A critical appraisal of the quality of care of hypertensive disorders of pregnancy at primary care level in the Southern region of Sierra Leone

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# A critical appraisal of the quality of care of hypertensive disorders of pregnancy at primary care level in the Southern region of Sierra Leone

A thesis submitted in partial fulfilment of the requirement for the degree of

Master of Science in International Health

by

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Sierra Leone

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## List of abbreviations

ANC Antenatal care

BEMONC Basic emergency obstetric and neonatal care

CEMONC Comprehensive emergency obstetric and neonatal care

CHC Community health center
CHO Clinical health officer
CHP Community health post

CUAMM An Italian NGO, with Italian acronym for Doctors with Africa

FHCI Free health care initiative

GA Gestational age

HDP Hypertension disorders of pregnancy

HCW Health care worker HR Human resources

KIT Dutch acronym for the Royal tropical institute in Amsterdam

MCHP Mother and child health post MCHAID Mother and child health aid

MGSO4 Magnesium sulphate MMHG Millimetre of mercury

NEMS National emergency ambulance service

NGO No governmental organization

NNT Number needed to treat

OR Odds ratio
PE Pre-eclampsia

PIERS Pre-eclampsia integrated estimation of risk SECHN State enregistered community health nurse

WHO World health organization

## List of Key terms

#### Antenatal care

The care provided by skilled health-care professionals to pregnant women and adolescent girls in order to ensure the best health conditions for both mother and baby during pregnancy. The components of ANC include: risk identification; prevention and management of pregnancy-related or concurrent diseases; and health education and health promotion (1)

#### Hypertensive disorders of pregnancy

An umbrella term that includes pre-existing and gestational hypertension, pre-eclampsia, and eclampsia, complicating up to 10% of pregnancies and representing a significant cause of maternal and perinatal morbidity and mortality (2).

## Mild hypertension

A systolic blood pressure ≥ 140 mmHg but below 160 mmHg or a diastolic blood pressure ≥ 90 mmHg but below 110 mmHg based on an average of at least two measurements taken at least 15 minutes apart, using the same arm (3).

## Severe hypertension

A systolic blood pressure  $\geq$  160 mmHg or a diastolic blood pressure  $\geq$  110 mmHg based on an average of at least two measurements taken at least 15 minutes apart, using the same arm (3).

### Pre-eclampsia

A new onset of hypertension after 20 weeks of gestational age combined with proteinuria, and/or thrombocytopenia <  $100.000 \, \mu$ l, a serum creatinine > 1,1 mg/dl, liver transaminase levels of at least twice the normal concentration, pulmonary edema, or cerebral or visual symptoms (3).

## Maternal death

A death of a pregnant women, or a death within 42 days after termination of the pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes (4).

## **Abstract**

INTRODUCTION. Sierra Leone is one of the countries with the highest maternal mortality ratios. Hypertensive disorders of pregnancy (HDP) are the second most frequent cause of maternal mortality. Most maternal mortality caused by HDP is preventable if treatment is initiated early. The aim of the current study is to assess the quality of antenatal care (ANC) for HDP in Southern Sierra Leone.

METHODS. A cross-sectional descriptive study was conducted. A questionnaire and knowledge assessment among health care worker (HCW) of 348 health centers in three districts was done. Furthermore, direct clinical observations from ANC visits in 66 peripheral health centers (PHUs) were done combined with patient exit interviews. The Morestin quality assessment framework was used for the study design and analysis of the data.

RESULTS. The study reveals that the screening of HDP is substandard, shown by the fact that half of the PHUs do not have availability of a functional BP machine and dipstick. In PHUs with a functional BP machine only 63% of the patients was measured correctly by the HCW (≤ 15 mmHg difference of the reference). Secondary prevention is not known among HCW and Aspirin is available at 13% of the PHUs. Despite the availability of first line medication, treatment of HDP is substandard due to limited knowledge among HCW on standard treatment of HDP.

DISCUSSION. Quality of ANC for HDP is not up to standard. BP machines with interpretation aid, like CRADLE® and supply of second line antihypertensives are recommended for PHUs. A comprehensive training and supervision program directed at HDP is needed, and secondary prevention with Aspirin is recommended to be included in the antenatal care.

**Keywords;** Hypertensive disorders of pregnancy, Pre-eclampsia, Antenatal care, Quality of care, Sierra Leone

Word count thesis; 10.725

## Country profile

Sierra Leone is a West African country bordering Guinee and Liberia. The population of 7.1 million is divided in 5 administrative regions consisting of a total of 14 districts (Figure 1). The capital, Freetown is based in the Western area urban. The majority of the people (59%) are based in rural settings. The religion is mostly Muslim (78%) followed by Christian (21%) and one percent traditional religions. (5) Sierra Leone is a low income country with a gross domestic product is \$ 630 per capita (6). Two third of the population depends directly on agriculture forestry and fishing and the main export products are diamonds minerals and cacao (5). The literacy rate among adults is 32%; for men 41% and for women 25%. The life expectancy is 51 years for men, and 52 for women (7). The infant mortality rate of 78.5 per 1000 live births and the maternal mortality rate of 1.360 per 100.000 live births (8).



Figure 1, Map of Sierra Leone

#### Context of health care system in Sierra Leone

Health care in Sierra Leone is provided at secondary health care level, primary health care level and community level. Secondary health care facilities include; district government hospitals, regional government hospitals, regional faith-based hospitals, hospitals owned by non-governmental organizations (NGO) and private hospitals. Primary health care is provided in peripheral health units (PHU). These PHUs are classified according the staff level. The lowest level PHU is a Mother and child health posts (MCHP) and are staffed with usually one or two mother and child Health aids (MCHAID). These MCHAIDs receive a basic training of 18 months. Community health post (CHP) is the second level PHU staffed with also a community health assistant (CHA), who received a 2-year university level certificate. The Third level PHU is a community health center (CHC) where a community health officer (CHO) is in charge. The CHO training is three-year university diploma level training. The highest level PHU is a basic emergency obstetric and neonatal care unit (BEmONC), were also a midwife is posted

to supervise maternal health care. In the community, community health workers responsible to treat very basic illnesses, like pneumonia, diarrhea and malaria. Moreover, they are trained to identify referral indications as pregnancy and malnutrition. All health care for pregnant and lactating women and children is free since the introduction of the free health care initiative (FHCI) in 2010, resulting initially in an increase from 30% in institutional deliveries, and 25% for ANC4 visits. However during the Ebola outbreak from 2014-2016 facility deliveries and C section rate decreased again with more than 20% (9). The FHCI is challenged by frequent stockouts of medication and equipment and low staffing, resulting in an increase of pocket expenditures and limiting health care access for the poorest patients and the ones with middle income (10). Moreover in Sierra Leone women from a rural setting, women with less educated, with a Muslim religion are less likely to have an institutional delivery or attend regular ANC visits than urban, more educated and Christian women. (10)

## Southern region.

The Southern region of Sierra Leone consists of 4 districts; Bo, Bonthe, Moyamba and Pujehun. The total population is 1.4 million (5). Its capital is Bo, which is also the second largest city in Sierra Leone. The population is largely from the Mende ethnic group. The main occupational activity among the working population is agriculture with 72% being involved in agriculture, forestry and fishing (5). The Southern Region contains four government hospitals, and three NGO run hospitals and several private clinics and hospitals. The total number of PHUs in the Southern district is 393.

## Background

## Hypertensive disorders

Approximately 1% of pregnancies are complicated by preexisting hypertension, 5-6% by gestational hypertension, 1–2% by pre-eclampsia (3) and 0.05-1% eclampsia (11). The incidence of pre-eclampsia/eclampsia varies greatly among regions. WHO's secondary analysis of the global survey on maternal and perinatal health conducted in 2004-2005 shows the highest incidence in Sub-Sahara Africa and South America 2,3% and 4.0% respectively, based on a global sample of 313,030 deliveries (12). However, a large cross country study among nine million immigrant deliveries in western settings, shows a higher incidence among women with Sub-Sahara African origin compared to south American women (13). In addition, it has even been shown that in low income countries HDP is underdiagnosed due to limited diagnostic capacity. This would imply that the real incidence in Sub Sahara Africa might be higher than the reported 2.3% (14).

## Textbox 1; Definitions of hypertensive disorders of pregnancy

Hypertension in pregnancy is usually defined as a systolic blood pressure ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg. Severe hypertension is defined as systolic blood pressure ≥160 mmHg (3). Pre-eclampsia is a new onset of hypertension after 20 w of gestational age combined with proteinuria (at least 1 positive on protein dipstick, or > 0.3 gr in a 24 h urine specimen) AND/OR combined with thrombocytopenia < 100.000 /μl, a serum creatinine > 1,1 mg/dl, liver transaminase levels of at least twice the normal concentration, pulmonary edema, or cerebral or visual symptoms (3). Eclampsia is defined as preeclampsia complicated with one or more seizures (11).

## Risk groups

Several studies have indicated that patients with a history of pre-eclampsia/eclampsia are at higher risk of a recurrent pre-eclampsia or eclampsia in a subsequent pregnancy compared to other patients. The risk ratio varies among the studies (3,15,16). A multicenter cross country study in Argentina, Zimbabwe and South Africa (17) showed that in these patients 26% developed pre-eclampsia and two percent developed eclampsia. Other risk groups are nullipara (OR 2.04 95%CI 1.92-2.16), elderly pregnant women (>30 year) OR 1.4 (95%CI 1.31-1.5)), patients with chronic hypertension (OR 7.7 95%CI 6.67-8.87), severe anemia (OR 2.0 95%CI 2.47-3.61) and obesity with BMI>35 (OR 3.9 95%CI 3.52-4.33) among others (14).

#### Screening and prevention

It is estimated that 98.1 % of maternal deaths due to HDP in Africa could be prevented(18). Timely identification and treatment of HDP can prevent complications. This is why WHO recommends history taking for pre-eclampsia and eclampsia during the first antenatal care visit. Moreover, routine blood pressure measurement, patient history taking, and urine analysis for protein should be conducted every ANC visit to identify HDP cases and at-risk cases for HDP (1). Using this strategy, HDP will be diagnosed early, which allows early initiation of treatment and prevention of complications.

Progression to eclampsia and potential maternal death can be partially prevented in these risk groups by Calcium supplementation and Aspirin. Calcium supplementation 1 gr/day after a gestational age (GA) of 20 weeks in women with low Calcium intake, like in Sierra Leone (<600mg/d), prevents preeclampsia RR 0.45 (CI 0.31-0.65) and severe maternal outcome with RR 0.80 (CI 0.65-0.97) (17). In high income settings it has been shown that patients with a history of pre-eclampsia/eclampsia

benefit from treatment with Aspirin 75 mg started before a gestational age (GA) of 16 weeks. This can reduce eclampsia and pre-eclampsia with a number needed to treat (NNT) 19 to prevent eclampsia, NNT 75 to prevent preterm delivery, and perinatal death with a NNT 243 (3).

#### **Treatment**

Treatment of HDP includes both blood pressure management and termination of the pregnancy.

Severe hypertension is recommended to be treated instantly since severe hypertension is an independent risk factor of intracranial hemorrhage (3). Intravenous antihypertensives like hydralazine or Labetalol are recommended for severe hypertension until blood pressure < 160/110 mmHg (3). Additional treatment with Magnesium sulphate and terminating the pregnancy by induction of labor or Caesarean section can prevent complications like eclampsia (OR 0.40, 95%CI 0.27-0.57) (11). Also pulmonary edema and kidney failure have showed to be reduced by Magnesium sulphate administration and induction of labor (19).

In case of a preterm pregnancy before 34 weeks of gestational age it has been recommended to provide a course of antenatal corticosteroids to improve the neonatal outcome with a risk reduction of neonatal death with OR 0.69 (95%CI 0.59-0.81) (20).

In case of mild hypertension oral antihypertensives are recommended, like Methyldopa. Treatment reduces the progression to severe hypertension (RR 0.52 (95%CI 0.41-0.56)) (21). Termination of pregnancy is needed when the life of the mother is endangered. Also in cases of mild hypertension evidence is available to terminate pregnancy form a GA of 37 weeks onwards (21). For a GA between 34-37 weeks it has been recently published that induction will reduce maternal morbidity and although it increases neonatal admissions, it doesn't result in greater neonatal morbidity in the UK (22). If termination of the pregnancy is delayed, close monitoring is needed. In Sierra Leone a biweekly follow up is recommended (23).

# Challenges in quality of health care provided for hypertensive disorders of pregnancy in primary health care setting

Identification of HDP is vital to understand the burden of the disease. Moreover, early recognition is essential to start early treatment and prevent complications as described above. However, the WHO recommended pre-eclampsia and eclampsia screening practices (24) are poorly used in low resource settings. This has been studied in a cross country study in six African countries; in lower level health facilities blood pressure was appropriately measured in only 68% of the patients and danger signs assessment was done in 27% of the ANC visits (25). A similar study assessing 246 health centers specifically for hypertensive disorders in pregnancy in Afghanistan showed that in 14% blood pressure is not measured during ANC, 27% of health care providers did not recognize a severe pre-eclampsia using a case scenario and only 38% of the patients was asked about pre-eclampsia /eclampsia symptoms (26).

# International programs to improve the early identification, treatment and prevention of hypertensive disorders of pregnancy

A large multicenter study is ongoing about community level interventions for the prevention of preeclampsia (CLIP). This study is a cluster randomized controlled trial in low resource settings which aims to address maternal and perinatal mortality resulting from the failure to identify and rapidly manage pre-eclampsia and eclampsia at the community level. The study consists of a package of community engagement, community based screening with mobile health screening devices, early oral/IM treatment and capacity building (27). Results however are not published yet.

To address the problem of not adequately trained health care workers to perform and interpret a blood pressure, an electronic color-coded BP machine has been developed; the CRADLE® BP machine. Using this BP machine might contribute to improve quality of care in regards to high blood pressure detection and adequate referral. A blood pressure from >160/110 mmHg will be linked to a red light, indicating a referral indication, a blood pressure from 140/90 mmHg until 160/110 mmHg is linked to an orange light and < 140/90 mmHg will trigger a green light. It has been shown that this BP machine is easy to use (28). However, a large multicenter study with over half a million participants to evaluate this device, did not show a difference in maternal mortality and mortality (29). The study did show a reduction in eclampsia and emergency hysterectomies; however, this was not significant after adjustment for all planned variables. The centers included in this study where all higher-level health centers. From the participating centers in Sierra Leone, all included health centers have at least a midwife or community health officer, so centers with a higher cadre healthcare worker available, raising the question if there might be an effect in the health centers without higher cadre health care workers. Since the CRADLE® BP machine is cheap, easy to use and robust it is currently being implemented in several places in low income settings. E.g. South Africa already added the CRADLE® BP machine as golden standard for blood pressure assessment in the national guidelines for hypertensive disorders of pregnancy (30).

Lastly a clinical assessment score is developed to predict the risk of poor maternal outcome in hypertension/ pre-eclampsia patients; the minimizers (Pre-eclampsia Integrated Estimation of Risk). This miniPIERS model is used as categorical decision tool and could help to identify referral indications (31).

## Burden of HDP in Sierra Leone

Hypertensive disease of pregnancy in Sierra Leone caused 14% all maternal deaths in 2017 (16% in 2016) (32). The incidence of pre-eclampsia in primary care setting is not well documented. However, eclampsia cases are well documented at CUAMM supported hospitals. In Pujehun district, where there is only one hospital and a well implemented ambulance referral system, 45 cases of eclampsia are recorded for a total of 11.621 facility based deliveries in 2018, resulting in a incidence of 39 per 10,000 deliveries (33). Reliable national data are not available.

#### Quality of antenatal care regarding HDP in Sierra Leone

According to the last demographic health survey 98% of the women attended ANC at least one time during their last delivery (34). According to the multi survey indicator study from UNICEF in 2017, 93.8 % of all pregnant women visiting the ANC, had their blood pressure taken during ANC, and 85.1 % had a urine sample taken (35). No local data was available about the quality of the treatment regarding ANC care.

## **Problem statement:**

Sierra Leone is among the countries with the highest maternal mortality ratios of the world with 1,360 per 100.000 live births in 2015 (7). Even though it has been informally acknowledge by the ministry of health that the 2019 demographic health survey will show a significant reduction, official numbers are yet to be published. After hemorrhage, hypertensive disorders of pregnancy are the second most frequent cause of maternal mortality accounting for 14 % of all maternal deaths, as illustrated in figure 2 (32). With early recognition and treatment according to international standard a majority of these mortality cases could be prevented (3). Despite high ANC attendance in Sierra Leone, maternal mortality caused by HDP remains high causing 14 % of all maternal deaths. It has been proven that quality of antenatal care in low income countries is often below standard (36). Quality of care has many determinants, including availability of human resources, health care provider knowledge and availability of medication and equipment among others (37).

Currently several global initiatives are undertaken to improve the quality of primary health care for HDP, addressing different aspects of quality improvement (27) (38). One of those initiatives is to focus on improving quality of diagnosis and initial treatment of complications of pregnancies (38). Currently there is no documentation published about the quality of primary antenatal care in Sierra Leone regarding hypertensive disorders.

This study aims to gain understanding of the current quality of ANC with regards to HDP in Southern Sierra Leone in primary health care setting. The results will be used to formulate recommendations to improve the outcome of patients with HDP and prevent maternal mortality.

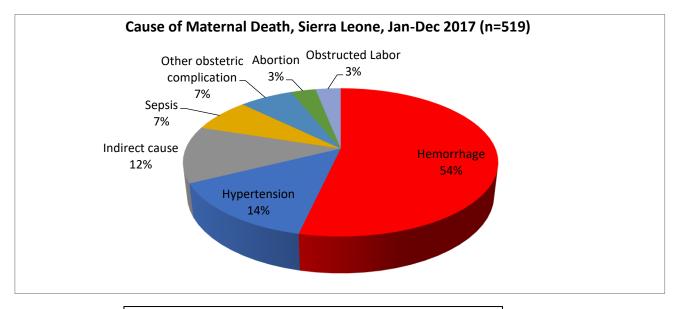


Figure 2 Causes of maternal death, Sierra Leone.

#### Justification

After hemorrhage, hypertensive disorders of pregnancy are the most frequent cause of maternal mortality in Sierra Leone. Hemorrhage is recently addressed by the implementation of a national ambulance service (2018-2019). Moreover, there are continuous efforts to improve basic and comprehensive emergency obstetric and neonatal care (BEMONC and CEMONC) services to address hemorrhage. However, for prevention and management of hypertensive disorders, in addition to ambulances and improvement of BEMONC and CEMONC, different strategies are required. One possible strategy is to focus on early recognition of HDP during ANC. Although, the ANC attendance is high with 98% (34), the quality of care has not been described in the literature.

As principal investigator I am also working for an NGO, called CUAMM. With our projects we aim to improve maternal health care in Sierra Leone. The current study was conducted in three districts in the Southern region of Sierra Leone since that is the main area of CUAMM's activities, facilitating access to district data, and with the professional networks to be able to collect data in the district.

## Research objectives and research questions

Despite all the recent effort of Ministry of health and sanitation (MOHS) in collaboration with health partners to improve ambulance referral system and supporting BEmONC facilities and hospitals, maternal mortality remains high, and HDP is the second cause of this mortality. The aim of this thesis is to assess the quality of care for women with HDP in primary health care, specifically in the Southern region of Sierra Leone. Results from this study will be used both to formulate specific recommendations for ministry of health and sanitation and health partners to improve the quality of care for hypertensive disorders and as base line assessment before introduction of interventions. This same study can be repeated to evaluate the effect of the proposed interventions.

## Objective

To assess the quality of antenatal care regarding hypertensive disorders of pregnancy in primary care level in the Southern region of Sierra Leone.

### Sub objectives

- 1) To assess the quality of care provided for <u>screening</u> of HDP during ANC at primary care level in Southern region of Sierra Leone.
- 2) To assess the quality of care provided for the <u>prevention and health care promotion</u> regarding HDP during ANC at primary care level in Southern region of Sierra Leone.
- 3) To assess the quality the first line <u>treatment and referral</u> indications and timing of HDP during ANC at primary care level in Southern region of Sierra Leone

#### Research questions

- 1) What is the availability of human resources for HDP care at government ANC clinics?
- 2) What is the availability of material and resources for HDP care at government ANC clinics?
- 3) What are the organizational resources to perform HDP care at government ANC clinics?
- 4) What is the quality of single patient care visit for ANC regarding HDP care in government ANC clinics?
- 5) What is the quality of the continuity of ANC for HDP care at government ANC clinics?
- 6) What is the outcome from patient care of ANC for HDP at government ANC clinics?

## The Morestin Framework.

A framework of quality of healthcare is adopted in order to design the study and analyze the results. This 'Conceptual framework for the quality of obstetric care' designed by Morestin et al is specifically designed for low resource settings like Sierra Leone. It is based on the original framework to assess quality described by Donabedian in 1988. This original framework is one of the founding models of measuring quality of health care in the international literature. Since this Morestin model is more detailed and specified for obstetric care compared to the Donabedian framework, the Morestin model, shown in figure 3, is used to design and analyze the fundament of quality of care measurement for this study

The Donabedian model starts with the structure in which the health care is delivered, and the inputs required to provide the care. It continues with the process of giving the care and finally analyses the outcome of the care provided (39)

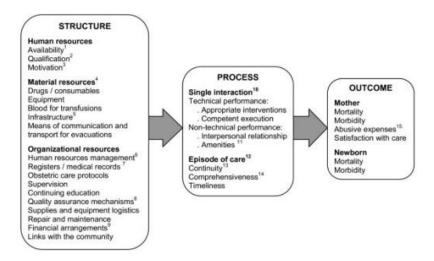


Figure 3. Morestin's conceptual framework for the quality of obstetric care. (5)

The model has been adjusted and verified by Morestin et al making it appropriate for analyzing obstetric care in low resource settings specifically (37). For the structure; the availability, qualification and motivation of human resources is important to ensure quality of care. Moreover, material resources are essential; medication, equipment, infrastructure, communication means between centers and referral infrastructure are needed. Furthermore, systems need to be in place for HR management, registration and data collection, obstetric protocols, supervision strategy of health facilities, continuous education, quality insurance mechanisms, appropriate supply chain, repair and maintenance of infrastructure and equipment, financial arrangement, and links to the community. These structure elements contribute to the process of giving health care, where focus needs to be on both the technical performance and the none technical performance in care of single interaction with patients. Continuous health care should be guaranteed with timeliness comprehensive follow up. This process of health care provision is necessary to reach the final health outcome. Both maternal and neonatal outcome should be considered, as is patient satisfaction

## Study methods

## Study design

Literature was consulted for the background information and discussion. In Pubmed search terms used where: Hypertensive disorders of pregnancy, eclampsia, pre-eclampsia, incidence, burden, interventions, risk factors, quality of care, task shifting and combinations of these terms. Moreover, the websites from WHO, World bank, Demographic health surveys and UNFPA were consulted for data, reports, and guidelines for antenatal care. National guidelines and policies have been obtained directly at the Ministry of Health and Sanitation in Sierra Leone.

A cross-sectional descriptive study design with several research tools was used in order to answer the research questions. The research tools allowed to collect and describe factors influencing structure; human resources, material resources and organizational resources. Also, factors influencing process are collected; including single patient interaction and episodes of care. Finally, factors concerning the maternal outcome are gathered; including patient satisfaction and abusive expenditure. The information collected is categorized based on the elements shown in Morestin's model of determinants of quality of care as described in table 1.

### Study population

The study population is all HCW providing ANC from three districts in the Southern region of Sierra Leone; Bo, Pujehun and Bonthe district. These districts combined have a total of 302 PHUs, however the exact number of staff in each facility conducting ANC is not known due to high staff turnover and reposting of HCW. Furthermore, not all HCWs conduct ANC visits. ANC visits are usually conducted by one or two, but might be up to four HCW per facility. Since the exact number of HCW performing ANC is unknown, the sample size is calculated based on four HCW per PHU; a total of 1208 HCW.

## Research table

				Direct clini-		
			Knowledge	cal observa-	Exit inter-	
		Questionnaire	assessment	tion	views	Comments
Human re-						
sources	Availability	Х			Х	
	Quality		х	х	х	
	Motivation	x				
Material and	Medication and					
recourses	consumables	x				
	Equipment	х				
		,				Not applicable in
						first line treat-
	Blood transfusion					ment of HDP
	Blood transfasion					Not applicable in
						first line treat-
	Infrastructure					ment of HDP
						ment of fibr
	Means of communi-					
	cation	Х				
	Transport for evac-					
	uations	Х				
Organiza-						
tional re-	Registers availabil-					*
sources	ity	Х				*
	Obstetric care pro-					
	tocols	X				
	Links with commu-					
	nity	X				
Single patient	Technical perfor-					
interaction	mance		x	х	x	
	None technical per-					
	formance				x	
Episode of						
care	Continuity of care			х	x	
	Comprehensiveness			x		
	Proper treatment					
Outcome	received**				x	**
	Abusive expenses			х	х	
	Satisfaction with			^	^	
					v	
*This research	care				X	111 6 11

<sup>\*</sup>This research does not focus on policies from MOH, despite they are included in the framework of quality of care, they are not studied in the research. Policies in place might be object of future investigation to address the quality gabs identified.

Table 1. Research table indicating the variety of determinants assessed using several research tools

<sup>\*\*</sup>this indicator had been changed from mortality and morbidity to the proper treatment initiated. Since treatment of HDP has been shown in other research to reduce maternal morbidity and mortality, as reducing neonatal morbidity and mortality.

### Questionnaire and knowledge assessment

A questionnaire combined with a knowledge assessment has been conducted among 283 HCW (Annex 1). This questionnaire was used to collect data regarding the availability of human resources, medication, medical equipment, registers, protocols and a personal mobile smartphone. Furthermore, information on referral possibilities and manners of ANC defaulters tracing was gathered. Finally, heath centre staff motivation was assessed. The content of the questionnaire has been developed by the principal investigator and is based on WHO guidelines for ANC and adjusted to be used with the Morestin model (1,37). The knowledge assessment assessed the technical knowledge of the HCW (Annex 1). The assessment included several clinical case scenarios, of which HCWs were asked to describe the proposed treatment and to indicate whether there is a referral indication. Moreover, knowledge about danger signs for HDP and knowledge about secondary prevention of HDP were assessed using the assessment.

The questionnaire and knowledge assessment were pretested by five local health care workers in the district referral hospital, in order to assess the clarity of the questions and the case scenarios. The sample size was calculated assuming a population of 1208 HCW. The sample size was calculated with openepi.org, using the formula  $n = [DEFF*Np(1-p)]/[(d2/Z21-\alpha/2*(N-1)+p*(1-p)]]$ . Based on results from previous studies (26) the proportion of HCWs correctly identifying severe pre-eclampsia in a clinical case scenario was assumed to be 72%. Precision was set at 10 % precision, and significance at 5%. This led to a calculation of a sample size of 73 health care providers. The questionnaire and the knowledge assessment were conducted during a regular monthly PHU meeting organized by the DHMT. Representative of all PHU are participating in this meeting and all were asked to participate to this study. This strategy resulted in a sample of 348 HCW. The assessment was completed on paper in English, the language used in medical communication in the country.

#### Direct clinical observation and exit interviews

In order to assess the actual technical performance during ANC clinic visits, direct clinical observations were conducted. Using this tool, the medical practice of the HCW as well as the continuity of care has been assessed. After the ANC visit an exit interview was conducted for the same patients included for the clinical observations. The patient was asked what she remembered from the provided health promotion. Furthermore, the blood pressure measurement was checked using an electronic CRADLE® BP machine. In addition, continuity of care has been assessed by asking the awareness of the patient regarding the date of next visit. Finally, questions regarding patient satisfaction of the visit, the attitude from the nurse and experience of staff absence in the facility were included.

Validated ANC assessment observation tools have been adapted to be used especially for HDP disorders in the local situation, based on WHO guidelines and informed by the Morestin model (1,24,37). Similarly, for the exit interviews the assessment tool was based on the WHO standard for ANC (16). The normal variation of BP machines and the most common errors of blood pressure measurement has been taken into consideration to establish a definition for a correct measured blood pressure. The association for the advancement of medical instrumentation, states that if the readings of the BP machines have a variability of more than 4 mmHg, the BP machines should be repaired before further use (40). Furthermore, the most common source of error for blood pressure

measurement error is end-digit preference. End-digit preference is a term whereby the user tends to prefer a certain end-digit of the blood pressure, usually ending the recorded blood pressure with zero. This could cause an additional 10 mmHg difference of blood pressure measurement in case a manual BP machines is used (41,42). For this study a correct measurement was defined as a difference in measurement between the HCW and the research assistant of 15 mmHg or less.

For the direct clinical observations and exit interviews the sample size is calculated assuming a study population of 302 PHUs. The sample size was calculated with openepi.org, using the formula n =  $[DEFF*Np(1-p)]/[(d2/Z21-\alpha/2*(N-1)+p*(1-p)]]$ . Based on results from previous studies (36) the estimated prevalence of good clinical blood pressure measurement was 68%. Precision was set at 10% precision, and significance at 5%. This led to a calculation of a sample size of 66 PHUs health care providers. A cross sectional random sample of 66 health care facilities has been taken among all the 302 PHUs in three districts in Southern Sierra Leone. Random numbers were used to make a selection from a list of all PHUs in the Southern region of Sierra Leone. At the PHU, the health care provider performing ANC consultations on a routine ANC day were observed during clinical setting for maximal six patients. The first six patient attending ANC and consented with the research after arrival of the research team were observed. In PHUs with six or less patients attending ANC, all patients who consented were included. In case of several MCHAIDs providing ANC care the provider on the left side was selected to prevent selection bias. The observation charts were completed on paper in the English language.

#### **Ethics**

Since this study includes observations and interviews with human beings' ethical approval has been sought before starting of the study. Both the Amsterdam Royal Tropical institute (KIT) and the Sierra Leone ethics and scientific review committee have reviewed and approved the study proposal. The ethical considerations are shared in annex 4. The different informed consents are attached in annex 5.

All participants for the knowledge assessment and questionnaire during the in charges meeting were explained about the research, the informed consent procedure and the research document by a member of the research teams. Subsequently participants were asked to fill the informed consent. It has been pointed out that participation of the study did not have influence on their job performance appraisals, or further career. Only HCW who completed the informed consent were included in the research.

For the direct clinical observations and exit interviews, the selected health centres where contacted by phone to explained the study and PHU staff was requested to participated in the study. Those who accepted to participate were visited. In the centre the study was explained again and the informed consent of the health care provider and the patients were asked before proceeding. In case of illiterately of a patient the content of the informed consent was read out and signed by thumb printing. To ensure privacy the exit interviews were conducted in a separate room in the PHU. In case no spare room was available a place was identified which could provide privacy.

None of the observation forms, questionnaires or knowledge assessment did contain names of participants or health care workers. Data was inputted by the principal investigator and a research assistant. The data collection forms are stored at the CUAMM office where it is under supervision of the principal investigator. This office is locked with key if not in use. After five year the clinical data

will be destroyed. The soft copy data will only contain reference numbers and types of PHU, but names of centres will not be used.

## Data collection and Analysis

The data of the direct clinical observations and exit interviews was collected by a research team of two people, a CHO with previous experience in research and a MCHAID. Both had more than two years clinical experience, and both were trained for two days for this study by a medical doctor and a researcher (PhD), experienced in conducting research in low income settings. Apart from clinical procedures, privacy policies and data collection tools were included in the training program.

During the clinical observation no feedback has been given by the observer, nor was intervened in the medical care. However, in case of a severe clinical condition not identified by the health care provider the observer could have advised to correct the treatment after the exit interview, without changing the initial observations on the assessment form.

All obtained information has been inserted in SPSS (version 23) by the principal investigator and a sample of the data has been cross checked by another member of the research team. The data was systematically analysed according the framework of Morrison using SPSS by the principle investigator. Subgroup analysis are done for level of the centre, district and years of experience of the health care provider (0-2,3-5,5-10,>10y).

## Limitations of study design

The study only included Southern region of Sierra Leone. Despite that it contains both urban and rural settings, these results might not be extrapolated to other regions in Sierra Leone.

The assessment of antenatal care was only conducted during normal ANC clinic days. This might have a selection bias, since that day the most experienced health care provider for ANC will be available, missing potentially less experienced staff.

This study assesses only the primary health care aspect of HDP, further research should be conducted to assess also the secondary health care quality component at hospital level. Maternal outcome is a result of both primary and secondary health care quality, and in this study maternal outcome is not measured. However, reported national available data is included.

English might be a limiting factor for several MCHAIDs. Limited understanding might be a bias, underestimating the quality of the health care worker. However, since their medical training is conducted in English, as is the medical record keeping, it was decided to use English only

Conducting knowledge assessments during monthly meetings in the district headquarter might have resulted in selection bias, since it might be that the most senior health care provider of the centre is attending the meeting. To correct for these bias years of professional experience was taken into account. Observation of clinical patient care will possibly change health care provision. Health care providers who are aware of being observed are possibly taking more time to provide comprehensive care and are more complete in their patient care than usual. This will result in overestimating the quality of provided care.

Identification of hypertension has not been directly assessed using the observation and exit visit. With a prevalence of hypertension of eight percent of all pregnancies, it was not feasible within the available budget to increase the sample size needed to include the identification if hypertension

itself. However, the knowledge assessment did include the theoretical skills of the HCW to identify hypertension

## Results

## Characteristics of visited PHUs and participating health care workers

A total of 66 PHUs has been visited for direct clinical observations and patient exit interviews, documenting 348 patient visits as illustrated in table 2. The majority of the visited PHUs are MCHP (63%). The majority (57%) are located in Bo district, and MCHAIDs performed the majority of the ANC clinic visits (89%).

A questionnaire and knowledge assessment were conducted among 283 PHU staff. Most participants are representatives of a MCHP, (124 PHUs, 49%), as indicted in table 3.

Table 2; Baseline ch	aracteristic	s PHU visits
n=66 PHUs		
Visited PHUs	N°	Percentage
Bo district	37	57%
Bonthe district	12	18%
Pujehun district	16	25%
Type of centre		
MCHP	41	63%
СНР	13	20%
CHC	9	14%
BEmONC	3	5%
Health care provide	ers	
MCHAID	58	89%
SECHN	2	3%
CHA	1	2%
СНО	0	0%
Midwife	5	8%
Years of experience		
0-2y	12	18%
3-5y	6	9%
5-10y	24	37%
>10y	13	20%

Table 3; Baseli	ne characteristics	questionnaire
and knowled	ge assessment.	n=283 health care
workers		
District	N°	Percentage
Во	129	47%
Pujehun	83	30%
Bonthe	62	23%
Missing	9	
Type of centre		
MCHP	124	49%
СНР	67	26%
CHC	63	25%
Missing	28	
Work experien	ce	
1-2 year	68	27%
3-4 year	54	22%
5-10 year	56	22%
> 10 year	72	29%
Missing	27	

#### Structure; Human resources

During clinic visits two percent of the patients (five from 348) recalled that there was one episode in the last three months there was no staff available in the centre, (table 4). In the questionnaire 13% of the health care workers did confess that activities were interrupted in the last three months for some period of time due to a lack of staff availability in the PHU as illustrated in table 5. This was significantly more in Bo (21%) compared to Pujehun (seven percent) or Bonthe district (five percent). Eighty-two percent of the health care providers is satisfied with the level of care they can provide,

and 98% of the patients is satisfied with the provided quality of care, and 99% is satisfied with the attitude of the nurse.

# Structure; Availability of medication, equipment communication and referral possibilities.

Regarding availability of equipment the questionnaire showed that only 143 from the 274 (52%) of the centres had a working BP machine and stethoscope, as shown in table 6. However, during the PHU visits only in 46 of the 348 (14%) of the PHUs no BP was measured due to a lack of BP machines as stated in table 4. Several PHUs reported using their private BP machines to assess BP. Most of the available BP machines are the manual type (65%), only 20 % had access to an electronic machine.

Table 4; Results from the d	lirect clinical ob	servatio	ns and
exit interviews			
	N° of	Pe	ercentage
	patie	nts	
Obstetric history taken		344	99%
Danger signs assessed	Headache	321	91%
	Epigastric	109	28%
	pain		
	Blurred	288	81%
	vision		
Fetal heart rate assessed		344	99%
Fundal height measured		345	99%
BP machine availability		56	85%
	Manual	42	65%
	Electronic	14	20%
Bp measured correctly ≤15	MmHg	188	63%
difference with CRADLE®)			
Incorrect PE diagnosis		5	2%
Dipstick performed		160	51%
Danger signs explained in	Epigastric	135	34%
to the patient	pain		
	Headache	323	92%
	Blurred	291	82%
	vision		
	No fetal	109	29%
	movement		
	Oedema	320	91%
Danger signs recalled by	Headache	309	87%
the patient			
	Epigastric	214	24%
	pain		
	Blurred	253	59%
	vision		
	No fetal	52	13%

	N° of	Percentage
	centres	
Period with staff	35	13%
absence during the		
last 3 months (HCW		
reporting)		
Во	26	21%
Pujehun	4	7%
Bonthe	4	5%
Access to a personal	33%	268
smartphone		
MCHP	29%	120
СНР	40%	65
CHC	41%	57
Health care providers	82%	262
satisfied with quality		
of care they provide		

	movement		
Patent awareness about next visit		335	95%
Medication availability	Methyldopa	60	92%
	Nifedipine	1	3%
	Furosemide	1	2%
	Labetalol	0	0%
	Magnesium	63	95%
	sulphate		
	Diazepam	50	65%
Period with staff absence during the last		5	2%
3 months (Patients reporting)			
Patients satisfaction	Quality of	343	98%
	care		
	Attitude of	346	99%
	the nurse		

With regards to the availability of medication the PHU visits showed that in 60 of the of the 66 visited PHUs (92%) Methyldopa was available and 63 (95%) had access to Magnesium sulphate. Comparable, in the questionnaire 257 from 275 (91%) of the HCW reported Methyldopa is available and 263 (93%) had access to Magnesium sulphate as shown in table 6. However, second line antihypertensives are only available in one centre (3% Nifedipine) and Labetalol, another second line antihypertensive was not available in any of the visited PHUs. According to the questionnaire 12% (34 of 302) had Nifedipine, four percent (10 of 266) Labetalol and Hydralazine was available in 16% (46 of 297). Aspirin for prevention of pre-eclampsia was available in nine percent (26) of the PHUs and Calcium to treat Magnesium intoxication in 58% (165).

Table 6; Availability of medication, equipment			
and guidelines; resul	ts from the o	questionnaire	
Type of medication	of medication N° of Percentage		
	centres		
Aspirin	26	9%	
Calcium	165	58%	
Dexamethasone	73	26%	
Hydralazine	46	16%	
Labetalol	10	4%	
Magnesium	263	93%	
Methyldopa	257	91%	
Nifedipine	34	12%	
Oxytocin	258	92%	
Type of equipment			
Functional BP	143	52%	
machine and			
stethoscope			
Urine dipstick	151	53%	

Table 7; Technical performance of HCW; timing				
of referrals				
Referral timing for severe	N° of	Percentage		
PE according to HCW	HCW	-		
Immediately	127	54%		
Other	54	23%		
When it becomes	54	23%		
severe				
Referral timing for severe PE				
according to HCW				
At 37w to be induced	2	1%		
At 40 w to be induced	2	1%		
When it becomes	83	35%		
severe				
Other	74	31%		
Immediately	77	32%		
Unavailability of referral	27	10%		
possibility during last 3				
months				

Only 53 % of the centres had a urine dipstick available according to the questionnaire (in BEmONC 100% had urine dipstick available, versus 48% in none-BEmONC facilities). This is comparable with the results of the PHU visits where it has been observed that in 51% of the visits a urine protein assessment with a dipstick was conducted, as mentioned in table 4. When the blood pressure machine was not available, patients were also less likely to get a urine dipstick done OR 0.47 (95%CI 0.29-0.77) with significance of < 0.001.

Referrals possibilities are generally available as shown in table 7. Twenty-seven (10%) from the 260 PHU experienced a problem with a referral in the last three months. Mostly this occurred in MCHP (13%), less in CHC (5%), and CHPs (9%).

## Structure; Organizational resources

ANC government registers are generally available in 94% of the PHU according to the questionnaire, shown in table 8. Guidelines about hypertensive disorders and medication dosage are available in only 59% of the PHUs as informed by the questionnaire. The majority of the health care workers indicate in the questionnaire that they work with the community to trace ANC defaulters. A total of 241 from 265 (91%) traced defaulters.

Table 8; Organizational resources; results from the questionnaire					
	N° of PHU	Percentage			
Availability of Guideline pre-eclampsia	168	59%			
Availability of Guideline for medication	166	59%			
dosage					
Centres with ANC defaulter tracing	241	91%			
Availability of ANC register	257	94%			

## Process; Single patient interaction

#### Technical performance

#### Theoretical knowledge

Four case scenarios about hypertensive disorders where presented and participants were asked whether they would refer the case and if they suggest treatment. Results are illustrated in figure 4. A case of severe PE with both systolic and diastolic severe hypertension was treated according to the national guideline with Magnesium sulphate and referred by 9% (21 of 234) of the HCW. 15% (34) of the HCW treated the case incorrectly, by not referring this case. Of 34 HCW, five (2%) also did not start any medication. The remaining 76% referred the patient, but only with Methyldopa (99, 42%) or no pre-referral medication (72, 31%).

A case of isolated severe hypertension was treated according to the national guideline with Magnesium sulphate and referral by 2% (5 of 199) of the health care providers. Eighty-seven (43%) of the cases were treated incorrectly, by not being referred to the hospital. The remaining 52% (107) did refer the patent with only Methyldopa (33%,65), or without medication (20%,39).

A mild pre-eclampsia was treated according to the guideline with Methyldopa by 42% (86 of 204) of the participants. 42% (86 of 204)) referred this case to a higher-level facility without indication, treating the patient sub optimally. However, 16% (32 of 204) did not treat this patient at all. From the

not-indicated referrals 38% was done from an MCHP, 21% form a CHP and 17% from the CHC level facility.

A final case scenario with a normal blood pressure was commenced on antihypertensive treatment by 52% (96 of 186) of the participants.

The clinical case scenario management was not significantly different among representatives from different types of PHUs, or different experience levels, as illustrated in table 9

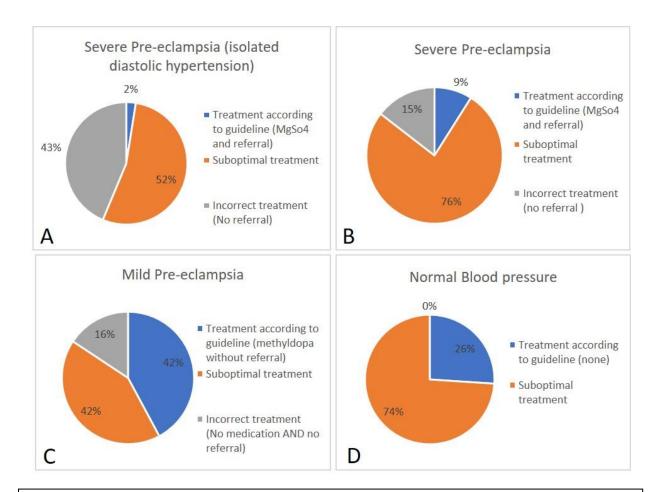


Figure 4, Technical performance of HCWs; patient management assessed using clinical case scenarios. Case A) Severe pre-eclampsia due to only severe diastolic hypertension. B) severe pre-eclampsia, with both systolic and diastolic hypertension. C) Mild pre-eclampsia. D) Normal blood pressure.

The use of secondary preventive treatment for HDP was assessed with a question about how to handle a patient with a history of eclampsia. The use of low dose Aspirin, recommended by WHO, was never mentioned.

Referral indication and timing where assessed using the questionnaire, shown in table 7. Two persons from the 238 participants (one percent) would refer a mild preeclampsia a term at 37 weeks for induction of labour (referral according to the protocol). Most people, 83 (35%) would refer when it becomes severe, 77 (33%) people would refer immediately. A severe pre-eclampsia would be referred immediately by 127 participants (54%).

Table 9; Technical performance of HCW; case scenarios									
Severe pre-				Severe pre-eclampsia		Normal blood pressure			
	eclampsia			(only diastolic)					
Experience	Refer-	Percent-	P-	Referral	Percent-	p-value	Refer-	Percent-	p-
of HCW	ral	age	value		age		ral	age	value
1-2y	48	71%	0.352	24	35%	0.162	8	12%	0.927
3-4y	38	70%		18	33%		6	11%	
5-10y	36	64%		16	29%		8	14%	
>10y	54	75%		33	47%		10	14%	
Type of centr	е								
СНС	43	68%	0.314	21	33	% 0.26	10	16%	
						1			0.821
СНР	51	76%		24	36%		8	12%	
МСНР	85	66%		52	42%		16	13%	

#### Practice; identification, treatment and health promotion about hypertensive disorders.

During the clinical observation only five cases of pre-eclampsia presented. Due to a small group of identified pre-eclampsia no conclusion can be drawn about the actual treatment. Rather diagnostic assessment and health promotion were observed. Results are depicted in table 4.

The none technical performance was assessed using the knowledge retention by the patient, from the previously explained health promotion. Headache and vision complaints are assessed, mentioned during health promotion, and remembered by the patients with 91% (321 from 348 patients), 92% (323 from 348) and 87% (309 from 348) respectively for headache. Vision disturbance where assessed, mentioned in health promotion and remembered by patients in 81% (288), 82% (291), and 59% (253) respectively. Epigastric pain is only assessed in 28% (109) of the patients, included in health promotion in 34% (134) and remembered by 24% (214). Epigastric pain was remembered better by patients visiting a BEMONC facility or CHC 41.7% and 43.8%, compared to 21% and 19% in CHP and MCHP respectively. Fetal movement is not assessed during consultations, however it is mentioned in the health promotion by 29% (109) of the health care providers and 13% (52) of the patients recalls less fetal movement as an indication to visit the clinic. In BEMONC 58% of the patients remembered no fetal movement as danger signs, compared to 10.4 % in MCHP.

Table 10; Danger signs recall by the patient								
Danger sign	Explained	Remembered	Not explained	Remembered	P-value			
		by the patient		by the patient				
Headache	294	88%	22	73%		p<0.05		
Epigastric pain	109	40%	209	15%		p<0.05		
Blurred vision	262	67%	56	20%		p<0.05		
Oedema	292	76%	26	35%		p<0.05		
No fetal movement	93	19%	219	11%		p<0.05		

Patient who received health education about a specific danger sign were significantly better in recalling that danger sign compared to patients who did not receive the health promotion before as shown in table 10.

## Practice; Assessment of Blood pressure measurement

Blood pressure measurement was done in 86% of the clinic visits. In 63% (188 from 301) the blood pressure was less than 15 mmHg different than measured by the CRADLE® BP machine. In the sample from normal ANC visits five patients had pre-eclampsia (two percent). In five cases the different measurement of the blood pressure resulted in a different diagnosis of pre-eclampsia or no pre-eclampsia; one pre-eclampsia was misdiagnosed and four pre-eclampsia diagnosis were missed. No significant change was identified between type of BP machine (electronic or manual), level of the center, or level of the health care provider. A subgroup of health care providers with 3-4 years' experience performed significant less, and only measured a correct blood pressure in 39% (p<0.001).

## Process; Episode of care

Only 14 from 349 patients (four percent) did not know when to come back for follow up.

#### Outcome

Due to a low number of presented pre-eclampsia cases during direct observations no conclusions can be drawn about the clinical outcome of the patients.

However, the questionnaire reveals that unnecessary referrals probably are happening. For example; 38% of the health care providers indicated that they would refer a mild pre-eclampsia before term (without indication). Furthermore 52% of the HCW did indicate to start antihypertensive treatment in patient with a normal blood pressure.

Patients are satisfied with the provided care as shown in table 4. Only six out of the 349 (two percent) observed patients were not satisfied with the quality of the care, and only three (one percent) were not satisfied with the attitude of the nurse.

## Discussion

This research provides a comprehensive overview of the quality of ANC for HDP in three districts in Southern Sierra Leone. Overall it is found that the quality of provided care is below standard. However, despite limited knowledge of health care provider, both patients and healthcare providers are satisfied with the care they receive or provide.

Unpublished data from the three district health management teams recorded that 16 of the reported 102 maternal deaths in 2019 are caused by HDP (16%). By improved ANC most of these deaths could have been prevented (18). Extrapolating this data to the national data would mean a reduction could be achieved from 1.360 per 100.000 live births (7) to 997 per 100.000, justifying an additional investment in quality of ANC for HDP. Furthermore, HDP contributes to perinatal deaths. (43,44) Therefore, improving quality of care regarding HDP might contribute to a reduction of the neonatal mortality rate in Sierra Leone which is currently 32.8 per 1000 live births (7).

#### The quality of screening for HDP

In the current study, three elements of screening were assessed; blood pressure measurements, screening for proteinuria and danger signs assessment. All three elements are below standard. In 15% of the ANC visits blood pressure has not been assessed as observed during the facility visits and 48% of the HCWs have indicated not to have access to a functional government-owned BP machine. In case of blood pressure measurement, only 63 % of the HCW recorded a correct blood pressure as defined as less than 15 mmHg different than the reference CRADLE® BP machine measurement.

Altogether not-measured or incorrectly measured blood pressure account in this study for 46% of all clinic visits. This implies that only 54% of the patients is appropriately screened for hypertension. Furthermore, screening for proteinuria is performed in only 51% of the observed clinic probably due to due to unavailability of the urine dipstick as 53% of the HCW indicated in the questionnaire non-availability of these screening tools in the facility.

It has been shown that other countries experience similar challenges. Where 90% of women reported to have their blood pressured measured, only 58% reported to have their blood pressure measured at each visit in a rural district of Kenya (45). The same study described that 78% of the women reported to have had a urine test during ANC. A similar ANC observation study in Tanzania showed that only during 69% of the ANC visits the blood pressure was assessed and only 22% of the women were assessed for proteinuria (46). Interestingly, a cross-country analysis of ANC in six sub-Saharan countries in 68% of ANC visits the blood pressure was taken in the right position and 46% was screened for proteinuria (25). None of the studies assessing quality of ANC service included a secondary assessment of the blood pressure during an exit interview.

Despite the higher percentage of blood pressure taken in the current study compared to some other Sub-Sahara African countries, there is room for improvement of the frequency of blood pressure measurement taken during ANC. More importantly, this study shows that only 63% of the taken blood pressure measurements was correct, indicating the need for interventions to improve blood pressure measurement practice and thereby improve screening for HDP. Incorrect measurement

might lead to missed cases of pre-eclampsia, as illustrated in this study where only one of the five cases of hypertension has been diagnosed during the ANC visit.

The third screening element included in this study is related to danger signs. Where only 27% of women were counselled for danger signs of headache and blurred vision as demonstrated in a cross-country study in Sub Sahara Africa (25), this study shows that headache and blurred vision are mostly assessed in the centres in three Southern districts in Sierra Leone. However epigastric pain and loss of fetal movement are hardly assessed. This is a missed opportunity, since 18 % of the patients with an eclamptic insult experienced epigastric pain as precedent symptom before convulsing (47). Therefore WHO recommends assessment of epigastric pain during ANC for preeclampsia detection in their guidelines (24). However, as indicated in the study, this is not well implemented in Sierra Leone. In addition loss of fetal movement can be a sign of fetal death, a complication of pre-eclampsia (3). Including assessment of both these signs might allow early diagnose of pre-eclampsia. It might to be considered specify all danger signs, including epigastric pain and loss of fatal movement into the national guidelines and to increase the awareness among HCW.

Interestingly, this study shows that continuous health promotion about danger signs does increase the knowledge of the patients about these danger signs. Even though patients might have been educated during other ANC visits, or by alternative sources of information, mentioning danger signs during health promotion results in a significantly better recall of this information by the patients during the exit interviews. This shows that health education about danger signs during ANC is an important tool to create awareness of these danger signs and possibly increases health seeking behaviour when danger signs occur.

The direct clinical observations illustrate that 95% of the patients is aware of the next follow up visit which is relatively high compared to some other low- and middle-income countries. Similar studies about ANC assessment in Nigeria and Afghanistan and Nigeria show that respectively only 67% and 81% of ANC patients knew when to return for a follow up visit (26,48).

## Prevention

The quality of care regarding prevention for HDP is below standard. The questionnaire illustrated that among HCW there is lack of knowledge about the WHO recommendations for the use of Aspirin, as secondary prevention for eclampsia. Moreover, Aspirin is not available in most PHUs. Since Sierra Leone is one of the countries with the highest prevalence of eclampsia (49); this is a missed opportunity. Especially since Sierra Leone has a 98% ANC attendance rate which is higher than other West-African countries (35). Implementing a program for secondary prevention is proven to be cost effective in high income settings, no specific data is available about the cost effectiveness in low income settings (50). However, since both Aspirin and Calcium are relatively inexpensive, it might be feasible to implement also in low income setting an effective prevention strategy with only limited financial barriers.

#### Treatment

During the direct clinical observations it was not possible to assess the quality of the treatment of HDP, since only one case of hypertension was diagnosed by the HCW. However, the clinical scenarios illustrate that treatment of severe pre-eclampsia is inadequate. Only 9% of the participants followed the guideline and prescribed Magnesium sulphate and referred the patient. A case scenario with a normal systolic blood pressure but with isolated diastolic hypertension resulted only in 2% of the questionnaires in a treatment according to national protocols. This indicates that there is a knowledge gap of blood pressure interpretation. It has been shown that in other low-income settings that limited staff knowledge is an important barrier for quality ANC. In Nigeria a study by Salamon et al. (48) indicates that 58 % of the staff was capable to diagnose HDP and 13.7% had correct knowledge about use of antihypertensives. A study in a middle-income country shows slightly better staff performance; Ansari et al. (26) showed that in Afghanistan 88% of HCW in a primary health centre were able to identify a severe pre-eclampsia in a case scenario. In our study 85% of HCW would refer a similar case scenario correctly, but only in nine percent with correct pre-referral treatment. It might be considered to conduct further training to improve staff knowledge. A strategy might be to include blood pressure interpretation aids, like CRADLE®, or smart phone apps (28,51)

The benefit for a blood pressure interpretation aid is also illustrated by the case scenario with a normal blood pressure, which resulted in 20% referrals, and in 49% in treatment with antihypertension. This indicates that the current health care systems are unnecessary pressured by not indicated referrals, and not indicated prescription of medication. This would imply that investments in additional training or purchase of BP machines could reduce the cost of unnecessary referrals and treatment.

The first line treatment for severe pre-eclampsia is available in almost all centres. Furthermore, emergency referrals are almost always possible without financial threshold in case of emergencies by the National ambulance service (NEMS). This confirms that the main compromising factor of quality health care for HDP patients is the measurement and interpretation of blood pressure, rather than a lack of medication or the lack of referral capacity. However, the provision of second line antihypertensive medication could contribute to improvement of the quality of care for HDP.

Furthermore, knowledge about treatment for mild pre-eclampsia also is below standard. The main barrier for quality health care in this aspect is within the knowledge of the HCW. Only two percent of the HCW had knowledge about the indication for induction of labour at a gestational age of 37 weeks. Similarly, to severe hypertension additional training to HCW combined with blood pressure interpretation aids might be beneficial.

According to Sierra Leone obstetric guideline, cases of mild pre-eclampsia at term are recommended to be referred for induction of labour. Although here is a free ambulance system for emergency cases, patients for these elective referrals do not benefit from the same free services. The cost involved in referral might cause a barrier in receiving the induction, although this has not been investigated in the current study. Literature suggests that in other settings financial barriers delay referral (52,53). Previous data from Pujehun district shows that after taking away financial barriers of referral by a motorbike cost refund system, the incoming referrals tripled. (33)

Strengths and Limitations

This study is the first to describe the quality of ANC care for HDP in Sierra Leone in a systematic way. The Morestin framework helped to make a comprehensive assessment of the provided health care. Moreover, both the direct observation and the questionnaire shows the same results for medication and equipment available increasing the reliability. Moreover, using several study methods allow to assess different aspects of quality of care. This study includes the factor of correct measurements which is a missing aspect in the published literature.

Although this study has been conducted in the Southern region of Sierra Leone, the results are likely to be extrapolated to Norther and eastern region since they have comparable ANC attendance, institutional deliveries and maternal deaths (32,35). However this study might not be representative for the Western region, including the densely populated Freetown, where 17% of women claims to have visited a medical doctor for ANC, compared to three percent in the other regions (35).

This study indicates that the main barriers for quality of care are knowledge of health care providers, and the HCW capacity to measure the blood pressure. However other factors cannot be excluded;

Non-availability of human resources has an impact on the poorly provided care. To assess the availability of human resources two research methods have been used; staff self-reporting and patient recall. Patient recall during ANC exit interview might be biased, since patients were questioned during the routine ANC care. This might not be representative about availability of health care providers outside routine ANC days. During the questionnaire a higher staff absence was reported, but even self-reporting could underreport negative outcomes. It might be advisable to conduct additional studies about the availability of the HCW for ANC.

Similarly, the staff motivation has only been assessed by self-reporting of HCW with a simple question 'are you satisfied with the quality of care you are able to provide?'. Due to the limited study capacity this might give only part of the reality. No in-depth analysis is done about staff motivation. It has been documented that demotivated staff perform less and might compromise the quality of the provided care (54). Staff motivation could be further assessed including intrinsic and external motivators like professional development opportunities, salary scales, infrastructure etc.

Furthermore, a lack of patient compliance to follow up dates cannot be excluded as factor of delay of diagnosing HDP. Even though this study indicates that patients are satisfied with the provided health care, it doesn't mean that patients will comply to follow up. Furthermore, it needs to be acknowledged that satisfaction was only confirmed by one question during the exit interview 'Are you satisfied with the provided care?' And 'Are you satisfied the attitude of the nurse'. Additional research including a more in-depth assessment of the satisfaction might be beneficial to confirm this satisfaction.

## **Conclusions**

The quality of antenatal care for hypertensive disorders of pregnancy in primary care settings is low in Sierra Leone.

This study identifies three factors contributing to the low standard of ANC regarding DHP. Equipment and medication are insufficient available. Furthermore, knowledge of HCW regarding HDP is below standard. The later includes incorrect measurement of the blood pressure, a knowledge gap in interpretation of blood pressure measurement resulting in under and over treatment of hypertension and comprehensive practice of counselling including all danger sign. Due to low standard of these factors, the quality of screening pregnant women for HDP, prevention, diagnose and treatment of HDP is below standard.

Low quality of care regarding HDP services might lead to maternal morbidity and mortality. Therefor it is recommended to focus on all three aspects in order to improve quality of HDP service as a strategy to improve maternal health care in a country with a high maternal mortality due to eclampsia.

## Recommendations

Based on this research three priority recommendations are proposed. An additional two recommendations are formulated, to complement results after implementation of the first recommendations.

- 1) BP machines can be made available in all PHUs, preferably a type with interpretation aid, like the CRADLE® BP Machine.
  Distribution of CRADLE® BP machines might improve quality of care in two ways. Providing BP machines will address the issue on non-availability of BP machines in 14% of the health centers which enable HWC to measure the blood pressure during ANC. Provision of the specific color-coded interpretation aid of the CRADLE® device could provide the opportunity to improve the interpretation of the blood pressure and might prevent the 43% of non-treated severe hypertension as suggested by the results of the questionnaire.
- 2) A comprehensive training and supervision program for PHUs is recommended to be organized about HDP with special attention towards;
  - a. Diagnosis of HDP and blood pressure interpretation
  - Referral indications and enforcement of induction of labor.
     Only two percent of health care providers knows about the need of referral for induction a term in case of a mild pre-eclampsia, and many referrals are not indicated, in case of a mild pre-eclampsia preterm.
  - Indication when to start Magnesium sulphate
     Only 9% of the health care providers started Magnesium sulphate in a case scenario of severe hypertension.
  - d. Recommendations about secondary prevention of HDP with Aspirin, since it was never mentioned in the treatment or counseling in a case scenario from a patient with a history of eclampsia.
- 3) It is recommended to improve provision of specific medication to PHUs
  - a. Second line antihypertensive medication can be provided to PHUs to be used in case of severe hypertension before referral.
    - Currently only 3% of the visited centers had access to Nifedipine, and none of the visited centers had Labetalol even though both are included in the national protocol to treat HDP.
  - b. Aspirin for secondary prevention of Eclampsia is recommended to be available in PHUs.
    - Currently only nine percent of the PHU in charges reported to have Aspirin available in their facility.
  - c. Urine dipsticks can be made available since 49% of the centers did not have access to dipstick to assess proteinuria.
- 4) Patient motorbike referral cost re-imbursement for all patients with mild pre-eclampsia at

term could be considered, to prevent a financial threshold to referral and delay of induction.

5) Additional research could be conducted about barriers of referral, specifically for mild preeclampsia a term. These barriers could be targeted in future projects. Moreover, additional research might be conducted to assess the quality of ANC care in Western region specifically. Finally, in additional research about quality of care for HDP in secondary health care could be conducted to include assessment of the quality of treatment at hospital level and the further investigation of outcome measures, like maternal mortality and neonatal death.

## Implementation of recommendations

After conducting this research, I advise the DHMTs of Bo, Pujehun and Bonthe district the following activities. Some activities might need collaboration and support from partners, among others CUAMM, Doctors with Africa.

- 1) To employ a full-time midwife in each district to conduct an overall training about HDP diagnosis, treatment and prevention. Furthermore, the midwife could be made responsible for supervision at PHU level.
- To advocate at national level or from partners to provide CRADLE® BP machines for all PHUs.
   Moreover, a training would be needed for all HCW about the usage of this specific BP Machine.
- 3) To advocate at national level to increase to provision of Aspirin, Nifedipine and Labetalol, and distribute these medications at all PHU levels.
- 4) To advocate with partners to implement a motorbike voucher system, to reimburse patients for the travel costs from the PHU to a referral hospital for elective inductions of labour.
- 5) To design a study to determine referral barriers for patients with mild HDP at term.

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## Annex 1 Questionnaire and knowledge assessment

Name of center	MCHP/ MCP/ CHC/ BEmONC
	(please encircle the right one)
Date	
Function	MCHAID, SECHN, CHA, CHO, Midwife(please encircle the right one)
Year of graduation	

Thank you for taking the time to fill out this questionnaire. Please write the name of the center above, and mention if it is an MCHP, CHP, CHC or BEmONC. This data will be used for research and possible project implementation in the future. The document consists about 3 parts. The first part addresses the PHU you work at. The second part has some clinical scenarios, and the last some more general medical questions. None of the answers will be shared with third parties like the DHMT's. The document will be anonymized, and data will used only in a report aimed to formulate recommendations to improve quality of health care.

#### A) Health center

Is the following currently available in your clinic? Was there a stock out of that item in the last 3 months.

			Not	now available, but recent stock
		Available	available	out (in last 3 months)
in the health	Methyldopa	Available	available	months
centre	Labetalol			
	Hydralazine			
	Magnesium sulphate			
	Dexamethasone			
	Calcium gluconate			
	Oxytocin			
	Nifedipine			
	Aspirin			
	Urine dipstick			
	Guideline how to treat Preeclampsia?			
	Eclampsia			
	Guideline for medication dosage			
	Functioning BP machine and			
	stethoscope			

	Official government ANC register		
	Flip chart to explain danger signs		
		<u>.</u>	
organization	Has there been a period in the last 3		
PHU	months when there was no medical		
	staff in the PHU? If yes, how many		
	days?		Nr of days:
	Has there been a period in the last 3		
	months when there was no possibility		
	to refer an obstetric patient with the		
	ambulance? If yes, how many days?		Nr of days;
	Do you know if patients default from		
	ANC? If so, could you trace them?		
	Do you trace ANC defaulters?		
Personal	Do you have a personal functioning		
	smartphone, you could use for		
	protocols		
	Is there a possibility to charge a		
	smartphone in the center		
	Are you satisfied with the quality of		
	the work you are able to offer?		

#### B) Case scenario's

Please read the simplified case scenarios about blood pressures. Write down if you would start medication, if you would refer and why, if not when would you ask the patient to come back?

medication	ves/ no	if yes what medication + dose	

referral? yes/ no If yes; why?

In No; when review?

2) G2P1,  $1^{st}$  SVD, now  $1^{st}$  ANC 26w FH, no edema, FHR +, 155/90 mmHg

1) G4P3, 1st ANC 35 w Gestational age, edema, FHR +, 170/115 mmHg

medication	yes/ no	if yes what medication + dose
referral?	yes/ no	If yes; why?
		In No; when review?

3) G1	.P0, 2 <sup>nd</sup> ANC 30	w FH, no ede	ma, FHR +, 140/110 mmHg	
	medication referral?	yes/ no yes/ no	if yes what medication + dose If yes; why? In No; when review?	
4) G1	.P0 33 w FH, no	edema, 130/8	85 mmHg	
	medication referral?	yes/ no yes/ no	if yes what medication + dose If yes; why? In No; when review?	
	previous case s rtensive disordo		t should you mention in the health pro	omotion about
	hat would your eeks ago.	advice a wom	nan presenting with a history of eclamp	osia? Now G2P1, LMF
7) WI	nat are danger	signs for pre-e	eclampsia?	
	hen would you ro a patient with se	-	vith mild pre-eclampsia to the hospital? Ar	nd when would you

## Annex 2 Direct clinical observation chart

Name observe	r	Date
Center name		MCHP/ MCP/ CHC/ BEMONC(please encircle the right)
District		years of experience (year of graduation)

District	years of experience (year of graduation)						
		(	Case 1	Ca	ase 2	C	Case 3
		yes	no	yes	no	yes	No
Gravida/para							
History taken	about eclampsia/ /blood						
pressure? Last	pregnancy						
Asked about s	ymptoms of PE?						
- T	igastric pain, vision						
problems, ede	ema) this pregnancy						
	headache						
	epigastric pain						
	vision problem						
Listened to fet	al heart?						
FHR measured	1?						
BP measured	(if yes indicate value)						
Danger signs							
explained							
for PE							
	epigastric pain						
	headache						
	vision (light flashed/						
	blurred vision)						
	oedema						
	no fetal movement						
Urine dip							
stick done							
Medication							
prescribed							
	Methyldopa						
	Nifedipine						
	Furosemide						
	Labetalol						
	Magnesium sulphate						
	Diazepam						
Referral							
	ambulance						
	Motorbike						

## Annex 3 Exit interview observation chart

Name observer Date

Center name

MCHP/ MCP/ CHC/ BEmONC

(please encircle the right one)

		Cas	e 1	Case	2	С	ase 3
		yes	no	yes	no	yes	no
re-check Bp a	nd document						
Danger si	igns remembered for PE						
	epigastric pain						
	headache						
	vision (light flashed/						
	blurred vision)						
	oedema						
	no fetal movement						
medication							
prescribed							
	are medication available in						
	PHU						
	is the patient planning on						
	buying medication?						
Do you know back?	when you need to come						
In case of PE	is the patient informed						
	about delivery needs to be						
	induced at 37w?						
Did you ever o	come for ANC in the last 3						
months, and t	here was no staff at the						
clinic?							
is the woman	is the woman satisfied with the received						
health care?							
	quality of the care						
	attitude of the nurse						

		(	Case 4	Ca	ase 5		Case 6
		yes	no	yes	No	yes	no
Re-check Bp a	nd document						
Danger s	igns remembered for PE						
	epigastric pain						
	headache						
	vision (light flashed/						
	blurred vision)						
	oedema						
	no fetal movement						
Medication							
prescribed	<del>,</del>						
	are medication available in						
	PHU						
	is the patient planning on						
	buying medication?						
back?	when you need to come						
In case of PE	is the patient informed						
	about delivery needs to be						
	induced at 37w?						
Did you ever o	come for ANC in the last 3						
	here was no staff at the						
clinic?							
is the patient health care?	satisfied with the received						
caitii care:	quality of the care						
	attitude of the nurse					1	
	attitude of the fluide	<u> </u>	1				

#### Annex 4 Ethical considerations of the research

Since humans are used and analyzed in this study ethical implications are being considered. We took the four main ethical principles into account.

#### Autonomy

Participation to this study is voluntary. Not participating will have no financial or work-related implication. Participants can leave the study at any time, without implications. The study aims and procedure has been explained to each participant. Participants were informed about confidentially of the acquired data. Written consent was obtained before starting from both the patient and the health care provider. In the consent the following information is included; Nature of the study, how the data will be used, privacy protection mechanisms, risks, benefits, right to refuse or stop participating at any time.

The same applies to women attending ANC care in the selected clinics. It has been explained that no participation will not result in difference in health care, waiting time, or future health care.

#### **Bon-Maleficence**

We did not foresee harm to the participants other than the time used to participate in the study. To minimize risk of confidentiality violation, we did not include names of health care providers on the observation form, nor on the questionnaire or knowledge test. Moreover, in case of any violation of the confidentiality agreement of one of the team members this team members contract would have been terminated with immediate effect.

In case of identification of hypertension of pregnancy by the cost consultation interview not being identified by the initial health care provider, the patient was be referred back to the initial health care provider for re-assessment.

For the women attending ANC during the time of the research we did not foresee significant harm. However pregnant women may have had a bad outcome during a previous pregnancy. This study with additional questions from normal ANC could trigger memories of these experience and could have triggered anxiety. The researchers were aware of this risk and a special focus has been given to explain the purpose of the interview during their training.

In case of anxiety triggered by the research patients could have been referred to the health care provider of the facility to be counselled, or they could have been referred to the tertiary referral hospital in Bo where the principal investigator is responsible for all obstetric related care.

#### Beneficence

The participants did not benefit directly from their participations. However, the obtained data will result in a better understanding of the provided quality given by health care providers. Therefor better focused interventions will be proposed of which the participants will benefit to increase their knowledge and providing higher level medical care. The study region will benefit by an increased level of quality of care when recommended improvement suggestions are taken into consideration.

#### **Justice**

Written policies were followed by the research team to ensure fair procedures. Moreover, results of the study will be shared with authorities in a written report. Knowledge gathered by this study will be available for others in this way.

Approval by the ethical committee of Sierra Leone; *Sierra Leone ethics and scientific review committee*, was sought before starting the data collection. The participants had the right to contact the committee for more information of issues around this study.

## Annex 5 Informed consents

# Informed Consent Form – Questionnaire and knowledge assessment CUAMM – Doctors with Africa

#### Part I: Information Sheet

#### Purpose of the research

The research is designed to assess the quality of care for women with high blood pressure during pregnancy. This assessment can be used later to improve care later on, with the aim to reduce mothers and new-borns from dying.

#### Type of Research Intervention

A questionnaire will be completed among PHU in charges, to assess equipment and medication to conduct an ANC according to international standards. Moreover, a knowledge assessment about hypertensive disorders will be included in this questionnaire. Furthermore, direct clinical observations in the PHU will be conducted and exit interviews will be done with patients after ANC visit.

#### **Participant Selection**

You are being selected as participant of an PHU in charges meeting. All participants will be asked to complete a questionnaire and knowledge assessment.

#### **Voluntary Participation**

Your participation in this research is entirely voluntary. It is your choice whether to participate or not.

The choice that you make will have no bearing on your job or on any work-related evaluations or reports. You may change your mind later and stop participating even if you agreed earlier.)

#### **Procedures**

We are asking you to fill a written questionnaire and knowledge assessment that will take about 45 minutes. This can help us learn more about quality gabs in current ANC for hypertensive disorders. This questionnaire and knowledge assessment will be conducted during an in-charge meeting.

The questions are based on internationally validated checklists for ANC developed on the basis of WHO recommendations.

We will not ask you to share personal beliefs, practices or stories and you do not have to share any knowledge that you are not comfortable sharing. The information recorded is confidential, and no one else except CUAMM will have access the information. The information will be destroyed after 6 months.

#### Risks

We foresee only minimal risk for you to participate. There is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable about being questioned about your professional capacity. However, we do not wish for this to happen as it is an opportunity to detect possibilities to improve quality of ANC.

#### **Benefits**

When completing the questionnaire and knowledge assessment, you will receive a soda as sign of appreciation of the time you invested. There will be no monetary compensation for your contribution, but your participation is likely to help us find out more about how to improve antenatal care for patients with

hypertensive disorders of pregnancy.

#### Reimbursements

You will not be provided any incentive to take part in the research.

#### Confidentiality

We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except with the CUAMM research team.

#### **Sharing the Results**

Nothing that you tell us today will be shared with anybody outside the research team, and nothing will be attributed to you by name. The overall conclusions and knowledge that we get from this research will be shared with the Ministry of health and CUAMM to develop quality improvement programs in the future.

#### Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your job or job-related evaluations in any way. You may stop participating at any time that you wish without your job being affected.

#### Who to Contact

If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following: Dr Arne Béguin, obstetrician, CUAMM, Bo government hospital,

This proposal has been reviewed and approved by the Sierra Leone ethic committee. which is a committee whose task it is to make sure that research participants are protected from harm. You have the right to contact the ethics and scientific review committee, if you sustain a research-related injury, or have issues with the study

The Sierra Leone ethical committee is reachable at;
Ministry of Health and Sanitation Directorate of Policy,
Planning & Information (DPPI) Youyi Building, Fifth Floor, East Wing. +23278 366493

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

#### **Part II: Certificate of Consent**

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study

Print Name of Participant	
Signature of Participant	
Date	

#### Informed Consent Form – Clinical observations

#### **CUAMM – Doctors with Africa**

#### **Part I: Information Sheet**

#### Purpose of the research

The research is designed to assess the quality of care for women with high blood pressure during pregnancy. This assessment can be used later to improve care later on, with the aim to reduce mothers and new-borns from dying.

#### **Type of Research Intervention**

During the research a research assistant will join a health care provider to assess with a checklist the current quality of ANC, for detection and treatment of high blood pressure related diseases. Furthermore, exit interviews will be conducted with patients to gain better understanding of the acquired information by the patient. Exit interviews will take 10 minutes to complete.

#### **Participant Selection**

You are being selected by a random chance. A random selection has been made from all PHUs in the southern region of Sierra Leone. One of the health care providers providing ANC services are included, if there are more than one health care provider conducting ANC the one in the left room will be included.

#### **Voluntary Participation**

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. The choice that you make will have no bearing on your job or on any work-related evaluations or reports. You may change your mind later and stop participating even if you agreed earlier.)

#### **Procedures**

We are asking you to welcome the research assistant to your ANC visits of today. This can help us learn more about the current strengths and gabs of the current health care. We will invite the patients to take part in an exit interview with a checklist, to assess the retained knowledge about their condition.

The checklists are based on internationally validated assessment checklist developed on the basis of WHO recommendations.

The exit interview with the patients are similarly based on interventional validated examples adapted for hypertensive disorders. We will not ask you to share personal beliefs, practices or stories and you do not have to share any knowledge that you are not comfortable sharing. The information recorded is confidential, and no one else except CUAMM will have access the information. The information will be destroyed after 6 months.

#### Risks

We foresee only minimal risk for you to participate. There is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable being observed of your professional competence during patients care. However, we do not wish for this to happen.

#### **Benefits**

There will be no direct benefit to you, but your participation is likely to help us find out more about how to improve antenatal care for patients with hypertensive disorders of pregnancy.

#### Reimbursements

You will not be provided any incentive to take part in the research.

#### Confidentiality

We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except with the CUAMM research team.

#### **Sharing the Results**

Nothing that you tell us today will be shared with anybody outside the research team, and nothing will be attributed to you by name. The overall conclusions and knowledge that we get from this research will be shared with the Ministry of health and CUAMM to develop quality improvement programs in the future.

#### **Right to Refuse or Withdraw**

You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your job or job-related evaluations in any way. You may stop participating at any time that you wish without your job being affected.

#### Who to Contact

If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following: Dr Arne Béguin, obstetrician, CUAMM, Bo government hospital,

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You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

#### **Part II: Certificate of Consent**

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study

Print Name of Participant	
Signature of Participant	
Date	

#### Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

- 1. direct clinical observations with a checklist
- 2. exit interviews from the patients

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions
asked by the participant have been answered correctly and to the best of my ability. I confirm that the
individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Name of Researcher/person taking the consent
Signature of Researcher taking the consent
Date

## Informed Consent Form – exit interview CUAMM – Doctors with Africa

#### Part I: Information Sheet Purpose of the research

The research is designed to assess the quality of care for women with high blood pressure during pregnancy.

#### Type of Research Intervention

During the research a research assistant will join the health care provider with a checklist to check the current quality of ANC for detection and treatment of high blood pressure related diseases. Furthermore, exit interviews will be conducted with patients to understand better what patients remember and understand from the clinic visit. Exit interviews will take 10 minutes to complete.

#### **Participant Selection**

You are being selected because we selected this clinic by random chance, if there are more than one health care provider conducting ANC the persons in one in the left room will be included.

#### **Voluntary Participation**

Your participation in this research is entirely voluntary. It is your choice whether to participate or not.

The choice that you make will have no difference in the treatment or medication you will receive. You may change your mind later and stop participating even if you agreed earlier.

#### **Procedures**

We are asking you to allow the research assistant to join your ANC visits today, and to participate in an exit interview after the NC visit. This can help us learn more about the quality of ANC care clinics. We will not ask you to share personal beliefs, practices or stories and you do not have to share any knowledge that you are not comfortable sharing. The information recorded is confidential, and no one else except CUAMM will have access the information. The information will be destroyed after 6 months.

#### Risks

We foresee only minimal risk for you to participate. There is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable being observed during receiving medical care. However, we do not wish for this to happen.

#### **Benefits**

There will be no direct benefit to you, but your participation is likely to help us find out more about how to improve antenatal care for patients with hypertensive disorders of pregnancy.

#### Reimbursements

You will not be provided any incentive to take part in the research.

#### Confidentiality

We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except with the CUAMM research team.

#### **Sharing the Results**

Nothing that you tell us today will be shared with anybody outside the research team, and nothing will be attributed

to you by name. The overall conclusions and knowledge that we get from this research will be shared with the Ministry of health and CUAMM to develop quality improvement programs in the future.

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You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

#### Part II: Certificate of Consent

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Print Name of Participant	
Signature of Participant	
Date	

#### Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

- 1. direct clinical observations with a checklist
- 2. exit interviews from the patients

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Name of Researcher/person taking the consent
Signature of Researcher taking the consent
Date