ABSTRACT:
Preeclampsia results in ~63,000 maternal deaths each year, the majority occurring in resource-limited countries where the correct diagnosis is often delayed. The Congo Red Dot (CRD) test is under development as a diagnostic for assessing misfolded (congophilic) proteins in urine found to be associated with preeclampsia. The CRD test was superior in establishing and ruling out preeclampsia compared to standard of care in a study of 346 consecutive women enrolled prospectively in a tertiary level obstetrical triage unit in the U.S. Tests were read by trained clinical nurses at bedside before a final diagnosis and a management plan was established. With funding from Saving Lives at Birth and in partnership with a start-up company, we have embarked on a transition-to-scale project to: refine the CRD test prototype to a lateral flow chromatography assay (LFA) fulfilling the attributes of ASSURED diagnostics; determine diagnostic cut-offs for urine congophilia in 4 countries (U.S., South Africa, Mexico and Bangladesh) and analyze the local healthcare ecosystems with respect to preeclampsia diagnosis. The Congo Red test is a point-of-care solution with potential to aid healthcare providers in effectively managing pregnant women up and down levels of care thereby reducing preeclampsia-related morbidity and mortality.

Congo Red Tests for misfolded (congophilic) proteins in urine

A CRD Simple Test Kit
B CRD Simple Test Results
C CRR CRD array (batch format)

Cross-validation of CRD Simple Test Kit to CRD array

D

CRD Simple Test Accuracy for Adjudicated Diagnosis

The CRD Simple Test was used to test urine in a Clinical study of 346 prospectively enrolled women presenting for rule-out preeclampsia in a tertiary level obstetrics triage unit in the U.S. Results show the CRD Simple Test at the Point of Care was superior in both establishing and ruling out the diagnosis (adjudicated) of preeclampsia compared to other urine and serum markers. a. Accuracy characteristics b. Comparative Likelihood ratio

Refinement of the CRD test to a LFA (lateral flow assay)

Cross-validation of CRD LFA to CRR Array

D LFA CRD Test Score vs. CRR

CRD Test Packaged for convenience and stability, includes disposable pipette and desiccant. B. CRD Test device. C. CRD Test Results are semi-quantitative and visually read. No equipment is required.

D. Cross Validation of LFA CRD test to the CRR Array in a pilot study of 71 fresh urine samples from women being evaluated for preeclampsia. LFA CRD Test results were scored by 5 trained clinical research nurses. Samples were tested on the CRD Array in the research lab. CRD LFA test results were significantly correlated with both the CRR Array (r=0.865, P<0.001) and the CRD score (r=0.399, P=0.001) (not shown) with excellent level agreement (kappa=0.86)

Transition from HIC to LMIC

The Congo red test for preeclampsia has the potential to aid in the diagnosis of preeclampsia, differentiating women who require care and thereby further optimizing healthcare resources in LMIC as well as HIC settings.

"Positive maternal and perinatal outcomes for women with PE/E depend on how soon the condition is identified and how quickly the woman can access the recommended treatment package." PATH Proteinurina testing Feb 2012