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# A qualitative document analysis of policies influencing preeclampsia management by midwives in Ghana

Isabella Garti<sup>a,\*</sup>, Michelle Gray<sup>b</sup>, Angela Bromley<sup>a</sup>, Jing-Yu (Benjamin) Tan<sup>a</sup>

<sup>a</sup> College of Nursing and Midwifery, Charles Darwin University, Darwin, Australia

<sup>b</sup> School of Nursing and Midwifery, Edith Cowan University, Joondalup, Australia

ARTICLE INFO	A B S T R A C T			
<i>Keywords:</i> Preeclampsia Standards Midwifery Scope of practice Qualitative document analysis	Background: Preeclampsia is a global issue that causes significant morbidity and mortality in low- and middle- income countries (LMICs). The care women with preeclampsia receive in LMICs is below the standard experi- enced by women in westernised countries due to multiple interacting factors. A review of policy factors influ- encing the management of preeclampsia in Ghana is needed. <i>Aim:</i> This study focuses on the midwife's role and scope of practice concerning preeclampsia management. The			
	study aimed to explore the congruence between Ghanaian preeclampsia guidelines and international best practice recommendations for midwifery practice. The study also aimed to describe how recommendations are incorporated into Ghanaian guidelines. <i>Method/design</i> : This study was a qualitative document analysis of national and tertiary hospital policies related to midwives' scope of practice in Ghana. Altheide's five-step process (sampling, data collection, data coding and organisation, data analysis and report) was used to systematically source and analyse the content of written			
	documents. <i>Results:</i> The findings illustrated several recommendation shortcomings in Ghanaian documents at the national and tertiary hospital levels. The content of Ghanaian preeclampsia management guidelines was not compre- hensive, contained conflicting information, and was not backed by research evidence. The standards of practice for midwives were consistent at both the national and tertiary hospital levels. Midwives had limited roles in detection, management, stabilisation, and referral of women with preeclampsia. <i>Conclusion:</i> Uniform guidelines incorporating international recommendations are urgently needed to improve			
	multi-professional collaboration, solidify midwives' roles, and optimise maternal and fetal outcomes.			

# Statement of significance

#### Problem or issue

Women who develop preeclampsia and are managed in limitedresource settings experience multiple adverse outcomes at alarming levels.

# What is already known

Worldwide, the consensus is that women experiencing complications in childbirth should receive the best possible care from a multidisciplinary team, which includes midwives. Midwives are expected to provide evidence-based care according to prescribed recommendations within guidelines.

# What this paper adds

This policy review has shown that international recommendations that identify the midwife's scope of practice of caring for women with preeclampsia are not being enacted at the national or tertiary hospital level in Ghana. Inconsistent policy factors can challenge midwives' ability to effectively function in interprofessional settings and reduce women's access to timely interventions. It is crucial to support and equip practising midwives who will, in turn, greatly improve the quality of care for women who develop preeclampsia.

\* Corresponding author at: Charles Darwin University, 7 Ellengowan Dr., Casuarina, NT 0810, Australia. *E-mail address:* Isabella.garti@cdu.edu.au (I. Garti).

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## 1. Introduction

Preeclampsia (PE) management in low- and middle-income countries (LMICs) is less than optimal in poorly resourced settings [1–4]. To reduce maternal deaths and long-term disability, multi-disciplinary care is recommended for all women who develop complications, and the provision of prompt evidence-based treatment is essential [2,5–8]. In LMICs prevailing health disparities, technological challenges and lack of country-specific standard care policies make the application of interventions for PE management challenging [2,7,9]. Worldwide, overwhelming evidence shows that within their defined scope of practice, and regardless of the birth setting, midwives are pivotal in recognising deviations from normal and providing lifesaving interventions for both normal and high-risk pregnancies including PE and eclampsia [10].

#### 1.1. Background: the context of Ghana

Despite a downward trend in maternal mortality, considerable effort is required for Ghana to meet the United Nations Sustainable Development Goal (SDG) targets for reducing maternal mortality by 2030 [11]. PE and eclampsia are the leading causes of direct maternal mortality, 50% of which occur in tertiary hospitals [12,13]. In the largest tertiary hospital in Ghana, between 2015–2019, there were 45,676 live births and a maternal mortality ratio of 604/100,000 live births 13]. More than 250 maternal deaths occurred in that period, 37.3% of which resulted from hypertensive disorders including PE. Some Ghanaian studies have ascribed maternal deaths from PE to mismanagement, socio-cultural factors, and unavailability of medications and other supplies at healthcare facilities [12–16].

The Ghanaian health system is organised and delivered in three tiers. Tertiary hospitals are the highest in the hierarchy, followed by secondtier district hospitals. The lowest tiers are the community health centres and Community-based Health Planning and Services which are often poorly resourced [17]. The Greater Accra region is the most populous out of 16 regions in the country with over 5 million people living in peri-urban and urban centres where high birth rates are recorded [18]. Antenatal visit trends show a high number of women in Greater Accra attend hospitals and about 50% have access to skilled attendants at birth [19,20].

In Ghana, the Ministry of Health provides policy oversight whilst the Ghana Health Service implements and oversees the running of all public health facilities at the district and community levels. Tertiary hospitals are autonomous and report directly to the Ministry of Health. Maternity services in Ghana are subsidised by the government thereby making them freely accessible to women attending public healthcare facilities. This pregnancy care policy aims to improve access to maternal healthcare, however, due to inadequate health infrastructure and other systemic issues such as challenges in the referral system, the impact of these maternal health policies has not been fully realised [11,21].

The majority of midwives in Ghana receive 12-36 months of midwifery education based on a standardised curriculum. Although this range of training translates into different levels of registration, all midwives across different settings in the health system are expected to have the same skill set and the same professional scope [22-24]. In Ghana, there are 7 midwifery ranks in a hierarchy based on the years of experience [23]. Junior level midwives include newly qualified staff midwives and senior staff midwives who have practised for at least 4 years. Midwifery officers are mid-level midwives whilst senior midwifery officers and principal midwifery officers are the clinical managers. The deputy director and director of midwifery service ranks are managerial positions and they do not perform direct clinical care [23]. Midwifery practice in Ghana is guided by national and local policies. Ghanaian midwives provide routine care and perform basic emergency obstetric and neonatal care at the primary and secondary levels. In primary healthcare facilities, midwives work together in group practice models compared with tertiary hospitals where maternal care is obstetric led and medicalised [23]. Recently, the Ghanaian midwifery workforce has undergone a dramatic demographic shift, largely caused by increased training programs to meet the demand for more midwives [25]. As a consequence, many young inexperienced midwives are taking on management roles with few clinical mentors to provide clinical supervision contrary to health system requirements.

The Ghana Standard Treatment Guidelines and the Ghana National Safe Motherhood Service Protocol provide the national requirements for PE management in the country [26–28]. Although these guidelines are available, distribution is poor resulting in low visibility and therefore underutilisation by frontline health workers thereby compromising the quality of care [26,29]. Midwives' contributions to PE management in Ghana and other LMICs remains largely undocumented, and an examination of existing policies influencing PE management by midwives is needed.

#### 1.2. Aim

The aims of this study were twofold. First, to explore whether Ghanaian PE guidelines are congruent with international recommendations, and second, to explore the international best practice recommendations for midwifery practice specific to PE management and describe how these could be adopted and incorporated into the Ghanaian guidelines.

#### 2. Methodology

This study utilised a document analysis approach. Document analysis is the collection of key documents which are then systematically examined to answer posed research questions [30]. A document analysis aims to uncover the root of a specific problem and provides valuable additions to the knowledge base which is useful in health research [31, 32]. Altheide and Schneider propose a 12-step approach to identify and evaluate the information contained in documents [30]. Altheide's method was applied because it is flexible and allows a wide variety of non-published material to be analysed alongside official documents. Also, the detailed stepwise process is reflective and facilitates consistency in managing the data which enables an in-depth exploration of rich context-specific information [30].

Altheide's 12 steps are embedded in five stages which include document sampling; protocol development and data collection; data coding and organisation; data analysis; and reporting. See Supplementary Table 1 [32].

## 2.1. Stage 1: document sampling

Documents were retrieved from international and Ghanaian sources via the internet and personal communication. Key people in Ghana were contacted by email and phone calls. Policy briefs, documents not relevant to the study aims, documents created more than 10 years ago, ongoing revisions, and older editions of the same documents were excluded.

#### 2.2. Stage 2: protocol development and data collection

A protocol was created to guide the data collection process. The protocol outlined the search terms, databases and other sources, inclusion and exclusion criteria and data analysis procedures. Websites were searched to locate a comprehensive set of policies from Ghanaian health institutions. Search terms included single words and phrases including: "preeclampsia management"; "hypertensive disorders treatment guide-lines"; "preeclampsia flowchart"; "midwifery scope of work"; "nurse-midwives job scope"; "midwives guidelines". Twenty-four documents published in the last ten years were retrieved (Fig. 1), and an Endnote™ (version 20) database was created for data management. Supplementary Table 2 outlines the background information of the documents located.

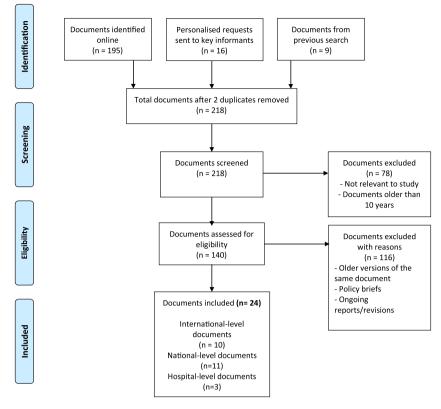


Fig. 1. PRISMA flow diagram.

#### 2.3. Stage 3: data coding and organisation

A total of 24 documents were analysed: 10 international documents [5,6,33–40] and 14 Ghanaian documents [22–24,27,28,41–49]. Data coding was done manually and through QSR's NVivo 12.0 software as a backup. A deductive coding approach involved using preset codes identified from a previous literature review to each selected document [50]. This helped to sort the data into three tentative broad topic areas relevant to the study: category one: PE management guidelines, category 2: midwives' scope of practice and category 3: supporting policies. Further, emergent first level and second-level open codes were assigned to the documents and evaluated by the supervising team to ensure reliability.

## 2.4. Stage 4: data analysis

Descriptive content analysis was performed [51]. Coded data in each of the three data sets were listed in two data tables (Supplementary Tables 3 and 4), checked, compared for key similarities, variations, and contrast within and between international standards, Ghanaian national and tertiary hospital recommendations. Similarly, the midwife's scope of practice documents was compared. Analytic memos were created throughout the analysis.

## 2.5. Stage 5: reporting

The final stage involved synthesising and interpreting the findings against the research questions. Findings are presented descriptively under two headings related to the research questions: guidelines on PE management, and midwives' scope of practice.

#### 2.6. Trustworthiness

To reduce potential bias, documents were thoroughly appraised by

two members of the research team who examined the authenticity, accuracy, and usefulness of the documents. Analytic memos were created and maintained throughout the coding process to serve as a visible audit trail. Regular debriefing sessions were held with the research supervisors. The study adhered to the standards for reporting qualitative research (SRQR) (Supplementary Table 5).

#### 3. Results

One hundred and twenty-five key recommendations were coded from the WHO documents [6,35,40]; 55 statements from the ISSHP document [33]; 107 from the national documents [27,28,42,45,46], and 82 key points from the hospital-level documents [47,48]. In total 369 key recommendations were extracted during primary coding and arranged in 29 categories to facilitate easy comparison across the documents (Supplementary Table 6). A total of 22 key findings emerged from the documents, 12 from the national level and 10 from the hospital clinical practice guidelines (Table 1).

The two fundamental Ghanaian national PE guidelines did not have supporting research evidence and lacked consistent statements about the level of care and interventions for PE management. The documents were not comparable, had several omissions and did not reference one another. The methodological processes were unclear, and some international requirements were omitted and outdated. There were no review processes highlighted in any of the Ghanaian PE guidelines. In comparison, international documents had more detailed explanations about the scope of the guideline, development processes, and outlined robust evidence underlying interventions [6,33,35,40].

The hospital PE guidelines had a similar style to the national documents and the recommendations mirrored the format and national expectations in PE management. At the hospital level the recommendations were not explicit for clinicians, and similarly lacked evidence and was not comprehensive. In addition, the language was not woman-centred, but task-oriented.

#### Table 1

Findings from	ı national	and	tertiary	hospital	PE	guidel	ines
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	Findings
National documents	<ol> <li>Recommendations align with WHO standards</li> <li>Guideline development processes not detailed</li> <li>Little empirical evidence is provided for the rationale of clinical interventions</li> <li>Classification of PE by severity contravenes ISSHP recommendations</li> <li>Rigid criteria for establishing PE diagnosis with proteinuria, however, little guidance on proteinuria assessment.</li> <li>Little details on blood pressure assessment considerations</li> <li>No information on preventative measures (aspirin and calcium prophylaxis); prediction of PE; HELLP syndrome; post-partum care; and long-term follow-up</li> <li>Contradictions in the guidelines e.g., prenatal corticosteroids in NSMSP but not STG.</li> <li>Insufficient details regarding magnesium sulphate monitoring and the management of toxicity</li> <li>Refer to outdated practices in PE management such as bed rest, routine antenatal weighing, fetal kick counting.</li> <li>Little information for pregnant women and their support persons</li> <li>No specific midwifery actions</li> </ol>
Hospital level documents	<ol> <li>No empirical evidence supporting interventions and development methods not explicit</li> <li>Content mirrors national recommendations</li> <li>Lack of clear specification on health professionals' roles</li> <li>There are no criteria for antenatal assessment and management</li> <li>No recommendations on PE prevention for high-risk groups</li> <li>There is scant information about considerations for magnesium sulphate administration and management of toxicity</li> <li>No antenatal and intrapartum care considerations (maternal observations on the inpatient unit; birth and third stage management; woman and family education)</li> <li>Lack of shared decision making and woman-centred health education</li> <li>No recommendations on postnatal management and follow up</li> <li>Recommended midwifery actions are stated but they are vague and not holistic</li> </ol>

## 3.1. Characteristics of guidelines on PE management

International documents were written by collaborations of multidisciplinary teams and research evidence was used to underpin recommendations [6,26,35,40]. At the national level, there were two main documents [27,28] and four other supporting documents [24,42,45,46] that were created by experts through consensus to guide PE and eclampsia management. Tertiary hospital documents were the results of collaborative teamwork among multidisciplinary staff [47,48]. Information from international guidelines was used to create an outline of the best practice standards for comparison with PE management at national and tertiary hospital levels in Ghana. Internationally, the scope of PE management was identified and addressed in the documents under headings; diagnosis, antenatal, labour, postnatal and eclampsia management sections [6,33] (Table 1).

At the national level, the Ghana National Safe Motherhood Service Protocol is a guideline for the management of pregnancy and labour complications [28]. Its counterpart, the Ghana Standard Treatment Guidelines is used alongside and serves as a resource for all health professionals to guide the overall management of conditions [27]. Both of the national guidelines had the accepted regimens for first-line and second-line antihypertensive medications, magnesium sulphate administration and also included some information about blood pressure (BP) assessment, fetal monitoring, laboratory tests and referral [27,28]. The Guidelines included information on the accepted regimens for the treatment of severe and non-severe hypertension and emphasised a less tight BP goal of 140/90 mmHg. However, the national documents had scant information concerning outpatient care; intrapartum care; eclampsia management; postpartum care; and follow-up [27,28] (Supplementary Table 5).

The tertiary hospital guidelines reflected the same information as the national standards (Table 1). From a medical management perspective, there was a useful flowchart illustrating the management of PE and eclampsia that provided guidance based on the severity and gestation of the pregnancy. Additional information on HELLP syndrome and eclampsia management was outlined. The antihypertensive drug regimens contained within the obstetric triage protocol met international standard care provision. The documents had no information about antenatal screening for PE and postnatal follow-up and care (Table 1).

In terms of guidance for midwives, there were 11 actions for midwives listed in the hospital guidelines. Three actions were nonspecific and included preparing the pregnant woman for surgery, employing aseptic techniques, nursing in a comfortable bed, and administering intravenous fluids [47]. There was insufficient detail on the assessment and diagnosis of PE. The single recommendation on blood pressure assessment did not provide sufficient detail on the technique and reporting procedures: 'Check BP, pulse, and respirations every 15 minutes and record till BP is less than or equal to 140/90 mmHg, then every 30 minutes till fetus is born, then hourly for 24 h after birth' [47]. There was no guidance for midwives on emergency management of a woman with severe hypertension or during an eclamptic seizure and communication between health professionals. Also, the guidance on immediate and subsequent PE care was not distinct and the midwifery duties and responsibilities did not cut across the antenatal, labour, or postnatal wards (Supplementary Table 5). Of concern is the lack of guidance on emergency management of a severe hypertension episode and eclampsia care. Also, the care pathway in the documents did not distinguish between immediate and subsequent PE care and midwifery responsibilities did not cut across the antenatal, labour, or postnatal sections (Supplementary Table 6).

#### 3.2. Midwifery scope of practice

Midwives' scope of practice specific to PE management were analysed.

International, Ghanaian national and tertiary hospital documents which outline the midwife's scope of practice when caring for women with PE were compared and contrasted. From the analysis, there were three findings noted from the national documents and five from the hospital level documents.

# 3.2.1. Characteristics of documents on midwives' scope of practice

International documents included the ICM core competencies for midwifery practice [34], ICM position statements [5,37-39], and the strengthening midwifery toolkit developed by WHO [36]. The ICM documents identify the scope of the midwife as an expert in normal physiology, able to respond to emergencies such as PE, and after notifying the obstetrician for their expertise in complicated care, work collaboratively with the multidisciplinary team to provide care for the ill woman. The ICM has specified four broad midwifery competency areas that outline the minimum best practice standards of care midwives provide globally [34]. This includes general competencies, pre-conception and antenatal care competencies, labour competencies and postpartum competencies. The scope of a midwives' knowledge, skills, and behaviour in each of the four competency areas is dependent on their role, experience, qualifications, and the country context. The international documents articulated that the midwife's role in the management of complications such as PE included four pillars of detection, stabilisation, management, and referral of pregnant women [5,34,36,37].

Nationally, the documents referred to the midwifery scope of practice as the job descriptions. Generally, in Ghana, regulatory requirements specify that the midwife' scope of work includes performing initial and ongoing comprehensive assessments, identifying abnormalities, and initiating treatment [22]. Midwives are responsible for preconception, antenatal, labour and postnatal care. The documents provided a varying scope of practice based on seven different levels of midwifery. For example, mid-level midwifery officers were responsible for identifying and managing obstetric emergencies and their scope of practice in PE management encompassed urine protein assessment and magnesium sulphate administration. There were no specific PE management roles for junior midwives as they were ascribed more assistive routine functions and were required to provide primary care in pregnancy, promote normal birth, and refer when necessary (Supplementary Table 4).

Midwifery responsibilities in the hospital were nonspecific for PE management and had inferred content. The job descriptions at the hospital level were listed as main duties and were not in domains. Junior and mid-level midwives with one to eight years post qualification experience were required to assist with antenatal services, attend normal births, and perform protocol-based management whilst senior midwives, from the rank of senior midwifery officer onwards, perform only administrative tasks. There was no mention of escalation procedures when a situation is outside the midwives' scope, collaboration with other cadres, and postnatal care.

## 4. Discussion

This research set out to examine the congruence between international best practice standards and Ghanaian national and hospital guidelines on PE management with particular reference to Ghanaian midwives' scope of practice. The analysis demonstrated that there were several recommendation gaps in the Ghanaian documents which may undermine the country's efforts in the reduction of maternal deaths resulting from PE. These gaps include omissions and discrepancies, lack of sufficient detail, and underutilisation of midwifery staff.

## 4.1. National management of PE: omissions and discrepancies

Aspirin and calcium prophylaxis for at-risk groups are widely recommended [4,40] but were omitted from Ghanaian national guidelines even though these drugs are available in Ghanaian hospital pharmacies [42]. In LMICs, calcium supplementation is of great importance due to a high probability of limited dietary intake and this oversight requires immediate action [2,4,40]. Although blood pressure gradually returns to baseline following the birth, women are still at risk of complications including post-partum eclampsia, and therefore blood pressure assessment is critical within 72 h after the birth, yet this was not addressed by the guidelines [4,33]. The guidelines also did not have content on HELLP syndrome management and the approach to care was not woman-centred which may negatively impact on a positive birth experience [52]. The apparent lack of updated information in the Ghanaian national-level guidelines is of immediate concern. Contrary to ISSHP recommendations, the Ghanaian national guidelines differentiated between mild and severe PE. Stratifying women by severity can be detrimental to survival if tags such as "mild" are misinterpreted and could delay referral. It also trivialises atypical symptoms that may be severe manifestations of the disorder 33].

#### 4.2. PE management at the tertiary hospital-level: lacking sufficient detail

Tertiary hospital guidelines lacked reference to multidisciplinary working and teamwork, which may negatively impact continuity of care for women who develop PE. In promoting quality of care, women should have their care led by an obstetrician but midwives should also be fully involved within their scope [5,6]. PE guidelines should provide a comprehensive point of reference to promote best practice [4]. Co-created practice policies can build a shared understanding and reduce task duplication [53].

## 4.3. Underutilisation of Ghanaian midwives in PE management

Although midwifery has an internationally recognised scope of practice, in Ghana there is disagreement among some stakeholders regarding the midwife's scope of practice based on place of work [54]. In Ghana, midwives' roles in detection, stabilisation, treatment, and referral of women with PE is limited by Ghanaian PE guidelines as they do not delineate midwives' roles, the care expectations, and midwifery practice outcomes. While the term scope of practice has been used in this paper the actual documents referred to the work of midwives as tasks and activities. This observation signifies that perhaps the midwifery practice model is not fully recognised in the Ghanaian health system [55,56].

Over a ten year period Ghana has increased the number of midwives [25] however the professional rank system is an impediment to responsiveness to women's needs. We found that in PE management, the lowest-ranked midwives, especially those in the teaching hospital, where pregnant women present in a relatively high volume, did not have any specific responsibilities in PE management in their job descriptions. However, Ghana's reproductive health policy outlines that the administration of anticonvulsant drugs is a basic emergency obstetric care function for which all midwives have been trained [24]. This finding suggests that midwives' need practice protocols that describe midwifery care for all midwives to follow. In LMICs, midwives' scope of practice and the management of pregnancy complications should not appear to be mutually exclusive, rather midwives must work to their full scope of practice which includes their involvement in high-risk pregnancy care [10,56].

#### 5. Recommendations

PE and eclampsia management are established priority areas in the WHO's quality care framework and Ghanaian documents must integrate the acceptable criteria. First, we recommend that stakeholders should prioritise PE and eclampsia care in Ghana and similar contexts to accelerate progress in maternal health indicators. Second, national guidelines need consolidation to reduce fragmentation and overlap. It is also important to formulate actionable statements for multidisciplinary teams to illicit behaviour and role-based competencies [26]. Third, stakeholders must use standardised methods to generate high-quality guidelines and maintain dynamic documents by regularly updating guidelines to inform current practice [2,57]. Fourth, urgent dialogue is needed for scope expansion and empirical evidence should be used to support the expansion of midwife-led care for women with PE and eclampsia. The scope of practice between the different levels of midwives in Ghana needs further exploration based on the practice setting or the woman's need. At the hospital level, developing and auditing midwives' guidelines in addition to expanding midwives' practice boundaries is an effective strategy to reduce restrictive practice environments and circumvent barriers to midwives' active participation in PE management. These strategies will enhance overall efficiency in the facility and improve the quality of care.

#### 6. Strengths and limitations

This study reports findings that shed light on how national management guidelines and scope of practice boundaries may affect PE management in Ghana. Findings from this document analysis can stand alone to inform policy direction and can also be integrated by triangulation in a broader context. As a strength to support further approaches, document analysis is cost-effective, produces rich supplementary data, and covers a broad area.

Due to current COVID-19 restrictions, physical access to some national documents was hampered because some documents were not in the public domain. Also, bureaucratic processes in some national institutions resulted in selection bias because some documents were not retrievable. We also had delays in obtaining some documents, a few records were incomplete, whilst others had a small amount of useful data. As the documents we analysed were written for other purposes beyond the scope of this study, the information covered may not fully address the researchers' interests. However, because this document analysis is a supplemental component within a broader study, and the analysis provides insights for some aspects of the broader study, even a few documents can provide a useful means of addressing the aim of the study.

#### 7. Conclusion

This is the first policy review that highlights notable gaps related to PE management guidelines and midwives' scope of practice in the Ghanaian context. Midwife competence is a global agenda and Ghana has supporting structures and policies that are focused on capacity building, development of the midwifery workforce, and ensuring highquality maternity care [24,41,43]. However, this document analysis found disparities in PE guidelines and limited scope of practice roles that can negatively impact women's care by reducing their access to timely interventions for the treatment of PE. Furthermore, disparities challenge midwives' ability to effectively function in interprofessional settings. The findings of this study identify areas that represent an opportunity for change, to create a supportive environment, and eliminate the apparent structural barriers that impede midwives' management of PE not just in Ghana but in similar settings.

#### Author contributions

The authors confirm that this work is original and forms part of a PhD study. This article has not been published nor submitted for publication elsewhere. All authors have reviewed and approved the final version being submitted. The authors abide by the copyright terms and conditions of Elsevier and the Australian College of Midwives.

Isabella Garti: Conceptualization, Methodology, Investigation, Data Curation, Visualization, writing original draft; Michelle Gray: Conceptualization, Writing- Reviewing and Editing; Angela Bromley: Writing- Reviewing and Editing; Jing-Yu (Benjamin) Tan: Supervision, Writing- Reviewing and Editing.

#### **Ethical approval**

No humans were involved in this research and access to publicly existing documents does not require ethical approval. However as is the norm in Ghana, we obtained permission from the appropriate authorities and sent formal request letters via email.

This study is also part of a doctoral research project. Ethical clearance for the broader project has been granted by Charles Darwin University Human Research Ethics Committee and Korle Bu Teaching Hospital Institutional Review Board and Scientific Committee (CDU-HREC H20118; KBTH-STC/IRB/00013/2021).

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#### **Conflicts of interest**

None declared.

# Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.wombi.2022.01.006.

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