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INNOVATION NODES: INSIGHT REPORT No 1

The business of bringing next generation biosensor diagnostics to vulnerable women

Collaboration with
Harvard Consulting on Business and the Environment

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Innovation Nodes are collaborative and transdisciplinary spaces to reflect, explore and create novel wisdom in new and unknown areas of potential innovation for children. These collaborations are with preeminent organizations, from research institutions to think tanks, with deep expertise and capabilities in new and unknown domains of impact on children.

Insight Reports serve as a resource for practitioners and decision-makers to gain awareness of new and unknown areas of potential innovation for children.

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Abbreviations and acronyms

CHW	Community health workers
Harvard CBE	Harvard Consulting on Business and the Environment
HICs	High-income countries
LICs	Low-income countries
UNICEF	United Nations Children's Fund
RUBIC	Rhodes University Biotechnology Innovation Centre
SPT	Smart Pregnancy Test
WHO	World Health Organization

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Contents

Summary

Sustainable Development Goal 3
Ensure healthy lives and promote wellbeing for all at all ages.

The focus of this innovation node with Harvard Consulting on Business and the Environment is to explore potential global market and private and public sector pathways to maximize equitable global access to Smart Pregnancy Tests (SPTs) that are highly accurate, low-cost, and resistant to temperature and humidity.

This ground-breaking diagnostic is an outcome of research by Rhodes University Biotechnology Innovation Centre in South Africa, which was enabled by the UNICEF Office of Innovation.

A market-based approach would mean the SPTs become commercially viable, and the private sector has a financial incentive to continue at scale. This could lead to more sustainable outcomes for women over time.

Cross subsidization is a potential strategy that could make SPT affordable for all vulnerable women, because the profits earned in high-income countries can be used to subsidize units sold in low-income countries and in low-income areas in high-income countries.

Community health workers (CHW) are key to delivering health care to women and children, particularly for those who live in remote, hard-to-reach areas. The right training and incentives to CHWs will be critical to the overall success of getting the SPTs to the hands of the most vulnerable women and thereby contributing to the reduction of maternal and newborn mortality.

1. Introduction

95%

of all maternal deaths occur in low- and middle-income countries.[1]

Healthy mothers have healthy babies.

Substantial progress has been made in reducing the global maternal mortality ratio - defined as the number of women who die from pregnancy-related causes while pregnant or within 42 days of pregnancy termination per 100,000 live births. Between 2000 and 2020, the maternal mortality ratio dropped by about 34.3% worldwide.[2]

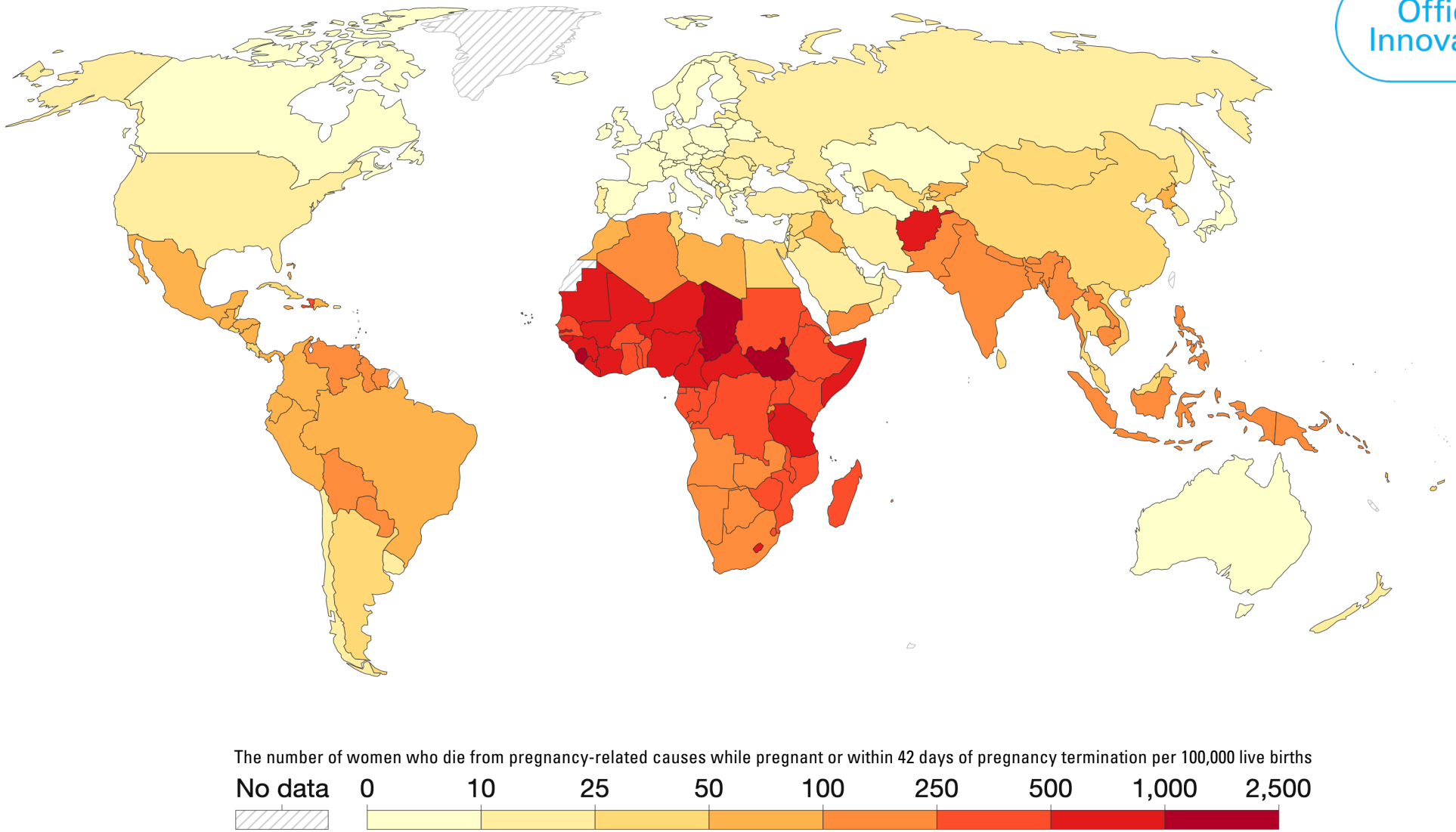
But in 2020, a woman still dies every two minutes due to pregnancy or childbirth.[3] An estimated 2.8 million pregnant women and newborns still die every year, mostly of preventable or treatable causes.[4] Figure 1 provides a global picture of the maternal mortality in 2020.

Women who receive antenatal care from the beginning of pregnancy until the onset of labour have the best chance to ensure they stay healthy throughout their pregnancy and give birth to a healthy baby.

Antenatal care includes recording medical history, assessment of individual needs, guidance on pregnancy and delivery, screening tests, education on self-help care, and identification of conditions detrimental to health during pregnancy.

Pregnancy testing is a common entry point to receiving antenatal care.

Figure 1: Maternal mortality ratio, 2020[5]



Source: Gapminder; WHO; OECD www.gapminder.org/documentation/documentation/gapdoc010.pdf; https://data.worldbank.org/indicator/SH.STA.MMRT; https://stats.oecd.org/index.aspx?queryid=30116

OurWorldInData.org/maternal-mortality • CC BY

2. The challenge

Many women in low-income countries do not have access to affordable and timely diagnostics that can identify pregnancy because a pregnancy test can cost more than an entire day's income. By the time a preventable problem is detected, it is often too late for the mothers to reach the health facility or receive the medical expertise they need.

In 2014, UNICEF identified the potential of biotechnology to help address this challenge, and established a partnership the Rhodes University Biotechnology Innovation Centre (RUBIC) in South Africa.

Established in 2014, the RUBIC is the home of the applied field of biotechnology, where its applications within human and environmental health combined with the development and improvement of new products and processes holds direct benefits for socioeconomic development.

RUBIC is developing a Smart Pregnancy Test (SPT) that is highly accurate, low-cost, and resistant to temperature and humidity.

3. Reframing
from challenge to opportunity

- Antenatal care during pregnancy and childbirth is a smart investment with a triple return:
  - saving mothers and newborns,
  - preventing stillbirths, and
  - paving the way for optimal child development.

- Pregnancy testing as a component of antenatal care is an important opportunity to diagnose and treat pregnancy-related complications and to deliver interventions aimed at improving health and survival of both mother and the newborn.

- Rhodes University Biotechnology Innovation Centre in South Africa is producing a Smart Pregnancy Test, a biotechnology breakthrough that will be accessible to more women because it will be affordable and it will not be affected by storage conditions in remote areas. Research commercialization can help to bring the innovation to market. Future research may extend SPT application for pregnancy health monitoring and identification of risks.

4. Breakthrough from antibody to aptamer

- Antibodies and aptamers are both powerful diagnostic tools that can be used to detect specific targets in clinical samples. Antibodies are widely used since their inception in the late 19th century. They are the predominant technology used in diagnostic tests today, including in pregnancy tests.
- Aptamers have the potential to be the next generation of diagnostics and are emerging as a promising alternative to antibodies for diagnostics and therapeutics.
- Antibodies and aptamers have some fundamental differences in their properties and applications, and the choice of which to use depends on the specific application and requirements of the assay. Aptamers are more suitable for use in point-of-care testing and in developing novel diagnostic assays.
- While aptamers offer many advantages over antibodies, they are still relatively new and have not yet been widely adopted in diagnostics.

The biotechnology breakthrough

In the late 19th century, scientists began to apply their growing understanding of the immune system to develop new diagnostics and therapeutics. They devised tests to detect the presence of a disease through the presence, in blood or urine, of the body's antitoxins (antibodies) produced in response to invading organisms or toxins (antigens).[6]

Antibody-based diagnostics are widely used today in lateral flow and immunoassays, where antibodies are used to capture or label antigens in the sample. Antibodies are produced by injecting antigen samples into laboratory or farm animals and then extracting the antigen-specific antibodies in their serum.[7] Antibodies are the predominant technology in clinical diagnostics today.[8, 9]

Next-generation diagnostics

Aptamers are short, single-stranded nucleic acids (DNA or RNA molecules) that can fold into specific 3D shapes, allowing them to bind to target molecules with high affinity and specificity – a specific key to a specific lock. They bind to proteins, peptides, carbohydrates, small molecules, toxins, and even live cells. They can be used similarly to antibodies in diagnostic tests and were first used in 1992 to detect a blood clotting protein.[10]

Aptamers are chemically synthesized molecules[11], mostly oligonucleic acids that can easily be synthesized in quantity with high purity, and can be modified with various molecules using simple chemical reactions.[12]

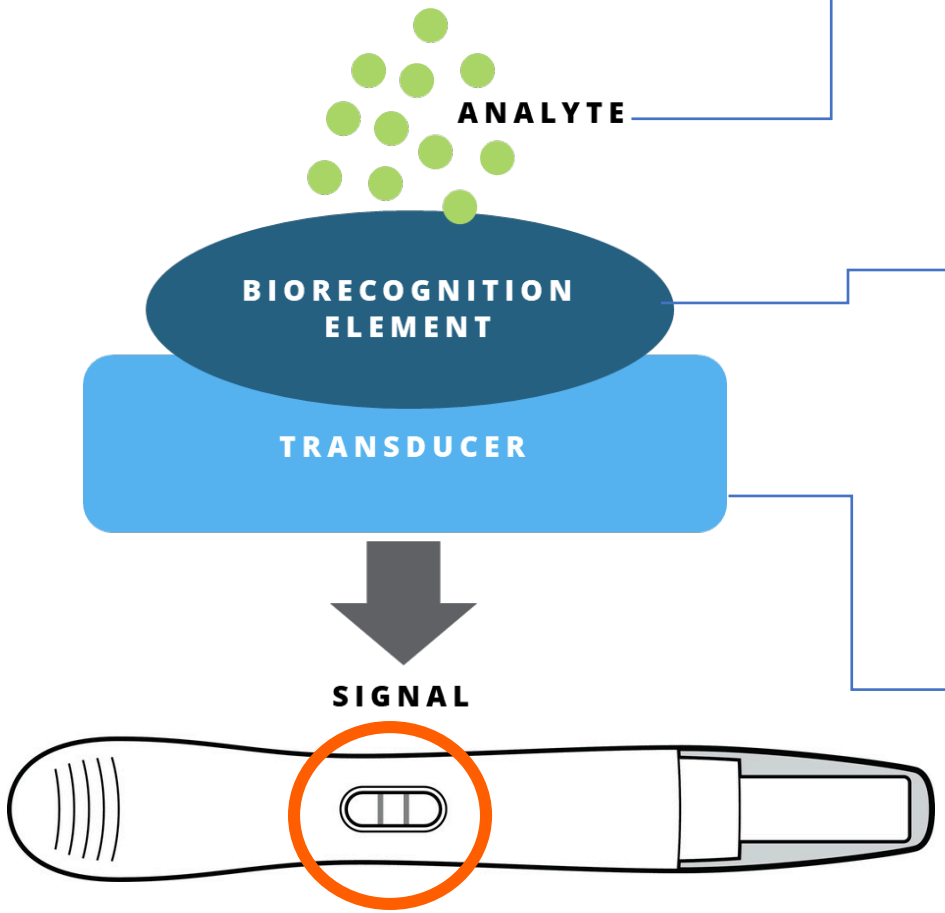
Aptamers are emerging as a promising alternative to antibodies for diagnostics and therapeutics, more suitable for use in point-of-care testing and in developing novel diagnostic assays. While aptamers offer many advantages over antibodies, they are still relatively new and have not yet been widely adopted in diagnostics.[13, 14]

How antibodies and aptamers compare

Specificity	Antibodies are highly specific and can recognize a wide range of targets[15]. Aptamers can produce better diagnostic accuracy as they can be designed to have high specificity and affinity for their target, and their smaller size allows them to have a lower likelihood of non-specific binding[16].
Cross-reactivity	Antibodies often fail in multiplex discovery platforms due to cross-reactivity problems, whereas aptamers can be effectively used to simultaneously detect thousands of proteins[17].
Versatility	Antibodies can be easily conjugated to different detection methods such as fluorescent dyes or enzymes[18]. However, aptamers are considered the most versatile reagent in proteomics[19]. The types of target molecules for aptamers are unlimited, and they can be designed to be more sensitive and specific in detecting small molecules.[20] A vast range of additional functional groups can be added at any desired position in the oligonucleotide sequence through chemical reactions[21, 22]. Aptamers can also be used as sensors or probes in diagnostic devices due to their fluorescence or electrochemical properties[23].
Stability	The stability of antibodies can be affected by environmental conditions, limiting their use in certain settings. Aptamers are very stable under hot or hazardous conditions[24], and pH levels, although they can be sensitive to nuclease degradation, which can affect their stability in biological fluids[25].
Cost-effectiveness	Antibodies can be expensive and time consuming to produce. They are produced by injecting antigen samples into laboratory or farm animals to evoke high expression levels of antigen-specific antibodies in the serum, which is then recovered from the animal[26]. By contrast, aptamers are produced using chemical synthesis which is less expensive[27] and more humane[28].
Production	Aptamers are less costly to produce because they are chemically synthesized[29], and changes are simpler to introduce because aptamers are easier to modify through chemical modification[30].
Consistency & replicability	Due the the way they are produced, aptamers are less prone to batch-to-batch variability than antibodies[31], are highly scalable and replicable with reliable consistency and purity[32].

A better biorecognition agent powers the smart pregnancy test

A biosensor consists of two core elements: a **biorecognition agent** and a **transducer**.



The analyte is the part of the sample that the test is designed to find or measure. The smart pregnancy test measures Beta human chorionic gonadotropin (hCG). The analyte is Beta-hCG.

The biorecognition agent is used to specifically detect the marker; only one specific key (the target) can fit (bind to) the lock (biorecognition agent) and detect it.

Existing pregnancy tests use antibodies on the lateral flow test strips, where urine interacts with an antibody to provide the result.

The smart pregnancy test uses a better biorecognition agent – a novel aptamer. Replacing a traditional antibody produces a specific, consistent, cost-effective, scalable biosensor that is stable. This test will be accessible to more women due to affordability and stability across a wider range of conditions.

The transducer monitors when the biorecognition agent locks onto its target. When this happens, the transducer produces a signal that can be visualised and measured, such as a colour change in pregnancy test strips.

5. Three big questions

1. How might we ensure women everywhere, particulary vulnerable and hard-to-reach marginalized women, have access to the SPTs?

2. How might we maximise the opportunity of a biotechnology breakthrough like the SPT through a market-based approach that is sustainable and cost-effective?

3. Who are the key players with the resources and capabilities to deliver SPTs at the most accessible part of the public health infrastructure and maternal health ecosystem?

6.
Research goal and objectives

The purpose of the research is to conduct a market assessment on pregnancy diagnostics.

The research team collected and analyzed secondary research to:

- provide a pregancy test market outlook;
- assess manufacturers and distributors with suitable infrastructure, geographical reach and technical capabilities in high-income countries and low-income countries;
- review antenatal programmes and the use of ‘smart’ health products in low-income countries, and
- review the marketing strategies and pricing structure of industry leaders to help position the SPT in the market.

Sources include: company websites, literature reviews, research publications, and market analysis reports.

The assessment will help inform how UNICEF and RUBIC can be most effective in shaping the market to ensure that when these tests are produced, women in low-income countries and marginalized women in all countries will benefit from this innovation as UNICEF and RUBIC intended.

The research also explored business models, specifically tailored to the uniquely limited involvement of UNICEF in the actual production, operations or marketing while continuing to manage the intellectual property.

7. Key findings

- **The private sector** plays an important role in healthcare, providing access to quality, essential services and safe, effective, and affordable medicines in many low-and middle-income countries. In these regions, people's healthcare needs far outweigh what the public sector is able to provide, and if existing private sector capacity, investment, and innovation are leveraged, more could be done to address the issues of access, quality, and cost.

- **A market-based approach**, successfully implemented, would mean the SPTs become commercially viable, and the private sector has a financial incentive to continue at scale. This could lead to more sustainable outcomes for women over time.

- **Community health workers** provide a critical link between women and the health system. They are key to delivering health care to women and children who live in remote, hard-to-reach areas, or the "last mile".

Community Health Workers

The research found that the community health model and community health workers are critical to the success of the Smart Pregnancy Tests in three ways:

1. Technologies such as SPTs should be integrated with the existing continuum of care services provided by community health workers.

2. Material incentives will bolster efforts by CHWs to provide pregnancy diagnostics and information to mothers.

3. CHWs are usually known in the community and by the women. The familiarity will help reduce hesitation to adopting a new product – even though the SPT will look very similar to products currently available on the market, women in low-income contexts may not have had the opportunity of accessing one before.

8. Market assessment

❖ **The global pregnancy test market:**

- Estimated at USD 1.3 billion in 2022.[33]
- North America and Europe are the most established markets.
- The Asia Pacific region is the fastest growing market.

❖ **Market constraints:**

- Lack of awareness regarding reproductive health and pregnancy tests
- Limited capacity of prenatal programs and health clinics
- Social-economic barriers
- Social-cultural practices

❖ **Market drivers:**

- Technological advances in gynecology
- The increased age of women becoming pregnant for the first time
- Growing popularity of self-detecting tests
- More planned pregnancies
- Rising disposable income
- Supportive government initiatives

❖ **Market positioning:**

- The SPT holds a unique competitive advantage and market position in the pregnancy test market.
- It is a high-end product.
- Its unmatched capabilities and relative low production cost holds promise of high growth and solid market share in the future.

❖ **Assessment criteria for potential manufacturers:**

- Manufacturing sites
- Country presence
- Market position
- Experience

❖ **Potential distributers:**

- High-income Countries (HICs) - pharmacies, hospitals and healthcare providers, and online
- Low-income countries (LICs) - Ministries of Health through their community health workers

❖ **Options to distribute SPTs to low-resource women in HICs:**

- Community health clinics
- Family and community service delivery agencies
- NGOs
- Dollar stores based on data on spatial inequalities

❖ **Potential marketing strategies:**

- Product personalization
- Brand recognition
- Strategic market segmentation
- 360° marketing campaign

9. Potential business strategy

The findings from the analysis allowed us to consider the strategic positioning of the SPT in the global pregnancy test market, the value proposition, and potential business model options.

Cross subsidization is an option that could make SPT affordable for women in low-income countries and all marginalized women if the revenue model in high-income countries can be used to offset costs or subsidize units in low-income countries and in low-income areas in high-income countries.

Cross subsidization is a strategy of setting higher prices for one set of consumers in order to make it possible to sell at lower prices for another set of customers.

The research team explored the feasibility of the cross-subsidization strategy for a number of countries across the African continent. Core assumptions were tested based on possible market share, estimated cost of production and price points, and on the existing level of maternal health services and public health infrastructure.

The region provides for a range of scenario models as it is composed of low, lower-middle, upper-middle, and high-income countries, some of which are fragile or conflict-affected, and some of which have the highest maternal mortality rates in the world and with the lowest level of antenatal care.[34]

10. Potential impact and opportunities

… for children

SDG 3
Target 3.1 Reduce maternal mortality

SDG 3
Target 3.2 End all preventable deaths under 5 years of age

A child's chance of survival depends greatly on where they are born. Children born in sub-Saharan Africa are subject to the highest risk of childhood death in the world – 15 times higher than the risk for children in Europe and north America.[35] Mothers in sub-Saharan Africa and south Asia sadly endure 77% of all stillbirths in 2021.[36] The risk of a woman having a stillborn baby in sub-Saharan Africa is 7 times more likely than in Europe and north America.[37]

Mothers die as a result of complications during and following pregnancy and childbirth, most of which are preventable or treatable. The major complications related to maternal deaths include severe bleeding, infections, high blood pressure during pregnancy (pre-eclampsia and eclampsia), and delivery complications.[38]

The smart pregnancy test can contribute to closing these health and wellbeing gaps and towards achieving the Sustainable Development Goal 3, targets 3.1 and 3.2.

The impact of this innovation for children goes beyond health. Research has linked the impact of maternal mortality on education for children. School participation falls by 9 percentage points following the death of a parent, often the death of the mother.[39] Girls who have lost both parents are 13 percentage points less likely to be enrolled in school than non-orphans.[40]

… for the development community

Biotechnology and global health

Biotechnology is changing global health. Biopharmaceutical companies used novel biotechnology techniques to make COVID-19 vaccines because this was smarter, quicker, more robust, and flexible than traditional approaches.[41]

It is useful to consider the following as a first step to exploring the potential of biotech for impact for children:

- **Impact.** Will the biotech innovation address the most pressing health needs and reach the most vulnerable children and women?
- **Relevance.** Will it be affordable and adaptable in low-resource settings?
- **Feasibility**. Will it be scientifically, technically and financially feasible within a defined timeframe?
- **Indirect benefits**. Will the innovation indirectly contribute to other SDG outcomes?

SPT and the 'continuum of care'

The SPT can be seen as part of a 'continuum of care' needed, before, during and after pregnancy and childbirth. It strengthens the overlapping ecosystems of maternal and child health.

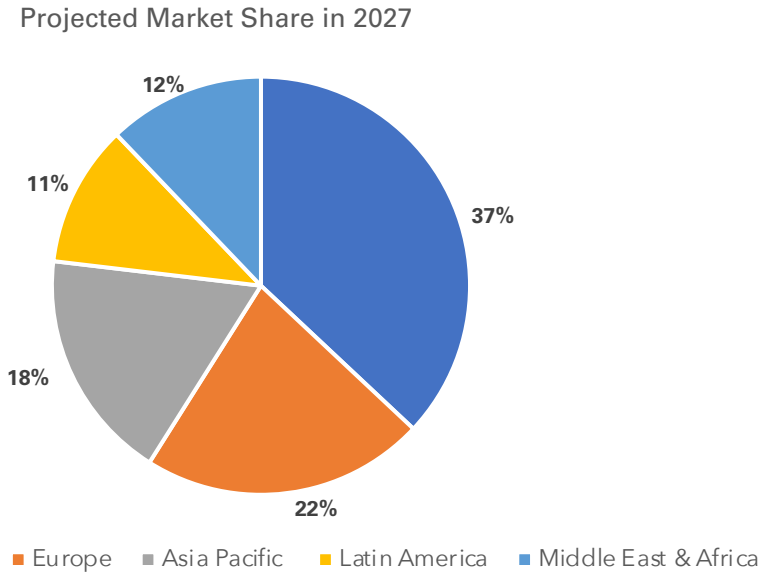
The linkage between SDG 3, 5 and 4

Education helps women make better decisions about many health and disease factors such as prenatal care, basic hygiene, nutrition and immunization. Improving access to education enables more women to be community health workers.

… for the private sector

The global pregnancy testing market is estimated to be worth USD 1.36 billion in 2022. It is forecasted to grow to USD 1.74 billion by 2027.[42]

For the private sector, the opportunity exists to implement business models that both do good and do good business throughout the biotech value chain from discovery, development, and commercialisation to market entry.



Source: Market Data Forecast - Pregnancy Testing Market, <www.marketdataforecast.com/market-reports/pregnancy-testing-market>, accessed May 2022.

11. Next steps

Remember our challenge: 2.8 million mothers and children, mostly in low-income countries, die at childbirth every year due to pregnancy complications that are preventable if detected early, because these mothers do not have access to affordable diagnostics that can identify pregnancy in time.

UNICEF seeks to change this by bringing RUBIC's next generation pregnancy diagnostic technology to market.

The market assessment has yield insights on the market size, drivers, constraints, and opportunities.

The ambition is to build on this and create a business model that improves health outcomes for mothers and newborns at scale and to sustain these outcomes over time.

UNICEF and RUBIC have prosecuted a global patent application to protect the invention that is key to the SPT innovation. The next steps will include, developing an investment prospectus, and negotiating license agreements that bring these next generation pregnancy tests to vulnerable women. Future research may extend SPT application for pregnancy health monitoring and identification of risks.

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