with a background in employee benefits management started one of the leading organizations promoting medical tourism, and a major focus of their meetings is to connect medical tourism facilitators with commercial insurers and employee benefits managers.

These medical tourism facilitators or concierges come from a variety of backgrounds. Many are travel agents, some are physicians or nurses, and others have experience in the insurance industry. They assist patients in finding providers of the medical or surgical care they seek in foreign countries, arrange for the transfer of medical records to the international providers, including the therapeutic recommendations of the domestic physicians, schedule procedures once the patient is agreeable with the proposal, arrange for visas and travel documents, book airplane flights and hotels, and in some cases, provide a representative in the host nation to assist with transfers and translation. Depending on the nature of the surgery, a recovery program may also be arranged, which may include necessary postoperative therapy or a vacation at a resort. The "surgeon and safari" program in South Africa offers patients the opportunity to recover in "authentic bush styled accommodations."[13]

Risks in Medical Tourism

Although these medical tours may sound enchanting on the surface, they are inappropriate or even impossible for most patients recovering from major surgery, including aesthetic surgery.

- There are major risks associated with traveling long distances before and after surgery, including venous thromboembolism and pulmonary embolism, dehydration, fatigue, pain, and disorientation.
- There is also no possibility of any preoperative face-to-face visit with the surgeon to establish a doctor-patient relationship, and no ability to directly consult with the surgeon postoperatively if a problem should occur after returning home.
- The sanitary conditions in some developing countries increase the risk of infections, including some that are rare in the United States, such as malaria, tuberculosis, and dysentery, as well as more common infectious diseases, which can be catastrophic in the postoperative patient.
- Language barriers can dramatically interfere with the quality of care because, even if the surgeon speaks English, the anesthetist, nurses, and aides often cannot, and they are responsible for much of the care.
- Similarly, even if the surgeon has received proper education and training, the quality of the preoperative and postoperative care largely depends on nurses and others who may have little or no education, training, or certification.
- It is difficult enough to identify the best surgeons in the United States, much less in a foreign country with differing processes for board certification and little or no information available about practitioner competence, success rates, deaths, and reputation.
- In most foreign countries, there is no ability to file a grievance if something goes wrong, either with the hospital or with the surgeon and, even if it is possible, it is impractical to pursue a complaint from thousands of miles away. The lack of malpractice insurance in foreign nations is partly responsible for the lower costs of care.
- If complications develop after returning home, it can be difficult to obtain care from the local physicians and hospitals, because they would automatically assume all the liability for a bad outcome even though they are not responsible for the cause of the complication, and received no reimbursement for the original care.
- The costs of care for such complications can be significant, and would quickly eliminate any savings realized from the original procedure.
- Traveling abroad to obtain experimental procedures or treatments increases the risks of unproved and potentially dangerous therapies, and using unapproved drugs or devices can lead to major complications, including

death, or becoming a victim of medical frauds and scams.

There are no large studies of the incidence of surgical complications and mortality comparing surgical care received abroad with that obtained in the United States, but anecdotal reports indicate that major complications are more commonly seen by American and British surgeons in patients who traveled abroad for care, and this is not unexpected in light of the numerous additional risks of medical tourism compared with care at home.

THE IMPACT OF INTERNATIONAL ACCREDITATION ON MEDICAL TOURISM

The outreach of the American accreditation agencies into international accreditation provides the potential of increasing patient safety for those who choose to travel abroad. Choosing hospitals and ambulatory surgery facilities that are accredited by AAAASF-I, JCI, or AAAHC International would reduce some of the many increased risks of medical tourism. Some would argue that these programs thereby encourage medical tourism, even although most increased risks are not minimized by accreditation. The motives for patients to seek surgical and dental care abroad are such that this medical travel will occur whether there is accreditation of facilities or not. The increase in accreditation does provide for increased patient safety and quality care for foreign patients as well as patients in those countries. It stimulates an increase in the quality of training for staff members, and higher standards for sanitation, medication, anesthesia, physical plants, and so forth. It also encourages the facilities that are not accredited to improve so that they may qualify for accreditation.

Traveling abroad for medical and surgical care has always existed, and it will continue to grow, for many reasons. Changes in medical coverage that may occur under health care reform in the United States may slow that growth, but medical tourism for aesthetic surgery will continue to grow for economic reasons. Rather than trying to stop this growth, improving the quality of care delivered is more realistic, and more beneficial.

SUMMARY

The growth of mandatory accreditation for ambulatory surgical facilities in the United States has been driven by:

a. the recognition by states that external oversight is required to ensure patient safety and quality care in these centers where no standards previously existed and
b. the requirements of the commercial insurers that facilities be accredited, certified by Medicare, or licensed by the states to receive reimbursement for facility fees. As American accrediting organizations have begun international outreach efforts as a part of the general international movement in all aspects of American medicine, the growth of international accreditation has been driven by increasing demand for patient safety and quality care in all countries, and by the growth of medical tourism, with the marketing advantages of having an American accreditation.

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