BMJ Open

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| Journal: | *BMJ Open* |
| Manuscript ID | bmjopen-2024-084978 |
| Article Type: | Original research |
| Date Submitted by the Author: | 02-Feb-2024 |
| Complete List of Authors: | Amoakoh, Hannah; University Medical Centre Utrecht, Julius Center for Health Sciences and Primary Care, Department of Global Health and Bioethics; University of Ghana Noguchi Memorial Institute for Medical Research, Epidemiology<br>Browne, Joyce; University Medical Centre Utrecht, Julius Center for Health Sciences and Primary Care<br>Zobrist, Stephanie; PATH<br>Arhinful, Daniel; University of Ghana Noguchi Memorial Institute for Medical Research, Epidemiology<br>Owusu, Rosemond; PATH, West Africa Hub<br>Ampofo, Nana Kwame ; Ghana Health Service, Greater Accra Regional Hospital<br>Yeboah, Abena ; Ghana Health Service, Greater Accra Regional Hospital<br>Cofie, Patience; PATH, West Africa Hub<br>Srofenyoh , Emmanuel; Ghana Health Service, Greater Accra Regional Hospital<br>Adu-Bonsaffoh, Kwame; University Medical Centre Utrecht, Julius Center for Health Sciences and Primary Care, Department of Global Health and Bioethics; University of Ghana Medical School<br>Yevoo, Lucy; University of Ghana Noguchi Memorial Institute for Medical Research, Epidemiology<br>Wuobar, Vinkpenubar ; Ghana Health Service Council, Eastern Regional Hospital<br>Metzler, Mutsumi; PATH, Medical Devices and Health Technologies<br>Coffey, Patricia S.; PATH, Medical Devices/Health Technologies |
| Keywords: | OBSTETRICS, Blood Pressure, Pregnant Women, QUALITATIVE RESEARCH, Quality Improvement |
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# Implementation of protein-to-creatinine dipstick test for proteinuria detection in Ghana: user perspectives, challenges, and opportunities

Hannah Brown Amoakoh[1,2*], Joyce L Browne[2], Stephanie Zobrist[3], Daniel K Arhinful[1], Rosemond Owusu[4], Nana Kwame Asare Ampofo[5], Abena Odurowaa Yeboah[5], Patience Cofie[4], Emmanuel K. Srofenyoh[6], Kwame Adu-Bonsaffoh[2,7,8], Lucy Yevoo[1], Vinkpenubar Francis Wubar[9], Mutsumi Metzler[10], Patricia S Coffey[10]

Affiliations:

[1]University of Ghana, Noguchi Memorial Institute for Medical Research, Department of Epidemiology, Accra, Ghana
[2]Utrecht University, Julius Center for Health Sciences and Primary Care, University Medical Centre, Utrecht, Netherlands
[3]PATH, Diagnostics, Seattle, United States
[4]PATH, West Africa Hub, Accra, Ghana
[5]Ghana Health Service, Accra, Ghana
[6]Ghana Health Service, Greater Accra Regional Hospital, Department of Obstetrics and Gynecology, Accra, Ghana
[7]University of Ghana Medical School, Accra, Ghana
[8]Korle-Bu Teaching Hospital, Department of Obstetrics, Accra, Ghana
[9]Eastern Regional Hospital, Department of Obstetrics, Koforidua, Ghana
[10]PATH, Medical Devices and Health Technologies, Seattle, United States

*Corresponding author: Dr. Hannah Brown Amoakoh, University Medical Center Utrecht, P.O. Box 85500, 3508 GA Utrecht, H.B.Amoakoh-2@umcutrecht.nl

*Word Count*: 2994

## Abstract

**Background:** Measurement of blood pressure and proteinuria is recommended at antenatal care (ANC) visits to screen for preeclampsia. Protein-only dipsticks are the commonest proteinuria screening tests but have significant limitations. Dipsticks measuring the protein-to-creatinine (PrCr) ratio have shown performance benefits over those measuring protein alone.

**Objective:** To assess the appropriateness, acceptability, and feasibility of implementing the Test-it™ PrCr Urinalysis Dipstick Test (LifeAssay Diagnostics, South Africa) in referral hospitals in Ghana.

**Methods:** Ninety-six (96) healthcare professionals were trained on the PrCr test, which was integrated into protocols alongside standard-of-care tests between November 2021-April 2022. Test users completed questionnaires post-training. Three focus group discussions and seven key informant interviews were conducted to evaluate test procedure comprehension, insights into training effectiveness, usability/user confidence, perceptions, attitudes toward the test, and barriers and facilitators of use.

**Results:** High product usability, user confidence, and satisfaction were reported. Staff perceived the test as easy-to-use and similar to current products. Facilitators of use included effective trainings, sensitization of the product, and key stakeholder endorsement. Challenges impacting implementation feasibility were identified, including the short shelf life of test strips (3 months) after opening cannisters, added complexity of the ratiometric result interpretation, and the test's lack of other parameters that are included in current products (e.g., glucose, nitrate), limiting its broader clinical utility for ANC screening.

**Conclusion:** Although the Test-It PrCr test is easy-to-use and well accepted, key product attributes limit its implementation feasibility in this setting. It may be more appropriate for monitoring high-risk women in this context.


**Keywords:** Preeclampsia, proteinuria, point-of-care diagnostic, implementation research, LifeAssay Test-it™ PrCr Urinalysis Dipstick

## Key messages summary box:

- **What is already known on this topic**
  - Low-cost urine dipstick-format tests to measure the protein-to-creatinine (PrCr) ratio at the point-of-care have shown performance benefits over those measuring protein alone and provide an opportunity to address the significant gap in accurate, affordable, and simple tests for proteinuria that are appropriate for use—particularly in LMIC settings and in the context of preeclampsia.
- **What this study adds**
  - We present the results of implementation research that aimed to assess the operational fit of integrating a new point-of-care PrCr ratio measurement test (Test-it™ PrCr Urinalysis Dipstick Test, manufactured by LifeAssay Diagnostics (Pty) Ltd., Cape Town, South Africa)).
  - The test performed well on appropriateness (the perceived fit, usefulness, practicality) and acceptability (test user satisfaction). Feasibility (the extent to which the test can be successfully integrated into screening and monitoring protocols in referral hospitals) is affected by inherent product attribute limitations of this PrCr-only test. As such, the test may be more appropriate for monitoring of high-risk women in this context, rather than ANC screening of general population of women when other parameters (i.e., glucose, nitrate) may also be of interest.
- **How this study might affect research, practice or policy**
  - Given the importance of reliable proteinuria measurement in the screening and monitoring of women with PE, this implementation research can serve to inform health policy decision-makers considering the introduction of this or other new urine dipstick tests for proteinuria, while highlighting the importance of exploring innovations that can improve identification of proteinuria and address the limitations of this and other urine dipstick tests.

## Introduction

Preeclampsia (PE), a hypertensive disorder of pregnancy (HDP), affects approximately 5-7% of pregnant women and contributes to an estimated 70,000 and 500,000 annual maternal and fetal deaths, respectively.[1–3] The International Society of the Study of Hypertension in Pregnancy (ISSHP) defines PE as new onset hypertension (BP ≥140 mmHg systolic or ≥90 mmHg diastolic) at or after 20 weeks' gestation accompanied by proteinuria and/or evidence of maternal acute kidney injury, liver dysfunction, neurological features, hemolysis or thrombocytopenia, or fetal growth restriction.[5] Global guidelines recommend routine measurement of blood pressure and proteinuria at antenatal care (ANC) visits to screen for PE.[6]

The gold standard for proteinuria measurement is 24-hour urine collection; however, this method is technically complex, costly, and a significant burden to patients and providers.[7,8] Urine dipstick tests are the most widely used proteinuria screening tools, and the ISSHP considers a result of ≥1+ (30 mg/dL) abnormal.[5] Despite their low cost and ease of use, these tests have considerable performance limitations constraining their clinical utility.[6,9–12] A recent systematic review by Teeuw and colleagues concluded that urine dipsticks perform poorly at excluding PE in hypertensive women, reporting a pooled performance of 68% sensitivity and 85% specificity across nineteen studies.[13] Importantly, urine dipsticks measuring only protein are unable to adjust for patients' hydration, which can result in over or underestimation of the protein measurement.[10]

In view of these limitations, the protein-to-creatinine (PrCr) ratio has been recognized as an acceptable measurement of proteinuria, with a clinical cut-off point of ≥0.3 mg/mg.[14–16] Spot urine PrCr ratios are typically determined using automated chemistry analyzers, which like the 24-hour urine method, require precision instruments, skilled personnel, and laboratory infrastructure.[17] Low-cost urine dipstick tests to measure the PrCr ratio at the point-of-care provide an opportunity to address the significant gap in accurate, affordable, and simple tests for proteinuria that are appropriate for low- and middle-income country (LMIC) settings where the PE burden is greatest.

One such product is the Test-it™ PrCr Urinalysis Dipstick Test (LifeAssay Diagnostics (Pty) Ltd., Cape Town, South Africa), hereafter called the PrCr test. This product is a urine dipstick test that detects both protein and creatinine semi-quantitatively to assess proteinuria. Results are available in 60 seconds and read visually using a ratiometric colorimetric scale. Early laboratory verification reported 85% sensitivity and 71% specificity for correct disease classification.[18] A subsequent clinical performance evaluation in Kintampo, Ghana, observed improved performance for detection of proteinuria over the current standard of care dipstick tests; however, overall, performance decreased from prior lab studies (51% sensitivity, 69% specificity).[19] User feedback suggested that the test would be well accepted by ANC providers in Ghana, but highlighted that adequate training and resources would be critical to support successful implementation.[19] The product was registered in 2021 with the Ghanaian Food and Drugs Authority.

Here, we present the results of implementation research that assessed the operational fit of integrating the PrCr test into referral hospital protocols in Ghana, among facilities and providers who serve populations with a high prevalence of PE. Operational fit was assessed according to three dimensions, as described by Proctor et al.[23]:

1. Appropriateness: Perceived fit (usefulness, practicality) of the test.
2. Acceptability: Test user satisfaction.
3. Feasibility: The extent to which the test can be successfully integrated into screening and monitoring protocols in referral hospitals.

# Methods

## Ethical considerations

This study was reviewed and approved by the Ghana Health Service Ethics Review Committee (GHS-ERC: 022/05/21) and the Korle-Bu Institutional Review Board (KBTH-STC 000113/2021). All participants provided informed consent.

## Study design and procedures

Between November 2021 and April 2022, the PrCr test was implemented at three facilities in the Greater Accra and Eastern Regions of Ghana: Korle-Bu Teaching Hospital (KBTH) and the Greater Accra and Eastern Regional Hospitals (GARH and ERH). Facilities were selected due to their referral functions, large patient volumes, and experience managing HDPs. This study was nested in the research infrastructure of the Severe Preeclampsia Adverse Outcome Triage (SPOT) study, a transdisciplinary research collaboration to improve the quality of care for women with HDP remote from term (26-34 weeks gestation).[20]

Hands-on training workshops that focused on test use and results interpretation were organized for health workers (HWs) involved in maternal care at participating facilities. Trainings lasted approximately four hours. Subsequently, participants used the test in routine care of HDP patients, alongside standard urine dipsticks. Operational fit was assessed quantitatively at baseline and qualitatively at endline.

## Sampling and sample size

At baseline, all trainees (96) were purposively sampled to assess the acceptability and feasibility of the PrCr test. Additionally, 20 trainees were conveniently sampled to assess their experience of the test. At endline, 27 participants were conveniently sampled to assess operational fit of the PrCr test.

## Data collection methods

*Quantitative data collection (baseline)*

Data on user comprehension and proficiency were gathered using a label comprehension and result interpretation questionnaire that employed images of static test results during training sessions. A post-training questionnaire was administered to assess training strengths/weakness. Training practice sessions were observed using a checklist and structured questionnaire that included a Systems Usability Scale (SUS).[21,22] User experience feedback was collected through a structured questionnaire.

*Qualitative data collection (endline)*

Seven key informant interviews (KIIs) were conducted with stakeholders caring for women with HDP at health facilities, including midwives, doctors, and maternity ward supervisors/managers. Interviews focused on perceptions of the test, its value proposition, appropriateness of its features/use in referral hospital settings, and strategies to facilitate successful introduction in Ghana. One FGD was performed per facility. The objectives of FGDs were to 1) seek HW's feedback on the test following use, 2) identify facilitators and barriers to use of the test, and 3) identify strategies to facilitate uptake and integration into ANC and monitoring of HDP in Ghana.

## Data management and analysis

Data from baseline questionnaires was entered into EpiData. Descriptive statistics were used to summarize these data. SUS scores were calculated according to standard methods, and a composite score >68 was considered acceptable.[21,22] FGDs and KIIs were audio-recorded and transcribed verbatim for analysis through deductive thematic coding. All transcripts were analyzed separately by at least two investigators using Excel, jointly discussed, and consensus reached on the interpretation of key thematic findings.

# Results

## Characteristics of study participants

Of the 96 HWs who completed the training workshops, 10 were from GARH, 51 from KBTH, and 35 from ERH (Table 1). Most training participants were midwives (90.0%, n=78/87).

Seven KIIs were conducted with six midwives and one Obstetrics and Gynecology specialist. The majority (5/7) described serving in supervisory capacities. Three FGDs were conducted, with ten participants at ERH, and five each at KBTH and GARH. All FGD participants were midwives.

## Assessment of operational fit of PrCr test

*Appropriateness: Perceived fit (usefulness, practicality) of the test*

Nineteen of 20 trainees who completed the baseline user experience questionnaire found the PrCr test useful or very useful, 18 were likely/very likely to recommend the test to others, and 19 felt that the test fit well or very well with existing clinical practices and the needs of pregnant women (Figure 1). Most midwives (14) thought the test was useful for ANC screening for proteinuria, and three thought that the test should be used primarily for monitoring high-risk women. When asked about perceived health system fit, 18 indicated that the test was better than the standard test but 13 wanted to use it in addition, rather than as a replacement.

At endline, similar themes emerged from qualitative data. Two key informants mentioned the utility of the PrCr test among populations at high-risk for PE. However, several expressed concerns about the test being a replacement for current tools, which include additional parameters, and the additional workload and cost associated with performing two tests. Three participants noted that the test may be able to replace 2-parameter protein/glucose tests, but not the 10-parameter tests. All FGD participants agreed that use of the PrCr test would not change current practices/protocols for dipstick use. Although a few participants from two facilities supported the use of the PrCr test for both screening and monitoring of pregnant women at risk of PE and suggested its use as a replacement, others suggested that it be used only as an additional test because it lacks other parameters (e.g., glucose) available on current tests.

> *"PrCr test can be used to support the existing ones being used in the facility . . . Combi 10 measures a lot of parameters and this is the one being used regularly at triage so we can add the PrCr to it. For total replacement more parameters should be included such as glucose" (FGD; Midwife, Facility 1)*

> *"It can't replace the combo. It can replace the two strips [2-parameter test] . . . but the combo has a lot." (KII, Facility 3)*

One participant suggested the use of the test for home monitoring of pregnant women:

> *"The product should be accessible at pharmacy shops so that pregnant women . . . can purchase for use in their homes since preeclampsia is on the increase." (FGD; Midwife, Facility 1)*

**Table 1: Characteristics of study participants**

*Acceptability: Test user satisfaction*

Respondents at baseline were (very) satisfied (17/20) with the test and found it easy to use (19/20). Eleven liked the easy reading and interpretation of results best (Figure 1). Dislikes included difficulty reading/interpreting the colors (4/20) and the absence of a glucose parameter (3/20). Participants rated the following aspects of the test procedures as either "difficult" or "very difficult": visibility of the

protein result (10/20), visibility of the creatine result (11/20), matching the colors on the strip to the cannister (10/20), and interpretation of the result (9/20). The test's mean composite SUS score was 75 (Figure 2).

FGD participants reported liking the colors, ease of use, rapid time to result, that the strips are wide enough to be divided in half and used for two patients, and that the color pads are placed far enough apart to prevent color bleeding. In two facilities, participants reported liking that the test provided creatinine results without the need for costly laboratory tests. Dislikes included the strict 60-second waiting interval for results, the short expiration period of the test strips (3 months) after the cannister is opened, the number of steps/added complexity of result interpretation (e.g., color comparison), the fact that the test does not measure glucose, and the need for paper towel/tissue to blot strips (which is not included with the kit). Overall, participants felt that the instructions were clear, were satisfied with the results, and were confident in running and interpreting the test.

Key informants similarly reiterated dislikes of absence of additional parameters beyond Pr and Cr, the added workload of using the test, and its cumbersome nature.

> *"The only disadvantage is that now, when you let's say, fine you are looking for specific preeclampsia. But then you also need to do another test, then with a dipstick, it means you'll have to go and pick the combi 10 or the combi 2 to come and look for the glucose" (KII; Facility 1)*
>
> *"What I will not like is using it and then going for another products to run other test which could have been, that's all so it is like you are billing the patient twice." (KII; Facility 1)*

**Figure 1: *Results of selected baseline user experience responses**

**Figure 2: Systems Usability Scale responses**

*Feasibility: The extent to which the test can be successfully integrated into screening and monitoring protocols in referral hospitals*

**Test procedure comprehension and user proficiency.** Trainees showed good knowledge retention (Table 2) and product label comprehension (Table 3). Correct interpretation of images of static, pre-made test results ranged from 74% to 100% (Table 4). Misinterpretations of test results were less likely for strong results; the most misinterpreted test was image #3, which showed mid-range Pr and Cr values. When considering only the interpretation of the user-assigned Pr and Cr values using the manufacturer's scale, errors decreased, with 88% to 100% of participants correctly interpreting results based on their assigned bins.

**Table 2: Test user proficiency assessment during training**

**Table 3: Post-training product label comprehension assessment**

**Training feedback.** Results of the training feedback questionnaire are summarized in Supplementary Table 1.

**Barriers/facilitators to use**. At endline, participants reported that existing clinical practices, protocols, and systems in place for urine dipstick use could be easily adapted to facilitate introduction, given product similarities. Cost and test performance were consistently identified as important attributes that would influence decisions regarding adoption. Concerns about introduction included consistent and reliable availability, training requirements, short expiration dates of the cannisters once opened, and cost. Identified measures to increase uptake and coordinated use included robust trainings, sensitization and awareness programs with key stakeholders, and availability of posters/job aids with the color interpretation charts in the wards.

To facilitate test introduction, participants voiced that endorsement/support from key stakeholders including department heads, facility managers, in-charges of units, administrators, midwives, obstetricians and gynecologists, procurement officers, the Ghana Health Service, and the Ministry of Health is critical, and that such stakeholders should be intentionally engaged in decision making processes and sensitization programs.

> *"Change is difficult, but once the device is accepted by management for use, it will be readily accepted by midwives, but there should be intensive sensitization to promote the use of the device." (FGD; Midwife, Facility 2)*

**Table 4: Post-training results interpretation assessment**

## Discussion

Early identification of PE is essential to improve outcomes through efficient resource allocation and targeted prevention, triage, and treatment strategies. Improved screening tools have been identified as an innovation priority by global stakeholders and researchers.[17,24–28] Here, we present the results of a mixed-methods implementation research study that assessed the operational fit of introducing a new point-of-care PrCr ratio measurement test at referral hospitals in Ghana.

Generally, the product was considered appropriate and acceptable by stakeholders and end users given similarities to current products; however, its implementation feasibility is affected by inherent limitations of the attributes of this PrCr-only test. While some of the reported challenges and dislikes are relevant to all urine dipsticks as a product class, notable product-specific reported disadvantages of the Test-It PrCr test included the lack of a glucose parameter, the three-month expiration date of the strips once cannisters are opened, and the cumbersome nature of ratiometric result interpretation.

Multiple participants indicated that the absence of a glucose measurement on the dipstick was a significant limitation, presumably as this information is used in gestational diabetes mellitus screening. Glucosuria-based screening for gestational diabetes is not the preferred approach due to low to modest sensitivity.[29–33] However, given limitations associated with better performing and recommended glucose screening tests (i.e., the two-hour 75g oral glucose tolerance test [OGTT] or self-monitoring of blood glucose), urine dipstick glucose assessment is used at these facilities and was deemed desirable by participants. The extent to which performance limitations associated with urine dipstick glucose screening might influence participants' perceptions of health-system fit of the Test-It PrCr test was not assessed in this study. Nonetheless, this could suggest that the test is most appropriate for monitoring women at high risk for PE when proteinuria is the clinical focus. In cases where other parameters are of interest (e.g., ketones with hyperemesis or diabetes, nitrate or leukocytes for urinary tract infection screening), multi-parameter tests may be more appropriate.

The short shelf life of the test strips once cannisters are opened (3 months) was also highlighted as a product limitation. The impact of this limitation on implementation feasibility will likely vary by facility and health system, depending on patient volumes and cost considerations, and may be more critical for low-volume facilities. Future efforts could explore cost-benefit considerations related to different packaging options for test strips, and product development efforts could aim to extend the shelf life. Similarly, the reported practice that strips may be split to extend their use amidst resource constraints should also be pragmatically considered.

On the label comprehension questionnaire, participants also scored lowest when asked about the PrCr cut-point ratio for the test. This finding was likely due to misinterpretation of the question as being related to a particular test result rather than the abnormal/normal cut-off point (0.3) for the test.

Finally, the cumbersome nature of the ratiometric result interpretation step was highlighted as a challenge. However, results from the post-training result interpretation questionnaire suggest this challenge is surmountable with appropriate training and resources for end users. Job aides, in-service refresher trainings, and other resources for test users can serve to ensure that errors in result interpretation decrease over time as users become more familiar with the test.

Notably, participants from one facility suggested that the test could be made available to pregnant women for home self-monitoring. This aligns with increasing interest of self-monitoring of blood pressure as part of HDP care,[34] and emerging research on the feasibility and performance of self-monitoring for proteinuria using urine dipsticks.[35,36] Such innovative use cases for urine dipsticks warrant further exploration.

## Limitations

There are several limitations associated with this study. The training sessions were longer and more detailed than would be expected with real-world implementation of a new urine dipstick test. This was partly a consequence of the hybrid nature of the study, where test performance data was also collected (not presented herein). However, findings offer recommendations to stakeholders regarding how to optimize trainings for this and similar dipstick tests and adapt key components to local requirements. Participant observation could have been deployed to observe how the tests were used in practice; however, logistical challenges rendered this infeasible. Lastly, challenges were encountered in arranging FGDs and KIIs due to heavy workloads and participant availability, which is reflected in small sample sizes.

## Conclusions

Although the PrCr test is easy-to-use and well accepted by stakeholders and end users, key product attributes limit its implementation feasibility in this setting. As such, the test may be more appropriate for monitoring high-risk women, rather than in routine ANC screening of general populations of women when other parameters may also be of clinical interest. Future research on cost-effectiveness and impact on health outcomes can guide decisions about appropriate implementation strategies of the PrCr and other similar tests. Future research and product development efforts should continue to explore innovations that can improve proteinuria identification and address limitations of this and other urine dipstick tests.

## Acknowledgements

We would like to acknowledge the contributions of the health care providers in all participating health facilities, the pregnant women enrolled in the SPOT study, SPOT study research assistants and all who assisted to make data collection, analysis, and write-up for this study possible.

## Author contributions

HBA, JLB, SZ, MM designed the study. HBA, JLB, DKA, RO, NKAA, AOY, PC, EKS, KAB, LLY, VFW implemented the study. HBA, JLB, DKA, SZ and RO, conducted the analysis and drafted the manuscript. LLY, DKA, PC, EKS, KAB, MM, and PSC reviewed the manuscript and provided critical comments. All authors have read and approved the final manuscript.

## Competing interests

The authors have no competing interests to declare.

## Funding statement

This study was funded by the UK's Foreign, Commonwealth and Development Office under a grant for the Devices, Diagnostics and Drugs to Address Women's Needs ($D_3$AWN) Product Development Partnership. Funding ID: 300341-113.

## Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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# Tables

## Table 1: Characteristics of study participants

| Facility/participant group | Number | Years of experience in maternal healthcare (n) | | | Role (n) | | |
|---|---|---|---|---|---|---|---|
| | | *<2* | *2-10* | *>10* | *Midwife* | *Doctor* | *Other*[†] |
| ***[δ]Baseline trainees*** | | | | | | | |
| GARH* | 10 | 0 | 6 | 4 | 10 | 0 | 0 |
| ERH | 29 | 12 | 15 | 2 | 23 | 2 | 4 |
| KBTH | 49 | 6 | 25 | 13 | 45 | 1 | 2 |
| ***Baseline test user experience respondents*** | | | | | | | |
| GARH | 7 | 0 | 3 | 4 | 7 | 0 | 0 |
| ERH | 13 | 5 | 5 | 3 | 13 | 0 | 0 |
| ***Endline focus group participants*** | | | | | | | |
| GARH | 5 | NC | NC | NC | 5 | 0 | 0 |
| ERH | 10 | NC | NC | NC | 10 | 0 | 0 |
| KBTH | 5 | NC | NC | NC | 5 | 0 | 0 |
| ***Endline key informants*** | | | | | | | |
| All[^] | 7 | NC | NC | NC | 6 | 1 | 0 |

*Abbreviations:* ERH: Eastern Regional Hospital; GARH: Greater Accra Regional Hospital; KBTH: Korle Bu Teaching Hospital; NC: not collected.

[δ]Although there were 96 trainnees, only 88 provided all baseline data required; one person at KBTH did not name their role

*The low number of participants from GARH was due to staff availability for training. KBTH is the largest referral center in Ghana hence the observed high number of participants.

[†]Refers to nurse.

[^]To maintain key informant anonymity, participant characteristics are not disaggregated by facility for KIIs.

**Table 2: Test user proficiency assessment during training**

| Step in test procedure | Total number of observations | Frequency of correct responses (%) |
|---|---|---|
| 1. Demonstrates hand hygiene protocol and wears gloves. | 96 | 93 (96.9%) |
| 2. Checks that the expiration date on the canister has not been exceeded. | 94 | 94 (100%) |
| 3. Collects sample in a clean, dry container. If specimen has been stored in refrigerator or freezer, allows specimen to reach room temperature and mixes well before performing analysis. | 87 | 87 (100%) |
| 4. Removes one strip from the container, taking care not to touch the reagent areas. | 96 | 96 (100%) |
| 5. Immediately closes the container securely using the original cap. | 96 | 95 (98.9%) |
| 6. Dips the test strip into the urine briefly (no longer than 1 second), so that both reagent pads are wet, then removes. | 96 | 95 (98.9%) |
| 7. Blots the side of the test strip on absorbent paper to remove excess urine. | 96 | 96 (100%) |
| 8. Waits 60 seconds.[a] | 95 | 91 (95.8%) |
| 9. After exactly 60 seconds, compares the colors on the test strip with the corresponding color scale on the container.[b] | 93 | 90 (96.8%) |
| 10. Discards the used strip in a biohazard waste bin | 92 | 90 (97.8%) |
| 11. Documents results in appropriate log[c] | 89 | 87 (97.8%) |
| 12. Understands and interprets test results appropriately. Re-tests if needed[d] | 90 | 87 (96.7%) |

[a] One person failed at first attempt, 1 person needed to be reminded, 1 person waited a little longer.
[b] One person failed at first attempt, 3 waited a little over 60 seconds.
[c] One person documented what the strips performed; 1 person needed assistance.
[d] One person failed at first attempt, 2 needed to re-test

**Table 3: Post-training product label comprehension assessment**

| Question | Total number of responses | Number of correct responses (%) |
|---|---|---|
| 1. True or False: The test can be used to screen for proteinuria during pregnancy. | 91 | 90 (98.9%) |
| 2. What does the dipstick measure? | 91 | 86 (94.5%) |
| 3. How long should the dipstick be submerged into the urine sample? | 91 | 85 (93.4%) |
| 4. True or False: After dipping the test strip into the urine, the user should blot the side of the test strop on absorbent paper to remove excess urine. | 91 | 90 (98.9%) |
| 5. How long should you wait to read the results of the test? | 91 | 91 (100%) |
| 6. Is it okay to read the test result after 60 seconds? | 91 | 86 (94.5%) |
| 7. Can you re-use the test strip? | 91 | 91 (100%) |
| 8. The test strips should be used within ____ month(s) of first opening the container. | 91 | 90 (98.9%) |
| 9. What is the storage temperature range of the test cannister? | 90 | 86 (95.6%) |
| 10. True or False: The protein and creatinine results on the test should be read at different times. | 91 | 86 (94.5%) |
| 11. What is the protein:creatinine ratio for proteinuria on this test? | 76 | 68 (63.2%) |

**Table 4: Post-training results interpretation assessment**

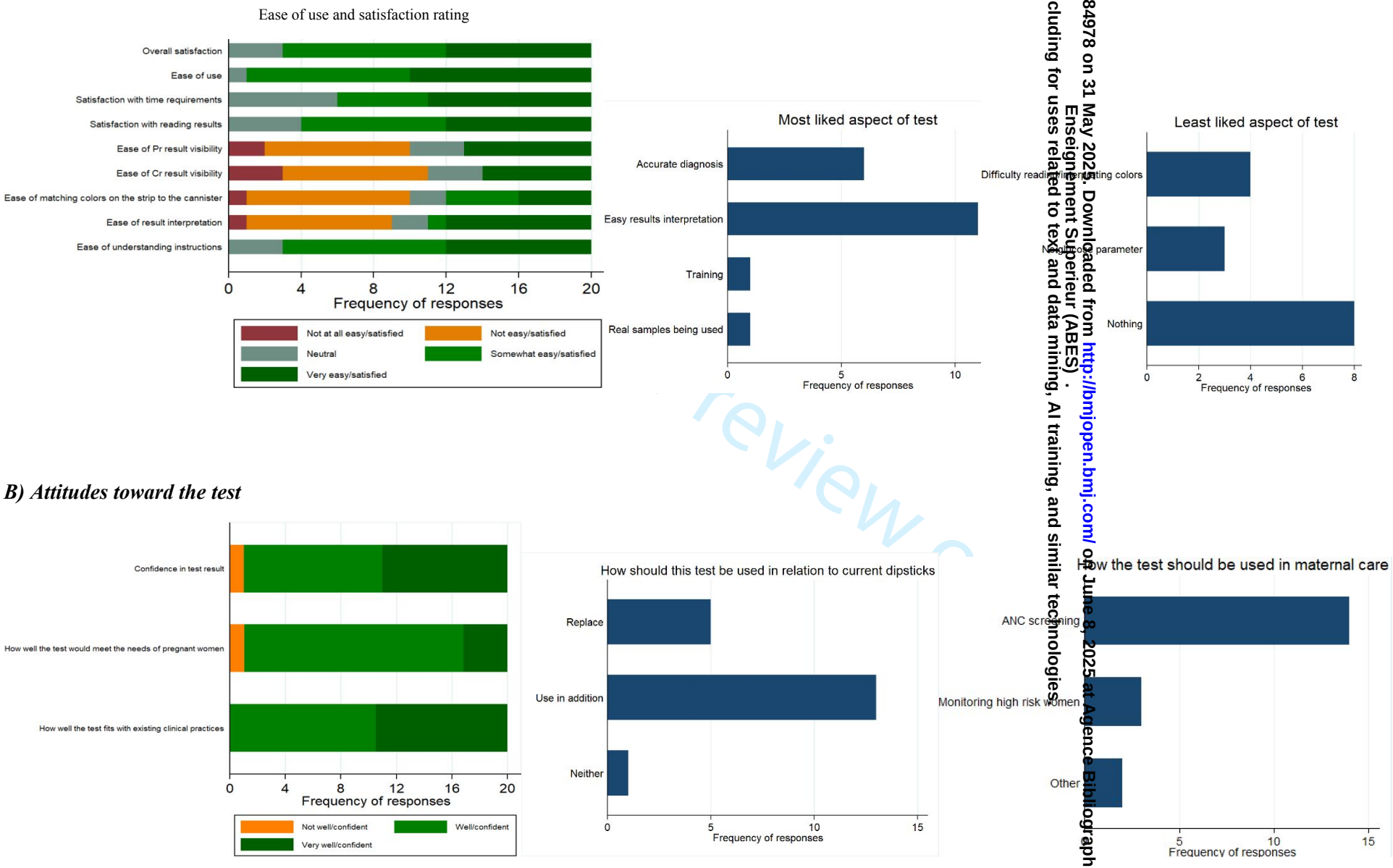
| # | Image | Pr result | Cr result | Interpretation | Total responses | Correct interpretation, n (%) | Incorrect interpretations, n (%) | Correct interpretation of user-assigned PrCr values*, n (%) |
|---|---|---|---|---|---|---|---|---|
| 1 |  | 0 | 1+ | Normal | 89 | 76 (85.4%) | Proteinuria: 5 (5.6%) Invalid: 8 (9%) | 84 (94.4)% |
| 2 |  | 4+ | 4+ | Proteinuria | 88 | 84 (95.5%) | Normal: 1 (1.1%) Invalid: 3 (3.4%) | 85 (96.6)% |
| 3 |  | 2+ | 2+ | Proteinuria | 87 | 64 (73.6%) | Normal: 21 (24.1%) Invalid: 2 (2.3%) | 83 (95.4)% |
| 4 |  | 0 | 2+ | Normal | 86 | 75 (87.2%) | Proteinuria: 10 (11.6%) Invalid: 1 (1.2%) | 76 (88.4)% |
| 5 |  | 3+ | 1+ | Proteinuria | 85 | 78 (91.8%) | Normal: 2 (2.4%) Invalid: 5 (5.9%) | 81 (95.3)% |
| 6 |  | - | - | Invalid | 89 | 89 (100%) | - | - |

* Excludes entirely blank responses. See Supplementary Material B for full details.

*Note: Variable print quality may have influenced accuracy of user interpretation against correct response*

**Figure 1: *Results of selected baseline user experience responses**

***A) Experiences with the test***

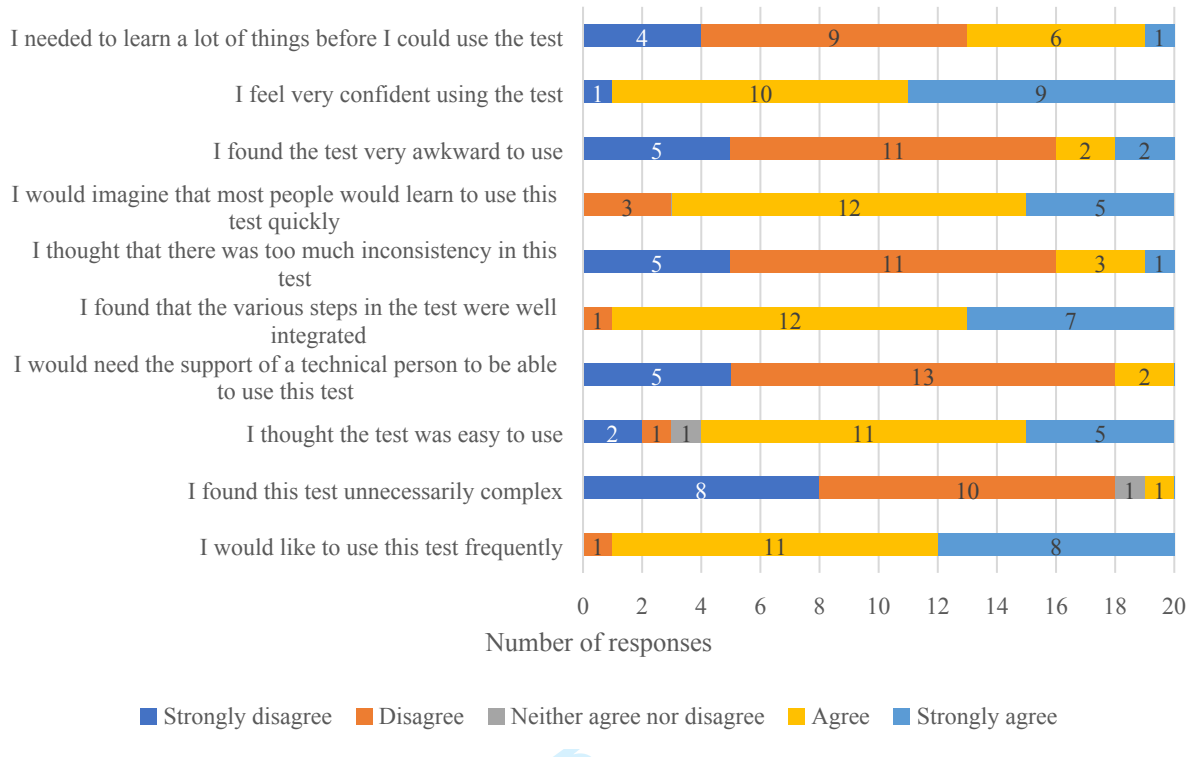



***B) Attitudes toward the test***




*The remaining responses can be found in the supplementary file 2.

**Figure 2: Systems Usability Scale responses**



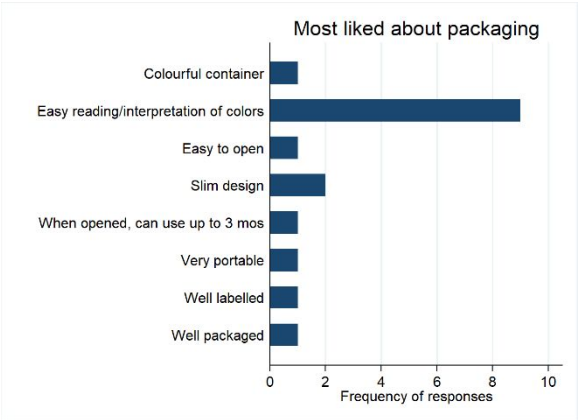
# Supplementary Material

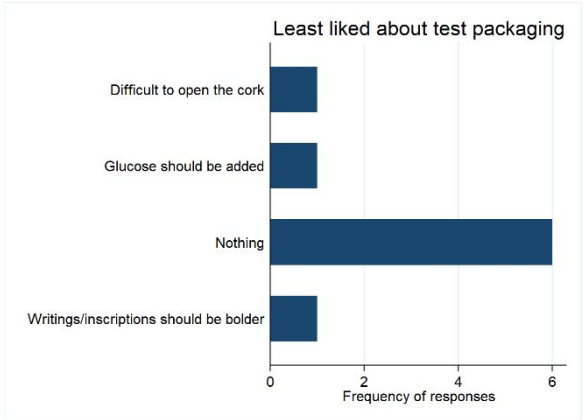
## Supplementary Table 1. Training feedback from test users

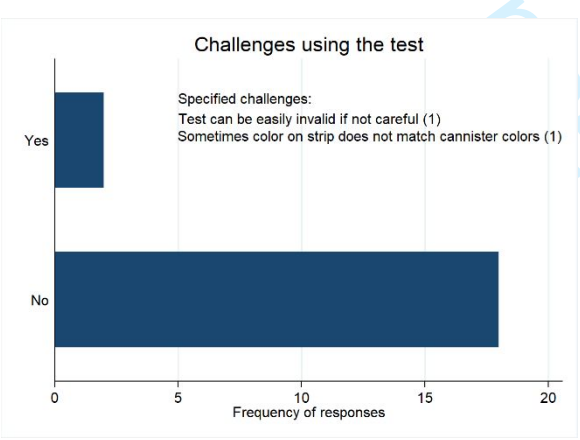
| Item | Frequency (n) | Percentage (%) |
|---|---|---|
| **Preferred method of learning** | | |
| Formal training | 38 | 40 |
| Hands on practice | 78 | 83 |
| Watching videos | 25 | 27 |
| Learning from peers | 10 | 11 |
| Informal learning, personal research | 9 | 10 |
| **Overall satisfaction with training** | | |
| Not satisfied at all | 0 | 0 |
| Not satisfied | 2 | 2 |
| Average | 2 | 2 |
| Satisfied | 21 | 22 |
| Very Satisfied | 68 | 72 |
| Missing | 1 | 1 |
| **Confidence in ability to correctly use the test after training** | | |
| Not confident at all | 0 | 0 |
| Not confident | 0 | 0 |
| Average | 3 | 3 |
| Confident | 18 | 19 |
| Very Confident | 72 | 77 |
| Missing | 1 | 1 |
| **What, if anything, would you have liked more of during the training** | | |
| Practice using the test | 18 | 19 |
| Practice interpreting the result | 22 | 24 |
| Information on common errors and how to avoid them | 23 | 25 |
| Information on the accuracy of the test | 25 | 27 |
| Nothing | 5 | 5 |
| **Do you wish the training had been longer, shorter, or was it the right length?** | | |
| Longer | 5 | 5 |
| Shorter | 8 | 9 |
| Duration of training was appropriate | 79 | 84 |
| Missing | 2 | 2 |
| **Open-ended feedback** | | |
| **Most liked about the training** | | |
| Everything | 8 | 9 |
| Presenter's presentation skill | 8 | 9 |
| Practical aspect | 50 | 53 |
| The clear, precise and educative nature of training | 23 | 24 |
| ***Least liked about training*** | | |
| No refreshments, no projector | 4 | 4 |
| Nothing | 31 | 33 |
| Poor visuals (images, videos, colors) | 5 | 5 |
| Practical, explanation and documentation | 3 | 3 |
| The urine samples used and how they were handled | 4 | 4 |
| Poor time management (time wasting) | 15 | 16 |
| **Suggested improvements to training** | | |
| Visuals (images, videos, colors) | 6 | 6 |
| Samples (acquire fresh samples from eclamptic patients) | 8 | 9 |
| Practical aspect, interpretation and documentation of results | 13 | 14 |
| PPEs, dustbins, and train more staff | 7 | 7 |
| Refreshments and allowance | 4 | 4 |
| Time management and organization | 16 | 17 |
| None | 19 | 20 |

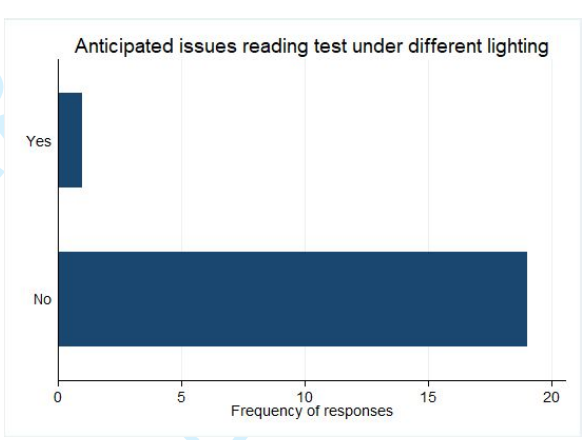
**Supplementary File2:**

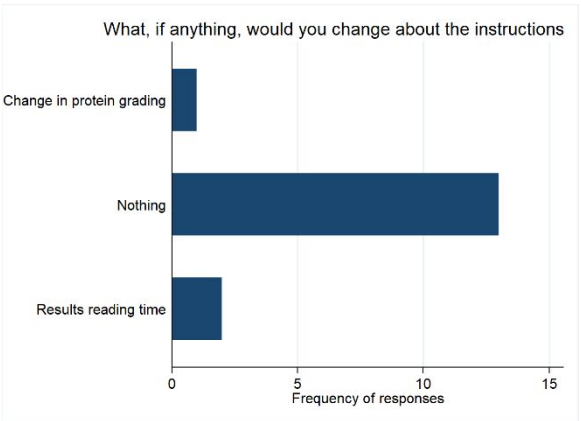
**Figures of user experience with the test at baseline**

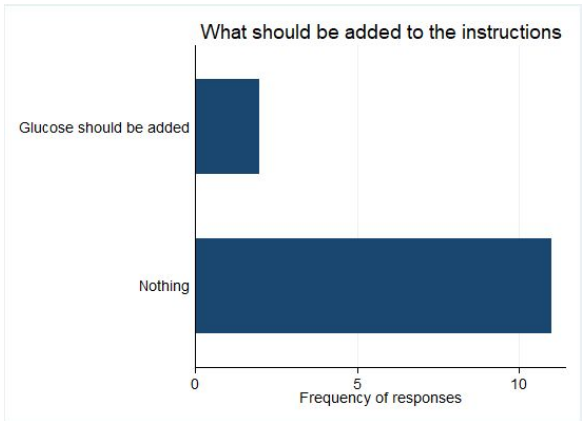


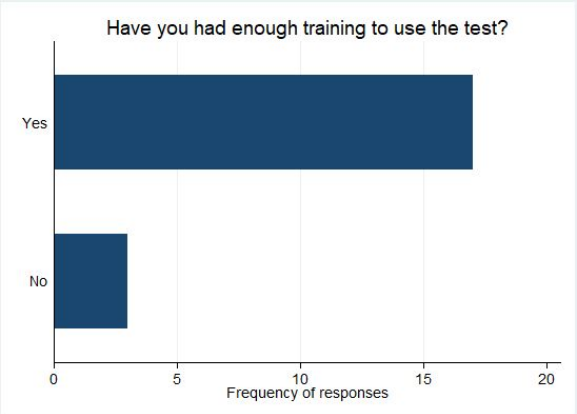



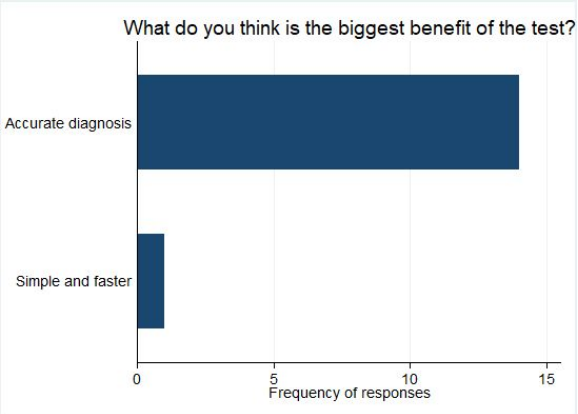



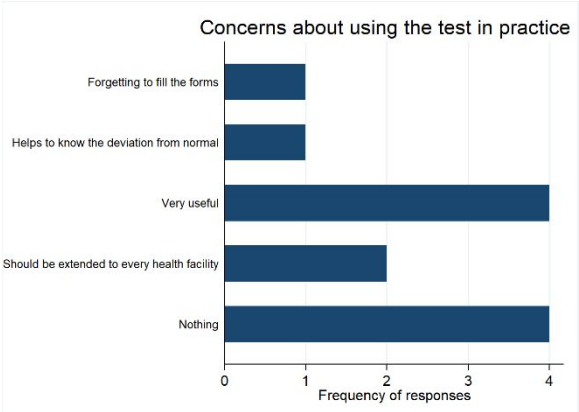



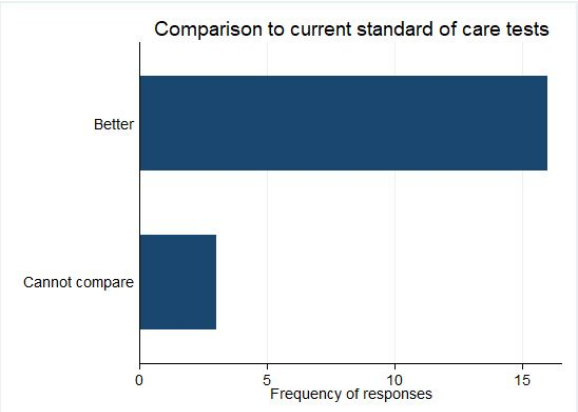



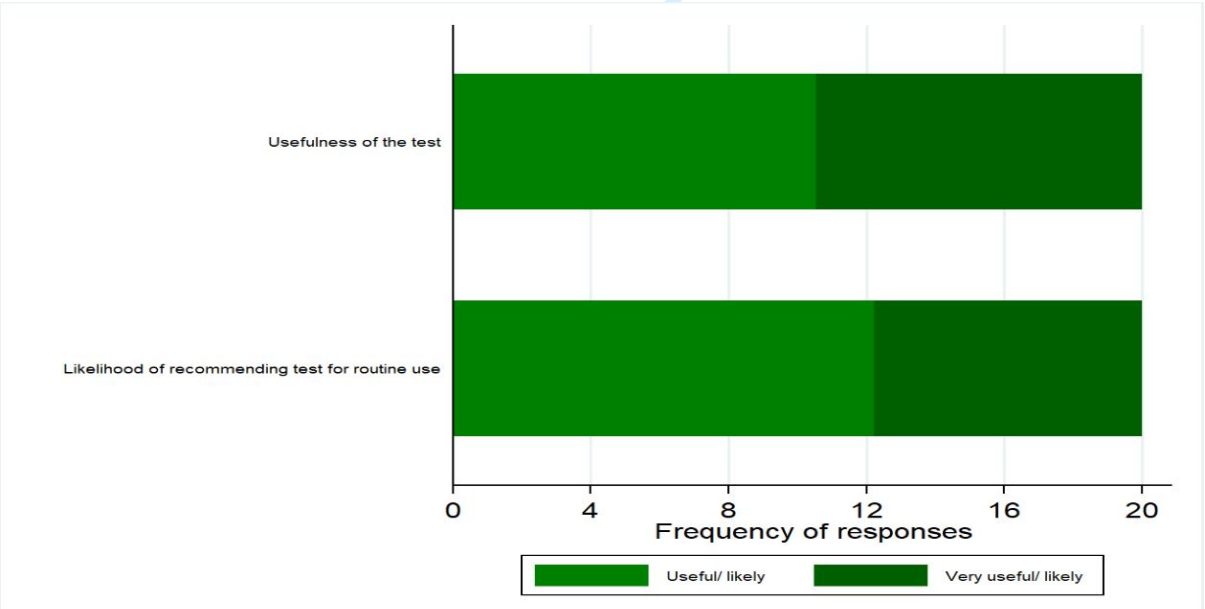





BMJ Open

# User perspectives, challenges, and opportunities in implementation of protein-to-creatinine dipstick test for proteinuria detection in Ghana: A mixed methods study

| | |
|---|---|
| Journal: | *BMJ Open* |
| Manuscript ID | bmjopen-2024-084978.R1 |
| Article Type: | Original research |
| Date Submitted by the Author: | 04-Mar-2025 |
| Complete List of Authors: | Amoakoh, Hannah; University Medical Centre Utrecht, Julius Center for Health Sciences and Primary Care, Department of Global Health and Bioethics; University of Ghana Noguchi Memorial Institute for Medical Research, Epidemiology<br>Browne, Joyce; University Medical Centre Utrecht, Julius Center for Health Sciences and Primary Care<br>Zobrist, Stephanie; PATH<br>Arhinful, Daniel; University of Ghana Noguchi Memorial Institute for Medical Research, Epidemiology<br>Owusu, Rosemond; PATH, West Africa Hub<br>Ampofo, Nana Kwame ; Ghana Health Service, Greater Accra Regional Hospital<br>Yeboah, Abena ; Ghana Health Service, Greater Accra Regional Hospital<br>Cofie, Patience; PATH, West Africa Hub<br>Srofenyoh , Emmanuel; Ghana Health Service, Greater Accra Regional Hospital<br>Adu-Bonsaffoh, Kwame; University Medical Centre Utrecht, Julius Center for Health Sciences and Primary Care, Department of Global Health and Bioethics; University of Ghana Medical School<br>Yevoo, Lucy; University of Ghana Noguchi Memorial Institute for Medical Research, Epidemiology<br>Wuobar, Vinkpenubar ; Ghana Health Service Council, Eastern Regional Hospital<br>Metzler, Mutsumi; PATH, Medical Devices and Health Technologies<br>Coffey, Patricia; PATH, Medical Devices/Health Technologies |
| Primary Subject Heading: | Obstetrics and gynaecology |
| Secondary Subject Heading: | Health services research, Public health, Global health |
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# User perspectives, challenges, and opportunities in implementation of protein-to-creatinine dipstick test for proteinuria detection in Ghana: A mixed methods study

Hannah Brown Amoakoh[1,2*], Joyce L Browne[2], Stephanie Zobrist[3], Daniel K Arhinful[1], Rosemond Owusu[4], Nana Kwame Asare Ampofo[5], Abena Odurowaa Yeboah[5], Patience Cofie[4], Emmanuel K. Srofenyoh[6], Kwame Adu-Bonsaffoh[2,7,8], Lucy Linda Yevoo[1], Vinkpenubar Francis Wubar[9], Mutsumi Metzler[10], Patricia S Coffey[10]

Affiliations:

[1]University of Ghana, Noguchi Memorial Institute for Medical Research, Department of Epidemiology, Accra, Ghana
[2]Utrecht University, Julius Center for Health Sciences and Primary Care, University Medical Centre, Utrecht, Netherlands
[3]PATH, Diagnostics, Seattle, United States
[4]PATH, West Africa Hub, Accra, Ghana
[5]Ghana Health Service, Accra, Ghana
[6]Ghana Health Service, Greater Accra Regional Hospital, Department of Obstetrics and Gynecology, Accra, Ghana
[7]University of Ghana Medical School, Accra, Ghana
[8]Korle-Bu Teaching Hospital, Department of Obstetrics, Accra, Ghana
[9]Eastern Regional Hospital, Department of Obstetrics, Koforidua, Ghana
[10]PATH, Medical Devices and Health Technologies, Seattle, United States

*Corresponding author: Dr. Hannah Brown Amoakoh, University Medical Center Utrecht, P.O. Box 85500, 3508 GA Utrecht, H.B.Amoakoh-2@umcutrecht.nl

# Abstract

**Objective:** To assess the appropriateness, acceptability, and feasibility of implementing the Test-it™ PrCr Urinalysis Dipstick Test (LifeAssay Diagnostics, South Africa) in referral hospitals in Ghana.

**Participants:** Ninety-six (96) healthcare professionals were trained on the PrCr test, which was integrated into protocols alongside standard-of-care tests between November 2021-April 2022. Test users completed questionnaires post-training. Three focus group discussions (FGDs) and seven key informant interviews were conducted to evaluate test procedure comprehension, insights into training effectiveness, usability/user confidence, perceptions, attitudes toward the test, and barriers and facilitators of use.

**Results:** High product usability, user confidence, and satisfaction were reported. Staff perceived the test as easy-to-use and like current products. Misinterpretations of test results were less likely for strong results. Facilitators of use included effective trainings, sensitization of the product, and key stakeholder endorsement. Challenges impacting implementation feasibility, included the short shelf life of test strips (3 months) after opening cannisters, added complexity of the ratiometric result interpretation, and the test's lack of other parameters that are included in current products (e.g., glucose, nitrate), limiting its broader clinical utility for ANC screening. All FGD participants agreed that use of the PrCr test would not change current practices/protocols for dipstick use.

**Conclusion:** Although the Test-It PrCr test is easy-to-use and well accepted, key product attributes limit its implementation feasibility in this setting. It may be more appropriate for monitoring high-risk women in this context.


**Keywords:** Preeclampsia, proteinuria, point-of-care diagnostic, implementation research, LifeAssay Test-it™ PrCr Urinalysis Dipstick

# Strengths and limitations of this study:

- Implementation of the new point-of-care PrCr ratio measurement test (Test-it™ PrCr Urinalysis Dipstick Test, manufactured by LifeAssay Diagnostics (Pty) Ltd., Cape Town, South Africa)) in referral facilities where preeclampsia is primarily managed in Ghana ensured that the appropriate end-users in the given context experienced and provided feedback on the test.

- Adopting an in-person PrCr test execution training with an assessment of performance and results interpretation comprehension allowed thorough assessment of health workers' ability to use and interpret the results of the PrCr test before its deployment.

- This study had a small sample size and thus perspectives of the PrCr test use is limited to the views of those health workers who participated in this study and may not reflect the views of all end-users of the test.

- We did not use ethnographic methods like participant observation to assess the utility of the PrCr test in practice therefore our findings are limited to self-reports by the health workers.

# Introduction

Preeclampsia (PE), a hypertensive disorder of pregnancy (HDP), affects approximately 5-7% of pregnant women and contributes to an estimated 70,000 and 500,000 annual maternal and fetal deaths, respectively.[1–3] The International Society of the Study of Hypertension in Pregnancy (ISSHP) defines PE as new onset hypertension (BP ≥140 mmHg systolic or ≥90 mmHg diastolic) at or after 20 weeks' gestation accompanied by proteinuria and/or evidence of maternal acute kidney injury, liver dysfunction, neurological features, hemolysis or thrombocytopenia, or fetal growth restriction.[5] Global guidelines recommend routine measurement of blood pressure and proteinuria at antenatal care (ANC) visits to screen for PE.[6]

The gold standard for proteinuria measurement is 24-hour urine collection; however, this method is technically complex, costly, and a significant burden to patients and providers.[7,8] Urine dipstick tests are the most widely used proteinuria screening tools, and the ISSHP considers a result of ≥1+ (30 mg/dL) abnormal.[5] Despite their low cost and ease of use, these tests have considerable performance limitations constraining their clinical utility.[6,9–12] A recent systematic review by Teeuw and colleagues concluded that urine dipsticks perform poorly at excluding PE in hypertensive women, reporting a pooled performance of 68% sensitivity and 85% specificity across nineteen studies.[13] Importantly, urine dipsticks measuring only protein are unable to adjust for patients' hydration, which can result in over or underestimation of the protein measurement.[10]

In view of these limitations, the protein-to-creatinine (PrCr) ratio has been recognized as an acceptable measurement of proteinuria, with a clinical cut-off point of ≥0.3 mg/mg.[14–16] Spot urine PrCr ratios are typically determined using automated chemistry analyzers, which like the 24-hour urine method, require precision instruments, skilled personnel, and laboratory infrastructure.[17] Low-cost urine dipstick tests to measure the PrCr ratio at the point-of-care provide an opportunity to address the significant gap in accurate, affordable, and simple tests for proteinuria that are appropriate for low- and middle-income country (LMIC) settings where the PE burden is greatest.

One such product is the Test-it™ PrCr Urinalysis Dipstick Test (LifeAssay Diagnostics (Pty) Ltd., Cape Town, South Africa), hereafter called the PrCr test. This product is a urine dipstick test that detects both protein and creatinine semi-quantitatively to assess proteinuria**.** The test format and workflow are like that of currently available dipstick tests for proteinuria at the point of care. The PrCr test includes reagent pads for protein and creatinine. Results are available in 60 seconds and are interpreted visually by comparing the color of the reagent pads against a reference color scale provided by the manufacturer. The ratio of the protein and creatinine results is then subsequently used to differentiate abnormal proteinuria based on the manufacturer's established threshold (0.3mg/mg) The test's Instructions for use have been provided as Supplementary material file 3. The price of the test is comparable to that of currently available protein-only urine dipstick tests. The test should be stored between 8 and 28°C, and strips should be used within three months after opening the cannister. Early laboratory verification reported 85% sensitivity and 71% specificity for correct disease classification.[18] A subsequent clinical performance evaluation in Kintampo, Ghana, observed improved performance for detection of proteinuria over the current standard of care dipstick tests; however, overall, performance decreased from prior lab studies (51% sensitivity, 69% specificity).[19] User feedback suggested that the test would be well accepted by ANC providers in Ghana, but highlighted that adequate training and resources would be critical to support successful implementation.[19] The product was registered in 2021 with the Ghanaian Food and Drugs Authority.

Here, we present the results of implementation research that assessed the operational fit of integrating the PrCr test into referral hospital protocols in Ghana, among facilities and providers who serve populations with a high prevalence of PE. Operational fit was assessed according to three dimensions, as described by Proctor et al.[23]:

1. Appropriateness: Perceived fit (usefulness, practicality) of the test.
2. Acceptability: Test user satisfaction.
3. Feasibility: The extent to which the test can be successfully integrated into screening and monitoring protocols in referral hospitals.

# Methods

## Ethical considerations

This study was reviewed and approved by the Ghana Health Service Ethics Review Committee (GHS-ERC: 022/05/21) and the Korle-Bu Institutional Review Board (KBTH-STC 000113/2021). All participants provided informed consent.

## Patient and Public involvement statement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this study.

## Study design and procedures

Between November 2021 and April 2022, the PrCr test was implemented at three facilities in the Greater Accra and Eastern Regions of Ghana: Korle-Bu Teaching Hospital (KBTH) and the Greater Accra and Eastern Regional Hospitals (GARH and ERH). Facilities were selected due to their referral functions, large patient volumes, and experience managing HDPs. This study was nested in the research infrastructure of the Severe Preeclampsia Adverse Outcome Triage (SPOT) study, a transdisciplinary research collaboration to improve the quality of care for women with HDP remote from term (26-34 weeks gestation).[20]

Hands-on training workshops that focused on test use and results interpretation were organized for health workers (HWs) involved in maternal care at participating facilities. Trainings lasted approximately four hours. Subsequently, participants used the test in routine care of HDP patients, alongside standard urine dipsticks. Operational fit was assessed quantitatively at baseline and qualitatively at endline.

## Sampling and sample size

At baseline, all trainees (96) were purposively sampled to assess the acceptability and feasibility of the PrCr test. Additionally, 20 trainees were conveniently sampled to assess their experience of the test. At endline, 27 participants were conveniently sampled to assess operational fit of the PrCr test.

## Data collection methods

### Quantitative data collection (baseline)

Data on user comprehension and proficiency were gathered using a label comprehension and result interpretation questionnaire that employed images of static test results during training sessions. A post-training questionnaire was administered to assess training strengths/weakness. Training practice sessions were observed using a checklist and structured questionnaire that included a Systems Usability Scale (SUS).[21,22] User experience feedback was collected through a structured questionnaire.

### Qualitative data collection (endline)

Seven key informant interviews (KIIs) were conducted with stakeholders caring for women with HDP at health facilities, including midwives, doctors, and maternity ward supervisors/managers. Interviews

focused on perceptions of the test, its value proposition, appropriateness of its features/use in referral hospital settings, and strategies to facilitate successful introduction in Ghana. One FGD was performed per facility. The objectives of FGDs were to 1) seek HW's feedback on the test following use, 2) identify facilitators and barriers to use of the test, and 3) identify strategies to facilitate uptake and integration into ANC and monitoring of HDP in Ghana.

## Data management and analysis

Data from baseline questionnaires was entered into EpiData. Descriptive statistics were used to summarize these data. SUS scores were calculated according to standard methods, and a composite score >68 was considered acceptable.[21,22] FGDs and KIIs were audio-recorded and transcribed verbatim for analysis through deductive thematic coding. All transcripts were analyzed separately by at least two investigators using Excel, jointly discussed, and consensus reached on the interpretation of key thematic findings.

# Results

## Characteristics of study participants

Of the 96 HWs who completed the training workshops, 10 were from GARH, 51 from KBTH, and 35 from ERH (Table 1). Most training participants were midwives (90.0%, n=78/87).

Seven KIIs were conducted with six midwives and one Obstetrics and Gynecology specialist. The majority (5/7) described serving in supervisory capacities. Three FGDs were conducted, with ten participants at ERH, and five each at KBTH and GARH. All FGD participants were midwives.

## Assessment of operational fit of PrCr test

## Appropriateness: Perceived fit (usefulness, practicality) of the test

Nineteen of 20 trainees who completed the baseline user experience questionnaire found the PrCr test useful or very useful, 18 were likely/very likely to recommend the test to others, and 19 felt that the test fit well or very well with existing clinical practices and the needs of pregnant women (Figure 1). Most midwives (14) thought the test was useful for ANC screening for proteinuria, and three thought that the test should be used primarily for monitoring high-risk women. When asked about perceived health system fit, 18 indicated that the test was better than the standard test but 13 wanted to use it in addition, rather than as a replacement.

At endline, similar themes emerged from qualitative data. Two key informants mentioned the utility of the PrCr test among populations at high-risk for PE. However, several expressed concerns about the test being a replacement for current tools, which include additional parameters, and the additional workload and cost associated with performing two tests. Three participants noted that the test may be able to replace 2-parameter protein/glucose tests, but not the 10-parameter tests. All FGD participants agreed that use of the PrCr test would not change current practices/protocols for dipstick use. Although a few participants from two facilities supported the use of the PrCr test for both screening and monitoring of pregnant women at risk of PE and suggested its use as a replacement, others suggested that it be used only as an additional test because it lacks other parameters (e.g., glucose) available on current tests.

> *"PrCr test can be used to support the existing ones being used in the facility . . . Combi 10 measures a lot of parameters and this is the one being used regularly at triage so we can add the PrCr to it. For total replacement more parameters should be included such as glucose" (FGD; Midwife, Facility 1)*

*"It can't replace the combo. It can replace the two strips [2-parameter test] . . . but the combo has a lot." (KII, Facility 3)*

One participant suggested the use of the test for home monitoring of pregnant women:

*"The product should be accessible at pharmacy shops so that pregnant women . . . can purchase for use in their homes since preeclampsia is on the increase." (FGD; Midwife, Facility 1)*

**Table 1: Characteristics of study participants**

| Facility/participant group | Number | Years of experience in maternal healthcare (n) | | | Role (n) | | |
|---|---|---|---|---|---|---|---|
| | | *<2* | *2-10* | *>10* | *Midwife* | *Doctor* | *Other*[†] |
| ***[δ]Baseline trainees*** | | | | | | | |
| GARH* | 10 | 0 | 6 | 4 | 10 | 0 | 0 |
| ERH | 29 | 12 | 15 | 2 | 23 | 2 | 4 |
| KBTH | 49 | 6 | 25 | 13 | 45 | 1 | 2 |
| ***Baseline test user experience respondents*** | | | | | | | |
| GARH | 7 | 0 | 3 | 4 | 7 | 0 | 0 |
| ERH | 13 | 5 | 5 | 3 | 13 | 0 | 0 |
| ***Endline focus group participants*** | | | | | | | |
| GARH | 5 | NC | NC | NC | 5 | 0 | 0 |
| ERH | 10 | NC | NC | NC | 10 | 0 | 0 |
| KBTH | 5 | NC | NC | NC | 5 | 0 | 0 |
| ***Endline key informants*** | | | | | | | |
| All[^] | 7 | NC | NC | NC | 6 | 1 | 0 |

*Abbreviations:* ERH: Eastern Regional Hospital; GARH: Greater Accra Regional Hospital; KBTH: Korle Bu Teaching Hospital; NC: not collected.

[δ]Although there were 96 trainees, only 88 provided all baseline data required; one person at KBTH did not name their role

*The low number of participants from GARH was due to staff availability for training. KBTH is the largest referral center in Ghana hence the observed high number of participants.

[†]Refers to nurse.

[^]To maintain key informant anonymity, participant characteristics are not disaggregated by facility for KIIs.

## Acceptability: Test user satisfaction

Respondents at baseline were (very) satisfied (17/20) with the test and found it easy to use (19/20). Eleven liked the easy reading and interpretation of results best (Figure 1 and supplementary file 2). Dislikes included difficulty reading/interpreting the colors (4/20) and the absence of a glucose parameter (3/20). Participants rated the following aspects of the test procedures as either "difficult" or "very difficult": visibility of the protein result (10/20), visibility of the creatine result (11/20), matching the colors on the strip to the cannister (10/20), and interpretation of the result (9/20). The test's mean composite SUS score was 75 (Figure 2).

FGD participants reported liking the colors, ease of use, rapid time to result, that the strips are wide enough to be divided in half and used for two patients, and that the color pads are placed far enough apart to prevent color bleeding. In two facilities, participants reported liking that the test provided creatinine results without the need for costly laboratory tests. Dislikes included the strict 60-second waiting interval for results, the short expiration period of the test strips (3 months) after the cannister is opened, the number of steps/added complexity of result interpretation (e.g., color comparison), the

fact that the test does not measure glucose, and the need for paper towel/tissue to blot strips (which is not included with the kit). Overall, participants felt that the instructions were clear, were satisfied with the results, and were confident in running and interpreting the test.

Key informants similarly reiterated dislikes of absence of additional parameters beyond Pr and Cr, the added workload of using the test, and its cumbersome nature.

> *"The only disadvantage is that now, when you let's say, fine you are looking for specific preeclampsia. But then you also need to do another test, then with a dipstick, it means you'll have to go and pick the combi 10 or the combi 2 to come and look for the glucose" (KII; Facility 1)*

> *"What I will not like is using it and then going for another products to run other test which could have been, that's all so it is like you are billing the patient twice." (KII; Facility 1)*

**Figure 1: *Results of selected baseline user experience responses**

**Figure 2: Systems Usability Scale responses**

## Feasibility: The extent to which the test can be successfully integrated into screening and monitoring protocols in referral hospitals

**Test procedure comprehension and user proficiency.** Trainees showed good knowledge retention (Table 2) and product label comprehension (Table 3). Correct interpretation of images of static, pre-made test results ranged from 74% to 100% (Table 4). Misinterpretations of test results were less likely for strong results; the most misinterpreted test was image #3, which showed mid-range Pr and Cr values. When considering only the interpretation of the user-assigned Pr and Cr values using the manufacturer's scale, errors decreased, with 88% to 100% of participants correctly interpreting results based on their assigned bins.

**Table 2: Test user proficiency assessment during training**

| Step in test procedure | Total number of observations | Frequency of correct responses (%) |
|---|---|---|
| 1. Demonstrates hand hygiene protocol and wears gloves. | 96 | 93 (96.9%) |
| 2. Checks that the expiration date on the canister has not been exceeded. | 94 | 94 (100%) |
| 3. Collects sample in a clean, dry container. If specimen has been stored in refrigerator or freezer, allows specimen to reach room temperature and mixes well before performing analysis. | 87 | 87 (100%) |
| 4. Removes one strip from the container, taking care not to touch the reagent areas. | 96 | 96 (100%) |
| 5. Immediately closes the container securely using the original cap. | 96 | 95 (98.9%) |
| 6. Dips the test strip into the urine briefly (no longer than 1 second), so that both reagent pads are wet, then removes. | 96 | 95 (98.9%) |
| 7. Blots the side of the test strip on absorbent paper to remove excess urine. | 96 | 96 (100%) |
| 8. Waits 60 seconds.[a] | 95 | 91 (95.8%) |
| 9. After exactly 60 seconds, compares the colors on the test strip with the corresponding color scale on the container.[b] | 93 | 90 (96.8%) |
| 10. Discards the used strip in a biohazard waste bin | 92 | 90 (97.8%) |
| 11. Documents results in appropriate log[c] | 89 | 87 (97.8%) |
| 12. Understands and interprets test results appropriately. Re-tests if needed[d] | 90 | 87 (96.7%) |

[a] One person failed at first attempt, 1 person needed to be reminded, 1 person waited a little longer.
[b] One person failed at first attempt, 3 waited a little over 60 seconds.
[c] One person documented what the strips performed; 1 person needed assistance.
[d] One person failed at first attempt, 2 needed to re-test

**Table 3: Post-training product label comprehension assessment**

| Question | Total number of responses | Number of correct responses (%) |
|---|---|---|
| 1. True or False: The test can be used to screen for proteinuria during pregnancy. | 91 | 90 (98.9%) |
| 2. What does the dipstick measure? | 91 | 86 (94.5%) |
| 3. How long should the dipstick be submerged into the urine sample? | 91 | 85 (93.4%) |
| 4. True or False: After dipping the test strip into the urine, the user should blot the side of the test strop on absorbent paper to remove excess urine. | 91 | 90 (98.9%) |
| 5. How long should you wait to read the results of the test? | 91 | 91 (100%) |
| 6. Is it okay to read the test result after 60 seconds? | 91 | 86 (94.5%) |
| 7. Can you re-use the test strip? | 91 | 91 (100%) |
| 8. The test strips should be used within ____ month(s) of first opening the container. | 91 | 90 (98.9%) |
| 9. What is the storage temperature range of the test cannister? | 90 | 86 (95.6%) |
| 10. True or False: The protein and creatinine results on the test should be read at different times. | 91 | 86 (94.5%) |
| 11. What is the protein:creatinine ratio for proteinuria on this test? | 76 | 68 (63.2%) |

**Training feedback.** Results of the training feedback questionnaire are summarized in Supplementary Table 1.

**Barriers/facilitators to use**. At endline, participants reported that existing clinical practices, protocols, and systems in place for urine dipstick use could be easily adapted to facilitate introduction, given product similarities. Cost and test performance were consistently identified as important attributes that would influence decisions regarding adoption. Concerns about introduction included consistent and reliable availability, training requirements, short expiration dates of the cannisters once opened, and cost. Identified measures to increase uptake and coordinated use included robust trainings, sensitization and awareness programs with key stakeholders, and availability of posters/job aids with the color interpretation charts in the wards.

To facilitate test introduction, participants voiced that endorsement/support from key stakeholders including department heads, facility managers, in-charges of units, administrators, midwives, obstetricians and gynecologists, procurement officers, the Ghana Health Service, and the Ministry of Health is critical, and that such stakeholders should be intentionally engaged in decision making processes and sensitization programs.

> *"Change is difficult, but once the device is accepted by management for use, it will be readily accepted by midwives, but there should be intensive sensitization to promote the use of the device." (FGD; Midwife, Facility 2)*

**Table 4: Post-training results interpretation assessment**

| # | Image | Pr result | Cr result | Interpretation | Total responses | Correct interpretation, n (%) | Incorrect interpretations, n (%) | Correct interpretation of user-assigned PrCr values*, n (%) |
|---|---|---|---|---|---|---|---|---|
| 1 |  | 0 | 1+ | Normal | 89 | 76 (85.4%) | Proteinuria: 5 (5.6%) Invalid: 8 (9%) | 84 (94.4)% |
| 2 |  | 4+ | 4+ | Proteinuria | 88 | 84 (95.5%) | Normal: 1 (1.1%) Invalid: 3 (3.4%) | 85 (96.6)% |
| 3 |  | 2+ | 2+ | Proteinuria | 87 | 64 (73.6%) | Normal: 21 (24.1%) Invalid: 2 (2.3%) | 83 (95.4)% |
| 4 |  | 0 | 2+ | Normal | 86 | 75 (87.2%) | Proteinuria: 10 (11.6%) Invalid: 1 (1.2%) | 76 (88.4)% |
| 5 |  | 3+ | 1+ | Proteinuria | 85 | 78 (91.8%) | Normal: 2 (2.4%) Invalid: 5 (5.9%) | 81 (95.3)% |
| 6 |  | - | - | Invalid | 89 | 89 (100%) | - | - |

* Excludes entirely blank responses. See Supplementary Material B for full details.

*Note: Variable print quality may have influenced accuracy of user interpretation against correct response*

# Discussion

Early identification of PE is essential to improve outcomes through efficient resource allocation and targeted prevention, triage, and treatment strategies. Improved screening tools have been identified as an innovation priority by global stakeholders and researchers.[17,24–28] Here, we present the results of a mixed-methods implementation research study that assessed the operational fit of introducing a new point-of-care PrCr ratio measurement test at referral hospitals in Ghana.

Generally, the product was considered appropriate and acceptable by stakeholders and end users given similarities to current products; however, its implementation feasibility is affected by inherent limitations of the attributes of this PrCr-only test. While some of the reported challenges and dislikes are relevant to all urine dipsticks as a product class, notable product-specific reported disadvantages of the Test-It PrCr test included the lack of a glucose parameter, the three-month expiration date of the strips once cannisters are opened, and the cumbersome nature of ratiometric result interpretation.

Multiple participants indicated that the absence of a glucose measurement on the dipstick was a significant limitation, presumably as this information is used in gestational diabetes mellitus screening. Glucosuria-based screening for gestational diabetes is not the preferred approach due to low to modest sensitivity.[29–33] However, given limitations associated with better performing and recommended glucose screening tests (i.e., the two-hour 75g oral glucose tolerance test [OGTT] or self-monitoring of blood glucose), urine dipstick glucose assessment is used at these facilities and was deemed desirable by participants. The extent to which performance limitations associated with urine dipstick glucose screening might influence participants' perceptions of health-system fit of the Test-It PrCr test was not assessed in this study. Nonetheless, this could suggest that the test is most appropriate for monitoring women at high risk for PE when proteinuria is the clinical focus. In cases where other parameters are of interest (e.g., ketones with hyperemesis or diabetes, nitrate or leukocytes for urinary tract infection screening), multi-parameter tests may be more appropriate.

The short shelf life of the test strips once cannisters are opened (3 months) was also highlighted as a product limitation. The impact of this limitation on implementation feasibility will likely vary by facility and health system, depending on patient volumes and cost considerations, and may be more critical for low-volume facilities. Future efforts could explore cost-benefit considerations related to different packaging options for test strips, and product development efforts could aim to extend the shelf life. Similarly, the reported practice that strips may be split to extend their use amidst resource constraints should also be pragmatically considered.

On the label comprehension questionnaire, participants also scored lowest when asked about the PrCr cut-point ratio for the test. This finding was likely due to misinterpretation of the question as being related to a particular test result rather than the abnormal/normal cut-off point (0.3) for the test.

Our FGDs respondent reported liking that the PrCr test provided creatinine results without the need for costly laboratory tests. We did not assess whether the reference to costly laboratory tests were related to urine creatinine or serum creatinine. Our findings regarding creatinine results being liked by respondent should therefore be interpreted considering this limitation.

Finally, the cumbersome nature of the ratiometric result interpretation step was highlighted as a challenge. However, results from the post-training result interpretation questionnaire suggest this challenge is surmountable with appropriate training and resources for end users. Misinterpretation of the test result images as compared to pre-determined results from an expert operator were less likely for strong results. However, because we used printed images of real life test results for this exercise, it is possible that variable printing quality may have impacted the results, For this reason, we also examined the frequency of errors in the user calculation of the PrCr ratio using the operator-assigned

results and observed significantly fewer errors, with 88% to 100% of participants correctly interpreting the ratio based on their assigned color grading for each reagent pad.. Nonetheless, attention is required in results interpretation during future (refresher) trainings because some test users may still misinterpret results as our finding show deviation from true results. Job aides, in-service refresher trainings, and other resources for test users can serve to ensure that errors in result interpretation decrease over time as users become more familiar with the test. Opportunities for automated digital reader technologies to support results interpretation could also be explored.

Notably, participants from one facility suggested that the test could be made available to pregnant women for home self-monitoring. This aligns with increasing interest of self-monitoring of blood pressure as part of HDP care,[34] and emerging research on the feasibility and performance of self-monitoring for proteinuria using urine dipsticks.[35,36] Such innovative use cases for urine dipsticks warrant further exploration.

## Limitations

There are several limitations associated with this study. The training sessions were longer and more detailed than would be expected with real-world implementation of a new urine dipstick test. This was partly a consequence of the hybrid nature of the study, where test performance data was also collected (not presented herein). However, findings offer recommendations to stakeholders regarding how to optimize trainings for this and similar dipstick tests and adapt key components to local requirements. Participant observation could have been deployed to observe how the tests were used in practice; however, logistical challenges rendered this infeasible. Further, challenges were encountered in arranging FGDs and KIIs due to heavy workloads and participant availability, which is reflected in small sample sizes. Lastly, this study specifically focused on the implementation of this product in the context of proteinuria measurement as a screening indicator for PE among pregnant women. However, future studies could investigate the clinical utility of this tool for other use cases in which disease physiology includes proteinuria (for example, kidney diseases) and point of care tests may be needed to support early and rapid clinical decisions.

## Conclusions

Although the PrCr test is easy-to-use and well accepted by stakeholders and end users, key product attributes limit its implementation feasibility in this setting. As such, the test may be more appropriate for monitoring high-risk women, rather than in routine ANC screening of general populations of women when other parameters may also be of clinical interest. Future research on cost-effectiveness and impact on health outcomes can guide decisions about appropriate implementation strategies of the PrCr and other similar tests. Future research and product development efforts should continue to explore innovations that can improve proteinuria identification and address limitations of this and other urine dipstick tests.

## Acknowledgements

We would like to acknowledge the contributions of the health care providers in all participating health facilities, the pregnant women enrolled in the SPOT study, SPOT study research assistants and all who assisted to make data collection, analysis, and write-up for this study possible.

## Author contributions

HBA, JLB, SZ, MM designed the study. HBA, JLB, DKA, RO, NKAA, AOY, PC, EKS, KAB, LLY, VFW implemented the study. HBA, JLB, DKA, SZ and RO, conducted the analysis and drafted the manuscript. LLY, DKA, PC, EKS, KAB, MM, and PSC reviewed the manuscript and provided critical comments. All authors have read and approved the final manuscript. HBA is the guarantor of this contributorship statement.

## Competing interests

The authors have no competing interests to declare.

## Funding statement

This study was funded by the UK's Foreign, Commonwealth and Development Office under a grant for the Devices, Diagnostics and Drugs to Address Women's Needs ($D_3$AWN) Product Development Partnership. Funding ID: 300341-113.

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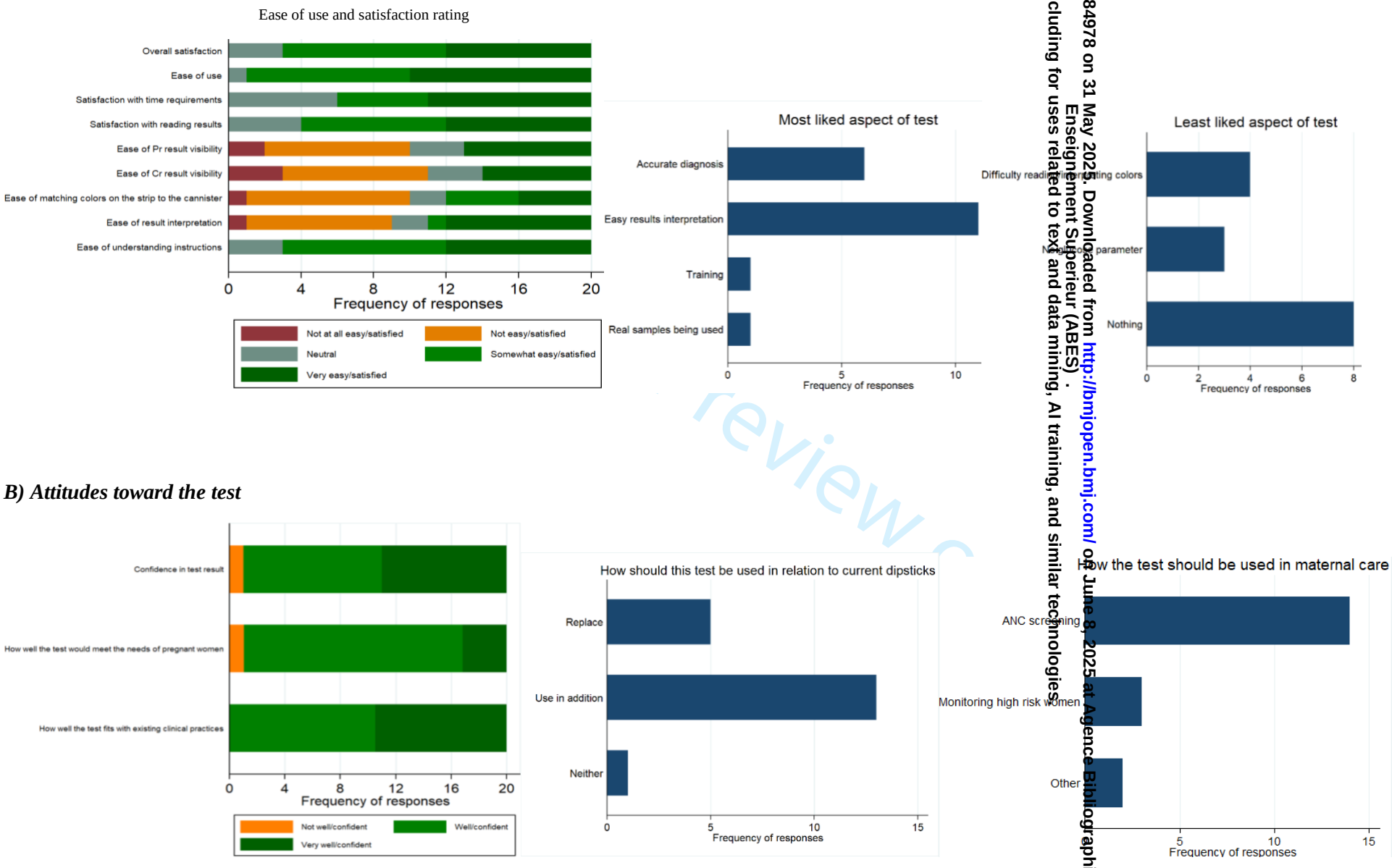
**Figure 1: *Results of selected baseline user experience responses**

***A) Experiences with the test***

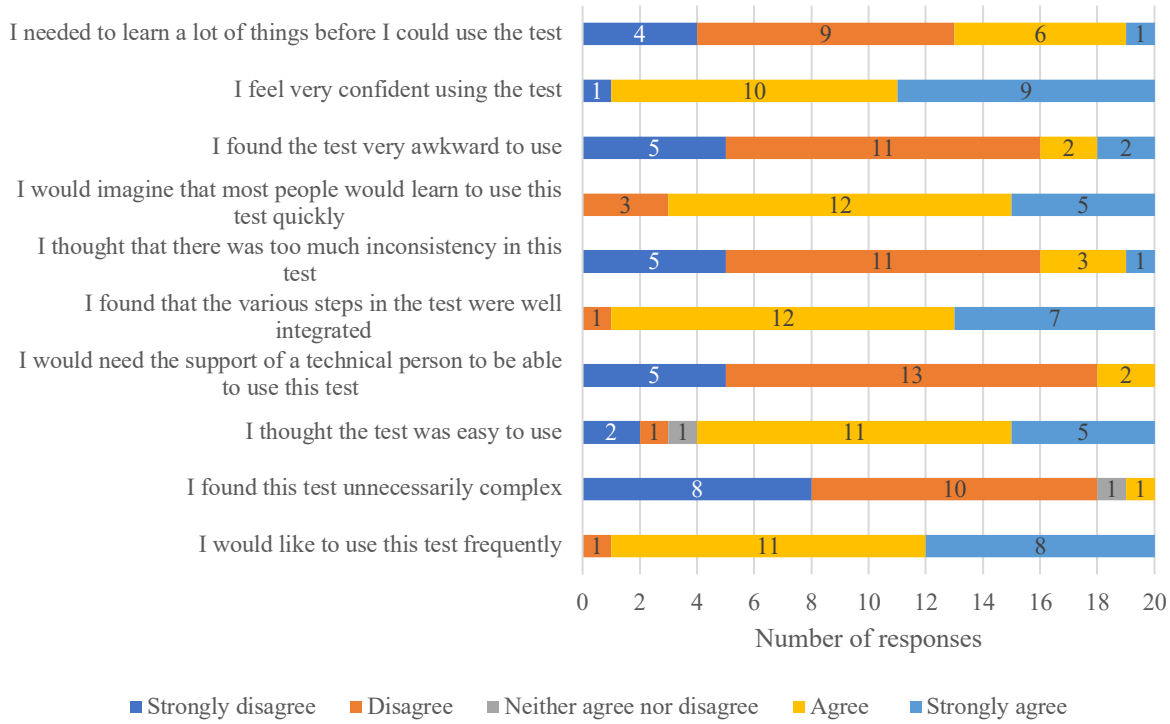



***B) Attitudes toward the test***




*The remaining responses can be found in the supplementary file 2.

**Figure 2: Systems Usability Scale responses**



# Supplementary Material

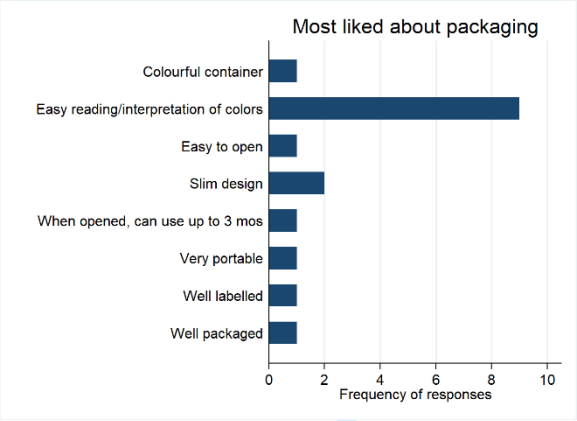
## Supplementary file 1

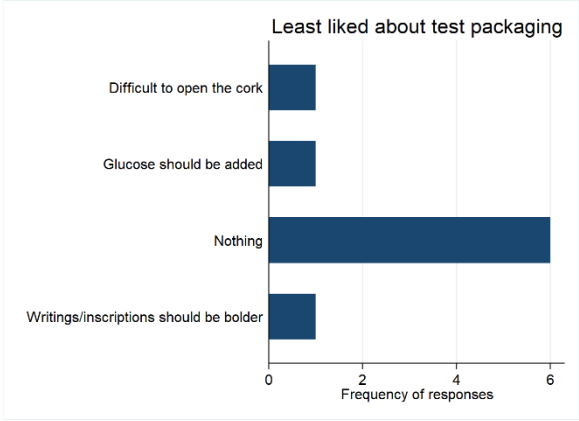
### Supplementary Table 1. Training feedback from test users

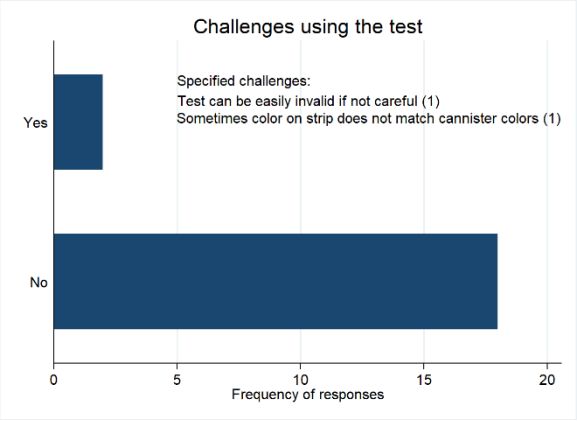
| Item | Frequency (n) | Percentage (%) |
|---|---|---|
| **Preferred method of learning** | | |
| Formal training | 38 | 40 |
| Hands on practice | 78 | 83 |
| Watching videos | 25 | 27 |
| Learning from peers | 10 | 11 |
| Informal learning, personal research | 9 | 10 |
| **Overall satisfaction with training** | | |
| Not satisfied at all | 0 | 0 |
| Not satisfied | 2 | 2 |
| Average | 2 | 2 |
| Satisfied | 21 | 22 |
| Very Satisfied | 68 | 72 |
| Missing | 1 | 1 |
| **Confidence in ability to correctly use the test after training** | | |
| Not confident at all | 0 | 0 |
| Not confident | 0 | 0 |
| Average | 3 | 3 |
| Confident | 18 | 19 |
| Very Confident | 72 | 77 |
| Missing | 1 | 1 |
| **What, if anything, would you have liked more of during the training** | | |
| Practice using the test | 18 | 19 |
| Practice interpreting the result | 22 | 24 |
| Information on common errors and how to avoid them | 23 | 25 |
| Information on the accuracy of the test | 25 | 27 |
| Nothing | 5 | 5 |
| **Do you wish the training had been longer, shorter, or was it the right length?** | | |
| Longer | 5 | 5 |
| Shorter | 8 | 9 |
| Duration of training was appropriate | 79 | 84 |
| Missing | 2 | 2 |
| **Open-ended feedback** | | |
| **Most liked about the training** | | |
| Everything | 8 | 9 |
| Presenter's presentation skill | 8 | 9 |
| Practical aspect | 50 | 53 |
| The clear, precise and educative nature of training | 23 | 24 |
| ***Least liked about training*** | | |
| No refreshments, no projector | 4 | 4 |
| Nothing | 31 | 33 |
| Poor visuals (images, videos, colors) | 5 | 5 |
| Practical, explanation and documentation | 3 | 3 |
| The urine samples used and how they were handled | 4 | 4 |
| Poor time management (time wasting) | 15 | 16 |
| **Suggested improvements to training** | | |
| Visuals (images, videos, colors) | 6 | 6 |
| Samples (acquire fresh samples from eclamptic patients) | 8 | 9 |
| Practical aspect, interpretation and documentation of results | 13 | 14 |
| PPEs, dustbins, and train more staff | 7 | 7 |
| Refreshments and allowance | 4 | 4 |
| Time management and organization | 16 | 17 |
| None | 19 | 20 |

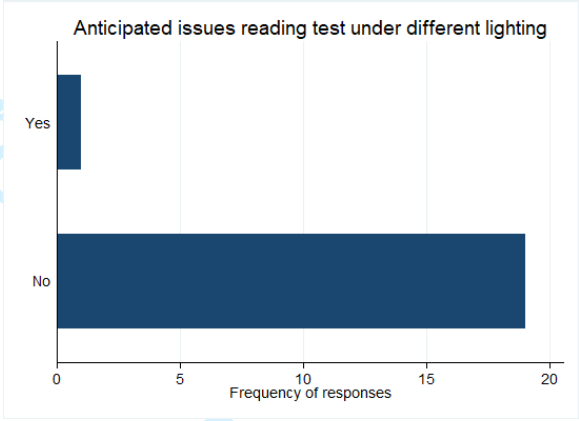
**Supplementary File 2:**

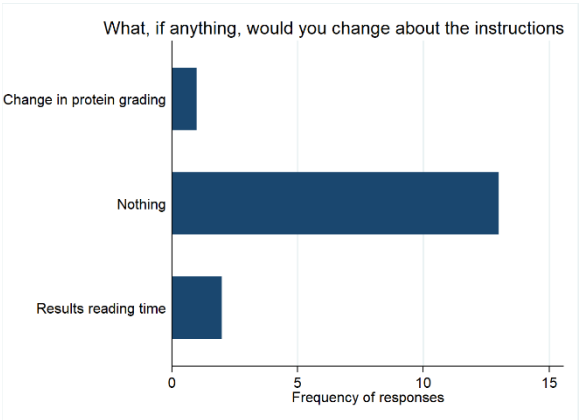
**Figures of user experience with the test at baseline**

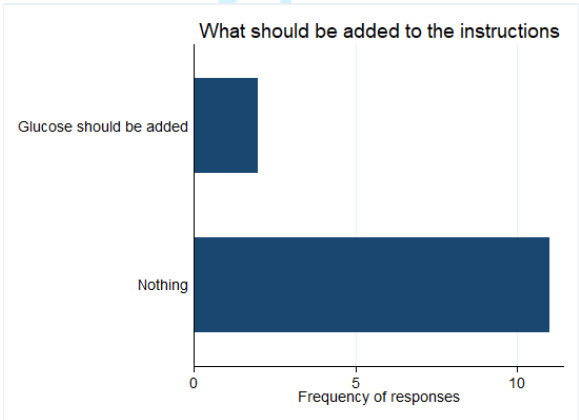


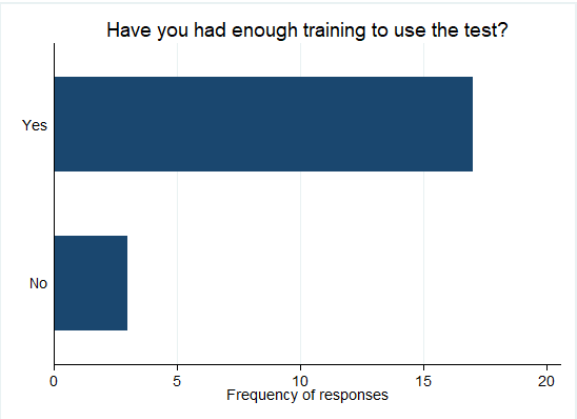



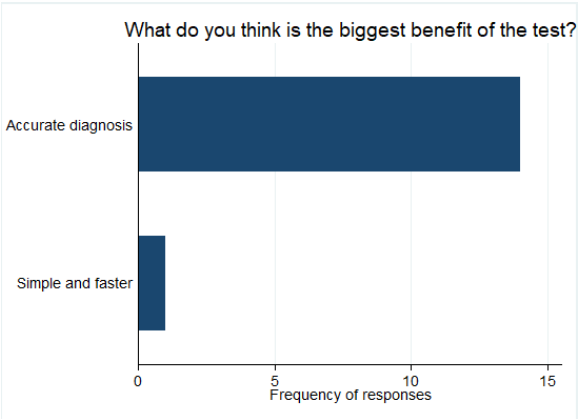



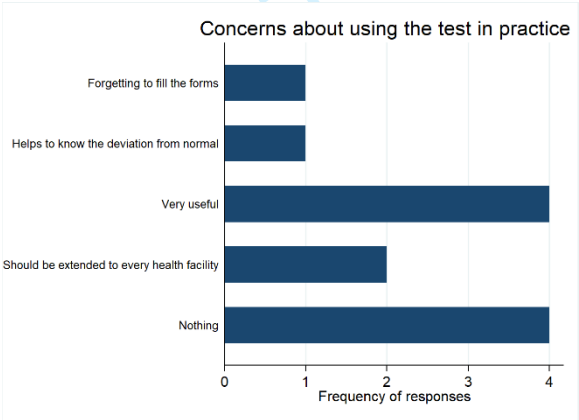



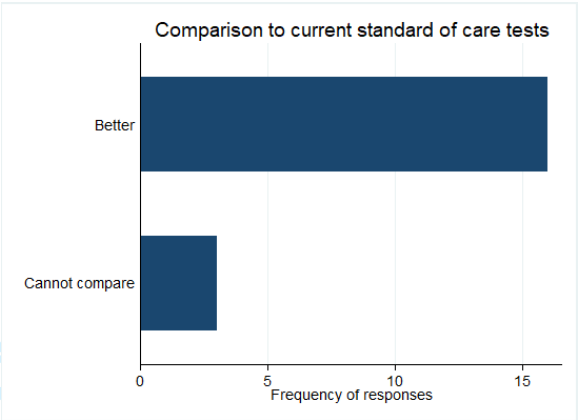



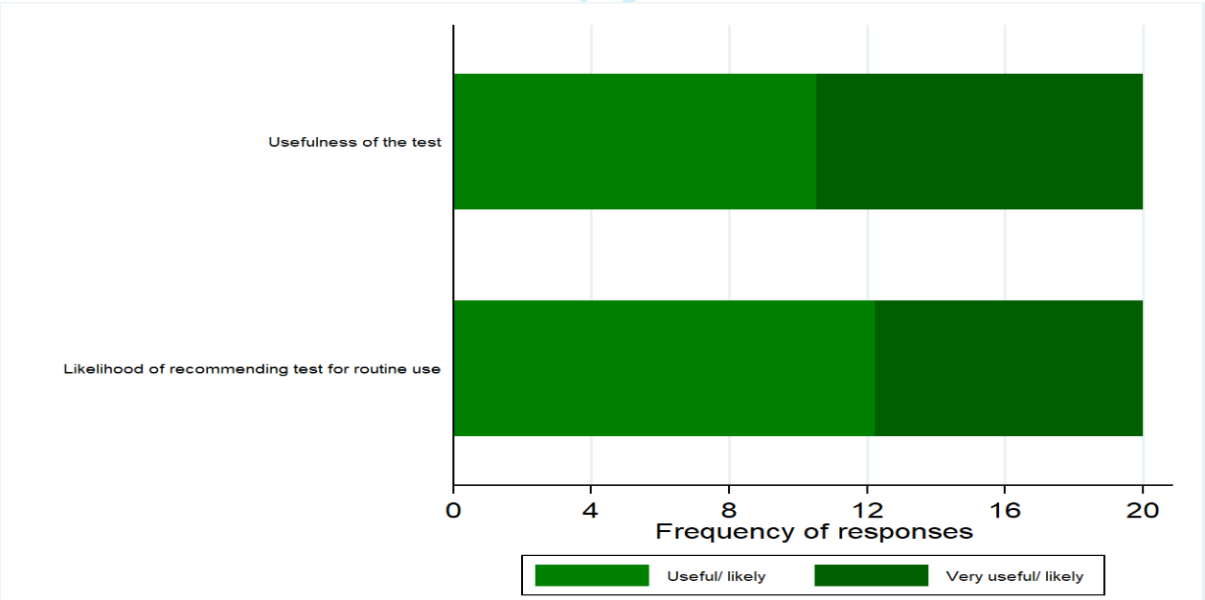





# Test-it™ PrCr

REF PRCR50

## **Proteinuria screening test** as an aid in early detection of **PREECLAMPSIA**

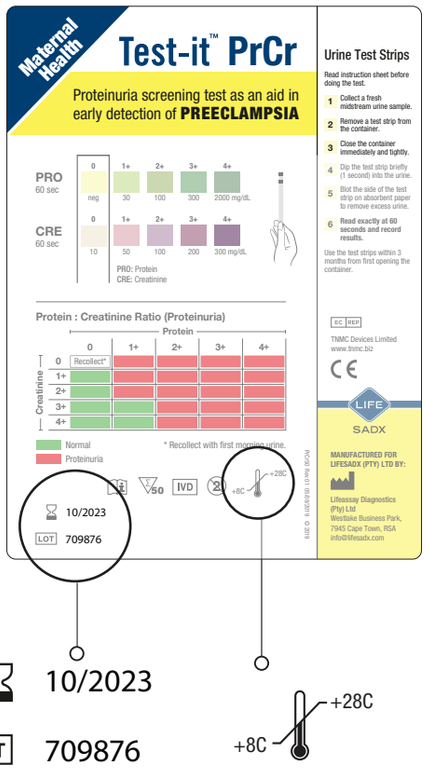
Preeclampsia (PE) is a serious disease associated with high blood pressure (hypertension) and protein in the urine (proteinuria) during pregnancy. It can affect women during the second half of pregnancy, and up to six weeks after delivery. PE risks include seizures or death for pregnant women, and premature birth or death for babies. PE is a leading cause of maternal and infant deaths and affects 10% of pregnancies worldwide. It is responsible for 1 in 10 maternal deaths in Africa and Asia. If diagnosed early, the life of the mother and baby can be saved with treatment.

### Intended Use

Test-it PrCr urine test strip was developed to screen the urine of pregnant women for proteinuria, which is one of the early signs of P
It therefore has special application in MATERNAL HEALTH. Each test strip includes 2 reagent pads – one for protein and one for creatinin
When the protein to creatinine ratio is determined, the screening of proteinuria becomes very accurate and reliable. The protein: creatinin
ratio for proteinuria has been pre-determined at 0.3.

## How to Use:

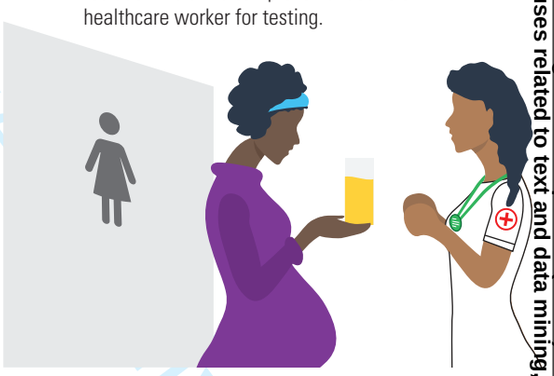
**1** Check the colour label that the **expiry date** and maximum **storage temperature** of the test strips have not been exceeded. Do not use if product is beyond the expiry date, or if stored at wrong temperatures.





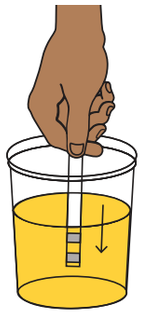


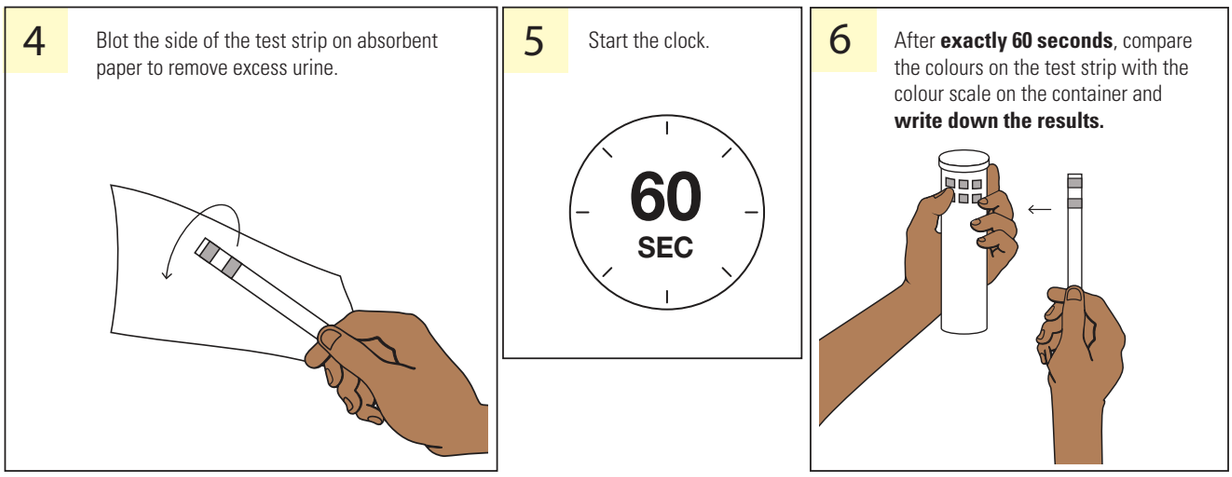
**2** Ask the patient to collect **midstream** urine in a **clean container**, free of any disinfectant or soap residue. The urine sample is handed to a healthcare worker for testing.



**3** Now, remove one test strip from the container. Do not touch the reagent areas.
**Immediately close the container securely using the original cap.**

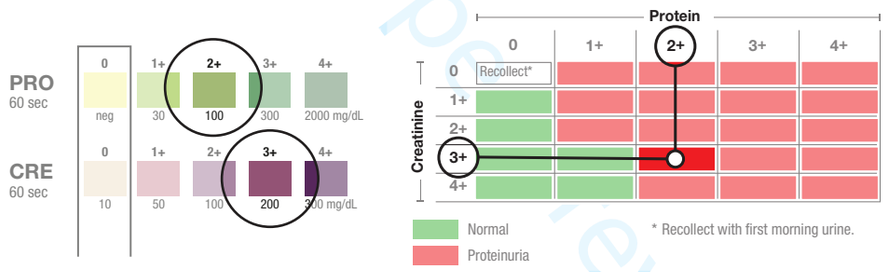
Briefly (1 second only), dip the test strip into the urine so that both reagent pads are wet, then remove.






## Estimate **Proteinuria** as follows:

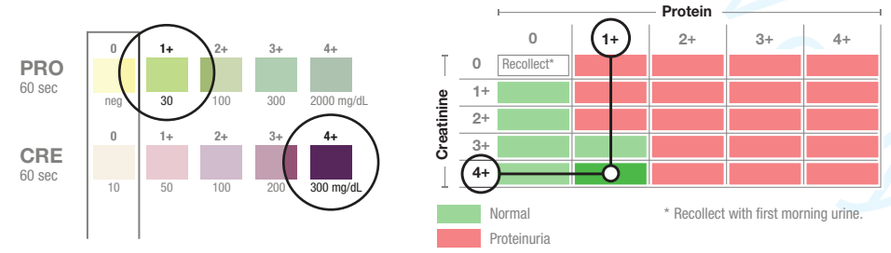
| Protein 2+ | Creatinine 3+ | **Example 1:** |
|---|---|---|




In the table to the left, find the PROTEIN 2+ value on the top row, and then find the CREATININE 3+ value on the left row as indicated.

Find the spot on the table where the PROTEIN 2+ and the CREATININE 3+ meet. In example 1 above, the 2 values meet on a **RED** colour block, which suggests **Proteinuria**.

| Protein 1+ | Creatinine 4+ | **Example 2:** |
|---|---|---|




In the table to the left, find the PROTEIN 1+ value on the top row, and then find the CREATININE 4+ value on the left row as indicated.

Find the spot on the table where the PROTEIN 1+ and the CREATININE 4+ meet. In example 2 above, the 2 values meet on a **GREEN** colour block, which suggests **Proteinuria** is NOT present **(Normal)**.

**Notes:**

1. This test is intended for screening of proteinuria during pregnancy. Always confirm results with a clinician before taking any action.
2. Product performance data available from the manufacturer.
3. Perform the test in good lighting conditions.
4. Do not interpret results after 60 seconds as this may lead to false results.
5. For single use only. Do not use more than once.
6. Keep out of reach of children.
7. Treat used strips as medical waste.

**References:**

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DOC. LAM-PrCr Rev. (01) 07-08-2019. 