Medical Xpress

MeMed's blood test accurately distinguishes bacterial and viral infections, research shows

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MeMed today announced publication of the results of a large multicenter prospective clinical study that validates the ability of its ImmunoXpert in-vitro diagnostic blood test to determine whether a patient has an acute bacterial or viral infection. The study enrolled more than 1,000 patients and is published in the March 18, 2015 online edition of *PLOS ONE*. Unlike most infectious disease diagnostics that rely on direct pathogen detection, MeMed's assay decodes the body's immune response to accurately characterize the cause of the infection.

Bacterial and viral infections are often clinically indistinguishable, leading to antibiotic overuse and contributing to the spread of antibiotic resistance, which the World Health Organization says is approaching crisis proportions. Paradoxically, the inability to rapidly differentiate infections also results in the underuse of antibiotics, estimated to occur in 20-40% of all bacterial infections, putting patients at risk of complications and increasing healthcare costs. MeMed researchers developed the ImmunoXpert test to accurately distinguish between bacterial and viral infections, with the goal of improving patient management by providing physicians with information that enables them to reduce both the overuse and underuse of antibiotics.

Eran Eden, PhD, CEO of MeMed, noted, "Antibiotic misuse is a pressing public health concern, with devastating healthcare and economic consequences. Rapid, accurate and actionable diagnostic tools are an important part of the solution because they can aid physicians in making better informed treatment decisions. For the past four years, our

team has been collaborating with leading clinicians and scientists from around the world to develop and validate our novel approach for distinguishing between bacterial and viral infections. Unlike most traditional diagnostics, this approach builds on an exquisitely informative system crafted by nature - the human immune system. Our scientists have figured out how to decode the actions of the immune system doing what it does best—detecting and responding to the precise cause of infection."

MeMed's technology leverages the fact that bacteria and viruses trigger different pathways in the immune system. By conducting extensive screening of immune system proteins in patients with acute infections, researchers identified three soluble proteins that are uniquely activated by bacteria or viruses. They then developed proprietary algorithms that integrate these proteins to produce an immune signature that accurately identifies the cause of infection.

In the *PLOS ONE* study, the ImmunoXpert immune signature was developed and independently validated on a cohort of 1002 patients with acute infections and yielded highly accurate results, with sensitivity and specificity greater than 90%. The assay was validated in a diverse group of pediatric and adult patients at different time points after the onset of symptoms (from the first day up to 12 days) and across 56 different pathogen species. ImmunoXpert remained robust over all sub-groups studied. The predictive power of the assay's immune signature outperformed routine biomarker and laboratory tests, as well as combinations of these tests. The signature is amenable to rapid measurement using a blood test run on standard hospital and laboratory-deployed automated platforms, or using a point-of-care device now in development.

"We conducted big data filtering, followed by extensive screening of 600 immune system-related proteins," said Kfir Oved, PhD, MeMed CTO.

"A few of the proteins showed distinctly different patterns in bacterial and viral infected patients. In particular, the most informative protein we found, called TRAIL, dramatically increased in the blood of patients infected with a wide range of viruses, but surprisingly, decreased in bacterial infections. Our team developed an algorithm that computationally integrates TRAIL with other immune proteins to diagnose the cause of the infection with high accuracy."

The ImmunoXpert immune-based approach overcomes inherent limitations of many traditional diagnostics tools. It is accurate and rapid, it can diagnose infections that are not readily accessible such as pneumonia (because immune system components circulate throughout the entire body), and it prevents false alarms due to the benign presence ("carriage") of potentially pathogenic bacteria and viruses that are not causing active disease.

"This study represents a breakthrough in our efforts to develop more accurate, rapid and actionable diagnostic tools that improve the management of patients with acute infection." said Professor Isaac Srugo, MD, Head of the Pediatric Department and Microbiology Lab at Bnai Zion Medical Center. "The incorporation of novel viral-induced proteins, currently not in clinical use, enables ImmunoXpert to attain high levels of accuracy, which can help physicians make better informed antibiotic treatment decisions. This should result in more bacterial infected patients receiving timely therapy that is actually useful for treating their illness. Additionally, it can lead to fewer prescriptions to viral patients for whom antibiotics do nothing to speed recovery, while causing potential harm to the larger community."

MeMed's ImmunoXpert test is CE marked and approved for clinical use in the European Union and Israel. It is currently in pilot distribution in these territories, with a broader commercial roll-out planned for later this year. Additional clinical studies are underway and the company is

planning to conduct clinical trials in the U.S. using a specially-designed point-of-care platform currently in development.

More information: Laxminarayan R. et al. Antibiotic resistance—the need for global solutions. *Lancet* Infect Dis. 2013 (www.thelancet.com/journals/lan … rticle/PIIS1473-3099%2813%2970318-9/abstract)

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Craig JC, et al. The accuracy of clinical symptoms and signs for the diagnosis of serious bacterial infection in young febrile children: prospective cohort study of 15 781 febrile illnesses. *BMJ*. 2010 (www.bmj.com/content/340/bmj.c1594)

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