

HTA

HEALTH TECHNOLOGY UPDATE

A newsletter on new and emerging health care technologies in Canada

Scanning the Horizon

Informing Decision Makers About Emerging Medical Technologies

As we launch into 2007, our fifth issue of *Health Technology Update* brings you information on several new health technologies for the diagnosis and treatment of disease. The *Update* also introduces an innovative system that follows up with patients after they go home from hospital.

For this issue, we've enlisted help from Dr. William Freeland, a British-trained family physician who served as Health Canada's Chief of the Device Evaluation Division in the Bureau of Medical Devices from 1992 until his recent retirement. Dr. Freeland has prepared a primer article for us on how medical devices are regulated in Canada. We are very fortunate to be able to benefit from Dr. Freeland's expertise in this area.

We hope that you find this issue of the *Health Technology Update* informative and useful. And from all of us at CADTH, we wish you a happy, healthy and fulfilling New Year!

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A wintry Niagara Falls, Ontario.

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Your feedback on the newsletter is always welcome, as are suggestions for new technologies to review in future issues. Please send comments to: Catherine Allison, Editor.

E-mail: catherinea@cadth.ca

Medical Device Regulation in Canada: A Primer

Medical devices are used in the diagnosis, treatment, mitigation or prevention of a medical condition. They include a vast range of equipment, from a simple thermometer or tongue depressor to highly sophisticated magnetic resonance imaging (MRI) machines or robotically assisted surgical equipment.

In Canada, medical devices are regulated by Health Canada's Therapeutic Products Directorate and are subject to the Medical Devices Regulations under the Food and Drugs Act. The goal of the *Medical Devices Regulations* is to ensure, to the extent possible, that devices offered for sale in Canada are safe, effective, and meet quality standards.

Device Licensing

Most medical devices must have a licence before they can be sold in Canada. Health Canada categorizes devices as Class I, II, III, or IV, based on the risks associated with their use, including the degree of invasiveness, duration of contact with the patient, energy transmission hazard, and consequences of device malfunction or failure.

Class I devices present the lowest potential risk and do not require a licence. Class II devices require the manufacturer's declaration of device safety and effectiveness, whereas Class III and IV devices present a greater potential for risk and are subject to in-depth regulatory scrutiny before licensing and sale. The cost-effectiveness of medical devices is not considered. Surgical procedures do not require Health Canada licensing.

In vitro Diagnostic Devices

In vitro diagnostic devices (IVDDs) include reagents, assays and equipment used for examining specimens taken from the body. IVDDs are regulated with a separate classification system, but are also designated as Class I, II, III and IV, based on the degree of risk associated with their use. For example, a blood test that detects bacterial meningitis is categorized as a Class III IVDD because of the risk that a false-negative test result may cause death or long-term disability due to delayed diagnosis. Class IV IVDDs include donor screening tests for transmissible viruses such as HIV and hepatitis, which present a high public health risk.

Quality Requirements

The Medical Devices Regulations require Class II medical devices to be manufactured under a quality standard (ISO standard 13488:2003) developed by the International Organization for Standardization. Class III and IV devices must meet ISO standard 13485:2003, which deals with both design and manufacturing standards.

Medical device classification system			
Device Class	Risk	Examples	Licence Requirements
Class I	Lowest	Surgical instruments, laboratory culture media	A device licence is not required, but the establishment where it is made and/or distributed must be licensed.
Class II	Low	Contact lenses, pregnancy test kits, endoscopes, ultrasound scanners	Manufacturers require a Health Canada licence before selling or advertising Class II, III and IV devices. Annual licence renewals are required.
Class III	Moderate	Orthopedic implants, glucose monitors, dental implants, hemodialysis machines	
Class IV	High	Cardiac pacemakers, angiography catheters, cranial shunts	

Application Process

The Medical Devices Regulations are supplemented by guidance documents, which outline the safety and effectiveness data required for each class of medical device. Licence applications are reviewed by Health Canada staff and licences are issued once all requirements are met. Manufacturers may appeal a decision if licensing is refused, or resubmit applications if additional information is required.

The regulations allow two instances where a medical device may be sold even though it has not met general safety and effectiveness requirements: investigational testing, and special access.

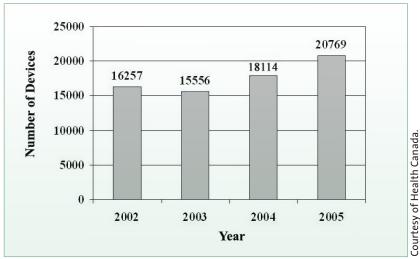
Modifications

Manufacturers frequently make small changes to their devices. Licence amendments are required if significant changes are made to Class III or IV devices, and manufacturers must provide objective evidence of device safety and effectiveness.

Investigational Testing in Human Clinical Trials

Manufacturers or importers may submit a clinical trial application to use unapproved Class II, III, and IV devices in clinical trials provided that:

 the life, health or safety of patients, users or other persons is not seriously endangered



Number of medical device licences renewed annually by Health Canada.

- it is not contrary to the best interests of the patients recruited to the trial
- the objective of the testing will be achieved.

Formal authorization is not required to use a Class I device in a clinical trial, although full trial records must be retained. Devices must be labelled "for investigational use only" and any serious adverse events must be reported to Health Canada within 72 hours.

Trial sponsors must identify all investigators and clinical trial sites and must comply with Research Ethics Board requirements, including protocol approval and informed patient consent. In making their final decision on the application, Health Canada reviewers evaluate the study protocol and design, the hypotheses, the validity of the endpoints and statistical methods, as well as the documentation and management of the trial.

The Special Access Program

This program allows health care professionals to apply for authorization to use medical devices that are not yet licensed in Canada for emergency use, or if conventional therapies have failed, are unavailable or unsuitable. Therapeutic

Products Directorate staff review each individual application to assess whether potential risks of using the device outweigh potential benefits.

Harmonization of Regulation with Other Countries

In July 1998, a new regulatory framework was implemented that brought Canada's regulatory requirements closer to those of the US, the European Union, Japan, and Australia. This framework will undergo continual modification and fine-tuning to appropriately regulate new and emerging medical devices.

The Medical Devices Active Licence Listing (MDALL) is a searchable database that lists Class II, III, and IV devices licensed in Canada.

Both active and archived licences may be viewed at: http://www.mdall.ca A listing of Class I devices is not available.

More information on regulations for Canadian medical devices is available at: http://www.hc-sc.gc.ca/dhp-mps/md-im/index e.html

CyberKnife®: Stereotactic Radiosurgery

The CyberKnife is a radiosurgery system that destroys tumours or other lesions using beams of radiation, rather than a surgical knife. The radiation is precisely focused, minimizing damage to healthy surrounding tissue.

While other radiosurgery systems are restricted to intracranial treatments, the CyberKnife can deliver radiosurgery to any part of the body.

How it Works

The CyberKnife uses a linear accelerator (linac), mounted on a robotic arm, to produce a high energy "killing beam" of radiation. In contrast to standard stereotactic techniques where a rigid metal frame is bolted to the patient's skull to restrict movements, the CyberKnife uses two ceiling-mounted x-ray cameras to guide the imaging in "real time" and makes constant adjustments for slight

movements. Patients with extracranial tumours or lesions may need to have metallic markers implanted to target the area and guide treatment.

Regulatory Status

The CyberKnife (Accuray Inc.) was licensed by Health Canada in August 2006;¹ however, to date, no CyberKnife units have been installed in Canada. According to the CyberKnife Society, there are more than 80 CyberKnife units operating worldwide, with about 50 in US centres.²

Evidence

Randomized controlled trials that compare patient outcomes and costs for CyberKnife treatments to those using other radiosurgery systems have not been published. Most of the available evidence is limited to case studies reporting the use of CyberKnife treatments for various conditions.

Several health technology assessments have reviewed the evidence on the CyberKnife.³⁻⁵ These reports concur that, at present, there is insufficient good quality evidence available to determine the efficacy and safety of the CyberKnife relative to other stereotactic radiosurgery techniques.

Photo courtesy of Accuray Inc.

The CyberKnife® Robotic Radiosurgery System.

Cost

The CyberKnife costs approximately US\$4 million, which includes the manufacturer's guidance during installation and staff training. Additional capital costs include facility construction or renovations to house the CyberKnife and special radiation shielding requirements.

A 2003 economic evaluation compared the costs of CyberKnife, Gamma Knife and Novalis stereotactic radiosurgery for neurological applications, including equipment, staffing and annual unit costs, with estimated patient loads based on modelling for Alberta.⁶ A 2006 ECRI assessment outlined additional costs that might be involved, including installation costs, extended warranties, closed-circuit cameras to monitor patients during treatment, and workstations for treatment planning.⁵ The estimated life expectancy of the CyberKnife system is 10 years.

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Ultrasound Has Potential in Stroke Treatment

The use of ultrasound to augment drug treatment may improve outcomes in acute stroke.

Tissue plasminogen activator (tPA) is a drug used to treat acute ischemic stroke – stroke associated with a clot causing blockage of blood flow to the brain. Continuous transcranial ultrasound monitoring of an occluded (or blocked) artery induces changes in the structure of the clot, resulting in faster penetration of tPA and enhanced clot breakdown (thrombolysis).'

Other approaches to augment tPA treatment include micro-bubble administration with transcranial ultrasound, ²³ and a catheter with an ultrasound transducer.⁴

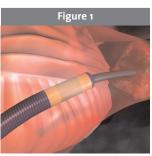
How it Works

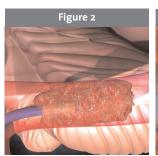
SonoLysis® therapy (ImaRx Therapeutics, Inc., Tucson, AZ) uses micro-bubbles – composed of a lipid shell and an inert, biocompatible gas – which are injected intravenously, with or without a thrombolytic drug. SonoLysis bubbles penetrate the clot, and transcranial ultrasound causes them to expand and contract. It is thought that this mechanical energy helps break up the clot.

The EKOS® Micro-Infusion Catheter (EKOS® Corporation, Bothell, WA) is a disposable infusion/ultrasound catheter with an ultrasound transducer at the tip. The ultrasound energy transmitted by the catheter helps to loosen the fibrin matrix and drive tPA into the blood clot for faster thrombolysis.

Who Might Benefit

These technologies have the potential to





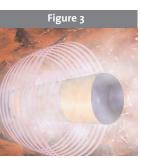


Image courtesy of EKOS Corporation.

The EKOS Micro-Infusion Catheter is guided to the site of the clot (Figure 1). Once positioning is verified (Figure 2), the ultrasound in the catheter tip is activated (Figure 3).

benefit persons diagnosed with acute ischemic stroke. In 2004 to 2005, there were 19,197 "new stroke episodes" in Canada, 88% of which involved ischemic stroke.⁵

Regulatory Approval

The SonoLysis system has not yet received approval from any regulatory body. Though not approved in Canada, the EKOS Micro-Infusion System has approval from the US Food and Drug Administration for regional infusion of contrast materials into selected vessels in the neurovasculature.⁶

Evidence

A non-randomized trial compared patients treated with tPA, ultrasound and galactose-based micro-bubbles to patients who received only tPA and ultrasound, and those who received only tPA.³ The complete recanalization rate (re-opening of blocked brain arteries) was significantly higher in patients treated with micro-bubbles than those in the other groups (54.5% versus 40.8% and 23.9%, p=0.038).

SonoLysis therapy is being evaluated for the treatment of acute ischemic stroke in a Phase I-II study.⁷

In a Phase II study, the EKOS Micro-Infusion Catheter was used in 34 of 52 patients who had a visible, treatable clot. The recanalization rate was higher than that found in an earlier Phase I study, which did not use ultrasound catheters (69% versus 55.6%).⁸ A 40-centre Phase III trial will provide further evidence on the efficacy of the EKOS Micro-Infusion Catheter in the treatment of ischemic stroke.⁸

Cost

The cost of these devices is unknown.

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Testing Newborns for Exposure to Alcohol During Pregnancy

The presence of a biomarker in a newborn baby's meconium – the first bowel movement – may determine whether a mother drank alcohol during her pregnancy.

The biomarkers are metabolic by-products of alcohol called fatty acid ethyl esters (FAEEs). FAEEs provide a biological record of prenatal alcohol exposure during the second and third trimesters since meconium begins to form during the 13th week of pregnancy and continues to accumulate until birth.¹ Testing for FAEEs at birth may help identify children who are at risk for fetal alcohol spectrum disorder (FASD). Alcohol consumption during the first trimester, which can also negatively affect fetal development,² is not detected by meconium testing.

Fetal Alcohol Spectrum Disorder (FASD)

FASD encompasses a range of physical,

mental, and behavioural effects due to prenatal alcohol exposure. Secondary disabilities associated with FASD include mental health problems, disruptions in schooling, employment problems, criminal behaviour, and alcohol or drug problems.³

FASD is difficult to diagnose because it requires confirmation of heavy maternal drinking, which is under-reported because women are reluctant to admit to risky behaviour during pregnancy. There are currently no specific laboratory markers for diagnosing FASD.'

Benefits of Early Diagnosis

Early diagnosis of FASD is associated with better long-term outcomes.¹³ Targeted interventions in childhood can reduce the risk for later secondary disabilities.³⁴ The diagnosis of FASD may also help prevent alcohol use during subsequent pregnancies by providing high-risk mothers with counselling and education.²

Prevalence of Alcohol Use During Pregnancy

An estimated 1% of infants show some prenatal alcohol-related damage.^{2,3} In

Reprinted with modifications from CMMJ 25-Nov-03;169(11): p. 1184 with permission. © 2003 Canadian Medical Association. 1. Alcohol consumption 3. Alcohol metabolized in fetal tissues Alcohol + Fatty acids (Alcohol) synthetase Fatty acid ethyl esters (FAEEs) 2. Alcohol crosses placenta and enters fetal circulation Placenta 4. FAEEs detectable in newborn's meconium **FAEEs**

Fetal alcohol spectrum disorder.

Canada, lifetime costs for additional education, disability payments, and health care for one person with FASD have been estimated at more than \$800,000.²

Evidence

In published studies, the sensitivity of the meconium test (to correctly identify babies that have been exposed to alcohol) ranges from 26.9%⁴ to 100%.³ Its ability to truly identify those who have not been exposed to alcohol ranges from 96.8%⁴ to 98%.³ Variation could be due to maternal consumption of small amounts of alcohol in medications or foods, genetic variations in alcohol metabolism, or illness.¹

Elevated levels of meconium FAEEs have not yet been correlated with adverse outcomes in newborn babies. Studies that monitor infants for several years are needed to determine whether FAEEs in meconium can be used as biomarkers of neurodevelopmental delay due to fetal alcohol effect.⁴

In a recent Calgary study, no association was found between a mother's self-reported alcohol use during pregnancy and FAEE levels in the meconium of 238 infants.⁵ Publication of the study results is pending.

Availability and Cost

The Motherisk lab at Toronto's Hospital for Sick Children offers the only meconium FAEE testing in Canada. The assay costs C\$150. It is not covered by provincial health insurance plans.

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Interactive Voice Response System Helps Bridge **Continuity of Care Between Hospital and Home**

A telephone follow-up program allows doctors to closely monitor patient recovery after hospital discharge. The automated calls use an Interactive Voice Response (IVR) system to ask personalized questions, and speech recognition technology to monitor responses.

How it Works

The IVR system calls the patients at home, early in their recovery phase, to ask a sequence of questions that screens for problems, such as inadequate pain control or shortness of breath. Patients respond with natural speech and, depending on their answers, subsequent questions may branch into several new series.

If a particular response – or combination of responses – suggests a serious problem, the call is transferred directly to a clinician at the hospital. Patients reporting minor symptoms receive a callback from a clinician within one day. Responses are electronically recorded in a database and clinicians can view results online or print data that are tabulated in various formats.

Algorithm

In each proprietary IVR algorithm (step-bystep procedure), questions are placed in a sequence that mimics a conversational interaction, with branching determined by specific responses. Voice professionals record the questions and the algorithm is tested in patient focus groups.

Algorithms can be customized to provide follow-up for patients for many health interventions, ranging from diabetes management to smoking cessation.

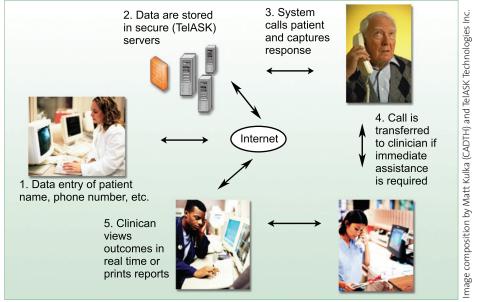
Potential Benefits

IVR increases clinician efficiency by monitoring the post-discharge progress of all patients and separating out those who need to speak to a clinician in person. Prompt intervention during recovery at home can avoid re-admission to hospital.

Studies have shown that patients may be willing to disclose more sensitive information, such as compliance with medication or alcohol use, during an IVR call compared to speaking with a human interviewer.1

for coronary heart disease. Smoking abstinence in the control group was 34.7% (17 of 49 patients) compared with 46.0% (23 of 50) in the patients who received IVR follow-up calls after discharge on days three, 14, and 30.

At the October 2006 Canadian Cardiovascular Congress, an Ottawa Heart Institute researcher reported that IVR follow-up was effective in the early identification of serious complications developing among 1,116 patients recovering at home following cardiac surgery.



The Interactive Voice Response (IVR) process.

IVR in Canada

Although telephone interviews with IVR systems were developed several years ago, their application in health care is relatively new in Canada. Several IVR systems have been developed by Ottawabased TelASK Technologies Inc., in collaboration with the University of Ottawa Heart Institute.

Preliminary Evidence

An unpublished, randomized controlled feasibility study, conducted at the Ottawa Heart Institute, reported the results of IVR follow-up to support smoking cessation after patients were hospitalized

Cost

According to TelASK, developing an IVR application costs from C\$35,000 to C\$50,000, depending on the complexity of the algorithm and the reporting required. Ongoing charges of up to C\$20 per patient cover the costs of placing the calls, hosting the system in a secure Internet data centre, and providing training and support to hospital staff.

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New and Emerging Health Technology Reports

Recent Reports from CADTH and Other HTA Agencies

These reports are available without cost at the web sites shown below:

Australia and New Zealand Horizon Scanning Network (ANZHSN)

Primer and probe set for the diagnosis of avian influenza

Available: http://www.health.gov.au/internet/horizon/publishing.nsf/Content/8F86C8B4D8513895CA25715Cooo5D972/\$File/Primer%20and%20probe%20set%20of%20avian%20influenza%20Vol%2014%20N0%201%2oSept2006.pdf

Nicotine metabolite ratio test as a predictor of smoking cessation

Available: http://www.health.gov.au/internet/horizon/publishing.nsf/Content/8F86C8B4D8513895CA25715Cooo5D972/\$File/Nicotine%20metabolite%20Vol%2014%20N0%204%20Sept2006.pdf

Canadian Agency for Drugs and Technologies in Health (CADTH)

Transient elastography (FibroScan) for non-invasive assessment of liver fibrosis

Available: http://www.cadth.ca/media/pdf/ 442_fibroscan_cetap_e.pdf

Digital mammography: an update

Available: http://www.cadth.ca/media/pdf/ 444 digital mammography_cetap_e.pdf

Open magnetic resonance imaging (MRI) scanners

Available: http://www.cadth.ca/media/pdf/ Eoo11_MRIScanners_cetap_e.pdf

"Hot" techniques for tonsillectomy

Available: http://www.cadth.ca/media/pdf/ E0003 tonsillectomy cetap e.pdf Intra-articular hyaluronic acid (viscosupplementation) for knee osteoarthritis

Available: http://www.cadth.ca/media/pdf/ E0010 viscosupplementation cetap e.pdf

Ontario Medical Advisory Secretariat (MAS)

Energy delivery systems for treatment of benign prostatic hyperplasia

Available: http://www.health.gov.on.ca/eng lish/providers/program/mas/tech/reviews/p df/rev bph o81806.pdf

Gastric electrical stimulation

Available: http://www.health.gov.on.ca/eng lish/providers/program/mas/tech/reviews/p df/rev_ges_081806.pdf

☐ Negative pressure wound therapy

Available: http://www.health.gov.on.ca/eng lish/providers/program/mas/tech/reviews/p df/rev_npwt_070106.pdf

US California Technology Assessment Forum (CTAF)

An interspinous process distractor (X Stop) for the treatment of spinal stenosis of the lumbar spine

Available: http://www.ctaf.org/content/ass essments_pdf/82151206101_XSTOP0606.pdf ;jsessionid=3C7B8118D138F067D1855CF9E44 FEFC7

Brachytherapy for accelerated partial breast irradiation following conserving surgery

Available: http://www.ctaf.org/content/ass essments_pdf/82151206100_Brachytherapy 0606.pdf;jsessionid=3C7B8118D138F067D18 55CF9E44FEFC7



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600-865 Carling Ave. Ottawa, ON Canada K1S 5S8

Tel: (613) 226-2553

Fax: (613) 226-5392

Web site: www.cadth.ca

Editor/Writer: Catherine Allison

Contributing Writers: William Freeland, David Hailey, Leigh-Ann Topfer

Information Specialists: Michelle Fiander, Hayley Fitzsimmons, Shaila Mensinkai, Andra Morrison

Copy Editor: Kinneret Globerman

Layout and Design: Matt Kulka, Nathalie Charron **Web Designers:** Martha Hodgson-Oram, Paul Ting

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