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MEDIA RELEASE:

Announcement of large research grant to develop Oral Swab for TB Diagnosis

University of Washington and South Africa Team receive funding from the Bill & Melinda Gates Foundation

About 8 million people develop tuberculosis (TB) each year, resulting in about 1.5 million annual deaths. The **World Health Organization** reported last year that alternatives to the current diagnostic method were badly needed to identify suspected TB cases.

Researchers at the **University of Washington** and the **University of Cape Town** in South Africa received a \$1.02 million grant from the **Bill & Melinda Gates Foundation** for a two-year study to test a low-cost, simpler and safer method in diagnosing TB. The new larger study builds on earlier pilot study which found that oral swabs correctly detected most adult participants positive for TB. [<http://hsnewsbeat.uw.edu/story/simple-swab-test-holds-promise-ease-tuberculosis-detection>]

Currently, diagnosing TB relies on sputum, a thick, sticky phlegm coughed up from the lungs. The gelatinous quality and complexity of the material make finding the TB bacteria difficult. Sputum samples are examined under a microscope or run through molecular testing instruments such as Cepheid Inc.'s *GeneXpert MTB/RIF*, where such technology is available.

Using sputum is problematic for other reasons, too. Healthcare providers who collect sputum are at risk; asking TB-sick patients to cough up sputum releases aerosols that can spread infection. Moreover, neither those yet ill with symptoms nor children will be able to produce sputum.

“An alternative to sputum testing has been a Holy Grail in TB testing and diagnostics. There’s a huge need, and we think the oral swab addresses this need,” said **Gerard Cangelosi**, [http://deohs.washington.edu/faculty/cangelosi_gerard] who leads the research study and is a professor of environmental and occupational health sciences and global health in the **UW School of Public Health**.

TB bacteria can be found in mouths of people infected with the disease. Oral swabs gently scrape inside of the mouth and then the samples are analyzed for the bacteria.

Lisa Jones-Engel, a research scientist with the *UW National Primate Research Center* involved in this study, pioneered the method to screen monkeys and apes for TB. [<http://www.washington.edu/news/2012/06/20/from-the-mouths-of-monkeys-new-technique-detects-tb/>]. Rachel Wood, a research scientist working with **Cangelosi**, led the pilot study that correctly detected TB in oral swabs taken from 18 out of 20 patients.

The disease is preventable and curable with antimicrobial drugs. Yet, treatment is often delayed because it can be difficult to motivate people to visit a clinic and provide a sputum sample for testing. As a result of these delays, those ill with TB may infect up to 15 people a year through contact at home, school, work, or in clinics.

“By the time people are coughing and producing sputum, they are often sick and highly contagious. An important goal in eradicating TB is to diagnose and treat people early to prevent the disease spreading to others,” said **Mark Hatherill**, a professor at the University of Cape Town in South Africa who directs the South African Tuberculosis Vaccine Initiative.

The blinded study will include 245 South African adults over the age of 18 and 100 South African children, most under the age of five. The adults will include 175 people suspected of TB infection and an additional 70 people confirmed with a blood test not to have TB. The study subjects may be positive for HIV infection. The areas in the world with the most HIV-positive individuals also have the highest burden of TB.

The researchers will compare two different kinds of oral swabs and three sampling locations in the mouth: cheek, tongue and gums. Results of the blinded oral swab samples will be compared to traditional methods including sputum testing as well as clinical diagnosis.

Felicia Nguyen is also involved from the UW. In addition to Hatherill, Angelique Luabeya, Justin Shenje and Mark Nicol will lead the clinical research activities in South Africa.

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For Academic and clinical queries	For request for media interviews and media queries
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