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CGD ◢ DARTMOUTH ◢ UCHICAGO
MARKET SHAPING ACCELERATOR

NEOTEST: ACCELERATING NEONATAL SEPSIS DIAGNOSTICS

Proposal for a $60 Million Market-Shaping Facility to Accelerate Rapid Triage Diagnostics for Neonatal Sepsis and Save Newborn Lives

Report of the NeoTest Working Group

July 2026

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Advance Words

It is very exciting to see this fully worked out design of an advance market commitment for a neonatal sepsis diagnostic backed by so many experts across multiple disciplines. It is exciting because we can save hundreds of thousands of newborn lives and at the same time reduce antibiotic resistance by reducing unnecessary antibiotic use. This mechanism also sets out a framework for incentivizing future innovations.

—**Rachel Glennerster**, President, Center for Global Development

It is very exciting to see the team's hard work and detailed thinking lead to a clear and credible incentive scheme to help crack the appalling market failure for a rapid, affordable diagnostic for neonatal sepsis. Beyond the huge applicability of it in this setting, success will almost definitely serve as a model for other settings to help improve the prescription and provision of antibiotics where they are truly needed and likely to be effective, and to avoid the blanket use where they are often not needed.

—**Lord Jim O'Neill**, former UK Minister and Chair of the AMR Review

Neonatal infections kill 400–700,000 babies each year, many because they are not diagnosed and treated in time. A rapid diagnostic test would fill this gap, help save many lives, reduce the unnecessary use of antibiotics, and be a highly cost-effective intervention. This facility would serve as an accelerator, unlocking funding for promising innovations from around the world, while supporting those with a high chance of success. We need such partnerships and models to deliver global public goods, especially where there is a market failure.

—**Soumya Swaminathan**, pediatrician, former director of the World Health Organisation, and former director of Indian Council for Medical Research

Detect early. Treat quickly. Save lives. Rapid neonatal sepsis diagnostics would be a game-changer for newborn survival. They would save lives, reduce unnecessary antibiotic use, and enable timely, targeted care for the smallest and sickest newborns

—**Chinyere Ezeaka**, Professor of Pediatrics and Neonatology, University of Lagos

Advance market commitments are a generalizable tool that can "pull" important new products into existence. This is an exciting application of advance market commitments to a new area beyond vaccines and carbon removal—this time for neonatal sepsis.

—**Nan Ransohoff**, Founder of Frontier and Head of Climate at Stripe

At CARB-X, we are pleased to serve as the push incentive partner of NeoTest. Linking public health–focused innovation with innovative payment mechanisms is critical to advance antibacterial solutions to the patients who need them. This report illustrates how NeoTest—a first-of-its-kind advanced market commitment for antimicrobial resistance diagnostics—could add value to the neonatal sepsis diagnostics space, strengthening both investment confidence and the delivery of life-saving solutions. We welcome the opportunity to collaborate and learn from this pull incentive as we explore ways in which we can bridge the gap between innovation and access going forward.

—**Kevin Outterson**, Executive Director, CARB-X

The lack of diagnostics to determine whether a newborn has or is at risk of developing sepsis is leading to the needless loss of life and contributing to the growing threat of antimicrobial resistance, especially in low- and middle-income countries. Developing diagnostics for neonatal sepsis is scientifically and commercially challenging, which is why incentives such as Advanced Market Commitments are critical. They help to de-risk investment, drive innovation, and accelerate the development of life-saving tools for vulnerable newborns and their families.

—**Jutta Reinhard-Rupp**, interim-CEO, FIND

Sepsis is notoriously difficult to treat without a reliable diagnostic, and it is even more complex and deadly in neonates. This exciting report offers the promise of an accelerated breakthrough to significantly reduce death and illness. Through careful analysis and clear policy vision, the proposed approach outlines a credible path to harness innovative finance and market-shaping mechanisms to drive much-needed technological advances.

—**Michael Anderson**, CEO MedAccess

Too many newborn deaths are caused not by lack of treatment, but by late or uncertain diagnosis. Neonatal sepsis is exactly the kind of problem where science, delivery systems, and market-shaping must come together: innovators need a clear demand signal, health systems need solutions that work at the bedside, and clinicians need rapid, affordable tools to act with confidence. If we can align incentives around real-world adoption and outcomes, diagnostics can save lives, strengthen antibiotic stewardship, and show how private-sector innovation can deliver public health impact at scale.

—**Rizwan Koita**, Co-founder, CitiusTech and Koita Foundation

The NeoTest facility's value proposition and potential impact is clear: accurate and rapid point-of-care testing will enable both timely antibiotic treatment for sick newborns and support safe antibiotic discontinuation. An affordable and reliable bedside diagnostic test could save up to a quarter of a million newborn lives in the next decade.

—**Angela Dramowski**, Professor of Paediatric Infectious Diseases, Stellenbosch University

What excites me about NeoTest is the combination of rigor and ambition. The problem is urgent and tractable; the mechanism is carefully designed; and a formidable group of experts has aligned behind the thesis. Neonatal sepsis kills one newborn every 45 seconds—not because the science to detect it is out of reach, but because no one has yet made it worth anyone's while to build the diagnostic. The NeoTest fund changes that calculus entirely. We at Renaissance Philanthropy are excited about the potential of this work and would be eager to see it get supported.

—**Kumar Garg**, President, Renaissance Philanthropy

Pull mechanisms can be a powerful means of bringing societally valuable innovations to market. The 2009 pneumococcal advance market commitment did this for vaccines; NeoTest would be the first for diagnostics. It is exciting to see the mechanism applied to an innovation as important as neonatal sepsis diagnostics, which have the potential to save hundreds of thousands of newborn lives.

—**Michael Kremer**, Professor of Economics, University of Chicago

This proposal reflects the work of the Market Shaping Accelerator at the Center for Global Development, which serves as the secretariat for the NeoTest initiative. Our design draws on the advice and recommendations of the NeoTest Working Group, an expert body chaired by Lord Jim O'Neill, whose members contribute expertise across neonatal care, diagnostics, economics, market shaping, and global health financing and implementation.

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Institutional affiliations are listed for identification only; they do not imply institutional endorsement. Endorsement does not imply agreement with every finding, analytical assumption, or modeling parameter or create a financial, legal, or institutional commitment by any individual or affiliated organization. This Working Group was made possible by the support of Bukhman Philanthropies, Coefficient Giving, Founder's Pledge, and Jascha Hoffman.

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Note: Appendices are available separately at: www.cgdev.org/sites/default/files/appendices-neotest-accelerating-neonatal-sepsis-diagnostics.pdf

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Executive Summary

Neonatal sepsis kills one newborn every 45 seconds. Defined as a bloodstream infection in the first 60 days of life, it is responsible for 400,000–700,000 deaths per year—more young lives than malaria claims across all ages combined.

Early treatment of neonatal sepsis is highly effective, but no rapid diagnostic exists to identify infections early. The only available tool—blood cultures—takes more than 48 hours, by which time the window for life-saving intervention has passed. As a result, clinicians must rely on nonspecific signs such as fever, lethargy, and poor feeding to decide whether to treat. This imprecise approach leads to the dual problem of preventable deaths from missed infections and unnecessary antibiotic use, which fuels antimicrobial resistance.

An accurate and rapid point-of-care test would transform neonatal care by enabling timely and appropriate treatment. We estimate that such a test could **save 100,000–280,000 newborn lives in low- and middle-income countries (LMICs) while cutting unnecessary antibiotic prescribing for neonates by more than half.**

We have coordinated and aligned with the World Health Organization (WHO) Target Product Profile (TPP) on the diagnostic supported by NeoTest. It calls for a rapid, low-complexity, point-of-care or near-patient triage test for newborns and infants up to 59 days old to rule in or rule out sepsis at the first clinical decision point.

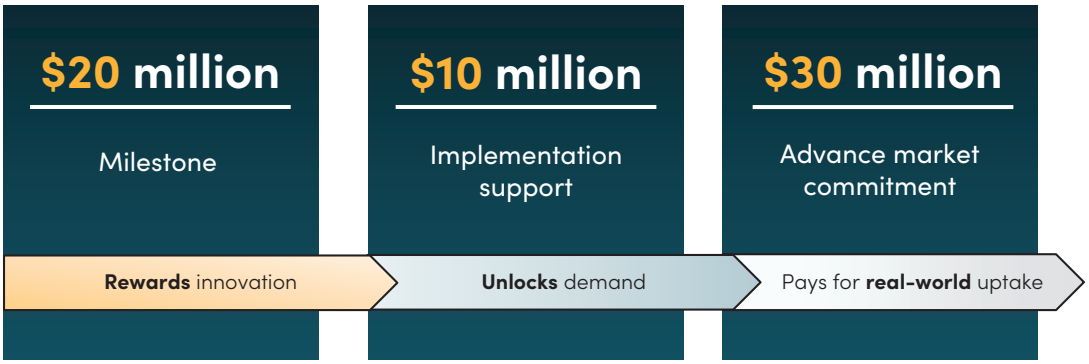
Despite its transformative potential, no such rapid diagnostic exists for neonatal sepsis—not because developing one is scientifically infeasible but because the commercial incentives to do so are insufficient.

Market frictions occur for four reasons:

1. **Commercial returns to innovation are limited.** Although LMIC health systems may be able to afford paying a price equal to the marginal cost of producing tests (or a small margin above), this price does not cover firms' research and development (R&D) costs. Firms therefore do not have the profit incentive to innovate for these markets.
2. **First-movers face copycat competition.** Diagnostic tests are particularly vulnerable to imitation products that evade intellectual-property protections, narrowing the window during which first-movers can recoup R&D costs.
3. **Diagnostics face adoption risk.** A diagnostic generates returns only when clinicians use it, requiring guideline integration, clinical utility evidence, and securing reimbursement. As institutions to support adoption are not in place and adoption infrastructure built by one firm benefit all, such institutions are systematically underprovided.
4. **Antimicrobial resistance and health-system benefits are undervalued.** Diagnostics create value beyond improving the care of the tested neonate. They reduce antimicrobial resistance by curbing unnecessary empiric antibiotic use, lower long-term healthcare costs, and improve population-level surveillance. Because procurers do not factor these broader benefits into purchasing decisions, they do not factor into firm development decisions.

To address these market frictions, funding must come from public and philanthropic sources, as available commercial returns do not justify private investment. NeoTest is a proposed $60 million funding facility designed to accelerate the

FIGURE ES.1 Mechanism design of the NeoTest fund



development, commercialization, and adoption of rapid triage diagnostics for neonatal sepsis in LMICs. It plans to deploy this capital across three components (Figure ES.1):

- **A $20 million milestone payment** that rewards the first firms to bring a qualifying test meeting the TPP to market;
- **A $10 million implementation support fund** that builds the country-level infrastructure needed for adoption;
- **A $30 million advance market commitment (AMC)** that pays a per-test top-up on qualifying tests used.

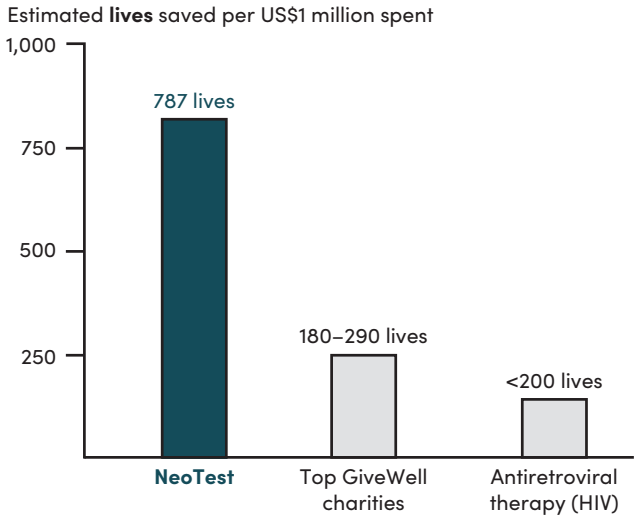
Together, these components create a pay-for-success mechanism that addresses each of the market frictions cited above. The fund includes three critical features:

1. **It pays only for progress.** All three incentives are paid only upon the successful invention of the target diagnostic test. If no successful test is developed, no funds are disbursed.
2. **It lets healthcare workers pick the winners.** Instead of paying innovators upfront, the AMC rewards the tests clinicians actually use. This feature encourages quality, efficiency, and real-world fit.
3. **It invites competition.** By rewarding any firm that meets the defined performance bar, the mechanism encourages diverse approaches—including AI–based solutions—and lets competition sort out which firm succeeds first.

Innovation also requires upstream, early-stage R&D funding. Accordingly, we are working in partnership with the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), a global nonprofit partnership focused on supporting the development of new antibacterial products, which has committed early-stage R&D funding to support neonatal sepsis diagnostics.

With $60 million in funding, the NeoTest facility has an estimated return on investment of $39 per disability-adjusted life year (DALY), equivalent to $1,271 to save a newborn life. Its benefit–cost ratio (78:1) is considerably higher than that of other global health investments (Figure ES.2).

FIGURE ES.2 Return on investment of the NeoTest fund and other global health investments



Note: Based on our adoption modelling and estimated per-test mortality reduction, described in Appendix H.

Source: GiveWell top charities (1) and a meta-review of antiretroviral therapy cost-effectiveness.

1. The Problem: Difficulty Diagnosing Sepsis in Newborns

Neonatal sepsis—a bloodstream infection in the first 60 days of life—kills 400,000–700,000 newborns every year (2). Infections account for approximately 25% of all newborn deaths globally (3, 4) and are the second-largest cause of newborn mortality in low- and middle-income countries (LMICs[1]) (5).

Left untreated, neonatal sepsis has a mortality of 30% (6–8). The risk of death can be dramatically reduced with timely administration of effective antibiotics. Early administration is critical, as **every hour of delay in starting appropriate antibiotics increases the risk of death by 7.6%** (9).

The current reference diagnostic—blood culture—is too slow to guide this first, life-saving decision. Results commonly take more than 48 hours (10), require laboratory infrastructure, and can be difficult to perform reliably in unwell newborns. As a result, blood cultures are performed in only 5% of cases (11).

Given the high mortality rate of neonatal sepsis, clinicians cannot wait for blood culture results. They must make initial treatment decisions based on clinical signs and symptoms, maternal risk factors, basic laboratory markers (such as white blood cell count and C-reactive protein) when available, and their own clinical judgment (12, 13).

Deciding whether to treat for sepsis is difficult, because a newborn with sepsis may not look dramatically ill on initial presentation or during the early stages of infection. The baby may feed poorly, breathe slightly more rapidly than expected, have a fluctuating temperature, or show subtle changes in perfusion. These signs are nonspecific: they can indicate sepsis, another condition, or normal neonatal variation (14).

> I watched closely, counting [breaths] in my head; I kept asking myself: is this just how babies breathe? There was no clear sign that told us to act immediately, only a small feeling of unease. Neonatal sepsis does not announce itself loudly. It hides itself in small changes that are easy to miss.
>
> —Pharmacist and mother of a baby diagnosed with sepsis, Kenya

Clinical guidelines therefore appropriately err firmly on the side of caution. The initial management of possible serious bacterial infection (PSBI) is generally based on Integrated Management of Childhood Illness (IMCI) guidelines (12), which recommend antibiotics when newborns or young infants show the specified danger signs. But detection of these signs is imperfect (15, 16), especially in busy and lower-resource settings. **A systematic review of the clinical signs for diagnosis found that even well-applied clinical assessment misses over 20% of sepsis cases** (17). In models containing only clinical parameters (n = 23 evaluations), median sensitivity was 67% (3%–100%) and median specificity 72% (11%–99%) (17). Roughly 30% of neonates who have sepsis are thus not diagnosed or misdiagnosed based on clinical assessment alone, and 30% of neonates who do not have sepsis are incorrectly diagnosed as having it.

1 We use the World Bank's definition of LMICs, which is an economy with a GNI per capita below $13,935 as of the 2026 fiscal year.

> Sepsis is missed everywhere, more at the general hospitals and clinics, where they really struggle, maybe they don't even know how to assess the signs right. They don't know how to assess fast breathing and [other signs] properly. Some mothers never bring the baby to hospital, or they do when it is very, very late, and there is little that we can do.
>
> —Neonatologist, Nigeria

> Cases are missed at every level, because signs are non-specific. The higher risk for complete[ly] missed recognition is at lower-level facilities, especially when the baby is not dramatic yet.
>
> —Neonatologist, Kenya

As one study notes, "Even with the use of standardized clinical tools, confirming a diagnosis of neonatal sepsis in LMICs remains challenging. . . LMIC healthcare facilities lack accurate, affordable, and point-of-care sepsis diagnostics" (18). The result is a double failure: **Some babies with sepsis are missed or treated too late, and many babies without bacterial infection receive unnecessary antibiotics, referrals, and hospitalization.** Inappropriate antibiotic use contributes to antimicrobial resistance—a significant issue in neonates (19, 20) and the world more broadly (21). Unneeded clinic or hospital stays expose neonates to hospital-acquired infections.

A rapid triage diagnostic is needed to reduce uncertainty at the moment the first treatment decision is made. Such a test would inform whether to start antibiotics immediately, continue observation, refer to higher-level care, or safely discharge (22). More advanced tools—including pathogen identification and antimicrobial susceptibility testing—are important for targeting and optimizing therapy once sepsis is suspected or confirmed (23). But the first and most important diagnostic need is establishing whether a baby is infected at all. A rapid triage test addresses this gap. By stratifying which newborns are likely infected, it raises the pre-test probability and the clinical yield of downstream diagnostics.

> [Neonates] are dying because of missed infections. Some cases are certainly due to resistant infections that we need new antibiotics for, but I think most are because they come to us late. The thing about resistance in neonates is that by the time they come to the tertiary hospital, they have had first-line antibiotics at a primary health center, some second-line antibiotics at a district hospital, and then we give them third-line antibiotics [at the tertiary hospital] and take cultures for the first time. So of course, if you measure the number of resistant infections, you say, oh look, 70% of infections are resistant. Then we just say that many deaths are resistant. But actually, most babies are falling through the cracks earlier. They are missed at primary and secondary health facilities, or treatment is delayed.
>
> —Neonatologist, Pakistan

2. The Product: A Rapid Triage Diagnostic

Diagnostics help inform timely and accurate clinical decisions. Their impact is greatest when they are used widely by healthcare professionals and meaningfully fit within clinical management pathways.

For diagnostic products that do not yet exist, a Target Product Profile (TPP) can be defined that outlines the desired profile or characteristics of a new product aimed at a particular disease (or diseases). TPPs state intended use, target populations, and other desired product attributes, including safety and efficacy-related characteristics. Such profiles, often created by the WHO and other global partners, guide innovation.

TARGET PRODUCT PROFILE

The NeoTest TPP is guided by two main principles:

1. It must work well in low-resource healthcare settings, including both primary care and hospital settings, from subdistrict to tertiary hospitals.
2. It should guide the initial care decision, ruling sepsis in or out to determine whether to initiate antibiotics for newborns with possible serious bacterial infection (PSBI).

The TPP balances accuracy with simplicity, speed, near-patient use, small blood sample volume, and minimal dependency on supporting infrastructure.

It specifies a diagnostic that requires a capillary (heel prick) blood or other less invasive sample given the difficulty of collecting blood in unwell newborns, provides results in under 30 minutes to guide urgent initial management decisions, and has a minimum sensitivity of 90% and specificity of 80% to ensure accurate and trustworthy information (Table 2.1).

The NeoTest TPP builds on earlier versions of a neonatal sepsis diagnostic TPP created by global leaders—the Indian Council for Medical Research (ICMR), NEST360, FIND, and the WHO—all of which participated in our working group. A draft TPP created by the ICMR (24) built on use case analysis from FIND and NEST360 (25) that explored the different objectives of a diagnostic. FIND, and then the WHO, undertook an extensive process to validate the benefit and feasibility of the proposed diagnostic. In mid-2025, the WHO published its TPP (26).

Building on these institutions' insights and work, we developed an expert-consensus, evidence-based TPP designed to suit the intent of the NeoTest facility. Table 2.1 outlines its key parameters; Appendix Table A.1 provides the full TPP.

Our TPP aligns very closely with the WHO TPP.[2] The differences between them, which have been discussed with the WHO, are the following:

1. **Accuracy:** The WHO TPP slightly relaxes the required specificity for a test used in primary care (70%) compared with a test used in hospitals (80%). We adopted a higher performance characteristic (80% specificity), which we deemed essential to building trust, spurring adoption, and ensuring safe decision-making for a test intended for use across both primary care and hospital settings.

2 Any blood-based test that meets the NeoTest TPP criteria would also meet the WHO TPP. The inclusion of analytes other than blood was proactively discussed with the WHO, whose primary reason for including only blood was its assessment that it is the most common and feasible analyte.

TABLE 2.1 Summary of the NeoTest target product profile

FEATURE	NEOTEST REQUIREMENT
Aim	Aid diagnosis of possible serious bacterial infection (PSBI), including bacterial sepsis, among newborns and young infants
Target population	Infants 0–59 days, including newborns (0–28 days), assessed for PSBI or neonatal sepsis
Use setting	Primary care and Level 1–3 hospitals, including subdistrict, district, provincial, and tertiary facilities
Decision supported	Whether to initiate antibiotics
Sample	Capillary (heel prick) whole blood sample or less invasive analyte; sample volumes must be small
Turnaround time	≤30 minutes essential; ≤15 minutes desirable
Hands-on time	≤10 minutes essential; ≤3 minutes desirable
Accuracy	At least 90% sensitivity and 80% specificity essential; higher specificity desirable
Operational profile	Low complexity; near-patient; robust to heat, humidity, dust, limited electrical power, and lower training levels
Instrument	Portable table-top device no larger than 25 x 25 x 25 cm and 2 kg
Affordability	$3–$5 per test, inclusive of amortized implementation and maintenance costs

2. **Price:** The WHO TPP specifies a maximum target price of US$5 and an optimal target price of US$3 per test. It does not specify a target instrument cost, should a test require one. Based on our consultations on willingness to pay and our analysis of other instrument-based diagnostics, we also set the maximum target price at US$5 and the optimal price at US$3 per test. The difference is that we state explicitly that these prices include not only the consumables but also instrument costs, maintenance, and servicing, with the latter cost categories amortized over the test volume.
3. **Analyte:** The WHO TPP specifies a test that uses a 'heel prick' or capillary blood sample of 100uL or less. Our TPP also allows for analytes that are less invasive than blood, such as saliva or wearable-based tests analyzed with artificial intelligence (AI).

INTEGRATION INTO CLINICAL CARE

A neonatal sepsis diagnostic must be thoughtfully integrated into clinical care. Through our extensive stakeholder consultation with physicians and other healthcare workers from South Asia and Sub-Saharan Africa (including those responsible for publishing national and global guidelines for the investigation and management of neonatal sepsis in LMICs), we identified the use cases in which a test would and would not be useful. Appendix B presents the full report. Three conclusions emerged from these consultations.

1. **The test would benefit the 25%–35% of neonates who fall into the "grey zone" (not obviously unwell or healthy).** The test should be used when there is considerable uncertainty about whether or not a neonate may have sepsis. Clinically, this group may include newborns who have reduced feeding but are otherwise well, are experiencing isolated single fevers, have mildly deranged blood work or mildy increased rate of breathing, or have specific risk factors (such as maternal fever).
   A test would not replace clinical judgment in obviously critically unwell infants (5%–15% of all infants), who should be treated immediately with antibiotics. It would also not be used for universal screening of newborns who appear to be healthy (50%–60%), because even with a high accuracy test, universal screening would likely produce many false positives (Figure 2.1).
   Only the 25%–35% of neonates falling into the grey zone in a hospital setting would be tested. Among neonates brought to a healthcare facility from home (who by definition would be expressing symptoms that are cause for concern), all of them would be tested.

FIGURE 2.1 Clinical zones of treatment

> [A test] would be used a lot; approximately half of the babies are in this grey zone. Also, this is something that clinicians want; we are using clinical judgment and imperfect tests like CRP [C-reactive protein] at the moment; the fact that we are making do with imperfect tests shows that there is a strong demand for something that is actually high sensitivity and specificity.
>
> —Neonatologist, South Africa[3]

2. **The test would have high uptake,** given the difficulty of diagnosing sepsis, the high mortality rate associated with it, and the growing need to curb AMR. Clinicians reported that uptake would be shaped by healthcare worker confidence, ease of use, cost, and the clinical condition of presenting neonates, with simpler, cheaper, and more intuitive tests more likely to be adopted. They indicated that they would almost certainly treat a neonate who tested positive with antibiotics but would not always refrain from using antibiotics if the results were negative. They also indicated that adherence would be higher where there were clear treatment guidelines, capacity for reassessment, and confidence in the test's reliability.

> They would certainly start antibiotics if a positive test. I think in most cases they would hold back on giving antibiotics if there was a negative test, especially if a baby is not critical.
>
> —Neonatologist, India

3. **A diagnostic test should be designed for use in both hospital and primary care settings.** Neonates are first assessed for sepsis in two types of settings: hospitals (subdistrict, district, and tertiary) and primary health centers. Understanding the proportion of neonates first assessed for sepsis in each type of setting was an important goal of our work, as the operational and performance characteristics required of a diagnostic in hospital and non-hospital settings differ. For example, a test intended for use in primary care needs to be operationally robust (e.g., small to no instrument; tolerant of unreliable electrical power, heat, and dust) but may not require as high an accuracy as a hospital-based test.

Our stakeholder consultation found that a diagnostic test would be of significant value in primary care, as many babies are either born in primary care clinics or discharged home and re-present to a primary health center with symptoms of PSBI. A meta-analysis of Demographic and Health Surveys (DHS) conducted in LMICs revealed that 28% of babies in surveyed countries were born at home or in birthing centers with limited resources (27). Experts also noted that because many hospitals in LMICs are resource-constrained, uptake would be higher if the test had an operational feasibility akin to that required by a primary care setting.

3 This expert described the grey zone as including substantially more than 25%–35% of newborns. Several other experts also reported a higher figure. Our breakdown reflects a conservative assessment.

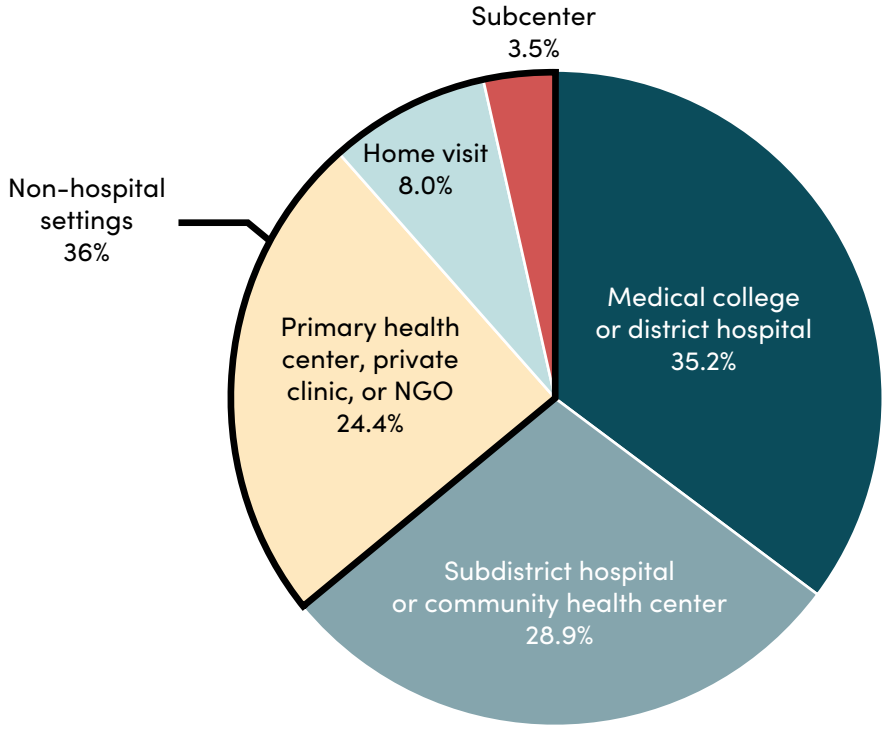
> Even for hospitals, it has to be able to work in settings that really don't have a lot of resources. They might not even have reliable electricity. They cannot have a big machine.
>
> —Healthcare worker, Zambia

> For tertiary centers in South Africa. . . [the device] can probably be quite a large device that is highly accurate. But if you want it to actually affect the masses, you need something that can be used at the patient bedside, that can sit on the NICU ward. It has to be small, it should run regardless of whether electricity is out, and everyone should know how to use it. It should be a skill that takes one hour to train how to use, like taking a blood pressure.
>
> —Pediatrician, South Africa

> Regardless of the setting, you need a test that is decentralized, easy to use by someone without skill. It should sit directly in the ward, rather than in a room or somewhere separately. Especially if you want it to be used at a primary health clinic or a district health clinic, it should fit on my desk or even on my hand. It cannot be a big device.
>
> —Community health worker and social activist, India

To extend our confidence in the importance of the Neo-Test TPP being designed for both primary care and hospital settings, we conducted our own epidemiological modeling of how individual sepsis cases move through India's health-care system (see Appendix C). Estimates from the modeling suggest that 36% of neonates with suspected sepsis are first assessed outside a hospital (in primary care or community settings), confirming that the non-hospital use case is large (Figure 2.2).

FIGURE 2.2 Where neonates are first assessed for neonatal sepsis in India, 2019–21, NFHS-5 and MoHFW



Note: For more information on our modelling estimates, see Appendix C. Survey data are from 2019–21; some parameters are triangulated across data from other years for robustness.
Source: National Family Health Survey (NFHS-5); Health Management Information System (HMIS); Ministry of Health and Family Welfare (MoHFW).

3. The Value of a Rapid Triage Diagnostic

Studies suggest that about **84% of neonatal sepsis deaths could be prevented with earlier diagnosis and appropriate treatment** (28). We conducted a health technology assessment (HTA) to examine what share of these deaths could be averted with a rapid, rule in/rule out neonatal sepsis diagnostic. The HTA was conducted by the Health Intervention and Technology Assessment Program (HITAP), the National University of Singapore (NUS), and the Center for Global Development (CGD), with co-authors from the WHO, AfroHTA, and HTA India; it built on prior modelling by FIND and Boston University (29).

The assessment finds that **a rapid, point-of-care test (POCT) designed to rule neonatal sepsis in or out would reduce the number of cases that go undetected by almost two-thirds and avert 54% of unnecessary antibiotic prescribing, reducing mortality from neonatal sepsis by 12% and sepsis-related healthcare costs by 11% (Figure 3.1).** Appendix D presents the full HTA.

The HTA estimated the potential health and economic impact of a diagnostic meeting the TPP. Using a decision tree model with a lifetime horizon and healthcare system perspective, the HTA compared the impact of a POCT against current diagnostic and management pathways for two populations of neonates: infants managed in their facility of birth ("inborn cohort") and infants brought into facilities from home or the community ("community-presenting cohort").

We organized the outcomes in terms of three types of value:

1. **Clinical value** measures what the test does at the bedside: identifying sick newborns who would otherwise be missed and ruling out newborns who would otherwise receive unnecessary antibiotics.
2. **Health system value** measures changes beyond the bedside: better antibiotic stewardship, fewer inpatient stays, fewer hospital-acquired infections, and avoided long-term complications.
3. **Economic value** measures what the clinical and health system value is worth in DALYs and dollars and the price at which the test justifies the health gains.

FIGURE 3.1 Modeled effect of neonatal sepsis point-of-care testing on mortality, missed cases, and unnecessary antibiotic use

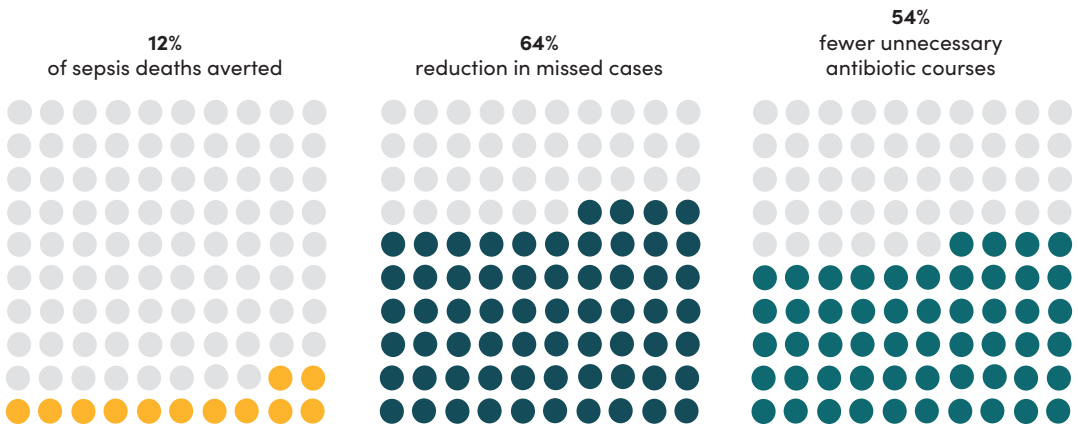
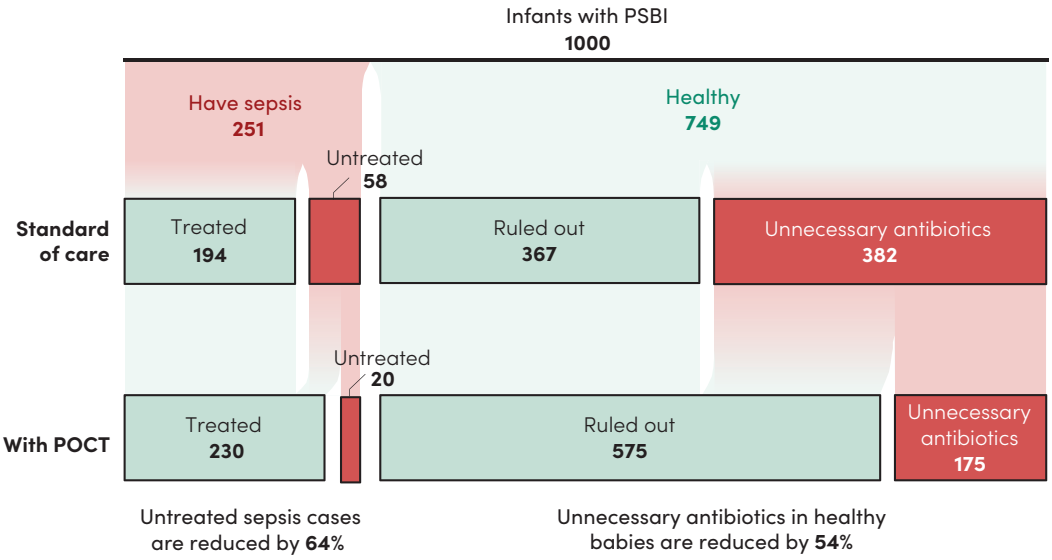


FIGURE 3.2 Modeled effect of neonatal sepsis point-of-care testing on diagnostic outcomes, per 1,000 infants with PSBI



Note: Presented results are a weighted average across the inborn and community-presenting cohort.

Clinical value

A diagnostic has two direct benefits: It improves identification of neonates with sepsis that are currently missed and prevents antibiotic use in neonates without sepsis.

Among the inborn and community-presenting cohort, the test:

- Increased the number of correctly diagnosed cases (true positives) by 17% and 26%, respectively;
- Reduced missed cases (false negatives) by 62% and 70%, respectively;
- Prevented the unnecessary administration of antibiotics (false positives) by 59% and 51%, respectively.

As a result, deaths from neonatal sepsis declined by 13% in the inborn cohort and 9% in the community-presenting cohort. Figure 3.2 depicts the average effect across the two cohorts.

Value to health system

The test's estimated value extends beyond the direct health benefits to the diagnosed infant. By correctly ruling out infants without sepsis, the tests avoids nearly 1,000 unnecessary inpatient bed-days in the inborn cohort (per 1000 infants). Shorter hospitalization reduces exposure to hospital-acquired infections (HAIs)—a major driver of neonatal mortality in under-resourced wards—preventing an estimated 5.7 HAI cases per 1,000 inborn infants with PSBI and reducing deaths from HAI by 20%. Fewer unnecessary

TABLE 3.1 Modeled effect of neonatal sepsis point-of-care testing on mortality, disability-adjusted life years, total inpatient days, and total healthcare costs per 1,000 PSBI births

OUTCOME	STANDARD OF CARE	WITH POINT-OF-CARE TEST	PERCENTAGE CHANGE
Deaths from neonatal sepsis	39	34.5	–12
Lost DALYs from all causes	1,537	1,370	–11
Inpatient hospital days	4,411	3,860	–14
Healthcare costs ($)	191,674	170,146	–11

prescriptions would also reduce selection pressure for AMR and antibiotic-related long-term complications, such as necrotizing enterocolitis and inflammatory bowel disease linked to early-life antibiotic exposure.

Economic value

For every 1,000 inborn babies presenting with PSBI, the test would save an estimated 206 DALYs and over $37,000 in healthcare costs. For every 1,000 community-presenting babies presenting with PSBI, it would save 127 DALYs and nearly $6,000 in healthcare costs.

Even when key parameters (baseline sepsis prevalence, illness severity at presentation, test accuracy, or healthcare costs) were varied, the test remained a high-value intervention (30). It was both clinically superior and cost-saving in 93% of simulations for the inborn cohort and 85% for the community-presenting cohort.

Benefits not included in our model

Our HTA underestimates the value of a neonatal sepsis diagnostic because it fails to capture several important benefits. First, **by reducing inappropriate antibiotic use in neonates without sepsis, a rapid triage diagnostic could both help reduce the burden of AMR and extend the effective lifespan of existing antibiotic therapies** (31). We did not model the latter.

> Improved diagnostics will not only help preserve the lifespan of existing drugs but also accelerate the development and clinical adoption of novel therapeutics.
>
> —Industry expert, United States (32)

Second, we modeled the benefit of a diagnostic for neonates suspected of sepsis in LMICs. It is possible that, with some changes to the immune signature or the technological platform it is used on, a diagnostic test could be adapted for use in children up to the age of five or to a high-income country (HIC) setting.[4] We did not model these benefits because of uncertainty about the likelihood that a neonatal sepsis diagnostic would be adapted to a pediatric population or HIC setting.

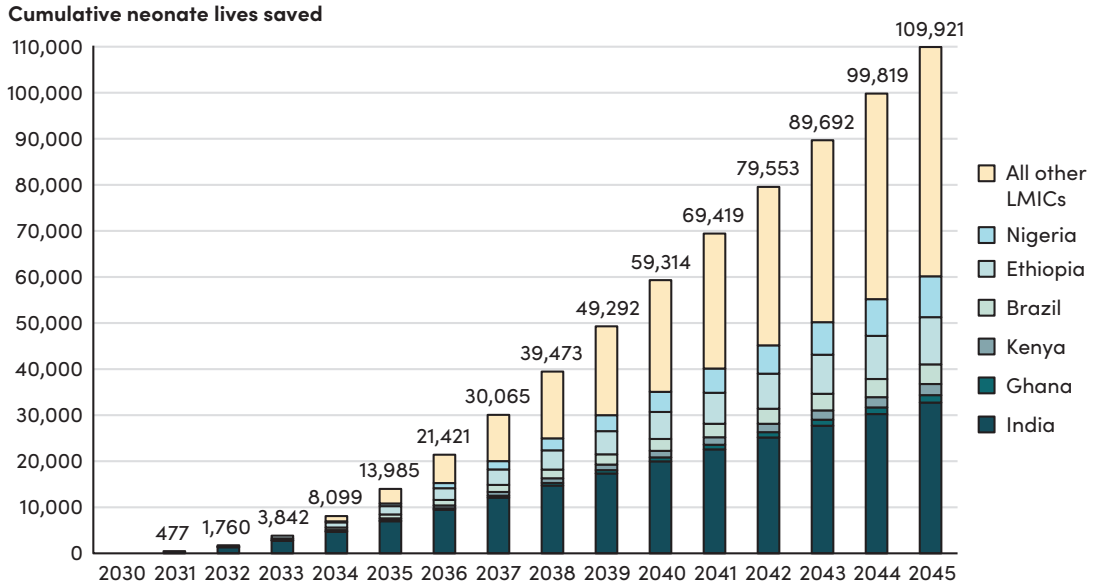
SCALING MODELED BENEFITS TO NEWBORN POPULATIONS IN LOW- AND MIDDLE-INCOME COUNTRIES

To extend our HTA to the population level, we built a bottom-up adoption model across six countries—India, Ghana, Kenya, Brazil, Ethiopia, Nigeria—plus a residual LMIC tier. For each market, we applied the setting-specific incidence of PSBI to projected live births, tracing uptake through a logistic adoption curve calibrated to the rollout of comparable diagnostics. We then adjusted each market by country-specific commercialization probabilities to estimate test use over time (see Appendix H for more information on the adoption modeling).

Based on this modeled demand, we estimate that NeoTest would avert close to 110,000 newborn deaths and save 3.7 million DALYs over a 15-year time horizon (Figure 3.3).

4 In a HIC setting, a test would likely need to have a greater specificity, as low rates of sepsis might mean that the primary benefit of a test would be in ruling out sepsis.

FIGURE 3.3 Modeled lives saved by a neonatal sepsis diagnostic, by country, 2030–45



Note: Figures are based on applying the estimated lives saved per test to modeled demand for tests. Modeled demand is built from country live births, the incidence of PSBI, and logistic adoption curves calibrated to comparable diagnostic rollouts in LMICs, risk-adjusted against per-region commercialization probabilities. Earliest market launch is indexed to 1 year post-test launch.

4. Technological Feasibility

Our assessment finds that **a rapid diagnostic for neonatal sepsis is technologically feasible and could meet the WHO TPP in the near- to medium-term future (roughly three to five years) if incentive pathways are credible.**

Our assessment drew on four sources:

- an extensive literature review of candidate test modalities;
- interviews with over 20 developers and industry experts (anonymized interviews can be shared on request);
- a mapping of firms working on neonatal sepsis or adjacent technologies (see Appendix E);
- comparison with existing point-of-care platforms for other infectious diseases.

This assessment led to several conclusions (Table 4.1):

SCIENTIFIC BASIS OF A TEST

Industry experts believe that the development of a diagnostic test is technically feasible.

A test would likely interpret the host response to infection, through either biological host responses (via several biomarkers or a molecular signature) or clinical information (such as real-time vitals data) (33). It would likely require a compact instrument or reader with an algorithmic component, potentially leveraging AI, to interpret host response information into an actionable binary or semi-quantitative result.

Although the biological basis of sepsis is not well understood, there is strong emerging evidence of many different potential approaches to measuring host-immune response (34). Each of these approaches—immunoassay, molecular, morphodynamic, and clinical data enhanced through AI—shows strong potential. It is unclear which approach is most likely to deliver a diagnostic that meets the TPP (Table 4.2).

This assessment of the feasibility of a neonatal sepsis diagnostic is further strengthened by a comparison with other point-of-care diagnostics with a similar biological basis that are approved and widely used (see Appendix E).

TABLE 4.1 Technological feasibility of a rapid triage diagnostic for neonatal sepsis

FEATURE	PROJECTION
Scientific basis of a test	The most likely scientific basis of a test is a host immune response to infection, such as a multiplex immunoassay, a molecular assay, a morphodynamic cell function, or wearable-based test. Many companies are integrating AI into diagnostics to improve performance and accuracy.
Innovator landscape	Firms are already working on neonatal sepsis, adjacent sepsis diagnostics, or adaptable point-of-care platforms.
Competition and leading firms	There is no clearly superior scientific approach or a leading set of firms.
Technical challenges	Although firms anticipate technical problems in developing a neonatal sepsis diagnostic—such as working with small blood volumes and unclear regulatory processes—they are surmountable with a sufficient demand signal and expected commercial returns.

TABLE 4.2 Summary of the scientific basis of a rapid triage diagnostic for neonatal sepsis

MEASURE	EVIDENCE	NOTES
Immunoassay		
Measures combinations of host response proteins or inflammatory markers; examples include immunochromatography, microfluidic, electro-immunoassay, nanofluidic, and digital ultra-sensitive immunoassays.	Individual biomarkers are not sensitive enough, but combinations show promise (35–37).	Multiplex immunoassay platforms are mature; the main barrier is establishing the combination of biomarkers. Several firms are developing multiplex immunoassays that would meet the TPP requirements.
Molecular		
Genetic material (DNA/RNA) and immune signatures (either RT-PCR or isothermal NAAT).	Meta-analysis of 68 studies reveals pooled sensitivity of 0.91 (95% confidence interval 0.85–0.95) and specificity of 0.88 (0.83–0.92) (37).	Immune signatures meet (or are close to meeting) required accuracy; the main barrier is the operational requirements (size of instrument, robustness) required by the TPP, although several firms are likely to meet them.
Morphodynamic cell function		
Cell morphology and function.	Evidence is limited, but several studies show promising sensitivity and specificity (38, 39).	Promising; would likely meet the TPP if basic R&D were derisked.
Clinical data easily collected and analyzed through AI		
Vitals data (heart rate, blood pressure, temperature, oxygen saturation) collected automatically and over the course of several minutes and subsequently integrated with AI algorithms.	Data from academic studies and innovators in this space are promising (8, 19).	Several companies are working on wearables, but it is unclear whether they would meet accuracy requirements.

We have enough background on the scientific approach to make a test of this nature work. A lot of cytokines are interesting. In the review of molecular assays we did, a lot were very close to the performance required. It is exciting with AI, using heart rate rhythm and other things to diagnose neonatal sepsis. Especially in age of -omics [proteomics; multinomics], we are seeing very accurate tests with a drop of blood.

—Industry expert, Canada

We could make a test easily. We have been interested in neonatal and maternal sepsis; it is a natural progression of the utility of our platform. Ultimately, if there was money to get this to a working platform that has been cleared by the regulatory authorities, we would.

—Innovator, United States

Technology has come a long way in the last 10 years. Having a look at the different devices, the technology is there. It might need some fine tuning.

—Industry expert, United Kingdom

INNOVATION LANDSCAPE

We conducted a mapping of firms working directly on neonatal sepsis or in adjacent fields (e.g., pediatric or adult sepsis) and firms with relevant POCT or near-POCT devices.

We used three approaches to identify the firms:

1. coordinating with FIND and NEST360, which conducted a large survey of innovators (contacting over 150 innovators, 30 of which responded) (40);
2. reviewing the landscape-mapping exercises conducted by the India Health Fund, PACE, and CARB-X;
3. conducting our own search.

We identified 43 firms working either directly on neonatal sepsis rule in/rule out diagnostics or on diagnostics with strong potential to be adapted to neonatal sepsis. The latter included firms working on either one of the promising technology types identified above or on diagnostics for pediatric or adult sepsis triage. We spoke to 24 of these firms, focusing on those at more advanced stages of development.[5] The results revealed three key takeaways.

1. **Several firms are working directly on neonatal sepsis diagnostics.** Some of them are in early R&D stages or are clinically validating prototypes. Most would require further development or modifications to their current development pathway to address R&D challenges (outlined below in "Innovation Challenges") to meet the NeoTest TPP. A broader set of companies have mature POCT platforms that could be adapted for a neonatal sepsis application. These firms indicated that such an adaption could be possible.

TABLE 4.3 Descriptions of the 10 most promising firms that could meet the NeoTest TPP

LOCATION	APPROACH	STAGE OF DEVELOPMENT
Asia	Reverse Transcription Polymerase Chain Reaction (RT-PCR) and Reverse Transcription Loop-Mediated Isothermal Amplification (LAMP) using mRNA signature	Mature and miniaturized mRNA platform used for other indications; no specific sepsis signature
	Multiplex immunoassay	Approved products throughout Asia; interested in neonatal sepsis, no active trial
Canada	RT-PCR using a neonatal mRNA signature	Clinical validation of an immune signature for pediatric sepsis; some validation of a neonatal signature
Europe	Immune cell morphodynamics on a small benchtop machine	Early clinical validation trials
United Kingdom	Multiplex immunoassay	Clinical trials for pediatric sepsis; no active trial for neonatal sepsis, though interested
United States	Clinical data integrated into AI–driven algorithm	Working on pediatric sepsis; starting a trial for neonatal sepsis soon
	Multiplex immunoassay	Approved in the United States for adult sepsis; considering a neonatal application
	Multiplex immunoassay	Promising trial data for neonatal sepsis; clinical validation trials underway
	RT-PCR using two gene signatures	Approved product for adult sepsis; interested, but no active trial for neonatal sepsis
	Wearable that continuously monitors vitals integrated with AI algorithm	Approved as vitals monitor in Sub-Saharan Africa; working on the sepsis prediction side (early validation trials)

5 Interviews can be shared on request.

2. **Promising technologies are unlikely to progress to commercialization without a clear demand signal.** It is relatively easy for firms to enter the neonatal sepsis space: Early-stage R&D work is largely grant funded and requires relatively little capital. The downstream development stages—validation, regulatory approval, manufacturing, and commercialization—are substantially slower and costlier. Firms invest in such development only when the end-market is attractive—and without outside intervention, LMIC markets are rarely attractive on their own. Accordingly, early-stage R&D for diagnostics with a primary use case in LMICs does not progress through to later development stages. Firms capable of bringing these diagnostics to LMIC markets prioritize larger, more predictable markets instead.

> We won't [focus on neonatal sepsis diagnostics] unless the incentives are there. Technically, we think the R&D team can get it done, [we] just haven't focused in on it.
>
> —Diagnostic developer working on pediatric sepsis, United States

> We need a recurring budget for R&D to generate clinical trial evidence, which we currently don't have.
>
> —Diagnostic firm working on neonatal sepsis, India.

> [We] need a clear message that there is a big issue there and that physicians would want and use a test.
>
> —Diagnostic developer, Europe

3. **The field remains fragmented, with no clear leading firm or technology.** Innovation is spread across firms of different sizes and in different places, including small- and medium-size companies and large diagnostic firms across Europe, North America, and Asia. The fact that we were unable to identify a single leading firm or technology is consistent with a market that has scientific promise but has not yet received the investment or demand signal needed to converge toward a small set of firms at a later stage of development.

Table 4.3 presents information on the ten firms we found most promising with respect to their ability to meet the NeoTest TPP. Additional information on these or other firms we spoke to is available upon request.

INNOVATION CHALLENGES

Interviews with developers supported our conclusion that a rapid triage diagnostic for neonatal sepsis is technically feasible. These interviews also identified the following technical and commercialization barriers:

- **Very small blood volumes:** Some developers described adapting platforms to use very small neonatal blood volumes as a challenge (41). Others already had platforms designed to use small volumes of blood.
- **Need to achieve both high sensitivity and useful specificity:** The test must maintain high sensitivity so that sick newborns are not missed but be specific enough to avoid overtreating well newborns.
- **Low-resource settings:** The test must be robust enough to function reliably outside well-equipped laboratories and simple enough for primary care and low-level hospitals to use.

> It is about getting the technology on a simple device that is usable. The technical background is already there.
>
> —Industry expert, Canada

- **Need to perform across neonatal subgroups:** Sensitivity must hold for infants of all ages (up to 60 days), prematurity status, and the primary locations in which sepsis is suspected (hospital or community).
- **Small scale:** Many developers described their target price and cost of goods sold (COGS) as within our TPP range—with the caveat that such a price could be achieved only if demand were sufficiently strong for them to scale up

their manufacturing. One developer indicated that its test price of €10 could fall by half if volume increased substantially; several other firms noted similar expected price reductions with volume. Analysis of the cost per test of comparable diagnostics with established markets is consistent with these claims (see Appendix E).

- **Slow regulatory processes in LMICs:** Several firms mentioned that slow regulatory approval processes present a significant opportunity cost, encouraging them to focus on well-established regulatory systems in high-income markets.

> AI is opening the skies of possibility, yet discovery collides with the crawl of outdated approvals and trial processes. This is the first handcuff.
>
> —Industry expert, India (42)

- **Unclear regulatory standards:** The regulatory and evidentiary standard against which a *de novo* neonatal sepsis triage test should be assessed is unclear. To address this problem, several working group members—including CGD, FIND, the ICMR, and other technical partners—are conducting a technical consultation on the evidentiary and regulatory pathway for a *de novo* rapid triage diagnostic. This consultation will inform acceptable regulatory standards in India's Central Drugs Standard Control Organisation (CDSCO) and the WHO's Prequalification Programme.
- **Lack of a clearly broadcasted demand signal:** The lack of a clear demand signal from countries discourages firms, which tend to prioritize high-income or better-established markets.

> We need a clearly broadcasted demand signal, with the promise of returns. The promise of jam tomorrow doesn't work today.
>
> —Diagnostic developer, United Kingdom

5. Market Challenges in Developing and Commercializing New Diagnostics

We identified market barriers by drawing on three sources:

- interviews with diagnostic developers (including developers working on neonatal sepsis diagnostics);
- case studies on the innovation, adoption, and rollout of comparable POCT diagnostics in LMIC markets;
- the literature on the economics of innovation.

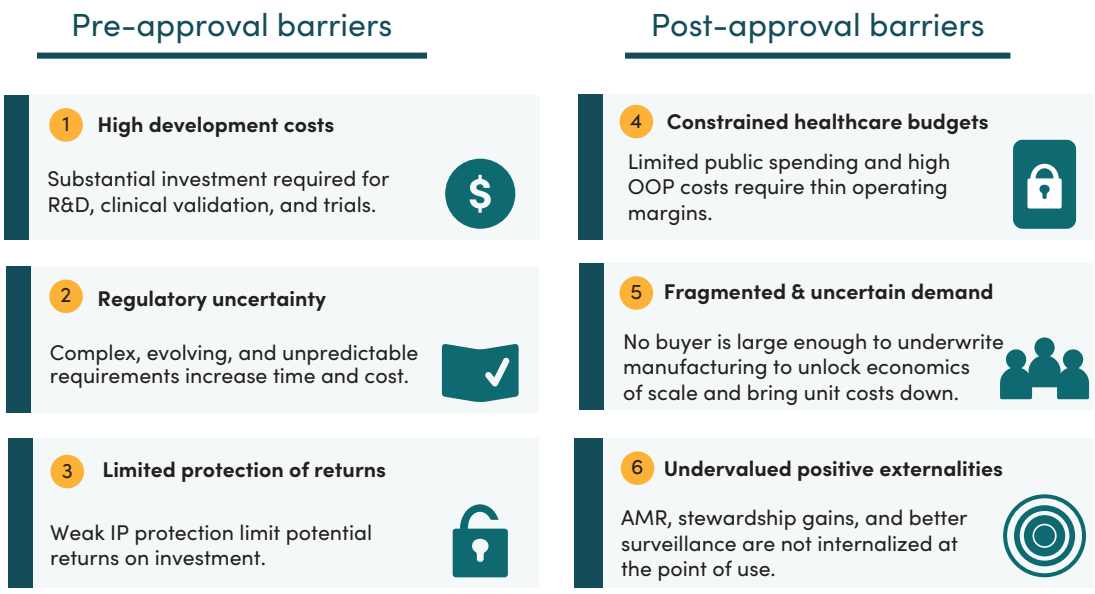
This work revealed that diagnostic developers considering LMIC markets face barriers at different points in the product lifecycle (Figure 5.1). Pre-approval barriers affect investment in discovery, prototyping, and clinical validation. Post-approval barriers affect whether a successful product is adopted, procured, and used at scale. Pre-approval barriers primarily affect innovation. Post-approval barriers inhibit both innovation and access, because barriers that suppress adoption or procurement also suppress lifetime product revenues, reducing the reward from innovation.

HIGH DEVELOPMENT COSTS

Bringing a point-of-care diagnostic to market involves a series of capital-intensive stages, including investing in assay development, platform adaption and engineering, and multisite clinical validation in neonates (43). Clinical validation is particularly demanding, as small blood volumes make recruitment challenging and culture-confirmed cases are difficult to enroll at adequate statistical power.

Across interviewed developers, total costs incurred up to and including regulatory approval averaged $15–$23 million over six to seven years. These costs are incurred years before any revenue begins. For indications without a sizable, lucrative HIC market, the opportunity cost of dedicating R&D capacity to them is high (44).

FIGURE 5.1 Pre-and post-approval market challenges in diagnostic markets



LIMITED INTELLECTUAL-PROPERTY PROTECTION

Diagnostics have less intellectual property protection than therapeutics and vaccines (45). Many biomarkers are unpatentable, and immune signatures can often be reverse-engineered from published validation studies and regulatory filings (46).

In interviews, developers reported that they rarely resorted to patents to preserve the returns on their innovations, depending instead on platform complexity, manufacturing know-how, accumulated clinical data, and having lower prices than their competitors. The effective exclusivity period for an innovation is therefore defined by how rapidly competitors can reverse-engineer a diagnostic. This exclusivity window is important because it is when first-movers recoup the higher development and commercialization costs associated with pioneering scientific advances, regulatory approval, procurement processes, and country adoption pathways. If firms cannot recover these costs before follow-on competitors undercut prices, they are unlikely to seriously attempt innovation.

CONSTRAINED HEALTHCARE BUDGETS

The invention of a diagnostic does not guarantee wide uptake in LMICs; the test must also be affordable. In low-income countries, combined government and donor health spending averages $17 per capita (47), of which only 3.5%–4.6% is dedicated to laboratory medicine (48). High out-of-pocket costs and limited government health spending in LMICs mean diagnostic prices must be low to achieve broad uptake, supporting only thin operating margins. Firms anticipate these constraints, which reduce ex ante R&D incentives while also limiting ex post commercialization.

UNDERVALUED POSITIVE EXTERNALITIES

Diagnostics generate value beyond the immediate clinical act for which they are bought: they help avert empiric antibiotic use, reduce unnecessary hospitalization and hospital-acquired infections, help improve population-level surveillance, and reduce the risk of long-term complications and their costs. Because this value is diffuse and does not accrue solely to the individual or facility buying the test, it is not factored into procurement decisions. Current health technology assessment methods compound this problem: only 5 of 20 published economic evaluations of point-of-care diagnostics incorporate societal AMR costs, even though several interventions became cost-saving once societal AMR costs were included (49). The result is that prices reflect a small share of the true social value of a test.

> [Existing health technology assessment] frameworks fail to capture the full value of diagnostics, including operational efficiencies, system-level benefits, and long-term population impacts such as AMR mitigation. The omission of these broader and often "hidden" value elements, combined with difficulties in attributing downstream clinical benefits, results in health gains frequently being credited to subsequent antibiotic treatments alone, while diagnostics are primarily viewed as a cost rather than an investment.
>
> —Office for Health Economics (50)

FRAGMENTED AND UNCERTAIN DEMAND

Unlike vaccines, for which Gavi coordinates procurement at scale across LMICs, diagnostics have no centralized global procurer. Demand is dispersed across dozens of LMICs and often fragmented within them across national, state, and local

procurement agencies. Because each country often requires its own regulatory submission, distributor arrangements, and tender process, entering a market carries a high fixed cost. As a result, when firms do concentrate on LMIC markets, they focus on the few that are large enough to justify entry, passing over the many smaller ones. Doing so harms both firms—which cannot cost-effectively unlock the additional volume that would help justify the initial R&D expense and decision to scale up manufacturing—and patients, who never gain access to the test.

> The problem with all of this is that diagnostics are very hard to sell. Let's say you invest all of this money, come out with a solution for sepsis, and then nobody buys it. You face lots of regulatory hurdles within each individual country—there's lots of friction in each market.
>
> —Diagnostic developer, Europe

The result is a low-volume, high-risk equilibrium, in which barriers reinforce one another:

- High fixed R&D costs raise the revenue a firm needs to justify entry;
- Weak intellectual property protection shortens the period in which a first-mover can earn above-competitive returns;
- Low willingness to pay caps the unit price a firm can charge;
- Fragmented demand caps the volume a firm can expect to sell;
- Uncertain adoption makes future revenue hard to forecast at the point of investment.

Each barrier is manageable in isolation. Combined, however, they push diagnostics for LMIC indications below the threshold at which a rational firm would invest, even when the science is plausible and the clinical need great.

6. The NeoTest Facility: A $60 Million Pull-funding Mechanism

Public funding for innovation typically operates through two channels: "push" funding, which pays for inputs (e.g., research grants) and pushes ideas out of the lab, and "pull" funding, which pays for outputs (e.g., prizes and advance commitments) and pulls them all the way to market. The latter incentivizes innovation by creating demand for a specific product, which draws private investment towards it.

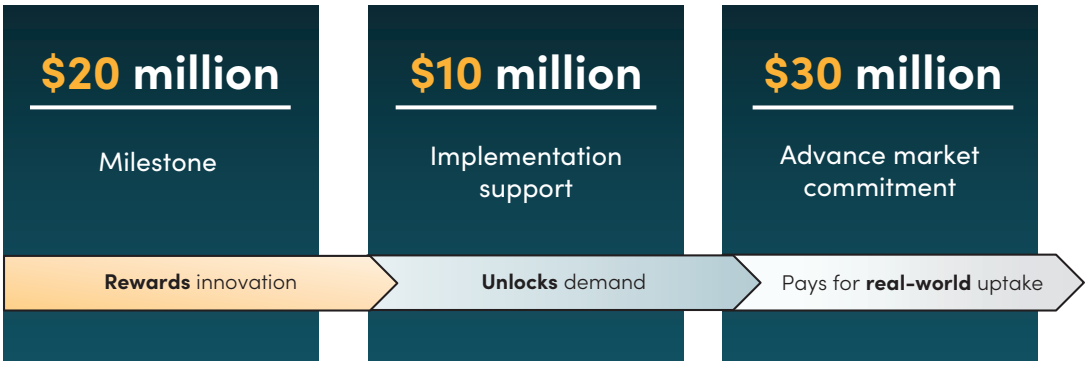
The NeoTest facility seeks to deploy $60 million in pull incentives across three components to close the gap between what a successful neonatal sepsis diagnostic is worth to society and what developers need to justify investing in R&D (Figure 6.1). **Each component targets a different market friction in the development ecosystem; together, they form a single pay-for-success mechanism.**

This hybrid pull mechanism has two key benefits:

1. **It pays on delivery, so funders do not have to bet on firms upfront.** No technological approach or firm is clearly ahead. Rather than asking funders to pick a winner among these firms, the mechanism draws in the whole field, paying out only to the firm or firms that develop a test that meets the TPP.
2. **It is designed to catalyze and sustain a long-term market.** Because the advance market commitment (AMC) pays out per unit rather than as a lump sum, a firm's reward scales with usage, giving firms a continued incentive to build adoption infrastructure and reduce unit costs. A consequence is that the market should remain and sustain itself after the subsidy ends.

The NeoTest pull fund is collaborating with existing push-funding efforts for rapid triage neonatal sepsis diagnostics. Push funding is essential for derisking early-stage science; when combined with pull funding, developers gain the confidence that their innovations have both a development pathway to advance through and a viable market at the end of it.

FIGURE 6.1 Components of the $60 million NeoTest facility



NEOTEST PARTNERS WITH CARB-X

NeoTest is actively partnering with CARB-X, the world's leading push funder for AMR diagnostics (as well as preventatives and therapeutics). CARB-X provides non-dilutive grants, gated milestone payments, and customized scientific support for early-stage R&D projects. It has already committed US$10 million in push funding to neonatal sepsis diagnostics. Its 2026 funding call is targeting a rapid triage test that is aligned with the TPP used by NeoTest. Together, CARB-X and NeoTest support a healthier economic ecosystem for the development and deployment of much-needed neonatal sepsis diagnostics.

For more details on the rationale behind the mechanism design and alternatives we considered, see Appendix F.

THE MILESTONE COMPONENT

Description

A $20 million prize will be awarded for the firm (s) that obtain regulatory approval for a product that meets the TPP (in addition to other criteria specified below). The first qualifying firm will receive $5 million. A 12-month eligibility window will then open; when it closes, the remaining $15 million will be divided equally among all firms that meet eligibility criteria, including the first qualifying firm.[6]

Purpose

The first developers to bring a TPP–compliant test to market create a public good: They prove technical feasibility, clarify the regulatory pathway, and validate the LMIC commercial market. Once that knowledge exists, follow-on entrants (including low-cost copycats) can free-ride on it, eroding the first-mover's ability to recoup its investment. The milestone therefore compensates first-movers upfront, independently of whatever market share they later capture.

Eligibility

An expert committee will determine whether firms meet milestone eligibility against pre-specified criteria. These criteria include the following:

1. Compliance with the TPP (meeting the minimum requirements of each criterion). Firms are not additionally rewarded for meeting "optimal" criteria or achieving better performance outcomes than competitors.
2. Regulatory approval through a WHO prequalification or a pre-approved Stringent Regulatory Authority (SRA).
3. An independent cost-of-goods sold (COGS) audit conducted by a pre-established list of vendors, demonstrating that the COGS can allow the firm to meet the price point specified in the TPP.
4. A binding commitment to commercialize the product in LMICs within a defined window.
5. The delivery of pilot units.

Thinking behind the design

The two-tranche, 12-month structure frontloads a meaningful, liquid reward for the first- mover, avoiding a winner-take-all dynamic, which may disincentivize competitor firms. The window is set wide enough for parallel development efforts to qualify but not wide enough to allow for true reverse-engineering purely from observing the first mover's approved product.

The commercialization commitment to LMIC markets prevents the milestone from going to firms with no intention of entering them. The COGS audit enables both procurers and the administrator to examine the marginal cost of the winning diagnostic(s). Doing so prevents procurers from negotiating procurement tenders below a developer's sustainable production cost and allows the expert committee to evaluate a test's marginal cost as part of the milestone eligibility determination.

6 For example, if a firm qualifies and no other firm qualifies before the 12-month window closes, that firm receives the remaining US$15 million, giving them US$20 million in total. If a second firm qualifies within the window, the US$15 million is split equally between the two: the first firm receives US$5 million on qualification and a further US$7.5 million when the window closes, while the second firm receives US$7.5 million when the window closes. If three further firms qualify within the window, the $15m prize is split four ways: each of the three later firms receives US$3.75 million when the window closes, while the first firm gets their initial US$5 million + US$3.75 million.

THE IMPLEMENTATION SUPPORT COMPONENT

Description

A $10 million pool will be allocated through a competitive request for proposal (RFP) process open to LMIC governments, NGOs, implementers, and multilateral partners. RFPs will be evaluated against transparent criteria.

Purpose

The implementation support fund builds the country-level infrastructure that helps turn an approved product into a routinely used one. Because there is no centralized global procurer for diagnostics, a firm bringing a new test to market must navigate dozens of country-specific systems, each with its own regulatory processes, essential diagnostics lists, treatment guidelines, procurement practices, training pipelines, and clinical workflows. Even a technically excellent TPP compliant test can fail to reach patients because the institutional structure for adoption does not exist.

Eligibility

Eligible activities could include, but are not limited to, those outlined in Table 6.1.

Thinking behind the design

Implementation support is deliberately flexible, because the binding constraint differs across markets. In one country, it may be the absence of clinical trial data on its population; in another, it might be an outdated essential diagnostics list or the lack of a procurement entity with authority to aggregate facility-level demand. A rigid category-by-category allocation would force the facility to spend against the wrong constraints in some markets.

THE ADVANCE MARKET COMMITMENT (AMC) COMPONENT

Description

A $30 million subsidy pool will pay a per-test top-up for 6 million units: $7 for the first 2 million qualifying tests, $5 for the next 2 million, and $3 for the last 2 million (Figure 6.2). The top-up is in addition to the country co-payment, which is the price paid by the procuring body[7] of an LMIC for the test (i.e., what it would have counterfactually paid in the absence of an AMC).

Once the AMC subsidy is exhausted, the mechanism no longer operates. The diagnostic would then be procured at an

TABLE 6.1 Eligible activities under the implementation support fund

ACTIVITY	DESCRIPTION
Clinical utility evidence	Local or multi-country studies to build confidence and support regulatory and guideline decisions
Guidelines and an essential diagnostic list	Support for updates to treatment guidelines, essential diagnostics lists, and referral pathways
Procurement readiness	Tender design, demand aggregation, volume planning, and co-pay arrangements
Workflow integration	Training, checklists and facility-level implementation support
Targeted demand support	Limited volume guarantees or conditional subsidies where demand credibility is the main barrier
Learning and verification	Monitoring of uptake, use, outcomes, and operational lessons for future diagnostic mechanisms

7 A procuring body is an entity that purchases diagnostics within an LMIC health system. Such bodies include ministries of health, NGOs, individual facilities, and multilateral partners. Examples include the Kenya Medical Supplies Authority (KEMSA), the Tamil Nadu Medical Services Corporation, and UNICEF's supply division.

unsubsidized, market price, which we term the "tail price." We anticipate the tail price would be anchored to the country co-payment of $3–$5 per test. Ideally, this price would be even lower if the market were competitive by the end of the subsidy period (which the firm-agnostic nature of the AMC encourages). The tail price is not a contractual outcome of the mechanism; it is an intended outcome—one we think the unique design of NeoTest has a strong chance of achieving.

Purpose

The primary purpose of the AMC (as with the milestone) is to increase returns to, and thereby incentivize, innovation. The distinctive way in which an AMC distributes this funding aligns development incentives to health system needs.

Because the mechanism pays only as tests are procured, firms must factor in real-world clinical workflow throughout the development process. If firms design a test that is not useful, clinicians will not buy it, and firms will not be able to capture the subsidy. Moreover, because the mechanism remains open to any firm meeting the TPP, commercial returns depend not only on developing a clinically valuable test but also on outperforming competitors. This feature creates an ongoing incentive to produce tests that are inexpensive, easy to use, and increasingly informative (for instance, by incorporating pathogen identification and antimicrobial susceptibility data). Over time, these features will help guide the market toward a long-run, sustainable purchasing price (the tail price) once the subsidy runs out.

Eligibility

Any firm selling a test in public LMIC markets that meets the TPP is eligible for the top-up. A firm need not have been a recipient of the milestone component to be eligible for the AMC.

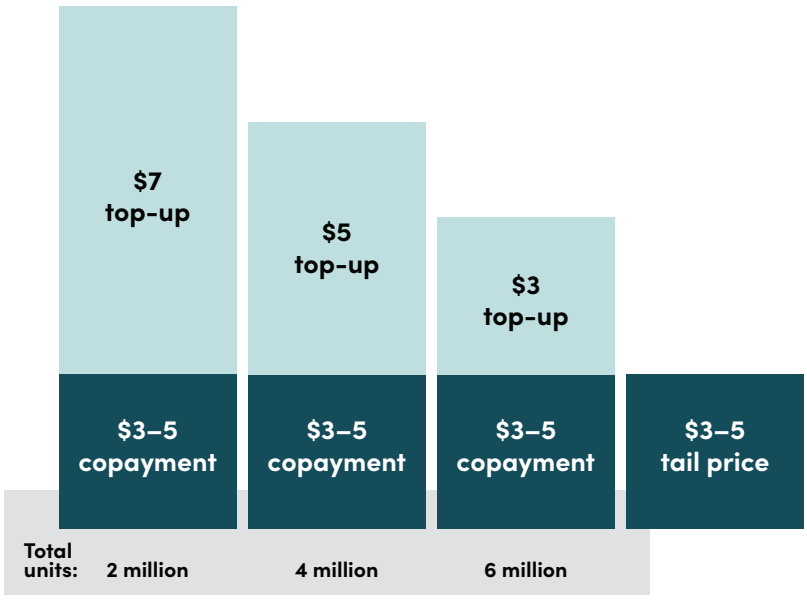
Thinking behind the design

The AMC is designed to benefit three groups of stakeholders: users (patients and countries), developers, and funders.

Patients and countries

- Because the subsidy goes only to the tests that are procured by in-country facilities or local procurers, it is on-the-ground stakeholders who direct financial flows. Funders cannot push a chosen test into the system; rather, patients, clinicians, and facilities reward the test they prefer.
- Because the subsidy is firm-agnostic, firms must compete for it. Competition encourages firms to both lower prices and make the diagnostic more valuable to patients and clinicians.

FIGURE 6.2 Stylized representation of AMC subsidy pool disbursement



Developers

- The subsidy replaces the role that patent-protected profits play in high-income markets, enabling firms to recover development and commercialization costs they could not otherwise recoup at standard price points in LMIC markets. Unlike a patent, however, the mechanism does not increase costs for health procurers or out-of-pocket costs for patients—an important feature for LMICs, given their constrained healthcare budgets.

Funders

- Because patients and countries decide which tests to buy and use, funders pay only if a test is used. A test that is developed but not adopted triggers no disbursement from funders, eliminating the risk of funder capital rewarding a test that has little real-world value and utilization.
- By not picking winners, an AMC is firm-agnostic, shifting risks from funders to firms. Only firms that privately judge that they can meet the TPP and achieve real-world uptake will stake their own capital to enter. For a neonatal sepsis diagnostic, this is important, as there a range of factors which make it difficult for funders to reliably identify the leading firms in advance (e.g., firms are globally disbursed, integration into clinical workflow and trustworthiness are difficult to screen for in a TPP).

TIMELINE

The facility is expected to have a 10-year lifecycle from announcement to completion (Figure 6.3).

WHY $60 MILLION?

A larger funding facility motivates more firms to develop a test that meets the NeoTest TPP, increasing the chance that at least one reaches market. But this comes with diminishing returns: each additional firm drawn in costs proportionally more than the last, so each additional dollar buys a smaller increase in the probability of at least one firm getting to market. Sizing the facility is therefore a matter of finding the point at which the chance of success is reasonable but each additional dollar put in still meaningfully raises it.

To find that point, we first estimated the expected cost for a firm to commit to the full development pathway and the per-firm probability of success. We also considered expected revenue from developing a test (outside of that rewarded by our facility), existing push funding, and risk premia, recognizing that paying firms only upon development of a test entails risk. These parameters were drawn from over 700 data points collected from the academic literature (49–54), case studies, expert consultations, and interviews with 24 diagnostic developers. These firm-level inputs anchor our stage-wise costs, durations, and probability of success parameters (see Appendix G).

We input these parameters into the Market Shaping Accelerator's pull-incentive sizing tool (55), which generates a curve mapping facility size to the probability that at least one compliant diagnostic reaches market (Figure 6.4). From this curve, we chose $60 million, which corresponds to a 70% chance of success and is before the point where diminishing returns set in.

FIGURE 6.3 Stylized timeline of NeoTest, 2026–36

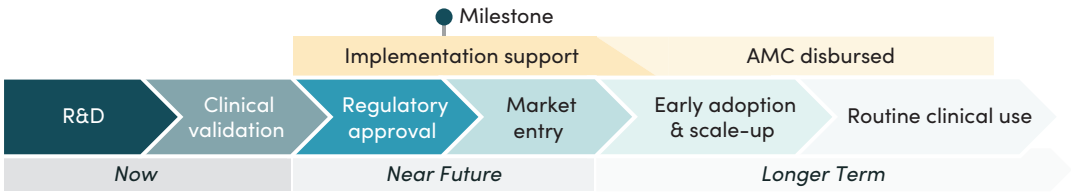
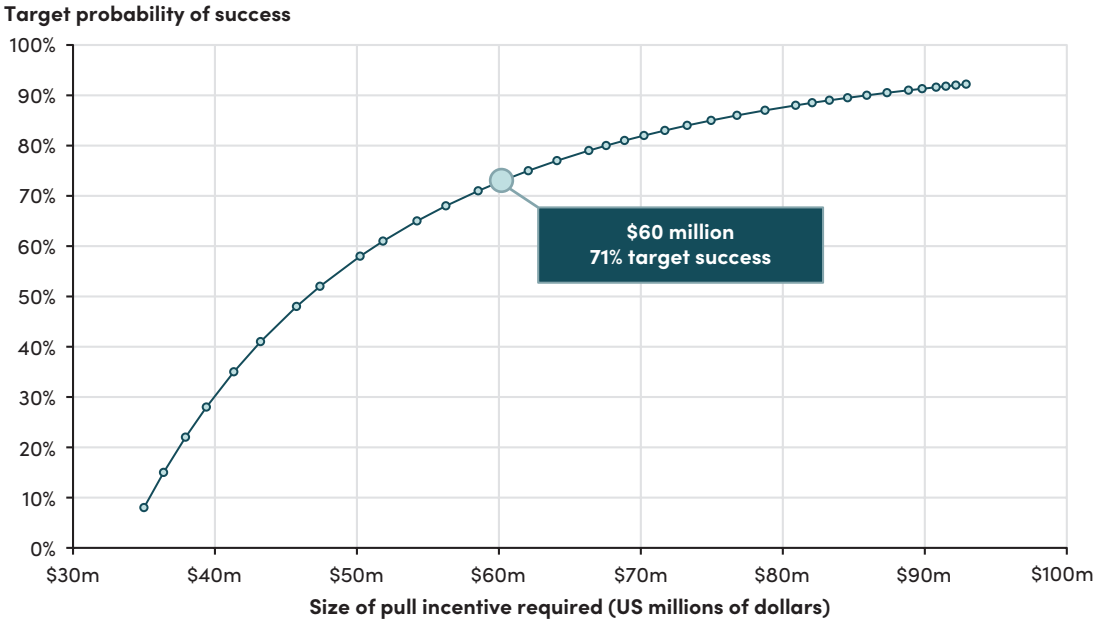


FIGURE 6.4 Target probability of success at selected pull incentive sizes



The $60 million fund size is our target, but not a ceiling; we aim to raise more. A larger fund would attract more firms, increasing both the probability of a diagnostic being successfully developed, as well as the speed of its development and adoption. Although a larger fund risks overpaying the winner, the benefit–cost ratio remains highly favorable even at higher funding levels (see Section 8), because the social benefits of an effective neonatal sepsis diagnostic are so large.

7. Country Engagement

NeoTest is structured to be responsive to country demand and needs. A diagnostic generates AMC payments only if it is affordable, operationally suitable, and clinically trusted enough to be taken up by LMIC health systems.

It also avoids paying for innovation that does not translate into impact. A recurring challenge in diagnostics is the creation of products that are technically strong but still fail to achieve scale because they do not fit procurement systems, clinical workflows, financing constraints, or implementation realities (56). Because payment of the AMC is contingent on country uptake, we sought to validate that there are countries likely to be early adopters and to understand their needs, perspectives, and likely pathways to adoption.

PLAUSIBLE EARLY ADOPTERS

To identify where early adoption is most plausible (57), we prioritized countries with the following characteristics:

- The burden of neonatal sepsis is great.
- Neonatal mortality, infection management, and/or AMR are salient policy concerns.
- Procurement and regulatory systems can feasibly introduce a new diagnostic.
- Health system infrastructure and financing can support use at scale.

This process identified eight countries—Brazil, Ethiopia, Ghana, India, Kenya, Nigeria, South Africa, and Tanzania—that seem most plausible as early adopters.

India has been a focus of this process. It has one of the world's largest neonatal sepsis burdens. It also has a substantial domestic diagnostics ecosystem and has directed policy attention to neonatal sepsis and newborn survival. It is also a complex adoption environment, because procurement is decentralized. Many decisions are made at the state level, but national technical bodies and ministries remain important for guideline setting, evidence generation, and market signaling. For this reason, our work in India has focused on both national policy and "bottom-up" implementation pathways. Accordingly, the NeoTest team has been coordinating with the Indian Council of Medical Research (ICMR) and the Ministry of Health and Family Welfare (MHFW); additionally, the health technology assessment (HTA) described in Section 3 was undertaken with Indian partners at HTA India, a government agency within the Department of Health Research.

Alongside work in India, we have undertaken targeted outreach and scoping activities for Brazil, Ethiopia, Kenya, Nigeria, and South Africa, with further analysis continuing through PATH. Based on these conversations, we found that there is clear interest in, and capacity for, adoption of a neonatal sepsis diagnostic across the eight countries. Stakeholders consistently identified neonatal sepsis diagnosis as an important unmet need and viewed a rapid diagnostic as a valuable addition to existing care pathways. Although no country was able to commit to procuring a product before it existed, discussions validated both demand and plausible routes to uptake in several priority settings.

Any diagnostic that helps neonatal care will be a top priority. Once we show that the tool works, then [purchasing] it won't be that difficult. The ministry is looking for anything that can reduce neonatal mortality, so long as it is supported by evidence.

—Senior public health expert, Ethiopia

Neonatal sepsis remains a critical challenge, and the prospect of rapid, affordable diagnostics could be transformative. We would be very interested in engaging further to understand more about the initiative, explore potential early adoption, and discuss how ongoing work in maternal and newborn health could align with and support this effort.

—Maternal and newborn health leader, Kenya

COUNTRY ADOPTION AND IMPLEMENTATION

Adoption barriers differ by country. In some settings, approval and uptake may require local clinical trial data and utility studies; in others, regulators and technical bodies may accept decisions from trusted regulators or evidence generated in peer countries. Some systems will need support on value assessment, budget impact, reimbursement, and procurement planning; others will need physician and provider training, integration into neonatal care pathways, quality assurance, and supply-chain readiness.

The implementation support component of the NeoTest fund is designed to address these country-specific barriers. It aims to build a pathway that supports countries in generating evidence, demonstrating value, training clinicians, planning procurement, integrating the test into newborn-care pathways, and supporting scale-up. We view the implementation support from NeoTest as catalytic, not sufficient on its own: once a qualifying product is available, NeoTest will work with countries, implementation partners, and maternal, newborn, and child health funders to co-finance support.

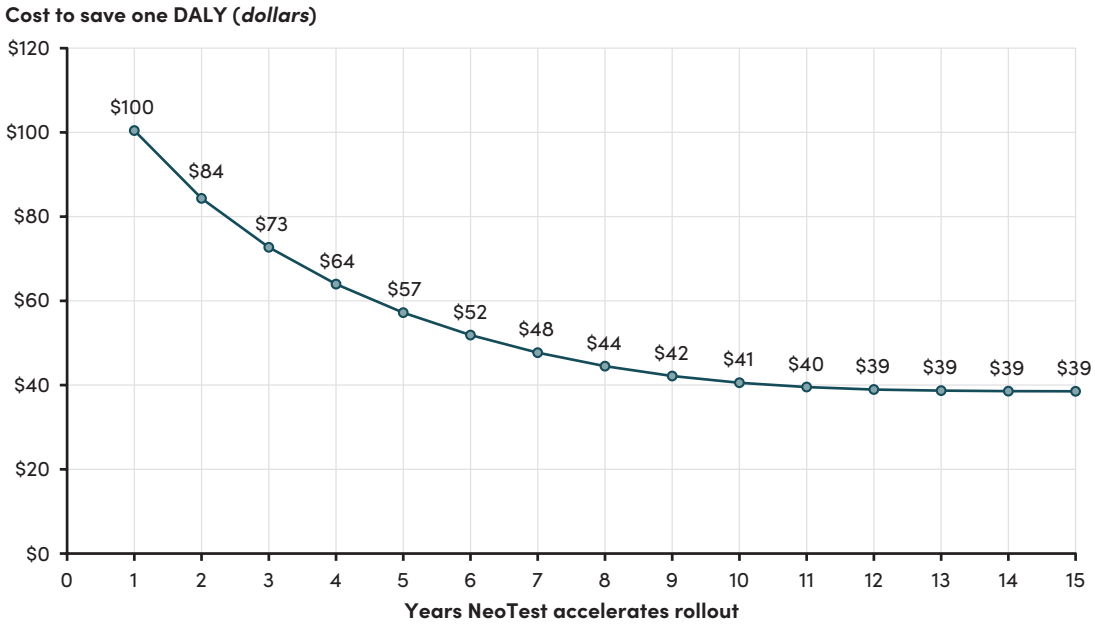
8. Funder Proposition

The funder proposition is straightforward:

- Neonatal sepsis causes one newborn death every 45 seconds, in part because of diagnostic uncertainty. NeoTest aims to accelerate the development and deployment of a specific, high-value, feasible, and urgently needed diagnostic. **It offers funders a high-return opportunity to accelerate a technology that could save hundreds of thousands of newborn lives.**
- **The NeoTest facility has an estimated return on investment of $39 per disability-adjusted life year (DALY), equivalent to a cost of $1,271 to save a newborn life** (see Appendix H for this calculation). **The benefit–cost ratio is a highly favorable 78:1.** The fund's high return on investment reflects the high mortality burden of neonatal sepsis, the cost-effectiveness of a diagnostic test, and the structure of the facility.
- NeoTest is inviting commitments to establish a $60 million pay-for-success facility. **NeoTest funds are paid only when successful diagnostics are produced and used, limiting the risk for funders.** Because of this feature, funders have the option of holding their funds until verified success criteria are met.

Our benefit–cost modeling extends for 15 years. We assume that without a pull incentive like NeoTest, a rapid triage neonatal sepsis diagnostic appropriate for use in LMICs would not come to market. This is because of the insufficient commercial incentives and the market failures described in Section 5. Put another way, we model that NeoTest accelerates rollout of a diagnostic by 15 years. However, the facility's cost-effectiveness is robust across a wide range of assumptions, including scenarios in which the NeoTest fund accelerates rollout by substantially less than 15 years (Figure 8.1).

FIGURE 8.1 Cost-effectiveness of the NeoTest facility given different rollout speeds



Even if NeoTest accelerated the development of a diagnostic by just five years, the facility's cost-effectiveness would be exceptionally high ($57/DALY).

NeoTest is now at the point at which funder commitments can turn a completed design into a credible market signal. **The facility can accommodate different forms of funder participation** (see Table 8.1). Some funders may prefer financing the milestone payment, others the country implementation support, while some may wish to make contingent commitments that are called upon only when a diagnostic test is successfully developed and used (the AMC).

Funders retain full flexibility over when their capital moves: Funders who prefer to hold funds until disbursement can do so through a contingent commitment, meaning their capital continues earning returns in the interim. For those who transfer funds to the administrator, the investment yield on held funds would go towards covering administrative costs. This means the full value of the commitment flows to the AMC and not overhead.

TABLE 8.1 The role of funders

ACTION	ROLE
Commit capital	Provide funding to the facility or one of its components. **For a funder supporting the entire milestone contribution ($20 million), the milestone prize would be named at the funder's discretion**. For funders that want to support global health within a particular geographic area, the AMC could be tied to top-up subsidy payments for diagnostics purchased and used in specific countries. The organization administering the NeoTest mechanism (described in Section 9) will be able to accrue significant interest on any committed capital, which will be directly used to offset their administrative costs.
Provide contingent commitments	Make legally binding commitments to the facility that are disbursed only when a diagnostic test is approved and qualifying tests are sold. Funders retain funds (which can accumulate interest) until diagnostic tests meet pre-specified criteria.

9. Administration and Governance of NeoTest

Learning from the architecture employed by the pneumococcal vaccine AMC (58) and AgResults (59), the NeoTest fund will involve three distinct actors: a design architect, an administrator, and a governance body (Table 9.1).

1. The design architect is CGD and the Market Shaping Accelerator (MSA): CGD hosted this Working Group and designed the fund mechanism, rules, eligibility criteria, and market-shaping logic. Once the facility is established, CGD/MSA will help preserve the original design intent and provide technical input when decisions require judgment. It will not run the facility.
2. The administrator will be the operational and fiduciary platform. This organization may hold and coordinate committed funds, contract with firms and implementers, run verification and payment processes, and disburse funds as criteria are met.
3. A governance body, housed at a credible organization distinct from the administrator, will instruct and contract the administrator of the fund. It will not run the facility day to day but will provide oversight, accountability, and a forum for major decisions, disputes, and conflicts of interest. This body will include relevant technical and governance representation.

TABLE 9.1 Institutional structure of NeoTest

	ACTOR		
FUNCTION	CENTER FOR GLOBAL DEVELOPMENT/MARKET SHAPING ACCELERATOR	ADMINISTRATOR	GOVERNANCE BODY
Mechanism design	Designed the facility, rules, and market-shaping logic; as required, will support interpretation of design intent through the governance body	Provides operational input on feasibility and implementation	Reviews and approves material changes if needed
Administration and fund management	No day-to-day operational role after launch	Holds, manages, or coordinates committed funds; administers the facility	Oversees fund administration and major fiduciary decisions
Contracting and payments	Provides technical input where needed through the governance body	Leads contracting, disbursement, financial management, and payment processes	Oversees or approves major contractual or payment decisions
Technical/scientific assessment	Supports interpretation of the original design intent through the governance body	Runs the assessment process and documentation; may commission independent external experts	Makes or endorses judgment-based decisions; may use independent external experts
Decision-making for disputes and conflicts	No day-to-day role after launch	Implements decisions and maintains records	Resolves disputes, manages conflicts of interest, and decides edge cases

We are in mature discussions with several organizations with the credibility and operational capacity to serve as the NeoTest administrators and to hold, manage, and disburse a multiyear $60 million facility. We anticipate confirming a relationship with an administrative partner alongside anchor commitments and are happy to share information on administrators on request.

The fund would be established upfront with committed funds from donors (even if donors hold this money and disburse it only once diagnostics are approved and used) to provide a clear, strong demand signal.

> The goalposts cannot change. The money has to be there.
>
> —Diagnostic developer interview, India

Additionally, NeoTest could do more than accelerate a neonatal sepsis diagnostic. **NeoTest could also create reusable administrative and contractual infrastructure for future diagnostic pull mechanisms.** Once an administrator, governance process, eligibility framework, verification system, and contracting model exist, similar funding facilities could be adapted for other AMR, infectious disease, and high-priority LMIC diagnostics.

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