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. 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 developing country is approximately 300 times greater than in developed countries. 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. 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. 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.

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.

**Technology solution**

Since 2012, PATH has worked to advance new solutions 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 test is CE marked and is now commercially available. 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 increased access to PrCr testing offers an immediate opportunity to improve the quality of testing and to better inform care for PE, PATH continues to look ahead. Next-generation PE biomarker diagnostics have the potential to further improve the accuracy and timeliness of PE diagnosis in turn increasing the window.
of opportunity to link women to proper care to avoid adverse clinical outcomes. Our program is currently working to advance 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.

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 the UK Department for International Development, 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

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, and LifeAssay Diagnostics. Funding for this project has been provided by the Grand Challenges Saving Lives at Birth Program, Bill & Melinda Gates Foundation, Merck for Mothers, South African Medical Research Council under the Grand Challenges South Africa program grant to LifeAssay Diagnostics, and UK Department for International Development.

Contact

Troy Leader, Preeclampsia Diagnostics Product Manager, bleader@path.org.

References

3. Morris RK et al. BMJ. 2012;345