



UNIVERSITY OF MALAWI

College of Medicine

**Female Support Companionship During Labour: Effects on Infant
Apgar Score and Maternal Pain Experience.**

By

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CERTIFICATE OF APPROVAL

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DECLARATION

I, Grace Neema Banda hereby declare that this thesis is my original work and has not been submitted for any other awards at the University of Malawi or any other University.

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ABSTRACT

Introduction: Pregnant women in Malawi receive inadequate emotional support during labour in hospital settings related to critical shortage of midwives and restrictive policies on supportive companionship.

Objective: To assess whether the provision of emotional support by a female companion during labour and delivery in a hospital setting reduces adverse perinatal and maternal birth outcomes such as infant's apgar score, mode of delivery, postpartum infection and maternal pain experience.

Methods: This was a randomized controlled non-blinded clinical trial conducted in two mission hospitals and one government health centre. 671 pregnant women classified as 'low risk pregnancy consented to the study and were randomly allocated into intervention (n=372) and control (n=299) arms. The intervention arm was supported by a female companion in addition to the standard midwifery care offered by midwives and doctors while the control arm received the standard care alone. A questionnaire and exit interviews were used to collect quantitative and qualitative data respectively. Quantitative data were analyzed using Epi info package while qualitative data were categorized according to emerging themes, coded and analyzed quantitatively.

Results: The incidence of low apgar score at one minute of birth was significantly lower for infants in the intervention (11%) than those in the control (32%) arm (Chi-square=32.238, $p<0.001$). Although not statistically significant, mothers in the intervention arm were 6% more likely to experience less pain unlike women in the control arm. The proportion of women who felt less severe pain during the current childbirth was significantly higher in the intervention (71%) than in the control (52%) arm, Chi-square=12.503, $p<0.001$). The prevalence of postpartum infection was statistically not different in infants and women in the intervention and control arms.

Conclusion: Supportive companionship during labour and delivery decreases the incidence of low Apgar score among infants born to supported mothers. Supportive companionship also reduces maternal pain experience and does not increase risk of postnatal infection to infants and their mothers. Therefore, promoting companionship during labour in our hospitals could reduce perinatal deaths related to birth asphyxia.

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ABBREVIATIONS AND ACRONYMS

COMREC:	College of Medicine Research and Ethics Committee.
CPD :	Cephalopelvic disproportion
C/S :	Caesarean section
DHO :	District Health Office
DHS :	Demographic and Health Survey
HB :	Hemoglobin level
JICA :	Japanese International Cooperation
MMR :	Maternal mortality ratio
MOH :	Ministry of Health
MOHP:	Ministry of Health and Population
NND :	Neonatal death
PMR :	Perinatal mortality rate
SB :	Stillborn
SD :	Standard deviation
SVD :	Spontaneous vertex delivery
UK :	United Kingdom
UNICEF:	United Nations Children Education Fund
US :	United States
VDRL :	Venereal Disease Research Laboratory
WHO :	World Health Organization

CHAPTER ONE

INTRODUCTION

1.1 Background information

Maternal and neonatal mortality have remained very high for the past decade in Malawi compared with other countries in Africa. Malawi doubled her maternal mortality ratio (MMR) from 620 deaths per 100, 000 live births in 1992 to 1120 deaths in 2000 (Malawi DHS 2000). Although a modest decrease of 12% is reported in the 2004 Malawi DHS, a ratio of 984 deaths per 100,000 live births remains the highest rate compared with neighbouring countries that have a larger proportion of women in the childbearing age in the sub-Saharan region. For example, in the year 2000, MMRs were estimated at 100 deaths in Botswana, 230 in South Africa, 300 in Namibia, 750 in Zambia and 880 in Uganda for every 100,000 live births (Population Reference Bureau 2005). Malawi also reported a perinatal mortality rate (PMR) of 34 per 1,000 (3.4%) deliveries in 2004 (Malawi DHS 2004), similarly, this is a high rate compared with the situation in developed countries. For example, United Kingdom registered PMR of 8 per 1,000 (0.8%) total live births for England, Wales and Northern Ireland between the years 2000-2003 (Flemmings 2005). In these industrialized countries PMR mainly results from non-preventable risk factors such as fetal malformations (Chalumeau et al 2002; UK National Statistics 2004) while in developing countries like Malawi PMR is a result of fetal asphyxia and early neonatal infections.

The high maternal and perinatal mortality in Malawi is associated with home deliveries and substandard intrapartum care (MOHP/Malawi Safe Motherhood Initiatives Study Report 2003; Ratsma 2001). Despite the fact that 90% of pregnant women attend at least one visit of antenatal care during their pregnancy and are advised to deliver at health facilities, only 40-55% of all births take place at health facilities (Malawi DHS 2000; MOHP/Malawi Safe Motherhood Initiatives Study Report 2003; Population Reference Bureau 2005). Reasons for the low health facility deliveries include long distances, costs of services in some institutions and worsening shortage of skilled personnel. The Safe Motherhood report identified in addition, bad staff attitudes and increasing poor birth outcomes to affect the quality of intrapartum care women receive hence barring them to access health facility deliveries (MOHP/Malawi Safe Motherhood Initiatives Study Report 2003, Banda 2000, Ratsma 2001). Home deliveries in Malawi are not attended by skilled health workers due to absence of community midwives in the national health care system. In contrast, countries with low MMR in sub-Saharan Africa have extremely high proportion of births attended by skilled health workers. For example, the proportion of births attended by skilled health worker ranges from 80%-94% in Namibia, South Africa and Botswana (Population Reference Bureau 2005; UNICEF/The State of the World's Children 2004). Thus, increasing numbers of hospital deliveries and skilled attendance at birth both at facility and community level appear to be major factors that contribute to the significant reduction of maternal and perinatal mortality.

Quality in midwifery care is assessed by obstetrical outcomes for both the mother and the infant and satisfaction of clients (Pittrof 2002). Home deliveries are associated with

high rates of obstetric complications that pose risk not only to the mother's life but also her infant's life. Avoidable factors such as prolonged and obstructed labour, ruptured uterus, hemorrhage and increased maternal distress increase risk of severe fetal hypoxia which leads to low apgar score that eventually result into fresh stillbirth and early neonatal death (Chalumeau et al 2002; Smith et al 2004; Guise et al 2004; Ratsma 2001). High PMR may be used as an indicator of the quality of the intrapartum care pregnant women receives. Therefore, good obstetric care is a key factor to reducing maternal and perinatal mortality in Malawi.

Provision of emotional support during intrapartum period is one aspect of midwifery care that is given little attention in many health facilities in Malawi. This has been attributed to shortages of skilled personnel, which has recently reached crisis level. A health facility survey conducted by the Japanese International Corporation Agency and Ministry of Health in 2002 showed that of the 26 districts in Malawi, 15 (~60%) had less than 1.5 nurses per health center, while 5 (~20%) had less than 1 nurse per health center. Due to these shortages and overworked existing staff, it is unlikely that sufficient and continuous emotional support could be rendered to pregnant women in labour. Despite the human resource problems, the midwifery practice in Malawi does not permit the presence of a guardian during labour in hospital settings. Reasons for this include hospital policy that does not allow visitors in restricted areas, inadequate space in delivery rooms, risk of infections and that a companion may use traditional medicine (Ministry of Health Infection Prevention and Control Policy, 2006). Experience shows that guardians are called to give support only when complications are eminent or develop, particularly, when there is poor maternal effort in the second stage of labour.

Similarly, these policies are usually not observed when female staff relations have mostly been permitted.

1.2 Statement of the problem

In Malawi, pregnant women receive inadequate or no emotional support during labour and delivery in hospital settings related to critical shortage of midwives and restrictive policies on supportive companionship. This has led to failure of pregnant women to appreciate the quality of intrapartum care they receive at hospitals. A large proportion (45%) of pregnant women in Malawi deliver at home. However, home deliveries in Malawi are conducted without skilled attendance, as a result pregnant women and their neonates are exposed to obstetric complications such as hemorrhage, maternal distress, birth asphyxia and infection. Hemorrhage and infection are direct causes of maternal and perinatal mortality. In the situation that Malawi has no community midwifery structures with skilled personnel, it is important to promote interventions that increase health facility deliveries in order to accelerate the reduction of maternal and perinatal mortality.

1.3 Literature review

A possible way of alleviating the impact of human resource constraints on the quality of intrapartum care is to allow a companion to be present with a pregnant woman in labour. The companion's role could be to continuously offer non-medical comforting measures and coping strategies such as back massaging and reassuring the woman throughout the birth process (Klaus et al 1986; Kroeger and Smith 2004; WHO:

Integrated Management of Pregnancy and Childbirth 2003), while allowing the midwife to concentrate on skilled medical interventions. A companion may also protect the woman and work as a watchdog towards hostile staff attitudes during labour (Maimbolwa 2001) and report obvious complications such as hemorrhage and loss of consciousness, which may occur during or soon after labour. There is a glut of studies showing that use of a layperson (companion) to provide emotional support during labour in a hospital setting, complementing the standard midwifery care rendered by midwives and doctors, improves self-esteem and confidence of women in labour, reduces infant and maternal complications and stimulates the natural childbirth environment compared with the standard care alone (Klaus et al 1986; Kennel and Klaus 1991; Madi et al 1999; Maimbolwa et al 2001; Kroeger and Smith 2004; Pascal-Bonaro and Kroeger 2004; Yogev 2004).

Randomized clinical trials on the efficacy of childbirth companionship in the US found that supported women had shorter duration of labour, fewer caesarian and vacuum extractions, and less need for oxytocin augmentation (Kennel and Klaus 1991; Kroeger and Smith 2004; Pascal-Bonaro and Kroeger 2004). For example, Kennel and Klaus (1991) in their study at an American hospital found that only 17% of the supported group (n=212) needed oxytocin augmentation compared to 43% ($p < 0.0001$) in the control group (n=202), and 1.4% had maternal fever compared with 10% ($p = 0.0007$) in the control group. In addition, a case-control study conducted in Guetamala found that supported women had significantly shorter duration of labour (mean=8.8h) compared to control group (mean=19.3h) (Sosa et al 1980). Furthermore, a clinical trial at Guetamala hospital (n=168 cases, 249 controls) found similar results. The study in addition, found

that the supported group had fewer perinatal complications compared to the control group (Klaus et al 1986). Similar to the studies in the Northern and Southern America, previous studies in resource-poor countries have produced similar results. A randomized controlled clinical trial in Botswana found that 91% of the supported women had normal spontaneous deliveries compared to 71% in controls ($p=0.03$), 4% had vacuum extraction compared to 16% in the control group ($p=0.03$), supported women suffered less stress and less pain hence had less need for analgesia (Madi et al 1999).

A qualitative study in Zambia looking at attitudes of women and staff concerning childbirth companion in Zambian maternities found mixed reactions. The majority of women were in favour of being attended by a supportive companion. In contrast, most health workers were against the idea citing the following reasons; lack of space, risk of infection, not a hospital policy, only staff are experts and interference with professional care as reasons for limitations (Maimbolwa et al 2001). However, other staff felt a companion would be an assistant to staff, security and an encouragement to the woman during despair and that the strategy would promote greater family involvement during childbirth. Later hospital policy was changed in Zambia and a female supportive companion was permitted during labour (Kroeger 2004). The situation of the health care system, practices and beliefs towards childbirth in Malawi is different from that of US, Botswana and Zambia. For example, the labour room designs and set up to promote privacy may be different. Also, the human resource shortages in Malawi are far worse than in the above-mentioned countries where studies on this topic were done. Hence, there was need to replicate the study before the intervention could be implemented.

1.4 Justification of the study

In Malawi, no previous studies have been conducted to assess the role that guardians of pregnant women can play in a health facility, to reduce poor birth outcomes, in the context of current staff shortages. This study assessed the effects of utilizing a layperson of a woman's choice to provide emotional support during labour in a hospital setting, in addition to the standard midwifery care rendered by skilled health workers, on the reduction of adverse perinatal and maternal birth outcomes. Results from the study could be used to advocate for policy changes in the current midwifery practice to permit labour companionship in hospital settings. It is anticipated that presence of a companion will protect a woman in labour from potential negligence and negative staff attitudes. This would also improve the relationship between the communities and hospitals hence attract more hospital deliveries in the long run.

CHAPTER TWO

OBJECTIVES OF THE STUDY

2.1 Broad Objective

The purpose of the study was to assess whether provision of emotional support by a companion during labour reduces adverse perinatal and maternal birth outcomes and improves maternal experience of childbirth.

2.2 Specific Objectives

The study aimed to determine whether the presence of a female companion during labour:

1. Decreases the incidence of low Apgar score among newborn infants
2. Decreases the incidence of instrumental deliveries (vacuum extraction and emergency cesarean section) during the second stage of labour
3. Increases the risk of postpartum infection to newborns and their mothers
4. Reduces maternal pain experience during the course of labour

CHAPTER THREE

METHODS

3.1 Type of research study

This was a randomized controlled non-blinded clinical trial conducted in three health facilities.

3.2 Study place

The study was conducted at two mission hospitals and one government health centre. St Luke's Hospital in Zomba District and St Anne's Hospital in Nkhotatkota District were the mission hospital sites while Area 25 Health Centre under Lilongwe District Health Office (DHO) was the government site. Selection of the sites was based on interest to implement the strategy. Area 25 Health Centre is located in the urban area of Lilongwe City and serves the urban population. St Luke's and St Anne's hospitals are in the rural areas and largely serve the rural population of their districts.

3.3 Study Population

The target population was pregnant women, in the late third trimester (>36 weeks gestation), attending antenatal and delivered at either St Luke's and St Anne's hospitals or Area 25 health centre.

3.4 Study period

Data were collected from July 2006 to April 2007. This followed data analysis, report writing and submission of the thesis report in June 2007.

3.5 Sample size

The average antenatal clinic attendance rate at the three hospitals was 784 per month for subsequent visits. Of these only 439 deliveries took place at the health facility. The incidence of low Apgar score in the total deliveries per month was 16 (4%). On average, 49 cesarean sections and 13 vacuum extractions took place at the three facilities per month. Therefore, combined estimates for low Apgar score at the three sites was 16/439 deliveries. Taking a difference of 2% between the control and intervention group, the standardized difference was 0.16. Using a nomogram calculation, a standardized difference of 0.16, power 0.8 and a level of significance 5%, the sample size of 1320 with equal numbers in each arm was estimated. This sample was considered adequate to accommodate comparisons of other variables and 10% loss to follow up. Random numbers of 660 participants each arm were generated through the computer by the statistician.

3.5 .1 Inclusion and exclusion criteria

Eligible women were those who were willing to participate in the study and carrying their first, second, third or fourth pregnancy. In addition, these women were those classified by a midwife or obstetrician following physical assessment as “low risk pregnancies” according to the standard Ministry of Health guidelines, and remained low

risk upon admission into labour ward. All women classified as “high risk pregnancies” through physical assessment by the midwife in attendance were excluded. These included all primgravida less than 150cm height; multigravida and primgravida with multiple gestation, malpresentation, malposition and those carrying a big baby compared with their pelvis. Multigravida with previous caesarean section and sick pregnant women with either a medical or obstetric condition were also excluded.

3.5.2 Enrolment

Eligible women were recruited and randomized in the antenatal clinics at approximately 36 to 40 weeks gestation. General awareness information about the study aim and role of companion were given on daily basis to antenatal women during group information sharing before they underwent physical assessments. Following physical assessments in the examination room, each eligible woman was asked to give consent to participate in the study voluntarily, by signing a consent form (Appendix I) that was explained in detail, using the woman’s local language. Those who consented were randomized into intervention and control groups by asking them to pick a random number in a sealed envelop. The random numbers were generated by a statistician through computer and were grouped into intervention and control groups of equal size. All numbers in the intervention and control groups were coloured green and pink respectively before sealing them in opaque envelopes. The sealed envelopes were mixed in a bag and placed in each examination room. The women themselves opened the envelopes and the health worker assisted them to identify themselves if the number picked required them to bring a companion or not. Depending on which group the woman belonged, all recruited women had their identity random number marked on their Antenatal Card and

shaded with a bright marker of their group colour for easy identification upon admission in labour and follow up in postnatal ward. The intervention group received both standard care from midwives and the support of a companion while the control group received standard care alone. During admission to labour ward, the woman and her companion were oriented to the physical set up of the labour ward so that they both do not get lost. The companion was offered a chair and asked to stay by the woman's bedside and informed of her role as to continuously offer non-medical comforting measures like back massaging; and not to conduct delivery. In order to reduce risk of cross infection, companions were requested to wash hands with soap and wear a plastic apron wherever necessary.

3.6 Data Collection

Data were collected by qualified nurse/midwives working at each contact point with study women, thus, antenatal, labour and postnatal wards. The principal investigator briefed the recruited midwives and demonstrated the enrolment procedure; the Dos and Don'ts of the companion in labour ward and exit interviews postnatally. A questionnaire (Appendix II) was used to collect quantitative data on Apgar score, instrumental/assisted deliveries and infection rate by reviewing delivery and postpartum records. The infant's score at birth was recorded at one and five minutes. The infant's score between zero and six out of the recommended ten scores of Apgar at one and five minutes of birth were considered low according to the Ministry of Health Obstetric Training Manual, 2000. The condition of the baby on discharge was recorded as alive or dead. Further data were collected if the infant died to determine whether the perinatal death was a fresh or macerated stillbirth, or an early neonatal death. Infant

deaths reported under the results section include only those that occurred in the first 36 hours of birth, thus, during the time that women were followed while in the hospital, therefore, do not include NNDs that occurred after discharge. The infants' body temperature and umbilical cord were checked every 12 hours in the first thirty-six hours until discharge using a thermometer and observations respectively. Infant's postpartum infection was confirmed by a raised body temperature of higher than 37.5 degrees Celsius and redness around the umbilical cord in the first 36 hours of birth. Maternal infection was measured through body temperature check and observations of the smell and characteristics of lochia during postnatal examinations. Maternal infection was suspected if the mother's body temperature rose to ≥ 38 degrees Celsius with or without foul smelling lochia and cramping lower abdominal pains. Face to face exit interviews were conducted on discharge to collect qualitative data on pain experience. Every woman in both groups was asked to express their perceptions towards their pain experience during labour. A set of guiding questions (Appendix III) was used to probe women's feelings. Labour records were checked for any type of analgesics given to the woman to relieve labour pains. Women in the intervention group were individually asked to explain what they perceived as the role of the companion under their care. Interviewers recorded responses to the questions in writing.

3.7 Data management

Quantitative data were coded, entered into a computer, cleaned and analyzed using Epi info 6.0. Chi-square test was used to test whether there were any significant differences in the various outcomes between the intervention and control arms. Two independent translators translated qualitative data from Chichewa into English. A research scientist

compared the translation to ensure reliability. Discrepancies identified were resolved through discussion with the translators. The “clean” data were categorized according to emerging themes extracted from women responses. Themes were coded and analyzed quantitatively as responses did not warrant a pure qualitative model analysis.

3.8 Study limitations

The major limitation for this study is small sample size that may limit generalization of findings. The reasons for reaching out this small sample size were that enrolment was slow as it depended on willingness and there was high loss to follow up despite high acceptance rate. We observed that despite consenting to participate in the study during the antenatal period, only 56% of women in the intervention arm and 44% of women in the control arm reported for hospital delivery. The demographic characteristics of women who defaulted did not differ from those who reported for hospital delivery. It was assumed that those who did not turn up at the study site delivery unit had delivered at another hospital nearby. This was obvious with women from the urban areas of Lilongwe City and Zomba District since they had a wider choice of which hospitals to go to for delivery. However, the hospital delivery rates observed in this study are comparable with the national hospital delivery rate (57%) reported in the 2004 MDHS.

3.9 Ethical considerations

College of Medicine Research and Ethics Committee (COMREC) approved the study on 30th May 2006. Institutional clearance was obtained from the management of St Luke’s and St Anne’s hospitals; and Area 25 Health Centre through Lilongwe DHO.

Potential participants were informed antenatal about the study purpose and expectations of the companion. A written consent was obtained from interested and eligible pregnant women individually. Privacy was maintained through screening with curtains in between delivery beds. Letting the women choose a companion of their choice ensured social privacy. Available skilled personnel exposed every woman in the study to a safe and standard professional midwifery care. The companion's comfort was maintained by offering her a chair or high comfortable stool placed by the labouring woman's bedside. Any study woman who developed a complication or a risk factor was immediately referred to available obstetricians for specialized obstetric care. Risk of infection and harmful substances from the companion was reduced by requesting the companion to wash hands with soap upon entry into delivery room, and instruction not to give anything by mouth to the woman before approval of the midwife responsible.

CHAPTER FOUR

RESULTS

4.1 Participants characteristics

A total of 1,329 pregnant women who met the inclusion criteria were approached for enrolment during antenatal clinic attendance. Of these 1,127 (85%) women consented in all the three sites comprising 27% St Luke's hosp, 54% St Anne's hosp and 19% Area 25 H/Centre. Acceptance rate differed marginally between government and mission institutions. The average acceptance rate in the two mission hospitals was 88% compared with 72% at a government institution. Of the 1127 women who consented, 563 were randomly allocated into intervention arm and 564 into the control arm. The 169 (15%) women who refused to consent provided the following reasons; their guardian either died or lived in another district, stayed with husband only and neighbours, never trusted available guardian and fear of exposure. Of the 1127 women who were randomized, 692 (61%) reported for hospital delivery in all the three sites. Of the hospital deliveries, 388 (56%) were the intervention arm while 304 (44%) were controls. Of the 388 women in the intervention arm, 16 (4%) either did not come with their companions or refused the company of their companion in labour hence were excluded from analysis. Reasons for refusing their companion during labour were feelings of embarrassment because the accompanied companion was mother in-law or neighbour. Those who left companions behind said their companions were committed on the day, or were sick and some companions came late or refused last minute. Data for five more women in the control group were not included in the analysis due to gross

missing information. Thus, data analysis was based on 671 women, 372 (55%) in the intervention arm and 299 (45%) had in the control arm.

4.1.1 Demographic characteristics

Table 1 shows the baseline characteristics of women in the intervention and control arms. Over half of the women in each arm had primary education. Slight variations were observed at secondary level. Thus, 31% of women in the intervention arm had secondary education compared with 27% of the controls. Seventy-two percent (72%) of women in the intervention arm had mild to moderate anaemia compared with 66% of the controls. Two percent (2%) of the women in the intervention arm had a positive VDRL test antenatally compared with 4% of the controls. The means of age, parity, haemoglobin levels, maternal body weight and number of antenatal visits were evenly distributed in the intervention and control arms (Table 2). Overall, characteristics of women in the two arms did not differ.

Table 1: Baseline characteristics of women in the intervention and control arms

	With companion (n=372)		Without companion (n=299)	
Characteristic	n	%	n	%
Maternal age (Years)				
14-20	114	31	82	27
21-27	160	43	129	43
28-34	90	24	77	26
≥35	8	2	11	4
Parity				
1	127	34	81	27
2	94	25	82	27
3	67	18	77	26
4	84	23	59	20
Educational level				
Not educated	56	15	40	13
Primary	200	53	175	59
Secondary	114	31	82	27
Tertiary	2	1	2	1
HB levels (g/dl)				
≤8	61	16	80	27
9-12	267	72	197	66
≥13	44	12	22	7
Antenatal visit				
1-4	250	67	226	76
≥5	122	33	72	24
VDRL Status				
Reactive	6	2	11	4
Non reactive	278	75	211	71
Not indicated	88	24	77	26
Maternal weight (Kg)				
≤60	216	58	173	58
61-70	124	33	88	29
71-80	22	6	29	10
81-90	7	2	5	2
≥90	3	1	4	1

Table 2: Distribution of means of different attributes of women in the intervention and control arms

Attribute	With Companion (n=372)		Without Companion (n=299)	
	Mean	±SD	Mean	±SD
Age (years)	23.9	5.0	24.4	5.25
Parity	2.3	1.2	2.4	1.1
Antenatal visits	4.1	1.7	3.7	1.7
HB Level (g/dl)	9.9	3.7	9.5	4.9
Maternal weight (Kg)	57.4	15.9	57.6	16.2

4.2 Labour and delivery

4.2.1 Method of delivery

Table 3 shows method of delivery and length of labour for women in the intervention and control arms. SVD was the commonest mode of delivery (86% in each arm). The proportion of women who delivered by C/S was lower in the intervention arm (10%) than in the control arm (11%), however, this difference was not statistically significant (Chi-square=1.515, $p=0.679$). Likewise, the total prevalence of instrumental deliveries was lower in the intervention (12%) than control (13%) arms. Indications for C/S were mainly prolonged first stage of labour secondary to cephalopelvic disproportion (CPD), cord presentation in second stage and cervical abnormalities for example, stenosis. The other methods of delivery were breech and undiagnosed twin deliveries.

Table 3: Mode of delivery and length of labour for women in the intervention and Control arms

Variable	Companionship		Total
	With companion	Without companion	
Mode of delivery	%	%	
SVD	86	86	578
Vac Ext	2	2	14
C/S	10	11	71
Other	2	1	8
	(n=372) 100	(n=299) 100	N=671
Length of labour hours)			
≤ 2	17	15	103
3-7	53	57	357
8 – 12	26	27	171
≥13	4	1	19
	(n=358) 100	(n=292) 100	N=650

4.2.2 Length of labour

Length of delivery for women who delivered by SVD was 5.8 hours (SD 3.3 hours) for the intervention compared with 5.7 hours (SD 3.6) for the control arm, Chi square =5.287, $p=0.152$. The difference in the length of labour was statistically not significant between the two arms.

4.3 Infant outcomes

In this study, the main outcomes of interest were Apgar score, perinatal deaths and infant postpartum infection. Nevertheless, data on other outcomes such as birth weight, maturity, birth defects and injuries were collected. Infants who were born through vacuum extraction, caesarean section and breech were excluded in this analysis in order to control for confounding.

4.3.1 Apgar score

Figure 1 **a** and **b** shows infants' Apgar score at one and 5 minutes of birth in the intervention and control arms. The proportion of infants born with low Apgar score at 1 minute (Figure 1 a) was significantly lower in the intervention arm (11%) than in the control arm (32%), [Chi-square=32.238, $p<0.001$]. Comparatively, the proportion of infants with low Apgar score at 5 minutes (Figure 1 b) was not statistically significant between the intervention arm (3%) and the control arm (2%) [Chi-square=1.402, $df=1$; $p=0.23$]. Overall, 90% of all low Apgar scores occurred in mission hospitals than in government hospital both in the intervention and control arms (Figure 1 c). However, the observed difference was statistically not significant for infants in the intervention

arm (chi-square=2.460, $p=0.117$) while it was highly significant for infants in the control arm (Chi-square=14.527, df1; $p<0.001$). The low Apgar scores that occurred in infants in the control arm took place in mission hospitals (100%).

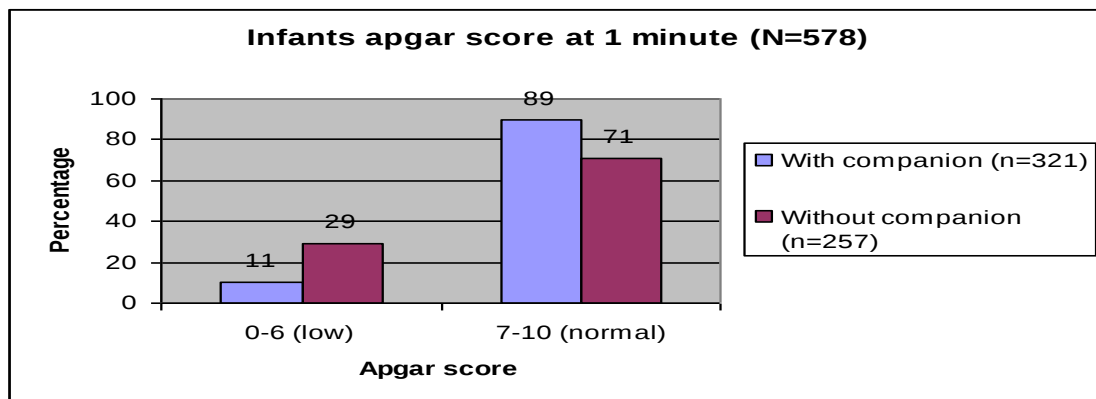


Fig. 1 a: Apgar score at 1 minute

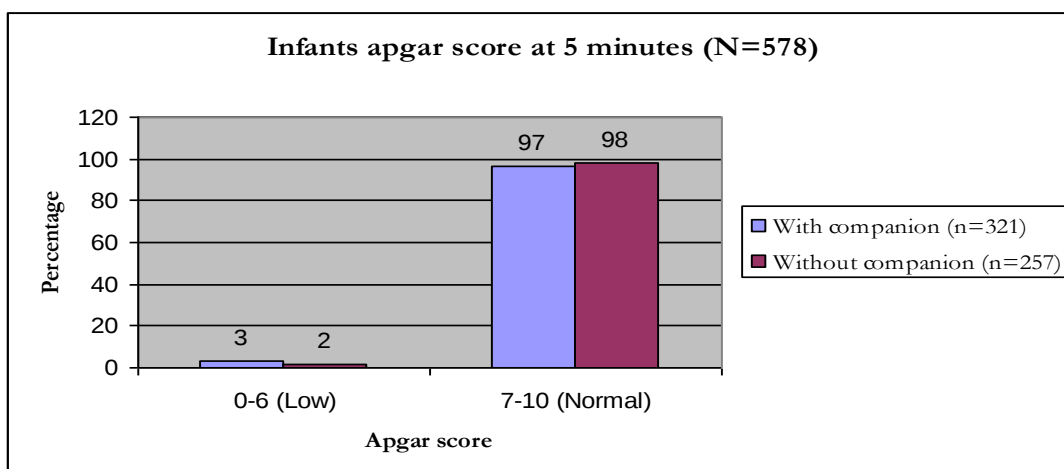


Fig. 1 b: Apgar score at 5 minutes

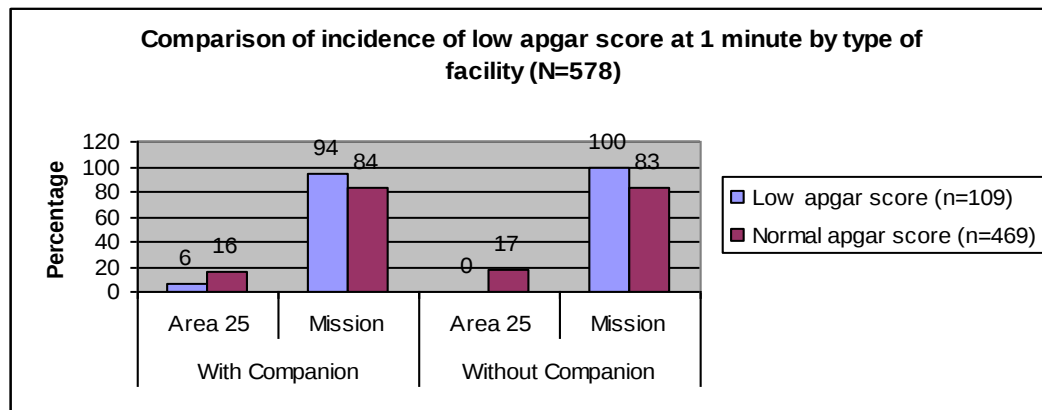


Fig. 1 c: Apgar score at one minute by type of facility

4.3.2 Perinatal deaths

Table 4 below shows the prevalence of perinatal deaths for infants in the intervention and control arms. The total perinatal deaths at 36 hours of birth were lower in infants born in the intervention arm (1.9%) than infants born in the control arm (2.3%). This difference was statistically not significant (Chi-square=1.409, $p=0.494$). The incidence of fresh SB and NND among infants in the intervention arm was 0.9% compared with 1.6% for infants in the control arm, (Chi-square=0.533, $p=0.465$).

Table 4: Prevalence of perinatal deaths for infants in the intervention and control arms (N=578).

Variable	With Companion (n=321)		Without companion (n=257)		
	n	%	n	%	Total
Fresh SB	1	0.3	2	0.8	3
Macerated SB	3	0.9	2	0.8	5
Early neonatal death (NND)	2	0.6	2	0.8	2
Fresh SB+NND	3	0.9	4	1.6	7
Fresh SB+Mac SB+NND	6	1.9	6	2.3	12

4.3.3 Infant postpartum infection

The prevalence of fever (body temperature >37.5 degrees Celsius) at 36 hours postpartum was lower in infants in the intervention arm (0.3%) than those in the control arm (1.2%). However, the observed difference was statistically not significant (Chi-square=1.365, $p=0.243$). Similarly, although twelve infants (3.8%) in the intervention arm ($n=313$) had infection on their umbilical cord at 36 hours of birth than seven (2.8%) in the control arm ($n=246$), the difference was also not significant statistically (Chi-square=0.410, $p=0.522$).

The mean birth weight for infants born in the intervention arm was 3063.1g (SD 505.5g) compared with 2996.8g (SD 555.4g) of the control arm, $p=0.656$. Ninety-nine percent ($n=318$) of the infants in the intervention arm were mature compared with 97% ($n=248$) in the control arm. Three infants (0.9%) in the intervention arm sustained birth injuries compared with one infant (0.4%) in the control arm, $p=0.432$. The birth injuries reported were lacerations on the head and caput succedaneum. Two infants (0.6%) in the intervention arm had birth defects compared with three infants (1.2%) of the control arm. The commonly presented defects were deformed feet, extra digits, spinal bifida and hydrocephalus head. The disparities observed in infants' birth weight, maturity status, birth injuries and defects were statistically not significant between the intervention and control arms.

4.5 Maternal Outcomes

4.5.1 Maternal postpartum infection

The women compared were those that delivered by SVD. The proportion of women who developed fever (temperature of 38+ degrees Celsius) 36 hours following delivery was higher in the intervention arm (0.9%) than in the control arm (0.4%), however, the difference was statistically not significant (Chi-square=0.619, $p=0.431$). The proportion of women who had infected lochia was higher in the intervention arm (3.5%) than in the control arm (3.2%) and similarly, the proportion of women who reported cramping lower abdominal pain was higher in the intervention arm (19%) than control arm (15%). The differences observed in the condition of lochia and lower abdominal pains between the two arms were statistically not significant ($p=0.822$ and $p=0.162$ respectively). Therefore, the risk of maternal postpartum infection was not associated with the woman being accompanied during labour.

4.5.2 Pain experience

Five major themes extracted from women responses of their pain experience were; pain severity, pain character, response to pain, pain comparison with previous pregnancy and role of companion. Women described their pain during childbirth as severe or less severe. The proportion of women who reported less severe pain was greater in the intervention arm (80 [25%]) than in the control arm (48 [19%]). The observed difference was statistically not significant ($p=0.061$). Women also stated the character of their pain as intermittent or continuous in nature. The proportion of women who experienced intermittent pain was higher in the intervention arm (102 [32%]) than in the

control arm (76 [30%]). Many women in the intervention arm (147[47%]) experienced continuous pain compared with those in the control arm (117 [46%]). The differences observed in the character of pain were statistically not significant ($p=0.551$). Further, women described their response to pain as either emotionally bearable or unbearable. The proportion of women who had bearable pain was greater in the intervention arm (245 [79%]) than in the control arm (197 [77%]) but this difference was statistically not significant ($p=0.663$). Multiparous women compared the current pain experience with their recent previous childbirth. The proportion of women who felt less severe pain during the current childbirth was significantly higher in the intervention arm (123 [71%]) than in the control arm (62 [52%], Chi-square=12.503, $p<0.001$). The reporting of pain experiences differed between government and mission health institutions, particularly those with companions. The proportion of women who had less severe pain in the intervention arm was significantly higher in mission hospitals (94%) than in the government hospital (6%, $p=0.010$) while in the control arm the difference was statistically not significant between mission and government hospitals ($p=0.682$).

It was observed that women who felt continuous pain also reported severe and unbearable pain while those who had intermittent pain reported less severe and bearable pain. Emphasizing her point, a 24 year old para 2 in the intervention arm said, *'...I felt severe pain continuously that I kept on crying,'* while a 23yr old para 2 in the same arm cited, *'...this birth was much better, the pain was on and off...I had some rest periods compared to my first pregnancy.'* Women in the intervention arm attributed the presence of their companion to have contributed to the reduction of the pain by strengthening the woman's coping mechanisms through comforting touch and words of

encouragement. A 20 year old para 2 confirmed by saying, *'I felt severe pain but I was able to cope because my mother was comforting me. ...she was rubbing my back and chatting with me.'*

4.5.3 Role of companion

Women in the intervention arm described the role of their companion as massaging lower back (57%), chatting or telling stories (17%), encouragement (16%) and some said their companions were not helpful (10%). Women who perceived their companion not helpful gave the following reasons: the severity of the pain did not reduce despite the companion's actions listed above; companion continuously blamed the mother for being uncooperative and companion being talkative. Overall, women who perceived their companions not helpful had also reported severe unbearable pain.

CHAPTER FIVE

DISCUSSION

This randomized clinical trial found out that the incidence of low apgar score at one minute of birth was significantly lower in infants in the intervention arm than those in the control arm ($p < 0.001$), but the prevalence of perinatal deaths did not differ between the two arms. Women in the intervention arm were also 6% more likely to experience less severe pain that was more bearable in nature unlike women in the control arm. Mothers in the intervention arm attributed the presence of the companion to have reduced the pain and helped them cope with labour stress through actions like back massage and encouragement. Further, the study found that the prevalence of postnatal infection in infants and their mothers was similar between the intervention and control arms. Similarly, the proportion of instrumental deliveries did not differ between mothers in the intervention and control arm.

In this study we found that female companionship during labour and delivery in a hospital setting significantly reduced the incidence of low Apgar score among infants in the intervention arm than those in the control arm. This finding is consistent with earlier clinical trials conducted in both developed and resource-poor countries. In these trials authors cited that infants born to companion supported mothers had significantly low incidence of birth asphyxia than infants born to unsupported mothers (Pascali-Bonaro and Kroeger 2004, Kennel et al 1991, Kroeger and Smith 2004). Although the prevalence of perinatal deaths was not significantly different in the two arms in the current study, the incidence of perinatal deaths (particularly fresh SB and NND) was

lower in the intervention arm (0.9%) than in the control arm (1.6%). The lack of significance in this outcome may be attributed to the small sample size other than bias. We therefore, suggest that further research with a larger sample size be conducted to verify this observation. The current study also found that the prevalence of postnatal infection among infants and their mothers was similar in the intervention and control arms. This indicates that companionship did not increase the risk of postnatal infection to infants and mothers in the intervention arm. Similarly, studies in the US found lower proportions of maternal and infant fevers in the supported mothers than in the unsupported mothers (Kennel et al 1991, Sosa et al 1980,, Kroeger and Smith 2004), Pascali-Bonaro and Kroeger 2004). The fact that companionship is not associated with postnatal infection, the current study finding contradicts the fears expressed by midwives working in Malawian maternities that increased risk of infection would be the reason why they would not promote childbirth companionship in hospital settings (Banda G.W 2006, Maimbolwa et al 2001,).

Labour pains are the most terrible events that women experience during childbirth. In this study we also found that women in the intervention arm experienced less severe pain that was more bearable in nature than women in the control arm. A randomized clinical trial conducted in Botswana found similar results, and authors reported that companion supported women suffered less stress and less pain hence had less need for oxytocin during labour than those who were not supported (Madi et al 1999). The role of a companion cannot be overemphasized from evidence that has already been cited in this report (Klaus et al 1986; Kennel and Klaus 1991; Madi et al 1999; Maimbolwa et al 2001; Kroeger and Smith 2004; Pascal-Bonaro and Kroeger 2004; Yogev 2004). Our

findings show that many women in the intervention arm (56%) ranked back massage as the most useful action that reduced the pain followed by chatting and encouragement. It is important to mention that choice of companion should be left to the woman and may be dependent on who knows the woman best and who is trusted (Price et al 2007). In the current study, women chose a companion of their choice during antenatal period, so that feelings of untrustworthy and embarrassment should be reduced. In line with the Blanytre acceptability study findings, a variety of relationships were observed ranging from close relations such as mother, sister, grandmother and aunt to mother in-laws, friends and neighbours.

Contrasting the available evidence that companionship reduces the need for instrumental deliveries (Kennel and Klaus 1991; Kroeger and Smith 2004; Pascal-Bonaro and Kroeger 2004, Madi et al 1999), we found that companionship during labour did not decrease the incidence of instrumental deliveries between the intervention and the control arms. The proportions of women who delivered by C/S and vacuum extraction were equal in each arm, and their infants' birth weight did not differ between the two arms. The mean birth weight was 3063g, SD 505.5g in the intervention versus 2997g, SD 555.6g in the controls; $p=0.656$. Therefore, we attributed this inconsistency to our small sample size.

This study has two major strengths, thus, the design used and consistency with previous studies. A randomized controlled clinical trial used in this study is a strong experimental design recommended in epidemiological studies and it plausibly compares outcomes of interest between the intervention and control groups (Rothman et al 1998). Specifying a

criterion for enrolment and randomization ensured a reasonably homogeneous group of women with and without companions at the beginning of the study. Therefore, any differences observed between the two arms resulted from chance or effect of the intervention (companionship) other than biases of the investigators. Randomization also ensured that any potential confounding variables are equally distributed between the intervention and the control arms. However, we acknowledge the major limitation of our small sample size that may limit generalization of these findings to a population from which the sample was drawn.

The current study findings have a social, psychological and public health relevance to the midwifery practice in the country. Socially, the study shows that pregnant women need company during childbirth so that they are continuously interacting with someone particularly family members. Findings show that pregnant women in the study sites were willing to be accompanied by supportive companion during labour and delivery. 85% of eligible pregnant women consented to participate in the study. This finding is similar to a cross sectional study on acceptability of supportive companionship during labour conducted in Blantyre District that reported 83.6% of recently delivered mothers expressing interest to be supported (Banda G.2006). Psychologically, supported mothers were relieved from severe labour pains and this encouraged them not to despair but endure the stress of labour pains. Evidence from this study also show that the public health benefits of having a supportive companion out weigh the limitations hence it should be promoted in a resource-poor country like Malawi. In this respect, we noted that there was a 15% increase in attraction for hospital delivery for women in the intervention arm (69%) than those in the control arm (54%). The resultant effect would

be increased access to skilled attendance during childbirth hence, reduced risks of infant and maternal morbidity and mortality.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The study aim was to assess whether provision of emotional support by a companion during labour and delivery reduces adverse perinatal and maternal birth outcomes. The study found that companionship during labour and delivery decreases the incidence of low Apgar score among infants hence should be promoted in hospital settings so that perinatal and infant mortality could be reduced in Malawi. We also found that risk of postnatal infection to infants and their mothers is not associated with mother being accompanied or not during delivery. Although the study found that companionship did not decrease the prevalence of instrumental deliveries, promoting normal deliveries (SVDs) as opposed to instrumental deliveries would not only increase maternal satisfaction of having a normal childbirth but also decrease risks and complications of surgery such as sepsis. The study also established that emotionally supported women suffer less severe labour pains hence experience much satisfying and exciting childbirth process than unsupported women. Therefore, promoting companionship during labour and delivery does not only give social and emotional support to the mother but also promote greater family involvement during childbirth.

6.2 Recommendations

With reference to the current study findings, it is we recommended that hospital policies that restrict health workers to permit supportive companions in delivery rooms for fear of increasing risk of infection should be reviewed in order to permit companionship. Availability of a companionship policy would guide midwifery care providers and promote implementation of the strategy in all maternities. It is also recommended that the choice of the companion should be left to the pregnant woman herself in order to maintain social respect and privacy.

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APPENDICES

APPENDIX 1 PARTICIPANT'S INFORMED CONSENT FORM

STUDY TITLE : **Female Support Companionship during labour**

INVESTIGATOR:

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Mrs. Jane Banda, Malawi
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PARTICIPANT'S ID NO: _____

Aim of Study

In partial fulfillment of the Master of Public Health Degree, the investigator would like to conduct this study. The purpose of the study is to determine whether provision of emotional support by a companion during labour reduces the incidence of low apgar score, assisted deliveries and reduces maternal pain experience.

Participants' role

If you participate in the study you will either be asked to bring a female companion of your choice to support you throughout labour and delivery in addition to standard care given by the medical personnel or the medical personnel alone will support you as is the usual practice. Upon discharge the researcher will review your hospital records and you will also be asked to describe your pain experience during the care.

Privacy and confidentiality maintenance

You are assured of confidentiality of your medical information because the people handling your information are medical personnel. All the information gathered will be used only for the purposes of the study. Privacy will be maintained through screening with curtains between cubicles.

Risks and safety

Refusal or discontinuation to participate in the study at any stage you feel like will not subject you to any form of penalty nor jeopardize the standard of care that you will get. You are assured of attendance from qualified midwives at all times of need. There are no adverse risks anticipated except unavoidable complications that may develop for some other reasons beyond the control of this study. If such happens, immediate referral for emergency care will be done.

Benefits

There are no immediate benefits apart from those appreciated by having a guardian by your bedside.

The investigator would, therefore, like to ask for your voluntary participation in the study as one of the participants. If you accept to participate, please sign below:

I _____ hereby voluntarily agree to participate in the study. I have understood the study procedures and consequences that may follow.

Signature _____
(Participant)

Signature _____
(Witness)

OR

Thumb print _____
(Participant)

Thumb print _____
(Witness)

Date_____

Date_____

Investigator's signature_____

Date_____

APPENDIX 2 QUESTIONNAIRE -
A QUESTIONNAIRE ON THE EFFECT OF THE PRESENCE OF A
COMPANION DURING LABOUR ON THE MATERNAL AND PERINATAL
OUTCOMES OF PREGNANCY

PART A

1.0 Demographic characteristics

1.1 Participant ID 1.2 Age 1.3 Educ level 1.4 Parity

PART B

2.0 Antenatal Care

2.1 Number of antenatal visits

2.2 Nutrition status:

2.3 Hb levels

2.4 Average weight

2.5 Iron supplement received (*Tick*):

Once ☐ Twice ☐ > Twice ☐

2.6 TTV status; received (*tick*):

1dose ☐ 2doses ☐ 3 doses ☐ >3 doses ☐

2.7 VDRL status: Reactive ☐ Non-Reactive ☐

2.8 SP status , received (*Tick*):

dose ☐ 2 doses ☐ > 2 doses ☐

PART C

3.0 Labour and delivery

3.1 Length of labour:

Time from 3cm dilation of cervix to complete expulsion of placenta and membranes (in hours)

3.2 Mode of delivery (*Tick*): SVD ☐ Vac/extr ☐ C/S ☐ Other specify)
.....

PART D

4.0 Infant outcomes

4.1 Apgar scores: At one minute At five minutes

4.2 Birth weight (*in grams*)

4.3 Maturity status (*Tick*): Mature ☐ Premature ☐ Post mature ☐

4.4 Birth defects present : No ☐ Yes ☐ If yes , (specify)

.....
.....

4.5 Birth injuries sustained: No ☐ Yes ☐ If yes (specify)

.....
.....

4.6 If stillborn, describe status as (*Tick*): Fresh SB ☐ Macerated SB ☐

PART E

5.0 Postpartum infection

Infant condition

5.1 Body temperature reading on discharge (*degrees Celsius*)

Temp readings in the past 36-48hr: 1st twelve hr 2nd twelve hr 3rd twelve hr

5.2 Condition of umbilical cord stamp (*Tick*): Not Infected ☐ Infected ☐

If infected, (describe the infection).....

.....
.....

5.3 Was the infant given any antibiotic postnatally? (Check records): Yes ☐ No ☐

If yes, name the antibiotic that was given and state the reason why the drug/s was given?.....

.....
.....

Mother condition

5.4 Body temperature on discharge (*degrees Celsius*)

5.5 Condition of lochia for the past 36hr (*tick*): Normal smell & amount ☐ Foul smelling ☐

5.6 Cramping lower abdominal pains (*tick*): Present ☐ Not present ☐

5.7 Was the woman given any antibiotic postnatally (Check records): Yes ☐ No ☐

If yes, write name of the antibiotic that was given and state the reason why the drug was given.

.....
.....
.....

EXIT INTERVIEWS -GUIDING QUESTIONS

PART A:**Guiding questions on pain experience**

1. What would you say about how you felt in labour?
2. How would you describe your pain experience during labour?
3. What can you say on the severity of the pain you felt?
4. Were you given any injection to relieve labour pain?
5. What actions of the companion worsened or reduced the pain you felt?
6. What was your experience with previous pregnancies?

PART B:

What type of analgesic was the mother given to relieve labour pains? (Check records)

Paracetamol ☐ Pethidine ☐ Other (specify)

.....

.....

Thank you for responding to these questions