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The feasibility and acceptability of self-testing for proteinuria during pregnancy: A mixed methods approach

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ABSTRACT

Objective: To investigate feasibility and acceptability of self-testing for proteinuria during pregnancy.
Study design: Mixed methods approach which included: an accuracy study where pregnant women (n = 100) and healthcare professionals (n = 96) tested seven synthetic protein samples and completed a questionnaire, a feasibility study where pregnant women who were self-monitoring their blood pressure were asked to self-test for proteinuria (n = 30), and an online questionnaire about women's experiences of self-testing (n = 200).
Main outcome measures: Sensitivity and specificity of testing and questionnaire results.
Results: There were no significant differences in the accuracy of synthetic sample testing by pregnant women (sensitivity 0.81 (95% confidence intervals (CI) 0.78–0.85), specificity 0.93 (95% CI 0.91–0.95)) and healthcare professionals: (sensitivity 0.83 (95% CI 0.79–0.86), specificity 0.92 (95% CI 0.90–0.94)). Automated readers had significantly better sensitivity (0.94 (0.91–0.97) ($p \leq .001$ in each case), but worse specificity 0.78 (0.69–0.85). Similar results were gained using self-tested urine samples compared to staff-testing using a reference standard of laboratory urine protein-creatinine ratio (uPCR). Women who completed the online survey with experience of self-testing (n = 39, 20%) generally found it easy, and with support from healthcare professionals felt it improved involvement in their care and reduced anxiety.
Conclusions: Self-testing for proteinuria by pregnant women had similar accuracy to healthcare professional testing and was acceptable to both groups. Self-testing of urine combined with self-monitoring of blood pressure could provide a useful adjunct to clinic-based surveillance for the detection of pre-eclampsia. Such novel strategies warrant further research.

1. Introduction

Apart from blood pressure measurement, urinalysis for protein is the most commonly performed antenatal screening test and is central to pre-eclampsia diagnosis [1]. The development of proteinuria in a hypertensive pregnancy is an important feature of multi-organ involvement [2]. Urine testing is routinely carried out by midwives, obstetricians or family physicians at antenatal visits [1]. Urinalysis reagent strips (dipsticks) are widely commercially available, inexpensive, convenient, and provide a rapid result [4]. Such testing strips are examined with automated readers or by visual inspection, the latter still commonplace out of hospital settings, where automated readers are seldom available. If positive results are found, then further testing, using spot urine protein: creatinine ratio (uPCR) or 24-h sample analysis, is undertaken [5].

Confidential enquiries into maternal deaths in the United Kingdom report that women can develop pre-eclampsia between antenatal visits; and reiterate the importance of blood pressure and proteinuria testing at every opportunity [6,7]. Urine self-testing in pregnancy is widely acceptable for confirming a pregnancy through urinary beta-hcg assays [8,9], but few data on the accuracy of self-testing for proteinuria in the pregnant population exist [4]. An Australian study, comparing urinary protein self-testing by 212 women in clinic, to re-testing by a single nurse, found that self-testing was practical and easily implemented, but did not include an independent reference standard [10]. Several other studies describe providing pregnant women with urine dipsticks to

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periodically check for protein alongside self-monitoring blood pressure, but have not formally evaluated test performance [11–13].

The aim of this study was to assess the accuracy of self-testing for proteinuria during pregnancy compared to healthcare professionals (HCPs) or automated testing with a laboratory reference standard and to explore feasibility and acceptability in a UK context.

2. Methods

This was a mixed methods study combining test accuracy studies and questionnaires. There were four parts comprising: 1) test accuracy study for 'proteinuria' (using synthetic samples to provide a range of protein levels) comparing assessment by pregnant women, HCPs and an automated reader to a laboratory reference standard; 2) self-testing of urine by pregnant women compared to testing by HCPs and a laboratory reference standard; 3) a questionnaire to participating women and HCPs and 4) an online questionnaire aiming to understand women's experience of self-testing and opinions on its future use.

2.1. Test accuracy of urinary protein testing

Up to 50 pregnant women of any gestation and 50 HCPs from antenatal maternity services were selected on a convenience basis from hospital sites in Oxfordshire (John Radcliffe and Horton Hospitals, Ox) and London (St Thomas' Hospital, STH) between November 2015 and April 2016. Following written informed consent, participants were provided with simple instructions for protein testing, synthetic protein samples and standard dipstick reagent strips (a visually read enzymatic test) (ALBUSTIX reagent strips, SIEMENS, Surrey UK). Protein solutions were prepared using bovine serum albumin (Sigma-Aldrich, Dorset, UK) in 150 mmol/L sodium chloride (Fresenius Kabi Ltd, Cheshire, UK). Sodium azide was added at a concentration of 100 mg/L as a bacteriostat. Stock solutions were produced at protein concentrations equivalent to seven different dipstick readings between 'negative' and '3 + ' ($\geq$ 500 mg/dL). The level of protein in the samples was confirmed by repeated testing by urinary protein-creatinine ratio, (uPCR) (Supplementary Table 1). Samples were tested by participating women and HCPs using visual determination as well as using an automated reader (Clinitek Status + Analyzer, SIEMENS, Surrey, UK) by the research team. Researchers and participants were masked to the level of protein in each sample until recruitment and testing was complete. Samples were re-tested following the study to confirm that storage and testing had not resulted in contamination. Ethical approval was obtained from the Northern Ireland Research Ethics Committee (15/NI/0157/HSC REC-B).

2.2. Self and healthcare professional proteinuria testing compared to a PCR reference standard

Thirty women, participating in a pilot study of blood pressure self-monitoring in higher-risk pregnancy, attending antenatal care in Oxfordshire additionally tested their urine for protein. (National Institute for Health Research (NIHR) Central Research Network (CRN) Portfolio number: 14151) They used a standard testing strip for proteinuria (as above) and retained the sample, which was subsequently (same day) tested by the midwife and then sent for laboratory analysis (uPCR). Equivalent categories for testing were 0–14 mg/dL (negative), 15–30 mg/dL (trace), > 30 mg/dl (1 + or more). Ethical approval was obtained from Oxford South Central Research Ethics Committee (12/SC/0625 REC-B).

2.3. Questionnaire

Participants in the synthetic sample testing study above completed a short questionnaire about the potential for self-testing during pregnancy, included three closed statements and an open question asking for comments (Supplementary Fig. 1).

2.4. Online survey

An online survey (March 2106) collected information on women's views and experiences of self-testing, including multiple-choice questions and a free text section for women to comment on the idea of self-testing. A link to the survey was posted on the 'Action on Pre-eclampsia' (APEC) Facebook Forum, a UK charity and patient support group. Ethical approval was obtained from St Georges Research Ethics Committee (SGREC16/0005).

2.5. Statistical analysis

Data were analysed using Excel and R. Descriptive statistics were compiled from the questionnaire and survey results for questions with categorical answers. For proteinuria dipstick accuracy results, the errors of the dipstick readings were grouped into five categories (-2, -1, 0, $+1$, $+2$), representing the difference between the reading from the woman, the HCP and the automated reader respectively compared to the uPCR reference standard. (e.g. $+1$ error where the woman's reading was one category above that of the uPCR). Each participant's test performance (pregnant woman, HCP, automated reader) was calculated across all seven samples and a mean calculated per participant to obtain sensitivity and specificity for each participant. In the case of missing data for an individual, the sensitivity and specificity were calculated using the available samples. In order to compare sensitivity and specificity per group, mean sensitivity and specificity were calculated, using a threshold for a positive result of 1 + proteinuria (as errors across this threshold were considered clinically important) [3]. False positive and false negative rates were calculated and a logistic regression model was used to compare the difference between the three groups (pregnant woman, HCP, automated reader). All data were included.

2.6. Questionnaire analysis

Free text responses in the questionnaire and online survey were analysed using a thematic approach. The qualitative data was read multiple times by researchers (KT, LB and PM) and analysed using the 'one sheet of paper' (OSOP) method [15]. Themes were examined across the whole dataset and in the context of individual responses.

3. Results

3.1. Test accuracy study

A total of 100 pregnant women and 96 HCPs performed dipstick urine testing on the seven synthetic protein samples (Supplementary Fig. 2 Produced using STARD reporting guidelines [14]). Of the pregnant women approached, 100 of 105 (95%) agreed to participate. Participating women had a mean gestation of 31 weeks (range 9–41 weeks), with 21 (21%) having had raised blood pressure during their pregnancy. There were small numbers of missing data (three missed samples). The HCPs who participated included 54 (56%) midwives, 21 (22%) midwife support workers and 21 (22%) doctors.

Overall, the number and type of errors from pregnant women and HCPs were similar (Table 1; Fig. 1). There were a similar proportion of errors of potential clinical importance (Supplementary Fig. 2) (i.e. those around 1 + threshold (Table 1) between pregnant women (10% false negatives and 2% false positives) and HCPs (10% false negatives and 4% false positives) when compared to laboratory reference standards whereas the automated reader had fewer false negatives (4%) but more false positives (10%).

There was no statistically significant differences between pregnant women and HCPs in sensitivity, specificity ($p = .45$ for both), positive

Table 1
Percentages of testing at different thresholds by pregnant women, health care professionals and automated readers. Numbers in bold represent false positive readings, figures in bold and italics represent false negative readings defined in each case as a misclassification, which would change management.

	Negative	**Trace** (16 mg/dL)	**Trace** (26 mg/dL)	**1+** (32 mg/dL)	**1+** (36 mg/dL)	**1+** (52 mg/dL)	**3+** (500 mg/dL)
Pregnant women (n=100)							
Negative	97	80	6	***2***	0	***5***	0
Trace	2	19	79	***34***	***17***	***13***	0
1+	**1**	**1**	**15**	62	78	67	2
2+	0	0	0	2	4	15	12
3+	0	0	0	0	1	0	82
4+	0	0	0	0	0	0	4
Healthcare professionals (n=96)							
Negative	97	66	4	***1***	0	***6***	0
Trace	3	33	72	***33***	***15***	***15***	0
1+	0	**1**	**24**	65	83	57	0
2+	0	0	0	1	2	22	15
3+	0	0	0	0	0	0	73
4+	0	0	0	0	0	0	12
Automated readers (n=3)*							
Negative	100	85	0	0	0	0	0
Trace	0	11	33	***8***	***19***	0	0
1+	0	**4**	**67**	81	81	33	0
2+	0	0	0	11	0	67	0
3+	0	0	0	0	0	0	100
4+	0	0	0	0	0	0	0

Results are shown as a proportion of women answering to allow comparisons between groups. *each sample tested at least twice in each machine.

predictive value or negative predictive value (p = .58 for both); however the automated reader had higher sensitivity, lower specificity, a lower positive predictive value and higher negative predictive value (p= or < .001 in each case, Table 2) compared to pregnant women and HCPs.

3.2. Self and healthcare professional proteinuria testing compared to a PCR reference standard

All 30 women who were approached agreed to self-test urine in conjunction with blood pressure self-monitoring. Four women (13%) withdrew from the study (one due to pregnancy loss) before the urine testing phase. The baseline characteristics of the participants are shown in Supplementary Table 2. All remaining participants provided a sample for midwife and laboratory analysis and 25/26 (96%) self-tested. Of 25 comparisons of participant-read dipstick vs. HCPs, 22 (88%) were identical and three (12%) were discrepant, all between negative and trace readings with no subsequent potential impact on clinical action. Of 23 comparisons of participant-read dipsticks with uPCR (two samples were not analysed in error), 21 (91%) were identical with two (9%) discrepant results. All were between 0–15 mg/dL (negative categories) and 15–30 mg/dL (trace).

3.3. Questionnaire results

Of those who undertook the accuracy study, 99 (99%) pregnant women and 94 (98%) HCPs also completed a questionnaire. Of women completing the questionnaire, 95 (96%) agreed that they would be willing to check their urine at home and 89 (90%) thought it would make them feel more involved in their care. All were potentially happy to share any urine testing results with their midwife, family physician or obstetrician. There was very little discrepancy in responses between women in Oxfordshire (Ox) and London (STH) (Fig. 2).

Most HCPs respondents indicated that they would value self-testing by some women during their pregnancy (n = 83, 88%), and thought that proteinuria self-testing alongside blood pressure self-monitoring would add to usual care (n = 73, 78%). However, the majority also stated that they would always repeat urinalysis if a woman had already tested her urine (n = 66, 69%) (Fig. 2E).

Free text responses were provided by 57 (58%) pregnant women and 67 (71%) HCPs who completed the questionnaire, with similar proportions across sites (Quotes in Fig. 3). Themes emerging from analysis of these responses included reassurance from testing (women), the potential for earlier detection (HCPs), potential for saving time (both) and concerns about women testing (both).

Women were reassured by negative results and potentially saving time on trips to appointments (STH34). HCPs considered that self-

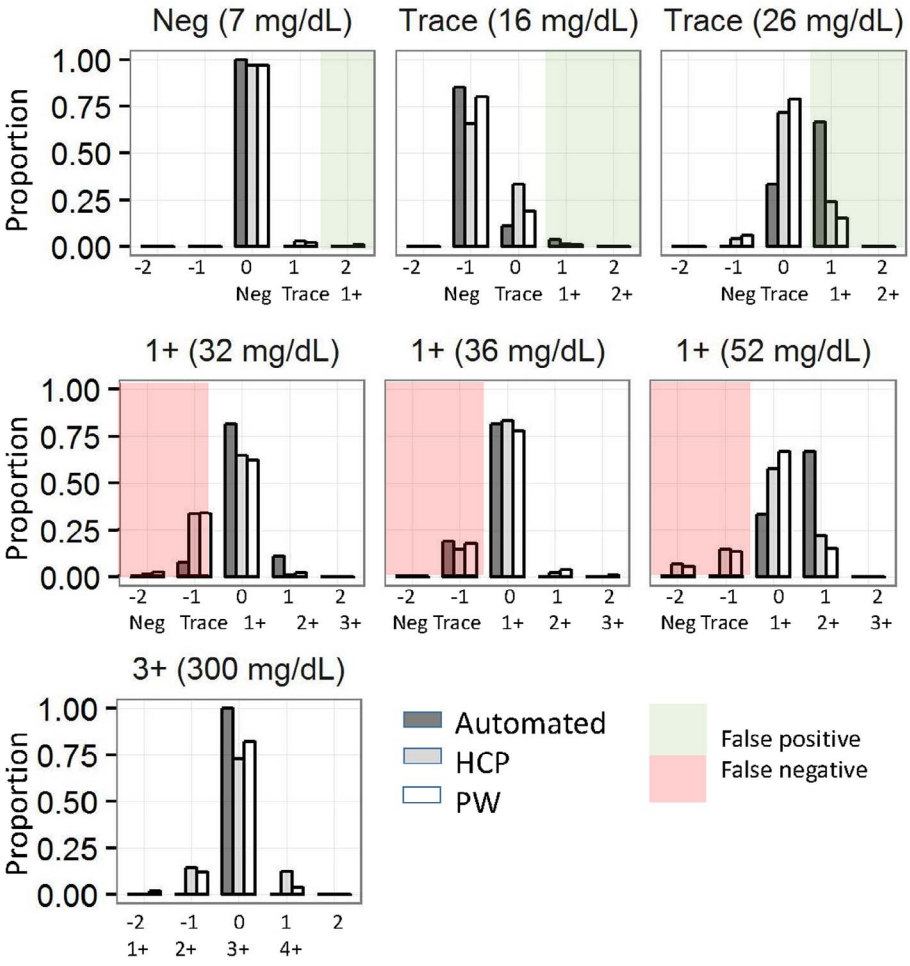

Fig. 1. Protein testing results by samples and categories. Test results are shown for 100 pregnant women (PW), 96 healthcare professionals (HCPs) and three automated readers. The errors of the results were grouped into five categories types (−2, −1, 0, 1, 2). The '0' results show no error, the type 1 error are outcomes with 1 category above the correct answers. Check shading indicates clinically important false positive results and spotted shading indicates clinically important false negative results.

Table 2
Group mean test accuracy of results by pregnant women, healthcare professionals and automated readers compared to uPCR (laboratory reference standard).

	Pregnant women	Healthcare professional	Automated readers
Sensitivity	0.81 (0.78–0.85)	0.83 (0.79–0.86)	0.94 (0.91–0.97)
Specificity	0.93 (0.91–0.95)	0.92 (0.90–0.94)	0.78 (0.69–0.85)
Positive predictive value	0.94 (0.90–0.96)	0.94 (0.91–0.95)	0.85 (0.79–0.90)
Negative predictive value	0.79 (0.75–0.83)	0.80 (0.76–0.84)	0.91 (0.87–0.95)

testing had potential for early detection of pre-eclampsia, empowering women and saving time and money (Ox53) (Fig. 3).

However, pregnant women and HCPs raised concerns about aptitude and suitability of women for testing. Whilst many women found the dipsticks easy to use, some were worried about their ability to read them accurately (STH 38). Several women indicated wanting access to midwives for a second opinion (STH 30). Similarly, HCPs also raised concerns around a woman's ability to read the dipsticks, their understanding of the importance of doing testing as regularly as instructed and acting on results appropriately. Some were concerned that women could fail to act on positive results (STH 19), while others were concerned that self-testing might make women more anxious and more likely to present at assessment units, increasing demand on services (Ox 47). Consequently some felt self-testing was only suitable for certain subgroups of women (STH 31) (Fig. 3).

3.4. Online survey

Two hundred women completed the online survey, (characteristics in Supplementary Table 3 and free text quotes Fig. 4) with the majority of respondents (77%, n = 152) having experienced a hypertensive disorder of pregnancy. One fifth of women (20%; n = 39) had previously undertaken proteinuria self-testing (Supplementary Table 4) and most of these had found the dipsticks easy to read (87%, n = 34). Women reported positive experiences of self-testing, with all agreeing that it helped them feel involved in their care, and only 10% (n = 4) reporting increased anxiety levels due to proteinuria self-testing.

Of 17 respondents who had previously tested, most indicated that prior experiences of pre-eclampsia motivated them to test their own urine and key themes were of reassurance, saving time and empowerment. Many discussed anxiety due to previous experiences, but found reassurance from negative results in this setting (PT1). One woman found self-testing useful because she perceived that it was less influenced by her immediate anxiety level compared to blood pressure readings (PT2). Three women said that they were reassured by self-monitoring between scheduled antenatal appointments, and that this prevented unnecessary trips to the hospital. One woman commented on the value of a positive proteinuria result (PT3) (Fig. 4).

Of those women who had not experienced self-testing for proteinuria (81%, n = 161), the majority (99%, n = 159) said they would be willing to check their own urine for protein after training (Supplementary Table 5). The majority (97%, n = 155) said that self-testing would help them feel more involved in their pregnancy care. Conversely, 26 women (17%) agreed or strongly agreed with the statement that self-testing would increase their anxiety during

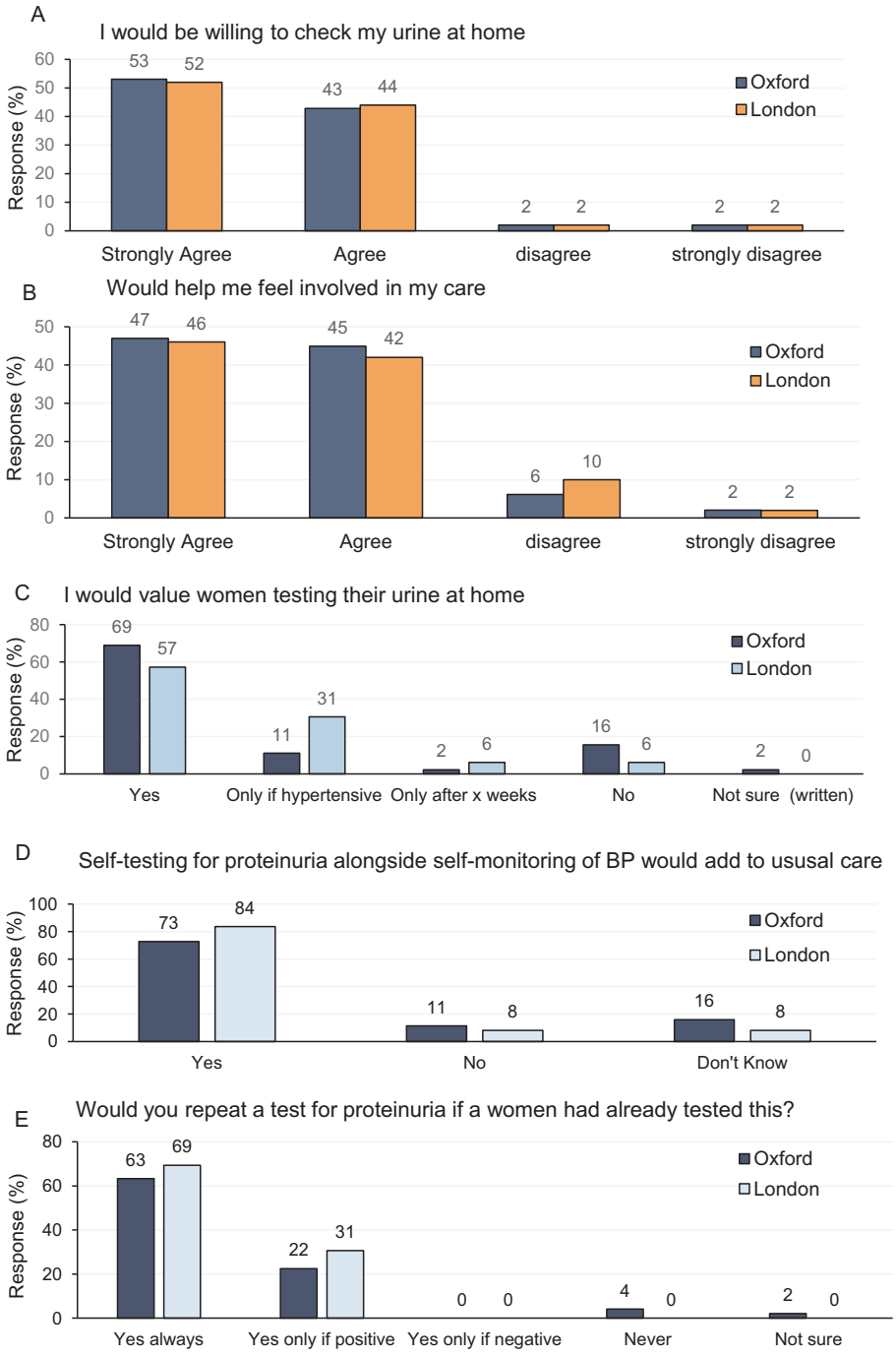

Fig. 2. Questionnaire responses by pregnant women (A & B) and health care professionals (C, D & E) who had undertaken the test accuracy study (n = 99 and 94 respectively).

pregnancy (Supplementary Table 5).

Women who had not tested their own urine had similar themes of reassurance and empowerment to those that had self-tested, with additional issues raised of training and HCPs' attitudes. Reassurance appeared particularly important in those who had previous experience of pre-eclampsia or hypertension (NT1) Urine testing could reduce rather than increase anxiety (NT2): Adequate training, explanation and clear instructions could also reduce any anxiety they felt (NT3). The women emphasised that it was important that HCPs were receptive to the results (NT4) (Fig. 4).

4. Discussion

4.1. Main findings

This study has shown that pregnant women and HCPs were able to test for proteinuria over a range of protein concentrations with similar levels of accuracy. As with previous research, testing by women and HCPs was less sensitive but more specific than automated testing using a reference standard of laboratory uPCR. Overall self-testing was acceptable to both pregnant women and HCPs both theoretically and alongside blood pressure self-monitoring. Self-testing was perceived as providing reassurance and convenience for women, particularly those with previous experience of hypertensive disease in pregnancy, though there were some concerns as to whether HCPs would always trust the

Quotes from free text responses

"Being high risk myself I feel it would give peace of mind and less stress of running to the GP constantly to be able to test your urine at home" (STH 34).

"I think that self-monitoring is very useful to save health professionals time and the women's time in going to appointments. I believe it is also empowering for the women." (Ox 53)

"The testing procedure is simple, although the results are sometimes hard to interpret if they are 'in between' colours" (STH 38).

"Some mums might not feel capable doing it if they are not trained and would want someone who has training to check it to be sure that they are getting the right answer" (STH 30).

"I'd worry about women forgetting to do it or saying they would and making up normal results to avoid being high risk." (STH 19).

"It could cause unnecessary admittance to MAU [Maternity Assessment Unit] if women not trained appropriately." (Ox 47).

"It would depend on the women and their understanding of the importance of this testing." (STH 31).

Fig. 3. Quotes from free text responses gained from the accuracy study.

Quotes from the free text section in the online survey

PT1 "I found it hugely reassuring to be able to check this myself at home, it was empowering and took away the anxiety around appointments."

PT2 "Also knowing how nervous I was about BP (therefore how it can fluctuate sometimes with stress levels) I also wanted something to measure that couldn't be influenced by anxiety or stress."

PT3 "The dipsticks gave me the confidence to go back in [to the hospital], which was the right decision to make."

NT1 "Having got severe PET and HELLP a few hours after birth with my firstborn I know that if I have another I would be really anxious about it occurring in pregnancy and would feel worried in between antenatal check-ups so it would reassure me."

NT2 "During pregnancy a lot felt out of my control and waiting between midwife appointments sometimes left me anxious. Self-testing would make me feel like I could do something myself to take away some anxiety".

NT3 "I also agree that it may cause more anxiety for some if the reading is not clear cut, as long as training and reference points are clear for mothers I do believe this would be beneficial overall."

NT3 "GP surgeries need to be better briefed as well on this, otherwise patients could self-test and still the doctor ignores the signs."

Fig. 4. Quotes from the free text section in the online survey.

results provided by pregnant women. Women felt that support from their HCPs would be important, perhaps reflecting the reticence of professionals to act on women's own results.

4.2. Strengths and limitations

This mixed methods study has included a relatively large number of women and HCPs who tested samples over a range of protein concentrations both on synthetic and real urine, providing comprehensive data on test accuracy. Use of synthetic urine samples ensured that sufficient numbers of positive samples were tested, and whilst the numbers testing their own urine were relatively small (n = 26) and for a limited period they provided similar results and were representative of women who might be asked to undertake such testing. This suggests that it is unlikely that the accuracy of testing would be altered in a clinical vs home setting, though the experience may be. Previous pilot work of self-testing of blood pressure in pregnancy completed by this group has indicated that women found blood pressure monitoring acceptable and reassuring. Women who completed proteinuria testing in the home environment were positive about the experience but further work on the experience of regular self-testing through pregnancy is required.

Questionnaire and online survey data gathered views from a large number of participants including currently pregnant women, those with and without experience of self-testing, women with both hypertensive and normotensive pregnancies and a variety of HCPs providing a range of experiences and opinions. The majority of online survey participants had experienced hypertensive disorders of pregnancy, and therefore those most likely to be considered for additional home testing. The survey provided both quantitative and qualitative data providing an in-depth understanding of views and experiences. The similarity between the questionnaire results of pregnant women and the online survey findings suggest broad acceptability and appeal of self-testing.

Some selection bias from the online survey is possible as respondents were limited to internet users; however, most of the target population will be web connected [16]. By engaging with the charity APEC and responding to the online survey, the participants were likely to be individuals with previous experience, who had sought extra information and support, and may therefore be more motivated to adopt health behaviours such as proteinuria self-testing.

4.3. Comparison with previous work

There are surprisingly few data on proteinuria self-testing in the pregnant population. A 2002 Australian study showed that women interpreting results in clinic had a tendency to overestimate proteinuria

compared to the midwife performing the same test; the authors suggested that self-testing of urine during pregnancy could be easily implemented at antenatal visits [10]. More recently, large screening studies undertaken within the general non-pregnant population for early detection of renal disease found that self-testing improves the chances for early diagnosis and therapy, though participants tended to report false positives for proteinuria [17,18].

There is heterogeneity in the reported sensitivity and specificity of testing with reagent strips within the literature across patient and staff groups, and limited data from studies in pregnancy. Bell et al. used five albumin samples to look at the accuracy of testing and reported a high false positive rate for the two non-proteinuric samples (nursing auxiliaries; 40% and 55% and midwives; 5% and 30%). For the three positive samples both groups recorded false negative rates of between 10–45% [19]. While automated readers had higher sensitivity, they also produced a lower specificity, i.e. yielding more false positive results that may lead to unnecessary anxiety and additional appointments and testing for some women [20,21]. These studies compare to false positive rates of only 2–4% in our study; the majority of false negative results related to differences between negative and trace amounts of proteinuria, and would therefore not have changed clinical action.

There are no published studies to date on user experiences of proteinuria self-testing. Most of the literature on patient views and experiences of self-monitoring come from studies of blood pressure self-monitoring outside of pregnancy, which have generally found similarly positive views to results reported here. A feasibility study done in low-risk pregnant women showed a preference for blood pressure self-monitoring with a reduced schedule of antenatal visits, and no change in anxiety levels [22]. Literature on blood pressure self-monitoring outside pregnancy indicates patients are confident at self-monitoring and report high levels of satisfaction and feelings of involvement, control, and support for their health [23,24]. In the current study similar findings for self-testing of urine are reported; women whose readings were used by HCPs felt valued and involved in their own care and reported positive experiences. Combined self-testing of blood pressure and urine could allow triggers for action based on home readings to mirror clinical diagnostic pathways for pre-eclampsia, could increase women's confidence in findings, improve self-involvement in antenatal care and reduce additional screening visits thereby providing a cost-effective intervention [25].

4.4. Implications for future research and clinical practice

The results of this study are an important first step in considering the potential for self-monitoring for proteinuria in pregnancy. This inexpensive, simple and rapid test could improve detection of pre-eclampsia, a potentially serious condition, and be used to reduce additional appointments required by some pregnant women (thereby alleviating burden on women and healthcare resources). Self-testing was acceptable and well received in a population of women who were at increased risk of pre-eclampsia. Participants were willing and able to test for proteinuria alongside blood pressure self-monitoring during pregnancy and self-testing appears to be as accurate as testing by HCPs. A full evaluation of the impact on detection rates of proteinuria and pre-eclampsia, cost effectiveness, pregnancy outcomes and women's experiences of regularly completing self-testing is needed before considering adopting self-monitoring more widely during pregnancy.

4.5. Intended population

This pilot work confirms that women at higher risk of pre-eclampsia are willing and able to complete this testing. The most suitable population for regular proteinuria self-testing may be pregnant women who have developed hypertension or those at high risk within the second half of pregnancy when pre-eclampsia is most likely to develop.

4.6. Barriers

While testing for urinary protein and monitoring of blood pressure are known to be of value during pregnancy, self-testing is unlikely to be suitable for all women. In addition, HCPs will need evidence to be convinced about the benefits of self-testing and require clear pathways to follow alongside current care.

5. Conclusion

This research suggests that self-testing of proteinuria is feasible, acceptable and potentially advantageous for both pregnant women and HCPs. If shown to be sufficiently accurate when tested at scale and is cost effective, proteinuria self-testing has the potential to be a valuable method of screening for pre-eclampsia in pregnancy, and may result in earlier diagnosis of this condition than current practice.

Authors' contributions

KT, LCC, PO, RJM and LB conceived the studies and in collaboration with CC, CB, and RJM gained the funding. The protocols were developed by KT, RJM, LCC and LH with the advice and support of all authors. Data were recorded by CC, LB, PM, and KT. Statistical analysis was carried out by ML and KST with advice from JO and CB. Qualitative analysis was completed by LB with advice from LH. The first draft of the paper was written by KT with LB and subsequently edited and approved by all co-authors. All authors have read, provided critical revision and approved the final version of the manuscript (KT, LB, CC, PM, LH, ML, JO, KST, CH, CB, LM, TJ, PO, LCC, RJM). KT will act as guarantor.

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Ethics statement

Test accuracy study

Ethical approval was obtained from the Northern Ireland Research Ethics Committee (15/NI/0157/HSC REC-B 22/07/2015, IRAS ID 179582, Protein testing in pregnancy).

Proteinuria self-testing alongside blood pressure monitoring

Ethical approval was obtained from Oxford South Central Research Ethics Committee (12/SC/0625 REC-B, 12/12/2012, IRAS ID 99244, Self-monitoring of blood pressure in pregnancy: developing the evidence base in primary care).

Online survey

Ethical approval was obtained from St Georges Research Ethics Committee (SGREC16/0005) 2016.

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We have no conflicts to declare.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.preghy.2017.11.009.

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