Blood Draw

Saliva Collection

Non-Invasive Diagnosis of Sepsis in Neonates Using Saliva

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What if we stopped stabbing babies? Imagine a world where we no longer need to draw blood from newborns to diagnose sepsis.

Sepsis, a severe systemic response to infection, poses a significant risk to all newborn infants. In fact, the most commonly performed diagnostic test in neonatal intensive care units is the “rule out sepsis” test, which requires a blood sample typically obtained by heel stick. The procedure is painful and repeated tests can cause anemia. The gold-standard assay relies on blood culture, where a pathogen in the blood is detected by growing it over multiple days. In developed countries, this test is inaccurate and slow. In low- and middle-income countries, the test is frequently unavailable. Thus, empirical antibiotic treatment is universally initiated as a precaution, but this practice carries substantial risks including harmful neurodevelopmental delays and increased likelihood of necrotizing enterocolitis (injury and death of the intestinal tissue). Consequently, there is a critical need for accurate, rapid, and non-invasive sepsis testing methods.

In the largest salivary study in neonates to date, we identified a promising panel of host-response proteins that can be used to diagnose sepsis with ~77% sensitivity and 75% specificity—a two-fold improvement over standard of care. Saliva testing offers a non-invasive, pain-free, and safe alternative for detecting sepsis as well as an opportunity to minimize unnecessary antibiotic exposure.

Future work is needed to bridge this breakthrough discovery of a saliva-based panel that is sensitive and specific to sepsis with point-of-care deployment in the NICU, where the test is desperately needed. Limited competition exists for neonatal sepsis detection, while a clear reimbursement pathway enables market entry. We seek partners for point-of-care device development, manufacturing at scale, regulatory approval, and distribution to bring this innovative solution to NICUs worldwide.