DIAGNOSTICS

Development of new diagnostic tools to improve preeclampsia screening

There are approximately 300,000 maternal deaths every year worldwide, with pregnant women living in low- and middle- income countries (LMICs) shouldering the vast majority of this health burden.[1] These deaths are often preventable when health providers have access to necessary medical devices and medicines that enable higher-quality obstetric care.

Health need: Improved screening for preeclampsia during antenatal care

The risk that a pregnant woman will die from preeclampsia/eclampsia (PE/E) in a LMIC is approximately 300 times greater than in high-income countries.[2] Prevention of severe clinical complications due to PE/E, including maternal and newborn death, requires accurate and timely identification of women at high risk and their linkage to proper care. Protein in urine, or proteinuria, remains one of the key diagnostic indicators used to identify increased risk for PE.

However, current screening and diagnostic tools available for proteinuria determination have significant limitations. Protein-only measurement using a low-cost urinalysis strip test is the most common method used at the point-of-care, but has major limitations in terms of accuracy.[2] Laboratory-based reference tests for proteinuria determination, including those using 24-hr urine collection, provide high accuracy; however, access to such testing remains very limited due to high technical complexity and cost.

Potential health impact

A spot urine test to measure the ratio of protein-to-creatinine (PrCr) can improve the accuracy of proteinuria detection, compared to a protein-only measurement, by accounting for dilution of a patient's urine sample. Proteinuria results using a PrCr measurement have also shown close correlation with the reference tests.[3] Increasing access to PrCr analysis offers the potential to improve the quality of proteinuria testing across antenatal care (ANC) and improve health outcomes related to PE.

Technology solution

Since 2012, PATH has worked to advance new solutions

PATH is working to advance development of new tests that can be used to support clinical decisions for preeclampsia in routine antenatal care settings. Photo: PATH/Evelyn Hockstein.

to improve access to high-quality screening and diagnosis for PE across ANC in LMICs. Increased access to PrCr testing through development of a low-cost, point-of-care option offers a near-term solution to improve the accuracy of proteinuria detection to better inform care for PE. The Test-it™ PrCr test developed by LifeAssay Diagnostics (Cape Town, South Africa) in collaboration with PATH is a simple, inexpensive urinalysis strip test targeted for use in routine ANC settings where protein-only measurement is currently the standard of care. The Test-it PrCr is a commercially available, CE marked test that is registered in South Africa, Kenya, and has ongoing registrations in Ghana and other countries. As part of PATH's ongoing efforts to support market access to PrCr testing, we will continue to generate new market intelligence to support the Test-it PrCr and other potential point-of-care PrCr tests.

While access to PrCr testing has improved, next generation biomarker diagnostics have the potential to further improve accuracy and timeliness of PE diagnosis. PATH is advancing development of a new low-cost rapid diagnostic test that will enable point-of-care use with one of the promising PE biomarker candidates, urinary adipsin (UA). To ensure the UA rapid test is an ideal fit for target markets, performance verification testing is planned with up to 500 samples from Brazil and South Africa to ensure

geographic diversity, and user research is ongoing to inform usability, acceptability, and considerations for introduction of the test as we move to the next phase of product development.

Health system use case

PATH's activities are primarily targeting use of the PrCr tests to support proteinuria detection during ANC. Results of recent field studies conducted with a prototype of the Test-it PrCr test in Kintampo, Ghana, indicated the test would be acceptable and appropriate for use in routine ANC settings. Under current funding from UK aid, PATH will be conducting implementation research studies in Ghana and Kenya to generate further evidence on the performance, usability, acceptability, and potential barriers for uptake of PrCr urinalysis strip tests in ANC settings. The results of our upcoming implementation research will help inform introduction of the Test-it PrCr test as well as facilitate market entry of other similar PrCr tests intended for LMIC markets.

Go-to-Market Plan (G2MP)

PATH is focused on creating a strong enabling environment for PrCr urinalysis strip tests. PATH will work to 1) promote adequate policy and clinical guidelines to facilitate introduction and use of PrCr tests, 2) gather market intelligence, including clarifying regulatory requirements, to reduce market entry barriers, and 3) generate evidence to ensure service and product delivery in the target countries. In addition to PATH's continued support for introduction of the Test-it PrCr test in Ghana and Kenya, the market intelligence that we will gather, including further defining market requirements and demand estimates, will benefit other PrCr tests that may be necessary to support the market needs of LMICs.

Partners and support

Our project partners include the Global Pregnancy Collaboration, Kintampo Health Research Centre, UMC Utrecht, and LifeAssay Diagnostics.

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D_3AWN PDP: Addressing the leading causes of maternal mortality with an innovative portfolio of products.

The new, four-year Devices, Diagnostics, and Drugs to Address Women's Needs Product Development Partnership (D_3AWN PDP) is tapping into PATH's deep PDP expertise to develop and introduce a portfolio of devices, diagnostics, and drugs to prevent or manage preeclampsia/eclampsia (PE/E) and postpartum hemorrhage (PPH).

To address this critical health need, the D_3AWN PDP is advancing affordable, accessible, safe, and effective tools for sub-Saharan communities. Solutions include:

- Heat-stable fast-dissolving tablet for PPH prevention.
- Reusable, electricity-free, low-cost infusion (RELI) pump for the delivery of lifesaving nutrients, fluids, and medicines.
- Uterine balloon tamponade (UBT) for the management of PPH.
- The PrCr urinary strip test for improved proteinuria screening to support clinical management of PE/E.

These lifesaving technologies are being developed in partnership with research institutions, manufacturers, and companies in Africa, accelerated through PATH's product development process and introduced into key African markets.

Contact

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