

THE UNIVERSITY OF ZAMBIA
SCHOOL OF MEDICINE

**AN EVALUATION ON THE USE OF INTRAVENOUS
MAGNESIUM SULPHATE IN THE MANAGEMENT OF
ECLAMPSIA AT THE UNIVERSITY TEACHING HOSPITAL,
LUSAKA, ZAMBIA**

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**DISSERTATION SUBMITTED IN PARTIAL FULFILMENT
OF THE REQUIREMENT AND FOR THE DEGREE OF MASTER OF
MEDICINE IN OBSTETRICS AND GYNAECOLOGY**

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DEDICATION

To my late father Simon whose dream I am living.

ACKNOWLEDGEMENTS

My heartfelt thanks to my supervisor Dr. Lackson Kasonka for the encouragement and constant supervision in making this piece of work a reality.

Special thanks to my co-supervisor Dr. Yusuf Ahmed for the advice, comments and encouragement in my work.

Special thanks to Prof. S. Siziya for giving me direction in the study.

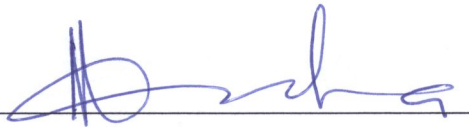
A big thank you to my research assistant Martha Chakulimba, my data entry clerk Mr. J. Banda and secretary Ms. Bridget Sialumano.

I would also like to show sincere appreciation to the wonderful staff in the Department of Obstetrics and Gynaecology who gave an input into this dissertation.

STATEMENT

I HEREBY STATE THAT THIS DISSERTATION IS ENTIRELY THE RESULT OF MY OWN PERSONAL EFFORT. THE VARIOUS SOURCES TO WHICH I AM INDEBTED HAVE BEEN CLEARLY INDICATED IN THE BIBLIOGRAPHY AND ACKNOWLEDGEMENTS.

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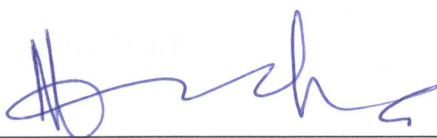


DR. WEBBY MACHA

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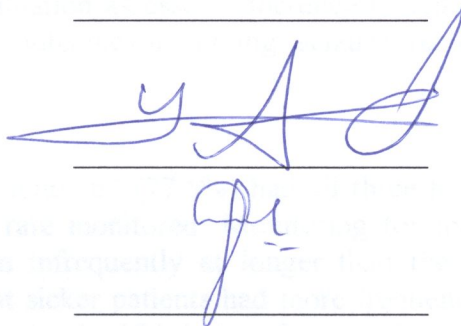
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DR. SWEBBY MACHA

APPROVAL

THE DISSERTATION OF **DR. SWEBBY MACHA** IS APPROVED AS
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ABSTRACT

Background

There is now compelling evidence that magnesium sulphate is effective and recommended for use in the prevention and treatment of eclampsia seizures^(1,2). The benefits of magnesium sulphate (MgSO₄) includes reduction of recurrent seizures by more than 50%, and improved maternal and neonatal outcomes. The reduction in maternal mortality can only be optimally achieved if the drug is administered in the setting of a high-dependency unit staffed by trained health care professionals as there would need to be great emphasis on monitoring of patients, strict adherence to magnesium sulphate administration protocols and looking out for adverse effects of the drug. Parenteral magnesium sulphate was introduced in the management of eclampsia seizures at the UTH, Lusaka in 2000. Since then no formal evaluation has been performed on its utilisation.

Methods

In this cross sectional prospective study conducted over a 3-month period at the UTH in 2005, the use of magnesium sulphate in the management of 80 eclamptic women was assessed. The evaluation assessed adherence to regimen of use of magnesium sulphate, and medical outcomes including seizure recurrence and maternal and perinatal outcome.

Findings

Of the 80 eclamptic patients, 62 (77.5%) had all three parameters of reflexes, urine output and respiratory rate monitored. Monitoring for most of the patients (n=70, 87.5%) was undertaken infrequently at longer than the recommended 1–2 hours, though it was noted that sicker patients had more frequent monitoring. 81.3% of the study subjects received a total of 24 doses of magnesium sulphate irrespective of the time from the last fit or delivery. Whether the magnesium sulphate doses were given for 24 hours after the last fit or for 24 hours after delivery did not impact maternal and perinatal outcome. A seizure recurrence while on magnesium sulphate occurred in 9 of the 80 cases (11.3%). There was one maternal mortality and 10 perinatal deaths in this cohort of 80 patients (1.25% and 12.5% respectively).

Interpretation

The regime for the administration of magnesium sulphate in the management of eclampsia at UTH has been effectively implemented with favourable maternal and perinatal outcomes. Challenges remain in fully adhering to the guidelines of administration of magnesium sulphate and of monitoring of patients.

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ABBREVIATIONS

CR	Clinic Referral
CVA	Cerebrovascular Accident
FSB	Fresh Stillbirth
IM	Intramuscular
IV	Intravenous
Magpie	Magnesium Sulphate for Prevention of Eclampsia
MgSO ₄	Magnesium Sulphate
MSB	Macerated Stillbirth
SB	Stillbirths
SOU	Special Observation Unit
SPSS	Statistical Package for Social Sciences
UK	United Kingdom
UNZA	University of Zambia
USA	United States of America
UTH	University Teaching Hospital

INTRODUCTION

Worldwide, an estimated 600,000 women die each year of pregnancy related causes, with 99% of these deaths occurring in developing countries⁽¹⁾. Eclampsia probably accounts for more than 50,000 maternal deaths worldwide each year^(1,2,3).

In almost all settings, eclampsia is among the top 5 causes of maternal death^(3,4) (see also Appendix I). In developed countries, it complicates 1 in 2000 deliveries, while in developing countries estimates vary from 1 in 100 to 1 in 1700^(1,2,3). Eclampsia is about 20 times more common in developing countries where both the incidence and case fatality rates of this disease are closely associated with scarce maternity care, particularly life-saving skills and drugs⁽³⁾.

Eclampsia is the occurrence of one or more convulsions in association with the clinical syndrome of pre-eclampsia. The word 'eclampsia' arises from the Greek 'like a flash of lighting' and this is how the disease may occur. In the majority of cases, this dramatic emergency (eclampsia) characterized by clonic and tonic convulsions will show the prodromal signs of pre-eclampsia. In as many as a quarter cases of eclampsia (10-30%), there are no warning signs - the fits occurring 'like a flash of lightning'.^(3,5)

The use of magnesium sulphate for eclampsia is increasing although a range of other anticonvulsant drugs continue to be used. These include diazepam and other benzodiazepines, phenytoin, barbiturates and a so-called 'lytic cocktail'.⁽¹⁾

The collaborative eclampsia trial ⁽²⁾ a multicenter study conducted across three continents found magnesium sulphate to be far superior to diazepam and phenytoin in the management of fits.

The Magpie Trial⁽¹⁾ (Magnesium Sulphate for Prevention of Eclampsia) was a large multicentre trial designed to evaluate the effects of magnesium sulphate on women and their babies. The aim was to find out if, overall, women with pre-eclampsia or their babies or both, do better if they are given magnesium sulphate rather than placebo, regardless of whether treatment is started before or after delivery and irrespective of any previous anticonvulsant therapy. Magnesium sulphate was found to halve the risk of maternal death. There do not appear to be substantive harmful effects to mother or baby in the short term⁽¹⁾.

In both the collaborative eclampsia and the Magpie trials, magnesium sulphate was given as an intravenous loading dose followed by intravenous infusion or intramuscular injections for 24 hours and no significant difference was found between the intravenous and intramuscular maintenance regimes.

The most commonly used regimes for the administration of magnesium sulphate are the Pritchard's and Zuspan's regimes (see Appendix II). Both of these regimes are effective and were used in the collaborative eclampsia and Magpie trials, the choice being at the discretion of doctors and midwives participating in the study.

At the University Teaching Hospital, Lusaka, a modified Zuspan's regime for the administration of intravenous magnesium sulphate is used (see Appendix II). The use of intravenous magnesium sulphate in the management of eclampsia fits at the University Teaching Hospital (UTH) – Lusaka is recent. It was introduced in 2000 despite the fact that magnesium sulphate use elsewhere has been decades old in the United States of America (since the 1920s) though not as common in other parts of the world. The recent introduction of magnesium sulphate use in the setting of UTH and elsewhere was mainly attributable to lack of very compelling evidence on its use and the fear of side-effects and the risk of toxicity. The encouraging results from both the collaborative and the Magpie trials led to the introduction of magnesium sulphate at the UTH.

Patients with eclampsia at the UTH Labour Ward are managed in a high-level dependency care area – the Special Observation Unit (SOU). Those that develop serious morbidity or require assisted ventilation are transferred to the Intensive Care Unit.

LITERATURE REVIEW

Historical Perspective

Magnesium sulphate has been used for treating eclampsia in the United States of America (USA) for much of the 20th Century. Its use for the treatment of eclampsia was first suggested in 1906⁽⁶⁾. However, the first documented use of magnesium sulphate for treating eclampsia seizures was in 1924 when an internist at Los Angeles General Hospital suggested using intravenous magnesium sulphate to treat eclampsia seizures, knowing that it controlled tetanic convulsions and had mild sedative effects. In the initial trial, which included 17 eclamptic women, all seizures were controlled by magnesium sulphate, and maternal mortality was only 6% compared with the historical average of 30%.⁽⁶⁾

By the 1960s, magnesium sulphate therapy combined with antihypertensive medication and delivery had been adopted in the United States as frontline therapy for eclamptic seizures – an approach that reduced maternal mortality to 5% or less. The associated perinatal mortality, which was largely due to abruptio placentae, prematurity and complications of fetal growth restriction, also was substantially reduced – from about 30% to about 10%.^(7,8,9,10)

Criticism of magnesium sulphate therapy was centred on 2 perceptions of the pharmacology of magnesium: -

- (i) That it acted only at the neuromuscular junction and
- (ii) It did not penetrate the blood brain barrier.⁽¹¹⁾

These effects seemed less than optimal when compared to those of newly developed anti-epileptic medications that had well described mechanisms of action involving rapid transfer from blood to brain and stabilization of neuronal membranes.

Recent Research Findings on Effectiveness of Magnesium Sulphate

Newer findings in the 1990s from small controlled studies suggested that magnesium sulphate was surprisingly effective in preventing seizures in both pre-eclampsia and eclampsia. Recurrent seizures occurred in 9% of eclampsia women who received magnesium sulphate. This was about 40% less than in those given the anticonvulsants diazepam or phenytoin. In patients with severe pre-eclampsia, magnesium sulphate prophylaxis reduced the risk of seizures to 0.9% from 2.8% in women who received antihypertensive agents but no anticonvulsants.⁽¹²⁾

Large randomized trials confirmed these findings. These were the International collaborative eclampsia trial (1995) and the landmark Magpie (Magnesium sulphate for prevention of eclampsia) trial (2002).^(1,2) These two trials provided the most compelling evidence on the use of magnesium sulphate. British obstetric practise has changed rapidly in response to these findings⁽¹³⁾ and standard treatment of eclampsia in the United Kingdom now much more closely corresponds to that of the USA, although some controversies remain about optimal dosage.

The International Collaborate Eclampsia Trial (1995) was set up to determine which anticonvulsant was best to treat eclampsia.⁽²⁾ Diazepam, phenytoin and magnesium

sulphate were compared in the study of 1,687 women with eclampsia to find out which one of these standard anticonvulsant regimes was superior in the management of eclampsia. Primary measures of outcome were recurrence of convulsions and maternal death. The study found that magnesium sulphate was far superior to the other anticonvulsants diazepam and phenytoin. Magnesium sulphate reduced seizure recurrence by more than 50% though maternal mortality was non-significantly lower among women allocated magnesium sulphate.

The Magpie trial (2002) was a large international trial designed to evaluate the effects of magnesium sulphate on women and their babies. ⁽¹⁾ The aim was to find out if, overall, women with pre-eclampsia or their babies, or both, do better if they are given magnesium sulphate rather than placebo, regardless of whether treatment is started before or after delivery and irrespective of any previous anti-convulsant therapy. The background to the study was that anticonvulsants are used for pre-eclampsia in the belief that they prevent eclamptic convulsions, and so improve outcome. Evidence supported magnesium sulphate as the drug to evaluate.

Eligible women (n=10,141) included those who had not given birth or were 24 hrs or less postpartum, had a blood pressure of 140/90 or more and proteinuria 1+ (30mg/dl) or more. Women were randomised in 33 countries to either magnesium sulphate (n=5 071) or placebo (n=5070). Primary outcomes were eclampsia and for women randomised before delivery, death of the baby. Follow-up was until discharge from hospital after delivery. Analyses were by intention to treat.

The interpretation of this study was that magnesium sulphate halves the risk of eclampsia and probably reduces the risk of maternal death. There did not appear to be substantive harmful effects to mother or baby in the short term.

A Regional Perspective on the Use of Magnesium Sulphate

A study to look at factors that influence unavailability of magnesium sulphate for the treatment of eclampsia and pre-eclampsia in Mozambique and Zimbabwe found that this drug, like many other effective treatments, is still not available widely in many low and middle income countries.⁽¹⁷⁾ However, the reasons for this remain unclear. Though both Zimbabwe and Mozambique have been using magnesium sulphate in their central hospitals since the 1980s; much earlier than Zambia, availability of the drug outside the central hospitals remains a problem. Failures in the registration, procurement, and distribution mechanisms for magnesium sulphate contribute to its poor availability in Mozambique and Zimbabwe. In addition, the low cost of magnesium sulphate means that the market forces cannot be relied on to ensure its availability. The study concluded that governments and international agencies must be prepared to intervene to ensure the availability of low cost effective drugs like magnesium sulphate in developing countries. The above study conducted in Zimbabwe and Mozambique concurs with the findings of a study on translating research into policy and practice in developing countries; a case study of magnesium sulphate for pre-eclampsia.⁽¹⁸⁾

Teaching hospitals in southern Africa contributed to the multicentre collaborative eclampsia trial that produced the overwhelming evidence for the superiority of magnesium sulphate as the drug of choice for eclampsia.⁽¹⁾ While other parts of the world have put this evidence into practice, this trend has not yet been comprehensively adopted in Africa.⁽¹⁹⁾

With the current strong evidence from systemic reviews of randomized trials to support the use of magnesium sulphate for the prevention and treatment of eclampsia, more developing countries should put the evidence into practise.^(1,2,16,20) However, this should also be followed by evaluations and assessments on how well the evidence has been put into practice since there are numerous logistical constraints in its implementation when not used in a formal research setting. This study aims to explore the use of magnesium sulphate in such a health care setting.

OBJECTIVES

(A) Overall Objective

To evaluate the use of intravenous magnesium sulphate in the management of eclampsia at the University Teaching Hospital (UTH) – Lusaka.

(B) Specific Objectives

- (i) To determine the adherence to the UTH regimen for the administration of magnesium sulphate in the management of eclampsia.
- (ii) To document how patients are monitored while on magnesium sulphate.
- (iii) To determine the seizure recurrence of patients on magnesium sulphate prophylaxis and treatment.
- (iv) To document the side effects of magnesium sulphate in patients treated with magnesium sulphate treatment in UTH.
- (v) To document the maternal and perinatal outcomes of women on magnesium sulphate treatment at the UTH.

Note: the specific objectives include process indicators (adherence, monitoring steps) and impact indicators (seizure recurrence, side-effects, maternal and perinatal outcome).

Since this was not an efficacy study, the impact indicators are simply collected to substantiate the evaluation through the processes indicators.

METHODOLOGY

A. Research Design

A cross-sectional prospective study on the evaluation of intravenous magnesium sulphate in the management of eclampsia was carried out at the UTH, Lusaka – Zambia over a 3-month period from 1st June to 31st August 2005.

B. Research Setting

The UTH is the largest hospital in Zambia with a bed capacity of 1,800 and serves as a referral centre for all patients in the country and the 23 clinics in Lusaka district. UTH provides comprehensive maternity care including blood transfusion, instrumental deliveries, induction and augmentation of labour and caesarean section.

The maternity services are organised such that all the 23 clinics in the district are linked by radio to an ambulance service running a 24-hour service for emergency transfers to UTH. In 2005 there were approximately 50,000 deliveries at UTH and the district clinics. Almost 25% of the deliveries (11,686) took place at the UTH. The Department of Obstetrics and Gynaecology comprises four teams of medical staff (Consultants, Residents from a 4 year Masters of Medicine program and Interns) as well as nursing and midwifery staff. There is a 24-hour theatre and anaesthetic cover.

C. The Sample: - Selection And Exclusion Criteria

The sample consisted of all cases of eclampsia managed at UTH over the 3-month period from 1st June to 31st August 2005.

An exclusion criterion was patients admitted with an established medical condition such as meningitis, epilepsy or cerebral malaria that can also cause fits.

D. Data Collection Methods

Data collection methods included: -

- a. A comprehensive review of patients cases records.
- b. An abstraction aide and checklist filled in by the attending midwife (and/or doctor) looking after the eclampsia patient (see Appendix III).

E. Treatment Regime for MgSO₄

This was the modified Zuspan's regime for the administration of magnesium sulphate prevalent at UTH at the time of the study (Appendix II).

F. Outcomes

The primary outcomes were: -

- a. Adherence to UTH magnesium sulphate regime (including patient monitoring)
- b. Seizure recurrence.
- c. Maternal and perinatal outcome.

G. Data Analysis and Presentation

All the information was analysed using SPSS. Analysis was both descriptive and comparative. Comparative analysis included the student's t-test and the chi-square test, both with their 'p' values. A 'p' value of <0.05 was considered significant.

H. Ethical Considerations

There were no ethical issues identified. All data were obtained from the case files without name identifiers. However, formal ethics approval for the study was obtained from the University of Zambia Research Ethics Committee.

RESULTS

Table 1(a): Distribution of Eclampsia cases by Age

Age	n	(%)
Less than or equal to 16 Years	6	(7.5)
17- 19 Years	27	(33.8)
20-24 Years	29	(36.3)
25-29 Years	14	(17.5)
30-34 Years	4	(5.0)
Total	80	(100.0)

Of the 80 eclampsia patients, 6 were younger than 16 years of age. Most of the eclampsia patients (n=29, 36.3%) were in the age category 20 – 24 years old, a generally active reproductive age group in Zambia. Only 4 (5%) were in the 30 – 34 year age category. None of the 80 eclampsia patients seen was above 34 years of age and the youngest was 14 years old.

Table 1(b): Distribution of Eclampsia cases by Gravidity

Gravida	n	(%)
1	47	(58.8)
2	14	(17.5)
More than 2	7	(8.8)
Postpartum	12	(15.0)
Total	80	(100.0)

Most of the eclampsia cases seen in the study were primigravidas (n=47, 58.8%). There were 7 (8.8%) who were of gravidity greater than 2, while 12 cases of postpartum eclampsia were observed (15%).

Table 1(c): Distribution of Eclampsia cases by Parity

Parity	n	(%)
0	49	(61.25)
1	16	(20.0)
2	7	(8.75)
More than 2	5	(6.25)
Missing parity	3	(3.75)
Total	80	(100.0)

Of the 80 cases seen, 49 (61.3%) were nulliparous (Para 0). Primiparity (para 1) accounted for 16 (20.0%) cases. Only 5 cases were of parity greater than 2 accounting for 6.3%. Information on Parity was missing on 3 cases of eclampsia (3.8%).

Table 2(a): Distribution of Eclampsia patients by booking status (UTH or Clinic Referral)

Booking Status	n	(%)
UTH Patients	14	(17.5)
Referred Patients	66	(82.5)
Total	80	(100.0)

Table 2(a) shows that most of the eclampsia patients (n=66, 82.5%) were referred from the local clinics in emergency situations. Only 14 (17.5%) were UTH booked patients.

Table 2(b): Booking status of Patient versus Final Maternal outcome

Booking Status	Recovered and discharged	Complications and taken to ICU	Died	Total
	n (%)	n (%)	n (%)	n (%)
UTH	14 (18.7)			14 (17.5)
Referred	61 (81.3)	4 (100.0)	1 (100.0)	66 (82.5)
Total	75 (100.0)	4 (100.0)	1 (100.0)	80 (100.0)

Chi-Square 1.13 p-value 0.57

Though all the 14 (18.7%) hospital booked patients with eclampsia completely recovered and were discharged from hospital by the fifth day, booking status (hospital vs. clinic referral) did not seem to have an impact overall on maternal outcome. (Chi-sq 1.13, P-value 0.57)

Table 2(c): Booking status of Patient versus Final Perinatal Outcome

Booking Status	Good APGAR*	Fresh/Macerated stillbirth	Admitted for complications	Total
	N (%)	n (%)	n (%)	n (%)
UTH	12 (23.1)	1 (10.0)	1 (5.6)	14 (17.5)
Referred	40 (76.9)	9 (90.0)	17 (94.4)	66 (82.5)
Total	52 (100.0)	10 (100.0)	18 (100.0)	80 (100.0)

Chi-Square 3.61 p-value 0.1, ns (bad outcome includes stillbirth and admissions for complications.)

*For purposes of this dissertation, ‘Good Apgar Score’ was defined as a 5-minute score of 8,9, or 10.

Booking status of the patient did not appear to impact on final perinatal outcome either.

Table 3: Type of Eclampsia cases seen

Type of Eclampsia	n	(%)
Antepartum	33	(41.3)
Intrapartum	35	(43.8)
Postpartum	12	(15.0)
Total	80	(100.0)

Of the 80 cases of eclampsia seen, most of them were intrapartum (n=35, 43.8%). 33 (41.3%) cases were antepartum whilst 12 (15%) cases of postpartum eclampsia were reported.

Table 4: Frequency of Fits before Admission

Number of Seizures	n	(%)
1-2	50	(62.5)
3-4	18	(22.5)
More or equal to 5*	10	(12.5)
Continuously**	2	(2.5)
Total	80	(100.0)

* But not continuous (or status epilepticus)

** Continuous or status epilepticus

Over 60% of women had 1 – 2 seizures. 18 (22.5%) of women convulsed 3 – 4 times while 10 (12.5%) women had 5 or more seizures. Continuous seizures lasting several minutes and recurring frequently occurred in 2 (2.5%) women.

Table 5(a): Timing of Magnesium Sulphate treatment

Commencement of Treatment	n	(%)
Immediately after admission	47	(58.8)
1-2 Hours after admission	26	(32.5)
More than 2 hours after admission to UTH	7	(8.8)
Total	80	(100.0)

In 47 (58.8%) cases of eclampsia, magnesium sulphate was started immediately on admission to UTH. In a further 26 (32.5%) cases treatment started 1 – 2 hours after admission. In only 7 cases (8.8%) had treatment been delayed more than 2 hours after admission.

Table 5(b): Total number of Magnesium Sulphate doses given

Number of Doses	n	(%)
Less than 24	14	(17.5)
All doses = 24	66	(82.5)
Total	80	(100.0)

Out of the 80 eclampsia cases seen, 66 (82.5%) received the stipulated total of 24 doses whilst 14 (17.5%) received less than 24 doses.

Table 5(c): How the Magnesium Sulphate doses were given

Dosage Giving Method	n	(%)
For 24 hours after delivery	1	(1.3)
For 24 hours after last fit	2	(2.5)
24 doses from admission*	65	(81.3)
Doses Stopped before 24 given	12	(15.0)
Total	80	(100.0)

* Irrespective of delivery or last fit

A large proportion of patients with eclampsia (n=65, 81.3%) received a total of 24 doses irrespective of the last fit or delivery whichever occurred last. Only 3 cases received magnesium sulphate for 24 hours either after last fit or delivery. In 12 (15%) cases, magnesium sulphate treatment was stopped prior to 24 doses having been administered.

Table 5(d): How the Magnesium Sulphate doses were given versus final maternal outcome

How Doses Given	Recovered and Discharged		Complications and taken to ICU		Died	Total	
	n	(%)	n	(%)	n	(%)	(%)
For 24 hours after Delivery	1	(1.3)				1	(1.3)
For 24 hours after last fit	2	(2.7)				2	(2.5)
24 doses from admission	63	(44.0)	2	(50.0)		65	(81.3)
Doses Stopped	9	(12.0)	2	(50.0)	1	(100.0)	12 (15.0)
Total	75	(100.0)	2	(100.0)	1	(100.0)	80 (100.0)

Chi-Square 10.01 p-value 0.12

A cross tabulation of how the magnesium sulphate doses were given versus final maternal outcome was statistically insignificant (Chi-Square 10.01 P-value 0.12)

Table 5(e): How the Magnesium Sulphate Doses were given versus Final Perinatal outcome

How Doses Given	Good APGAR n (%)	Fresh/Macerated stillbirth n (%)	Admitted for complications n (%)	Total n (%)
For 24 hours after Delivery	1 (1.9)			1 (1.3)
For 24 hours after last fit	1 (1.9)	1 (10.0)		2 (2.5)
24 doses from admission	42 (80.8)	9 (90.0)	14 (77.8)	65 (81.3)
Doses Stopped	8 (15.4)		4 (22.2)	12 (15.0)
Total	75 (100.0)	10 (100.0)	18 (100.0)	80 (100.0)

Chi-Square 5.56 p-value 0.47

A cross tabulation of how the magnesium sulphate doses were given by final perinatal outcome was statistically insignificant (Chi-Square 5.56 P-value 0.47).

Table 6(a): Monitoring of Clinical Signs

Monitoring	N	(%)
Reflexes, Urine Output, Respiratory Rate	62	(77.5)
Reflexes and Urine Output	2	(2.5)
Urine Output and Respiratory Rate	15	(18.8)
Urine Output Only	1	(1.3)
Total	80	(100.0)

62 (77.5%) cases of eclampsia had all the three clinical parameters monitored whilst the patient was on magnesium sulphate treatment. A further 15 (18.8%) had only urine output and respiratory rate monitored. 2 (2.5%) had reflexes and urine output monitored. 1 (1.3%) had only urine output monitored.

Table 6(b): Frequency of Monitoring

How Frequent Monitoring was	n	(%)
Hourly	9	(11.3)
Two Hourly	1	(1.3)
Infrequent	70	(87.5)
Total	80	(100.0)

Most of the eclampsia cases (n=70, 87.5%) were monitored infrequently (less frequently than every 2 hours). 9 (11.3%) cases were monitored hourly whilst 1 (1.3%) case was monitored 2 hourly.

Table 6(c): Frequency of Monitoring versus Final Maternal outcome

How Frequent Monitoring was	Recovered and Discharged	Complications and taken to ICU	Died	Total
	n (%)	n (%)	n (%)	n (%)
Hourly	5 (6.7)	3 (75.0)	1 (100.0)	9 (11.3)
Two Hourly	1 (1.3)			1 (1.3)
Infrequent	69 (92.0)	1 (25.0)		70 (87.5)
Total	75(100.0)	4 (100.0)	1 (100.0)	80 (100.0)

Chi-Square 25.75 p-value 0.00

A cross tabulation of frequency of monitoring versus final maternal outcome was statistically significant. (Chi-Square 25.75 P-value 0.00). This reflects the more frequent monitoring undertaken for sicker patients.

Table 6(d): Frequency of Monitoring versus Final Perinatal outcome

Frequency of Monitoring	Good APGAR	Fresh/Macerated stillbirth	Admitted for complications	Total
	n (%)	n (%)	n (%)	n (%)
Hourly	6 (11.5)	1 (10.0)	2 (11.1)	9 (11.3)
Two Hourly	1 (1.9)			1 (1.3)
Infrequent	45 (86.5)	9 (90.0)	16 (88.9)	70 (87.5)
Total	52 (100.0)	10 (100.0)	18 (100.0)	80 (100.0)

Chi-Square 0.57 p-value 0.97

A cross tabulation of frequency of monitoring versus final perinatal outcome was statistically insignificant (Chi-Square 0.57) P-value 0.97)

Table 7(a): Seizure Recurrence during Treatment

Experienced Seizures during Treatment	n	(%)
Yes	9	(11.3)
No	71	(88.8)
Total	80	(100.0)

9 (11.3%) had seizure recurrence during treatment with magnesium sulphate.

Table 7(b): Number of Recurrent seizures during treatment

Number of Recurrent Seizures during Treatment	n	(%)
1	7	(77.8)
2 – 3	1	(11.1)
>4	1	(11.1)
Total	9	(100.0)

Of the 9 patients who had recurrent seizures, 7 had 1 recurrent fit, one had 2 – 3 recurrent fits and the remaining one had 4 or more recurrent fits.

Table 8: Documented side-effects while on Magnesium Sulphate

Side Effects	n	(%)
Poor urine output	5	(6.3)
Drowsiness	2	(2.5)
Hot Flushes	1	(1.3)
No Side Effects	72	(90.0)
Total	80	(100.0)

8 patients demonstrated side effects of; poor urine output (n=5), drowsiness (n=2) and hot flushes (n=1).

Table 9(a): Final Maternal outcome

Maternal Outcome	n	(%)
Recovered and Discharged	75	(93.8)
Complications and Taken to ICU	4	(5.0)
Died	1	(1.3)
Total	80	(100.0)

75 (93.8%) cases of eclampsia recovered well and were discharged to the postnatal ward. 4 (5%) cases developed complications that required transfer to the Intensive Care Unit. One maternal death occurred representing a case fatality of $1/80=1.25\%$.

Table 9(b): Causes of Maternal Complications of eclampsia/pre-eclampsia

Cause of Maternal Complications	n	(%)
Respiratory Depression	2	(50.0)
Pulmonary Edema	1	(25.0)
Renal Failure	1	(25.0)
Total	4	(100.0)

Of the 4 eclampsia cases that developed complications and were transferred to the Intensive Care Unit, 2 had respiratory depression and the remaining 2 had pulmonary edema and renal failure respectively.

Table 10(a): Final Perinatal outcome

Perinatal Outcome	n	(%)
Baby with good APGAR*	52	65.0
Fresh/Macerated still birth	10	12.5
Baby admitted for complications	18	22.5
Total	80	100.0

* Good Apgar score was defined as a 5-minute score of 8,9, or 10.

52 (65%) of the babies had a good Apgar score and were transferred to postnatal ward nursery. 18 (22.5%) of the babies had complications that required admission to the Neonatal Intensive Care Unit (NICU). 10 (12.5%) babies were stillbirths (fresh or macerated). Accordingly the perinatal case fatality was: $10/80=12.5\%$.

Table 10(b): Cause of Perinatal Complications

Cause of Perinatal Complications	n	(%)
Asphyxia	11	61.1
Prematurity	7	38.9
Total	18	100.0

Of the 18 babies that had complications, 11 were due to birth asphyxia and the remaining 7 were due to prematurity.

Table 10(c): Cause of Perinatal Death

Cause of Perinatal Death	n	(%)
Hypertension in Pregnancy	6	60.0
Eclampsia	2	20.0
Fetal Distress	1	10.0
Asphyxia	1	10.0
Total	10	100.0

The perinatal case fatality was $10/80=12.5\%$. Of the 10 perinatal deaths, 6 were attributed to hypertension in pregnancy, 2 to eclampsia and the remaining 2 to asphyxia and fetal distress. Prematurity was a complicating factor in some cases.

Table 11: Problems encountered in the use of Magnesium Sulphate

<i>Drug Not Available</i>	N	(%)
Yes	3	(3.8)
No	77	(96.3)
Total	80	(100.0)
 <i>Erratic Drug Administration</i>		
Yes	11	(13.8)
No	69	(86.3)
Total	80	(100.0)
 <i>Shortage of Supplies as Syringes and Needles</i>		
Yes	0	(0)
No	80	(100.0)
Total	80	(100.0)
 <i>Infrequent Monitoring</i>		
Yes	68	(85.0)
No	12	(15.0)
Total	80	(100.0)

The most common problem encountered in the use of magnesium sulphate was infrequent monitoring (n=68, 85%). Erratic drug administration was reported in 11 (13.8%) cases and in 3 (3.8%) cases was the drug not available at the time of magnesium sulphate administration.

DISCUSSION

The discussion highlights important issues based on the results obtained from the description of the cases of eclampsia, adherence to the magnesium sulphate regime, monitoring of patients, seizure recurrence, side effects and final maternal and perinatal outcome. Problems encountered in the use of magnesium sulphate will also be highlighted.

(A) Description of Cases of Eclampsia

Age. Table 1(a) shows that a greater proportion of eclamptic fits were observed in the 20 – 24 years age category. This represents the most active reproductive age group among women in Lusaka. It has been shown from table 1(c) that 61.3% involves primiparas, most of whom (41.3%) were teenage girls (less than 20 years). Eclampsia has been closely associated with primigravidity and younger age in previous studies. ^(1,2,3,14)

Gravidity. Primigravidity was an important factor. 58.8% of women with eclampsia were primigravida compared to 8.8% of women with gravidity greater than two. This again has been shown in other studies that noted eclampsia to be commoner in first pregnancies compared to subsequent pregnancies. ^(1,2,3,5,14)

Booking status. 82.5% (n=66) of women with a clinical diagnosis of eclampsia were referred from the local clinics having fitted once or more. Only 17.5% (n=14) of women had eclampsia fits observed and who had been booked at UTH. It is noteworthy that even then 17.5% fitted while booked at UTH. This reflects those with severe pre-

eclampsia who proceed to eclampsia while on conservative management or have eclampsia unexpectedly before or after delivery. Similarly, a study by Mukosa at UTH in 1997⁽¹⁴⁾ showed that 79% of patients were clinic referrals and 20% were UTH booked. The larger case incidence of eclampsia in the local clinics is a reflection of the larger number of deliveries compared to UTH.⁽¹⁴⁾

The delay in referring patients to UTH from the clinic may partly explain the complications and death associated with eclampsia in the referred cases (table 2b). The delay could be multifactorial and include delays in decision-making by relatives to take the patient to the clinic, delays in decision-making at the clinic and also transport problems.

A higher percentage of stillbirths and admissions for fetal complications were seen in the referred cases of eclampsia, although this was not impacted by the booking status of patient (table 2c).

Type of Eclampsia Cases

Table 3 indicates that 44% of the cases of eclampsia fits were observed in the intrapartum period, whilst 41% were observed in the antepartum period. Postpartum eclampsia accounted for 15% reflecting a greater need for vigilance during these periods. This entails attendance by trained staff during labour, effective control of blood pressure, and an assisted second stage to minimize the stress associated with bearing down. Some 53% of women in Zambia deliver at home⁽¹⁵⁾ and would not have the opportunity of this type

of care. Good nursing care is of great importance with emphasis on fluid balance charts to avoid overloading patients with fluids and care of a semi-conscious patients to avoid aspiration.^(1,2,3)

Seizure Frequency before Admission

In over half the cases (63%), 1 – 2 eclamptic fits were observed. Up to four eclamptic fits were observed in 23% of the cases while 5 or more were observed in 13%. 3% (n=2) of the women had continuous seizures lasting several minutes and recurring frequently. In some cases (mainly those with few fits before admission to the high dependency unit – SOU at UTH), the patients were already inpatients. In the rest, they were either referred from clinics or came from home. In the Magpie trial there was an adverse maternal and perinatal outcome in relation to the duration and frequency of eclamptic fits.⁽¹⁾

(B) Adherence to the Magnesium Sulphate Regime

Timing of Magnesium Sulphate Treatment

Table 5(a) illustrates the timing of the magnesium sulphate treatment. 58.8% (n=47) of the eclampsia cases received their first magnesium sulphate dose soon after admission. 32.5% (n=26) received the magnesium sulphate dose 1 – 2 hours after admission. 7 (8.8%) had delayed administration of magnesium sulphate, i.e., more than two hours after admission. Although not systematically recorded, this was primarily due to shortage of nursing staff to administer and observe any potential adverse effects of the drug on the patient. A number of studies have stressed the importance that eclampsia patients receive

their first loading dose of magnesium sulphate soon after admission as this prevents further eclampsia fits ^(1,2,3).

Total Number of Magnesium Sulphate Doses Administered

As illustrated in table 5(b), 82.5% of patients with eclampsia received up to 24 doses of magnesium sulphate in 24 hours. 17.5% (n=14) received less doses than 24 due to side effects and/or erratic supply of the drug. In a few other patients, magnesium sulphate administration was discontinued due to remarkable improvement after delivery.

How Magnesium Sulphate Doses Were Administered

The Magpie trial recommended that magnesium sulphate be administered for 24 hours soon after fit or after delivery whichever occurred last.⁽¹⁾ 81% of the patients as shown in table 5(c) were given 24 doses of magnesium sulphate in 24 hours irrespective of the last fit or delivery. In 12 cases, magnesium sulphate administration was stopped prior to 24 doses.

(C) Patient Monitoring

Safe administration of magnesium sulphate requires vigilant monitoring of reflexes, respiratory status and urine output.^(1,2,3,16) In 77.5% (n=62) of the eclamptic cases, all the three clinical parameters were monitored whilst on treatment with magnesium sulphate. In 19% (n=15) only urine output and respiratory rate was monitored. 88% (n=70) of eclampsia patients (table 6b) were monitored infrequently. 11% (n=9) were monitored hourly while in 1 case (1.3%) the monitoring was two hourly.

For safe administration of magnesium sulphate, it is important that vigilance is exercised in monitoring reflexes, respiratory status and urine output. Ideally these clinical parameters should be monitored 1 – 2 hourly and any depression of the reflexes, respiratory rate should warrant stoppage of magnesium sulphate administration. A urine output of less than 25mls/hr requires that the dosage of magnesium sulphate should be halved.^(3,16) Magnesium sulphate toxicity can be reversed by calcium gluconate – which should be readily available.

(D) Seizure Recurrence

11.3% (n=9) of the study subjects experienced seizure recurrence during treatment with magnesium sulphate (table 7a). The majority of the patients experienced a single seizure recurrence (n=7, 77.8%) (Table 7b). The seizure recurrence of 11.3% is consistent with documented seizure recurrence of 5 – 15% in patients on magnesium sulphate treatment in other studies.^(1,2,3,14,16)

Recurrent seizures should be treated with repeat loading dose of magnesium sulphate and vigilance in monitoring reflexes, respiratory status and urine output to ensure safe administration of magnesium sulphate.^(1,2,3,16)

(E) Side Effects of Magnesium Sulphate

The study findings (table 8) showed 8 patients with side effects (10%). 5 (6.3%) had decreased urine output, 2 (2.5%) had drowsiness and 1 had hot flushes. Decreased urine output and drowsiness are also known to complicate eclampsia. In severe cases, the dose

should be withheld and this underlines the importance of intensive clinical monitoring of patients on magnesium sulphate.

(F) Final Maternal and Perinatal Outcomes

Maternal Outcome

Table 9(a) illustrates the one case fatality out of 80 cases (1.25%). The maternal death in the study (n=1, 1.3%) occurred from a cerebrovascular accident as a complication of the eclampsia. A case fatality of 1.25% competes favourably with that found in developed countries (case fatality of 1.8% to 7.2%^(3,16)). In developing countries, the case fatality ranges from 10 – 15% and can often be as high as 25%. Whereas a reduction in case fatality is dependent on factors apart from magnesium sulphate use, its adjunct use is important in reducing case fatality. A similar study at the UTH in 1997 of 101 eclampsia patients (before the use of magnesium sulphate) reported a case fatality of 5%.⁽¹⁴⁾

Of the 4 complications (5% of all 80 cases), 2 had respiratory depression, 1 renal failure and the remaining 1 had pulmonary edema. All the four patients were taken to the Intensive Care Unit for ventilatory support and high dependency care and all recovered well.

Perinatal Outcome

The perinatal case fatality was 12.5% (n=10) (table 10c). In developing countries, the perinatal case fatality in cases complicated by eclampsia can be as high as 30 – 40%.

Even in developed countries, the eclampsia-associated perinatal mortality can be as high as 10 – 20%^(1,3,14,16)

In this series, the perinatal case fatality of 12.5% could be even higher since not all the babies who had complications (n=18, 22.5%) were followed to find out those that survived through day 7.

Stillbirths in eclampsia are usually due to the effects of hypertension.⁽¹⁾ The higher perinatal mortality in eclampsia is partly explained by the need to deliver a premature baby with subsequent complications of prematurity. It should be noted that most management decisions in eclampsia are made for maternal considerations.

(G) Problems Encountered During Administration of Magnesium Sulphate

Table 11 shows problems encountered during administration of magnesium sulphate. The majority of the problems encountered were due to infrequent monitoring (n=68, 85%). Also there was erratic drug administration (doses not given at the stipulated times). This could have arisen from a chronic shortage of nursing staff prevalent at the time of the study. Adequate staffing of trained personnel in labour ward and other emergency obstetric wards is necessary to ensure regular administration and monitoring of patients on magnesium sulphate. Non-availability of magnesium sulphate and erratic supplies of needles and syringes was not common during the time of the study but is a potential problem. The drug availability at UTH was good due to the measures put in by the department and management to ensure the steady supply.

It may appear that the use of magnesium sulphate, particularly in developing countries, may be more costly than its alternatives (diazepam, phenytoin, phenobarbitone) when the cost of syringes, needles, staff to monitor side effects are considered. However, the experience of the use of magnesium sulphate at the UTH shows that a modified Zuspan's regimen can be administered.

STUDY LIMITATIONS

The study did not follow up babies admitted to the Neonatal Unit for various complications to determine the long-term perinatal outcome.

Despite the study attributing some side effects to magnesium sulphate, it is difficult to clearly link these solely to magnesium sulphate as eclampsia itself may cause some of the documented side effects.

Staffing levels were not systematically recorded to be able to comment on how restricted staffing levels impact adherence to the magnesium sulphate administration regimen.

A number of confounding factors were not collected, precluding a more comprehensive regression analysis. In addition, bivariate analysis was restricted to a limited number of variables.

The study did not formally assess staff perceptions, attitudes and practices on the use of the magnesium sulphate administration regimen. This can be the focus of a subsequent study.

CONCLUSIONS

The study on the use of intravenous magnesium sulphate in the treatment of eclampsia at the UTH has revealed that, despite shortcomings in monitoring and occasional erratic drug administration, it has been used with good adherence, favourable maternal and perinatal outcome and fewer seizure recurrences.

The study also suggests that a total of 24 doses of magnesium sulphate can feasibly be administered, irrespective of the last fit or delivery whichever occurred last, with equally good overall maternal and perinatal outcome.

Measures of maternal and perinatal outcome in cases of eclampsia treated with magnesium sulphate revealed a case fatality of 1.25% and 12.5% respectively, both of which compare favourably with those found in developed countries. A seizure recurrence of 11.3% was reported and is consistent with other published studies.

In order to make a substantial impact on reductions in maternal mortality and morbidity due to eclampsia, magnesium sulphate use should be continued at the UTH. Strategies should be developed to increase wider usage in centres apart from at the UTH.

RECOMMENDATIONS

1. Conduct Regular monitoring of reflexes, respiratory status and urine output of patients on magnesium sulphate to ensure safe administration.
2. Ensure regular monitoring and correct administration of magnesium sulphate through, for example, adequate staffing in specialised units of labour ward.
3. Ensure adequate supply of this inexpensive life-saving anticonvulsant magnesium sulphate in all delivery suites – with attendant training of staff in its use.
4. Administer magnesium sulphate for a total of 24 doses irrespective of the last fit or delivery whichever occurred last.
5. Increase usage of magnesium sulphate at primary-care level before transfer of women with eclampsia to tertiary or secondary care level to prevent seizure recurrence and decrease maternal morbidity and mortality.

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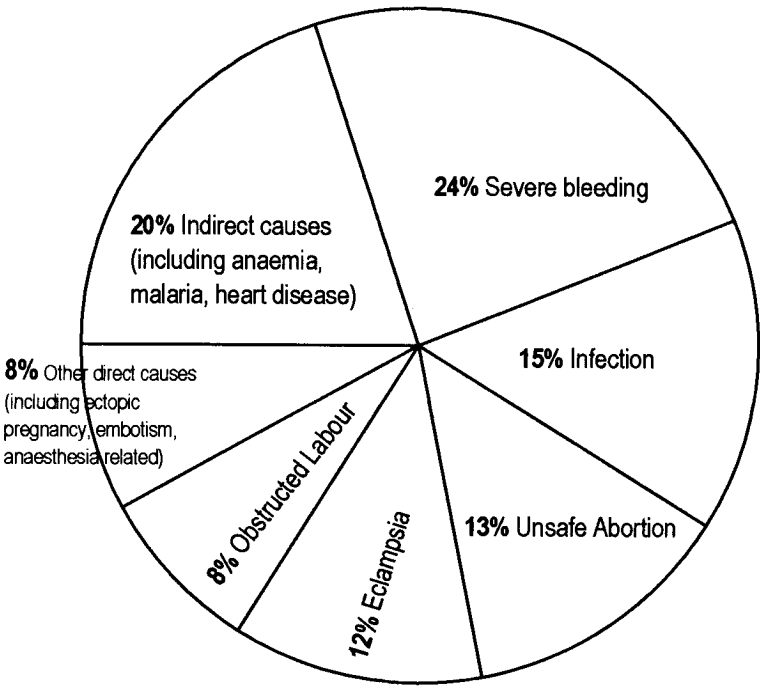
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APPENDIX I

CAUSES OF MATERNAL DEATH WORLDWIDE – (WHO 1998)



APPENDIX II

PRITCHARD'S AND ZUSPAN'S REGIMES FOR MAGNESIUM SULPHATE ADMINISTRATION IN ECLAMPSIA

At UTH, a modified Zuspan's regimen is used in which the maintenance dose is given as an hourly intravenous bolus as opposed to an intravenous infusion.

PRICHARD'S REGIME	
Loading Dose: 4g I.V. (administered over 5 to 10 mins; concentration not to exceed 20% ^a) plus 10g I.M. (using undiluted 50% solution)	Maintenance Dose: 5g I.M. q4h x $\geq$ 24h after last seizure (using undiluted 50% solution administered in alternate buttocks)
ZUSPAN'S REGIME	
Loading Dose: 4g I.V. (administered over 5 to 10min; concentration not to exceed 20% ^a)	Maintenance Dose: 1 – 2 g/h by controlled infusion pump x $\geq$ 24h after the last seizure (concentration not to exceed 20% ^a)

^a Lower concentrations, e.g., 10% are preferred

Abbreviations: h = hour (s); IM = Intramuscularly; I.V = Intravenously; Min = Minutes;

q4h = Every 4 hours

APPENDIX III

Abstraction aide and checklist

1. (Fill in the Patient's particulars)

(a) Patient's Study No. _____ (b) Age _____

(c) Gravida _____ (d) Parity _____

(e) Diagnosis _____ (f) Booking status (UTH/CR) _____

(f) Tick whether Antepartum, Intrapartum or Postpartum eclampsia: -

(i) Antepartum (ii) Intrapartum (iii) Postpartum

(g) Date of Admission ____/____/____ (Day, Month, Year)

(h) Date of discharge from S.O.U. ____/____/____ (Day, Month, Year)

2. Number of Seizures before admission

(i) 1 – 2 (ii) 3 – 4 (iii) ≥ 5 (iv) Continuously fitting

3. When was MgSO_4 treatment commenced? (Tick when it was started)

(i) Immediately after admission

(ii) 1 – 2 hours after admission

(iii) >2 hours after admission

4. What was the total number of MgSO_4 doses given? (Tick the appropriate response)

(i) <24 doses (ii) 24 doses (iii) >24 doses

5. How was the 24 maintenance dose of MgSO_4 given?
- (i) 24 hours after delivery
 - (ii) 24 hours after last fit
 - (iii) Given as a total of 24 doses irrespective of last fit or delivery whichever occurred last
6. Which of the following clinical signs were monitored?
- (i) Reflexes, urine output and respiratory rate.
 - (ii) Reflexes and urine output.
 - (iii) Reflexes and respiratory rate.
 - (iv) Urine output and respiratory rate.
 - (v) Reflexes only.
 - (vi) Urine output only.
 - (vii) Respiratory rate only.
 - (viii) None of the three above was monitored.
7. How frequent was monitoring of the patient on MgSO_4 done? (Tick the appropriate response)
- (i) Hourly (ii) Two Hourly (iii) Infrequently (iv) Not at all
8. Has the patient experienced any seizure recurrence once on MgSO_4 treatment? (Tick the most appropriate response)
- (i) Yes (ii) No

9. If the answer is Yes to the above response; how many recurrent seizures? (Tick the appropriate response)

- (i) 1 (ii) 2 – 3 (iii) ≥ 4 (iv) Continuously fitting

10. Document any side-effects experienced with MgSO_4 treatment.

11. What was the final maternal outcome after treatment with MgSO_4 ?

- (i) Patient recovered well and discharged to the postnatal ward
- (ii) Patient developed complications associated with eclampsia and was transferred to Intensive Care Unit
- (iii) Patient died

12. If the answer is (ii) or (iii) above; what complication did the patient develop or what is the most likely cause of death respectively? (Doctor's Assessment)

13. For those patients who had either Intrapartum or Antepartum eclampsia; what was the final neonatal outcome?

- (i) Baby born with a good APGAR score ($\text{A/S} \geq 8/10$) and Not transferred to Neonatal Unit
- (ii) Fresh/Macerated still birth
- (iii) Baby admitted to Neonatal Care Unit for some complications

14. If the answer is either (ii) or (iii) above; what are the possible causes of perinatal death or complications respectively? (Doctor's Assessment)

15. Did you encounter any problems in the use of MgSO_4 in this patient?
(Doctor/Midwife's response)

- (i) Drug not available
- (ii) Drug administration was erratic
- (iii) Shortage of supplies such as needles and syringes
- (iv) Infrequent monitoring
- (v) No problem encountered

Thank you very much for filling in this Questionnaire