

facturers to “demonstrate adherence to good design practices.”

This has since been expanded into what is known as the IEC 60601-1-6 design code, which sets a similar standard for the usability of medical devices around the world. To meet the standard, companies need both human factors skill and objectivity about their failures.

Tom Ulseth, Smith’s worldwide marketing manager, says “There is a lot of value to an objective perspective like that which Toronto brings. When you bring work inside it becomes too close to you, you become too biased about it working.”

To which Cooper adds: “The devices shouldn’t be evaluated by engineers, that is by the people who are designing them. They should be evaluated by the people who are using them.” — Stephen Strauss, Toronto, Ont.

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## The search for integrity in the cosmetic surgery market

The death of a Toronto woman from complications following liposuction has prompted Ontario to undertake a wholesale review of the regulation of cosmetic and aesthetic surgery, and sparked a national debate over which physicians should be allowed to perform invasive procedures.

In September, 32-year-old real estate agent Krista Stryland died following liposuction performed by Dr. Behnaz Yazdanfar of the Toronto Cosmetic Clinic. Yazdanfar is a family physician with no formal surgical training who claims on her website to perform a wide range of invasive procedures, including breast surgery, liposuction and tummy tucks.

In the aftermath of Stryland’s death, it was revealed that the College of Physicians and Surgeons of Ontario has failed to act after struggling for years with the issue of cosmetic surgery performed by physicians with no formal surgical training.

College President Dr. Preston Zuliani acknowledged that more could have been done to deal with the issue of

unqualified physicians performing cosmetic procedures. The college is now fully committed to a plan of action that ensures only qualified plastic surgeons can perform such invasive procedures.

“In retrospect, might we have been more aggressive, earlier?” Zuliani inquires. “Yes, that’s a fair statement. But I think we’re making up for it now. We consider this to be a very important issue of public safety and public trust.”

Following Stryland’s death, the college canvassed the more than 2400 members to determine the extent to which doctors may have expanded their practices to include cosmetic and aesthetic procedures without having obtained appropriate training. It is believed several hundred doctors, mostly family physicians, have been advertising themselves as “cosmetic surgeons,” but have not been telling patients they are not formally qualified to perform surgery.



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The lucrative and burgeoning area of cosmetic surgery has enticed some family physicians into the field, while also luring a few charlatans and hacks, including an unlicensed husband and wife team who performed home-based liposuction on a Massachusetts woman. She died, as did Toronto real estate agent Krista Stryland, after being operated on by a family physician with no formal surgical training.

By late December 2007, the college had notified 16 physicians that they are being investigated to determine if they are qualified to offer these medical services. Some 20 others who haven’t answered a college questionnaire about their qualifications had until the end of 2007 to respond or their licenses could be suspended.

The college has declined to identify the physicians, or indicate whether they have been asked to cease all invasive cosmetic procedures, until the investigation is completed.

A college committee of experts is also drafting recommended changes to provincial legislation that would expand the association’s regulatory authority and ability to shut down facilities that do not meet basic medical standards.

Plastic surgeons, who have long lobbied provincial colleges to impose restrictions on physicians advertising themselves as cosmetic surgeons, applauded the efforts but lamented the fact that cosmetic surgery remains unregulated in most Canadian provinces.

Dr. David Kester, president of the Canadian Society for Aesthetic Plastic Surgery, said only British Columbia and Alberta now regulate cosmetic procedures. The former initiated a rigorous regime in the early 1990s to rein in a growing number of private surgical clinics.

In Ontario, however, Kester says a family physician only needs to notify the provincial college that they are changing the scope of their practice and then meet with a mentor who assesses their ability to perform the new procedures. Most plastic surgeons consider that an inadequate assessment of ability to perform complex, invasive procedures, he adds.

Dr. Gordon Wilkes, president of the Canadian Society of Plastic Surgeons, says most so-called “cosmetic surgery” procedures are actually extensions of complex reconstructive surgery that plastic surgeons train for years to perfect. Despite this, aggressive advertising by cosmetic surgeons attempts to convince prospective patients that procedures are simple and risk free.

“There is no integrity in the marketplace,” Wilkes says. “The public confuses cosmetic surgery with plastic sur-

## Cosmetic surgery becoming the cash cow of medicine

Unregulated cosmetic and aesthetic surgery is a worldwide concern as both the number of doctors entering the lucrative field and the number of patients demanding cosmetic procedures has grown exponentially.

At the same time, however, the number of deaths from improperly performed procedures also appears to be growing.

Deaths from cosmetic surgery procedures, including tummy tucks and liposuction, have been reported from Australia to the United Arab Emirates. Meanwhile, many developing countries such as Vietnam and Thailand are reporting explosive growth in the number of clinics providing cosmetic surgery. The internet is rife with advertisements for cosmetic surgery clinics all over Asia and South America that offer cut-rate procedures mostly to patients in North America and Europe.

Venezuelan President Hugo Chavez used a television address last year to angrily denounce the growing number of physicians and surgeons willing to perform cosmetic procedures on teenage girls, in a nation obsessed with beauty pageants.

The Australian Society of Plastic Surgeons lashed out in December 2007 at a group of self-described cosmetic surgeons advertising half-price liposuction to patients willing to act as “live guinea pigs” for liposuction trainees, many of whom have no experience as surgeons. Society President Dr. Howard Webster acknowledged that in Australia right now, “any [general practitioner] can call themselves a cosmetic surgeon.”

In the United States, the industry is regulated on a state by state basis, and as a result, there is a broad array of approaches, from highly regulated to completely unregulated. But even in states with strict regulatory regimes, there has been a proliferation of cases involving unqualified physicians performing home-based cosmetic surgery.

In November, New Jersey police investigated the death of a 41-year-old woman who apparently underwent cosmetic surgery at a private home in Morganville. The case followed another tragedy involving a Massachusetts woman who died after a home-based liposuction procedure performed by a Brazilian husband and wife team who were not licensed anywhere in the United States as physicians.

California officials, meanwhile, are investigating the death of Dr. Donda West, mother of rap singer Kanye West, who died in November following a tummy tuck and breast reduction surgery at 1 of Hollywood’s most popular cosmetic surgery clinics. News reports confirmed that West, 58, had been previously turned down by another cosmetic surgeon because she had not been able to acquire a medical clearance certificate, which is standard practice in California for patients over the age of 40 who suffer from obesity.

## News @ a glance

**Island medicine:** Hoping it will yield a recruiting edge, Prince Edward Island will invest \$1.2 million per year to create 5 family medicine residencies each year on the island in conjunction with Dalhousie University’s Faculty of Medicine, starting in July 2009. “Medical residents who trained here and become familiar with the Island way of life, and style of medical practice, have the highest potential to stay,” provincial Health Minister Doug Currie said.

**Ebola strain no. 5:** The World Health Organization says a new form of the deadly Ebola virus has been detected in a major outbreak of the hemorrhagic fever in western Uganda. According to a Médecins Sans Frontières exploratory mission conducted last month, some 115 new cases of Ebola fever, and 31 deaths, had occurred as of Dec. 11, 2007. There is no known treatment for Ebola fever, which has a mortality rate of 50%–90%.

**Big stick:** The Alberta legislature wrapped up its fall sitting by passing new legislation that curbs self-regulation by 28 health care professions in the province. Controversial Bill 41 has been assailed by the Alberta Medical Association as nothing less than “draconian” because it empowers the minister to reduce educational requirements, permits censorship of physicians and threatens patient privacy (*CMAJ* 2007;177[11]:1342).

**Never events:** American style fines for medical negligence and hospital errors should be levied when patients suffer harm and need additional medical care and extended stays in hospital, says England’s Chief Medical Officer Dr. Liam Donaldson. “Why should the health service, funded by the taxpayer, pay for the care of a patient that’s had bad care,” Donaldson asked following the release of a United Kingdom National Patient Safety Agency report that indicated there were 700 000 “patient safety incidents” in 2006/07, resulting in nearly 3000 deaths. — Wayne Kondro, *CMAJ*

gery. And the term cosmetic surgery is thrown around a lot despite the fact it is not a term that has a lot of integrity for licensing and accreditation bodies.”

Zuliani notes 1 problem is that most provincial colleges are created by provincial legislatures, which are primarily interested in the regulation of insured medical procedures performed in public facilities.

Kester says many people within the medical establishment have long considered cosmetic procedures to be unworthy of regulation, only to be forced to confront the issue after a patient dies

unnecessarily. Others cast the dispute as a “turf war” and reject arguments that only plastic surgeons should perform cosmetic surgery.

“It’s always been a trivialized area of medicine, and not thought of as real surgery,” says Kester. “That attitude has contributed to this problem. The fact is, a tummy tuck is every bit as stressful and risky as having your uterus removed. It’s a 2 to 3 hour procedure with all of the complications of major surgery.” — Dan Lett, Winnipeg, Man.

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