BMJ Open

Competency of health care providers in detecting and managing gestational hypertension, pre-eclampsia, severe pre-eclampsia and eclampsia during antenatal check-up in primary care health facilities in Bangladesh

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-046638
Article Type:	Original research
Date Submitted by the Author:	05-Nov-2020
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Keywords:	EPIDEMIOLOGY, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Maternal medicine < OBSTETRICS, PRIMARY CARE, PUBLIC HEALTH

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Title: Competency of health care providers in detecting and managing gestational hypertension, pre-eclampsia, severe pre-eclampsia and eclampsia during antenatal check-up in primary care health facilities in Bangladesh

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Keywords

Hypertensive disorders of pregnancy; Preeclampsia; Eclampsia; Quality of Care; Competency

Word Count: 5223

Abstract

Study Objective: To evaluate the competency of trained health care providers in detecting and managing hypertensive disorders of pregnancy during routine antenatal check-up (ANC) at primary care facilities in Bangladesh.

Study Design and Settings: Cross-sectional study; conducted in 26 primary care facilities

Outcome measures: Accurate diagnosis of the hypertensive disorders of pregnancy

Method: In total 1,560 ANC consultations provided by primary health care providers, Family Welfare Visitors (FWVs), were observed using a structured checklist between October 2017 and February 2018. All consultations were re-assessed by study physicians for validation.

Result: Of these 'true' cases of gestational hypertension(n=32), pre-eclampsia(n=29), and severe pre-eclampsia(n=16), only 3%, 7%, and 25%, respectively, were correctly diagnosed by FWVs. Percent agreement for the diagnosed cases of any hypertensive disorders of pregnancy was 9% and kappa statistics was 0.50 (p-value 0.0125). For identification of any hypertensive disorders by FWVs, sensitivity and positive predictive value (PPV) was 14% and 50%, respectively. There was a moderate positive correlation between the blood pressure measurements taken by FWVs and study physicians. Only 27% of those who had 'some protein' in urine were correctly identified by FWVs. Women diagnosed with any of the hypertensive disorders of pregnancy by FWVs were more likely to be counselled on at least one danger sign of preeclampsia (severe headache, blurring of vision, and upper abdominal pain) than those without any such diagnosis (41% vs. 19%, p-value 0.008). All four cases of severe pre-eclampsia diagnosed by FWVs were given a loading dose of intramuscular Magnesium Sulphate and three amongst them were referred to a higher facility.

Conclusion: The FWVs should be appropriately trained on risk assessment of pregnant women with a practical demonstration on the diagnostic criteria and counselling on danger signs of pre-eclampsia.

Strengths and limitations

- Used a rigorous approach of evaluating the competency of health workers in diagnosing and managing hypertensive disorders of pregnancy during antenatal check-up by direct observation in a large sample of pregnant women (n=1560). In addition to direct observation, measured the accuracy of the performed activities (blood pressure measurement and urinalysis) by comparing with study physician's assessment
- Post-hoc analysis of outcome measures identified that health care providers could improve their competency in diagnosing hypertensive disorders of pregnancy if they strictly followed the nationally adapted "algorithm"
- Study assessed the competency of health workers in primary care facilities of rural areas in Bangladesh , therefore, the findings are not generalizable to health workers working in higher level of health facilities
- Could not determine the extent to which the deviations of measurements from the 'true' values was attributed to the error of the instruments (blood pressure machine or urine test kits) since we did not validate the instruments used by the health care providers
- Hawthorn effect was possible by the presence of observers and study physicians, however, their continual presence over two weeks in the selected facilities could potentially minimize the effect.

Introduction

Pre-eclampsia, a multisystem hypertensive disorder of pregnancy, is associated with high blood pressure (diastolic blood pressure > 90mmHg) and the presence of protein in urine [1]. The risks of adverse maternal and perinatal health outcomes are high when an advanced form of preeclampsia develops and leads to episodes of convulsion- a condition known as Eclampsia. Eclampsia may lead to serious maternal health consequences including renal failure [2] and placental abruption [3] and accounts for 10% of maternal deaths worldwide [4, 5]. Despite the substantial reduction of maternal mortality ratio (MMR) over the past decade in Bangladesh [6], eclampsia remains the second major direct cause of obstetric deaths constituting about 20% of all maternal mortalities [7]. The condition is also associated with adverse foetal outcomes such as stillbirth, preterm delivery, and intrauterine growth restriction [8].

The key strategy to mitigate the burden related to preeclampsia is to diagnose the condition early so that timely and appropriate management can prevent further complications [9]. The provision of injectable Magnesium Sulphate as the first stage management of severe preeclampsia can prevent the severity of its progression and lowers the risk of convulsion [10]. The availability of life-saving interventions alone, however, does not ensure its delivery to the beneficiaries without improving the overall service provision for maternity care by skilled health workers [11]. Some studies reported poor quality of ANC regarding the detection and management of preeclampsia and observed incomplete physical examinations by the ANC service providers [12, 13]. Lack of accuracy in measured blood pressure and urine assessment results can further compromise the detection of hypertensive disorders, including pre-eclampsia during pregnancy. There is, however, a scarcity of evidence on the accuracy of the clinical examinations conducted by the health workers.

In Bangladesh, female primary level health providers, known as Family Welfare Visitors (FWVs), with 18 months of pre-service training provide ANC services at community level primary healthcare centers (known as union health and family welfare center or UH&FWC) and community outreach centers, known as satellite clinics [14]. These providers are designated to identify, manage, and refer preeclampsia cases, and provide initial management of severe preeclampsia before referring the pregnant women to health facilities for comprehensive

emergency obstetric care (CEmOC) [15]. It is, therefore, crucial to accurately perform the essential components of ANC by the FWVs for accurate screening, diagnosis and subsequent management of preeclampsia or severe preeclampsia. The essential components of ANC include taking an appropriate history, measuring blood pressure, assessing urinary protein, and applying the appropriate clinical guidelines.

The study objective is to evaluate the competency of FWVs in diagnosing and managing 'hypertensive disorders of pregnancy' including gestational hypertension, preeclampsia, severe preeclampsia, and eclampsia. This study was conducted during the provision of routine antenatal services at the UH&FWC and satellite clinics in Bangladesh. The study also validated the competency of FWVs in blood pressure measurement and urinary protein assessment by comparing the values with those assessed by study physicians (gold standard).

The study will identify the quality gaps and the missed opportunities for the detection and management of hypertensive disorders in pregnancy during the antenatal check-up in primary care settings. The findings will guide the maternal health programmers and policymakers on possible interventions to improve the accuracy of antenatal screening procedures for hypertensive disorders of pregnancy and reinforce the implementation of the national screening and management protocols for preeclampsia and eclampsia.

Methodology

Study design

We conducted a cross-sectional assessment at UH&FWCs and satellite clinics, two important primary healthcare service delivery platforms for mothers and children in Bangladesh. UH&FWCs are situated at the lowest administrative units (union) of the country and administered by the Directorate General of Family Planning of Ministry of Health and Family Welfare in Bangladesh and serve a population of 24,000-30,000 on an average [14, 16]. In each UH&WFC, one female health worker known as 'Family Welfare Visitor (FWV)' is posted to provide antenatal, childbirth and postnatal care, and family planning services 6-days a week. In addition to the regular UH&FWC-based services, FWVs conduct outreach sessions i.e. attend satellite clinics on two selected days every week. These sessions are usually held in a pre-identified household of the village, a school premise, or a community clinic so that FWVs can

provide the standard antenatal care and family planning services close to the community. The FWVs carry the required logistics for antenatal care to the satellite clinics, such as registers, job aids, and counselling materials, blood pressure machines with the stethoscope, urine test kits, weighing machine, and essential medicines to provide standard ANC services.

Methods of data collection included – i) observation of ANC services provided by FWVs by trained paramedics, and ii) reassessment of the pregnant women by trained physicians which was considered 'gold standard' for validating the FWV's assessment.

Study site

We conducted the study in 26 UH&FWCs selected purposively from four sub-districts of three districts (Habiganj, Noakhali, and Lakshmipur) in Bangladesh. In these three districts, USAID funded MaMoni Health Systems Strengthening (MaMoni HSS) project provided technical support to effectively implement the management of hypertensive disorders of pregnancy through existing government health workers [17]. The project trained the FWVs in the selected UH&FWCs on detection, prevention, and management of hypertensive disorders of pregnancy using the loading dose of intramuscular Magnesium Sulphate according to the standard protocol between March and May of 2016. The 2-day long competency-based training was conducted by expert consultants following the CEmOC training manual developed by Obstetric and Gynaecological Society of Bangladesh (OGSB). MaMoni HSS also ensured the availability of injectable Magnesium Sulphate and 'urine strip' for urine assessment in government health facilities including UH&FWC, sub-district, and district hospitals through a strong liaison with the Government in these districts. The project also introduced referral slips to ensure that the identified severe pre-eclampsia or eclampsia cases at the UH&FWCs could be referred to the designated CEmOC health facilities of the respective districts for further management. The project also provided infrastructural and skill improvement inputs to improve the quality of CEmOC services at the referral facilities. MaMoni HSS's inputs at different levels for implementing appropriate detection and management of pre-eclampsia and eclampsia at antenatal care contact points of the public facilities have been described elsewhere in detail [18].

Data collection

We recruited six female paramedics with 4-years of training by government authorized "Medical Assistant Training School (MATS)" and three physicians (one female and two males) and provided them with a 3-day training on ANC and hypertensive disorders of pregnancy using the national protocol for detection and management of preeclampsia and eclampsia. Following the training, both study paramedics and physicians participated in a demonstration on the usage of blood pressure machine and urine assessment kit for standardization in the steps of assessment and recording the result. Before starting the actual data collection, the assessors spent two days in a government training hospital for practicing the assessment tools, blood pressure machine, and urine test kits.

Trained paramedics observed ANC service provided by the FWVs both at UH&FWCs and satellite clinics using a structured observation checklist. The checklist was developed from the components of the WHO focused ANC guideline and incorporated the detail of steps for diagnosing and managing hypertensive disorders of pregnancy [19, 20]. The observers recorded whether the health worker asked about the relevant history of current and previous pregnancy (if any), performed routine examinations such as measuring blood pressure and assessing urine for protein and made a diagnosis for any of the four hypertensive disorders of pregnancy- gestational hypertension, preeclampsia, severe preeclampsia, and eclampsia. The observers also recorded the diastolic and systolic blood pressure, and the findings from urine assessment as measured by the FWVs in the checklist. If the FWVs provided the first dose (i.e. the loading dose) of injectable Magnesium Sulphate to a diagnosed case of severe pre-eclampsia and eclampsia as per the protocol and/or referred the pregnant woman to CEmOC equipped health facilities, it was also recorded in the checklist. Study paramedics stayed in the ANC consultation room and collected observation-based data when the FWV provided the ANC services. They also extracted the obstetric and background information of the pregnant women from the FWV's ANC registers.

After completion of ANC service provision by the FWV, gold-standard study physicians re-assessed every pregnant woman for the symptoms of hypertensive disorders of pregnancy following the standard national protocol. The study physicians measured the diastolic and systolic blood pressure and tested urine for the presence of proteins and recorded the information on a structured form. Study physicians conducted the reassessments in a space with auditory and visual privacy and separate from the routine ANC consultation room/place so that the

reassessment activities were less likely to bias the routine practices of FWVs. The physicians independently applied the national protocol to identify the presence of any of the four conditions of hypertensive disorders. In situations, where an FWV missed the diagnosis of hypertensive disorders of pregnancy but the case was identified by the study physician, on ethical grounds, the woman was sent back to the FWV with a suggestion from study physician to re-evaluate the client. After the re-evaluation, the ANC recipients followed the instruction given by the FWV. Between October 2017 to February 2018 we conducted observation and re-assessment of 1,560 ANC consultations in total in 26 UH&FWCs - 955 in UH&FWCs and 605 in satellite clinics.

The study physicians also assessed the readiness status of the UH&FWCs for screening and managing hypertensive disorders of pregnancy using a structured health facility assessment checklist. The checklist included information on maternal service availability, human resources, availability of Magnesium Sulphate, urine strip, functional BP machine, and other required logistics. This checklist was adapted from an evaluation survey exploring the quality of antenatal care in government health facilities of Bangladesh [21].

Data quality assurance and management:

Several data quality checks were in place to correctly record and perform the assigned tasks by the data collectors. The most critical element of the study was the ascertainment of systolic and diastolic blood pressure and urine in protein during reassessment. To measure the blood pressure, manually inflated aneroid sphygmomanometers were used by the study physicians as this instrument is routinely used by the FWVs in UH&FWCs. This type of sphygmomanometer is more portable and preferable for community-level health services than any other blood pressure measuring device, though considered less accurate than mercury sphygmomanometer [22, 23]. To minimize the variation in measurements during reassessment, blood pressure was measured twice for each ANC recipient in the same hand (right arm, unless there was any clinical or physical condition), on a sitting position, and at 5 minutes of resting interval between two measurements. Both measurements were recorded during the reassessment by the study physicians and the average of these two measurements was used in the statistical analysis. These standards were also maintained during the 'Non-Communicable Disease Risk Factor Survey Bangladesh 2010' [24] and suggested in the WHO STEPS guideline [25]. For urine reassessment, a sample of urine was collected in a test tube maintaining adequate sterility and

hygiene. Reagent strips for urine analysis were used to assess the presence of protein in the sample. The same test-strips were also being used in the selected UH&FWCs for ANC services as supplied by the government with support from MaMoni HSS.

Study paramedics reviewed each other's ANC observation checklist for completeness before submitting it to the study physician of the team who rechecked each form for missing information or inconsistency. Throughout the study period, one medical officer of the central research team conducted spot-checking i.e. made unscheduled visits to study sites, reviewed the collected data on the spot, and provided necessary feedback to the study physicians and paramedics. Regular monitoring and supervision were conducted by the central team of research investigators led by the principal investigator of the study.

A central data management team was responsible for data entry, consistency checking, and cleaning. All data were entered into the database using a custom-designed data entry program with built-in range and consistency checks.

Definition of variables and data analysis:

Four conditions, namely-gestational hypertension, preeclampsia, severe preeclampsia, and eclampsia were collectively considered the hypertensive disorders of pregnancy in this study, and their operational definitions are summarized in Table 1. The diagnostic criteria mentioned in the operational definitions followed the nationally adapted protocol for the detection and management of hypertensive disorders of pregnancy (supplementary file 1). The study physicians re-assessed each ANC recipient, performed the required examinations, and applied the diagnostic criteria based on their assessment to reach a diagnosis. For the FWVs, on the other hand, if they made a diagnosis of one of the four hypertensives disorders of pregnancy and recorded it on ANC register or ANC card of the recipient, it was considered as the 'case detected by FWV' irrespective of the validity of their assessment for such conditions. In case the FWVs did not record or document any diagnosis for a pregnant woman, the diagnosis was considered as 'no hypertensive disorder of pregnancy'.

Table 1: Operational definitions of hypertensive disorders of pregnancy

Hypertensive disorders of pregnancy	Diagnostic criteria

Gestational hypertension	• Gestational age: 20 weeks or more, AND • Diastolic blood pressure: 90-109 mm Hg, AND • Protein in urine: Nil, AND • Absence of all three danger signs- severe headache, blurred vision, and upper abdominal pain
Preeclampsia	• Gestational age: 20 weeks or more, AND • Diastolic blood pressure: 90-109 mm Hg, AND • Protein in urine: Present, AND • Absence of all three danger signs- severe headache, blurred vision, and upper abdominal pain
Severe preeclampsia	Definition#1: • Gestational age: 20 weeks or more, AND • Diastolic blood pressure 90-109 mm Hg, AND • Protein in urine: Present, AND • Presence of at least one of the three danger signs- severe headache, blurred vision, and upper abdominal pain Definition#2: • Gestational age: 20 weeks or more, AND • Diastolic blood pressure: 110 mm Hg or more, AND • Protein in urine: Nil/Present
Eclampsia	• Gestational age: 20 weeks or more, AND • Diastolic blood pressure: 90 mm Hg or more, AND • Convulsion

Descriptive statistics were used to report the competency of the FWVs in screening, detection, and management of hypertensive disorders of pregnancy and presented in percentage of cases who received such care (exploring clinical symptoms, performing screening procedures, counselling, providing injectable Magnesium Sulphate, and referral) in adherence to the standard ANC guideline. Findings on screening procedures were further stratified by place of service delivery – UH&FWC and satellite clinics. Pearson's chi-squared test was conducted to assess the significance of the association between the FWV's practice and place of service delivery.

Inter-rater agreement between FWV and study physician was measured using percent agreement. Cohen's kappa coefficient along with the p-value was also estimated to account for the possibility of finding the agreement by chance. Cohen's kappa coefficient describes the strength of inter-rater agreement by comparing the observed agreement to the expected agreement, assuming the measurements are independent [26]. Sensitivity, specificity, and positive predictive values were calculated for assessing the validity of FWV's diagnosis of - i) any hypertensive disorder of

pregnancy (including gestational hypertension) and ii) pre-eclampsia, severe pre-eclampsia or eclampsia. For sensitivity and specificity analysis of the conditions (i) and (ii), the measurements and diagnosis made by the study physicians were considered as 'true' or 'gold standard'. Sensitivity was expressed as the percentage of 'cases detected by FWV' among those who had 'true' medical criteria for hypertensive disorders of pregnancy, specificity was expressed as the percentage of non-cases detected by FWV among those who did not have 'true' medical criteria for those conditions, and the positive predictive value was expressed as the percentage of 'true' cases among the 'case detected by FWV' as hypertensive disorders of pregnancy. As part of the validity analysis, two scenarios were compared with the study physician's diagnosis (gold standard) – i) diagnosis that was made by FWV and recorded in the ANC registers/ANC card irrespective of using the algorithm present in the national protocol for detecting hypertensive disorders of pregnancy, and ii) post-hoc diagnosis using the information from FWV's measurement of blood pressure and urine assessment, the status of danger signs from study physician's assessment and applying the algorithm during analysis. The latter indicates the extent to which cases could have been accurately diagnosed had the two diagnostic criteria (elevated blood pressure and protein in the urine) been appropriately used as per the national protocol for hypertensive disorders of pregnancy by FWVs.

Pearson's correlation coefficient was reported along with p-values to estimate the relationship between the measurements taken by an FWV and study physician. The comparison is presented in scatterplot graphs by plotting blood pressure recordings taken by FWVs against that taken by study physicians. Mean and standard deviation of absolute difference of blood pressure readings taken by FWVs and study physicians are calculated to estimate the accuracy of FWV's measurement of diastolic and systolic blood pressure. A first-order polynomial smooth curve of the absolute differences is also fitted in the scatter plot to show the deviation from the 'true' values. Accuracy of urine assessment is presented in the percentage of cases where FWV could correctly identify if there was 'no protein' or 'some protein' in the urine. The results of urine assessment by study physicians were considered 'correct'.

Patient and public involvement:

The study objective and outcome measure were related to assessing the competency of health care providers in detecting and managing gestational hypertension, pre-eclampsia, severe pre-

eclampsia and eclampsia during antenatal check-up in primary care health facilities in Bangladesh. Pregnant women were not involved in the design of, in the recruitment to and conduct of the study. The results will be disseminated among the health managers and maternal health workers in the government hospitals where the study was conducted.

Ethical consideration

The study protocol was reviewed and approved by the Ethical Review Committee (ERC) of the International Center for Diarrheal Disease Research, Bangladesh (icddr,b) (protocol number PR-17084). Permission was taken from the Ministry of Health and Family Welfare and health mangers of the selected health facilities were informed about the study. Written informed consent was obtained from the FWVs and verbal consent was sought from ANC service recipients during clinical observations. The respondents participated in the study voluntarily and had the right to withdraw themselves from the study at any time even after giving the consent. Privacy, anonymity, and confidentiality of the data were strictly practised and restrictions on access to data were enforced.

This study is not a clinical investigation. MaMoni HSS project only provided technical support for the implementation of the nationally adopted intervention of community-based provision of the loading dose of Magnesium Sulphate to the identified cases of severe pre-eclampsia and eclampsia through the government health system. Nonetheless, systematic reviews and the efficacy trial of Magnesium Sulphate have already proven that the drug is safe with no major side effects [27-29].

Result

Readiness of UH&FWCs

All 26 UH&FWCs provided antenatal services and mean (± SD) number of ANC provided in a month was 111 (±83). All the UH&FWCs had one designated FWV who provided ANC, childbirth, postnatal care, and family planning services. She also conducted regular satellite sessions twice a week to provide the same services in the satellite clinics. All 26 FWVs received hands-on training on screening, diagnosing, and managing hypertensive disorders of pregnancy. In only seven UH&FWCs (27%), at least one case of diagnosing and managing pre-eclampsia in

the last three months preceding the assessment was reported. Blood pressure machine and urine strip for measuring protein in urine were available in all 26 health facilities, but three did not have injectable Magnesium Sulphate available during the assessment period. The standard national guideline for managing hypertensive disorders during ANC was available in only 16 out of 26 facilities. The readiness of the satellite clinics regarding the service provision and logistics remained similar to that in the UH&FWC since the FWV carried the ANC logistics with her while attending the satellite sessions.

Characteristics of pregnant women and information on ANC care-seeking

Of the 1,560 pregnant women, the majority received ANC at UH&FWCs (61%) and the rest received this care at satellite clinics (Table 2). About 69% of women were aged between 20 to 29 years and 38% were first-time mothers (primigravida). One in five women came for ANC after 20 weeks of gestational age; among them, 40% came for the first antenatal visit.

Table 2: Characteristics of pregnant women and information on ANC care-seeking

Characteristics, N= 1560	%
Age (in years)	
Less than 20	16.7
20-24	38.4
25-29	30.6
30 and above	14.4
Gravida	
Primigravida	38.1
Multigravida	61.9
Gestational age	
less than 20 weeks	79.9
20 weeks or more	20.1
Place of care-seeking	
UH&FWC	61.2
Satellite clinic	38.8
ANC Visit*	
1st visit	59.5
2nd or more	39.7

* 12 missing information

Screening and assessment by FWV for hypertensive disorders of pregnancy during ANC

During antenatal service provision, FWVs asked only 8% of women whether they had a history of hypertension or taking any anti-hypertensive drug or of pre-eclampsia (if the women had previous pregnancy) (Table 3). Symptoms of pre-eclampsia for the current pregnancy such as severe headache, blurring of vision, upper abdominal pain, were assessed among 15%, 12%, and 18% of women, respectively. Only for 12% of women, any occurrence of convulsion during their current pregnancy was explored. FWVs were more likely to ask these screening questions if the services were given at a UH&FWC than in a satellite clinic ($p<0.05$). Blood pressure and urine assessment, two critical examinations for diagnosing the presence and severity of hypertensive disorders of pregnancy, were conducted among 97% and 76% of the women, respectively.

Table 3: Screening and assessment by FWV for hypertensive disorders of pregnancy

Screening and assessment by FWV during ANC	All, n= 1560	UH&FWC n= 955	SC n= 605	p-value[1]
Asked about last menstrual period	93.5	90.1	98.8	<0.0001
Asked whether the women had				
History of hypertension or using any anti-hypertensive drug or preeclampsia in a previous pregnancy	8.3	10.1	5.6	0.002
History of diabetes	3.8	4.7	2.5	0.025
History of renal disease or urine infection	0.9	1.4	0.2	0.015
Severe headache	14.8	19.1	8.1	<0.0001
Blurring of vision	11.9	15.9	5.6	<0.0001
Upper abdominal pain	18.3	25.0	7.6	<0.0001
Any episode of convulsion	12.1	15.7	6.5	<0.0001
Performed/examined				
Blood pressure measurement	97.4	98.1	96.2	0.021
Urine assessment	76.5	76.5	76.5	0.994

[1] Pearson's chi-squared test

Accuracy of FWV's assessment of blood pressure and urine

Blood pressure measurement:

Figure 1 and Figure 2 plot the diastolic and systolic blood pressures of pregnant women, respectively, as recorded by the FWVs against those recorded by the study physicians. Both figures show a tendency of FWVs to round off the blood pressures to the nearest tenth of the unit which either under- or over-estimated the 'true' values as evident by comparing with the study physicians' measurements. The correlation coefficients of the measurements taken by FWV and study physician was 0.50 (p-value <0.0001) for diastolic pressure and 0.60 (p-value <0.0001) for

systolic pressure, which indicates a significant moderate positive relationship. Overall, the mean (±SD) absolute difference between FWV and study physician's measurement of diastolic and systolic blood pressure of the same person was 7.1± 7.6 and 7.5± 8.4 mmHg, respectively (not presented in the table). The polynomial smooth curve of the absolute differences between study physician and FWV's measurement shows larger differences (>10 mmHg) when the 'true' diastolic pressure was higher than 100 mmHg or 'true' systolic pressure was higher than 160 mmHg. The difference also widened when 'true' diastolic pressure was below 50 mmHg or 'true' systolic pressure was below 100 mmHg.

Figure 1: Diastolic BP: recorded by FWV vs. Study physician

Figure 2: Systolic BP: recorded by FWV vs. Study physician

Urine assessment: Although there was high correct identification of 'no protein' in urine, only 27% of those who had 'some protein' were diagnosed correctly by FWVs (Figure 3).

Figure 3: Protein in urine: correctly identified by FWV

Status of hypertensive disorders of pregnancy among those receiving ANC in UH&FWC

The 'true' prevalence for gestational hypertension, pre-eclampsia, and severe pre-eclampsia diagnosed by the study physicians, was 2.1%, 1.9% and 1.0%, respectively (Table 4). The numbers of cases identified by the FWVs were substantially lower than the 'true' prevalence for all three types of hypertensive disorders. No woman was diagnosed with eclampsia by the study physician or FWV.

Table 4: Prevalence of hypertensive disorders of pregnancy

Hypertensive disorders of pregnancy	Cases identified/diagnosed by Study physician[1]		FWV[2]	
	n	%	n	%
Total pregnant women, N	1560	100.0	1560	100.0
Gestational hypertension	32	2.1	12	0.8

Preeclampsia	29	1.9	6	0.4
Severe Preeclampsia	16	1.0	4	0.3
Eclampsia	0	0	0	0

[1] According to the national protocol for hypertensive disorders of pregnancy based on the information recorded by study physician after reassessment of the pregnant women
[2] According to FWV's note recorded in ANC register/ANC card after ANC was provided

The validity of the diagnosis of hypertensive disorders of pregnancy

FWV's diagnosis recorded in ANC register: Only in 3%, 7%, and 25% of true cases of gestational hypertension, pre-eclampsia, and severe pre-eclampsia respectively, FWVs made a correct diagnosis during ANC (Table 5). Percent agreement for the diagnosed cases of hypertensive disorders of pregnancy is 9% and kappa statistics is 0.05 (p-value 0.0125). For identification of any hypertensive disorders, sensitivity, and positive predictive value (PPV) is only 14% and 50%, respectively. For identification of preeclampsia or severe preeclampsia or eclampsia, sensitivity and PPV are 18% and 80% respectively. In both cases, specificity is high (>99%).

Post-hoc diagnosis based of FWV's assessment of blood pressure and urine: When the diagnosis was made by applying the algorithm present in national protocol based on the two diagnostic criteria (elevated blood pressure and protein in the urine) measured by FWVs and status of three danger signs assessed by study physicians the accuracy of diagnosis (i.e. the percentage of 'true' cases accurately diagnosed), was markedly increased from that of the FWVs' original diagnosis of the conditions (Table 5). For instance, at least 63% of severe preeclampsia could be diagnosed if the protocol had been applied correctly by an FWV based on her assessment of blood pressure and urine. The percent agreement also improves from 9% to 29% and kappa statistics is 0.19 (p-value <0.0001). Moreover, in this scenario, both sensitivity and PPV of diagnosing 'any hypertensive disorder' and 'pre-eclampsia and/or severe pre-eclampsia' are markedly increased.

Table 5: Validity of diagnosis of hypertensive disorders of pregnancy

	Percentage of true cases[1] accurately diagnosed			Percent agreement[2]	Kappa coefficient	Sensitivity, %		Specificity, %		Positive predictive value (PPV), %	
	Gestational hypertension	PE	Severe PE			Any hypertensive disorder[3]	PE or severe PE	Any hypertensive disorder	PE or severe PE	Any hypertensive disorder	PE or severe PE
Diagnosis made by FWV[4]	3.1	6.9	25.0	9.1	0.05*	14.3	17.8	99.3	99.9	50.0	80.0
Diagnosis based on FWV's assessment of BP and urine[5]	25.0	13.8	62.5	28.6	0.19*	35.1	31.1	99.0	99.9	64.3	93.3

PE: Pre-eclampsia; BP: Blood pressure

[1] Cases identified by study physician as hypertensive disorders of pregnancy

[2] Among the cases with hypertensive disorders of pregnancy

[3] Gestational hypertension, pre-eclampsia, or severe pre-eclampsia or eclampsia

[4] According to FWV's note recorded in the ANC register/ANC card after antenatal services are provided

[5] According to the national protocol for hypertensive disorders of pregnancy based on the information recorded on blood pressure and urine assessment by FWV

Management provided by FWV

The women who were diagnosed to have any hypertensive disorders of pregnancy by FWVs were more likely to be counselled on at least one danger sign of preeclampsia (severe headache, blurring of vision and upper abdominal pain) than those without such diagnosis (41% vs. 19%, p-value 0.008). FWVs provided anti-hypertensive drugs in only two cases- for those with the diagnosis of gestational hypertension and pre-eclampsia (Table 6). All four cases of severe pre-eclampsia were given a loading dose of intramuscular Magnesium Sulphate and three among them were referred to a higher facility.

Table 6: Management of hypertensive disorders identified by FWV during ANC at UH&FWC

Cases diagnosed by FWV	Received in-facility management			Referred
	Counselling[1]	Anti-hyper tensive[2]	Magnesium Sulphate[3]	
No HTN disorders, n=1538	287 (18.7)	n/a	n/a	n/a
Gestational hypertension, n=12	4 (33.3%)	1 (8.3)	n/a	1 (8.3)
Pre-eclampsia, n=6	2 (33.3)	1 (16.7)	n/a	3 (50.0)
Severe pre-eclampsia, n=4	3 (75.0)	0 (0)	4 (100.0)	3 (75.0)

[1] Counselling on at least one dangers signs of pre-eclampsia
[2] Oral Hydralazine, Nifedipine, Labetalol, or Methyldopa
[3] A loading dose of intramuscular Magnesium Sulphate (10 gm)

Discussion

Our study identified gaps in diagnosing hypertensive disorders of pregnancy during ANC in community-level sessions and at primary health care centers in three districts of Bangladesh where USAID funded MaMoni HSS project intervened to improve maternal health care services. The undiagnosed or misdiagnosed cases could be linked with inadequate and inaccurate screening procedures performed by the health service providers called FWVs. The study also observed inadequate history taking, inaccuracy in blood pressure measurement and/or recording, and urine assessment for protein. A small proportion of the women who required antihypertensive drugs or counselling on disease management received such. All the detected cases of severe preeclampsia received the first dose of injectable Magnesium Sulphate as per the protocol.

The 'focused ANC package' by the WHO emphasised on blood pressure measurement and urine assessment during all ANC visit irrespective of gestational age to screen hypertensive disorders of pregnancy [20, 30]. In our study, nearly all women had their blood pressure measured and about three-fourth had their urinary protein assessed. The MaMoni HSS project trained FWVs on pre-eclampsia and eclampsia management before the study and this could have influenced the high coverage of these two screening procedures by the study participants. Detection of hypertensive disorders of pregnancy, however, requires screening for maternal comorbidities and proper history taking for danger signs of pre-eclampsia and convulsion during the current pregnancy, which was observed inadequate in our study. Nevertheless, the poor quality of ANC is consistent with that of other developing countries [31]. The practice was also significantly lower when the women received ANC in satellite or outreach sessions compared to in-facility antenatal services. Initiatives to improve quality of care often focus on bridging the coverage gap of specific activities by the health workers rather than focusing on the validity of the performed activities or developing reliable screening tools [31, 32]. For instance, blood pressure measurement and urine assessment are two key, critical diagnostic criteria for hypertensive disorders of pregnancy, yet their accurate ascertainment receives low priority in the training schemes for health workers in LMICs [33]. Our study found inconsistency in measured blood pressure between the health workers' assessment and the 'true' value especially when the blood pressure was beyond the normal range. This might allude to the tendency of the FWVs to record blood pressure within the normal range without accurately measuring the blood pressure of the ANC client. The study also detected terminal digit bias for both systolic and diastolic blood pressure recordings i.e. the tendency to report the values ending in zero. One study suggests that occurrence of recordings ending in zero in more than 30% cases, in general, indicates imprecise and inaccurate recording [34]. Periodic checking of the ANC registers for terminal digit bias by the supervisors could minimize such practice.

Despite the overall low sensitivity and positive predictive values for detecting hypertensive disorders of pregnancy by the FWVs, our study found an increase in these parameters when the algorithm present in the pre-eclampsia protocol was applied to diagnose the disease condition using the recordings of the screening tests performed by FWVs. This indicates either poor adherence to the evidence-based guideline or improper interpretation of the national protocol by the FWVs while reaching a diagnosis. Unavailability of the ANC protocol in 16 out of the 26

assessed health facilities could further worsen the knowledge gap of the health workers regarding the disease diagnostic criteria. A landscape-analysis on pre-eclampsia and eclampsia conducted in Bangladesh concluded that although 56% of health workers knew about diagnostic criteria of severe preeclampsia, only 8% knew that there was a national guideline on its diagnosis and management [15]. The landscape analysis also found that the pre-eclampsia/eclampsia protocol was not available in any of the assessed community-level primary health care centers (UH&FWC) [15]. In addition to making the guidelines available in health facilities, the antenatal service providers should be trained intensively on the diagnostic criteria of hypertensive disorders of pregnancy and quality measurement of BP and urinary protein. A review paper on improving the quality of care in LMICs suggested that such intervention should also maintain strong supportive supervision, along with the provision of on-site feedback based on health workers' performances, and audit of ANC registers and case reports [35].

In our study, a subtotal 16 'true' cases of severe preeclampsia were identified by the study physicians and these cases required the first dose of Magnesium Sulphate injection before their referral to a higher-level facility. Since only 4 were correctly identified and managed by the FWVs, the rest received no Magnesium Sulphate injection due to the missed diagnosis of the cases. The study physicians, however, had sent these women back to the FWV for re-assessment, which did not affect the initial recording of the events. Counselling regarding the hypertensive diseases of pregnancy or the provision of anti-hypertensive drugs to detected cases was also inadequate. The failure in the timely management of hypertensive disorders of pregnancy, therefore, poses a serious challenge in preventing maternal morbidity and mortality in LMICs. Besides improving the knowledge and skill of the ANC providers, prediction of risk and detection of cases can be aided by initiating a computerized clinical decision support system (CDSS) which has been proven effective for improved provider-care seeker communication and clinical decision making [36]. Unlike in developed countries, where CDSS was effective in improving providers' performance [37], implementation of such technology in developing countries could be challenging in the context of poor availability of health information, inadequate infrastructure, and limitation of skilled human resources [38]. Since the adoption of national eHealth policy in 2011 [39], Bangladesh is progressing with establishing electronic management information system (e-MIS) in the health facilities and has started to provide community health workers with computer tablets or smart-phones to deliver the essential health

services on the pilot basis [40]. The integration of CDSS into the e-MIS initiative could contribute to the sustainability of improving the quality of care during ANC, and thus the screening of hypertensive disorders. Further research is needed to identify and address potential constraints for smooth implementation of the decision support technology to ensure proper detection and management of gestational hypertensive disorders in Bangladesh and other developing countries.

Conclusion

Quality ANC should be ensured for all women at primary level health facilities and at outreach centers. Interventions should focus on increasing the availability, improving the utilization and accurate interpretation of the standard operating procedures or protocols for detecting and managing hypertensive disorders of pregnancy. The FWVs, union-level ANC providers, should be appropriately trained on risk assessment of pregnant women with a practical demonstration on the diagnostic criteria and management of eclampsia and pre-eclampsia. Strengthening the monitoring and supervision can further improve the screening of pre-eclampsia and severe pre-eclampsia using the algorithm and timely management of such cases to prevent eclampsia.

Author statement

SMB, SEA and JG conceptualized the paper. SMB, ANSK, SMR, NLH, MAK, SSP and IIM were involved in data acquisition, analysis, interpretation and literature review. SMB, ANSK, and SMR prepared the first draft. SMB, ANSK, SMR, NLH, MAK, IIM, SR, SEA, and JG contributed to revision and preparation of the final draft. All authors have reviewed and approved the final manuscript.

Acknowledgement

We acknowledge the Director (MCH Services) of Directorate General of Family Planning and Deputy Director Family Planning of Habiganj, Noakhali, and Lakhsmipur districts for allowing us to conduct the study. We also acknowledge the support from service providers and the pregnant women for accepting us to observe the service delivery procedure and providing necessary information. Also, icddr,b gratefully acknowledges the following donors who provide

unrestricted support: Government of the People's Republic of Bangladesh; Global Affairs Canada (GAC); Swedish International Development Cooperation Agency (Sida) and the Department for International Development, (UKAid). We used the STROBE cross sectional checklist when writing this manuscript [41].

Funding

This study was undertaken, and the article was produced as a part of MaMoni Health Systems Strengthening's (MaMoni HSS) learning agenda with the generous support of the American people through the United States Agency for International Development (USAID); Associate Cooperative Agreement No. AID-338-LA-13-00004. The views expressed in this article are solely the views of the authors and do not reflect the views of the United States Agency for International Development or the United States Government.

Conflict of interest

None declared

Data statement: Technical appendix, statistical code, and dataset available from a public repository [DOI: https://doi.org/10.6084/m9.figshare.12554330.v1]

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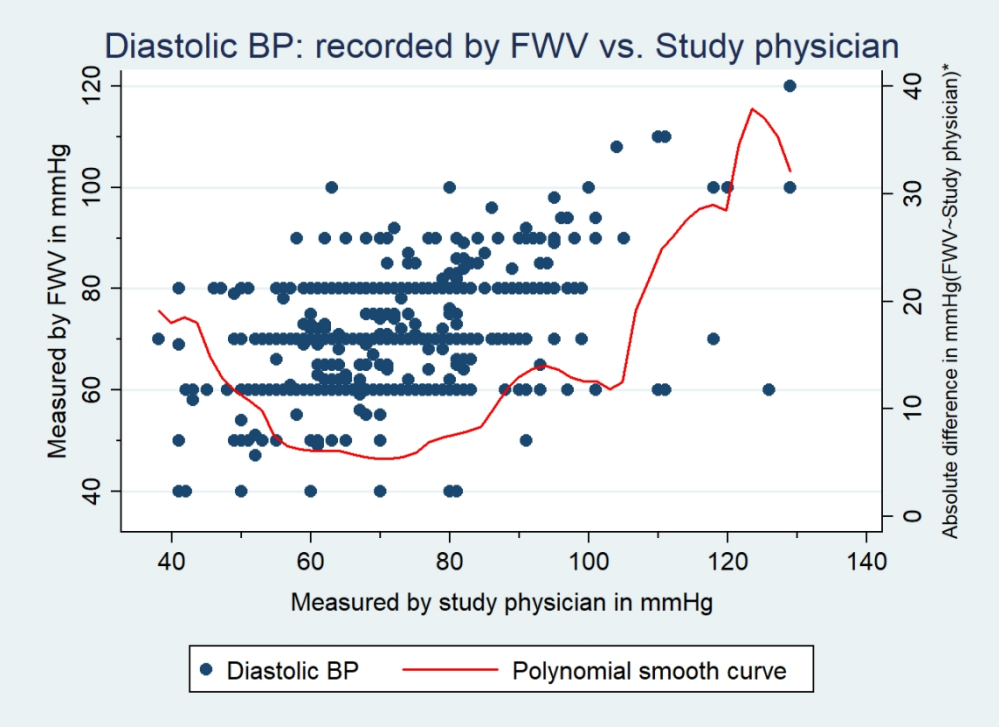
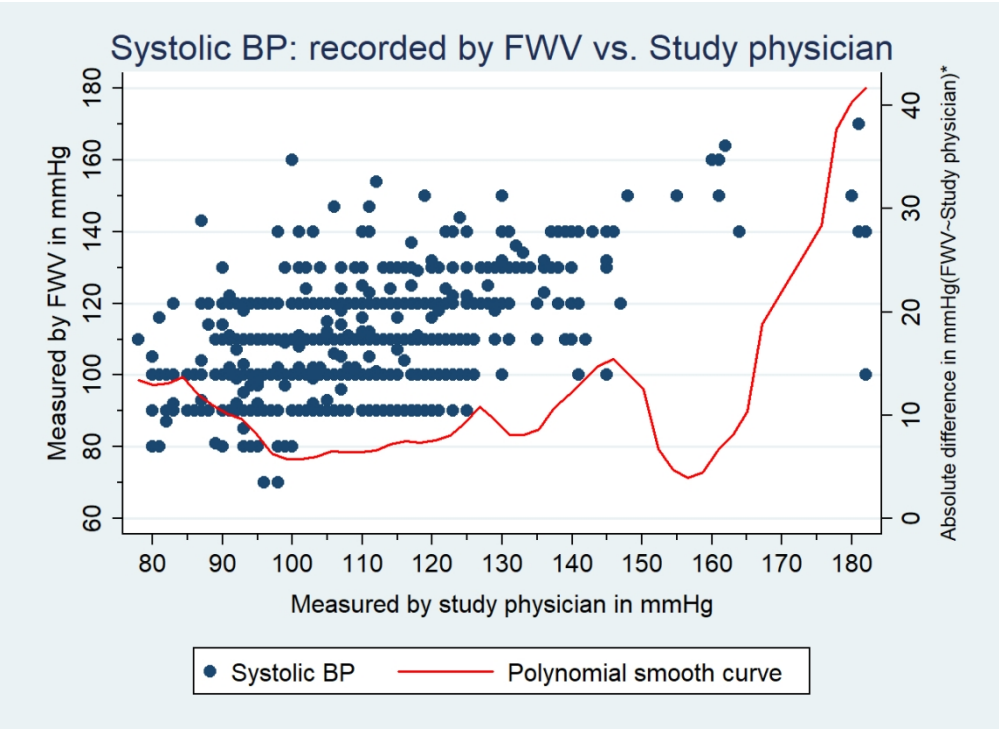


Diastolic BP: recorded by FWV vs. Study physician

108x78mm (300 x 300 DPI)



Systolic BP: recorded by FWV vs. Study physician

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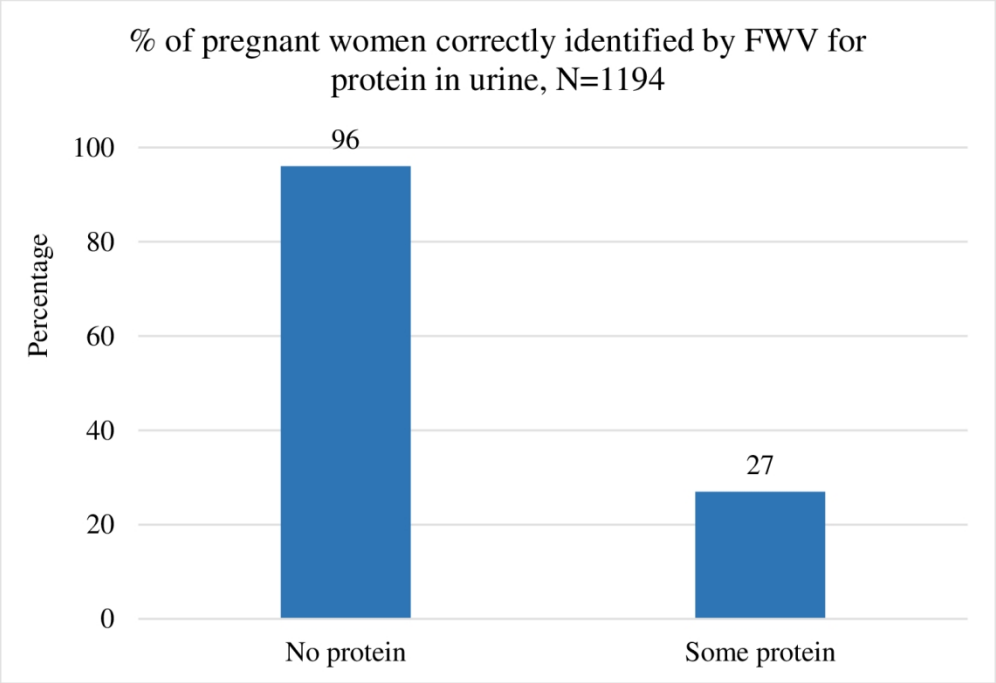
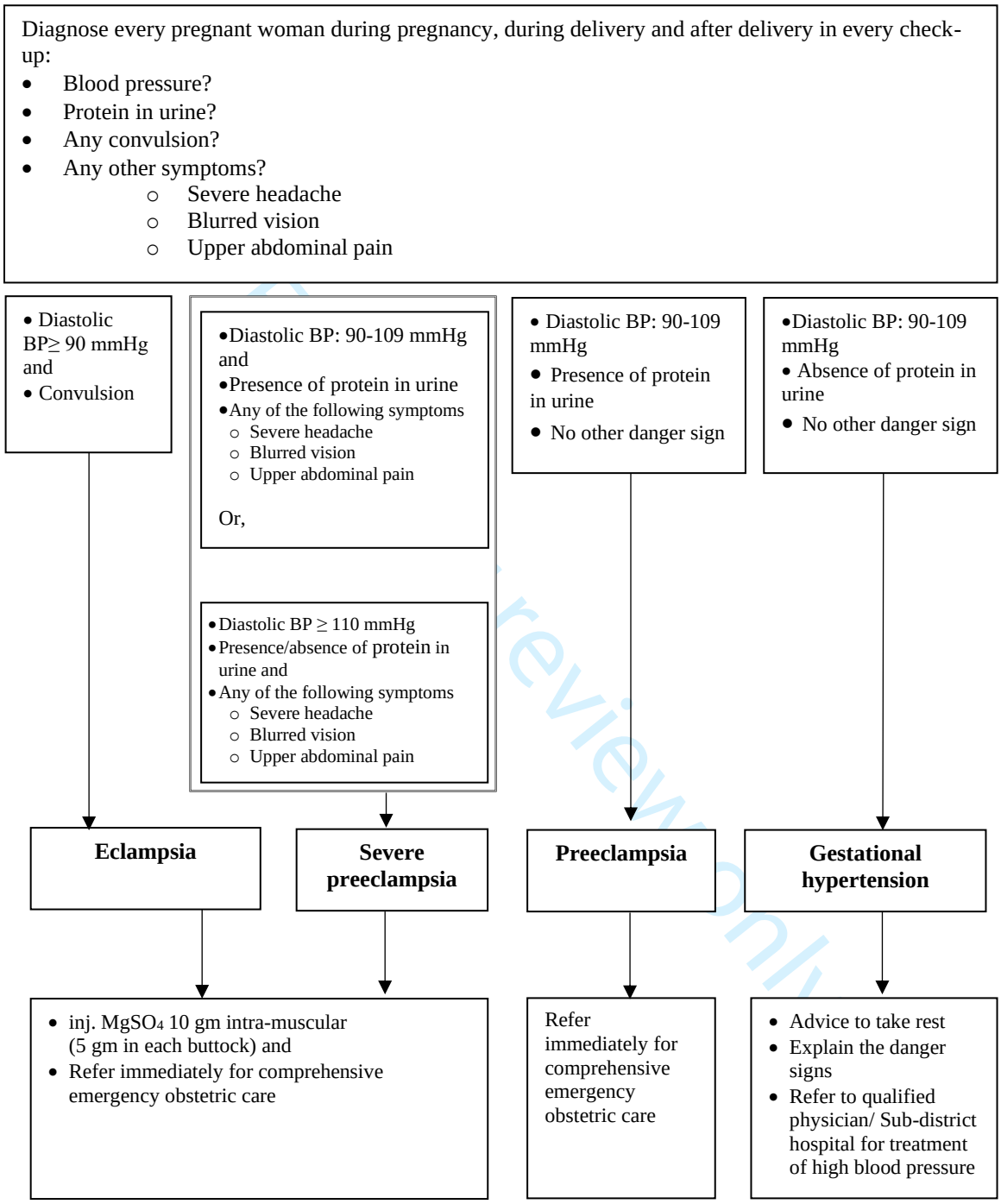


Protein in urine: correctly identified by FWV

137x94mm (300 x 300 DPI)

Supplementary file 1: Management guideline of preeclampsia, severe preeclampsia and eclampsia in Bangladesh



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Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

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		Reporting Item	Page Number
Title and abstract			
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	1

Abstract	#1b	Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background / rationale	#2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	#3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	#4	Present key elements of study design early in the paper	5-6
Setting	#5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants.	7-8
	#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	9-10

Bias	#9	Describe any efforts to address potential sources of bias	8-9
Study size	#10	Explain how the study size was arrived at	8
Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	9-10
Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	8-10
Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	8-10
Statistical methods	#12c	Explain how missing data were addressed	8-10
Statistical methods	#12d	If applicable, describe analytical methods taking account of sampling strategy	8-10
Statistical methods	#12e	Describe any sensitivity analyses	8-10
Results			
Participants	#13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.	12-18
Participants	#13b	Give reasons for non-participation at each stage	n/a

Participants	#13c	Consider use of a flow diagram	n/a
Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	13
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	12-18
Outcome data	#15	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	13-18
Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	13-18
Main results	#16b	Report category boundaries when continuous variables were categorized	13-18
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	17
Discussion			
Key results	#18	Summarise key results with reference to study objectives	18

Limitations	#19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	3
Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	18-21
Generalisability	#21	Discuss the generalisability (external validity) of the study results	3
Other Information			
Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	22

BMJ Open

Competency of health workers in detecting and managing gestational hypertension, preeclampsia, severe preeclampsia, and eclampsia during antenatal check-ups in primary care health facilities in Bangladesh: A cross-sectional study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-046638.R1
Article Type:	Original research
Date Submitted by the Author:	17-May-2021
Complete List of Authors:	Billah, Sk; International Centre for Diarrhoeal Disease Research, Maternal and Child Health Division; The University of Sydney, Faculty of Medicine and Health, Sydney School of Public Health Khan, Abdullah Nurus Salam; International Centre for Diarrhoeal Disease Research Bangladesh, Maternal and Child Health Division; University of South Carolina Arnold School of Public Health, Health Promotion, Education and Behavior, Arnold School of Public Health Rokonuzzaman, S M; International Centre for Diarrhoeal Disease Research Bangladesh, Maternal and Child Health Division Huq, Nafisa Lira; International Centre for Diarrhoeal Disease Research Bangladesh, Maternal and Child Health Division Khan, Marufa Aziz ; Pathfinder International, Shukhi Jibon Priyanka, Sabrina Sharmin; International Centre for Diarrhoeal Disease Research Bangladesh, Maternal and Child Health Division Mannan, Imteaz Ibne; JHPIEGO, Urban Health Initiative Rahman, Setara ; JHPIEGO, Maternal Health & Family Planning Arifeen, Shams E.; International Centre for Diarrhoeal Disease Research Bangladesh, Maternal and Child Health Division George, Joby; Save the Children Bangladesh, MaMoni Health Systems Strengthening
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Health services research, Epidemiology, Evidence based practice, Obstetrics and gynaecology, Public health
Keywords:	EPIDEMIOLOGY, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Maternal medicine < OBSTETRICS, PRIMARY CARE, PUBLIC HEALTH

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Title: Competency of health workers in detecting and managing gestational hypertension, preeclampsia, severe preeclampsia, and eclampsia during antenatal check-ups in primary care health facilities in Bangladesh: A cross-sectional study

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Keywords

Hypertensive disorders of pregnancy; Preeclampsia; Eclampsia; Quality of Care; Competency

Word Count: 5498

Abstract

Study Objective: To evaluate the competency of trained health workers in detecting and managing hypertensive disorders of pregnancy during routine antenatal check-ups (ANC) at primary care facilities in Bangladesh.

Study Design and Settings: Cross-sectional study; conducted in 26 primary care facilities

Outcome measures: Accurate diagnosis of the hypertensive disorders of pregnancy

Method: In total 1560 ANC consultations provided by primary health workers, known as Family Welfare Visitors (FWVs), were observed using a structured checklist between October 2017 and February 2018. All consultations were reassessed by study physicians for validation.

Result: Of the 'true' cases of gestational hypertension(n=32), preeclampsia (n=29), and severe preeclampsia (n=16), only 3%, 7%, and 25%, respectively, were correctly diagnosed by FWVs. Percent agreement for the diagnosed cases of any hypertensive disorders of pregnancy was 9% and kappa statistics was 0.50 (p-value 0.0125). For identification of any hypertensive disorders by FWVs, sensitivity and positive predictive values were 14% and 50%, respectively. There was a moderate positive correlation between the blood pressure measurements taken by FWVs and study physicians. Only 27% of those who had 'some protein' in urine were correctly identified by FWVs. Women diagnosed with any of the hypertensive disorders of pregnancy by FWVs were more likely to be counselled on at least one danger sign of preeclampsia (severe headache, blurring of vision, and upper abdominal pain) than those without any such diagnosis (41% vs. 19%, p-value 0.008). All four cases of severe preeclampsia diagnosed by FWVs were given a loading dose of intramuscular Magnesium Sulphate and three amongst them were referred to a higher facility.

Conclusion: The FWVs should be appropriately trained on risk assessment of pregnant women with particular emphasis on accurately assessing the diagnostic criteria of hypertensive disorders of pregnancy and its management

Strengths and limitations

- The study used a direct-observation based approach to evaluate the competency of health workers in diagnosing and managing hypertensive disorders of pregnancy during antenatal check-ups and also validated the accuracy of the performed activities (blood pressure measurement and urinalysis)
- Post-hoc analysis based on the two diagnostic criteria, elevated blood pressure and protein in the urine as per the national guideline, indicates the percentage of 'true' cases of hypertensive disorders of pregnancy accurately diagnosed to be markedly increased
- The study assessed the competency of health workers in primary care facilities of rural areas in Bangladesh, therefore, the findings are not generalizable to health workers working in the higher level of health facilities
- The study could not determine the extent to which the deviations of measurements from the 'true' values were attributed to the error of the instruments (blood pressure machine or urine test kits) since the instruments used by the health workers were not validated
- Hawthorn effect was possible by the presence of observers and study physicians, however, their continual presence over two weeks in the selected facilities could potentially minimize the effect

Introduction

Preeclampsia, a multisystem hypertensive disorder of pregnancy, is associated with high blood pressure (diastolic blood pressure > 90mmHg) and the presence of protein in urine [1]. The risks of adverse maternal and perinatal health outcomes are high when an advanced form of preeclampsia develops and leads to episodes of convulsion- a condition known as Eclampsia. Eclampsia may lead to serious maternal health consequences including renal failure [2] and placental abruption [3] and accounts for 10% of maternal deaths worldwide [4, 5]. Despite the substantial reduction of maternal mortality ratio (MMR) over the past decade in Bangladesh [6], eclampsia remains the second major direct cause of obstetric deaths constituting about 20% of all maternal mortalities [7]. The condition is also associated with adverse foetal outcomes such as stillbirth, preterm delivery, and intrauterine growth restriction [8].

The key strategy to mitigate the burden related to preeclampsia is to diagnose the condition early so that timely and appropriate management can prevent further complications [9]. The provision of injectable Magnesium Sulphate as the first stage management of severe preeclampsia can prevent the severity of its progression and lowers the risk of convulsion [10]. The availability of life-saving interventions alone, however, does not ensure its delivery to the beneficiaries without improving the overall service provision for maternity care by skilled health workers [11]. Some studies reported poor quality of ANC regarding the detection and management of preeclampsia and observed incomplete physical examinations by the ANC providers [12, 13]. Lack of accuracy in blood pressure measurement and urinary protein assessment can further compromise the detection of hypertensive disorders, including preeclampsia during pregnancy. There is, however, a scarcity of evidence on the accuracy of the clinical examinations conducted by the ANC providers.

In Bangladesh, female primary level health workers, known as Family Welfare Visitors (FWVs) with 18 months of pre-service training, provide ANC services at community level primary healthcare centres (known as union health and family welfare centre or UH&FWC) and community outreach centres (known as satellite clinics) [14]. The FWVs are designated to identify, manage, and refer preeclampsia cases, and provide initial management of severe preeclampsia before referring the pregnant women to health facilities for comprehensive

emergency obstetric care (CEmOC) [15]. It is, therefore, crucial to accurately perform the essential components of ANC by the FWVs for accurate screening, diagnosis and subsequent management of preeclampsia or severe preeclampsia [16]. The essential components of ANC include taking an appropriate history, measuring blood pressure, assessing urinary protein, and applying the appropriate clinical guidelines [17].

The study objective is to evaluate the competency of FWVs in diagnosing and managing hypertensive disorders of pregnancy including gestational hypertension, preeclampsia, severe preeclampsia, and eclampsia. The study also validated the blood pressure measurement and urinary protein assessment conducted by FWVs by comparing the values with those assessed by study physicians (gold standard). This study was conducted during the provision of routine antenatal services by the FWVs at the UH&FWCs and satellite clinics in Bangladesh.

The study will identify the quality gaps and the missed opportunities for the detection and management of hypertensive disorders in pregnancy during the antenatal check-up in primary care settings in Bangladesh. The findings will guide the maternal health programmers and policymakers to design effective interventions for improving the accuracy of antenatal screening for hypertensive disorders of pregnancy and reinforce the implementation of the national screening and management protocols for preeclampsia and eclampsia.

Methodology

Study design

We conducted a cross-sectional study at UH&FWCs and satellite clinics, two important primary healthcare service delivery platforms for mothers and children in Bangladesh. UH&FWCs are situated at the lowest administrative units (union) of the country and governed by the Directorate General of Family Planning of Ministry of Health and Family Welfare in Bangladesh and serve a population of 24,000-30,000 on average [14]. In each UH&WFC, one female health worker, known as 'Family Welfare Visitor (FWV)', is posted to provide antenatal, childbirth and postnatal care, and family planning services 6-days a week. In addition to the regular UH&FWC-based services, FWVs conduct outreach sessions i.e., attend satellite clinics on two selected days every week. These sessions are usually held in a pre-identified household of the village, a school premise, or a community clinic so that FWVs can provide the standard antenatal care and family

planning services close to the community. The FWVs carry the required logistics for antenatal care to the satellite clinics, such as registers, job aids and counselling materials, blood pressure machines with the stethoscope, urine test kits, weighing machine, and essential medicines to provide standard ANC services.

Methods of data collection included – i) observation of ANC services provided by FWVs by trained paramedics, and ii) reassessment of the pregnant women by trained physicians which was considered the *gold standard* for validating the FWV's assessment.

Study site

We conducted the study in 26 UH&FWCs selected purposively from four sub-districts of three districts (Habiganj, Noakhali, and Lakshmipur) in Bangladesh. In these three districts, USAID funded MaMoni Health Systems Strengthening (MaMoni HSS) project provided technical support to effectively implement the management of hypertensive disorders of pregnancy through existing government health workers [18]. The project trained the FWVs in the selected UH&FWCs on detection, prevention, and management of hypertensive disorders of pregnancy using the loading dose of intramuscular Magnesium Sulphate according to the standard protocol between March and May of 2016. The two-day long training was conducted by expert consultants following the CEmOC training manual developed by the Obstetric and Gynaecological Society of Bangladesh (OGSB). MaMoni HSS also ensured the availability of injectable Magnesium Sulphate and 'urine strip' for urine assessment in government health facilities including UH&FWC, sub-district, and district hospitals through a strong liaison with the Government in these districts. The project also introduced referral slips to ensure that the identified severe preeclampsia or eclampsia cases at the UH&FWCs could be referred to the designated CEmOC health facilities of the respective districts for further management. The project also provided infrastructural and skill improvement inputs to improve the quality of CEmOC services at the referral facilities. MaMoni HSS's inputs at different levels for implementing appropriate detection and management of preeclampsia and eclampsia at antenatal care contact points of the public facilities have been described elsewhere in detail [18].

Data collection

We recruited six female paramedics with 4-years of training by government authorized "Medical Assistant Training School (MATS)" and three physicians for the study. After recruitment, the paramedics and the physicians received a 3-day training on ANC and hypertensive disorders of pregnancy using the national protocol for detection and management of preeclampsia and eclampsia. Following the training, both study paramedics and physicians participated in a demonstration on the usage of blood pressure machine and urine assessment kit for standardization in the steps of assessment and recording the result. Before starting the actual data collection, the assessors spent two days in a government training hospital for practising the assessment tools, blood pressure machine, and urine test kits.

Study paramedics stayed in the ANC consultation room and collected observation-based data when the FWV provided the ANC services. They observed ANC service provided by the FWVs both at UH&FWCs and satellite clinics using a structured observation checklist. The checklist was developed from the components of the WHO focused ANC guideline and incorporated the detail of steps for diagnosing and managing hypertensive disorders of pregnancy [17, 19]. The observers recorded whether the health worker asked about the relevant history of current and previous pregnancy (if any), performed routine examinations such as measuring blood pressure and assessing urine for protein and made a diagnosis for any of the four hypertensive disorders of pregnancy- gestational hypertension, preeclampsia, severe preeclampsia, and eclampsia. The observers also recorded the diastolic and systolic blood pressure, and the findings from urine assessment as measured by the FWVs in the checklist. If the FWVs provided the first dose (i.e., the loading dose) of injectable Magnesium Sulphate to a diagnosed case of severe preeclampsia and eclampsia as per the protocol and/or referred the pregnant woman to CEmOC equipped health facilities, it was also recorded in the checklist. They also extracted the obstetric and background information of the pregnant women from the FWV's ANC registers.

After completion of ANC service provision by the FWV, gold-standard study physicians reassessed every pregnant woman for the symptoms of hypertensive disorders of pregnancy following the standard national protocol. The study physicians measured the diastolic and systolic blood pressure and tested urine for the presence of protein and recorded the information in a structured form. Study physicians conducted the reassessments in a space with auditory and visual privacy and separate from the routine ANC consultation room so that the reassessment

activities were less likely to bias the routine practices of FWVs. The physicians independently applied the national protocol to identify the presence of any of the four conditions of hypertensive disorders. To avoid bias during the reassessment of a woman, the study physicians were unaware of any diagnosis or management provided by the FWVs before the reassessment. For example, where an FWV managed a diagnosed case of preeclampsia or severe preeclampsia by administering the first dose of injectable Magnesium Sulphate, the study physicians still reassessed the woman. In another situation, where an FWV missed the diagnosis of hypertensive disorders of pregnancy but the case was identified by the study physician, on ethical grounds, the woman was sent back to the FWV with a suggestion from the study physician to re-evaluate the woman. According to the ethical principles, once these women were diagnosed with hypertensive disorders of pregnancy by physicians (gold-standard) and were referred to a re-evaluation by FWV, it was guaranteed that these women received appropriate management and followed the instructions given by the FWV.

Between October 2017 to February 2018, we conducted observation and reassessment of a total of 1560 ANC consultations, 955 in UH&FWCs and 605 in satellite clinics. The study physicians also assessed the readiness status of the 26 selected UH&FWCs for screening and managing hypertensive disorders of pregnancy using a structured health facility assessment checklist. The checklist included information on maternal service availability, human resources, availability of Magnesium Sulphate, urine strip, functional BP machine, and other required logistics. This checklist was adapted from an evaluation survey exploring the quality of antenatal care in government health facilities of Bangladesh [20].

Data quality assurance and management:

Several data quality checks were in place to correctly record and perform the assigned tasks by the data collectors. The most critical element of the study was the ascertainment of systolic and diastolic blood pressure and protein in urine during reassessment. To measure the blood pressure, manually inflated aneroid sphygmomanometers were used by the study physicians as this instrument was routinely used by the FWVs in UH&FWCs. This type of sphygmomanometer is more portable and preferable for community-level health services than any other blood pressure measuring devices, though considered less accurate than a mercury sphygmomanometer [21, 22]. To minimize the variation in measurements during reassessment, blood pressure was measured

twice for each ANC recipient in the same hand (right arm, unless there was any clinical or physical condition), on a sitting position, and at 5 minutes of resting interval between two measurements. Both measurements were recorded during the reassessment by the study physicians and the average of these two measurements was used in the statistical analysis. The standard procedures were also maintained during the 'Non-Communicable Disease Risk Factor Survey Bangladesh 2010' [23] and suggested in the 'WHO STEPS guideline' [24]. For urine reassessment, a sample of urine was collected in a test tube maintaining adequate sterility and hygiene. Reagent strips for urine analysis were used to assess the presence of protein in the sample. The same test-strips were also being used in the selected UH&FWCs for ANC services as supplied by the government with support from MaMoni HSS.

Study paramedics reviewed each other's ANC observation checklist for completeness before submitting it to the study physician of the team who rechecked each form for missing information or inconsistency. Throughout the study period, one medical officer of the central research team conducted spot-checking i.e., made unscheduled visits to study sites, reviewed the collected data on the spot, and provided necessary feedback to the study physicians and the paramedics. Regular monitoring and supervision were conducted by the central team of research investigators led by the principal investigator of the study.

A central data management team was responsible for data entry, consistency checking, and cleaning. All data were entered into the database using a custom-designed data entry program with built-in range and consistency checks.

Definition of variables and data analysis:

Four conditions, namely gestational hypertension, preeclampsia, severe preeclampsia, and eclampsia were collectively considered the hypertensive disorders of pregnancy in this study, and their operational definitions are summarized in Table 1. The diagnostic criteria mentioned in the operational definitions followed the nationally adapted protocol for the detection and management of hypertensive disorders of pregnancy (supplementary file 1). The study physicians reassessed each ANC recipient, performed the required examinations, and applied the diagnostic criteria based on their assessment to reach a diagnosis. For the FWVs, on the other hand, if they made a diagnosis of one of the four hypertensives disorders of pregnancy and

recorded it on the ANC register or the ANC card of the recipient, it was considered as the 'case detected by FWV' irrespective of the validity of their assessment for such conditions. In case the FWVs did not record or document any diagnosis for a pregnant woman, the diagnosis was considered as 'no hypertensive disorder of pregnancy'.

Table 1: Operational definitions of hypertensive disorders of pregnancy

Hypertensive disorders of pregnancy	Diagnostic criteria
Gestational hypertension	• Gestational age: 20 weeks or more, AND • Diastolic blood pressure: 90-109 mm Hg, AND • Protein in urine: Nil, AND • Absence of all three danger signs- severe headache, blurred vision, and upper abdominal pain
Preeclampsia	• Gestational age: 20 weeks or more, AND • Diastolic blood pressure: 90-109 mm Hg, AND • Protein in urine: Present, AND • Absence of all three danger signs- severe headache, blurred vision, and upper abdominal pain
Severe preeclampsia	Definition#1: • Gestational age: 20 weeks or more, AND • Diastolic blood pressure 90-109 mm Hg, AND • Protein in urine: Present, AND • Presence of at least one of the three danger signs- severe headache, blurred vision, and upper abdominal pain Definition#2: • Gestational age: 20 weeks or more, AND • Diastolic blood pressure: 110 mm Hg or more, AND • Protein in urine: Present
Eclampsia	• Gestational age: 20 weeks or more, AND • Diastolic blood pressure: 90 mm Hg or more, AND • Convulsion

Descriptive statistics were used to report the background characteristics of the ANC recipients; competency of the FWVs in screening, detection, and management of hypertensive disorders of pregnancy and presented in percentage of cases who received health services (exploring clinical symptoms, performing screening procedures, counselling, providing injectable Magnesium Sulphate, and referral) in adherence to the standard ANC guideline. The background characteristics of the ANC recipients and the findings on screening procedures were further

stratified by place of service delivery – UH&FWC and satellite clinics. Pearson's chi-squared test was conducted to assess whether participants' characteristics were significantly different between UH&FWC and satellite clinics and assess the significance of the association between the FWV's practice and place of service delivery.

Inter-rater agreement between FWV and study physician was measured using percent agreement. Cohen's kappa coefficient along with the p-value was also estimated to account for the possibility of finding the agreement by chance. Cohen's kappa coefficient describes the strength of inter-rater agreement by comparing the observed agreement to the expected agreement, assuming the measurements are independent [25]. Sensitivity, specificity, and positive predictive values were calculated for assessing the validity of FWV's diagnosis of - i) any hypertensive disorder of pregnancy (including gestational hypertension) and ii) preeclampsia, severe preeclampsia or eclampsia. For sensitivity and specificity analysis of the conditions (i) and (ii), the measurements and diagnosis made by the study physicians were considered as 'true' or 'gold standard'. Sensitivity was expressed as the percentage of 'cases detected by FWV' among those who had 'true' medical criteria for hypertensive disorders of pregnancy, specificity was expressed as the percentage of non-cases detected by FWV among those who did not have 'true' medical criteria for those conditions, and the positive predictive value was expressed as the percentage of 'true' cases among the 'case detected by FWV' as hypertensive disorders of pregnancy. As part of the validity analysis, two scenarios were compared with the study physician's diagnosis (gold-standard) – i) diagnosis that was made by FWV and recorded in the ANC registers/ANC card irrespective of using the algorithm present in the national protocol for detecting hypertensive disorders of pregnancy, and ii) post-hoc diagnosis using the information from FWV's measurement of blood pressure and urine assessment, the status of danger signs from study physician's assessment and applying the algorithm during analysis. The latter indicates the extent to which cases could have been accurately diagnosed had the two diagnostic criteria (elevated blood pressure and protein in the urine) been appropriately used as per the national protocol for hypertensive disorders of pregnancy by FWVs.

Pearson's correlation coefficient was reported along with p-values to estimate the relationship between the measurements taken by the FWV and the study physician. The comparison is presented in scatterplot graphs by plotting blood pressure recordings taken by FWVs against

those taken by study physicians. Mean and standard deviation of absolute difference of blood pressure readings taken by FWVs and study physicians are calculated to estimate the accuracy of FWV's measurement of diastolic and systolic blood pressure. A first-order polynomial smooth curve of the absolute differences is also fitted in the scatter plot to show the deviation from the 'true' values. Accuracy of urine assessment is presented in the percentage of cases where FWV could correctly identify if there was 'no protein' or 'some protein' in the urine. The results of the urine assessment ascertained by study physicians were considered 'correct'. We used the STROBE cross-sectional checklist when writing this manuscript [26].

Patient and public involvement:

The study objectives and outcome measures were related to assessing the competency of health workers in detecting and managing gestational hypertension, preeclampsia, severe preeclampsia and eclampsia during antenatal check-ups in primary care health facilities in Bangladesh. Pregnant women were not involved in the design of, in the recruitment to and conduct of the study. The results will be disseminated among the health managers and maternal health workers in the government hospitals where the study was conducted.

Ethical consideration

The study protocol was reviewed and approved by the Ethical Review Committee (ERC) of the International Center for Diarrheal Disease Research, Bangladesh (icddr,b) (protocol number PR-17084). Permission was taken from the Ministry of Health and Family Welfare and health managers of the selected health facilities were informed about the study. Written informed consent was obtained from the FWVs and verbal consent was sought from ANC service recipients during clinical observations. The respondents participated in the study voluntarily and had the right to withdraw themselves from the study at any time even after giving the consent. Privacy, anonymity, and confidentiality of the data were strictly practised and restrictions on access to data were enforced.

This study was not a clinical investigation. MaMoni HSS project only provided technical support for the implementation of the nationally adopted intervention of community-based provision of

the loading dose of Magnesium Sulphate to the identified cases of severe preeclampsia and eclampsia through the government health system. Nonetheless, systematic reviews and the efficacy trials of Magnesium Sulphate have already proven that the drug is safe with no major side effects [27-29].

Result

Readiness of UH&FWCs

All 26 UH&FWCs provided antenatal services and the mean (± SD) number of ANC provided in a month was 111 (±83) (data not presented in a table). All the UH&FWCs had one designated FWV who provided ANC, childbirth, postnatal care, and family planning services. She also conducted regular satellite sessions twice a week to provide the same health services in the satellite clinics. All 26 FWVs received hands-on training on screening, diagnosing, and managing hypertensive disorders of pregnancy. In only seven UH&FWCs (27%), at least one case of diagnosing and managing preeclampsia in the last three months preceding the assessment was reported. The blood pressure machines and urine strips for assessing protein in urine were available in all 26 health facilities, but three did not have injectable Magnesium Sulphate available during the assessment period. The standard national guideline for managing hypertensive disorders during ANC was available in only 16 out of 26 facilities. The readiness of the satellite clinics regarding the service provision and logistics remained similar to that in the UH&FWC since the FWV carried the ANC logistics with her while attending the satellite sessions.

Characteristics of pregnant women and information on ANC care-seeking

Of the 1560 pregnant women, 955 (61%) received ANC at UH&FWCs and the rest at satellite clinics (Table 2). About 69% of women were aged between 20 to 29 years and 38% were first-time mothers (primigravida). One in five women came for ANC after 20 weeks of gestational age; among them, 40% came for the first antenatal visit. The gestational age and the order of the ANC visits of the participants were significantly different between those who received care at UH&FWCs and satellite clinics.

Table 2: Characteristics of pregnant women and information on ANC care-seeking

Characteristics, N= 1560	All, %	UH&FWC, %	SC, %	p-value[1]
Total pregnant women, n	1560	955	605	
Age (in years)				
Less than 20	16.7	17.1	16.0	0.544
20-24	38.4	38.0	39.0	
25-29	30.6	31.4	29.3	
30 and above	14.4	13.5	15.7	
Gravida				
Primigravida	38.1	38.6	41.2	0.547
Multigravida	61.9	61.4	58.8	
Gestational age				
less than 20 weeks	79.9	82.0	76.7	0.011
20 weeks or more	20.1	18.0	23.3	
ANC Visit[2]				
1st visit	59.5	54.7	67.1	<0.0001
2nd or more	39.7	44.3	32.6	

UH&FWC: Union health and family welfare centre, SC: Satellite clinic

[1] Pearson's chi-squared test

[2] 12 missing information

Screening and assessment by FWV for hypertensive disorders of pregnancy during ANC

During antenatal service provision, FWVs asked only 8% of women whether they had a history of hypertension or taking any anti-hypertensive drug or of preeclampsia (if the women had previous pregnancy) (Table 3). Symptoms of preeclampsia for the current pregnancy such as severe headache, blurring of vision, upper abdominal pain, were assessed among 15%, 12%, and 18% of women, respectively. Only for 12% of women, any occurrence of convulsion during their current pregnancy was explored. FWVs were more likely to ask these screening questions if the services were given at a UH&FWC than in a satellite clinic ($p<0.05$). Blood pressure and urine assessment, two critical examinations for diagnosing the presence and severity of hypertensive disorders of pregnancy, were conducted among 97% and 76% of the women, respectively.

Table 3: Screening and assessment by FWV for hypertensive disorders of pregnancy

Screening and assessment by FWV during ANC	All, %	UH&FWC, %	SC, %	p-value[1]
Total pregnant women, n	1560	955	605	
Asked about last menstrual period	93.5	90.1	98.8	<0.0001
Asked whether the women had				
History of hypertension or using any anti-hypertensive drug or preeclampsia in a previous pregnancy	8.3	10.1	5.6	0.002

History of diabetes	3.8	4.7	2.5	0.025
History of renal disease or urine infection	0.9	1.4	0.2	0.015
Severe headache	14.8	19.1	8.1	<0.0001
Blurring of vision	11.9	15.9	5.6	<0.0001
Upper abdominal pain	18.3	25.0	7.6	<0.0001
Any episode of convulsion	12.1	15.7	6.5	<0.0001
Performed/examined				
Blood pressure measurement	97.4	98.1	96.2	0.021
Urine assessment	76.5	76.5	76.5	0.994

UH&FWC: Union health and family welfare centre, SC: Satellite clinics

[1] Pearson's chi-squared test

Accuracy of FWV's assessment of blood pressure and urine

Blood pressure measurement: Figure 1 and Figure 2 plot the diastolic and systolic blood pressures of pregnant women, respectively, as recorded by the FWVs against those recorded by the study physicians. Both figures show a tendency of FWVs to round off the blood pressures to the nearest tenth of the unit which either under-estimated or over-estimated the 'true' values as evident by comparing with the study physicians' measurements. The correlation coefficients of the measurements taken by FWV and the study physician was 0.50 (p-value <0.0001) for diastolic pressure and 0.60 (p-value <0.0001) for systolic pressure, which indicates a significant moderate positive relationship. Overall, the mean (±SD) absolute difference between FWV and the study physician's measurement of diastolic and systolic blood pressure of the same person was 7.1± 7.6 and 7.5± 8.4 mmHg, respectively (not presented in the table). The polynomial smooth curve of the absolute differences between the study physician and FWV's measurement shows larger differences (>10 mmHg) when the 'true' diastolic pressure was higher than 100 mmHg or 'true' systolic pressure was higher than 160 mmHg. The difference also widened when 'true' diastolic pressure was below 50 mmHg or 'true' systolic pressure was below 100 mmHg.

Figure 1: Diastolic BP: recorded by FWV vs. Study physician

Figure 2: Systolic BP: recorded by FWV vs. Study physician

Urine assessment: Although there was high correct identification of 'no protein' in urine, only 27% of those who had 'some protein' were accurately diagnosed by FWVs (Figure 3).

Figure 3: Protein in urine: accurately diagnosed by FWV

Status of hypertensive disorders of pregnancy

The 'true' prevalence for gestational hypertension, preeclampsia, and severe preeclampsia diagnosed by the study physicians, was 2.1%, 1.9% and 1.0%, respectively (Table 4). The numbers of cases identified by the FWVs were substantially lower than the 'true' prevalence for all three types of hypertensive disorders. No woman was diagnosed with eclampsia by the study physician or FWV. Although the numbers are too small to compare, the FWVs could detect a higher proportion of cases of hypertensive disorders if they provided care in UH&FWCs than in satellite clinics.

Table 4: Prevalence of hypertensive disorders of pregnancy

Hypertensive disorders of pregnancy	Cases identified/diagnosed by					
	Study physician[1]			FWV[2]		
	All, n(%)	UH&FWC n(%)	SC n(%)	All, n(%)	UH&FWC n(%)	SC n(%)
Total pregnant women, n	1560	955	605	1560	955	605
Gestational hypertension	32 (2.1)	18 (1.9)	14 (2.3)	12 (0.8)	11 (1.1)	1 (0.1)
Preeclampsia	29 (1.9)	18 (1.9)	11 (1.8)	6 (0.4)	4 (0.4)	2 (0.3)
Severe Preeclampsia	16 (1.0)	9 (0.9)	7 (1.2)	4 (0.3)	4 (0.4)	0
Eclampsia	0	0	0	0	0	0

UH&FWC: Union health and family welfare centre, SC: Satellite clinics

[1] According to the national protocol for hypertensive disorders of pregnancy based on the information recorded by study physician after reassessment of the pregnant women

[2] According to FWV's note recorded in ANC register/ANC card after ANC was provided

The validity of the diagnosis of hypertensive disorders of pregnancy

FWV's diagnosis recorded in ANC register: Only in 3%, 7%, and 25% of true cases of gestational hypertension, preeclampsia, and severe preeclampsia, respectively, FWVs made a correct diagnosis during ANC (Table 5). Percent agreement for the diagnosed cases of hypertensive disorders of pregnancy is 9% and kappa statistics is 0.05 (p-value 0.0125). For identification of any hypertensive disorders, sensitivity, and positive predictive value (PPV) is only 14% and 50%, respectively. For identification of preeclampsia or severe preeclampsia or eclampsia, sensitivity and PPV are 18% and 80% respectively. In both cases, specificity is high (>99%).

Post-hoc diagnosis based on FWV's assessment of blood pressure and urine: When the diagnosis was made by applying the algorithm present in national protocol based on the two diagnostic criteria (elevated blood pressure and protein in the urine) measured by FWVs and status of three danger signs assessed by study physicians the accuracy of diagnosis (i.e., the percentage of 'true' cases accurately diagnosed), was markedly increased from that of the FWVs' original diagnosis of the conditions (Table 5). For instance, at least 63% of 'true' cases of severe preeclampsia could be diagnosed if the protocol had been applied correctly by an FWV based on her assessment of blood pressure and urine. The percent agreement also improves from 9% to 29% and kappa statistics is 0.19 (p-value <0.0001). Moreover, in this scenario, both sensitivity and PPV of diagnosing 'any hypertensive disorder' and 'preeclampsia and/or severe preeclampsia ' are markedly increased.

Table 5: Validity of diagnosis of hypertensive disorders of pregnancy

	Percentage of true cases[1] accurately diagnosed			Percent agreement[2]	Kappa coefficient	Sensitivity, %		Specificity, %		Positive predictive value (PPV), %	
	Gestational hypertension	PE	Severe PE			Any hypertensive disorder[3]	PE or severe PE	Any hypertensive disorder[3]	PE or severe PE	Any hypertensive disorder[3]	PE or severe PE
Diagnosis made by FWV[4]	3.1	6.9	25.0	9.1	0.05*	14.3	17.8	99.3	99.9	50.0	80.0
Diagnosis based on FWV's assessment of BP and urine[5]	25.0	13.8	62.5	28.6	0.19*	35.1	31.1	99.0	99.9	64.3	93.3

* $p<0.05$

PE: Preeclampsia; BP: Blood pressure

[1] Cases identified by study physician as hypertensive disorders of pregnancy

[2] Among the cases with hypertensive disorders of pregnancy

[3] Gestational hypertension, or preeclampsia, or severe preeclampsia or eclampsia

[4] According to FWV's note recorded in the ANC register/ANC card after ANC was provided

[5] According to the national protocol for hypertensive disorders of pregnancy based on the two diagnostic criteria (elevated blood pressure and protein in the urine) measured by FWV

Management provided by FWV

The women who were diagnosed to have any hypertensive disorders of pregnancy by FWVs were more likely to be counselled on at least one danger sign of preeclampsia (severe headache, blurring of vision and upper abdominal pain) than those without such diagnosis (41% vs. 19%, p-value 0.008). The FWVs provided anti-hypertensive drugs only for those with the diagnosis of gestational hypertension and preeclampsia (Table 6). All four cases of severe preeclampsia were given a loading dose of intramuscular Magnesium Sulphate and three among them were referred to a higher facility.

Table 6: Management of hypertensive disorders identified by FWV during ANC at UH&FWC

Cases diagnosed by FWV	Received in-facility management, n(%)			Referred, n(%)
	Counselling[1]	Anti-hyper tensive[2]	Magnesium Sulphate[3]	
No hypertensive disorders, n=1538	287 (18.7)	n/a	n/a	n/a
Gestational hypertension, n=12	4 (33.3)	1 (8.3)	n/a	1 (8.3)
Preeclampsia , n=6	2 (33.3)	1 (16.7)	n/a	3 (50.0)
Severe preeclampsia , n=4	3 (75.0)	0 (0)	4 (100.0)	3 (75.0)

[1] Counselling on at least one danger signs of preeclampsia
[2] Oral Hydralazine, Nifedipine, Labetalol, or Methyldopa
[3] A loading dose of intramuscular Magnesium Sulphate (10 gm)

Discussion

Our study identified gaps in diagnosing hypertensive disorders of pregnancy during ANC in community-level satellite sessions and at primary health care centres in three districts of Bangladesh where USAID funded MaMoni HSS project intervened to improve maternal health care services. The undiagnosed or misdiagnosed cases could be linked with inadequate and inaccurate screening procedures performed by the health workers called FWVs. The study also observed inadequate history taking, inaccuracy in blood pressure measurement and/or recording, and urine assessment for protein. A small proportion of the women who required antihypertensive drugs or counselling on disease management received such. All the detected cases of severe preeclampsia received the first dose of injectable Magnesium Sulphate as per the protocol.

The 'focused ANC package' by the WHO emphasised blood pressure measurement and urine assessment during all ANC visit irrespective of gestational age to screen hypertensive disorders of pregnancy [19, 30]. In our study, nearly all women had their blood pressure measured and about three-fourth had their urinary protein assessed. The MaMoni HSS project trained FWVs on diagnosis and management of preeclampsia and eclampsia before the study and the training could have influenced the high coverage of the screening procedures performed by the FWVs. Detection of hypertensive disorders of pregnancy, however, requires screening for maternal comorbidities and proper history taking for danger signs of preeclampsia and convulsion during the current pregnancy, which was observed inadequate in our study. Nevertheless, the poor quality of ANC is consistent with that in other low and middle income (LMIC) countries including Bangladesh [20, 31]. The practice was also significantly lower when the women received ANC in satellite or outreach sessions compared to in-facility antenatal services as found in another study conducted in rural Bangladesh [32]. The satellite or outreach sessions are often hosted at the household of local rural elites upon their acceptance and the health workers providing ANC in UH&FWCs need to carry all the necessary equipment and register books from the UH&FWC to the place of satellite sessions on the designated day of the week [14]. Due to the makeshift nature of the satellite clinics, access to clean toilet facilities and provision of adequate privacy during physical examinations are often difficult to ensure at the service delivery points [33]. Despite having the required equipment for ANC, poorer readiness of satellite clinics might result in poorer performance of some critical components of ANC such as assessments of dangers signs, blood pressure measurement, and urine assessment at those clinics than in the health facility [20, 33].

Initiatives to improve quality of care often focus on bridging the coverage gap of specific activities by the health workers rather than focusing on the validity of the performed activities or developing reliable screening tools [30, 34]. For instance, blood pressure measurement and urine assessment are two key diagnostic criteria for hypertensive disorders of pregnancy, yet their accurate ascertainment receives low priority in the training schemes for health workers in LMICs [35]. Our study found inconsistency in measured blood pressure between the health workers' assessment and the 'true' value especially when the blood pressure was beyond the normal range. This might allude to the tendency of the FWVs to record blood pressure within the normal range without accurately measuring the blood pressure of the ANC client. The study also

detected terminal digit bias for both systolic and diastolic blood pressure recordings i.e., the tendency to report the values ending in zero. One study suggests that the occurrence of recordings ending in zero in more than 30% cases, in general, indicates imprecise and inaccurate recording [36]. Periodic checking of the ANC registers for terminal digit bias by the supervisors could minimize such practice.

Despite the overall low sensitivity and positive predictive values for detecting hypertensive disorders of pregnancy by the FWVs, our study found an increase in these parameters when the algorithm present in the preeclampsia protocol was applied to diagnose the disease condition using the recordings of the screening tests performed by FWVs. This indicates either poor adherence to the evidence-based guideline or improper interpretation of the national protocol by the FWVs while reaching a diagnosis. Unavailability of the ANC protocol in 16 out of the 26 assessed health facilities could further worsen the knowledge gap of the health workers regarding the disease diagnostic criteria. A landscape-analysis on preeclampsia and eclampsia conducted in Bangladesh concluded that preeclampsia/eclampsia guideline was not available in any of the assessed community-level primary health care centres i.e., UH&FWCs and only 8% of health workers working there knew that a national guideline on diagnosis and management of preeclampsia/eclampsia existed [15]. Although we have not assessed the reasons for the unavailability of the ANC protocol, lack of regular monitoring of the presence and use of guidelines in community level health facilities and lack of knowledge of the health workers about the content of the guidelines are some critical barriers to maintaining and keeping the guidelines in the facility [18, 34, 36]. In addition to putting effort from the central level to make the guidelines available in health facilities, the ANC providers should be made aware of the diagnostic criteria of hypertensive disorders of pregnancy and trained to accurately assess danger signs, measure blood pressure and urinary protein. A review paper on improving the quality of care in LMICs suggested that capacity development training should also maintain strong supportive supervision, along with the provision of on-site feedback based on health workers' performances, and audit of ANC registers and case reports to improve health workers' adherence to the evidence-based guidelines [38].

In our study, a subtotal of 16 'true' cases of severe preeclampsia was identified by the study physicians and these cases required the first dose of Magnesium Sulphate injection before their

referral to a higher-level facility. Since only 4 of them were correctly identified by the FWVs, the rest received no Magnesium Sulphate injection due to the missed diagnosis of the cases. The study physicians, however, had sent these women back to the FWV for re-evalutaion and guaranteed that they received appropriate care on ethical grounds. Counselling regarding the hypertensive diseases of pregnancy or the provision of anti-hypertensive drugs to detected cases was also inadequate. The failure in the timely management of hypertensive disorders of pregnancy, therefore, poses a serious challenge in preventing maternal morbidity and mortality in LMICs. Besides improving the knowledge and skill of the ANC providers, prediction of risk and detection of cases can be aided by initiating a computerized clinical decision support system (CDSS) which has been proven effective for improved provider-care seeker communication and clinical decision making [39]. Unlike in developed countries, where CDSS was effective in improving health workers' performances [40], implementation of such technology in developing countries could be challenging in the context of poor availability of health information, inadequate infrastructure, and limitation of skilled human resources [41]. Since the adoption of the national eHealth policy in 2011 [42], Bangladesh is progressing with establishing electronic management information system (e-MIS) in the health facilities and has started to provide community health workers with computer tablets or smartphones to deliver essential health services on the pilot basis [43]. The integration of CDSS into the e-MIS initiative could contribute to the sustainability of improving the quality of care during ANC, and thus the screening of hypertensive disorders. Further research is needed to identify and address potential constraints for smooth implementation of the decision support technology to ensure proper detection and management of gestational hypertensive disorders in Bangladesh and other developing countries.

Conclusion

Consistent application of the national protocol supports clinical-decision making by health workers during the provision of ANC. Efforts should be directed at accurate application and interpretation of the national protocols or guidelines by health workers as a prerequisite for task shifting for the detection and management of hypertensive disorders of pregnancy at primary level health facilities and outreach centres. The training of ANC health workers should emphasize the risk assessment of pregnant women with a practical demonstration on assessing

the diagnostic criteria and management of eclampsia and preeclampsia. Strengthening the monitoring and supervision can further improve the screening of preeclampsia and severe preeclampsia and timely management of such cases to prevent eclampsia.

Author statement

SMB, SEA and JG conceptualized the paper. SMB, ANSK, SMR, NLH, MAK, SSP and IIM were involved in data acquisition, analysis, interpretation and literature review. SMB, ANSK, and SMR prepared the first draft. SMB, ANSK, SMR, NLH, MAK, IIM, SR, SEA, and JG contributed to the revision and preparation of the final draft. All authors have reviewed and approved the final manuscript.

Acknowledgement

We acknowledge the Director (MCH Services) of Directorate General of Family Planning and Deputy Director Family Planning of Habiganj, Noakhali, and Lakhsmipur districts for allowing us to conduct the study. We also acknowledge the support from health workers and pregnant women for accepting us to observe the service delivery procedure and providing necessary information. Also, icddr,b gratefully acknowledges the following donors who provide unrestricted support: Government of the People's Republic of Bangladesh; Global Affairs Canada (GAC); Swedish International Development Cooperation Agency (Sida) and the Department for International Development, (UKAid). We used the STROBE cross-sectional checklist when writing this manuscript.

Funding

This study was undertaken, and the article was produced as a part of MaMoni Health Systems Strengthening's (MaMoni HSS) learning agenda with the generous support of the American people through the United States Agency for International Development (USAID); Associate Cooperative Agreement No. AID-338-LA-13-00004. The views expressed in this article are solely the views of the authors and do not reflect the views of the United States Agency for International Development or the United States Government.

Conflict of interest

None declared

Data statement

Technical appendix, statistical code, and dataset available from a public repository [DOI: https://doi.org/10.6084/m9.figshare.12554330.v1]

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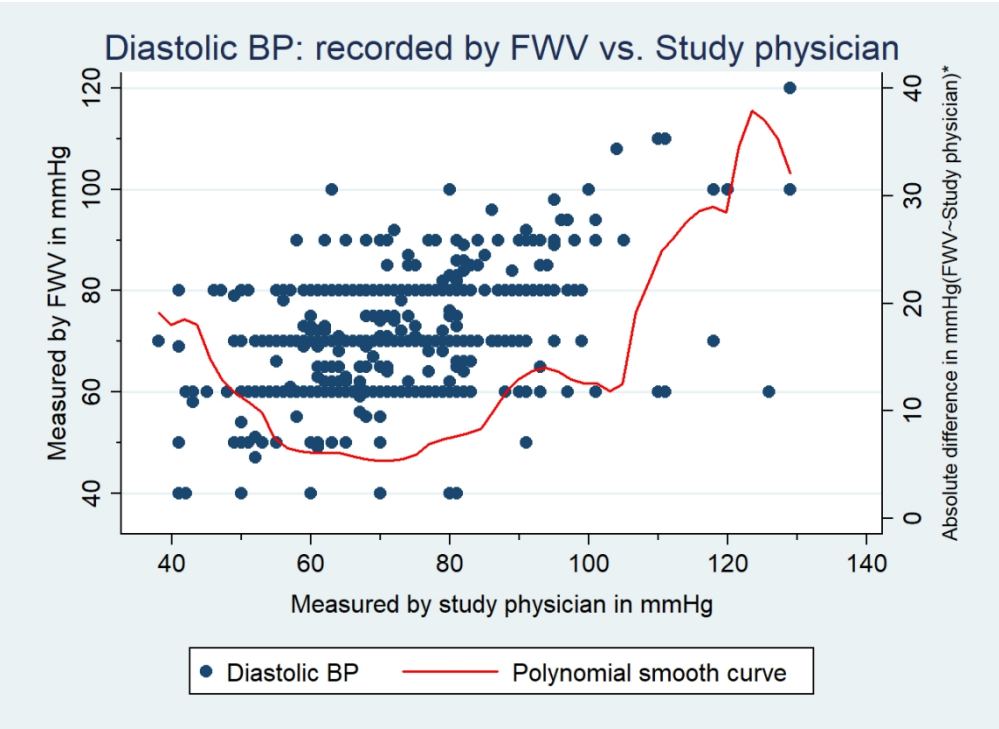
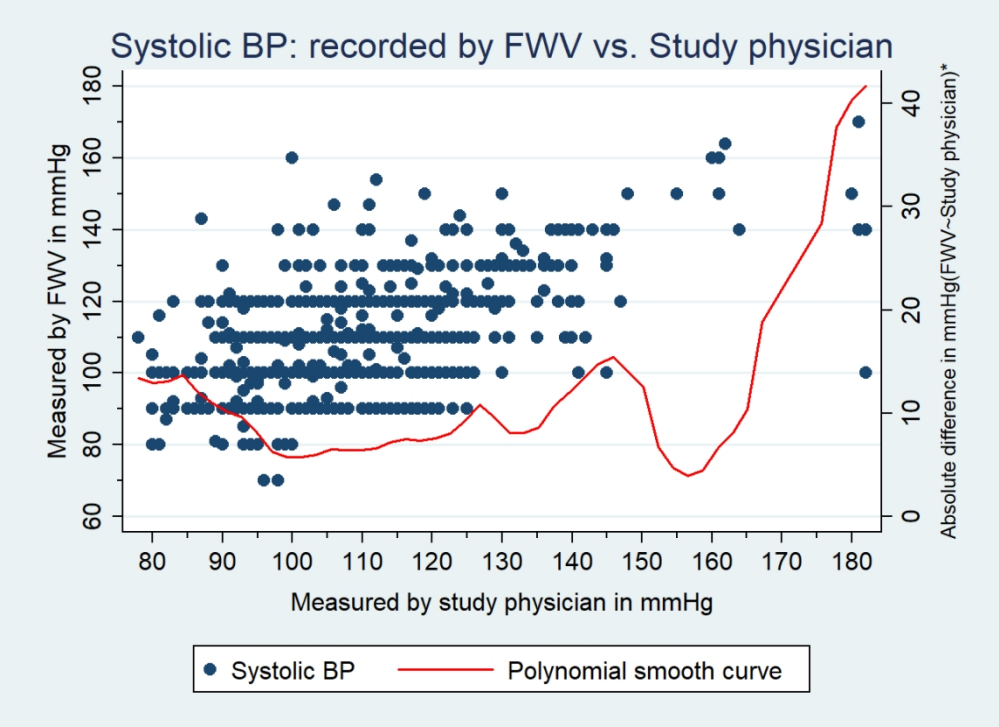


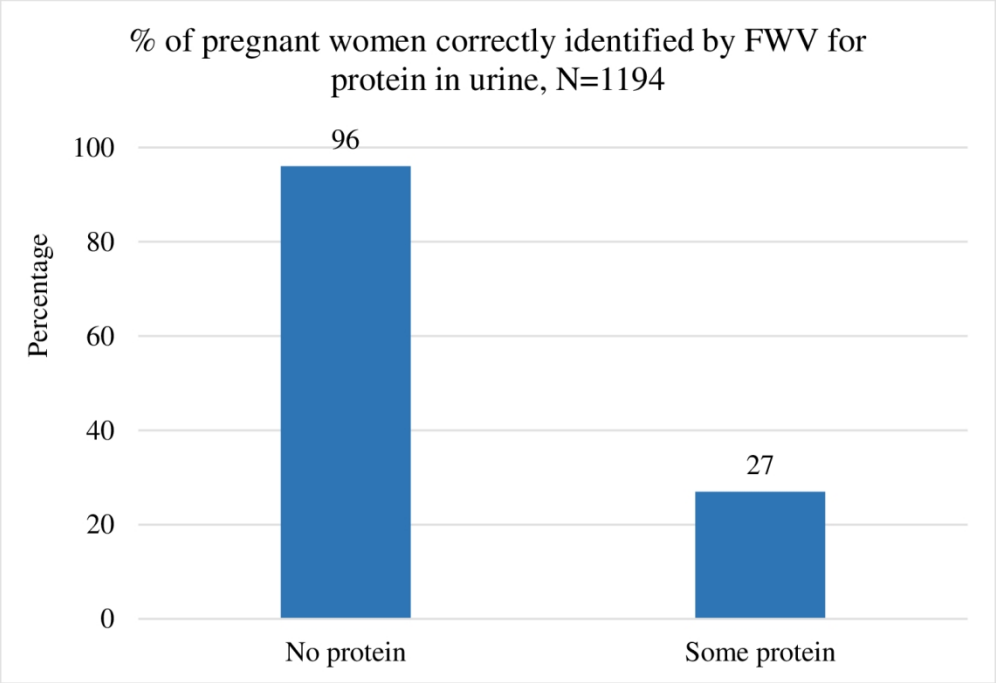
Diastolic BP: recorded by FWV vs. Study physician

108x78mm (300 x 300 DPI)



Systolic BP: recorded by FWV vs. Study physician

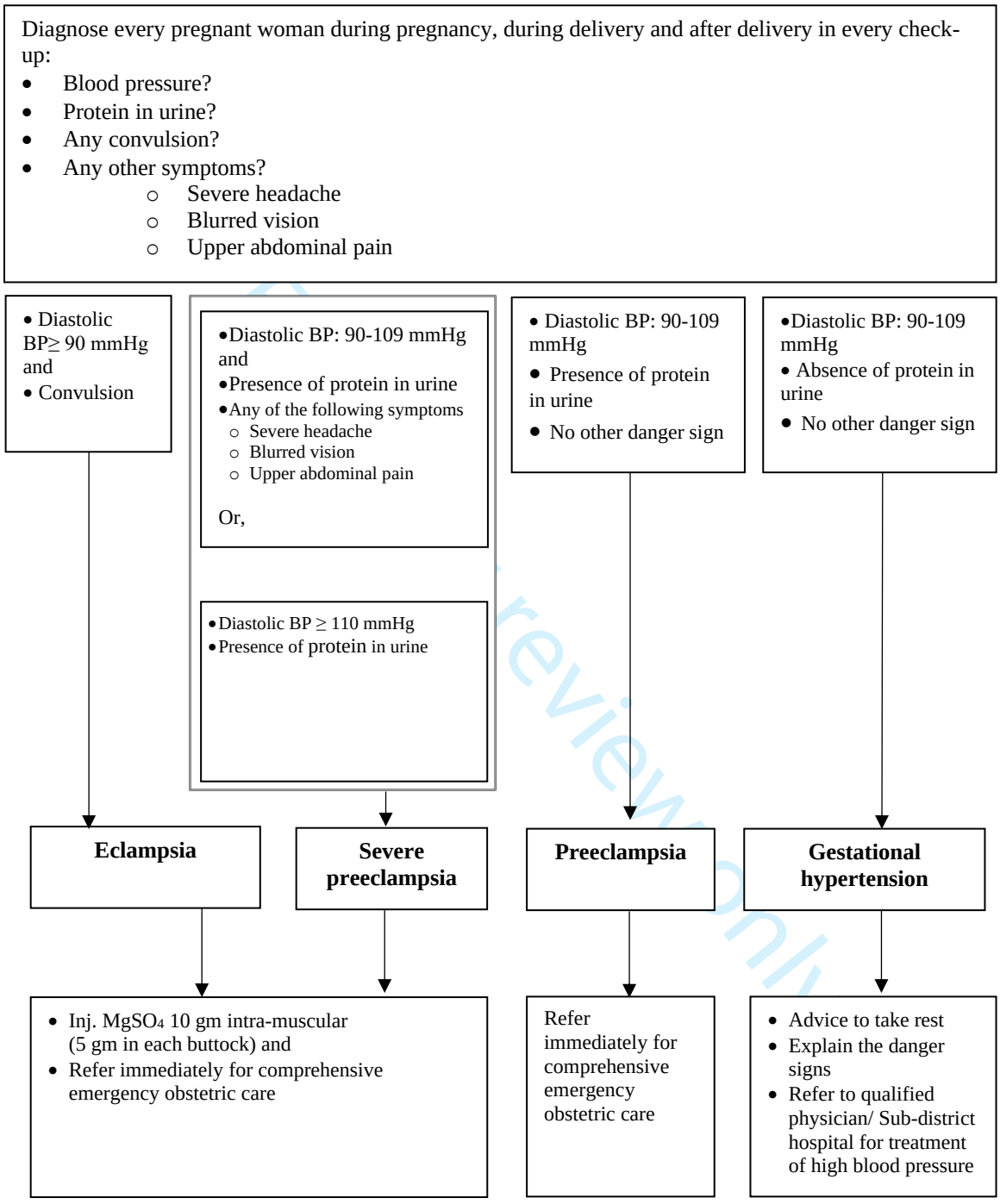
108x78mm (300 x 300 DPI)



Protein in urine: correctly identified by FWV

137x94mm (300 x 300 DPI)

Supplementary file 1: Management guideline of preeclampsia, severe preeclampsia and eclampsia in Bangladesh



Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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		Reporting Item	Page Number
Title and abstract			
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	1

Abstract	#1b	Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background / rationale	#2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	#3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	#4	Present key elements of study design early in the paper	5-6
Setting	#5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants.	7-8
	#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9-10
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	9-12

Bias	#9	Describe any efforts to address potential sources of bias	8-9
Study size	#10	Explain how the study size was arrived at	8
Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	9-12
Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	9-12
Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	9-12
Statistical methods	#12c	Explain how missing data were addressed	9-12
Statistical methods	#12d	If applicable, describe analytical methods taking account of sampling strategy	9-12
Statistical methods	#12e	Describe any sensitivity analyses	9-12
Results			
Participants	#13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.	12-18
Participants	#13b	Give reasons for non-participation at each stage	n/a

Participants	#13c	Consider use of a flow diagram	n/a
Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	13
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	13-19
Outcome data	#15	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	13-19
Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	13-19
Main results	#16b	Report category boundaries when continuous variables were categorized	13-19
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	13-19
Discussion			
Key results	#18	Summarise key results with reference to study objectives	19

Limitations	#19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	3
Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	19-22
Generalisability	#21	Discuss the generalisability (external validity) of the study results	3
Other Information			
Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	23