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Active Audit and Feedback Intervention to Increase Use of Magnesium Sulfate and Anti-Hypertensive Therapy among Women with Severe Pre-eclampsia and Eclampsia in Public Referral Hospitals in Ethiopia

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The Maternal and Child Survival Program (MCSP) is a global, $560 million, 5-year cooperative agreement funded by the United States Agency for International Development (USAID) to introduce and support scale-up of high-impact health interventions among USAID's 25 maternal and child health priority countries,* as well as other countries. MCSP is focused on ensuring that all women, newborns, and children most in need have equitable access to quality health care services to save lives. MCSP supports programming in maternal, newborn, and child health, immunization, family planning and reproductive health, nutrition, health systems strengthening, water/sanitation/hygiene, malaria, prevention of mother-to-child transmission of HIV, and pediatric HIV care and treatment.

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Acronyms

ANC	Antenatal Care
APH	Antepartum Hemorrhage
BEmONC	Basic Emergency Obstetric and Newborn Care
ESO	Emergency Surgical Officer
HC	Hypertensive Crises
HSS	Health System Strengthening
IM	Intramuscular
IV	Intravenous
MCHIP	Maternal and Child Health Integrated Program
MCSP	Maternal and Child Survival Program
MNCH	Maternal, Newborn, and Child Health
QI	Quality Improvement
PE	Pre-Eclampsia
PE/E	Pre-Eclampsia/Eclampsia
PNC	Postnatal Care
PPH	Postpartum Hemorrhage
SNNPR	Southern Nations, Nationalities, and Peoples' Region
USAID	United States Agency for International Development
WHO	World Health Organization

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Executive Summary

Ethiopia is among countries with high maternal mortality, with severe pre-eclampsia/eclampsia being one of the leading direct causes. If women receive effective care delivered according to evidence-based standards, the majority of deaths related to pre-eclampsia/eclampsia could be avoided. The management of severe pre-eclampsia/eclampsia, including controlling severe hypertension, through the correct use of magnesium sulfate and anti-hypertensive drugs, respectively, can significantly reduce complications and deaths related to severe pre-eclampsia/eclampsia. However, the use of magnesium sulfate was only recently adopted in Ethiopia in 2010 and it is still not widely used.

This study aimed to determine if an active audit and feedback intervention in public referral hospitals in Ethiopia improves the quality of care (i.e., increased and appropriate use of magnesium sulfate and anti-hypertensive therapy) provided to women who experience either pre-eclampsia/eclampsia or a hypertensive crisis.

The study employed a before-and-after design and used both quantitative and qualitative methods. Data were abstracted from registers prior to intervention retrospectively and over six months right after intervention was started. Knowledge and confidence of providers to treat women with pre-eclampsia/eclampsia according to protocols and standards was assessed before and after the audit and feedback intervention using a self-administered questionnaire. The feasibility and acceptability of the audit and feedback intervention was assessed using in-depth interviews with providers after five months of the intervention.

The audit and feedback intervention was carried out over five months (from mid-July to mid-December 2016) at eight public hospitals. These hospitals were purposively selected out of a total of over 200 hospitals in Ethiopia, chosen largely because of where the Maternal and Child Survival Program worked. In addition, they were representative of large-volume hospitals in four major regions of Ethiopia (Oromia, Amhara, SNNPR, and Tigray) and Addis Ababa City Administration. All eight hospitals have relatively high average numbers of monthly deliveries.

The following are key findings from the study:

- The number of pre-eclampsia/eclampsia cases documented before intervention (over six months) was much lower than the number of pre-eclampsia/eclampsia cases documented after intervention (over five months), indicating that audit and feedback intervention improved the case detection rate of PE/E or documentation or both.
- Over the five months of audit and feedback intervention, 481 women were admitted for pre-eclampsia/eclampsia, making the overall rate of pre-eclampsia/eclampsia among women admitted to hospital for labor and delivery 3.0%.
- Following the audit and feedback intervention, significantly more women with severe pre-eclampsia/eclampsia or mild pre-eclampsia in labor and with acute severe hypertension received the correct dosing of magnesium sulfate and anti-hypertensive therapy, respectively, compared with before the audit and feedback intervention.
- The perinatal mortality rate among women with pre-eclampsia/eclampsia was unacceptably high. In some hospitals, the perinatal mortality rate was as high as 293 per 1,000 deliveries over a five-month period.
- The mean percentage knowledge score showed a significant increase after the audit and feedback intervention as compared with the mean percentage knowledge score before the audit and feedback intervention (baseline=57.85 vs end-line=71.2%, $P < 0.001$).
- The mean confidence score did not show a significant increase after the audit and feedback intervention as compared with the mean confidence score before the audit and feedback intervention.

- While audit and feedback requires additional work, providers felt that by integrating it into routine service delivery the additional work time is mitigated, and that the investment in time pays off though improved quality of care and improved ownership and accountability.

Conclusion

If done properly and with the full participation of providers, audit and feedback interventions can bring significant, positive change in the quality of care for women with pre-eclampsia/eclampsia. Audit and feedback improves adherence to protocols and standards to provide proper treatment for women with pre-eclampsia/eclampsia and/or a hypertensive crisis. In addition, it increases providers' knowledge of the correct treatment of women with pre-eclampsia/eclampsia.

1. Introduction

1.1. The Problem of Severe Pre-eclampsia and Eclampsia

Globally, severe pre-eclampsia/eclampsia (PE/E) is the second leading cause of maternal mortality, with a disproportionate burden in low- and middle-income countries, where the risk of dying from severe PE/E is approximately 300 times higher than in developed countries.[1] Ethiopia is among the world's countries that have a high maternal mortality ratio, with severe PE/E as one of the leading direct causes. According to the Emergency Obstetric and Newborn Care National Assessment conducted in 2008, severe PE/E accounted for 16% of all institutional maternal deaths.[2] If women receive effective care delivered according to evidence-based standards, the majority of deaths related to PE/E could be avoided. The management of severe PE/E, including controlling severe hypertension through the correct use of anti-hypertensive drugs, can significantly reduce complications and deaths related to severe PE/E. Since the use of magnesium sulfate for the management of PE/E was only adopted in Ethiopia in the national protocol in 2010, it is still not widely used. According to the final report by Jhpiego on an earlier audit feedback intervention at six hospitals in Ethiopia, the correct use of magnesium sulfate was estimated to be 64% with variations among hospitals (ranging from 25% to 100%).

1.2. Magnesium Sulfate for Prevention and Treatment of Eclamptic Seizures

Global evidence clearly demonstrates that magnesium sulfate is a lifesaving drug and the anticonvulsant of choice for women with severe PE/E.[2-5] Use of magnesium sulfate reduces the risk of developing eclampsia by 58% compared with no anticonvulsant[2] and reduces the risk of recurrent convulsions by 52% compared with diazepam and by 67% compared with phenytoin.[4] Based on this evidence, the 2011 World Health Organization (WHO) recommendations for prevention and treatment of pre-eclampsia and eclampsia suggest magnesium sulfate as the anticonvulsant of choice for women with severe PE/E.[6] The regimens that have been used in the largest randomized trials, and shown to be effective, include: 1) the Magpie Trial,[2] for women with pre-eclampsia; and 2) the Collaborative Eclampsia Trial,[3] for women with eclampsia. These regimens, which have become the most widely used international regimens and those with greatest amount of evidence for use in severe PE/E, include the intravenous (IV) Zuspan regimen[7] and the intramuscular (IM) Pritchard regimen.[8] Given these guidelines, which are suitable for a variety of low-resource settings, magnesium sulfate should be considered for use at every level of the health care system where deliveries occur. However, magnesium sulfate is either underutilized or used inappropriately in many low-resource settings.

One of the challenges to properly treat women with PE/E is providers' lack of competence[9] in managing complications during pregnancy, labor, and child birth, which contributes to the underutilization of magnesium sulfate for severe PE/E. This lack of understanding stems from:

- **Lack of clear communication** about evidence-based clinical guidelines for dosing and monitoring of magnesium sulfate therapy for severe PE/E in their facility;
- **Lack of training and supervision** in correct dosing, preparation, administration, and monitoring of magnesium sulfate therapy; and
- **Safety concerns about magnesium sulfate.** These are largely overstated[2,10,11] but still contribute to low provider confidence and continue to be a barrier to widespread use. The Magpie Trial showed that while the side effects following magnesium sulfate administration are relatively common compared to placebo (24% vs. 5%), serious complications such as respiratory depression (0.9%) and respiratory arrest (0.1%) are rare with no large difference compared to placebo.[2] A recent integrative review[11] from studies in low- and middle-income countries including 9,556 women in the sample showed that signs of toxicity are rare

(average for absent patellar reflex 1.6%; average for respiratory depression 1.2%), and that delay in administration of magnesium sulfate was often adequately managed until the drug was cleared by the kidneys and the level came down to non-toxic levels. Severe toxicity (respiratory depression or respiratory arrest) requiring calcium gluconate to counteract the magnesium sulfate at very elevated levels was very rare (<0.2%).

1.3. Anti-hypertensive Therapy for Hypertensive Crises

Increasing the appropriate use of magnesium sulfate should be coupled with appropriate treatment of severe hypertension, particularly severe systolic hypertension. Severe systolic hypertension (≥160 mmHg) is an independent risk factor, and may be the most important predictor for stroke and myocardial infarction in pregnancy.[12,13] WHO strongly recommends anti-hypertensive therapy of severe hypertension in order to decrease maternal morbidity and mortality.[6] The Ethiopian Ministry of Health promotes the implementation of the WHO guideline and recommends starting anti-hypertensive therapy if the systolic blood pressure is greater than or equal to 160 mmHg or if the diastolic blood pressure is greater than or equal to 110 mmHg.[14] The goal is to keep the diastolic blood pressure between 90 mmHg and 100 mmHg and the systolic blood pressure below 160 mmHg to prevent cerebral hemorrhage, as stated in the national guideline.

Unlike with magnesium sulfate, which is recognized as the single anticonvulsant of choice for women with severe PE/E, globally there are three different recommended agents for anti-hypertensive therapy for severe systolic hypertension (oral Nifedipine, parenteral hydralazine, or parenteral labetalol).[12,15] In Ethiopia, hydralazine has been listed in the national guidelines as the first-line treatment of choice and should be available in all health facilities providing labor and delivery care, while Nifedipine is not commonly used during labor and delivery, and labetalol is not available. Similar to magnesium sulfate, many providers lack the knowledge and confidence in the appropriate use of anti-hypertensive therapy in pregnant women with severe systolic hypertension, which contributes to the underutilization of appropriate anti-hypertensive therapy in these cases.

1.4. Description of the Active Audit and Feedback Intervention

Audit and feedback is a behavior change intervention aimed at improving the quality of clinical services through improved provider uptake of evidence-based clinical practices. Studies have shown that audit and feedback can be effective in improving professional practice in the health care setting.[16,17] Overall, audit and feedback can result in small, but potentially important improvements in professional practice.[16-18] For example, a systematic review by Jamtvedt and colleagues revealed that audit and feedback can improve compliance to desired practices by a median of 16% for continuous outcomes and by 5% for dichotomous outcomes.[17] However, the effect size of audit and feedback on compliance to desired practices varies. The most effective way to deliver feedback is not currently clear. Effectiveness of the intervention seems to vary based on the source of the feedback (supervisor or colleague), intensity, whether it is delivered in both verbal and written formats, and whether it includes both explicit targets and an action plan. The most effective form of audit and feedback may well be context-specific.[16] Studies elsewhere have also shown that audit and feedback improves staff morale and motivation.[19]

Therefore, this study aimed to determine if giving clear guidance in an initial training, followed by implementation of audit and feedback, improved the quality of care through increased and appropriate use of magnesium sulfate and anti-hypertensive therapy among women who developed PE/E or a hypertensive crisis.

2. Aims of the Study

2.1. Primary Research Objective

The primary objective was to determine if an active audit and feedback intervention in public referral hospitals in Ethiopia improves the quality of care (i.e., increased and appropriate use of magnesium sulfate and anti-hypertensive therapy) provided to women who experience either PE/E or a hypertensive crisis.

2.2. Specific Research Objectives

1. Determine if introduction of active audit and feedback improves adherence to treatment protocols and guidelines;
2. Determine if maternal and newborn outcomes are improved in facilities implementing active audit and feedback for severe PE/E with hypertensive crisis;
3. Determine if application of active audit and feedback improves providers' knowledge and confidence in the appropriate use of magnesium sulfate for severe PE/E and mild PE in labor;
4. Determine if application of active audit and feedback improves providers' knowledge and confidence in the appropriate use of anti-hypertensive drugs for severe PE/E with a hypertensive crisis; and
5. Determine if active audit and feedback for PE/E and hypertensive crisis is feasible and acceptable in public referral hospitals in Ethiopia.

3. Study Design and Methods

3.1. Study Design

This study employed a before-and-after design and used both quantitative and qualitative methods (though the qualitative component was conducted only at end-line). The active audit and feedback intervention aimed to improve the quality of care provided to pregnant women with PE/E through the implementation of two interventions:

1. Technical update/coaching on the appropriate use of both magnesium sulfate and anti-hypertensive therapy as part of the management of PE/E; and
2. Regular review (audit) and feedback of information to providers on the correct use of magnesium sulfate and anti-hypertensive drugs for women with PE/E.

Intervention procedures

Identification of clinical leaders

A clinical leader at each of the participating health facilities was identified to act as a champion for improvement in the correct management of women with PE/E. The study team had adapted a short questionnaire based upon the criteria developed by Hiss and colleagues[20,21] to identify clinical opinion leaders. Hospital leadership and heads of maternity units were approached about anonymously applying the three-question survey among all providers on the maternity unit to identify the most influential person among each of the cadres. The staff identified were asked to become clinical leaders in this study, and when they agreed, they were recruited. These clinical leaders worked as focal persons to lead the active audit and feedback activities and work with all providers in their maternity ward. He/she also worked with the hospital leadership to promote ownership and ensure sustainability of this intervention.

Technical update/training of providers on magnesium sulfate and anti-hypertensive therapy

At baseline, data abstraction from registers on correct use of magnesium sulfate and anti-hypertensive drugs, and provider knowledge and confidence assessments, were done. Then the clinical leader co-facilitated a technical update and mentored health providers in their respective facilities. This technical update and mentoring included a review of the current evidence and guidelines for the appropriate use of magnesium sulfate and anti-hypertensive therapy in women with PE/E. It also ensured clinical competence in the preparation and administration of magnesium sulfate and anti-hypertensive therapy, and reviewed patient monitoring against the guidelines while providers administered treatment. The clinical leaders were also trained on how to implement the active audit and feedback process described below.

Description of regular review (audit) and feedback of information to providers

The components of the active audit and feedback process were as follows.

- **Development and display of standardized evidence-based clinical protocols** to encourage their use.
- **Regular tracking and review of PE/E cases and their management** through morning reports.
- **Monthly data abstraction** from maternity registers by clinical leaders on women diagnosed with PE/E, including review of maternal and newborn outcomes and determination of whether these women received: 1) magnesium sulfate; 2) the correct dose of magnesium sulfate; 3) anti-hypertensive therapy for hypertensive crises; and/or 4) the correct regimen of anti-hypertensive drugs.
- **Data visualization, analysis, and use for action:** Using the summary data from the register abstraction, clinical leaders generated a summary table and graph of magnesium sulfate and anti-hypertensive use among women with severe PE/E and mild PE in labor. Clinical leaders received technical support from the Maternal and Child Survival Program (MCSP) team on how to abstract and generate summary tables and graphs of magnesium sulfate and anti-hypertensive use. The study team developed dummy tables and figures to allow clinical leaders to enter and update data every month in Excel. This allowed tables and graphs to be generated automatically to show trends in the percentage of women with severe PE/E and mild PE in labor who received correct doses of magnesium sulfate and anti-hypertensive treatment. The clinical leaders then shared these tables and graphs with health providers during staff meetings to better visualize and analyze the data, leading to action for sustained quality improvement (QI) related to magnesium sulfate and anti-hypertensive use. The clinical leaders were encouraged to display the graph as a poster to further encourage sustained behavior change. The MCSP team also abstracted data every four weeks to check the accuracy of the data abstracted by clinical leaders. Feedback was provided to clinical leaders whenever a discrepancy was detected.

3.2. Sampling

Sampling of study hospitals

As mandated by MCSP, only public hospitals were included in this study. The eight public hospitals were purposively selected out of a total of over 200 hospitals in Ethiopia. Although these hospitals were chosen largely because of where MCSP worked, they were representative of high-volume hospitals in four major regions of Ethiopia (Oromia, Amhara, SNNPR, and Tigray) and Addis Ababa City Administration. All eight hospitals had relatively high average numbers of monthly deliveries, ranging from 250 to 400.

Sampling of PE/E cases for analysis

Delivery data from 2014/15 were analyzed retrospectively for the eight participating hospitals (Table 1). A total of 23,760 annual deliveries occurred at these hospitals; thus, 11,880 deliveries were expected in these hospitals over the six-month period. Although there were no specific data on the incidence of PE/E, the study team estimated that 4% of all pregnancies in Ethiopia, and women delivering at the study hospital, will

have PE/E. This gave an expected number of women with PE/E 487 over the six-month period. The analysis focused on comparing the proportion of cases managed according to the protocol at baseline (based on data abstracted from the six months prior to start of the intervention) and at month five (end-line). The data abstracted from the registers were examined for trends on a monthly basis.

The sample size calculation was based on a comparison of the proportion of cases for correct management of cases both for PE/E management with magnesium sulfate per national protocol and for hypertensive crisis with anti-hypertensive drugs per national protocol.

Table 1: Expected number of deliveries and PE/E cases in the study hospitals (Source: 2014/15 Ethiopia Facility Assessment data)

Name of the Hospital	Region	Estimated monthly delivery (2007 EFY)	Estimated number of deliveries in six-month study period	Estimated number of PE/E cases in study period (4% of total deliveries, based on pilot AF experience)
Bishefitu Hospital	Oromia	243	1,458	60
Adama Hospital	Oromia	356	2,136	88
Nekemt Hospital	Oromia	290	1,740	71
Adare Hospital	SNNPR	289	1,734	71
St. Paul Hospital*	Addis Ababa	148	888	36
Debre Markos Hospital	Amhara	318	1,908	78
Mekelle Hospital	Tigray	194	1,164	48
Axum Hospital	Tigray	142	852	35
Totals		1,980	11,880	487

* Estimated number of deliveries

The proportion of cases where PE/E was managed correctly by protocol was the outcome variable used to calculate the primary sample size. Data abstracted from registers by Maternal and Child Integrated Program (MCHIP) Ethiopia staff covering a recent eight-month period in six hospitals showed that 64% of mothers with severe PE/E and mild PE in labor received the correct full dosage of magnesium sulfate. Therefore, the sample size was calculated with 64% as the baseline compliance to desired practices. An estimate of improvement of 16 percentage points was used (i.e., bringing the level of adherence up to 80%). Based on experience with a similar audit and feedback pilot intervention done by the MCHIP in eight smaller hospitals in Ethiopia, this was deemed a realistic goal. Other standard assumptions used were: 95% confidence level and 80% power to detect a difference. The minimum sample size was calculated using the standard formula for comparison of proportions.

The aggregate minimum sample size calculated across all eight hospitals was 120 for baseline and 120 for end-line, meaning that 120 cases were needed in the baseline sample; similarly, 120 cases were required at end-line sample. The end-line sample was compared with the baseline data abstracted from the registers for the six-month period before the start of the intervention (the "baseline"). All cases with severe PE/E or mild

eclampsia in labor (as the national protocol recommends treatment with magnesium sulfate for women with mild PE in labor) who were diagnosed either six months prior to intervention or over five months of intervention were included in this study.

Sampling of providers for administration of the knowledge and confidence questionnaire

This study included all health providers working in labor and delivery, antenatal, and postnatal care units. They were asked to complete a self-administered questionnaire at the beginning and end of the study to assess their knowledge and confidence. There was an estimated total of 85 eligible providers. Using a 95% response rate (acceptance and availability to participate), we expected 80 providers in the final sample.

Sampling for key informant interviews of providers

For in-depth key informant interviews, three providers were purposively selected out of providers who completed the self-administered questionnaire in each hospital, in order to ensure representation among all provider types. In each of the eight hospitals, the following provider types were selected for semi-structured interview with key informants to explain some of the results and explore the feasibility and acceptability of the audit and feedback intervention:

- One obstetrician or emergency surgical officer;
- One clinical leader; and
- One midwife.

There were a total of 24 in-depth interviews across the eight study facilities.

3.3. Inclusion Criteria

All providers working in labor and delivery, antenatal care (ANC), and postnatal care (PNC) in the eight selected hospitals were eligible for the study.

In terms of clients, during the five-month intervention period, eligible to be included were: all cases of eclampsia (determined clinically through usual procedures), severe PE, mild PE in labor, and hypertensive crisis ("HC"; blood pressure 160/110 mmHg or higher).

3.4. Study Tools

The following tools were used to capture data during the study period:

Semi-structured key informant interview guide

This tool was used to determine the feasibility and acceptability of the audit and feedback intervention. Moreover, it included questions that addressed the reasons for perinatal deaths among women with PE/E from providers' perspective. This tool was applied at end-line of the study.

Structured questionnaire to assess provider knowledge and confidence

This was carried out by using a short, close-ended set of questions to test key areas of provider knowledge and their level of confidence in use of the correct therapies for women with PE/E. This tool was applied at baseline and end-line.

Facility assessment tool

The facility assessment tool was used to assess availability of magnesium sulfate and anti-hypertensive drugs both in the pharmacy and in the maternity ward. This tool was applied at baseline and end-line.

Data abstraction form

Information was abstracted on the management of mild PE in labor, severe PE/E, and hypertensive crises, focusing on the correct use of magnesium sulfate and anti-hypertensive drugs. The data abstraction form was applied at baseline and monthly throughout the five-month study period by clinical leaders and the study team.

3.5. Study Subjects Recruitment Process and Data Abstraction Procedures

The study team oriented all clinical leaders to the concept of clinical governance (monitoring, supervision, coaching, and leadership) and QI, and how this audit and feedback intervention fits into that framework. MCSP provided a one-day, whole-site training for 180 providers working at antenatal, delivery, and postnatal units from all intervention hospitals. Providers then conducted audit and feedback intervention to improve the quality of care for women with PE/E.

To conduct a knowledge and confidence assessment, interviewers first approached the head of the maternity unit and received lists of providers working at antenatal, delivery, and postnatal units. All providers on the list were invited to self-administer a knowledge and confidence questionnaire at baseline and end-line, and a subset of 24 of these providers were invited for in-depth interviews at end-line. The procedure to select providers for in-depth interview is spelled out in Section 3.2.

Data abstraction was conducted both internally by providers themselves as part of the audit and feedback intervention, and externally by the study team. The study team abstracted data from all sources to find out whether women with PE/E received treatment according to treatment protocols/standards. Data abstraction took place over five months (from mid-July to mid-December 2016).

3.6. Data Analysis

Knowledge and confidence data were entered at the Jhpiego office in Addis Ababa using EpiData and exported to Stata for further analysis. For the data on practices, the data abstracted from registers were exported to Stata and further analyzed to compare baseline and end-line results. Descriptive statistics and comparisons of the number and proportion of cases managed correctly were carried out to observe any significant difference between the end-line and the baseline. The proportion of patients who received magnesium sulfate and anti-hypertensive drugs according to the national protocol/standard were calculated at baseline and at end-line. Cross-tabulation was conducted and the number of patients treated according to the standard was compared before and after implementation of the audit and feedback intervention. The difference between the proportion of the correct use of magnesium sulfate and anti-hypertensive drugs before and after the audit and feedback intervention was computed with 95% confidence intervals. A p-value of less than 0.05 was considered statistically significant.

Provider knowledge was analyzed based on the proportion of correct responses. The mean percentage knowledge scores were calculated and an independent t-test was used to compare the differences in mean percentage knowledge scores between the baseline and the end-line. Providers' mean confidence scores were calculated and an independent t-test was used to compare the difference between the baseline and end-line scores. The absolute difference between the mean value in the two groups (groups before audit and feedback

intervention and groups after audit and feedback intervention) was computed with 95% confidence interval. A p-value of less than 0.05 was considered statistically significant.

For semi-structured interviews, audio-files were transcribed in Amharic and translated to English. Transcripts were analyzed thematically using ATLAS.ti, a qualitative data reduction and analysis software. The results from the qualitative data were triangulated to the quantitative results to explain the results from the quantitative data and to explore the feasibility of the audit and feedback procedure to apply and scale-up the intervention in other facilities.

For maternal and newborn outcomes, facility-based mortality rates were calculated and compared to estimate changes in outcomes before and after implementation of the audit and feedback intervention.

3.7. Ethical Procedures

The study was determined to be exempt by the John Hopkins Bloomberg School of Public Health Institutional Review Board (IRB No: 00006822) and a support letter was obtained from the Ethiopian Ministry of Health to conduct the study. In addition, ethical procedures were followed during data collection as outlined below.

Health providers: Verbal informed consent was sought from all participants. Consent forms were made available to all participants in English and all of these consent forms were countersigned by a member of the study team at MCSP-Ethiopia to document that consent was obtained. Providers were reassured that the purpose of this study was not to evaluate their performance, and that their participation or nonparticipation and the results of this study would not affect their employment at the hospital or any other facility in Ethiopia. Individuals who decided to participate were asked to read, and agree to participate in, the study. Finally, the providers were asked to complete the self-administered knowledge/confidence questionnaire and return the completed questionnaire to the study team.

Patient record abstraction: We requested a waiver of consent and a waiver to ask permission to view patient registers and health records. Access to patient registers and records were only used to determine if the patient was treated by the health provider according to the treatment protocols and to count outcomes. All patient identifiers were excluded and the abstracted data were de-identified. No personal identifiers were recorded for patients. Each participant health worker was identified only by a code.

4. Results

4.1. Five-Month Incidence of Pre-Eclampsia and Eclampsia at Intervention Hospitals

Table 2 shows both the number of deliveries per month for each hospital where the intervention was implemented and the proportion of PE/E cases from all facility deliveries. Overall, over 16,000 deliveries occurred in the eight hospitals over the five-month study period. The highest number of deliveries was reported by St. Paul Hospital (2,962 deliveries over five months) in Addis Ababa, while the smallest number of deliveries was reported from Axum Hospital (1,276 deliveries over five months) in Tigray Region. The highest monthly number of deliveries was reported in the first month of the intervention (July/August) with over 3,900 deliveries from all hospitals, while the lowest monthly number of deliveries was reported during the third month of the intervention (September/October) with 2,858 deliveries from all eight hospitals, down by more than 1,000 deliveries from the first month of the intervention.

Over the five months, 481 women were admitted for PE/E, setting the overall rate of PE/E among women admitted to hospital for labor and delivery at 3.0%, lower than previously reported facility-based incidences in

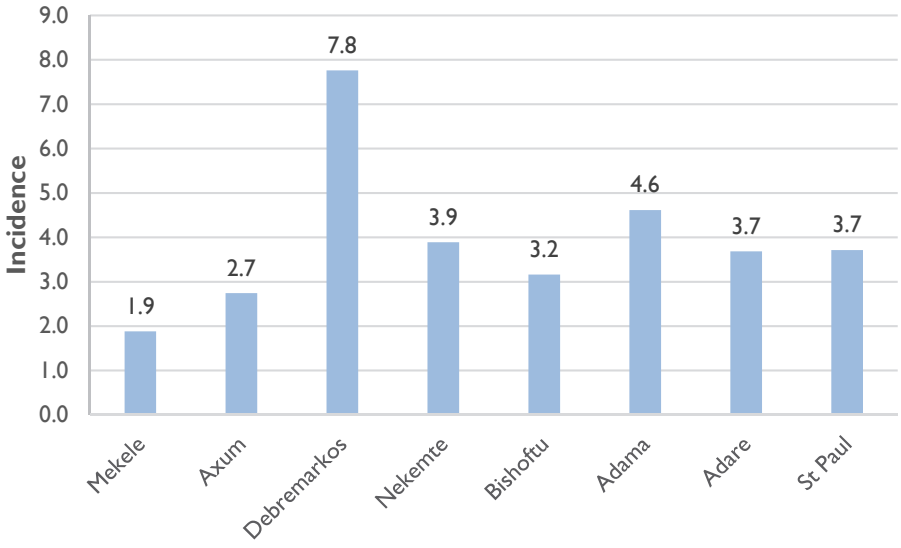
many low-income countries, albeit a wide variation among reports from different countries. Given that all hospitals in this study were referral hospitals that often receive complicated cases as referrals from health centers and primary hospitals, this rate is much lower than anticipated. However, this should be cautiously interpreted, since in most towns where the study hospitals are located there are more than one hospital receiving referrals from lower-level health facilities.

Table 2: Number of deliveries per month and percent of PE/E cases from total deliveries, by hospital, January 2017

Hospital	Months					Total deliveries per hospital
	Jul/Aug	Aug/Sep	Sep/Oct	Oct/Nov	Nov/Dec	
Mekele	651	426	398	549	369	2,393
Axum	281	257	239	258	241	1,276
Debremarkos	436	320	299	351	321	1,727
Nekemte	272	240	288	299	341	1,440
Bishoftu	514	430	353	330	334	1,961
Adama	736	448	399	410	435	2,428
Adare	479	383	288	349	348	1,847
St. Paul	570	656	595	632	509	2,962
Total deliveries	3,939	3,160	2,859	3,178	2,898	16,034
Total PE/E cases	104	84	95	105	93	481
% of PE/E from total deliveries	2.6	2.7	3.3	3.3	3.2	3.0

In this study, there were slight variations in the overall proportion of PE/E cases out of the total deliveries among hospitals. As Figure 1 shows, the highest facility-based, five-month incidence of PE/E was registered in Debremarkos Hospital (7.8%) followed by Adama Hospital (4.6%), while the lowest incidence of PE/E was registered in Mekele Hospital (1.9%). For the other five hospitals, the incidence ranged from 2.7% to 3.9%.

Figure 1: Facility-based, five-month incidence of PE/E, January 2017



4.2. Adherence to Treatment Protocols/Standards

Treatment of women with severe pre-eclampsia and eclampsia or mild pre-eclampsia in labor with magnesium sulfate

Table 3 presents health providers' adherence to protocols and standards to provide the correct dose of magnesium sulfate for women with severe PE/E or mild PE in labor both before and after intervention. A total of 141 PE/E cases (mild PE in labor, severe PE/E) before intervention, and 481 cases after intervention, were reviewed retrospectively using a data abstraction form.

A significant difference was observed in the use of magnesium sulfate between women with PE/E admitted to hospital before intervention, and women with PE/E admitted to hospital after intervention (90.7% vs 95.6%, P=0.024). While use of magnesium sulfate increased slightly (regardless of whether it is a correct dose or not), use of correct loading dose and correct full course increased much more markedly after the intervention. Before the intervention, 66.2% of women with PE/E received the correct loading dose of magnesium sulfate, while after the intervention almost all women (99.3%) received the correct loading dose (P<0.001).

In addition, before the intervention, 64.6% of women with PE/E from all intervention hospitals completed the full recommended course of magnesium sulfate, while after intervention, the vast majority of women with PE/E (92%) completed the full course of magnesium sulfate (p<0.001). No women developed toxicity while on magnesium sulfate in all study hospitals.

Table 3: Adherence to protocols/standards to provide correct dose of magnesium sulfate for women with PE/E before intervention and after intervention, January 2017

Diagnosis/Intervention	Before intervention		After intervention		Difference (after – before)	P-value
	N	%	N	%	Percentage points	
Diagnosis						
Mild PE*	35	25.0	87	18.1	-6.9	0.076
Severe PE	84	60.0	327	68.0	8.0	0.063
Eclampsia	22	16.0	67	13.9	-2.1	0.618
Drugs given to control seizure						
Magnesium sulfate	127	90.7	460	95.6	4.9	0.024
Diazepam	5	3.6	2	0.4	-3.2	0.002
Other	6	4.3	19	4.0	-0.3	0.859
Magnesium sulfate loading dose IM						
Correct dose (10gm) given	84	66.1	457	97.4	31.3	<0.001
Received, but not correct dose	21	16.5	0	0.0	-16.5	<0.001
Not received	22	17.3	3	2.6	-14.7	<0.001
Magnesium sulfate loading dose IV						
Correct dose (4gm) given	82	64.6	458	97.7	33.1	<0.001
Received, but not correct dose	22	17.3	0	0.0	-17.3	<0.001
Not received	23	18.1	2	2.4	-15.8	<0.001
Magnesium sulfate course completed						
Yes	82	64.6	423	92.0	27.4	<0.001
No	45	35.4	37	8.0	-26.6	<0.001

*Magnesium sulfate should be given for women with mild PE in labor according to the national guideline.

There was a slight variation with regard to adherence to protocols and standards among intervention hospitals in providing the correct full course of magnesium sulfate to control/prevent convulsions. A total of 98.2% of women with severe PE/E or mild PE in labor in Adama Hospital received the full course of magnesium sulfate, while merely 70.7% of women with severe PE/E or mild PE in labor in Bishoftu Hospital received it (Figure 2).

Figure 2: Percentage of women with severe PE/E or mild PE in labor who received full course of magnesium sulfate, by hospital, January 2017

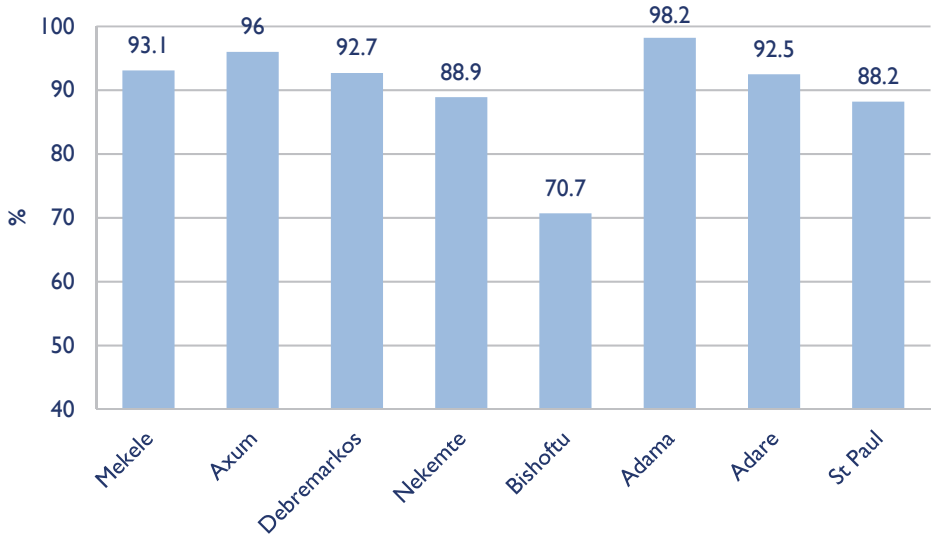


Figure 3 shows the percentage of women with severe PE/E or mild PE in labor who received the correct dose of magnesium sulfate six months preceding the audit and feedback intervention. Before the audit and feedback intervention, there was no clear upward or downward trend in the use of correct dose of magnesium sulfate over the six-month period. However, after the audit and feedback intervention started, there is a clear upward trend in the correct use of magnesium sulfate over time. Indeed, adherence to protocols and standards to treat women with PE/E using magnesium sulfate was improved over time after the audit and feedback intervention was started. As Figure 4 shows, the percentage of women who received the correct doses (loading and full course) of magnesium sulfate sharply increased in the first month of the audit and feedback cycle; subsequently, women who received the correct loading dose of IM and IV magnesium sulfate increased steadily. However, despite the stark increase in the percentage of women who received the full course of magnesium sulfate in the first two months of the audit and feedback intervention, there was still room for improvement thereafter as the progress was modest over the last three months of intervention.

Figure 3: Percentage of women treated with correct dose of magnesium sulfate over six months preceding audit and feedback intervention, January 2017.

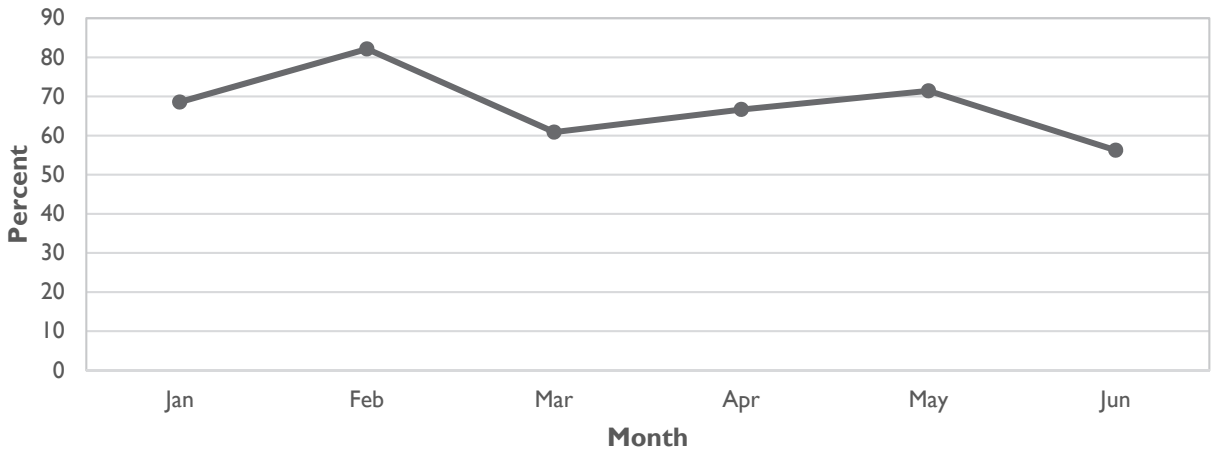
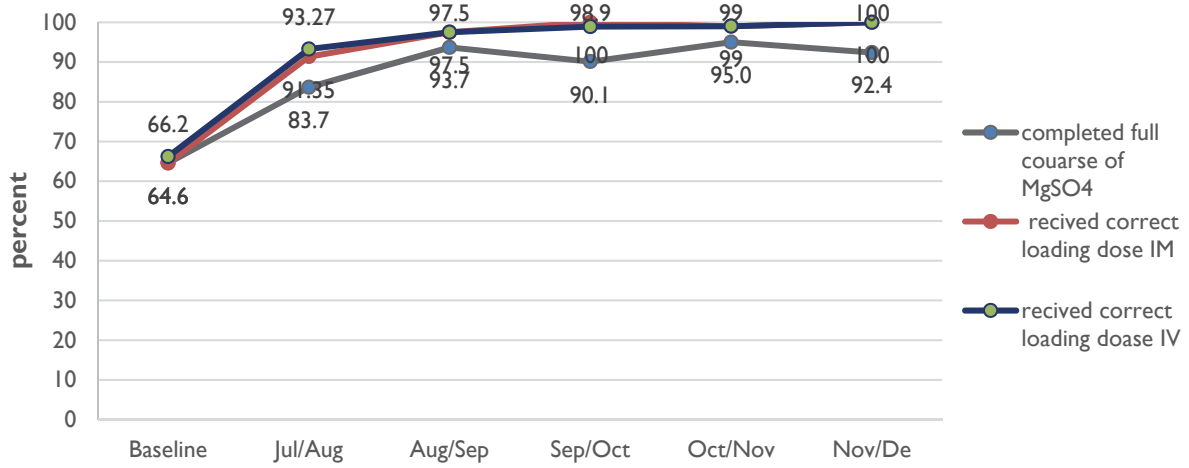


Figure 4: Percentage of women treated with correct dose of magnesium sulfate over five months of audit and feedback intervention, January 2017.



Results from in-depth interviews also revealed that implementation of active audit and feedback interventions brought sizable improvements in providing full courses of magnesium sulfate for women with severe PE/E or mild PE in labor to prevent and/or control convulsions. Most providers believed that the audit and feedback intervention improved providers' performance in choosing the correct drugs and in administering the recommended course of medications to control convulsions. A clinical leader from one of the intervention hospitals stated the following:

In the past, there were some challenges to provide proper treatment for women with PE/E. Some providers had no proper orientation about PE/E and its treatment. Only one or two midwives were trained about proper management of women with

PE/E using magnesium sulfate. Most women with PE/E did not receive the right drug at the right time.… after the audit and feedback intervention started, many of us are well-oriented and know how and when to provide magnesium sulfate. Every one of us can give magnesium sulfate properly and we see the change over the last three months. Currently, almost all women with PE/E in our hospital receive the right dose of magnesium sulfate. (Clinical leader, Study Hospital)

Treatment of women with pre-eclampsia and eclampsia with anti-hypertensive drugs

The national protocol outlines that a woman with PE/E should receive anti-hypertensive medication if the systolic blood pressure is greater than or equal to 160 mmHg or if the diastolic blood pressure is greater than or equal to 110 mmHg. The goal is to keep the diastolic blood pressure between 90 mmHg and 100 mmHg and the systolic blood pressure below 160 mmHg to prevent cerebral hemorrhage.

In this study, 62 (44%) of women with PE/E six months preceding the study, and 215 (44.7%) of women with PE/E over the five months of audit and feedback intervention, had systolic blood pressure greater than or equal to 160 mmHg or diastolic blood pressure greater than or equal to 110 mmHg at the time of admission.

Table 4 depicts the percentage of PE/E cases with hypertensive crisis who received anti-hypertensive medication according to national protocols and standards. The result showed that after the audit and feedback intervention was started, a higher proportion of women with hypertensive crises received hydralazine—the first-line drug of choice in Ethiopia for women suffering from hypertensive crises—compared with the proportion of women in hypertensive crises who received hydralazine before audit and feedback intervention (83.2% vs 69.8%, p=0.010). There were no significant differences in the blood pressure measured after two hours of anti-hypertensive administration, with blood pressure below the benchmark in 91.8% of women before intervention and in 86.8% of women after intervention (p=0.183). However, analysis of the abstracted data over the five months of audit and feedback intervention revealed that the percentage of women with blood pressure in the recommended range after two hours of treatment increased over time and almost all women had blood pressure in the recommended range after two hours of treatment in the fourth month of the audit and feedback intervention (Figure 5).

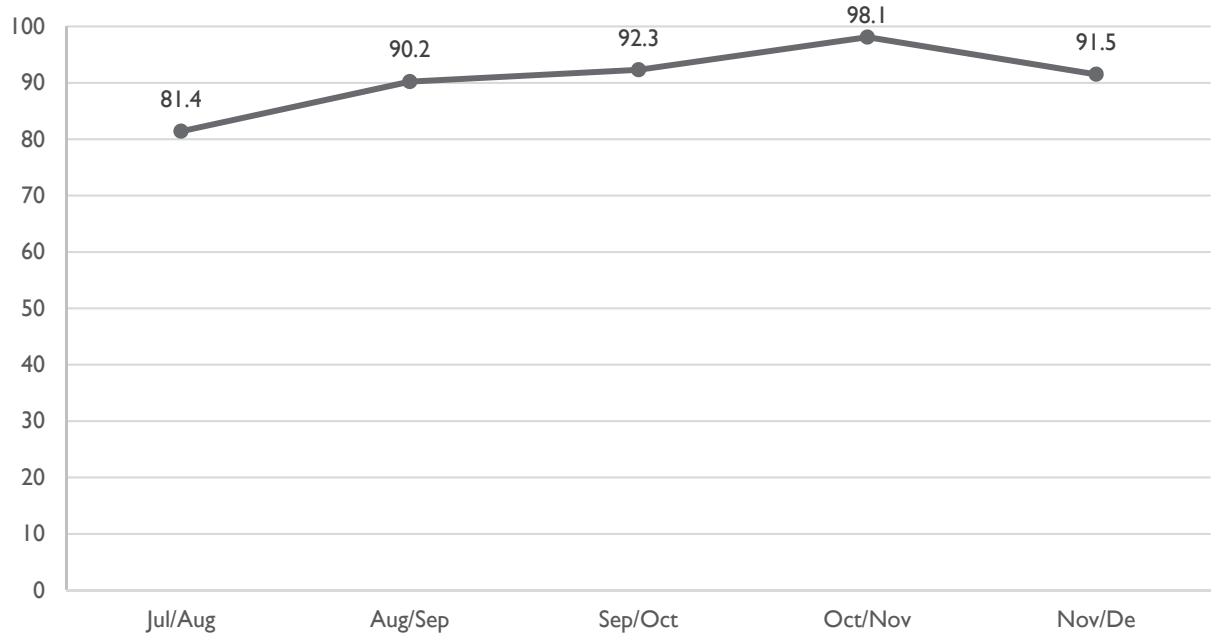
Table 4: Blood pressure at admission, and adherence to protocols/standards to provide correct dose of anti-hypertensive drugs to women with hypertensive crises before and after intervention, January 2017

Blood pressure status/Intervention soon after admission	Before intervention		After intervention		Difference (after – before)	P-value
	N	%	N	%	Percentage points	
Blood pressure status (in mmHg)						
Systolic BP 160 or more and diastolic BP 110 or more	62	44.0	215	44.7	0.7	0.792
Systolic 160 or more, diastolic less than 110	12	8.5	52	10.8	2.3	0.407
Systolic less than 160, diastolic 110 or more	12	8.5	20	4.2	-4.3	0.043
Systolic <160 and diastolic <110	54	38.3	186	38.7	0.6	0.895
Unknown/data incomplete	1	0.7	8	1.6	0.6	0.335
Eligible for anti-hypertensive treatment	86	61.4	287	60.8	-0.6	0.895
For eligible women, anti-hypertensive drugs given						
Hydralazine	60	69.8	238	83.2	13.4	0.010
Nifedipine*	5	5.8	8	2.8	-3.0	0.175
Other**	13	15.3	6	2.1	-13.0	<0.001
No evidence/No data/Not given	8	9.3	35	11.9	2.6	0.346
BP status after 2 hours of anti-hypertensive therapy in mmHg (n=373)						
Systolic <160 and diastolic <110	79	91.8	249	86.8	-5.0	0.183
Systolic ≥160 and diastolic ≥110	0	0.0	9	3.1	3.1	0.101
Systolic <160 and diastolic ≥110	0	0.0	4	1.4	1.4	0.279
Systolic ≥160 and diastolic <110	1	1.3	13	4.7	3.4	0.160
No evidence/No data	6	7.0	12	4.2	-2.8	0.323

* Nifedipine is the second line drug to treat severe hypertension in women with PE/E in Ethiopia

**Other includes a subsequent administration of hydralazine and Nifedipine

Figure 5: Percentage of women in hypertensive crisis whose BP is in the recommended range after two hours of anti-hypertensive therapy over five months of audit and feedback intervention, January 2017



4.3. Maternal and Newborn Outcomes

Table 5 shows maternal and newborn outcomes at the time of discharge from hospital among women with severe PE/E and mild PE in labor. There was no significant difference observed with regard to improvements in maternal outcome after the audit and feedback intervention. Regarding to newborn outcomes, there was a statistically significant drop in the number of stillbirths (P=0.005). However, the number of women with PE/E before intervention was much lower than the number of women diagnosed with PE/E after intervention, indicating that following the intervention, case detection and/or documentation likely improved markedly. Therefore, we are not able to determine if the undocumented cases before intervention had similar profiles of survival with that of documented cases.

Table 5: Maternal and newborn outcomes at the time of discharge from hospital among women with PE/E. January 2017

Maternal/Newborn outcome	Before intervention		After intervention		Difference (after – before)	P-value
	N	%	N	%	Percentage points	
Maternal outcome						
Stable during discharge	139	98.6	471	97.9	-0.7	0.184
Mother died before discharge	0	0	6	1.2	1.2	0.182
Status unknown	2	1.4	4	0.9	-0.5	0.531
Newborn outcome						
Stable during discharge	106	75.2	402	83.6	8.4	0.017
Still birth	29	20.6	55	11.5	-9.1	0.005
Died before discharge	0	0	2	0.4	0.4	0.445
Abortion/terminated before 28 weeks	0	0	3	0.6	0.6	0.349
Referred to next level	0	0	1	0.2	0.2	0.589
Status unknown	6	4.2	18	3.7	-0.5	0.781

In this study, the perinatal death rate among women with PE/E over the five-month period varied from hospital to hospital, with the highest death rate registered in Nekemte Hospital (293 deaths per 1,000 births). As Table 6 shows, the overall perinatal mortality rate for all hospitals was about 120 deaths per 1,000 births (when undocumented cases were removed from the denominators). The lowest perinatal death rate was reported from St. Paul and Adare Hospitals with 46 and 50 deaths out of 1,000 deliveries, respectively.

The perinatal mortality rate did not show a sign of significant decline over five months of audit and feedback intervention. In the first month of audit and feedback intervention, the perinatal mortality was 96 deaths per 1,000 deliveries. The mortality rate showed a sharp increase and reached a peak during the third month of the intervention (158 deaths per 1,000 deliveries) and showed a slow pace of decline in the fourth and fifth month of the audit and feedback intervention (Figure 6).

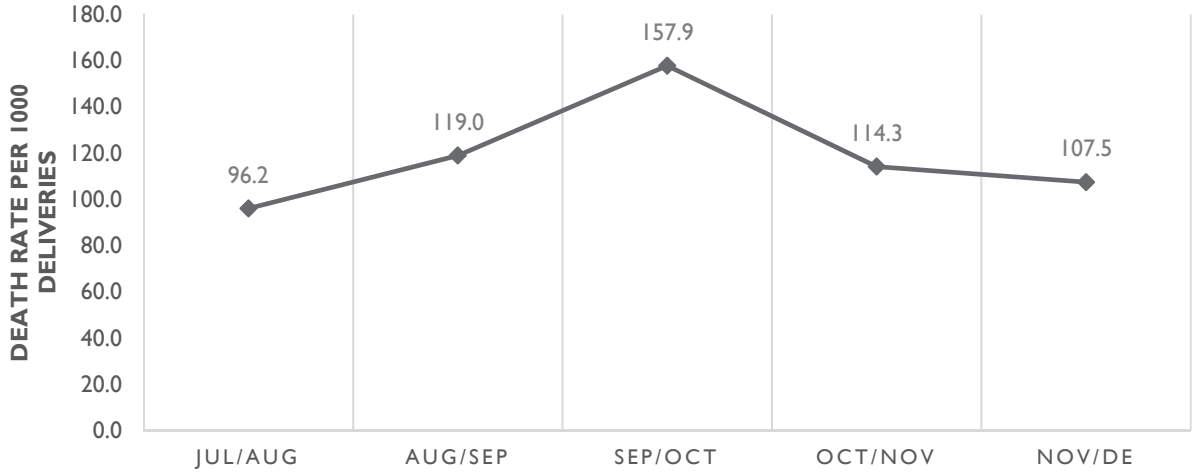
Table 6: Newborn outcomes during the audit and feedback intervention period by hospital, January 2017

Hospital	Discharged alive		Died before discharge/stillbirth	
	Number	%	Number	%
Mekele	27	93.1	2	6.9
Axum	21	84.0	4	16.0
Debremarkos	57	86.4	9	13.6
Nekemte*	27	65.9	12	29.3
Bishoftu	38	82.6	8	17.4
Adama	94	87.9	13	12.1
Adare*	35	87.5	2	5.0
St. Paul*	103	94.5	5	4.6
Total[+]	402	86.8	55	11.9

*As referrals and undocumented cases excluded from the analysis, totals do not add up 100.

[+]Undocumented cases removed from the denominator

Figure 6: Perinatal death per 1000 births at six hospitals in Ethiopia, January 2017



Health providers from all intervention hospitals reported a variety of reasons for the high rate of hospital-based perinatal deaths among women with PE/E. While most of the reasons, as stated by providers, were community and individual factors, some providers believed that health system factors also played a great role for perinatal mortality among women with PE/E. Uncoordinated referral systems, shortage of beds to admit and initiate treatment soon after diagnosis, and low technical ability of health providers at lower levels and referring health facilities were some of the reasons as outlined by key informants during in-depth interviews. A provider for example stated the following:

…about 60% of women with severe PE/E in our hospital are referred from health centers and primary hospitals. They often arrive to this hospital after a considerable delay because of various reasons, including delayed diagnosis, lack of transport, and lack of communication between referring and accepting facilities. On top of that, I think danger signs are often missed and not diagnosed early during antenatal visits at health centers. Because of all these things, most women arrive to hospital after convulsion and complications arise. Even after arrival to our hospital, we often have no adequate space and beds to start treatment immediately, especially when too many cases come at a time.

(Clinical Leader, Study Hospital)

4.4. Health Providers' Knowledge and Confidence on the Management of Women with Severe Pre-Eclampsia and Eclampsia Using Magnesium Sulfate and Anti-Hypertensive Drugs

Health providers knowledge on the management of women with severe pre-eclampsia and eclampsia using magnesium sulfate and anti-hypertensive drugs

Table 7 shows the change in the mean percentage knowledge score on the management of severe PE/E using magnesium sulfate and anti-hypertensive drugs among different professional groups involved in the management of a woman with severe PE/E. A total of 180 and 131 health professionals were assessed for their knowledge and confidence before intervention and after intervention, respectively, in the management of severe PE/E using a self-administered questionnaire. The number of participants at baseline was more than two-fold higher than the number initially anticipated and the number at end-line was higher by 51 participants than initially estimated.

Significant change in the mean percentage knowledge score was observed among midwifes (baseline=59.6% vs end-line=69.45%, P<0.001), nurses (baseline=40 % vs end-line=56%, P=0.010), Emergency Surgical Officers (ESOs) (baseline=70.2 vs end-line=82.5, P=0.014) and general practitioner (baseline=69.7 % vs end-line=78.9%, P=0.027). The overall mean percentage knowledge score showed a significant increase after intervention (baseline=57.85% vs end-line=71.2%, P= 0.001).

Health professionals from half of hospitals participated in this study (Axum, Nekemte, Bishoftu and Adare) showed a large increase in mean percentages knowledge scores after audit and feedback intervention, while the increase was modest in the remaining hospitals. Significant change in mean percentage knowledge score was observed in Nekemtie (baseline=50% vs end-line=67.4%, P=0.001), Adare (baseline=40.5% vs end-line=67.4%, P= 0.001), Bishoftu (baseline=59.1% vs end-line=78.2%, P=0.002) and Axum (baseline=44.5% vs end-line=64.2%, P=0.002) hospitals after audit and feedback intervention.

Table 7: Mean percentage knowledge score before and after audit and feedback intervention, by hospital and professional category, January 2017

Hospital/ profession	Mean percentage knowledge score		Mean Difference (percentage points)	95% CI	P-value	Number of participants before intervention	Number of participants after intervention
	Before intervention	After intervention					
Hospital							
Mekele	60.7	63.6	2.9	-14.5 - 8.7	0.614	21	13
Axum	44.5	64.2	19.7	7.9 - 31.6	0.002	20	10
Debremarkos	66.6	74.0	7.4	-19.4 - 4.6	0.223	26	18
Nekemte	50.0	67.4	17.4	7.4 - 27.5	0.001	24	16
Bishoftu	59.1	78.2	19.1	7.7 - 30.4	0.002	22	20
Adama	79.2	81.0	1.8	-9.2 - 5.5	0.617	24	23
Adare	40.5	64.6	24.1	10.5 - 37.7	0.001	23	11
St. Paul	58.9	65.3	6.3	-20.3 - 7.7	0.368	20	20
Profession							
Midwife	56.9	69.4	12.5	6.9 - 18.1	<0.001	109	82
Obstetrician	88.2	84.2	-4.0	-9.4 - 17.3	0.531	8	6
General Practitioner	69.7	78.9	9.2	1.1 - 17.3	0.027	22	21
ESO	70.2	82.5	12.3	2.8 - 21.8	0.014	10	9
Nurse	40.0	56.0	16.0	4.0 - 28.9	0.010	28	11
Health Officer	42.1	52.6	10.5	-61.1 - 40.1	0.466	3	2
Overall mean percentage score	57.8	71.2	13.4	8.9-17.8	<0.001	180	131

Providers who participated in the in-depth interviews at the fifth month of the audit and feedback intervention felt that health providers now have better knowledge on the proper management of women with PE/E using magnesium sulfate and anti-hypertensive drugs. Above all, they thought that adherence to treatment protocols has greatly improved because of the knowledge that providers acquired over the five months of the audit and feedback intervention. A provider, for instance, stated the following:

…now we are doing it according to the national PE/E protocol. Most of us know what the national guideline says and often use it. We also regularly discus with senior physicians and MCSP MNCH advisors. At the moment, most of us know the basic things. But we need to orient those providers who are newly deployed. They were not working with us before and may not know the national treatment protocol. (Clinical leader, Study Hospital)

Health providers' confidence on the management of women with severe pre-eclampsia and eclampsia using magnesium sulfate and anti-hypertensive drugs

Table 8 shows the mean confidence scores in the management of severe PE/E using magnesium sulfate among different professional groups involved in the management of a woman with severe PE/E. A total of 180 and 131 study subjects took a confidence assessment on management of women with severe PE/E before intervention and after intervention, respectively. The results showed a significant change in the mean confidence score only among general practitioners (baseline=37.2 vs end-line=42, P=0.020). For other

professional categories, no significant change was observed before and after intervention. Analysis per intervention hospitals revealed a significant difference in the mean confidence score before and after intervention only in Bishoftu Hospital (baseline=38% vs end-line 43%, P=0.024).

Table 8: Mean confidence scores before intervention and after intervention to treat a woman with severe PE/E using magnesium sulfate, by hospital and professional category, January 2017

Hospital/ Professional category	Mean confidence score		Mean difference (percentage points)	95% CI	P-value	Number of participants before intervention	Number of participants after intervention
	Before intervention	After intervention					
Hospital							
Mekele	34.0	37.5	3.5	-1.2 - 8.2	0.142	21	13
Axum	41.2	39.1	-2.1	-6.9 - 2.8	0.391	20	10
Debremarkos	37.7	38.1	0.4	-4.4 - 5.1	0.878	26	18
Nekemte	34.0	38.6	4.6	-0.2 - 9.6	0.061	24	16
Bishoftu	38.0	43.5	5.5	0.7 - 10.2	0.024	22	20
Adama	42.4	40.3	-2.1	-6.4 - 2.2	0.327	24	23
Adare	28.8	27.6	-1.2	-7.0 - 4.6	0.680	23	11
St. Paul	39.3	39.0	-0.3	-4.9 - 4.3	0.896	20	20
Profession							
Midwife	36.6	37.9	1.3	-3.7 - 1.1	0.303	109	82
Obstetrician	45.4	37.7	-7.7	-15.3 -(-0.1)	0.047	8	6
General Practitioner	37.2	42.0	4.8	0.6 - 9.1	0.028	22	21
ESO	39.8	43.9	4.1	-2.9 - 11.1	0.231	10	9
Nurse	34.4	33.9	-0.5	-6.1 - 5.2	0.854	28	11
Health Officer	27.0	40.0	13.0	-13.2 - 39.2	0.166	3	2
Overall mean confidence score	36.9	38.6	1.7	-3.6 - 0.1	0.060	180	131

Table 9 depicts the mean confidence scores in the management of severe PE/E using anti-hypertensive drugs among eligible clients by different professional groups involved in the management of a woman with severe PE/E. The result revealed that no significant change in mean confidence score was observed among different professional categories and intervention hospitals.

Table 9: Mean confidence scores before intervention and after intervention to treat a woman with severe PE/E using anti-hypertensive drugs, by hospital and professional category, January 2017

Hospital/ Professional category	Mean confidence score		Mean difference (percentage points)	95% CI	P-value	Number of participants before intervention	Number of participants after intervention
	Before intervention	After Intervention					
Hospital							
Mekele	16.8	17.5	0.7	-1.6 - 2.9	0.553	21	13
Axum	17.8	17.5	-0.3	-1.7 - 2.3	0.760	20	10
Debremarkos	17.6	17.4	-0.2	-1.8 -1.4	0.779	26	18
Nekemte	16.0	17.3	1.2	-0.7 - 3.2	0.218	24	16
Bishoftu	16.6	16.3	-0.3	-2.1 - 1.4	0.696	22	20
Adama	18.4	16.8	-1.5	-3.8 - 0.7	0.165	24	23
Adare	15.1	13.6	-1.5	-4.7 - 1.8	0.377	23	11
St. Paul	15.0	15.1	0.1	-2.4 - 2.6	0.936	20	20
Profession							
Midwife	16.6	16.3	-0.3	-1.2 -0.6	0.527	109	82
Obstetrician	18.8	16.8	1.9	-6.3 - 2.5	0.365	8	6
General practitioner	17.6	17.5	-0.1	-2.0 - 1.8	0.936	22	21
ESO	18.4	17.4	-1.0	-4.5 - 2.5	0.553	10	9
Nurse	15.7	15.1	-0.6	-4.1 - 2.8	0.716	28	11
Health Officer	12.0	15.0	3.0	-9.1 - 15.2	0.400	3	2
Overall mean confidence score	16.7	16.5	-0.2	-1.0 - 0.6	0.636	180	131

4.5. Feasibility and Acceptability of Audit and Feedback Interventions

Assessing the feasibility and acceptability of an audit and feedback intervention was one of the specific research objectives of this study. After five months of intervention, in-depth interviews were conducted with providers at intervention hospitals to determine if they felt audit and feedback interventions helped them to improve the quality of care and whether it is feasible to implement the intervention at a larger scale. Health providers felt that the audit and feedback intervention has made a difference in providing good quality care and, above all, greatly helped them to provide correct doses of magnesium sulfate and anti-hypertensive drugs for women with PE/E. A provider, for example, stated:

Before [the audit and feedback] intervention, health workers forgo to provide some medications often times. Especially during the night shift, they did not give magnesium sulfate maintenance dose every four hours rather they gave only once and then went to sleep. The [medication] charts were not reviewed in detail. …after we started the intervention, however, vital signs are measured and recorded frequently because the health workers know that it will be audited and don't want [to] make such a gap. Also health workers often provide the right medication at the right time, measure urine output, and record all medications given to a patient in the proper way. So the audit has brought significant change in the quality of care for women with PE/E.
(Maternity Unit Head, Study Hospital)

Providers also felt that audit and feedback should be part of the routine work at service delivery points. While audit and feedback requires additional work, providers felt that by integrating this into routine service delivery the additional work time is mitigated, and that the investment in time pays off though improved quality of care and improved ownership and accountability. Apart from helping women with PE/E, the spillover effects of audit and feedback interventions can help improve other maternal and newborn health services as well. As one of the informants stated, this intervention has also helped hospitals to improve the quality of services for women with other complications, such as antepartum and postpartum hemorrhage.

The intervention we did over the last five months has also helped us to improve the entire maternal and newborn health service quality in this hospital. Our documentation system has been immensely improved, not only for women with PE/E but also for other complications [in labor and delivery]. Now, women with APH and PPH are properly documented and received the right treatment because of PE/E audit. Obviously, all women with some sort of complications are now safe as they are properly monitored today better than five months ago. I feel that after the audit and feedback intervention has started, this hospital has provided a much safer environment for all mothers with complications related to labor and delivery. It is very applicable with minimal training, and therefore can be used for all types of care in the hospital. (Head Midwife, Study Hospital)

In this study, all providers who participated in the in-depth interviews believed that audit and feedback interventions can be used as a QI tool in their respective hospitals, even without or minimal external assistance. When asked to share his thoughts on whether audit and feedback interventions are feasible and could continue to be used as a QI tool in the future, a resident physician in obstetrics and gynecology said:

It must continue. Because we are achieving visible significant changes over the last five months.
(Obstetrics and Gynecology Resident, Study Hospital)

While audit and feedback interventions improved the quality of services provided, it is not without challenges, some of which cannot be addressed by this intervention but rather require a holistic health systems approach. These challenges include, for example, a lack of human resources (too few health providers), lack of support from facility leadership, and inadequate skills (lack of training) of some categories of health workers.

One informant said:

…There is little support from the leadership [of the hospital]. The delivery room and waiting areas are not conducive for clients and providers. The delivery room is a bit old and needs renovation. The leadership often promises to assign budget for renovation, but has not realized yet. That demotivates providers to work more and improve quality of care for women with PE/E and other complications. In addition, newly deployed health providers are badly in need of training, but the leadership has no plan to provide in-service training for them. (Clinical Leader, Study Hospital)

5. Program Implication, Recommendations and Limitations

5.1. Program Implications and Recommendation

This study revealed that audit and feedback interventions can bring significant positive change if done properly and with the full participation of health providers. Indeed, active audit and feedback interventions have been regarded as "moderately associated with health care quality" by different authors in the past.[16-18,22] However, context-appropriate interventions are desperately needed. Most studies reporting active audit and feedback interventions as effective in making a difference in the quality of care were conducted in high- or middle-income country settings—very different from the context encountered in low-income settings.

Although magnesium sulfate has long been considered the drug of choice to prevent and treat convulsions due to severe PE/E and been widely used in high-income countries, it is underutilized in low- and middle-income countries. Some issues that impede proper use of magnesium sulfate in low-income countries include: weak procurement and supply system; inadequate organization of services; lack of (or knowledge of) up-to-date guidelines and clinical protocols; shortage of trained staff; and poor data management (identification of key indicators; collection, tracking and use of data) to monitor quality-of-care measures.

While audit and feedback cannot directly address all of these issues, it can help improve service delivery at the facility level. In this study, while there was variation among hospitals, overall a significantly high proportion of women received correct full dose of magnesium sulfate and anti-hypertensive drugs after the audit and feedback intervention. The level of support from hospital management and the strength of clinical leadership can vary among hospitals, which can enable or create barriers for effective audit and feedback interventions and clinical quality-of-care measures.

No significant difference was observed in maternal outcome after intervention of the audit and feedback intervention. However, the number of women with PE/E before the intervention was much lower than the number of women diagnosed with PE/E after it. This likely indicates that the case detection rate of PE/E or documentation, or both, were much improved after the intervention. Therefore, we are not able to determine if the undocumented cases before intervention had similar profiles or survival with that of documented cases.

Perinatal mortality rates did not decline significantly over the five months of the intervention. While audit and feedback may improve provider performance and service delivery, health systems issues are complex and systems barriers to quality cannot be addressed merely by audit and feedback interventions. Therefore, audit and feedback could be considered as an essential part of broader QI approaches that include health system strengthening and data management. In addition, a five-month follow-up may not be adequate to reveal changes in maternal and newborn outcomes.

Past studies in Ethiopia revealed that facility-based perinatal deaths are extremely high, regardless of whether women are diagnosed with PE/E or other complications during labor and delivery. A systematic review from

published and unpublished literature since 1974 depicted that the hospital-based perinatal death rate in Ethiopia is in the range of 45 per 1,000 births (data compiled from 797 health facilities across all regions of Ethiopia) to 124 per 1,000 births (data from a referral teaching hospital).[23] The review showed that hospital-based perinatal death rates did significantly decline over the last five decades.

Health professionals from half of the study hospitals showed a large increase in mean percentages of knowledge scores following audit and feedback intervention, while the increase was modest in the remaining hospitals. Yet, increased knowledge did not correlate with improved adherence to protocols. For example, at Bishoftu Hospital providers showed significant improvement in knowledge, yet only 71% of women at the hospital received the full course of magnesium sulfate, which was much lower than at the other seven hospitals. Audit and feedback is a behavioral change intervention and thus knowledge acquired does not necessarily translate into practice.

In addition, only providers at Bishoftu Hospital reported a significant improvement in mean confidence score before and after the intervention; yet, the proportion of women who received full course of magnesium sulfate was the lowest in Bishoftu Hospital. This finding is a clear indication that the quality of service delivery is affected by a myriad of factors beyond health providers' knowledge and confidence.

The following are program implications and recommendations to improve the quality of care for women with PE/E.

Program Implication 1: Audit and feedback improves case detection and documentation. Appropriate case detection is essential to improve case management. Accurate documentation is an essential first step in quality data management, to enable better tracking of cases and outcomes.

Recommendation:

- Audit and feedback intervention can be used as a tool to improve detection, documentation, and tracking and to improve decision-making, and ultimately to improve the quality of care in referral hospitals in Ethiopia.

Program Implication 2: Audit and feedback improves case management of PE/E. Regular audit and feedback reinforces the use of evidence-based clinical protocols, including correct use of magnesium sulfate and anti-hypertensive drugs.

Recommendation:

- Consider audit and feedback interventions as a routine approach to improve uptake of priority evidence-based clinical interventions at hospitals in Ethiopia, not just PE/E.

Program Implication 3: Success of audit and feedback requires strong hospital leadership, clinical leaders, and health system. Support from hospital management is critical, as is a strong, dynamic clinical leader who can lead the effort until it becomes well-established. However, a weak health system will undermine the best of efforts.

Recommendation:

- Hospital leadership and management must be engaged and empowered in this intervention. Identifying the right clinical leader is also essential for success of the audit and feedback intervention. The intervention should take into account the unique circumstances of different health facilities and should be tailored to the specific setting and target groups.

- Further studies should be conducted at lower-level health facilities that have different contexts from referral hospitals to investigate the effectiveness of audit and feedback interventions at these facilities.
- Audit and feedback should be not be viewed as an isolated intervention, but should be integrated into a comprehensive QI approach that includes health systems strengthening.

Program Implication 4: The perinatal mortality rate among women with PE/E was unacceptably high. In some hospitals, the perinatal mortality rate was as high as 293 per 1,000 deliveries during the five-month period. Providers revealed that a range of factors are contributing to perinatal deaths, such as: delayed care-seeking, delayed recognition by providers at lower levels, weak referral system, and inadequate infrastructure at the referral facilities (e.g., shortage of beds and space to start treatment soon after arrival).

Recommendation:

- Increase the quality of service delivery at lower-level health facilities, including introducing audit and feedback at these sites.
- Strengthen the referral system at all levels (including clinical protocols, transport protocols, and coordination of care).
- Conduct further studies to assess the impact of audit and feedback on perinatal and maternal mortality, as well as strengthening Maternal and Perinatal Death Surveillance and Response processes.

5.2. Limitations

There were some limitations that could affect the outcomes of this study. However, we took a wide range of precautions to avoid unsubstantiated conclusions as a result of such limitations.

- Incomplete documentation of cases before intervention might introduce selection biases and could overshadow the comparability of intervention outcomes. Yet, the result was supported by in-depth interviews with providers, mainly to explain what the result of the quantitative results means from the providers' perspective. Hence, we believe that the changes observed in adhering to treatment protocols and guidelines after the audit and feedback intervention were real.
- The inherent problems with uncontrolled before-and-after designs (the design used in this study) is that secular trends or sudden changes may affect the outcome of interest over time, regardless of the intensity and effectiveness of the intervention. Moreover, these types of designs are often affected by the Hawthorn effect that leads to an overestimation of intervention outcomes.
- The intervention period was relatively short which limited us to observe dose response relationships, especially with regard to the effect of the audit and feedback intervention on providers' confidence to effectively manage women with PE/E. Likewise, because of the shorter intervention period, this study did not allow us to investigate longtime trends in maternal and newborn outcomes after the audit and feedback intervention.

6. References

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