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ADHERENCE TO MINISTRY OF HEALTH GUIDELINES IN MANAGEMENT OF SEVERE PRE-ECLAMPSIA/ ECLAMPSIA IN PUMWANI MATERNITY HOSPITAL, KENYA
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ABSTRACT

***Background*: Guidelines have shown to impact positively on the management of medical conditions. The impact of these guidelines has not been evaluated for severe preeclampsia and eclampsia in Kenya.**
***Objective*: To evaluate the level of adherence to Kenya Ministry of Health (MOH) guidelines in the management of severe pre-eclampsia and eclampsia at Pumwani Maternity Hospital, Kenya.**
***Design*: A cross sectional**
***Setting:* Pumwani Maternity Hospital, Kenya.**
***Subjects:* Records of women managed for severe pre-eclampsia and eclampsia, delivered between 2010 and 2013.**
***Results*: The overall adherence to guidelines was 31.4%. Adherence to specific parameters: history taking and examination, investigations, fetomaternal monitoring, use of recommended guidelines and post-partum guidelines was 67.8%, 13.9%, 26.1%, 29.5% and 20% respectively.**
***Conclusions*: Adherence to Kenya Ministry of Health (MOH) guidelines in management of severe pre-eclampsia and eclampsia in Pumwani Maternity Hospital is poor. Studies on the reasons for poor adherence and implementation need to be carried out.**

INTRODUCTION

Evidence based medicine is defined as the conscientious and explicit use of medical evidence to make decisions for patient management (1). The World Health Organisation (WHO) and the National Institute for health and Care Excellence (NICE), systematically reviews available evidence to come up with clinical guidelines (2, 3). These guidelines are adopted and customised in to specific country guidelines. This does not necessarily ensure their use in clinical practise dissemination and implementation strategies (2). To estimate the resource implications of these strategies. To develop a framework for deciding when it is efficient to develop and introduce clinical guidelines.

Kenya's maternal mortality ratio is 488 per 100,000 live births, a far cry from the national health policy target of 150 per 100,000 live births(3). Severe pre-eclampsia and eclampsia are hypertensive disorders in pregnancy, and are one of the top five causes of direct maternal mortality globally and in sub-Saharan Africa(4). They contribute substantially to the maternal mortality specifically in the developing countries, where 99% of maternal deaths occur(5). The pathophysiology of pre-eclampsia and eclampsia leads to multiple body organ failure, necessitating a well-orchestrated management guideline for optimum and timely management (6).Despite the use of evidence based medicine increasing, there is no evidence on the level of guideline adherence especially in resource limited settings where maternal mortality remains high (7).

Guidelines on the management of pre-eclampsia and eclampsia are available in Kenya, but no assessment on the level adherence has been done. We carried out an assessment on the adherence of Ministry of Health guidelines on the management

of severe pre-eclampsia and eclampsia in Pumwani Maternity Hospital, in 2014.

MATERIALS AND METHODS

This was a cross sectional study covering the period January 2010 to December 2013. The study was carried out in Pumwani Maternity Hospital, Nairobi Kenya. This is the largest maternity hospital in East and Central Africa and a major referral hospital for low and middle income patients in Nairobi. During the study period, a total of 50,851 deliveries were performed. The staff compliment includes four consultant obstetrician/gynaecologists, one Paediatrician, two hundred nurses and fifteen medical officers. The facility has Ministry of Health guidelines on the management of severe pre-eclampsia and eclampsia, and the staffs have been trained on the same. Standard of care magnesium sulphate is given as a loading dose of 4 grams followed by 2 grams every hour for 24 hours, in the prevention and treatment of seizures in severe preeclampsia and eclampsia. The hospital has a laboratory equipped to carry out investigations required for patients with severe pre-eclampsia and eclampsia. However it does not have an intensive care unit or a renal care unit. Case records are paper based and are kept in the Medical Records Department.

Patient records were obtained for patients admitted and managed with a clinical diagnosis of pre-eclampsia and eclampsia. Those who had gestation ≥20 weeks on admission, ≤ six weeks post-partum and had documented management in their case files were included. Those who were referred to other facilities before being managed were excluded from the study.

A total of 263 patients formed the sample size, which was calculated using the modified Karl Fisher's formula with a power of 80%.

Done using the modified Karl Fisher's formula for calculating sample size based on precision around a proportion. This type of study has not been published in Kenya and the sample size calculation was based on one study done at Garissa District Hospital that is unpublished.

$$N=\frac{Z2\ p\ (1-P)}{d\ 2}$$

Where

N=estimated sample size

Z= standard normal deviate for 95% confidence interval (1.96)

P =estimated prevalence of adherence to guidelines (0.361 from Garissa study)

d= degree of precision (5%)

Desired level of statistical significance (1.96) represents the desired power typically 0.84 for 80% power. Prevalence of guideline use in an unpublished study at Garissa Provincial Hospital estimated at 36.1%

$$N=\frac{1.962\ 0.36(1-0.36)}{0.052}$$

To correct for finite population

$$Nf=\frac{n}{1+n/N} \qquad Nf=\frac{359}{1+\frac{359}{1000}}$$

Where N is total finite population (1000)

N =sample size without finite population

Sample size 262

All patients records during the study period were retrieved from the Medical Records Department and a total of 1,000 records with a clinical diagnosis of pre-eclampsia and eclampsia were retrieved. These were each assigned a code according to the year of study and one hundred files per year were randomly selected from an electronically generated table of using Excel software. From the total one thousand files retrieved, three hundred patients' records were evaluated and data was extracted and files lacking more than 50 percent of the data were excluded. A total 263 files remained for evaluation.

The following data variables derived from the Ministry of Health, Kenya guidelines on the management of severe pre-eclampsia and eclampsia were history taking processes, clinical examination of clients that included the vitals, fundal height examination and vaginal examination, clinical management of the patients that included decisions for delivery and monitoring of the labour processes, the use of anti-hypertensive medication, use of magnesium sulphate to prevent and treat convulsions, laboratory investigations including complete blood count, renal and liver functions tests, urinalysis, coagulation profiles and uric acid levels. Other variables that were examined included postpartum assessment and evaluation of patients. Social-demographic and obstetric characteristics were also collected.

The Principal Investigator and two trained Research Assistants collected the data. A pretested data abstraction form was used to develop an MS Access database for direct electronic data entry. Data were verified and cleaned.

Data were exported from MS Access database into SPSS version 21 for analysis. To evaluate the level of adherence to guidelines for management of severe pre-eclampsia and eclampsia, proportions for different parameters were evaluated to determine the levels of adherence for each record assessed. Data were presented as proportions for categorical variables and mean with standard deviation (SD)

for continuous variables. The cut off for adequate adherence was 80%.

Ethical approval was given by the Kenyatta National Hospital/University of Nairobi Scientific and Ethics Review Committee. Permission to carry out the study was given by the Pumwani Maternity Hospital.

RESULTS

A total of 263 records formed the analysis for this study. The study population was mainly aged 20-24 years (32.3%) with a mean age (SD) of 26 (5.3) years and most were primigravidas (43%). The most common symptoms at presentation were abdominal pains (38%), headaches (30%), oedema (15%) and epigastric pains in 11%. Blood pressure, fundal height, vaginal examination and pulse rate were documented in 99%, 96%, 55% and 3% of case records respectively (table 1).

Requests for laboratory investigation were documented in 50% of the case records for complete blood counts and 61.5% for liver function tests and renal function tests. Uric acid and peripheral smears were not requested for in any of the case records. For all the laboratory tests requested, results were documented in between 8% to 37% of the case records. An obstetric ultrasound was requested and results recorded in 51% of the cases. The obstetric ultrasounds, however lacked important information with only 0.4%, 6% and 11% reporting on doppler studies, intrauterine growth restriction evaluation and biophysical profiles respectively (table 2).

Table 3, shows that time when decision to deliver and when delivery occurred was documented in 78% and 79% of case records respectively. Magnesium sulphate was administered intravenously in all cases, and recorded in only 56% and 52% for loading and maintenance doses respectively. The commonest antihypertensive used was oral methyldopa (88%), with hydralazine use recorded in only 2% of cases and no record for labetalol use was observed. Phenobarbitone use was documented in 40% of records. Post-delivery blood pressure monitoring and seizure prophylaxis was conducted in 71%, while input output monitoring and auscultation for pulmonary oedema were documented in only 0.4%. Of the 23 patients who convulsed, 57% had their airway managed, 13% had their blood pressure restored and 9% had control of convulsions.

Figure1 shows overall performance in Pumwani Maternity Hospital against the recommended MOH guidelines. The facility scored 68% on history taking and examination findings, the lowest score was in investigations (14%) and post-partum management of patients (20%). The mean level of adherence was 31.4%.

Table 1

Demographics and clinical characteristics of patients managed for pre-eclampsia and eclampsia in Pumwani Maternity Hospital, 2010-2013

Demographic Characteristic	(n)%
Age group	
15-19	18 (7)
20-24	85 (32)
25-29	78 (30)
30-35	60 (23)
35-39	18 (7)
>40	4 (2)
Parity	
0	119 (43)
1	72 (27)
2	42 (16)
3	18 (7)
>4	12 (5)
Clinical characteristic	
Symptoms recorded	
Lower abdominal pains	100 (38)
Headache	78 (30)
Oedema	39 (15)
Epigastric pains	29 (11)
Convulsions	23 (9)
Reduced fetal movements	13 (5)
Physical Examination	
Pulse rate	9 (3)
Blood pressure	262 (99)
Fundal Height	252 (96)
Vaginal Examination	144 (55)

Table 2
Adequacy of documentation of investigations requested and results recorded for patients managed for pre-eclampsia and eclampsia in Pumwani Maternity Hospital, 2010-2013

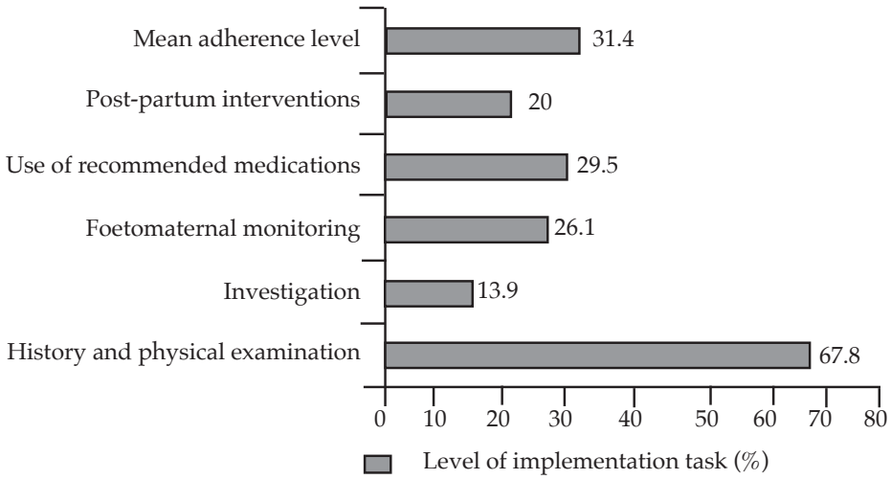
Investigation	Investigations requested N-263 n (%)	Results recorded N=263 n (%)	Actual results recorded No (%)
Haematologic			
Complete blood count	140 (53.)	34 (13)	34 (24)
Peripheral smear	0 (0)	0 (0)	0 (0)
Liver			
Liver function tests	133 (51)	20 (8)	20 (15)
Coagulation profile	0 (0)	0 (0)	0 (0)
Renal			
Urea/electrolytes/creatinine	143(54)	20 (7.6)	20 (15)
Uric acid	0 (0)	0 (0)	0 (0)
Urinalysis	162 (62)	98 (37)	98 (60)
Foetal well being	135 (51)	135 (51)	135 (100)
Evaluation for IUGR		16 (6.1)	16(12)
Doppler Studies		1 (0.4)	1(0.7)
Biophysical profile		29 (11)	29(21)

Table 3
Adequacy of management for patients managed with severe pre-eclampsia and eclampsia in Pumwani Maternity Hospital compared to Kenya Ministry of Health guidelines, 2010-2013

Time of intervention	Aspect of management (N-263)	n (%)
Pre-delivery	Timing of decision	
	Timing of delivery documented	78 (30)
	Monitoring of vital signs	
	Maternal pulse rate more than once	2 (0.8)
	Number of counts of maternal	
	pulse rate in 24hrs/record	<5 (100)
	No. of counts of fetal heart rate and	
	maternal BP in 24 hours	<5 168 (74)
		5-10 56 (24)
		>10 3 (1)
	Medications	
	IV Magnesium Sulphate loading dose	147 (56)
	IV Magnesium Sulphate Maintenance	136 (52)
	IV Labetalol	0 (0)
	IV Hydralazine	5 (2)
	Oral Nifedipine	164 (62)
	Oral Phenobarbitone*	104 (40)
	Oral Methyldopa*	231 (88)
Post-delivery		
	Time of delivery documented	208 (79)
	Blood pressure Monitoring	189 (71)
	Seizure prophylaxis	11 (4)
	Input output charting	13 (5)
	Auscultation for pulmonary Oedema	1 (0.4)
Acute management of convulsions	Parameters (N=23)	
	Airway management	13 (57)
	Blood pressure restoration	3 (13)
	Control of convulsions	2 (9)

*Not in guidelines

Figure 1
Overall adherence to Ministry of Health guidelines for management of severe pre-eclampsia and eclampsia, in Pumwani Maternity Hospital, 2010-2013



DISCUSSION

This is the first study in Kenya in a large maternity hospital setting, assessing adherence to pre-eclampsia and eclampsia guidelines, and has showed poor adherence (a mean of 31.4%) to guidelines with only half the patients administered magnesium sulphate. The patients who received the magnesium sulphate received both loading as well as maintenance doses.

These findings are similar to those from Garissa Provincial Hospital, a referral hospital in the north eastern part of Kenya (8), where the mean adherence to guidelines was 40% and those from a 22 Kenyan hospital survey in 2012, which showed that 65% of patients were administered magnesium sulphate(9). This scenario, is not unique to Kenya, Mexico and Thailand has also documented low administration of magnesium sulphate of between 0.8-8.5% (10). This is despite, magnesium sulphate being the corner stone in the management of severe pre-eclampsia and eclampsia both in the prophylaxis and treatment of seizures (7). These worrying statistics are suggestive of the existence of barriers to guideline implementation for the management of severe pre-eclampsia and eclampsia.

One of the barriers, could be none specificity on when to administer magnesium sulphate in the guideline. This is exemplified by a study carried out in the United Kingdom, a high resource setting, in 2010, that documented a low (17%) magnesium sulphate use attributed to lack of concrete documentation on when to use magnesium sulphate in the Royal College of Obstetricians and Gynaecologist (RCOG) guidelines of 2003-2005(11). This is not the case with the Kenyan situation, because the guideline is clear on when to adminsiter magnesium suphate.

The main limitation of this study is the inability to assess the barriers to guideline implimentation due to its retrospective nature of the design. However it has a strength of its pragmatic nature and that it was carried out in a large marternity hospital setting. From a policy perspective, data from this study gives a pointer towards a need to evaluate the barries towards implimenation of pre-eclampsia and eclampsia guidelines.

In conclusion, adherence to Kenya Ministry of Health guidelines in management of severe pre-eclampsia and eclampsia in Pumwani maternity hospital is poor. Analytical studies on the reasons for poor adherence and implementation need to be carried out.

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