Request for Quote (RFQ)

Develop a technical and economic understanding of glucose test strip production

Issue date: 12th March 2024
Closing date: 12th April 2024
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Background

Globally, 537 million people are living with diabetes, with 75% located in low- and middle-income countries (LMICs)[i]. Fewer than one in ten people with diabetes in LMICs receive comprehensive diabetes treatment[ii], leaving them highly vulnerable to the early onset of complications and premature death.

In diabetes care regular blood glucose monitoring is critically important to achieve good control of the condition and avoid long-term complications. Using a **blood glucose meter and test strips** is the simplest way to check glucose levels in a health care setting or at home. Yet, in many LMICs **this essential tool is not widely available** in basic primary care facilities or in the hands of people with diabetes for home-monitoring – both places where people with diabetes spend the majority of time managing their condition.

Reasons for this lack of supply availability and infrequent self-monitoring are multifactorial. While health system challenges certainly contribute, **high cost of blood glucose test strips** are a major contributor to this situation.

In many LMICs, a single strip costs around US$0.3. The price of a glucose test strip is shaped along its journey: from manufacturing to freight, import tariffs, distribution cost and sales margins.

The largest suppliers of glucose test strips are based in Europe and the US, covering 80% of the global market[iii] and making their commodities subject to costly journeys to LMIC markets.

World Health Organization adopted a resolution in 2021 to **strengthen local production of medicines and other health technologies** to improve access. Major organizations such as the Global Fund, the Bill and Melinda Gates Foundation and Unitaid are committing millions of dollars to strengthen local manufacturing for vaccines, medicines and health technologies for infectious diseases[iv,v,vi]. This will result in a strong ecosystem of locally manufactured commodities and shape access, affordability, and availability of products in LMICs.

For diabetes, **two of the largest global insulin manufactures have announced partnerships with African manufacturers in 2023**, to bring production to the continent sustainably at affordable prices[vii,viii]. This is seen as a major milestone towards broad inclusion of diabetes medicines into essential benefit packages under universal health coverage[ix].

Better availability of insulin requires better access to glucose test strips.

Project overview

Several activities will be led by FIND in the coming months in order to understand if and what **opportunity local manufacturing of glucose test strips** holds to overcome the current availability and affordability gap.

Through this specific RFQ, we want to start gain a deep technical and economic understanding of glucose test strip production. **This will include understanding of what is required to manufacture glucose test strips, the manufacturing process and the cost drivers.**

Objectives

The objectives of this work are to:

1. Gather information on technical aspects of a glucose test strip (including - but not limited to - material composition, enzymes, different configurations)
2. Map the manufacturing process of a glucose test strip
3. Determine the costs associated with glucose test strip manufacturing in different scenarios

Scope of the Work

The technology that is in scope are **test strips for quantitative determination of glucose in capillary blood** with the use of a hand-held glucose meter; capillary blood application must be directly to the test strip, i.e. without the need of a transfer device. Test strips out of scope are those designed to detect glucose in other body fluids (e.g. urine or saliva), as well as test strips that only yield semi-quantitative results (e.g. colorimetric range-indicators).

While there are no focus countries for this work, there will be a need to describe manufacturing and costs associated with production in different settings (e.g., manufacturing in countries with varying labor costs and IVD industry maturities, including HIC and at least two LMICs. HICs could include US, EU, South Korea. A country in Africa should be included in the LMIC analysis).

1. **Develop a thorough understanding of technical aspects of a glucose test strip**

   Gather information on:

   - Material composition: This includes the various components of the strip, such as the substrate material, conductive materials, enzyme layer, reference electrode, and any other layers involved.
   - Different configurations: Investigate the different designs and configurations of glucose test strips available in the market. This may include variations in size, shape, and layout of the components.
   - Enzymes: Understand the types of enzymes used in glucose test strips, such as glucose oxidase or glucose dehydrogenase, how they function to catalyze the reaction with glucose and benefits/challenges of using respective enzymes
   - Provide any additional information you would suggest exploring to provide a comprehensive understanding

2. Map manufacturing process

Gather information on:

- Key expertise: what are the capacities needed to be successful in low cost design and production of glucose test strips.
- Process steps: This involves understanding the sequence of operations involved in manufacturing the strips, such as strip layering, substrate preparation, enzyme deposition, drying, cutting, packaging, and quality control.
- Infrastructure and equipment: Describe the range of common set ups (equipment, facilities, technology), the rate limiting steps (throughput), level of automation, and high level estimation of cost to equip the different set ups.
    - What drives the choice of equipment of infrastructure and equipment
- Human resources: key personnel skills and expertise required for manufacturing.
- Materials: Identify the raw materials, reagents, and consumables needed, and assessment of the commercial availability and quality of critical raw materials.
- Synergies with other (strip-based) diagnostics: What other type of tests (immunoassays or other diagnostic test strips such as cholesterol, ketones or pregnancy tests) could be manufactured with similar production technology ? Or could benefit from synergies around packaging, lancets, desiccants…
- Manufacturing efficiency: provide information on the throughput, yield, and cycle time of the manufacturing process to understand its efficiency and capacity.
- Quality control measures: Investigate the quality assurance procedures implemented throughout the manufacturing process to ensure consistency and accuracy of the test strips.
- Regulations or trends: Identify regulations or trends around regulatory and standards requirements of the manufacturing process

3. Determine the costs associated with glucose test strips manufacturing

Gather information on:

- Cost drivers: Identify the key factors influencing strip costs, such as material sourcing, process complexity, labor rates, and regulatory compliance.
- Raw material costs: identify the costs of all materials and components used in manufacturing the strips, including substrates, enzymes, electrodes, and packaging materials.
- Estimation of cost of goods (COGS): Calculate the overall cost of manufacturing each strip (range), taking into account raw material costs, labor costs, overhead expenses, and any other relevant factors.
- Production techniques: Evaluate the cost implications of different manufacturing techniques.
- Strip compositions: Compare the costs of producing strips with different compositions or configurations, considering variations in materials and processes.
- Production volumes: Analyze how production volumes impact the overall cost per strip, including economies of scale and cost drivers associated with low-volume production.

- Cost optimization opportunities: Identify main challenges with blood glucose strips manufacturing and typical approaches to cost reduction and optimization of manufacturing processes.
- As price and many other elements (e.g., VAT for raw materials) could vary per country, there could be a focus on developed market vs a couple of LMICs

Additional information regarding the global project:

- Global project's name: Local manufacturing of glucose test strips: A key to better diabetes care in low-and middle-income countries?
- As an additional aspect of the outlined scope of work, FIND's team will conduct a mapping of glucose test strips manufacturers globally and in LMICs. The objective will be to better understand the industry, business models, and market trends / dynamics. The consultant chosen for the RFQ "technical and economic understanding" will have the opportunity to propose relevant questions to be used during these manufacturer interviews by FIND's team.
- In the subsequent phase of the project, FIND's team will focus on two selected manufacturers (located in a LMIC) for an in-depth analysis, supported by a consultant. This analysis will involve site visits to gather detailed information on production processes, procurement of raw materials, factory infrastructure, quality control measures, market presence, and meter production. The ultimate goal of this phase will be to support the development of the 2 manufacturers by identifying scenarios for production optimization and necessary investments.
- It should be noted that the consultant responsible for the "technical and economic understanding" aspect will receive preferential consideration during the selection process for this next phase of the project. A new RFQ will be released for this activity by end of Q2 or in Q3 this year.

Deliverables and requirements:

Deliverable #1: A intermediate Power Point presentation on :

- Technical aspects of a glucose test strip, including information material composition, detail on existing designs and configurations, type of enzymes used in glucose test strip, presented in written and graphical format.
- Manufacturing process of a glucose test strip including information on process steps, infrastructure, materials and human resources, efficiency, quality control measures, etc…

Deliverable #2: A simple Excel model should be developed, leveraging different inputs to estimate COGS. Input would include estimated raw material costs, costs associated with glucose test strip manufacturing in different settings (e.g., at least 1 developed countries vs 2 LMICs), different configurations (e.g., strips compositions, volumes), equipment/infrastructure hypothesis. The main outcome will be a few "common" scenarios, with different production volumes.

In addition to the excel model, an accompanying Power Point presentation should include key quantitative inputs and the "common" scenarios with identified cost drivers and cost optimization opportunities. Key quantitative results must be graphically represented together with a narrative.

Deliverable #3: A finalized report in Microsoft Word format, detailing all the findings of the analysis. A template/outline for the report will be agreed with FIND at the beginning of the project.

Requirements #1: A list and contact details for key stakeholders who could potentially be interviewed during this project. (this would help avoid duplicate as FIND will also interview some stakeholders during the other parts of the broader project)

Requirements #2: Standard interview guides for each type of stakeholder that will be engaged with, to be validated by FIND.

Requirements for Proposal Preparation

Candidates interested in responding to this RFQ should submit a proposal, in Microsoft Word or PowerPoint format, that includes the following information:

- Organizational profile, including short biographies, highlighting relevant experience and networks, of key staff involved in the work
- Services provided (consulting, market research, off-the-shelf data and reports, etc.)
- Proposed scope of work and work plan
- Proposed methodology and approach for the different analysis
- Experience, including a list of relevant projects that your organization has worked on
- Networks and partnerships in manufacturing
- Timelines and budget (including a full breakdown)
- Client references
- Contact details

Evaluation and Award Process

The evaluation process is designed to be objective, independent and transparent, to ensure that the most suitable proposals are identified. All proposals will be evaluated by an internal review panel comprising the Non-communicable Disease Programme and Business Intelligence team members from within FIND. All proposals will be evaluated against the following criteria:

- Organizational strength and team experience in IVD manufacturing (experience in test strips manufacturing will be preferred) and in the diagnostics field in LMICs.
- Verifiable past performance with similar projects
- Comprehensiveness of the proposed methodology and strategy
- Ability to deliver the requirements on time
- Access to networks of relevant stakeholders
- Budget

Budget

Up to US$ 45 000$, for professional expenses.

Timelines and Submission

- Please confirm that you will participate in this RFQ by 05t[h] of April.
- Please submit your proposal by 12[nd] April 2024.
- The successful applicant will be notified at the latest by 20[th] April.
- The work should be completed by the end of July 2024.
- Please send submissions and any questions to NCDs@finddx.org

About FIND

FIND is accelerating equitable access to reliable diagnosis around the world. We are working to close critical testing gaps that leave people at risk from preventable and treatable illnesses, enable effective disease surveillance, and build sustainable, resilient health systems. In partnership with WHO, other global health agencies and the G20/G7, we are driving progress towards global health security and universal health coverage. We are a WHO Collaborating Centre for Laboratory Strengthening and Diagnostic Technology Evaluation.

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[i] https://diabetesatlas.org/

[ii] The state of diabetes treatment coverage in 55 low-income and middle-income countries: a cross-sectional study of nationally representative, individual-level data in 680 102 adults (2022): https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8865379/

[iii] Diabetes Market report 2021: https://www.finddx.org/wp-content/uploads/2022/12/20221213_rep_market_diabetes_self.pdf

[iv] thematic_local-production_overview_en.pdf (theglobalfund.org)

[v] Unitaid Strategy: 2023-2027

[vi] https://www.gatesfoundation.org/ideas/media-center/press-releases/2023/10/mrna-vaccine-manufacturing-africa

[vii] https://investor.lilly.com/news-releases/news-release-details/lilly-and-eva-pharma-announce-collaboration-enhance-sustainable

[viii] https://www.novonordisk.com/news-and-media/latest-news/new-partnership-to-supply-human-insulin.html#:~:text=19%20September%202023,diabetes%20across%20the%20African%20continent.

[ix] WHO Director General Dr. Tedros Adhanom Ghebreyesus (2023): https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-un-general-assembly-side-event--empowering-lives--bridging-the-gap-for-insulin-access-in-africa---19-september-2023