

Patient Access to Medical Innovation

Optimal outcomes for patients undergoing orthopaedic care may depend greatly on the human factor — the expertise of the surgeons and other medical professionals who help restore function and mobility. But one shouldn't underestimate the impact of influential factors such as the medicines and medical devices surgeons and other health care providers have at their disposal. Indeed, advances in orthopaedic care rely greatly on translating new scientific knowledge into medical innovations such as safer and more effective pain relievers or new biologics, and longer lasting joint implants.

Expanded medicine and device options mean surgeons can more closely tailor treatment to their patients' individual needs. A new medication may mean a patient can avoid surgery altogether or get out of the hospital faster following surgery to the comfort of his or her own home. A new joint-implant design could add years to the device's longevity and, thus, significantly lengthen the time before a subsequent surgery becomes necessary – if at all. Medical innovations like these enhance surgical treatment and recovery and get patients back to living life faster, stronger, and longer than before possible.

However, patients' access to such medical innovations is often hampered by the slow-moving regulatory processes and restricted available funds of Canada's public health-care system:

Federal Approval Times: Canadian orthopaedic patients are often at a disadvantage compared to their counterparts in the US and European Union, because of Canada's comparatively slow regulatory process. Health Canada's Therapeutic Products Directorate (TPD), the national agency which approves and regulates medicines and medical devices for human use based on substantive scientific evidence of a product's safety, efficacy and quality, takes roughly double their own target time to review a new medication or medical device. This delay is of highest impact to patients concerning approval of medications – about 670 days from submission to approval – and is significantly longer than in other countries such as the United States and Australia (about 450 days), the European Union (475 days) and Japan (about 500) days.

Medicines and Listing for Reimbursement on Provincial Drug Plans: Many patients, if they are not covered by an employer's or their own private drug plan or not able to pay for medicines themselves, must wait even longer before they have access to new medicines. Up to two years may elapse following TPD approval before a new drug is listed on the provincial drug-benefit program and is available with public coverage (at little or no cost) to select patients. Each province has its own approach – based on factors particular to its region – for adding new drugs to its list of medications approved for reimbursement. The result is inequity across the provinces: What is available at no cost to the patient in one province may be only available in another at the patient's full expense.

Medical Devices and Budget Constraints: The slow-moving federal regulatory process also affects new medical devices of Class II and higher such as anaesthetic delivery systems, joint implants and other tools of the profession. Before receiving federal approval for use, all the hardware orthopaedic surgeons use to fix fractures, correct deformities, heal sports injuries and repair damaged joints undergo research-and-development, clinical trials

and rigorous scientific review. The most significant impediment to patient access, however, occurs at the hospital level. Provincial governments determine the size of the operating budgets they provide to most hospitals in Canada. Current under-funding leaves hospitals with the unenviable task of determining priorities for resource allocation. The resulting risk is that the lowest cost medical devices (and medicines used in hospitals) may be chosen over new innovations of equal or improved safety, efficacy and quality but with higher cost. While it may appear a fiscally responsible choice, the higher cost of the new device may include the added benefit of longer life or new application. In other words, the risk exists that cost, rather than patient outcomes, becomes the determining factor in deciding which drugs and medical devices to purchase and in what quantities.

The Canadian Orthopaedic Foundation contends that optimal patient outcomes should be the overriding motive for determining government and hospital decisions about regulated medicines and medical devices — whether it be safer anesthesia or improved pain-management or longer-lasting joint implants or minimally invasive surgical techniques or some other innovation. The Foundation supports regulatory reform that will bring approval times for drugs and devices in line with Canada's own targets and with other modern, industrialized countries. The Foundation also supports adequate, predictable funding for our public health care system. The Foundation believes that Canadians deserve access to the best available orthopaedic care including access to the best available medicines and devices for their conditions and outcomes delivered in a timely manner.