Top 10 New & Emerging Health Technology Watch List: **2014**

- Antimicrobial Copper Surfaces to Reduce Hospital-Acquired Infections in Intensive Care Settings
- Ex vivo Lung Perfusion Device to Preserve and Assess Donor Lungs Prior to Transplant
- Ipilimumab for Unresectable or Metastatic Melanoma
- Mitral Valve Clip for Degenerative Mitral Regurgitation
- Obinutuzumab (plus Chlorambucil) for Newly Diagnosed Chronic Lymphocytic Leukemia
- Remote Ischemic Conditioning (RIC) Device to Prevent Cardiac Ischemia and Infarction in Patients Undergoing Cardiac Surgery
- Retinal Implant to Improve Vision in Patients with Retinitis Pigmentosa
- Self-Expanding, Drug-Coated Stent for the Treatment of Peripheral Arterial Disease
- Trastuzumab Emtansine (T-DM1) for HER2-Positive Metastatic Breast Cancer
- Tympanostomy Tube Insertion Delivery System for Children With Chronic Ear Infections

Antimicrobial Copper Surfaces to Reduce Hospital-Acquired Infections in Intensive Care Settings

Who Might Benefit?

Health care-associated infections (HAIs) — infections that patients acquire while in health care settings — are a concern, especially for patients in the intensive care unit (ICU). In Canada, approximately 200,000 patients acquire HAIs on a yearly basis, with an estimated mortality of 8,000 per year. Bacterial contamination on various surface areas in health care facilities can be a source of transmission to patients, health professionals, and visitors. Adequate control of hospital-acquired infections can reduce morbidity and mortality, and increase the quality of life of patients receiving health care.

Current Practice

Regular touch surfaces are generally made of stainless steel, plastic, or other materials, and are cleaned regularly according to guidelines and policies. These policies outline the types of products to be used for cleaning, the frequency of cleaning, and describe how to clean specific surfaces. Factors that influence cleaning practices include: the type of activity conducted in the area (e.g., ICU) and its associated risk of infection, the frequency of contact with the touch surface, the vulnerability of patients, and the probability of contamination from bodily fluids.

> Antimicrobial copper surfaces that help prevent and control bacterial contamination, transmission, and rates of infection

What's New?

Touch surfaces made of antimicrobial copper and copper alloy (brasses and bronzes) appear to be a promising alternative that may improve the prevention and control of infection and, therefore, offer safer health care environments for patients. When incorporated on surface areas such as bedrails, handrails, door handles, work surfaces, intravenous (IV) poles, and washroom components, the natural antimicrobial properties of copper would reduce bacterial contamination, transmission, and rates of infection.

Potential Advantages

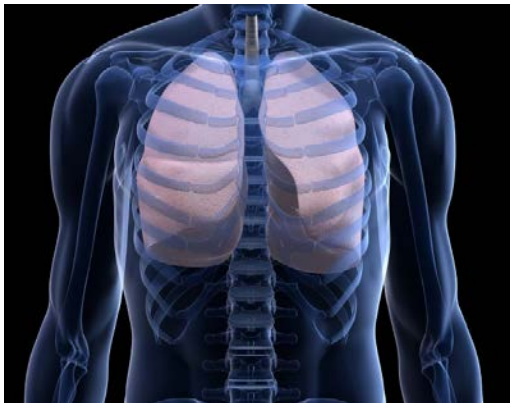
The lower levels of bacteria on copper surfaces in an ICU setting have led to a reduction in rates of health care-acquired infection. This new technology, which is intended to deliver antibacterial activity in between regular cleaning intervals, is purported to have antibacterial properties that last the product's lifetime. It appears the antimicrobial copper surfaces achieve a 99.9% reduction in both gram-negative and gram-positive bacteria within two hours of exposure.

Additionally, it appears the copper alloys are safe both for humans and the environment. Its effectiveness in decreasing infection rates in hospitals and other health care settings may also increase the quality of life for patients.

Ex vivo Lung Perfusion Device to Preserve and Assess Donor Lungs Prior to Transplant

Who Might Benefit?

Lung transplantation is a treatment option for a variety of respiratory conditions, including chronic obstructive pulmonary disease, interstitial lung disease, cystic fibrosis, and idiopathic pulmonary hypertension. In Canada, the number of people on the waiting list for a lung transplant has doubled during the last decade, from 150 people to more than 300. Although 180 lung transplants are typically performed annually in Canada, more than 40 patients die each year while on the waiting list for transplantation.



Current Practice

Successful lung transplantation depends on several factors throughout the process of organ donation, from preservation of the lung during transportation to transplantation into the recipient. Once the donor lungs have been removed, they are traditionally preserved by being flushed with a preservative solution and placed on ice; however, the longer the lung is kept on ice, the greater the risk of organ damage due to hypothermia and lack of oxygenated blood circulation. Deterioration of donor lungs can lead to impaired lung function, complications such as primary graft dysfunction, or death. It is estimated that 80% to 85% of donor lungs are unsuitable for transplantation.

Portable warm blood perfusion system for lung preservation before transplantation

What's New?

A new portable lung-preservation system uses normothermic (warm) oxygenated blood to keep donor lungs functioning outside the body while they are being transported from donor to recipient. The donor lungs are removed and placed into a perfusion module chamber designed to maintain the warm temperature and humidity. This system provides a constant supply of oxygen and preservation solution that contains packed red blood cells. A wireless monitor allows clinicians to continuously assess the function of the lungs to ensure the organ is viable.

Potential Advantages

The warm blood lung-perfusion system improves the condition of donor lungs by maintaining the circulation of oxygen and nutrients to the lung tissue. This system minimizes the organ damage commonly seen with cold storage methods. Continuous monitoring and quality assessment of the lungs can be conducted until transplantation. Compared with cold storage, early trial results have shown improved patient survival at six months and fewer lung-related complications. This technology has the potential to improve the quality of donor lungs. As a result, many lungs that previously would have been rejected for transplantation may be considered suitable. This could increase the number lungs available to patients currently on the waiting list for transplant.

Ipilimumab for Unresectable or Metastatic Melanoma

Who Might Benefit?

Rates of skin cancer in both men and women are increasing worldwide. An estimated 6,000 Canadians were diagnosed with melanoma in 2013, and 1,050 Canadians will die from the disease. When diagnosed early, melanoma may be cured by surgical removal of the tumour. However, if the melanoma cannot be removed with surgery or the cancer has spread or metastasized, the disease progresses quickly; patients with advanced melanoma have a median survival time of less than one year.

Current Practice

When surgery is not appropriate, melanoma treatment focuses on therapies to prevent tumour spread, shrink metastases, and relieve patients' symptoms. Treatment options include radiation therapy, chemotherapy, or drug therapy using biological agents. In Canada, chemotherapy with dacarbazine, temozolomide, or carboplatin plus paclitaxel are commonly used, but advanced melanoma is an aggressive disease and chemotherapies have been largely ineffective in extending patients' life expectancy. Due to the low effectiveness of currently available treatments for patients whose melanoma is not curable with surgery, there is no accepted standard of care.

> Ipilimumab immunotherapy for patients with previously untreated unresectable or metastatic melanoma

What's New?

Immunotherapy is a recent option in cancer treatment. Instead of targeting the tumour itself, immunotherapy works by stimulating the body's natural immune system to fight the cancer. Immunotherapy agents such as interferon alpha and interleukin-2 have been used in the treatment of advanced melanoma, but these treatments have low response rates with no improvement in overall survival. Ipilimumab is a human monoclonal antibody that has an innovative mode of action compared with other immunotherapy agents. Ipilimumab works by blocking cytotoxic T lymphocyte-associated antigen (CTLA-4) to increase the tumour-specific immune response. Ipilimumab is approved in Canada for the treatment of inoperable or metastatic melanoma in patients where other treatments have failed, or for patients who cannot tolerate other therapies for advanced disease.

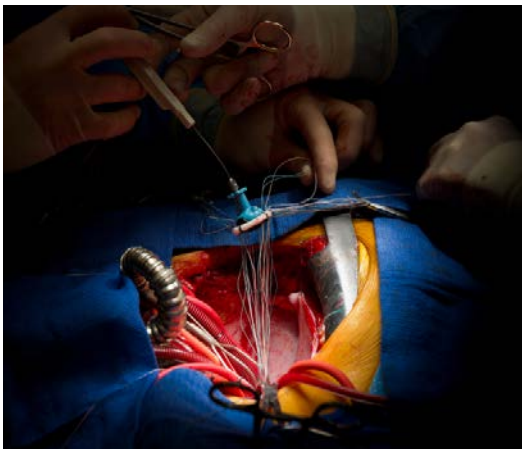
Potential Advantages

Ipilimumab is the first therapy to demonstrate an improvement in survival for advanced melanoma. In a study of patients who had tried previous therapies for metastatic melanoma, treatment with ipilimumab nearly doubled survival rates at both 1 year and at 18 months, compared with a glycoprotein vaccine. The survival benefit observed with ipilimumab may also occur in patients with previously untreated metastatic melanoma. Side effects are generally mild to moderate immune-related events. For patients with metastatic melanoma ipilimumab treatment is not associated with a significantly negative impact on quality of life.

Mitral Valve Clip for Degenerative Mitral Regurgitation

Who Might Benefit?

Mitral regurgitation, also called mitral insufficiency, is the most common heart valve disorder, where the heart valve that separates the upper and lower chambers on the left side of the heart does not close properly. The condition causes a backward flow of the blood in the heart and may raise the risk of irregular heartbeat, stroke, and heart failure. Significant (moderate or severe) mitral regurgitation occurs in approximately 2% of the population and its frequency increases with age. If untreated, the condition can be debilitating and fatal.



Current Practice

The choice of treatment depends on the symptoms, severity of the condition, and its effect on the heart's function. In milder cases of mitral regurgitation, the use of medication can help to ease disease symptoms. In more severe cases, however, heart surgery to repair or replace the valve is the treatment of choice. Although open heart surgery has a very good success rate, it may not be suitable for patients who are at high risk of developing surgical complications, such as patients who may be too ill or too frail to survive open heart surgery.

> A new catheter-based, less invasive approach to mitral heart valve repair

What's New?

The MitraClip device is a new catheter-based, less invasive approach to mitral valve repair that can provide an alternative option for patients with severe mitral regurgitation who are too high risk to undergo surgery. The device is inserted using a long, flexible, soft plastic tube (catheter) through a small incision in the groin area and delivered into the heart through the femoral (leg) vein. After positioning the clip in the region of the mitral valve, the catheter is removed. The procedure is performed under general anesthesia.

Potential Advantages

In a catheter-based percutaneous intervention, the mitral valve is repaired without the need for an invasive surgical procedure. The existing scientific evidence suggests that this procedure can be a safer approach than open heart surgery, especially for high-risk patients. It can also be considered as a preferred option by the patients who seek a less invasive treatment option. The device allows the heart to pump blood more efficiently by improving valve closure. As a result, the procedure can relieve the symptoms of mitral regurgitation and improve quality of life. In the recent clinical studies, patients who underwent percutaneous mitral valve repair interventions experienced shorter recovery times and a shorter hospital stay (two to three days).

Obinutuzumab (Plus Chlorambucil) for Newly Diagnosed Chronic Lymphocytic Leukemia

Who Might Benefit?

Chronic lymphocytic leukemia (CLL) is the most common adult leukemia in Western countries, representing approximately 3% of all new cancer cases each year in Canada. Most patients with CLL are older than 70 years of age, and many present with coexisting medical conditions.

Current Practice

There is no agreed standard treatment regimen for symptomatic CLL. Chemotherapy, considered the conventional therapy, involves the use of chemotherapy drugs that target and kill cancer cells. For previously untreated CLL patients who are in good health, aggressive chemotherapy with a combination of highly toxic drugs such as fludarabine, cyclophosphamide, and rituximab (FCR) has been shown to prolong patients' overall survival; however, for patients with coexisting medical conditions, limited treatment options are available. The common choices include drugs such as chlorambucil (with or without rituximab), bendamustine (with or without rituximab), ofatumumab (only in clinical studies), or reduced doses of FCR.

> Combination therapy with obinutuzumab and chlorambucil, a new and effective option to treat newly diagnosed CLL patients with coexisting medical conditions

What's New?

Obinutuzumab is a new anti-cancer drug that works by stimulating the body's immune system to attack cancer cells. This drug targets white blood cells (called B lymphocytes) that have a surface marker known as CD20. The combination of obinutuzumab and chlorambucil has shown promise as a superior treatment option for CLL patients with coexisting medical conditions who had not received treatment previously.

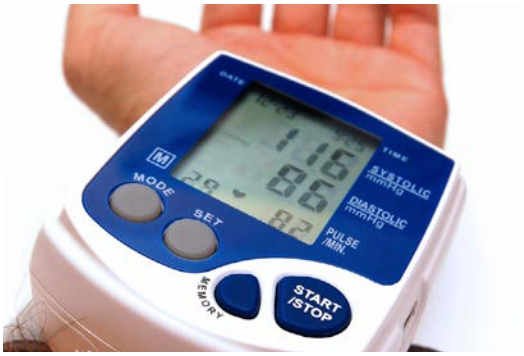
Potential Advantages

For previously untreated patients with CLL who have coexisting medical conditions, obinutuzumab in combination with chlorambucil appears to be a more effective treatment compared with chlorambucil alone. The combination therapy demonstrates a large (84%) risk reduction in disease worsening or death. Obinutuzumab in combination with chlorambucil more than doubles the chance of living without disease progression in CLL patients. The common adverse events are reported to be generally manageable infusion-related reactions.

Remote Ischemic Conditioning (RIC) Device to Prevent Cardiac Ischemia and Infarction in Patients Undergoing Cardiac Surgery

Who Might Benefit?

Every year, tens of thousands of Canadian patients suffer from severe cardiac ischemic injury — damage caused by a restriction in the blood supply to the heart — brought on by cardiac surgery or a heart attack. When blood flow to cardiac cells is disrupted and then restored, it creates a risk for a type of ischemic heart damage known as reperfusion injury.



Current Practice

Many treatments to limit or prevent reperfusion injury have been tested. Although there has been an improvement in health care providers' understanding of the processes that cause the damage, no therapies have emerged as an optimal solution to this problem. Two possible reasons for this lack of treatment success are that optimizing the timing of treatment administration is challenging, and the multitude of factors contributing to the reperfusion injury process is complex.

> A non-invasive automated device that may prevent or limit heart damage in patients undergoing cardiac surgery

What's New?

A non-invasive automated cuff is now available that is worn on the arm or leg to temporarily stop and then restart blood flow through a series of inflations and deflations.

This process is called remote ischemic conditioning. Conducted in non-critical tissue, the process can activate the body's defensive mechanisms against reperfusion injury. The cuff can be used prior to, during, or after cardiac surgery, or after an acute injury such as a heart attack. It can be applied in a hospital, in an ambulance, or at home. The device has a disposable cuff that operates in five-minute inflation and deflation cycles for a total of 40 minutes.

Potential Advantages

This is the first automated device to provide remote ischemic conditioning. For health care providers, it may offer a time saving compared with manually operating a standard blood pressure cuff to produce the same conditioning effect. The device has been found to significantly reduce major negative heart- and stroke-related events in patients undergoing heart surgery or suffering a heart attack. Since favourable results have been shown in many long-term studies, especially in patients who wear the cuff before surgery, the device has the strong potential to protect the heart from damage.

Retinal Implant to Improve Vision in Patients with Retinitis Pigmentosa

Who Might Benefit?

Retinitis pigmentosa is a group of eye disorders involving the retina that causes slow but progressive loss of vision. It affects approximately 11,000 Canadian adults. Although the cause of retinitis pigmentosa is not known, about half of all cases are linked to a family history.

Current Practice

There is currently no cure for retinitis pigmentosa, and no treatment to delay its progression. Vitamin supplements, dietary changes, and wearing darkened glasses may be of some benefit.

> A "bionic eye" that may restore some vision in adults with retinitis pigmentosa

What's New?

A new prosthetic, one that has been likened to a "bionic eye," has been developed to possibly restore some vision in adult patients with retinitis pigmentosa and severe sight impairment. The prosthetic retina is surgically attached to the back of the eye in patients who have some remaining light perception and nerve function in the eye. The implant electrically stimulates the retina in order to produce light perception. It is attached externally to a camera and video-processing unit through a cable connected to a pair of glasses worn by the patient.

Potential Advantages

The device has the potential to restore some level of vision and improve patients' independence and mobility, although proof of its long-term effects is not available. Studies have shown that patients who received the implant had improved performance in distinguishing motion, recognizing letters, and perceiving colours. The cost of the device and its surgical implantation is estimated to be US$115,000, with some additional associated costs, such as patient and health care provider training and support. It is suggested, however, that these costs would be outweighed because of potential savings related to reduced patient need for social care and support services.

Self-Expanding, Drug-Coated Stent for the Treatment of Peripheral Arterial Disease

Who Might Benefit?

The superficial femoral artery (SFA) is a long vessel in the thigh that carries blood and oxygen to the leg. This artery is a frequent site of vascular blockage due to the deposition of fatty plaques (atherosclerosis), inflammation, or blood clots. The narrowing or occlusion of this artery can cause pain or discomfort in leg muscles when the person walks, due to reduced blood flow. This condition can be debilitating and can prevent patients from working and performing daily tasks. The condition is more common in the elderly, smokers and diabetic patients. Its frequency rate is reported to be 4% in Canadians older than 40, and this number increases to 20% in people older than 75.

Current Practice

In addition to lifestyle changes and medications to manage underlying disorders, angioplasty and stenting or surgical procedures might be recommended in some cases. Angioplasty is a less invasive procedure where a catheter is inserted through a small puncture over an artery in the patient's arm or groin and guided to the blocked area. Once in place, a special balloon, which is attached to the catheter, is inflated and deflated several times to widen the vessel and allow the blood to flow. A tiny mesh-metal tube, called a stent, is often inserted into the narrowed area to hold the vessel open. In surgical revascularization, a graft (made from one of the patient's veins or from man-made materials) is used to create a detour around the narrowed or blocked area of the leg artery.

A new self-expanding, drug-eluting stent for peripheral artery disease of the superficial femoral artery

What's New?

An important advancement in the treatment of SFA occlusion has been the introduction of a stent that is coated with a drug to help prevent the artery from narrowing again. This drug-eluting stent is the first stent indicated for use in the SFA. It is made of a material that is self-expanding and that returns to its original shape after external pressures are removed. Its external surface is coated with a drug named paclitaxel to prevent the artery from narrowing again.

Potential Advantages

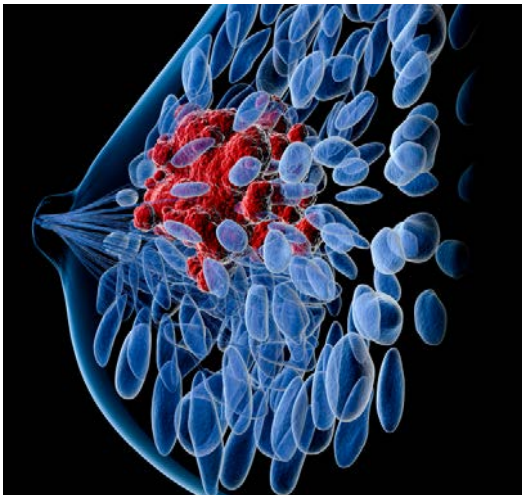
Drug-eluting stents have been shown to reduce re-occlusion rates by 50% and reduce surgical re-intervention rates significantly, when compared with regular (uncoated) metal stents. The use of drug-eluting stents for the treatment of SFA occlusion can potentially lead to an improvement in quality of life, as well as higher cost savings in public health care due to fewer reocclusions and a reduced need for repeated therapeutic interventions.

Trastuzumab Emtansine (T–DM1) for HER2-Positive Metastatic Breast Cancer

Who Might Benefit?

Breast cancer is the most frequent cancer and the leading cause of cancer-related death among women worldwide. In Canada, breast cancer is the second-leading cause of death in women. Every day in Canada, approximately 65 women are diagnosed with breast cancer and 14 women die because of the disease.

A specific protein called human epidermal growth factor receptor 2 (HER2) may be found in large amounts on the surface of some cancer cells. Women with breast cancer who are in an advanced stage of the disease, and who test positive for the HER2 gene, experience an aggressive form of the cancer and have shorter survival. Approximately one in five patients diagnosed with breast cancer will have HER2-positive disease.



Current Practice

Chemotherapy is the standard treatment for advanced breast cancer. This type of treatment involves the use of chemotherapy to stop the growth of cancer cells, either by stopping them from dividing or by killing them. Combining HER2-targeting medicines with standard chemotherapy is an effective therapeutic approach for patients with HER2-positive advanced breast cancer.

> T-DM1 is a novel, targeted therapy for the treatment of HER2-positive advanced breast cancer

What's New?

The introduction of trastuzumab emtansine (T-DM1) provides an alternative treatment option for patients with HER2-positive advanced breast cancer who have been previously treated with trastuzumab (an anti-HER2 treatment) and a taxane (a form of chemotherapy).

T-DM1 is a single agent that incorporates three components: an anti-HER2 agent (trastuzumab) that recognizes and attaches to HER2 receptors, a stable linker, and an anti-cancer substance (DM1). T-DM1 allows drug delivery specifically to HER2-cancer cells, thereby minimizing the exposure of normal cells to therapy.

Potential Advantages

When compared with standard treatment, clinical evidence suggests that T-DM1 alone can prolong the chance of living without disease progression, improve a patient's overall survival by 5.8 months, and lower adverse events. It potentially improves health-related quality of life. This targeted approach allows for greater efficacy and lowered toxicity, compared with standard treatment.

Tympanostomy Tube Insertion Delivery System for Children With Chronic Ear Infections

Who Might Benefit?

Middle ear infections are one of the most common childhood illnesses, with 75% of children having at least one episode by one year of age. Though ear infections are usually not serious, many children suffer from frequent infections, especially between six months and five years of age. Ear infections result in pain, anxiety, loss of sleep, and numerous doctors' visits for the children and their caregivers.

Current Practice

Generally, a child with frequent and persistent middle ear infections is referred to an ear, nose, and throat surgeon. The surgeon inserts a tympanostomy tube into the eardrum to equalize the air pressure in the middle ear and help drain any fluid. The procedure usually requires general anesthesia. Although there is some controversy surrounding whether inserting a tympanostomy tube improves a child's long-term development, it remains one of the most common same-day surgeries performed on children in Canada and has a significant cost impact on the health care system.

An integrated in-office tube delivery system to treat children with chronic ear infections

What's New?

A new, integrated in-office tube-delivery system may provide an alternative to conventional surgery. The device combines the administration of a local anesthetic with tube delivery. Ten minutes after administering the anesthetic, the tube-delivery system makes a rapid incision in the eardrum and deploys a tube into the ear in a single, automated motion.

Potential Advantages

Successful insertion rates for the new system are comparable to conventional surgery, though long-term follow-up information is not available. The new in-office tube-delivery system may offer fewer risks compared with conventional surgery because it eliminates the need for general anesthesia. It may also remove the costs and wait times associated with the use of general anesthetic in conventional surgery. The new procedure should be tolerated by most pediatric patients, as published evidence suggests the average level of pain felt during the in-office procedure was minimal.

The impact of this technology on the volume of surgeries currently being performed in Canada and the associated wait times is unknown; however, since the wait time between referral and treatment with conventional surgery is approximately five months, the impact of the tube-delivery system should be favourable.