Johns Hopkins University

Development of Point-of-need Diagnostics to Distinguish Viral vs. Bacterial Infections to Reduce Emergence of Antibiotic Resistance and Determine Severity of Infection

Prescribing antibiotics when unnecessary and for longer than necessary may expose patients to many health consequences including mild to serious side effects/allergic reactions, an increased risk for fungal infections and alterations in the microbiome. Moreover, inappropriate and overuse of antibiotics leads to the emergence of microbial resistance, a critical, global public health problem. An optimal diagnostic test would provide healthcare providers (HCPs) a timely and actionable result to determine whether a patient should start an antibiotic treatment regimen, as well as when to discontinue treatment. There are a number of proposed algorithms to support rational antibiotic stewardship, which utilize biomarkers such as complete blood count (CBC) with differential and levels of C-reactive protein (CRP), procalcitonin (PCT) and other cytokines in the blood. Current options for assessing whether a patient has a bacterial infection generally require a HCP to perform a venipuncture and send a blood sample to a central lab for testing. The time-to-result is typically 1 hour to a week, depending on the setting or the requested test, greatly limiting the efficient and timely implementation of rational antibiotic stewardship practices, in both the outpatient and inpatient settings. In addition, clinicians may require results from multiple diagnostic tests and the ability to efficiently repeat and evaluate such tests in the first 24-48 hours to increase their confidence in withholding or discontinuing antibiotics. Therefore, we propose to develop disposable, low-cost (<$10 to manufacture), rapid (<10 minutes to result), point-of-need (PoN) diagnostic tests for multiple biomarkers (CBC with differential, CRP+PCT), that would strategically i.e. prior to prescription, inform patient management decisions, such as the need for antibiotics and/or severity of infection. Our PoN diagnostics devices are intended for use in both outpatient and inpatient settings, would leverage the biomedical and diagnostic expertise at Johns Hopkins University, the globally-recognized expertise of imec in silicon chip engineering, as well as the success and innovation of the miLAB program, a unique public-private partnership supported by the miDiagnostics company.