THE UNIVERSITY OF TEXAS AT EL PASO

Researchers on Track to Move Biomedical Device from Lab to Marketplace

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Two faculty members from The University of Texas at El Paso are developing a low-cost test to rapidly diagnose pneumococcal disease and whooping cough that could potentially save lives.

UTEP faculty XiuJun James Li, Ph.D., left, and Delfina C. Domínguez, Ph.D., right, were issued a patent for instrument-free biochip technology to detect pneumococcal disease and whooping cough. Photographed in UTEP's Interdisciplinary Research Building, the background features patent numbers indicating translational development and innovations. Photo: Laura Trejo / UTEP Communications

Pneumococcal disease is a serious and highly contagious bacterial infection that can affect the lungs, blood, middle ear or nervous system. When the infection is diagnosed early, patients have the best shot at recovery.

But, in medically underserved or low-resource settings, a pneumococcal infection can quickly turn into a life-threatening health condition. This is particularly true in small clinics, rural areas and developing nations with poor access to diagnostic equipment and trained staff to test for *Streptococcus pneumoniae*, the bacterium that causes pneumococcal disease.

"Many respiratory pathogens from *Streptococcus pneumonia* to *Bordetella pertussis* can be lethal in high-risk populations, especially in young children and the elderly," said XiuJun James Li (https://expertise.utep.edu/profiles/xli4), Ph.D., UTEP associate professor of chemistry.

In 2021, Li and his co-investigator Delfina C. Domínguez (https://expertise.utep.edu/profiles/delfina), Ph.D., UTEP professor of clinical laboratory sciences, received $250,000 from the National Science Foundation's Partnerships for Innovation (PFI) program to create low-cost, point-of-care testing to rapidly diagnose both *Streptococcus pneumoniae* and pertussis, or whooping cough, a highly contagious respiratory infection caused by the *Bordetella pertussis* bacteria.

The PFI program selects projects that will transition the technology out of the lab and into the market for societal benefit.

Researchers will leverage their patented instrument-free biochip technology for whooping cough to prototype a paper-based hybrid microfluidic device, which integrates DNA amplification to rapidly detect bacterial pathogens as the new diagnosis method.

Also known as lab-on-a-chip, microfluidic systems make point-of-care testing more affordable and accessible, especially in low-resource settings, because the technology allows the analysis of a sample to take place on-site rather than in a laboratory. Li and Domínguez's goal is to make the device commercially available in a few years.

"There are laboratory-based technologies to detect different pathogens such as *Streptococcus pneumonia or Bordetella pertussis*, but small clinics, rural areas, and some low-income countries such as Africa or Latin America lack the facilities, equipment or trained staff to do the testing," Domínguez said. "In addition to being affordable, accurate and providing rapid results, the device we are working on will also be portable. The marvelous thing is that it could be taken to low-resource settings where diagnostic testing for infectious diseases is much needed."

Preventing Life-Threatening Complications

Some infections caused by *Streptococcus pneumonia* or *Bordetella pertussis* may be mild depending on which part of the body is infected, while others can lead to life-threatening complications, especially in young children, immunocompromised people and the elderly. Early diagnosis is critical to make the infection less severe and prevent it from spreading.

The Centers for Diseases Control and Prevention estimates that worldwide, there are 24.1 million cases of pertussis (https://www.cdc.gov/pertussis/fast-facts.html) and about 160,700 deaths per year from the infection in children younger than 5 years old.

Pneumococcal disease is a global health concern. In the United States, more 150,000 hospitalizations from pneumococcal pneumonia (https://www.nfid.org/infectious-diseases/pneumococcal/) occur each year, and about 5% to 7% of those who are hospitalized from it will die. The death rate is even higher in those age 65 years and

older.

With support from the PFI grant, Li and Hamed Tavakoli, a doctoral student in UTEP's Department of Chemistry and Biochemistry, will build a prototype of the microfluidic point-of-care device. The prototype will be used to troubleshoot and refine the design to make it more robust for the real-word application.

About the size of a microscope slide, the hybrid device, which will be made out of filter paper and synthetic polymer, would be able to detect the presence of *Streptococcus pneumoniae* or *Bordetella pertussis* simultaneously and without the need for expensive real-time quantitative PCR (qPCR) technology to perform diagnostic procedures. Because different antibiotics are used to treat different infections, it is vital to know the exact bacteria that is causing the disease.

"UTEP faculty like Dr. Li are doing more than just conducting exciting research and publishing papers, they are developing new technologies that are important for humanity and hold great commercial value," said Robert A. Kirken, Ph.D., dean of the College of Science. "I'm also energized by these types of projects because UTEP students are being trained in this entrepreneurial environment that will make them more qualified and competitive in the workforce."

From the Lab to the Marketplace

Once a working prototype is available, researchers will be ready for clinical trials, the next step in the project's development.

Domínguez will use positive and negative clinical samples from Children's Hospital Los Angeles to test the accuracy of the device before it is made available by a new startup company founded by Li called microBioChip Diagnostics LLC.

"I talked to doctors in Dallas, Canada and California to see if there was a place for this type of point-of-care device on the market," said Li, who fleshed out his idea for the technology at the NSF Innovation Corps (I-Corps) Teams program that he and Tavakoli attended in 2020. The program prepares students and researchers to move their discoveries from the research lab and into the marketplace to benefit society.

"They said they would like the device to have more functionality and be able to detect multiple diseases at the same time," said Li, a member of UTEP's Blackstone Stewardship Council for entrepreneurship. "Based on their feedback, we started to develop the device further."

Tavakoli said that working with Li provides him with interdisciplinary research and entrepreneurship experience.

"My research interest is developing state-of-the-art microfluidic devices for low-cost, point-of-care diagnosis of diseases," said Tavakoli, who was the entrepreneur lead on the NSF I-Corps team. "Dr. Li is a talented, brilliant and successful professor in this research field. In addition, his research is multidisciplinary so that I can receive not only interdisciplinary research experience but also entrepreneurship training."

Li also has received two NSF I-Corps grants to support his work on thermometer-based technology developed to detect a cancer biomarker and a genetic-based technique for infectious disease diagnosis.

"By taking our research out of the lab and moving our product into the marketplace, I think we can have a greater impact on society," Li said.

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