Grand Challenges Canada
at the Sandra Rotman Centre

MaRS Centre, South Tower
101 College Street, Suite 406
Toronto, Ontario, Canada M5G 1L7

T 416 673.6568 F 416 978.6826
E info@grandchallenges.ca
grandchallenges.ca

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News Release

Monday, May 25 2015

Innovative "Flocked Swab" Improves Diagnosis, Treatment of Deadly Childhood Diarrhoeal Diseases

In African study, new tool reveals 1/3 of children hospitalized with severe diarrhea were discharged with an undiagnosed, treatable infection

With device in use from Botswana to Nunavut, results could prompt global rethink of how to manage world's 2nd leading cause of death of children under 5

Federal Government-funded Grand Challenges Canada marks 5th anniversary May 28

Toronto, Canada — With Canadian government funding, medical scientists have created and demonstrated a new tool that could dramatically lower the tragic annual toll of 760,000 infants and children killed, and millions more stunted, due to severe diarrhoea.

Using an inexpensive innovation in specimen collection, the Canadian-led team diagnosed previously unrecognized pathogens that had caused the severe diarrhoea of over one-third of children in a group of southern African hospitals.

With a grant from federally-funded Grand Challenges Canada, McMaster University researchers designed and tested in Botswana a specially-designed "flocked swab" for collecting samples from children admitted to hospitals with severe diarrhoeal disease — the second-leading cause of death of children under five in developing countries.

The flocked rectal swab eliminates the wait and biohazard involved in obtaining and transporting a bulk stool (feces) sample from an infant or child. This efficiency enabled implementation of a randomized clinical trial evaluating same-day diagnosis and treatment for a broad number of pathogens – the first study of its kind anywhere.

Published May 16, 2015, by the *Journal of the Pediatric Infectious Disease Society* (http://bit.ly/1EPTjBH), the 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.

Because so many of these severely ill children had treatable conditions, the researchers subsequently clinically tested whether same-day rapid diagnosis, followed by timely, appropriate therapy, would lead to improved outcomes.

Children randomly chosen for rapid testing using the flocked swab and appropriate treatment were 55% less likely to have diarrhoea recur, compared with children not chosen, and they had a clinically significant height gain after 60 days. This measure of growth is an important indicator of children's ability to reach their full developmental potential.

Led by David Goldfarb, MD (formerly of McMaster University, now at the University of British Columbia), along with Jeff Pernica, MD (McMaster) and collaborators Isaac Quaye, PhD (University of Namibia) and Margaret Mokomane (University of Botswana), the researchers witnessed dramatic health changes as a result of the rapid test-and-treat strategy.

And the 'treatment gap' revealed in their Botswana research uncovers a major opportunity to make a significant, long-term impact in child health worldwide, they say.

"The simple fact is: diagnostics save lives," said Dr. Peter A. Singer, CEO of Grand Challenges Canada. "If health workers can quickly and accurately pinpoint the cause of a child's illness, timely help can be administered, preventing many deaths and improving many lives."

"The flocked swab offers a shining example of the sort of 'Bold Idea with Big Impact' in global health to which Grand Challenges Canada has been devoted since 2010. These are early days and results from an innovation are fully seen only in the long term, but we believe the global health potential of this innovation could be very large over time."

1.7 billion cases of diarrhoeal disease worldwide each year; 760,000 child deaths

According to the WHO (http://bit.ly/1JPcFv5), nearly 1.7 billion cases of diarrhoeal disease occur worldwide every year, illnesses that kill about 760,000 children under five years old. Other profound health consequences for children include physical and cognitive stunting, and severe malnutrition.

Said Dr. Pernica, "For many of the leading causes of severe diarrhoea in children, there are effective, low-cost treatments available. The issue, however, is that up until recently it was not possible to determine, in a timely manner, the specific pathogen causing illness."

"For this reason, the standard of care for child diarrhoea across the developing world has been to ignore what might be the specific pathogen and only provide antibiotics if blood is present in the stool. This may well be contributing to the high mortality observed in African children with severe diarrhoea; in Botswana, 4% of such children died in hospital, and in other sub-Saharan countries, the death rate is over 7%. Furthermore, most of those who survive will experience some degree of growth faltering and the possibility of cognitive developmental delay."

Phase Two of the work in Africa involves quantifying more precisely the difference this diagnostic breakthrough achieves.

Said Dr. Goldfarb, "Further demonstrating significant improvements in outcomes would necessitate an entire rethinking of how this very common condition is managed around the world."

Data inspires Botswana to fast-track Rotavirus vaccination program

Thanks to the group's research, valuable information acquired at a national level about the specific germs causing child diarrhoeal disease facilitated Botswana's fast-tracking of an immunization program and the development of rapid antibiotic treatment protocols.

Botswana's anti-Rotavirus program, addressing the leading cause of severe diarrhoea among infants and young children, has vaccinated over 100,000 children and is credited with an overall 55% decrease in the mortality rate among infants at four hospitals during the first Rotavirus season after the vaccine roll-out.

Further analysis two years after the vaccine introduction shows a 32% decrease in all-cause infant diarrhoea mortality, and a 26% decrease in all-cause infant diarrhoea hospitalizations.

Simple new device helps save kids

Resembling an oversized Q-tip® but with a furry 3.2-cm (1.25-inch) tip of nylon fibers attached perpendicularly to the end of a plastic stem, the flocked swab designed in Canada for this new diagnostic purpose, and manufactured by Copan Italia, began with a proof-of-concept grant in 2011 from Grand Challenges Canada. *(Download photo at http://bit.ly/1KcKAB5; credit: David Goldfarb, Jeff Pernica)*

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Unlike cotton swabs common in many homes, the flocked swab is like a soft brush with no absorbent core so the entire biological sample stays close to the surface, facilitating diagnostic tests.

Produced at scale, a swab costs as little as 25 cents.

In a study, published in November in the *Journal of Clinical Microbiology*, the innovators showed that a specimen obtained using the specially-designed flocked swab was 16% more likely than matched stool samples to reveal two leading, treatable bacterial pathogens causing diarrhea: shigella and campylobacter.

The flocked swab, the researchers add, will benefit healthcare systems worldwide but especially in low-resource settings where incorrectly and ineffectively treated diarrhoeal disease wastes precious medical resources.

The device will be used in Canada for the first time in the Gastroenteritis Surveillance Project in Nunavut, where acute gastrointestinal infections are at least two to four times higher than in other Canadian regions.

Said Dr. Pernica, “Stool collection and transport generally would be unfeasible in such a setting. Flocked swabs, therefore, will be crucial to enabling this surveillance. Enrollment has begun in five communities and is planned for seven remote communities in all across the territory.”

Celebration: Grand Challenges Canada turns five

The flocked swab is one of 22 innovations being showcased at a Grand Challenges Canada fifth anniversary event: “**Celebrating Legacy, Celebrating Partnerships and Results, Celebrating the Future**,” (Royal York Hotel, Toronto, Thursday, May 28, from 6:00 – 9:00 p.m.)

The May 28th event will feature presentations by innovators in mental health, early childhood development, maternal, newborn and child health, and many other areas.

Grand Challenges Canada is funded by the Canadian government, which has designated maternal, newborn and child health as the nation’s top international development priority.

Said Dr. Singer, “Thanks to the Government of Canada’s support, we have grown to an organization that has supported this and roughly 700 other innovations in 70 countries, all helping to reinforce Canada’s leadership in the area of global health.”

For more information, visit **grandchallenges.ca** and look for us on Facebook, Twitter, YouTube and LinkedIn.

About Grand Challenges Canada

Grand Challenges Canada is dedicated to supporting Bold Ideas with Big Impact® in global health. We are funded by the Government of Canada; we support innovators in low- and middle-income countries and Canada. The bold ideas we support integrate science and technology, social and business innovation to find sustainable solutions to health challenges – we call this Integrated Innovation®. Grand Challenges Canada focuses on innovator-defined challenges through its Stars in Global Health program and on targeted challenges in its Saving Lives at Birth, Saving Brains and Global Mental Health programs. Grand Challenges Canada works closely with Canada's International Development Research Centre (IDRC), the Canadian Institutes of Health Research (CIHR) and the Department of Foreign Affairs, Trade and Development Canada (DFATD) to catalyze scale, sustainability and impact. We have a determined focus on results, and on saving and improving lives.
www.grandchallenges.ca

MEDIA ENQUIRIES

Lode Roels
Press Officer
Grand Challenges Canada
+1-647-328-2021 / +1-416-673-6570
lode.roels@grandchallenges.ca

Terry Collins
+1-416-538-8712 / +1-416-878-8712
tc@tca.tc