Six Canadian Innovations Scaling Up to Improve Global Health

Projects in Vancouver, Waterloo, Hamilton, Ottawa, Kingston, Montreal to receive next-step scale-up funding from Grand Challenges Canada

Mobile phone app enables self-diagnosis of HIV/AIDS;
Sterile cover turns a hardware store drill into a surgery tool;
iPad audiometer makes hearing screening simple;
more

Toronto, Canada – Six Canadian innovations showing evidence of early promise for improving global health will “transition-to-scale” thanks to new support from Grand Challenges Canada, funded by the Government of Canada.

The new investments, matched by a wide range of partners, will enable the innovators to advance the development of their technologies and deploy them further throughout the developing world.

The investments build on significant results from seed projects also funded by Grand Challenges Canada:

- **Arbutus Medical (Vancouver, BC):** In clinical trials in East Africa, surgeons operated on bone injury patients using a low-cost hardware store drill enveloped in a safe, affordable Drill Cover system to reduce tool cost and improve infection control practices. Researchers recorded reduced surgical time using the covered power drill vs. hand drills, and performance was comparable to surgical drills valued at up to $30,000. Next steps: product launches in East Africa and India, and development of new products such as a surgical saw system that will help make safe surgical equipment more accessible worldwide.
  
  *Scaling partners:* Crown Healthcare Africa, priMED Medical Products, Intellecap

- **KA Imaging (Waterloo, ON):** A novel, high-resolution X-ray imager was shown to achieve the same levels of accuracy as conventional chest X-rays, at a significantly lower X-ray dose and cost. New support from Grand Challenges Canada and partners will
enable the innovators to continue building and testing their highly promising prototype in Zambia.

Scaling partners: Christie Medical Holdings, Delft Imaging Systems, Ontario Centres of Excellence

- McMaster University (Hamilton, ON): Studies in Botswana showed that over one-third of 671 babies hospitalized with severe diarrhea – including 17 of 26 who ultimately died – were infected with a treatable pathogen but had not been treated due to conventional clinical practice. Canadian researchers will develop a new approach that could fundamentally change the management of acute childhood diarrheal disease in low-resource settings, integrating a new rapid molecular syndromatic diagnostic tool (the FilmArray® Gastrointestinal panel), targeted antimicrobial treatment, and probiotic therapy.

Scaling partners: Botswana Ministry of Health, the Botswana-UPenn Partnership, bioMérieux, BioGaia, Copan Italia

- Clearwater Clinical (Ottawa, ON): In Uganda, the first iPad audiometer (ShoeBOX) was clinically validated, screening 868 children for hearing loss, 139 of whom were diagnosed with hearing loss. The low-cost, portable technology will now be used to screen hundreds of thousands of people for hearing loss across South America.

Scaling partners: Angel investors, Business Development Bank of Canada

- Wema Inc. and Queen’s University (Kingston, ON): In a pilot study in Tanzania, health workers shared smartphone images and consulted distant experts on possible cervical cancer cases. The project found experts fully agreed on 94.6% of diagnoses done by health providers within just one month of training. A second study in Bangladesh found that community health workers using the guidance and support of the smartphone applications interviewed more women, had superior data completeness, and identified more women with possible breast abnormalities. Now, the projects will be merged to develop mobile phone-based innovations for low resource settings to help local health workers screen for cervical cancer, and promote community awareness and early breast cancer detection.

Scaling partners: Ministry of Health and Social Welfare in Tanzania, Marie Stopes International, Elizabeth Glaser Pediatric AIDS Foundation (Tanzania) and multiple local partner organizations working in women’s health.

- Sympact-X and the Research Institute of McGill University Health Centre (Montreal, QC): A smartphone-based HIV self-test application (HIVSmart!) helped identify undiagnosed HIV cases and people at risk of infection. In a trial of 251 healthcare workers, all those who self-tested positive for HIV sought counselling and care. A majority (91%) of participants rated the tool easy-to-use, non-invasive, private and painless. With new support from Grand Challenges Canada and partners, HIVSmart! will be implemented and tested across South Africa.

Scaling partners: Grand Challenges South Africa, South Africa Medical Research Council’s Strategic Health Innovation Partnerships program, South Africa’s Department of
Science & Technology, Orasure Technologies, the Research Institute of McGill University Health Centre and the University of Cape Town.

Based on these promising outcomes funded by Grand Challenges Canada, the innovators will now receive “transition-to-scale” investments. The new funding, totalling CDN $5 million, will be doubled by partners in the six projects, creating a total investment of $10 million.

Since launching in 2010, Grand Challenges Canada has supported a pipeline of over 700 innovations in more than 80 countries, including 70 “transition-to-scale” investments.

“These Bold Ideas with Big Impact show how innovation can accelerate international development to save and improve the lives of the world’s poorest and most vulnerable people,” said Dr. Peter A. Singer, Chief Executive Officer of Grand Challenges Canada. “Canadians are an innovative people – as these Canadian innovators demonstrate.”

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**Transition To Scale Projects – Detailed Descriptions**

**Drill Cover: Novel cover enables safe use of low-cost hardware drills in surgery**  
*Arbutus Medical / Vancouver, BC (Implementation Regions: East Africa and India) $1 million*

A novel medical device revolutionizing orthopaedic surgery in the developing world will be launched in new markets through Grand Challenges Canada’s support, allowing hospitals to improve infection control and help thousands of patients to avoid permanent disability.

This product is now FDA listed in the US and has treated over 10,000 patients across 14 countries.

The Drill Cover, developed by Arbutus Medical, a Vancouver-based global health tech startup, is surgical grade, sterilizable, reusable, waterproof, and blood and pathogen resistant.

It envelops a low-cost hardware store drill, enabling its safe use for bone surgery – presenting a significantly more accessible alternative to surgical drills priced up to $30,000.

In low- and middle-income countries, basic surgical care has the potential to play a major role in reducing the burden of injuries. However, 5 billion patients do not have access to safe surgical care. Lack of access to affordable care is a significant barrier for many hospitals trying to provide surgical care to thousands of patients.

Surgical drills are often not available in resource-constrained areas, forcing hospitals to resort to
inefficient and dangerous “hand-crank” drills, or improvise with nonsterile construction drills.

In clinical tests comparing the Drill Cover innovation to hand drills, also funded by Grand Challenges Canada’s Stars in Global Health program, the Drill Cover shortened surgical time by nearly 30 minutes per case, while surgeons reported fewer problems during bone drilling tasks.

With new transition-to-scale funding from Grand Challenges Canada and partners, Arbutus has completed remaining product refinements, successfully achieved FDA listing in the US, and is currently scaling the product across East Africa and India, while developing new products for tools such as surgical saws.

Arbutus’ primary focus is on hospitals and surgeons in low- and middle-income countries, but has complementary opportunities with disaster/conflict relief organizations, veterinary surgeons, and military hospitals.

Arbutus is collaborating closely on scaling this product with distribution partners such as Crown Healthcare Africa, working on market strategy implementation in India with Intellecap, and is supported through mentorship by Edmonton-based medical device company priMED Medical Products.

Digital X-ray: A low-cost, low-dose and high-resolution x-ray imager
KA Imaging / Waterloo, ON (Implementation Country: Zambia) $1 million

New funding from federally-funded Grand Challenges Canada and partners will enable KA Imaging to build and test a low-cost, high-resolution digital X-ray imager for use in the developing world.

Between two-thirds and three-fourths of the world’s population has inadequate or no access to medical imaging - a critical problem, as medical imaging is used to diagnose some of the world’s top killers, including child pneumonia, tuberculosis, cancer, and cardiac disease.

With funding from Grand Challenges Canada’s Stars in Global Health program, KA Imaging addressed this issue by developing an affordable, high-resolution, low-dose medical imager, 40% more sensitive than current digital imagers.

Digital X-ray offers significant advance from current systems screening systems that use sputum microscopy or film x-rays, which can be time-consuming and expensive. The innovation costs under $.50 per test (compared to $8.72 with a standard X-ray) and offers rapid diagnosis. The imager is also the lowest-dose real-time X-ray detector available, which means that more X-rays can be taken, helping in the diagnosis of pneumonia in children.
KA Imaging, a University of Waterloo spin-off company led by Dr. Karim S. Karim and Amol Karnick, evaluated and validated their prototype with the help of a team of radiologists from Aga Khan University Hospital. Results demonstrated that the KA Imager achieve the same level of accuracy as conventional imagers, at a lower X-ray dose and cost.

With new transition-to-scale funding from Grand Challenges Canada, KA Imaging will continue to build and test their prototype. Through the installation of a single unit in Zambia, an estimated 960 individuals are expected to be diagnosed with tuberculosis by September 2016.

Partners include the University of Waterloo, Christie Medical Holdings, Delft Imaging Systems, and Ontario Centres of Excellence.

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**A new, innovative way to manage acute childhood diarrheal disease**

*McMaster University / Hamilton, ON (Implementation Country: Botswana) $475,000*

Building off the successful completion of two proof-of-concept projects funded by Grand Challenges Canada, Canadian innovators will develop a potentially transformative way to manage childhood diarrhea in low-resource settings.

Diarrhea is the second-leading cause of death of children under five, with the majority of deaths occurring in low-income countries. It is also a major contributor to stunting, malnutrition, cognitive dysfunction, and reduced adult human capital and economic productivity.

With new funding from Grand Challenges Canada, the researchers will develop and test a ‘test and treat’ method of addressing childhood diarrhea.

The new management algorithm has the potential to displace existing guidelines for the testing and treatment of childhood diarrhea, which recommend antimicrobial therapy if blood is found in a child’s stool. Studies funded by Grand Challenges Canada’s Point of Care Diagnostics and Stars in Global Health programs showed that these guidelines may leave significant numbers of cases untreated where death could be averted.

Published by the *Journal of the Pediatric Infectious Disease Society*, one study documented that over one-third of 671 babies hospitalized with severe diarrhea – including 17 of 26 (65%) who ultimately died – were infected with a treatable pathogen, infections that had gone unrecognized at the hospital and therefore generally went untreated. The pilot trial also demonstrated that *Lactobacillus reuteri* treatment of children with gastroenteritis showed much promise for the mitigation of damage caused by acute diarrhoeal disease.
The researchers say that the ‘treatment gap’ revealed in their Botswana research uncovers a major opportunity to make a big long-term impact in child health worldwide.

Now, led by David Goldfarb, MD (formerly of McMaster University, now at the University of British Columbia), along with Jeffrey Pernica, MD (McMaster) and collaborators Tonya Arscott-Mills, MD (Botswana-UPenn Partnership), Margaret Mokomane, MSc (Botswana National Health Laboratory), and Loeto Mazhani, MD (University of Botswana) the researchers will test the new management algorithm through a randomized control trial.

Results from the trial, to be carried out over 12 months across four hospitals in Botswana, could have a significant long term impact on the way childhood diarrhea is tested and treated in low-resource settings. The evidence could inform policy, change regulations and impact the development of future diagnostics in low-income countries.

Partners include the Botswana Ministry of Health, the Botswana-UPenn Partnership, bioMérieux, BioGaia, and Copan Italia.

ShoeBOX Audiometer: An iPad-based solution for sustainable hearing healthcare at the point of care
Clearwater Clinical / Ottawa, ON (Implementation Region: South America) $1 million

Innovators aim to diagnose hearing loss in tens of thousands of people in the developing world thanks to new funding from Grand Challenges Canada and the first clinically validated iPad audiometer.

Developed in partnership by Ottawa-based Clearwater Clinical and the Children’s Hospital of Eastern Ontario (CHEO), the “ShoeBOX Audiometer” allows audiologists and technicians to perform critically needed screening and diagnostic testing anywhere, with the same level of accuracy, but a fraction of the cost of traditional audiology systems.

Some 360 million people worldwide (including 32 million children) have disabling hearing loss and require hearing aids - the majority of whom live in developing countries, according to the World Health Organization. In low- and middle-income countries, less than 1% of people who need a hearing aid have one, due to their high cost, insufficient clinical services, a lack of audiologists, and low levels of access in rural communities.
At one-tenth the cost of traditional diagnostic audiometers, the tablet-based ShoeBOX Audiometer is an inexpensive and portable solution ideal for low-resource, rural settings. While screening and treatment from a qualified audiologist is ideal, the ShoeBOX Audiometer makes it easy for non-traditional individuals like family doctors and community health workers to provide hearing diagnostic services where audiologists are not available.

Led by Chief Executive Officer Michael Weider and founded by Chief Medical Officer Dr Matthew Bromwich, Clearwater and CHEO designed the ShoeBOX Audiometer with children in mind. The application is user-friendly and uses a form of ‘play’ audiometry to effectively diagnose hearing loss in children as young as 3.5 years.

The accuracy of ShoeBOX Audiometer as compared to the gold standard has been demonstrated and published in the Journal of Otolaryngology and the Journal of Oto-HNS; there was no statistically significant difference between thresholds obtained by ShoeBOX and traditional audiometry.

The ShoeBOX Audiometer has also been shown to be effective in low-resource settings. In an earlier study supported by Grand Challenges Canada’s Stars in Global Health program, funded by the Government of Canada, 868 children were screened and 139 were diagnosed with hearing loss in Iqaluit and Uganda. This earlier proof of concept work transitioned the project from a prototype to an FDA and Health Canada-approved, commercial-grade medical device.

In partnership with Grand Challenges Canada, angel investors, the Business Development Bank of Canada and World Wide Hearing, Clearwater is now looking to scale up the ShoeBOX Audiometer throughout South America, as well as continuing product development and refinement.

Clearwater estimates that the new funding from Grand Challenges Canada’s Transition to Scale program will enable them to reach tens of thousands of beneficiaries by the end of 2017.

**Mobile health platforms to support cervical cancer screening, treatment and follow-up**

*Wema Inc. and Queen’s University / Kingston, ON (Implementation Country: Tanzania) $500,000*

With new funding from Grand Challenges Canada, two promising innovations focused on women’s health management through mobile platforms will be merged, rolled out and evaluated in Tanzania.

Globally, breast and cervical cancer are the most common cancers affecting women. The majority of deaths (60 percent for breast cancer, 90 percent for cervical cancer) occur in developing countries. If detected early, these types of cancer are often treatable; however, large-scale screening programs have not been established in many low-resource
settings, and the quality of screening can be poor.

The first innovation allows community-based health providers to conduct cervical cancer screening using a smartphone. An innovative smartphone application, Servical, uses acetic acid to enhance visual inspection for cervical cancer, and allows for the resulting images to be shared securely between newly trained screening providers and expert reviewers at a distant location.

Through a custom-designed application, the expert communicates agreement or an alternative diagnosis and management plan or treatment. This ‘real-time’ supportive supervision is key to maintaining quality screening and sustainability of expanded cervical cancer screening programs because it significantly reduces the costs of supportive supervision, allowing for the rapid scale-up of cervical cancer screening programs in low resource settings.

In a study in Tanzania led by Queen’s University and funded by Grand Challenges Canada’s Stars in Global Health program, of 1072 women screened using the system, 96 (9%) were diagnosed with pre-cancerous lesions. The project found that nurses who conducted screenings could obtain adequate cervical images and that the expert was in full agreement on 94.6% of diagnoses within one month of training.

The second innovation involves an interactive mobile health smartphone application designed to increase awareness of women’s cancers and to increase screening acceptance among women.

A study conducted in Bangladesh concluded that trained community health workers guided by the smartphone application were more efficient and effective than workers without these tools. Workers guided via smartphone interviewed more women, had superior data completeness, and identified more women with possible breast abnormalities. The program also raised awareness about breast health and increased referral rates of women with breast symptoms for further care and management.

Building off these promising results, the new project will combine the distinct and potentially complementary innovations to aid in the effective management of cervical and breast cancer in low-income countries.

Based on proof of concept data and the need in the target population, the new project is expecting to screen 100,000 women; approximately 9,000 (9%) women will be diagnosed and successfully treated, saving 1000-2000 lives. The breast cancer application will train over 50 community health workers who will work in multiple rural communities and educate over 10,000 women about breast health and the importance of early recognition of breast cancer.

The transition-to-scale project will follow three parallel but connected tracks: 1) implementation 2) evidence generation and technology testing; and 3) business development.

Partners include the Ministry of Health and Social Welfare in Tanzania, Marie Stopes International, Elizabeth Glaser Pediatric AIDS Foundation and multiple local partner organizations working in women’s health.
**HIVSmart!**: A smartphone app-based HIV self-testing strategy to identify undiagnosed cases of HIV

*Sympact-X and the Research Institute of McGill University Health Centre / Montreal, QC (Implementation Countries: South Africa)* $1 million

A smartphone app-based HIV self-testing strategy making HIV self-testing a reality will scale up in South Africa thanks to a new investment catalyzed by Grand Challenges Canada.

A repayable grant provided by Grand Challenges Canada, which is funded by the Government of Canada, will be matched by a range of partners, including Grand Challenges South Africa, the South Africa Medical Research Council's Strategic Health Innovation Partnerships program, South Africa’s Department of Science & Technology, Orasure Technologies, the Research Institute of McGill University Health Centre (RI-MUHC) and the University of Cape Town.

Dr. Nitika Pant Pai, Associate Professor in the Department of Medicine at McGill University and medical scientist, RI-MUHC, is leading the scale up this self-testing technology, called *HIVSmart!*. Dr Keertan Dheda, Professor in the Department of Medicine, University of Cape Town will co-lead the transition-to-scale project in South Africa.

Five out of 10 people infected with HIV worldwide do not know their status. While treatment for HIV is universally available, stigma, discrimination, privacy, and confidentiality concerns are barriers to seeking conventional HIV testing in healthcare facilities.

Undetected, untreated HIV is a significant health challenge for individuals with HIV and for the general public. Undiagnosed individuals pose a strong risk to transmit the disease to others, such as their partners and children.

With initial funding from Grand Challenges Canada’s Stars in Global Health program, Professors Nitika Pant Pai (McGill University) and Keertan Dheda (University of Cape Town) evaluated *HIVSmart!*, a smartphone and web application-based strategy that engages, interprets and links self-testers to counselling and clinical care. *HIVSmart!* is used in conjunction with an approved HIV self-test kit, offering a de-stigmatized, private and confidential testing option for individuals who suspect they are infected with HIV.

The pilot project in South Africa showed that all of the 251 healthcare workers who self-tested positive for HIV sought counselling and care thanks to *HIVSmart!*. A majority (91% of participants) rated *HIVSmart!* positively because of the privacy it offered, ease of use and the non-invasive, painless nature of oral HIV self-testing.
In 2013, the HIVSmart! strategy won the international 2013 Accelerating Science Award Program (ASAP) for innovation from Google, PLOS and the Wellcome Trust. Dr. Pai’s pioneering work on oral HIV testing has been published in PLOS Medicine, The Lancet ID and PLOS One.

The scale-up of HIVSmart! aims to improve and save the lives of about 300 individuals who are estimated to be found to be HIV positive and linked to counselling and care, and 1500 lives will be improved through enhanced access to testing and improved linkages to clinical care and retention, thereby reducing the risk of transmission and infection in the communities.

This new funding will support the implementation of the program in South Africa, measuring and evaluating its impact and cost-effectiveness. With the support of South African partners, the strategy will be made available to many populations within Sub Saharan Africa.