

*A novel advance market commitment (AMC) for point of care diagnostic tests to aid in the diagnosis and management of neonatal sepsis. Such a rapid triage test would aim to both reduce neonatal mortality, and prevent overprescription of antibiotics, which drives antimicrobial resistance. The AMC aims to raise at least \$100 million, focused on India and other low and middle-income countries.*

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## The problem

Neonatal sepsis, a systemic bloodstream infection in newborns in their first 28 days of life, affects 1.3-3.9 million neonates per year, and is responsible for nearly a quarter of all neonatal deaths, with a disproportionate burden in low and middle income countries. Untreated, neonatal sepsis has a mortality rate of 30%.

Our ability to identify neonatal sepsis, however, is very limited. The only diagnostic we have currently is blood cultures- they take 48-72 hours and are falsely negative in 40% of cases.

Because we cannot properly direct treatment to the babies who need it, we paradoxically both miss a lot of cases of neonatal sepsis, but also inappropriately overtreat many neonates who do not have sepsis. This leads to a double burden; not only are babies dying from untreated neonatal sepsis, but the overuse of antimicrobials has also led to very high rates of antimicrobial resistance (AMR) in neonates- it is estimated that over 30% of neonatal sepsis cases are due to resistant pathogens, which are more difficult to treat. Both of these together contribute to the very high global health burden of neonatal sepsis.

## The case of the missing diagnostic

It is imperative to develop rapid point-of-care diagnostic tests to help identify neonates with sepsis, and to avoid inappropriate over-treatment. Diagnostic tests can save lives, money and antimicrobial drugs. Their importance is agreed upon by key experts and organisations in the field.

Frustratingly, such point-of-care tests (POCT) are technologically feasible, with several groups showing early, promising results.

Unfortunately, there are no tests available today because the commercial incentive to develop them fall far short of the vast social public benefit (fewer neonatal deaths and reduced antimicrobial resistance). This is because of high fixed innovation costs, and because there may be pressure to price such a test inexpensively to maintain affordability in LMICs. An AMC would serve to incentivise innovation AND maintain affordability.

In addition, there is market friction and uncertainty, with lack of coordination between healthcare systems and diagnostic developers on clinical need, regulatory pathways and projected adoption of a test. As a result, a diagnostic test that is technologically feasible and has the potential to save millions of lives has not been developed and is unlikely to be in the foreseeable future.

## The solution

We propose an advance market commitment (AMC), called the NeoTest AMC, to help incentivise the development, adoption and use of rapid diagnostics for neonatal sepsis. The proposed AMC design has two key components

1. Endorsements by national and provincial healthcare providers, who sign up to be a part of the AMC. Diagnostic tests which meet the target product profile (TPP) and countries local regulatory requirements can be purchased by providers, making a co-payment.
2. A 'pot' of money, funded by private and public donors. Every time a POCT is sold to one of the health provider, a 'top-up' payment would be made from the pot until it ran out.

This approach is informed by the work undertaken by GAVI to purchase pneumococcal vaccines and aims to incentivise innovation and development by increasing the overall potential value of the market, thereby increasing firms' incentives to devote resources to the area and financially incentivising the 'first to market' diagnostic firm. From the funder's perspective, it is attractive because they will only pay out for success i.e. when a product reaches the market and is bought.

For the AMC to sufficiently spark innovation and change, we have estimated an overall NeoTest AMC 'pot' of \$100 000 000 USD. Participating manufacturers would make a commitment to supply POCT for no more than \$3 per POCT (this represents the provider co-payment price). In return for agreeing to these terms, each validated manufacturer will receive a top-up payment of \$5 per POCT, up to the total amount of the prize of \$100M. This scenario will support purchases of 20M POCTs.

### Cost-benefit estimates

Although cost-benefit estimates are understandably difficult in this area, we estimate that this rapid triage test could be extremely cost-effective, at \$42/DALY. For every one million POCT, we estimate that we will identify 18 000 cases of neonatal sepsis that would otherwise be missed, and avoid 200 000 of unnecessary antibiotic prescriptions. We further model that this test may have a conservative cost-saving benefit for healthcare providers.

## What we need

There are several key components to the success of this proposal, with the 'asks' underlined:

1. Develop a thoughtful AMC contract, working with LMIC physicians and public health experts, world-leading economists and AMR experts. We are on track to do this, but welcome thought partnership and collaboration from interested partners.
2. Establish connections with, and ultimately commitments from, healthcare providers. If you know any key decision-makers in this space, please get in touch. We have prioritised India, as well as Nigeria, Ghana, Ethiopia and the Philippines.
3. Formalise the structure of the organisation that would be responsible for administering and overseeing the AMC
4. Raise the 100M funds for the AMC. If you or someone in your network might be excited about being a pioneering funder of an innovative, cost-effective global health initiative, please get in touch.