An analysis of the utilisation of research information, in policy making and guidelines for the use of Magnesium Sulphate in the treatment of Eclampsia and Pre-Eclampsia in South Africa

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Date	: July 2006

Mini Dissertation submitted in partial of fulfilment of the requirements for the degree of Masters in Public Health

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Declaration

I, Karen Lorraine Daniels, hereby declare that the work on which this dissertation is based is my original work (except where indicated otherwise in the text) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

Signed

Signed by candidate

Karen Daniels

Date

25 July 2006

Dedication

For Stevie.....and of course for you Josh.

Contents

Acknowledgments

Firstly, to Rodney for suggesting that I do the MPH long before it would even have occurred to me. Then to Judy, for your sleepless night spent thinking of how to finally push me into it. To Mickey for your patience, what more can I say. To Sylvia for always, always holding me up and for your assistance with the final layout. To Shanaaz and Lungiswa, my comrades in arms.

My co-supervisor Margaret Hoffman took on the unenviable task of stepping in near the end of the project. Thank you for your keen eye, your thoroughness and especially for your tenacity!

To our respondents:- thank you for your time, thank you for letting me into your offices and into your heads. I hope if you read this, that you now know what the interview was actually about ☺.

My bookclubers…. I owe my sanity to you, thank you for never letting on how boring my MPH stories were getting ☺. To my dear, dear friends I stand because you hold me up.

As for my family, words can hardly express the depth of my gratitude. You know that my thanks are not just for your help over these MPH years, but for always. Of course Steven thought that my field and other trips were a sign of my reckless and irresponsible approach to mothering. But then what are siblings for if not to call us into line. My cousin Gillian Fowler did an excellent final editing job!
Joshua, my baby, my buddy and my big boy. Who else but you could have made it so splendidly on this ride?

The transcribing was done by Leon van Wyk and Carron Favero.

I also owe many thanks to members of our main study team: Julie Cliff, Godfrey Woelk, Esperanca Sevene, Alda Mariano, Benedita Fernandes and Sheillah Matinhure.

Finally, to Simon Lewin my other co-supervisor, more friend than supervisor… more effort than money could afford, your caring brought the best out in me.

Thank you.

Abbreviations

ETCG:	Eclampsia Trial Collaborative Group
MgSO4:	Magnesium Sulphate
MTCG:	Magpie Trial Collaborative Group
NCCEMD:	National Committee for the Confidential Enquiry into Maternal Death
NMCGC:	National Maternity Care Guidelines Committee
PPCC:	Priorities in Perinatal Care Conference(s)
SAMTCG:	South African Magpie Trial Collaborative Group

As used to distinguish respondents in the findings

Acad:	Academic researcher and clinician
DoH:	Former or current national Department of Health official

Respondents are differentiated by number in the text, e.g. Acad 1, DoH 3. Some respondents had experience in both roles. They have for the purposes of this dissertation been grouped according to the main job function they held through the course of the policy making process.

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Abstract

Background: The literature suggests that although the idea of using evidence to inform policy making has come into favour, actualising this idea in practice is complex. Within the framework of these debates this dissertation focuses on the uptake of findings from research into policy making for the use of magnesium sulphate in the treatment of eclampsia and pre-eclampsia within South Africa. Despite the publication over the past decade of evidence suggesting the effectiveness of magnesium sulphate as a treatment for eclampsia and pre-eclampsia, eclampsia remains a leading cause of maternal death in South Africa and in many other low and middle income countries. This dissertation forms part of a larger study investigating the uptake of research into policy making in South Africa, Mozambique and Zimbabwe.

Aim: To describe and analyse the actual and perceived utilisation of research information in policy making and guideline development for the use of magnesium sulphate in the treatment of eclampsia and pre-eclampsia.

Methods: This qualitative study triangulated three techniques in order to understand research utilisation in contemporary policy making. The techniques employed were: policy document review, a historical overview and individual qualitative interviews with 15 key informants. Data generated through these methods are reflected upon in relation to each other and within the context of relevant scientific and intellectual debates.

Findings: This study shows a positive example of research utilisation in policy making and guideline development. In the late 1990's in South Africa, prompted by factors such as the recent political change, policies and management guidelines were being developed for maternal health. Simultaneously evidence from randomized controlled trials and systematic reviews showed the effectiveness of magnesium sulphate for the treatment of eclampsia and pre-eclampsia. Policies developed during this period make explicit reference to the use of the most recent published evidence. The uptake of this evidence into national policy development is likely explained by

the complex interaction of a range of factors: the existence of a previously established evidence-based culture among obstetricians; the movement of "networked" individuals immersed in that culture into key positions in the new government; the involvement of researchers in policy development; and the willingness of individuals and groups to lobby and advocate both for the development of policy and for the use of evidence in that policy.

Discussion and Conclusions: The findings highlight the role played by researchers in developing evidence based policies and guidelines. It also points to the complexity of the relationship between knowledge production and the utilisation of research in policy. It suggests that while researchers may not be in control of factors such as political change, they are presented with windows of opportunity that may allow them to affect policy change. Their capacity to affect such change can be enhanced through collective action when researchers are organised through academic networks.

Keywords: policy making, research utilization, evidence, reproductive health
Word count: 21342

Chapter One

1. Introduction

1.1. Using research to inform health care policy

A shift is taking place within debates on what the basis of health care decision making ought to be. Increasingly, the importance of basing health care decision making at both a clinical and a policy level on the outcome of sound research studies is being recognised (Davies, et al., 1999; Garner, et al., 1998; Hanney et al., 2003; Lavis et al., 2004; Macintyre et al., 2001; Swartz, et al., 2004; Volmink et al., 2004). This acknowledgement of the place of research information in decision making is fairly recent. Davies and Nutley (1999) suggest that this shift has been encouraged by the growth of evidence based medicine. Proponents of this approach suggest that policy decisions about resource allocation (Garner et al., 1998; Swartz, 2004) ought to be made on the basis of "what works" (Davies et al., 1999; Macintyre et al., 2001). In turn they believe that "what works" can be determined on the basis of sound research evidence from the evaluation of health care interventions, particularly evidence from systematic reviews of randomised controlled trials (Garner, et al., 1998; Lavis et al., 2004; Volmink et al., 2004). It is argued that decisions made on the basis of research evidence can be not only cost saving (Garner et al., 1998), but also life saving (Volmink et al., 2004). Supporting this change in attitude is the increasing growth and availability of a pool of evidence to base decisions upon (Lavis et al., 2004; Volmink et al., 2004). Yet none of these factors have led to the automatic uptake of

research into policy making (Black, 2001; Hanney et al., 2003; Innvaer, et al., 2002; Lavis et al., 2002).

The relationship between knowledge production (evidence from research) and knowledge utilisation (evidence used in policy making, programme implementation, programme design, etc.) is complex (Aaserud et al., 2005; Kothari, 2005; Lavis et al., 2002, 2003; Swartz, 2004). Furthermore, it is suggested that there are many impediments to the use of research in policy making (Black, 2001; Innvaer et al., 2002; Walt, Chap. 9, 1994). Thus beyond asking, "what works" in terms of health care interventions, the process of knowledge utilisation in health care policy making has in itself, become an area of study (Hanney et al., 2003; Lavis, 2003). Hanney et al. (2003, p. 2) contextualise the need to understand the process of research utilisation within the "growing demands for accountability for research expenditure". Paraphrasing from Shulock (1999), Lavis et al. (2002, p. 125) ask of the production of research "if it is not used, why do we produce so much of it?"

These questions become particularly pertinent in low and middle income countries which face a scarcity of resources coupled with a high disease burden. For many of the health problems contributing to the burden of disease in these countries, research has identified effective and affordable interventions. Often, however, these interventions are not implemented or are discarded in favour of unproven interventions. While the relationship between research and policy making is extensively studied in high income countries, very few studies have explored this complex phenomenon within low and middle income countries (Innvaer et al., 2002).

1.2. A three country case study of research utilisation in policy making

This study addresses itself to the question of how research information can be better utilised in policy making. It is set in South Africa, a middle income country. This piece of research is a sub-study within a larger qualitative study entitled:

> Barriers and facilitators affecting the implementation of findings from randomized controlled trials into health care policy and practice in low and middle-income countries: the implications for scaling up (Alliance for Health Policy and Systems Research [AHPSR] proposal, Appendix 1)

In this main study, collaborating researchers aim to "improve the uptake, by policy makers in low- and middle-income countries, of findings from randomized controlled trials by describing the barriers and facilitators to the use of such findings" (AHPSR proposal). In order to do so, the research focuses on policy making in two case areas, namely policies for the use of magnesium sulphate in the treatment of eclampsia and pre-eclampsia and policies on the use of bednets and indoor residual household spraying for the control of malaria. The main study will compare data collected in South Africa, Zimbabwe and Mozambique. It focuses on the perceptions of policy makers and researchers in these two case areas around the uptake of findings into policy.

The sub-study will limit itself to a focus on the uptake of findings from research into the policy making and guideline development for the use of magnesium sulphate in the treatment of eclampsia and pre-eclampsia within South Africa. The main

scientific work of this sub-study will be the analysis of qualitative data collected between 2004 and 2006 as part of the main study.

1.3. Background to this case study

1.3.1. The problem

Hypertension remains a leading cause of maternal death in South Africa. In 1998 hypertension in pregnancy was reported as the highest primary obstetric cause of maternal death (23.2%) in South Africa (NCCEMD, 1999). Within this, eclampsia (Box 1) accounted for the highest percentage (59%) of the deaths due to hypertensive disorders of pregnancy (NCCEMD, 1999). A subsequent enquiry into maternal death (NCCEMD, 2002) reported complications of hypertension as remaining the highest (20.7%) direct primary obstetric cause of maternal death. Again, eclampsia accounted for the highest percentage of deaths (57 %) within the hypertensive disorders. Hypertension-related deaths were surpassed only by non-pregnancy related infections (31.4%) amongst which death from AIDS related illness is included (NCCEMD, 2002). Hence hypertension remains the leading direct primary obstetric cause of maternal mortality (Pattinson, 2004).

Eclampsia is the occurrence of a convulsion (fit) in association with pre-eclampsia. *Pre-eclampsia has been defined as* "a multisystem disorder [of pregnancy] that is usually associated with raised blood pressure and proteinuria but, when severe, can involve the woman's liver, kidneys, clotting system, or brain. The placenta is also often involved, with an increased risk of poor growth and early delivery for the baby

Duley, L, Henderson-Smart, DJ: Magnesium sulphate versus diazepam for eclampsia. The Cochrane Database of Systematic Reviews 2003, Issue 3. Art. No.: CD000127. DOI: 10.1002/14651858.CD000127.)

Box 1: A definition of eclampsia and pre-eclampsia

1.3.2. A potential treatment solution

Since Egyptian times, but more so since the turn of the 20th century, a number of different treatments for eclampsia and pre-eclampsia have been used (Duley, 2005). Included in these were both non-obstetric methods such as keeping the woman calm in a darkened room, and the use of drugs such as Magnesium Sulphate, Diazepam, the 'Menom regime' of lytic cocktail (combination of 3 drugs, including chlorpromazine), Heminevrin and Phenytoin. Until recently the evidence for the effectiveness of any of these treatments has been weak (Duley, 2005; ETCG, 1995; MTCG, 2002; Sheth & Chalmers, 2002). Over the past decade, this situation has changed. Two large multinational randomised controlled trials showed the effectiveness of the use of magnesium sulphate for the treatment of eclampsia and pre-eclampsia (ETCG, 1995; MTCG, 2002). Included in this research was data collected at sites within South Africa, by South African collaborators who also published their opinions locally

(SAMTCG, 2003). The evidence from these two trials was further supported by three systematic reviews (Duley, et al., 2003a, 2003b, 2003c). Hence a potential treatment solution[1] to this high eclampsia related maternal mortality in South Africa is available. But experience from elsewhere suggests that this evidence has not necessarily been translated into policy and/or practice (Mohamed et al., 1998; Sheth & Chalmers, 2002). Using the example of magnesium sulphate, Garner et al. (1998) argue that while in 1995 a large trial showed that this drug was the most effective treatment for eclampsia, other less effective therapies were still being used in obstetric practices in one third of the world. This study explores, in terms of policy guiding obstetric care, how evidence from these trials (and potentially other research studies) has been taken up in South Africa.

1.3.3. The policy making context

South Africa's health system has been dramatically and negatively impacted upon by its apartheid past (Baldwin-Ragaven et al., 1999). Maternal health services as with other health services have suffered as a consequence (Penn-Kekana & Blaauw, 2002). Prior to the change of government in 1994, there was no single national maternal health policy, let alone coordinated treatment protocols. Instead, each institution decided upon its own protocols. Maternity services attached to tertiary institutions often adopted these protocols. Doctors and nurses enrolled at these various tertiary institutions would be taught according to these individualised protocols. This led to a lack of uniformity, with every institution believing that its treatment option was superior.

[1] This study acknowledges the impact of the health system on treatment success, but it is not the focus here.

Since the first democratic elections in 1994, there have been attempts at reforming the inequitable health system of South Africa's apartheid past into one more suited to the health needs of all South African citizens (Benatar, 1997; Davenport & Saunders, 2000; Head, 1996). One of the areas impacted upon by these reform attempts has been maternal health (Box 2).

- South African Constitution guarantees equality for women, right to health care including reproductive heath care, right to dignity.
- 1994 Free health care for pregnant women and children under the age of 6
- 1996 Choice on Termination of Pregnancy Act
- 1996 Maternal Child and Women's Health Policy Committee- MCWH organised in its own directorate with a National Director.
- 1997 All maternal deaths made notifiable & National Committee on Confidential Enquiries into Maternal Deaths appointed.
- 1999 Saving Mothers. Report on the Confidential Enquiries into Maternal Deaths 1998
- 1999 National Maternity Case Record
- Saving Babies. A Perinatal Care Survey of South Africa.
- 2001 Guidelines for Maternity Care in South Africa, Saving Mothers Policy & Management Guidelines

Penn-Kekana, L. & Blaauw, D. (2002) A rapid appraisal of maternal health services in South Africa: A Health Systems Approach. Johannesburg: Centre for Health Policy, University of Witwatersrand.

Box 2: Legislative and Policy Milestones since 1994 impacting on women's health

In their rapid appraisal of maternal health services in South Africa, Penn-Kekana and Blaauw (2002) point to the recognition by national government of child and women's as a priority since 1994. In this regard there has been the organisation of maternal,

child and women's health into a national directorate, which led the attempts at transformation.

During this period of transformation the National Department of Health recognised that the rate of maternal mortality was too high and that a significant number of these deaths were preventable (NCCEMD, 2001). Furthermore it was felt that clearly spelt out treatment regimes were a key strategy in preventing maternal death and reducing the maternal mortality ratio (Ibid.). Within this context national policies were regarded as broad statements of problems and goals (Ibid.). National guidelines in turn followed on from these statements by offering more detail as to treatment options. These then could be adapted to contextually specific detailed protocols for use at an institutional level. Our interest in this study has been in the national 'directives' on the treatment of eclampsia and pre-eclampsia, not just the broad statements. These directives were spelt out in the following documents published by the National Department of Health:

- National Maternity Care Guidelines Committee (NMCGC) of the Department of Health, **Guidelines for Maternity Care in South Africa: A manual for clinics, community health centres and district hospitals**, (2000 & 2002)
- NCCEMD, **Saving Mothers: Policy and Management Guidelines for Common Causes of Maternal Deaths,** (2001)
- NCCEMD, **Saving Mothers: Second Report on Confidential Enquiries into Maternal Deaths in South Africa, 1999-2001,** (2002)

In effect, these guidelines are the instruments through which national policy is given expression. Since it is these guidelines that suggest treatment options rather than the

broad policy statements, these documents were most likely to offer insight into utilisation of research evidence on treating eclampsia and pre-eclampsia.

1.3.4. An opportunity for research exploration

From the perspective of this study, what has occurred over the past decade is a contemporary convergence between the production of evidence at an international level and the development of policy and guidelines within the area of maternal health at a national level. This has opened up the opportunity to add to the empirical understanding of the relationship between evidence and policy making. It has allowed for a qualitative study with actors for whom the experience of engaging with knowledge production and policy making is still recent.

1.3.5. Building on previous research

A systematic review (Innvaer et al., 2002) of studies focusing on health policy-makers' perceptions of their use of evidence has been conducted (Box 3). Twenty-four studies met the inclusion criteria for the review. Of these, only four were conducted in developing countries. This study attempts to increase the body of empirical data from developing countries.

Facilitators to research utilisation	*Barriers to research utilisation*
• Personal contact between researchers and policy makers • Timeliness and relevance of the research • Research that included a summary with clear recommendations • Good quality research • Research that confirmed current policy or endorsed self-interest • Community pressure or client demand for research • Research that included effectiveness data	• Absence of personal contact between researchers and policy-makers • Lack of timeliness or relevance of research • Mutual mistrust, including perceived political naivety of policy-makers • Power and budget struggles • Poor quality of research • Political instability or high turnover of policy-making

Innvaer, S., Vist G., Trommald M., & Oxman A. (2002). Health policy-makers' perceptions of their use of evidence: a systematic review. J Health Serv Res Policy. Oct; 7(4):239-44.

Box 3: Summary from Innvaer et al., 2002

In response to concerns by collaborators in the Magpie Trial (MTCG, 2002), a previous study has looked specifically at the barriers and facilitators to the translation of results from this trial into "appropriate policies and actions" (Aaserud et al., 2005). The most frequent barrier cited by respondents in this study was lack of support from policy makers (Ibid), suggesting that more work needs to be done in order to enhance the link between researchers and policy makers. This sub-study attempts to move beyond a description of barriers and facilitators to providing more of a thick description, from the South African context, of the processes involved in the translation of evidence into national policy and guidelines. It also attempts a deeper analysis through the utilisation of theoretical frameworks drawn from the literature.

1.4. Scope of this study

1.4.1. Aim

This study aims to describe and analyse the actual and perceived utilisation of research information, in particular findings from randomised controlled trials, in policy making and guideline development for the use of Magnesium Sulphate in the treatment of Eclampsia and Pre-Eclampsia in South Africa.

1.4.2. Objectives

This study attempts to reach this aim through fulfilling the following objectives:

- To understand how evidence for the treatment of eclampsia and pre-eclampsia has been utilised (or not) within the current national policies and guidelines.
- To understand the influences shaping the relationship between research and policy making for the treatment of eclampsia and pre-eclampsia in South Africa, from the perspective of the respondents and historically.
- To understand and situate these findings within the related intellectual and scientific debates.
- To develop out of the analysis, a conceptual model explaining the relationship between research and policy making as emerging from this data set. In other words to develop a theoretical model of this relationship based on the empirical data for this sub-study (Kothari et al., 2005).

Note: The importance of issues around policy implementation such as drug availability and accessibility, and health systems challenges (Parkhurst, et al., 2005) are acknowledged. The issue of implementation however, is beyond the focus of this study, which only considered policy and guideline development.

1.5. Structure of the dissertation

This dissertation is divided into four chapters: an introduction, a literature review, a description of the methods employed and an overview and discussion of the findings.

The literature review starts off with a summary of selected theoretical and analytical approaches to understanding research utilisation. These have helped shape the student's understanding of the processes under investigation. The chapter then moves to explain some of the issues raised in the literature, which are pertinent to understanding research utilisation in policy making within developing country contexts. The recent evidence on the treatment of eclampsia and pre-eclampsia has been produced within the context of the Evidence Based Medicine paradigm. Furthermore, Davies and Nutley (1999) suggest that the growth in this approach has encouraged a shift in thinking as to what health care decisions should be based upon. This therefore warrants an explanation of how Evidence Based Medicine is defined and what some of the critiques to this approach are. From there the chapter moves on to describe some issues related specifically to the uptake of evidence-based practice in obstetrics.

The methodology chapter describes the qualitative approach taken. It argues for the appropriateness of this particular approach. It then describes the techniques employed and the resulting data set, which this generated. The chapter describes how this data was analysed. Some attention is also given to reflexivity.

The results chapter starts with a brief document review of the use of evidence in recent policies and guidelines. It then presents a summary of the findings, which emerged from the analysis of the interview and historical data. These findings are discussed in the context of the literature and the methods used, bearing in mind the limitations of the study. The dissertation ends with a brief set of conclusions and suggested recommendations.

Chapter Two

2. Literature Review

A note on how the literature was sourced:

Throughout the main study the investigators have been collecting and sharing relevant grey and published literature. The literature review presented in this study built upon that process through further searching. Both purposive and snowballing approaches to identifying appropriate literature were used. Electronic databases were purposively searched using specified terms. Cross referencing against the literature sourced through this strategy then yielded a snowball of further useful references (Greenhalgh et al., 2005). Thus, the primary search strategy combined electronic database searches using specified terms, with the deliberate sourcing of references cited in the literature in hand. The electronic search was conducted using the internet and electronic databases available at the Medical Research Council and the University of Cape Town library. This search included a combination of the terms: research information, research utilisation, research evidence, policy making, magnesium sulphate, eclampsia, pre-eclampsia, maternal health, obstetrics and gynaecology. Sourcing further literature through the following up of references cited in the literature in hand proved to be extremely valuable. It not only provided further insights into relevant debates, but also provided access to further literature, which may not necessarily have been found with a strict adherence to our original search terms.

Ongoing informal discussions with co-investigators and colleagues also proved to be a useful source for further references. The boundary for inclusion has been the extent to which the literature sourced has been able to enhance insight into the research question. The findings from this process are reported upon and important concepts discussed in the literature have been applied to the data analysis process.

2.1. An overview of theoretical and analytical approaches to understanding research utilisation

There have been arguments for less a theoretical and more empirical approach to research utilisation (Innvaer et al., 2002; Oxman et al., 2005). However theoretical approaches continue to influence contemporary thinking around research utilisation (e.g. see its use in Bowen & Zwi, 2005; Hanney et al., 2003; Kothari et al., 2005; Lavis et al., 2002; Lavis et al., 2003; Tomson et al., 2005). In arguing for a link between theoretical and empirical understanding, Lavis et al. (2003, p. 228) claim "Opportunities for improving how research organizations transfer knowledge can be found in the differences between what the research literature suggests that research organisations should do and what the directors of research organizations say that they do".

The six theoretical models of research utilisation described by Weiss (1979) still influence contemporary thinking (Bowen & Zwi, 2005; Tomson, et al., 2005). She suggested that research utilisation in policy making can be categorised according to the following models:

- Knowledge driven: this model assumes that because knowledge exists it will be used.
- Problem solving: this model suggests that when faced with a problem for which they have no answer policy makers seek out research information and thereby fill their knowledge gap.
- Interactive: this model suggests that information for policy making is sought from a variety of sources not just research and that the process of research utilisation is non-linear and disorderly.
- Political: in this model those who find its conclusions 'congenial and supportive' use research as ammunition.
- Tactical: here decision makers use research as a means of delaying taking action, thus they may argue that a lack of research findings on a particular issue means that a decision cannot be made until such finding are available.
- Enlightenment: this suggests the utilisation of research is not a singular event; instead decision makers over time are influenced in their thinking by the outcome of research (Wiess, 1979; Bowen & Zwi, 2005).

Kothari et al. (2005, p.118) state that these "conceptual models of research transfer have been developed to try to better understand how research findings are disseminated, received and acted upon". They review the historical development of these models suggesting that these have evolved over time. This development started with simple diffusion models, which assumed that research findings needed only to be dispersed for policy makers to take them up. This shifted to models which focused on how the findings were disseminated without considering the receptivity of those receiving them. Kothari et al. suggest that more recent models of research transfer

have been based on the idea that researchers and policy makers are 'two-communities' who need to interact with each other in order for research findings to be utilised.

The prominence of the 'two-communities' theory in contemporary thinking is pointed to elsewhere in the literature (Innvaer et al., 2002; Lavis et al., 2002). Lavis et al., (2002), refer to the 'two communities' metaphor as an interaction model and suggest that it has replaced earlier models. However, whether or not this model is any more helpful is still uncertain. Lavis et al. (2002, p. 145) claim:

> "Our exploratory study suggests that interaction between these "two-communities" does influence the use of research by policy makers, although from the research unit directors' comments it appears that many efforts at interaction yield no tangible impact."

The basis of this model is that researchers and policy makers come from two different perspectives of understanding and that in order for research to be utilised they need to be brought closer in understanding. In other words they need to start sharing perspectives. While Innvaer et al. (2002) recognise the value of bringing these 'two-communities' closer to each other, they also question whether a closer relationship between researchers and policy makers may lead to policy makers having an undue influence over the research, therefore increasing the possibility of bias and reducing the capacity for "scientific objectivity".

Innvaer et al. (2002) argue that next to the dominance of the two communities thesis as a theoretical perspective, the literature is also largely concerned with explaining the concept of research "use". In understanding the "how" in research utilisation, three

types of research use are defined: instrumental use, conceptual use and symbolic use (Hanney et al., 2003; Innvaer et al., 2002; Lavis et al., 2003). Instrumental use implies direct use of the findings to solve a problem. Conceptual use refers to policy makers becoming enlightened by the research in a generalised way, but not in a way that can be directly measured. Symbolic use is linked to the political and tactical models of research referred to earlier, where a policy maker uses the research to justify prior positions, actions and inactions. For researchers trying to understand empirically how research has been used or is being used, measuring and reporting on conceptual and symbolic use is difficult because it can be so indirect.

As evidence of the complexity of research utilisation, the literature points to the fact that research can be used at different stages (Bowen & Zwi, 2005; Lavis et al., 2002) within the policy making process and that it can be used in different ways within this process (Innvaer et al., 2002; Lavis et al., 2003). Drawing from the field of political science, Lavis et al. (2002, p.133) explain that research can be utilised in the "prioritisation, policy development and policy-implementation stages of the policy making process". Similarly Bowen and Zwi (2005) describe research utilisation in three stages: sourcing evidence, using evidence and implementing evidence. They suggest that at stage one the policy makers adopt the evidence, at stage two they adapt it and at stage three they act on it.

The literature points to what may seem obvious; that research information is not the only influence on policy and decision making (Court & Maxwell, 2005; Lavis et al., 2002; Swartz, et al., 2004; Walt, 1994; Young, 2005). Yet as Bowen and Zwi (2005,

p. 0601) suggest, researchers may not take account of the broader context. They argue that:

> "The social and political context and the many forces at work in the policy environment provide challenges to integrating evidence into policy and practice. Researchers often do not see or recognize these factors".

In a framework developed for understanding research utilisation in developing countries, (Court & Maxwell 2005, Young 2005) it is therefore suggested that it is not simply the credibility of the evidence, which is important, but also:

- the capacity of the political context to absorb the research findings,
- the links established between researchers, policy makers and other stakeholders,
- and external influences such as international factors or economic and cultural influences (Ibid).

In order to understand the place of research utilisation in policy making, we need therefore also to understand the broader policy making processes and to understand how shifts in policy making come about. In this regard Lavis et al. (2002, p. 141) (as reading from Goldstein & Keohane, 1993; Hall, 1993, 1996; Heclo, 1974; Weatherford & Mayhew, 1995) have applied a political science framework for distinguishing "three general categories of influence on the policymaking process" They refer to the influences as:

> Ideas: - research, values, etc.
>
> Interests: - people with a vested interest in the policy, those who will benefit or be harmed by the policy
>
> Institutions: - policy legacies and characteristics of the policy

During the course of our interaction with John Lavis (Lavis et al., 2002), he introduced a fourth category, which he and colleagues have also been working with, namely 'events'. Events are extraordinary occurrences such as a war, a devastating flood, a sudden rise in disease numbers or a dramatic change in government administration etc. The occurrences by their extra ordinary nature may influence opinions and attitudes and they may also open and close opportunities for change. For example, a flood may change attitudes toward housing, which may create the opportunity for policy in this area. Using this framework, research is but one component of one of the key influences, namely ideas, on policy making. The framework provides a useful lens through which to retrospectively assess the weight of the influence of research in policy making at a particular moment in time, as compared with all of the other influences operating at the same time.

Another useful analytical framework is that developed by Kingdon (1995) and also utilised in health policy analysis by Ogden et al. (2003). Similar to the political science framework referred to above, this framework was not developed for the analysis of research utilisation specifically, but for understanding how issues enter the policy agenda. Kingdon (1995, 2001) suggests that running through all major organisations such as governments are three streams: - the problem stream, the policy stream and the stream of politics. These streams he suggests are largely unrelated to each other. So people in the problem stream concentrate on what they believe are the priority problems, people in the policy stream concentrate on generating solutions, but these may not immediately relate to the problems being dealt with in the problem stream. In the political stream are political events such as changes in administration. The same author claims:

> "these streams develop, all independent of one another. The proposals are generated whether or not they are solving a given problem, the problems are recognized whether or not there is a solution, and political events have their own dynamics". (p.332)

However, change at a policy level can occur when advocates take advantage of the opportunity to join these three streams together. This he calls a 'policy window', when either the problem is so great or there is a change in the political stream and advocates have the chance to jump in and push for their proposals to get on to the policy agenda.

Ogden et al. (2003) have applied Kingdon's framework to understanding changes in international tuberculosis control policy. They identified lone health workers working on the problem of tuberculosis, strong networks pushing for a solution and the window of opportunity, which opened up as a result of the resurgence of the disease in New York, which was then taken advantage of by strong advocates. Although this framework was not developed with research utilisation in mind, this metaphor of streams and windows of opportunity is useful in trying to understand what evidence was available (policy stream), what windows of opportunity existed for pushing this evidence into policy and whether or not these opportunities were taken advantage of, and who the advocates for the use of the evidence were. This framework allows for the exploration of research utilisation as a dynamic moment in policy making. Linear models suggest that evidence is generated, is promoted and either gets used or not used. In contrast this framework suggests that this process is not as clear-cut as it seems. It suggests that there are moments when it is more opportune to push evidence onto the policy making agenda than others. Analytically this allows for an

exploration of the dynamics at play around those moments, and how advocates were either successful in taking advantage of them or missed the opportunity.

In the analysis and discussion of the findings, I attempt to balance looking at the data with a fresh eye while bearing in mind the theoretical approaches suggested previously. The discussion therefore attempts to show the place of the lessons from this case study within this broader literature.

2.2. Issues in research utilisation in policy making for developing countries

According to Garner et al. (1998, p.531) "Developing countries have limited resources so it is particularly important to invest in health care that works". While research utilisation in developing countries is not as well understood as it is for developed countries, there is certainly a growing interest and subsequently a growing literature in this area (Court & Maxwell, 2005). Thinking in this field can be dated back by at least a decade (e.g. Walt, 1994), if not further. Since this study is being conducted in a developing country setting, it was important to explore this growing literature. Translating research findings into policy in these settings is generally thought to be complex (Swartz, et al., 2004) and difficult (Walt, 1994). Walt (1994) described impediments here including political factors, difficulties with interpreting the findings, differing interpretations of the potential risk implied by the study, ideological influences on policy makers, perceptions of the usefulness of the findings and the timing and communication of the studies. Drawing from their work in Khayelitsha, Cape Town, Swartz et al. (2004) have suggested that decisions are often

politically motivated, that researchers need to take cognisance of the timeliness of their findings in relation to policy making and of the systems and developments in the real world. Furthermore, they suggest that research utilisation can be influenced by the priorities and values of its funders.

Few of these factors however seem particularly unique to developing country settings. For example, although this literature tends to emphasise the role of the political context, the weight of this factor here does not seem to be any different to that experienced in developed country settings. One distinct difference, though, is in the (resource) capacity for researchers based in developing countries to conduct local research and possibly in the capacity of policy makers to interpret and apply it. This indeed may add complications around interpretation and a sense of applicability.

2.3. What is evidence based medicine?

Thus far this review has addressed research utilisation in a very general sense. Within evidence based medicine, the methodological rigour of well conducted randomised controlled trials is perceived by many as the gold standard for generating evidence of the effectiveness of health interventions, although it is acknowledged that trials cannot answer all research questions and may not be feasible in certain circumstances (Davies & Nutley, 1999). However, since this study largely concerns itself with the uptake of evidence from two large randomised controlled trials, it is important to briefly discuss evidence based medicine as this is the paradigm (Albers, 2001) within which these trials have been conducted. The following quote well describes what evidence based medicine is and how it fits within the context of policy making:

> "Evidence based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The most reliable evidence should be used in combination with individual clinical expertise, including effective and efficient diagnosis, appropriate judgement for individual patient management, and identification and interpretation of patient's behaviours and needs.
>
> Reliable evidence is also essential for the healthcare system in order to improve healthcare quality and to support the most efficient use of limited resources. Decision makers in health care need high-quality scientific evidence to support clinical and health policy choices. This ensures that resources are invested in effective and appropriate strategies to promote personal and public health, and not wasted on ineffective, harmful or unnecessarily expensive interventions". (Abalos et al., 2005)

Evidence based medicine is seen as a paradigm shift (Albers, 2001) from opinion based medicine, where clinical decisions were based on the practitioners' knowledge of pathophysiology and their previous clinical experience, to decision making being based on the best available evidence. Within this paradigm, evidence is ranked (Davies & Nutley, 1999) on the basis of the appropriateness and soundness of the methods used to answer the research question. Proponents of this paradigm argue for its relevance to developing countries where the limited resources necessitate the implementation of interventions, which have been shown to be both the most effective and the most cost effective (Garner et al., 1998; Lavis et al., 2004; Volmink et al., 2004). Although evidence based medicine has its roots in decision making for individual patients, it is suggested that it could be applied to implementation of large

scale (population level) interventions (Lavis et al., 2004). Hence the possibility of evidence based or evidence informed policy making (Ibid.)

2.4. Critiques of evidence based medicine

Despite the relative good favour which evidence based medicine has come to enjoy (Davies & Nutley, 1999; Ter Meulen & Dickenson, 2002), it has come under critique methodologically and philosophically (Lambert et al., 2006; Ter Meulen & Dickenson 2002; Victora et al., 2004,).

Methodologically, the status given to randomised controlled trials and systematic reviews as the best source of evidence, has been questioned. Victora et al. (2004) suggest that while randomised controlled trials are rightfully the gold standard in clinical decision making, public health interventions would benefit from the utilisation of plausibility and adequacy evaluations. Green and Britten (1998) argue that research designs need to be appropriate to the questions they attempt to answer. They show the limitations of relying on experimental methods suggesting that these cannot answer all questions. Using qualitative designs, the authors suggest, "can broaden the scope of evidence based medicine" (Green & Britten, p1230, 1998) given its capacity to explore those questions which randomised controlled trials and systematic reviews cannot.

In an introductory overview paper, Ter Meulen and Dickenson (2002) summarise several critiques of evidence based medicine (Various, 2002). Their questioning of the underlying values of evidence based medicine is built up using the following arguments:

- Evidence based medicine is based on idealised populations with little relevance to individual care
- Evidence based guidelines are too abstract and formal, losing sight of the complexity of clinical practice
- The range of questions which can be asked is limited by the view of randomised controlled trials as the 'only road to wisdom'
- Drug trials could be unfairly advantaged in this because they lend themselves to study by randomised controlled trial
- The use of cost effectiveness studies in evidence based medicine are questionable:
    - It lends itself to rationing in health policy decision making, and this could unfairly disadvantage certain sectors of the population
    - It could be used to control costs such as in managed care
    - Evidence based guidelines and criteria could act as a barrier to accessing certain services
    - The possibility of professional autonomy in decision making could be lost
    - Evidence based decision making gives too much power to managers and purchasers.

Ter Muelen and Dickson (2002) question what they see as the regulatory function of evidence based medicine. What drives their arguments is a belief that the underlying value of evidence based medicine is rationing of services on the basis of what is good, bad and cost effective. Their view is that this rationing could result in the denial of services to certain people in a less powerful position (such as the aged), and this they question from the perspective of social justice. Largely, their critique is of evidence

based medicine which is linked to cost effectiveness research and which they believe is being used by powerful health managers. So for them the evidence may show that it is more cost effective to do something in a particular way, but from a social justice perspective they question whether or not this is fair. In my opinion, the issue of values lies not in evidence based medicine as a paradigm, but in the manner in which it is eventually applied. For me evidence based medicine can be used to make decisions which are fair or unfair, it really depends on who is making the decision and what their particular agenda is. As already discussed, research evidence is only one part of the complex process of decision making.

2.5. Research Evidence and Obstetrics

The use of evidence in the fields of obstetrics and midwifery has grown over the past thirty years alongside the growth of evidence based medicine (Albers, 2001; King 2005; Rooks, 1999). In an overview of the history of evidence based obstetric care, King (2005) describes obstetric practice as having made a dramatic shift since the days when Archie Cochrane awarded obstetrics the " 'wooden spoon' for being the speciality that had made the worst use of randomized trials to inform its practice" (King, 2005, p. 9). Reflecting on his own experience as a student of obstetrics, he describes having to learn a set of obstetric practices by rote, taught by all- knowing professors who had an established dogma. Where research was used, it was selective, non-systematic, ignoring results from randomized controlled trials and using instead information derived from flawed studies. He attributes the shift from "opinion-based obstetrics" to the work of Iain Chalmers and his colleagues in promoting and cataloguing randomized control trials in obstetric care.

Students currently being trained are likely to have a very different experience to that of King (2005). The literature suggests that the teaching of evidence based medicine in obstetrics is encouraged both in well resourced developed country settings (Grimes, 1995) and in poorer developing country settings (Olatunbosun & Edouard, 1997). This extends too to the practice and teaching of midwifery (Albers, 2001; Carr & Schott 2002; Tillet, 2005).

Nearly ten years ago Olatunbosun and Edouard (1997, p. 173) claimed that "teaching evidence-based reproductive health in developing countries is presently visionary and idealistic". They described several challenges at the time to changing attitudes towards evidence based obstetrics in developing countries. Firstly, they pointed to a severe under funding of health and education services limiting the possibility of effective teaching of evidence based medicine. Secondly they suggested a dependence on literature from affluent countries despite these studies offering scientific information which may be neither relevant nor applicable to local reproductive health problems. In contrast they felt that data available from developing countries was not applied to clinical decision making. Thirdly their arguments suggest that medical teaching in developing countries at the time was not structured towards imparting the skills needed for the up take of evidence based medicine. They claim that while clinical epidemiology was making an impact in affluent countries, "conventional medical teaching in developing countries emphasizes biological plausibility and pathophysiological reasoning as the basis for clinic practice" (Olatunbosun & Edouard, 1997, p. 173). In other words reproductive

health workers were not being taught how to assimilate evidence into their daily practice.

In response to these challenges the same authors made several suggestions for changing the prevailing attitude. They felt that there should be more collaboration between researchers in affluent and developing countries, including personnel exchange, collaborative research and access to bibliographic databases. Within specialist obstetric and gynaecology training there could be a focus on teaching evidence based medicine both philosophically and practically (i.e. critical appraisal). Evidence based guidelines developed elsewhere, could be made widely available, for example, through the internet. The authors felt it unlikely that researchers in developing countries would have the resources to initiate randomised controlled trials and therefore suggested adapting evidence collected elsewhere to local circumstances. They also suggest that some of the vehicles for distributing evidence at the time were unlikely to be read by busy clinicians and that this information should rather be marketed through journals or articles that are likely to be read.

While valuable, the opinions expressed by Olatunbosun and Edouard (1997) need to be reflected upon within their historical context. At the time, introducing evidence based medicine into obstetric training even at a well resourced university department in the United States was regarded as experimental and novel (Grimes, 1995). Therefore an attitude of caution towards evidence based obstetrics may not have been unique to developing country settings. However, much has changed over the past ten years, particularly with regards to advances in and access to information technology. These days students, researchers, policy makers, even in the least resourced settings,

are all likely to have some access to the internet. The consequence of which is that they are further likely to be overwhelmed with information, much of which is unlikely to be evidence based or relevant to poorer settings. This suggests that contemporary teaching should focus on the skills of searching and sourcing literature and critically appraising it. This may better enable practitioners, researchers and policy makers to appropriately filter what they find.

The World Health Organisation's Reproductive Health Library is one specific attempt at harnessing the capacity of information technology to advance evidence based reproductive health. Distributed (as portable electronic files) since 1997, this database is updated annually (Gülmezoglu et al., 2004). It is aimed at low income countries and contains mainly systematic reviews from the Cochrane Library, but also incorporates expert commentaries, guidance documents and implementation aids (Ibid.).

A cluster randomised controlled trial is underway in an attempt to evaluate whether active dissemination of the Reproductive Health Library has had any impact on obstetric practice (Gülmezoglu et al., 2004). Similarly the impact of the Reproductive Health Library was evaluated through case studies of the practice of evidence based obstetrics at four hospitals in China (Qian et al., 2001). This study found that the obstetric practices of most practitioners were not evidence based, but that some hospitals were making incremental changes and modifications to their guidelines. Another study has examined the factors that might affect the translation of findings from the Magpie Trial (MTCG, 2002) and other randomised controlled trials into policy and actions in developing countries (Aaserud et al., 2005). Through their

investigations with trial collaborators and country level drug information officers, they found that there were barriers to the uptake of evidence from the Magpie Trial. They argue that these barriers were "complex, multifactoral and context specific", suggesting that the publication of evidence is important but insufficient in changing policy and practice. Thus they suggest supported advocacy, interaction between researchers and the adaptation of international evidence based guidelines for use at a local level. They conclude that a wide programme of support would be better than multiple one-off efforts.

Both the studies by Qian et al. (2001) and Aaserud et al. (2005) then, found, that there were barriers to the uptake of evidence in practice and policy. The literature thus far has also suggested that evidence based policies whether in developed or developing country settings are necessary but difficult to actualise. This study attempts to contribute to the literature on the use of evidence in obstetric policy within developing countries.

Chapter Three

3. Methodology

3.1. The qualitative approach

Karlberg et al. (2002, p.22) claim, "the reason for choosing a research method is the nature of the actual research problem". In other words, they argue that the research problem should determine the research method. The research problem as expressed in this sub-study and in the main study, is to understand the process of research utilisation in policy making. Specifically, the student hoped to gain this understanding through exploring the perceptions of policy makers and researchers based upon their lived experiences of engaging with this process. The experiential nature of this problem therefore called for a qualitative research approach. Malterud (2001, p.398) argues that "the aim of such [qualitative] research is to investigate the meaning of social phenomena as experienced by the people themselves".

Further refining our attempts to understand this question within a qualitative approach, a case study methodology was chosen. This case study explores policy making for the treatment of eclampsia and pre-eclampsia in South Africa. Case-study methodology was useful in exploring this topic given the complexity of the issues involved. This approach involves "...the investigation of a *relatively small* number of *naturally occurring* (rather than researcher-created) cases" (Hammersley, 1992, p. 185, original italics). The selected social units (in this instance, a particular policy

making process) are viewed as a whole, allowing relationships and processes to be examined (Mitchell, 1983). In an attempt at method triangulation (Denzin 1989; Smaling, 1992), the study combined document analysis, key informant interviews and the development of timelines of key events. All of these methods have been used in previous studies of the utilisation of research information in health policy (Hanney et al., 2003).

The core research activity has been the collection and analysis of interviews with country level researchers and policy makers (Box 4). Exploring actors' own accounts of their experiences helped to enhance understanding of the processes, rather than simply the outcomes of research utilisation. Karlberg et al. (2002) suggest that data is socially constructed in qualitative interviewing in the interaction between the researcher and the participant. In the sub-study, as with the main study, the researchers sought to interact with the respondents about their experiences. We sought the opportunity to clarify and understand in the moment of a thought being expressed through the interview, what the respondent really meant (Buskens, 1998). This kind of interaction and its associated potential for depth is simply not possible using any other research tool (e.g. a non-interactive survey).

The student has been involved in the main study as a member of the South African research team under the supervision of the primary co-supervisor. As such she has been involved in all aspects of the main study except the drafting of the study proposal. Although the data collection preceded the sectioning off of this sub-study as an MPH dissertation, the student was herself actively involved in the data collection, conducting several of the interviews on her own.

3.2. Methods and Techniques

3.2.1. Document Review

Copies of the National Maternity Care Guidelines and reports and recommendations generated from the Confidential Enquiries into Maternal Deaths in South Africa were obtained from the National Department of Health. All of these contemporary national policies and guidelines have been read and reviewed with the aim of establishing the extent to which research information has been used (Lavis et al., 2002). This has been done through the checking of the referencing for each document, and the extent to which the use of research information is mentioned. Furthermore, the specific sections dealing with the treatment of eclampsia and pre-eclampsia have been read to establish whether or not the use of magnesium sulphate is recommended.

3.2.2. Historical Overview

The core component to the historical overview is a comprehensive timeline of the evolution of policy for the treatment of eclampsia and pre-eclampsia in South Africa. This timeline was compiled following these steps:

1. An expert in eclampsia research provided most of the information to be included in the first draft.
2. This draft was then shown to each respondent with a request for comment.
3. During the course of the interviewing, the timeline was updated using respondent comments and other information emerging from the interviews.

4. A report by Penn-Kekana et al. (2002) was used in combination with examination of recent policy and guideline documents, to establish relevant policy related dates.
5. Reference was made to the work of Duley (2005) in elaborating upon the history of the treatment of eclampsia.
6. The interview data suggested that the Peri-natal Priorities Conference was an important platform for the growth of an evidence based culture and for the exchange of evidence on the treatment of eclampsia. Thus, bearing in mind what had already been discussed in the interviews, the abstract database[2] of presentations made at this annual conference was mined so as to establish when influential individuals had addressed the conference and when issues related to policy making or eclampsia had been presented.
7. A Pubmed search was done to establish when related studies, conducted by South African researchers were published.
8. Finally, web sites for the Oxford Database[3], the Cochrane Collaboration[4] and the Department of Health in South Africa[5] were consulted to corroborate and further extend the timeline.

In much the same way as a transcript is regarded as a piece of data from which to draw, the full timeline has been regarded as a piece of data in the analysis of the findings. The historical overview therefore is presented through a summary of the full timeline, with further discussion incorporated into the presentation of the findings from the interview data.

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[2] http://www.perinatalpriorities.co.za/
[3] www.update-software.com/history/clibhist.htm
[4] http://www.cochrane.org/docs/cchronol.htm
[5] http://www.doh.gov.za/department/subdir_maternal.html

3.2.3. Qualitative Interviews

Individual qualitative interviews were conducted with 15 researchers and government officials (past and present). The student and the primary co-supervisor, who are both trained and experienced in qualitative interviewing, conducted the interviews. Of these interviews the student conducted twelve on her own, two were co-conducted with the primary co-supervisor and one was conducted by the primary co-supervisor on his own.

The respondents, all based in South Africa, were purposively sampled on the understanding that they had been influential and/or knowledgeable in the process of policy making and guideline development (Box 4). They were identified mostly by word of mouth. Initially this was through enquiries with colleagues who were familiar with people working in this subject area. At each interview respondents were also asked to identify further respondents. There was also attention to fair dealing and seeking out negative cases (Mays & Pope, 2000). It was realised that many of the respondents came from similar academic networks and in the interviews this reflected as very similar opinions. Hence persons outside of these networks and who potentially held different views were actively sought out.

Profile of Participants		
Label in text	***Professional background***	***Sex***
DoH 1	Midwife	Female
DoH 2	Professor of Obstetrics and Gynaecology	Male
DoH 3	Obstetrician and Gynaecologist	Male
DoH 4	Midwife	Female
DoH 5	Midwife, nursing tutor	Female
Acad 1	Professor in Obstetrics and Gynaecology	Male
Acad 2	Associate Professor in Obstetrics and Gynaecology	Male
Acad 3	Professor in Obstetrics and Gynaecology	Male
Acad 4,	Associate Professor in Obstetrics and Gynaecology	Male
Acad 5	Professor in Nursing and Midwifery	Female
Acad 6	Former Professor in Obstetrics and Gynaecology (semi-retired)	Male
Acad 7	Professor in Obstetrics and Gynaecology	Male
Acad 8	Professor in Obstetrics and Gynaecology	Male
Acad 9	Professor in Obstetrics and Gynaecology	Male
Acad 10	Retired Professor in Obstetrics and Gynaecology	Male
		Box 4

The interviews were conducted using an interview guide negotiated between the broader project team (Appendix 2). Some flexibility was used in the questioning as appropriate to the experience of individual participants.

The latest available technology (a voice recording memory stick and a mini-disk recorder) was utilised in conducting the interviews. This equipment was chosen for its potential capacity to capture everything that was shared verbally between the informants and the interviewers. The sound quality of the recorded interviews has been excellent. Experienced dictation typists then transcribed the audio files and recordings verbatim. The student later checked these transcripts against the audio

files, and they were cleaned where necessary. This enhanced the quality of the transcripts since the typists were not always able to distinguish some of the more technical terms used by respondents. However, one typist was relied on more than the other, thereby encouraging his familiarity with the content and reducing the potential for error. The transcripts offer an accurate account of the discussion between the interviewers and the respondents.

The audio file for one of the interviews had been corrupted, thus making it unreadable. This was established on the day after the interview. In order that this interview was not lost, the interview notes were immediately compiled (using the short hand notes taken during the interview supplemented by details from the interviewer's memory) and sent to the respondent for verification.

Overall the interviews and the transcripts are of good quality and the current data set adequately answers the research questions. The data set does generate further questions, but these are outside of the scope of this study. While it is always tempting to collect more and more data, saturation has been reached with the current data set in its capacity to answer the research question. This study has been guided by a methodological principle of objectivity, which seeks to let the object speak without distorting it (Smaling, 1990, 1992).

3.3. The qualitative data analysis

This study utilised a very general qualitative approach to answering the question, (i.e. not specifically focused on one approach such as grounded theory or

phenomenology). Therefore the analysis also was conducted using an approach common to many qualitative studies (Pope et al., 2000). The student read the transcripts with an open mind and open heart (Smaling, 1993) while simultaneously bearing in mind pertinent issues that were emerging from her reading of the literature. She coded the latent and manifest themes emerging from the data as she went along. Once coded, quotes from each transcript were cut and paste into a single word processor document. The coding list recorded in this document grew as more and more interviews were analysed. Quotes from different interviews, which fell into the same category (i.e. spoke to the same theme) were grouped together under one coding heading. The student continually shared this set of coded quotes with the primary co-supervisor as the data analysis progressed. Eventually, 149 word-processed pages of coded quotes were collected. This process yielded far more information than was actually related to the research question. Thus the student immersed herself further in the data, reading and re-reading the coded quotes, listening to the data for the essence of the answer to the research question. Out of this process a narrative account of a synthesis of the data is presented as the key research findings. The description of these findings is illustrated further by quotes drawn from the interviews.

Qualitative data analysis can be a subjective process and therefore one of the measures suggested for enhancing the objectivity of this process is inter researcher triangulation. However, since this study was conducted as part of the requirements for an MPH degree, it required the student to show a strong degree of independent thought and analysis. Therefore the analysis was carried out singularly by her, but the process was reviewed by the primary co-supervisor and discussed with the second

supervisor. Furthermore, detailed descriptions of the process make it transparent for further review (Mays & Pope, 2000) and external validation.

All findings from the qualitative analysis of the interviews have been triangulated against the document review and the historical overview. Together these data sources complement each other in addressing the research question. They also serve as a check against which to assess each other. The findings have been reflected upon in relation to the literature. In the discussion these findings are considered against the theoretical frameworks on knowledge translation, agenda setting and policy making described earlier.

3.4. Reflexivity

Throughout the process of this study, the student has attempted to adhere to the methodological principle of reflexivity (Mays & Pope, 2000). The influence of the researcher over the research object and subject is present constantly throughout any research study, whether qualitative or quantitative. However, the interactive nature of qualitative interviewing and the analysis process following, does present more opportunities for the researcher to shape the process and for the researcher to be shaped by the process. In this study the student was constantly vigilant of the fact that the research question had been generated from out of the discussions of a group of researchers with a strong interest in seeing the evidence from randomised controlled trials[6] utilised in policy making. The student herself had recently completed a short course on evidence based medicine. As she read further literature as part of this

[6] Pragmatic Randomised Controlled Trial in Health Care (Practihc)

study, she too became more convinced of the appropriateness of using research information to inform policy. The student was thus open with respondents about the interests of the group posing the research question and about her own interests. In the beginning the student felt anxious in the interviews as the subject area is very medical and her background is not at all medical. However, explaining this to respondents enhanced the interviews because neither she nor they took for granted the possibility of a shared understanding of terms or processes which need not be explained. The student was also very aware of how the interaction between herself and the respondents was shaped by the fact that she is a younger woman and many of them were older males. Some responded to this as if the interview were a novelty, others responded as if they were being bothered by a pesky young girl, in fact one respondent referred to her as "young lady". In the analysis process the student had to be careful not to let her opinion of each respondent, formed during the interview, colour her capacity to engage fully with the transcript as a fresh piece of data to be approached openly. The primary way in which the relationship between the researcher and the researched subject and object were observed and kept in check in this study has been through the regular debriefing between the student and her primary co-supervisor. This gave her the opportunity to talk about the process and to manage it.

3.5. Ethical considerations

The main study received approval from ethics committees at the Medical Research Council of South Africa, the London School of Hygiene and Tropical Medicine, the University of Zimbabwe, Eduardo Modlane University and the World Health

Organisation. This sub-study received approval from the ethics committee chairperson at the University of Cape Town.

In their review of the ethics of the study, the Medical Research Council was of the opinion that confidentiality may become a problem in a study of this nature. They felt that as the group of respondents in each content area may be limited, it might be easy to identify them in reporting, even if their names were not revealed. The research team acknowledged this potential and subsequently adjusted the informed consent form so as to give respondents a choice in how data from their interview would be used. Respondents were also verbally informed of this.

All participants in the study have signed a consent form after being given a written consent information sheet and a verbal explanation of the consenting process.

Chapter Four

4. Findings

This chapter presents a summary of the findings from the document review, the historical overview and the interview data. It starts with a description of how research evidence regarding magnesium sulphate has been utilised in contemporary national policies and guidelines. It then describes the key issues emerging from the analysis of the interview data in relation to the extended timeline (Appendix 3). A summarised version of this timeline (Box 5) is presented below.

4.1. Research utilisation in contemporary maternal health policies and guidelines

Since 1994 the following relevant guidelines for maternal care, including the management of eclampsia and pre-eclampsia, have been produced:

- National Maternity Care Guidelines Committee (NMCGC) of the Department of Health, **Guidelines for Maternity Care in South Africa: A manual for clinics, community health centres and district hospitals**, (2000 & 2002)
- NCCEMD, **Saving Mothers: Policy and Management Guidelines for Common Causes of Maternal Deaths,** (2001)
- NCCEMD, **Saving Mothers: Second Report on Confidential Enquiries into Maternal Deaths in South Africa, 1999-2001,** (2002)

Although the "Saving Mothers: Second Report", is primarily as its title suggests a report on the Confidential Enquiry, it carries an annexure of guidelines at the end of each chapter, specific to the cause of maternal mortality discussed in the chapter. Hence it warrants discussion here.

These documents are very different in the manner in which they reflect their use of research evidence. Both of the editions of the "Guidelines for Maternity Care" carry in their introduction a statement reading:

> "The guidelines are based on the best available evidence from published research, modified where necessary to suit local conditions. References are not given, but are available from the authors on request. Specifics of management and drug dosing are not cast in stone, and can be modified according to the experience of the reader and new evidence". (p. 8 in both editions)

They also both refer to the Cochrane Library in their suggested further reading lists. In other words, although this statement claims the guidelines are based on evidence, it is left to the person reading the guidelines to verify if they so wish. In these two documents, the authors' use of evidence while suggested is not made explicit. In the guidelines themselves though, magnesium sulphate is the only drug recommended for the treatment of severe eclampsia, imminent eclampsia and eclampsia. A box also details exactly how the drug should be administered.

The two "Saving Mothers" documents are far more explicit in their use of research evidence. The "Policy and Management Guidelines" states that it is "customary to grade the evidence, on which clinical statements are based, according to the strength

of such evidence" (p. 5). It then goes on to explain the grading levels, (e.g. "Grade A Evidence from randomised controlled trials"). Within each guideline section full references are given to the study from which the specific recommendation is drawn and the grade of the evidence is given, for example:

> "Magnesium sulphate is the best drug to arrest and prevent further convulsions Grade A evidence. (The Eclampsia Collaborative Group. Lancet 1995; 345:1455-63)"

At the end of each chapter the references are repeated. A different author writes each chapter and the style is slightly different from one to the other, but the emphasis on being explicit remains. However, not every single recommendation is referenced and graded, but no explanation is given as to why this is so or if these recommendations are simply based on the authors understanding of best practice. This style is repeated in the later "Saving Mothers" report (2002).

4.2. "An uncertain field" reflections on research and treatment for eclampsia and pre-eclampsia

4.2.1. Searching for an effective treatment for eclampsia and pre-eclampsia

The abbreviated (Box 5) and unabbreviated (Appendix 3) timelines reflect a long history of attempts to find an effective treatment for eclampsia and pre-eclampsia at both international and national levels. Influential amongst these efforts are the publication of the Pritchard case series (1955, 1967, 1975, 1984) on the use of MgSO4, the suggestion of the use of diazepam by a group British physicians in Hong Kong (1968) and the shift to the use of phenytoin in the United Kingdom in the

1980's. South African researchers not only followed the international trends by introducing first magnesium sulphate, and later phenytoin into their teaching and practice, they were also making sense of and generating evidence at a local level. During the 1970's at least three articles were published in the South African Medical Journal addressing eclampsia and /or pre-eclampsia as a cause for maternal mortality. In 1980, this same journal published a review (Moodley, 1980) of the drugs commonly used for the treatment of hypertension in pregnancy. This trend of contributing to the evidence and to the debate has continued steadily since then. Researchers disseminated their findings through national and international journals and through nationally hosted events such as the annual Priorities in Perinatal Care Conferences. In 1986, the first paper on pre-eclampsia was presented at this conference and between then and 2003 at least forty-eight papers were presented on the subject of eclampsia and pre-eclampsia. In 1990 a South African randomised controlled trial of the effect of phenytoin compared with MgSO4 for the treatment of eclampsia was published (Domisse, 1990). Respondents did not see this trial as having an impact beyond the institution in which it was conducted.

4.2.2. The use of magnesium sulphate in South Africa

Magnesium Sulphate for the treatment of eclampsia was introduced into medical training in South Africa long before the results of the Collaborative Eclampsia Trial (ETCG, 1995) were first made available. The earliest use of magnesium sulphate for the treatment of eclampsia in South Africa, as suggested by respondents, was during the 1950's (Acad 10). It was used by maternity services attached to the University of Cape Town but was later replaced by Avertin and then Diazepam and reintroduced

again in 1979. It was introduced at the University of Stellenbosch in the early to mid 1970's by an individual who it is claimed had experience of using it in other settings[7]. Respondents from both universities suggest that they consulted studies from the United States that were being published in the international literature and which showed the effectiveness of the drug. Some suggest that even though these studies may not have been randomised controlled trials, at the time that was the best available evidence:

> "I think the one thing, in the 70s there were very few randomized trials, and a descriptive study was regarded as a pretty good study. So if you look at the article by Grant in 1975, I think it was, where 100 cases of eclampsia were managed. He reported on 100 cases of eclampsia managed by magnesium sulphate. That was a very key article. That article changed a lot of practice because that was the article people quoted on safety." (Acad 7 p. 21)

Respondents suggest that there was a close link between the American academic obstetric fraternity and obstetricians based at local universities. A former head of obstetrics and gynaecology at Tygerberg Hospital (attached to University of Stellenbosch) was elected as a fellow of the American College of Obstetricians. He then hosted members of this fraternity at his institution, inviting members of other local obstetric and gynaecology departments to attend these lectures. Similarly, a former head of maternity care at Groote Schuur Hospital (attached to the University of Cape Town), hosted American researchers at his institution and visited their practices in the United States. According to the data the practice of using magnesium sulphate spread through medical training and as trained specialists moved to other institutions, so it spread there too.

[7] This is anecdotal as the person concerned was not interviewed, however it has both been suggested that he was introduced to it in practice in Harare and through training at the University of Cape Town.

Although respondents suggest that many obstetricians in South Africa were using magnesium sulphate before the results of the Collaborative Eclampsia Trial were available, this practice was certainly not unanimous:

> "I think it depended on where people studied. It's depended on what people read and it's depended on what people believed. And that's because there were convincing studies showing that either of those treatments are acceptable. So it was difficult for people to decide once you became used to something. It was difficult to start using the other *side* – so it was an uncertain field." (Acad 6 p. 3)

> "The point is, until the randomised studies were set up, no one had any basis for pointing a finger at anyone else and saying, what you're doing is right or wrong." (Acad 8 p. 12)

> " R: So I think those were the two poles, and people were sometimes quite adamant about what was working best; people very, very strongly believed in their treatment. We had quite warm discussions about it because everybody believed that they were actually giving the best treatment.
>
> I: And where did those discussions take place?
>
> R: It took place at local congresses. It took place at inter-departmental meetings. It took place at the international congresses. It took place at the congresses of the international society for the study of hypertension in pregnancy. So it was at many places that ... was occurring.
>
> I: But when we started out, you said that currently in South Africa, it's generally accepted
>
> R: Yes. Right.

I: Now when did that… how did that happen?

R: Well, that's from after the magnesium sulphate trials. So after the magnesium sulphate trials there was clear evidence that it was the best. So people who had not been using magnesium sulphate, changed, and I know of many members who had changed. … Of course, there was suddenly a very good randomised controlled trial to show a better treatment." (Acad 6 p. 7)

Date	Key Events in **The evolution of policy and guidelines for the treatment of eclampsia and pre-eclampsia in South Africa**
1955	First Pritchard case series published, showing effectiveness of MgSO4. Updated every 10 years until 1984
1968	British physicians in Hong Kong suggest use of diazepam
1970's	MgSO4 introduced into obstetric care at key medical faculties in South Africa
1979	Obstetrics criticised by Archie Cochrane as being least evidence based medical speciality.
1980's	Use of MgSO4 spreads through teaching and inter-institutional contact between academics. International divisions on the choice of anti-convulsant are reflected in the country.
1980's-90's	South African researchers become increasingly connected to the international obstetric research community and simultaneously the local research output increases. Although provinces and institutions have their own policies there are no national policies or guidelines
By early 1990's	MgSO4 in widespread use in SA for treating eclampsia
1990	Dommisse randomised controlled trial of MgSO4 vs phenytoin for eclampsia published in British Journal of Obstetrics and Gynaecology 1990 Feb; 97 (2): 104-9.
1992	Pregnancy and Childbirth Group, first Cochrane Review Group to be registered
1993-95	South African researchers collaborate in Eclampsia Trial at local trial sites
1994	Change of government promotes new focus on maternal health and openness to academic involvement in policy making
1995	**Collaborative Eclampsia Trial published**
1995	Senior obstetricians in South Africa publish editorial on implications of Collaborative Eclampsia Trial
1996	Maternal health organised into a separate directorate within national DoH Academic advocacy for maternal mortality monitoring followed by the appointment of the first National Committee for Confidential Enquiry into Maternal Deaths (NCCEMD)
1999	First NCCEMD report published. Eclampsia accounts for highest percentage of the deaths due to hypertensive disorders of pregnancy, which is the second largest cause of maternal deaths. National policy and guidelines recommended.
2000	*First national "Guidelines Maternity Care" published. Evidence is referred to but not referenced.*
2001	*NCCEMD publishes policy and management guidelines for common causes of maternal deaths. MgSO4 recommended and use of evidence made explicit.* South African researchers collaborate in Magpie Trial at local sites. South Africa is the regional trial co-ordinating centre.
2002	**Magpie Trial published**
2003	Following on from trial, MgSO4 is recommended for women with moderate to severe pre-eclampsia, where it can be administered safely, in South African Medical Journal.

Box 5: An abbreviated timeline of key events

4.3. Establishing and publicising the "evidence"

Respondents regarded the Collaborative Eclampsia Trial (ETCG, 1995) and the Magpie Trial (MTCG, 2002) as the most conclusive evidence on the treatment of eclampsia and pre-eclampsia. Thus when they referred to the "evidence", they referred to the results from these trials. Furthermore it was these results, rather than that from earlier studies, which were contemporary during the guideline writing process. Hence, the trials and their results were focused on in the interviews and are reflected upon here.

4.3.1. Reflections on the Collaborative Eclampsia Trial and the Magpie Trial

Not only were both the Collaborative Eclampsia Trial and the Magpie Trial familiar to respondents, several of them had been involved in one or both of these studies. For some respondents this involvement grew out of the relationships they had formed with researchers at the Oxford Database of Peri-natal Trials, including Lelia Duley (principal investigator for both trials) during the course of sabbaticals and fellowships spent at this unit. Local collaborators were also actively recruited at events such as the Priorities in Peri-Natal Care conferences, by both local and international researchers. South African trial sites recruited the most number of women in both trials and local collaborators were widely involved overall including representation on the steering committees (ETCG, 1995; MTCG, 2002).

The results of the Collaborative Eclampsia Study were well accepted according to respondents and, where, necessary changes to guidelines or practice were soon made:

> "…where guidelines were being developed, whether it was at a local level or a national level, I think the protocol originally from the eclampsia trial for the use in eclampsia, was taken up." (Acad 3 pp. 2-3)

For them, the findings from this study ended the debate as to which anti-convulsant should best be used, confirming for those already convinced that magnesium sulphate was the most appropriate anti-convulsant, in treating eclampsia.

> "… it didn't impact that much on the use of magnesium sulphate for eclampsia in our institution because we were already using it, although we were glad about, that it confirmed, I mean, what we believed to be the case, and that using that information it was much easier to convince other people." (Acad 1 p. 15)

One respondent however disputed the comparison being made in this trial. He felt that the drug dosage used for phenytoin (one of the comparative drugs) was inappropriate for its intended therapeutic effect. In his opinion, if this dosage had been different then a different trial result may have been reached and magnesium sulphate may not have been shown to be superior (Acad 8).

Unlike with the Collaborative Eclampsia Study, respondents suggested that the results from the Magpie Trial were not so easy to apply. They argued that treating a patient with magnesium sulphate, particularly intravenously is labour intensive, requires facilities, which are not always available and can lead to complications for the mother. As one respondent explained, researchers locally were hoping that the trial would identify a subset of women who would benefit more from the prophylactic use of magnesium sulphate than others (Acad 3). The trial however did not do this, the results suggesting instead that it should be used across all degrees of pre-eclampsia.

However, as another respondent suggested, the "number needed to treat" figures for mild, moderate and severe pre-eclampsia were quite different (Acad 2). Given the local hesitation around interpreting the findings from this trial, he claims that the editorial written by the South African collaborators was "a very guarded one" (Acad 2 p.15), in which it was suggested that the infrastructural conditions (availability of drips etc.) at each local setting should be taken into consideration when implementing these results.

For both trials however, respondents raised some concern about the ethics of conducting trials with drugs that they felt were known to be effective. At two institutions where researchers chose not to be involved in the Collaborative Eclampsia Study, they did so on the basis that they already felt the drug to be effective. One felt that it would be dangerous not to give magnesium sulphate to their patients (Acad 10). Another felt that it would be unethical to not give it to their patients during the course of the trial:

> "We didn't participate because we were convinced that magnesium sulphate is the best, and we thought it would be unethical to expose our patients to that study because we've been using magnesium sulphate for so long and we were convinced that it is really the best." (Acad 6 p. 2)

Similarly, ethical questions were raised in relation to the Magpie Trial. It was felt that it was unethical to do this trial in a developing country since there was no reason to think that magnesium sulphate would be any less effective in treating pre-eclampsia than it was in treating eclampsia and the risk for patients enrolled in a developing country setting was far greater than for those enrolled in well resourced settings (Acad 8 pp. 11-12). It must be noted though, that according to the publications from the two

international trials (ETCG, 1995; MTCG, 2002), no conclusive evidence existed prior to these trials. These comments show the strength of experience in shaping opinion, even when the respondents are otherwise convinced of the value of using evidence.

4.3.2. Local dissemination of the trial results

Although respondents themselves were familiar with the results of the Collaborative Eclampsia Study and the Magpie Trial, they were based either at academic institutions or had current or previous positions within the national department of health and thus were more likely to have been exposed to the trial findings. When reflecting on the extent of the dissemination of these results more broadly, respondents differed significantly in their opinion as to the reach of local attempts at dissemination. On the one hand some felt that it had been well disseminated and therefore the findings were well known:

> "I think it was presented at a number of local meetings. … the leader in South Africa of that trial, … he presented it at many meetings and so it was a well known research in this country and in Zimbabwe." (Acad 3 pp. 2-3)

Another respondent explained that the local dissemination was co-ordinated with the international dissemination in an attempt to do so with maximised effect:

> "our whole thing was the big bang, we tried to get a big bang effect, and it was very similar – … Within a month or so their presentations in Oxford were presented throughout the country at various local meetings, and I think that was quite powerful. … They, in the Eclampsia Trial and the Magpie Trial gave out the presentations and slides, and once the data was free then and long beforehand people knew on that date and at the first subsequent academic

meeting that was available, could be booked to, you know, to present the Magpie Trial, that created a vibe. People wanted to know what the final results were, especially, ja, the Magpie results, they especially wanted to know '... then each area was going to be presented, and at the SASOG and at the Priorities meetings, and so on. In a short period of time everyone, well, those who were interested would have had clear access to the results." (Acad 7 pp. 22-23)

A further respondent however suggested that this dissemination only happened at the level of national congresses and that it did not reach clinicians in the field:

"I: And to what extent do you think there has been a change – if at all – as a consequence of these two trials?

R: I think, *pause,* the change has not been as widespread as expected, but there has been quite a bit of change. The problem has been with the dissemination of the information where it depended on disseminating the information through *SASOG* for instance, obstetricians, gynaecologists coming together. But when it comes to the general doctor *out there,* it hasn't been. So I don't even know of a forum that we had that said, maternal and child health-care people, this is the policy. There hasn't been even a memorandum that went out from the provincial heads of health to say to the people on the ground, this is the accepted (practice)." (DoH 2 pp. 14-15)

And yet another comment suggests that the traditional route of dissemination may have little impact on the majority of obstetric practice.

"And just, sorry, the other thing is you must just remember the, that the majority of obstetrics is carried out by non-specialists in the country, and those

people will be only basically practicing what they learned at medical school. Very few of them will read The Lancet or read anything that comes out of The Lancet. And maybe they will read an occasional something, in the SAMJ but probably not that much. They'll go to CME lectures and probably very few will change their practice on those lectures unless there's a clear benefit for them to do it." (Acad 7 p. 10)

The data therefore suggests that academics and health officials involved in policy making and guideline development were well informed as to the results of the two international trials. Respondents were less certain of the extent to which it reached health workers on the ground.

4.4. The growth of a culture of evidence based obstetrics in South Africa

The literature describes well the determined attempts at making the science and practice of obstetrics internationally more evidence based and the subsequent growth of evidence based obstetrics (King, 2005). The timeline also reflects key events in this process. It shows the close relationship between the development of the Cochrane Collaboration and attempts by key international obstetricians such as Iain Chalmers at improving and systematising the evidence base for his profession. Obstetrics shifted from the days when it was criticised for being the least evidence based medical speciality (1979), to being a forerunner in the Cochrane Collaboration with the Pregnancy and Childbirth Group, being the first Cochrane review group to be registered (1992). This trend or shift in consciousness around evidence occurred within academic obstetric practice in South Africa, as well. Interestingly, this

occurred despite the isolation of South African academics due to the academic boycott in response to apartheid. It was very clear from this set of interviews that respondents' conceptualisation of evidence reflected the same understanding of the term as promoted by proponents of evidence based medicine. The interviews suggest that for respondents the results from systematic reviews and randomised controlled trials were regarded as the highest form of research evidence. The following quote is reflective of how most of the respondents related to the concept of evidence:

> "No, it was purely evidence based. We really tried to be as scientific as possible... the Oxford database was used very extensively, and subsequent to that the Cochrane database. So we tried to stick as close as possible to evidence-based medicine and not sort of traditional ways and means of dealing with things, but really to make it, have it scientifically founded." (Acad 1 p. 2)

What this quote reveals is a sense of evidence based practice and decision making as being more scientific and therefore better than the traditional practice of medicine. It carries with it a sense of being modern rather than old fashioned. In another quote, a respondent links evidence based medicine with best practice, suggestive even of a sense of prestige around the practice of evidence based medicine:

> "At that stage, I was a member of the society and attended all their congresses, and I was director of [a] perinatal mortality research unit... So of course, you wanted to do the best practice. You wanted to use the best protocols. You wanted to do evidence based medicine." (Acad 6 p. 5)

This conceptualisation of evidence was noted from the start of interviewing. More so, this conceptualisation was present and influential in the writing of the national policies and guidelines. Therefore, an attempt was made during the course of the

interviews and later in the content analysis stage, to understand from the respondents' perspective how the reliance on evidence in academic and in publicly funded obstetric practice had come about.

The data suggests that there are several interlinking factors that contributed towards the creation of an evidence based culture within obstetric care. One of the factors was the contact and exchange between opinion leaders in international research who promoted evidence based practice and South African researchers. International researchers increasingly presented at local conferences (PPCC abstract database).

> "We actually invited Murray Inken, who was attached to the Oxford database, and subsequent to that Iain Chalmers, who's the editor, was invited to attend. So we were sort of, I think from the word go, when the Oxford database became available for use, we were part of it, we were aware of it, we were using it, and I think quite a few South Africans became involved on their editorial board and as editors or reviewers, or whatever." (Acad 1 pp. 2-3)

At least three of the respondents spent time during their sabbaticals and fellowships working with key proponents of evidence based medicine at the Oxford Peri-natal Trials Unit. Two of them are particularly influential within the local obstetric fraternity and were within the core group of researchers who assisted in writing the current policies and guidelines. All of them suggest that their exposure while working at this unit was important in shaping their thinking around research and evidence.

> "And if you look at the proceedings of the first couple of conferences, most of the studies were epidemiological studies, and then you'll see, I think from the early 80s onwards, the move towards more and more randomized trials and systematic reviews were being presented. And I think it was really the

influence of the Oxford database of peri-natal trials which got us all thinking in that way." (Acad 3 pp. 8-9)

Another factor was the existence of the annual Priorities in Peri-natal Care conferences and the conferences of the South African Society of Obstetrics and Gynaecology. As suggested by the data, these "institutions", were both open to receiving the new ideas around evidence based medicine and provided platforms from which these ideas could be promoted and shared amongst a ready audience:

> "But I think that's one very important aspect is sort of the culture of research within a department, and the second one is exposure to events, like for instance, the Priorities in Peri-natal Care Conference where you gain knowledge and where you interact, not only with other departments in the country but also with overseas experts. That was very, very valuable, ja." (Acad 1 p. 3)

Regular attendance at these conferences allowed for the emergence of a closely linked national network of researchers who promoted evidence based medicine at their own academic departments and nationally. An example of a national attempt is the Better Births Initiative (Smith et al., 2001), which has been used to promote evidence based care in labour. Within academic departments the data suggests this idea was promoted through teaching, journal clubs and largely through involvement in research.

> "…so evidence, that sort of thing was really, ja, grasped with both hands. I think a lot of our research is clinical. So trials are our – if you want to do

> research is our bread and butter, we are not going to really be able to do much on the biochemical research cause of resources and so on. So our research and our strengths are in clinical trials. … I don't think there's any institution out there O & G academic institution which doesn't use Cochrane extensively." (Acad 7 p. 21)

Thus the attempts at an international level to promote evidence based medicine and the increased availability of evidence from trials through the Oxford Database of Peri-natal Trials and later the Cochrane Collaboration, was met by eagerness within the national obstetric fraternity.

There was one divergent voice amongst respondents. This person (Acad 8) felt that the use of evidence was important and to this end he taught the skills of evidence based medicine to his registrars. However, he also felt that there was a lack of critical appraisal in the use of evidence. He felt that sometimes people were more interested in the methods than in the relevance of question. He felt that patients needed to be treated individually, calling for the use of clinical judgement, not only adherence to the evidence. Furthermore he felt that the conducting of trials had become an industry.

4.5. Policy making and guideline development for maternal healthcare

There was no national policy or management guideline for maternal care until the publication of the Guidelines for Maternity Care in South Africa in 2000, followed by the Saving Mothers Policy and Management Guidelines for Common Causes of

Maternal Deaths in 2001. Prior to this, as respondents explained, the obstetric departments of the various medical universities around the country tended to draw up their own guidelines and protocols to be used at hospitals and maternity services attached to these institutions. As one respondent argued, these institutions tended to pursue "their own identities even in terms of protocol" (DoH 2 p.13). Students, both nurses and doctors, were taught practices that followed the protocol of the training institution where they were enrolled. This meant that there was no standardisation of practice across the country, with people coming from different practice backgrounds having to work together in one setting. This lack of national standardisation was compounded in some settings by having foreign doctors who had not even been trained using any of the protocols taught within the country. An attempt to standardise national practice was therefore one reason given as to why the national policies and guidelines were developed, but this needs some explanation in context.

As shown in the timeline, the national policies and guidelines were published six and seven years after the first democratic election. The interviews suggest that the change in government was important to policy development in South Africa. Policy development is described in the data as an aspect of democratic reform, with policies being formulated throughout health care, not just for maternal care. The change in government ushered in an openness to discussions around policy between researchers and government, which one respondent (Acad 7) suggested was not there before. During this time new staff were employed into the national department of health with different values to those who had been there before. Respondents, who had been employed by the Department of Health during this phase, spoke in the interviews of wanting to improve health for all. One respondent suggested that the record keeping

under the previous government was designed to hide the health problems experienced in communities, but the new cadre of people being employed had experience of these problems and wanted to correct them:

> "So there was a need to then say it was one country, and therefore, we need to reform this and we need to have policies that respect everyone irrespective of race, colour or creed. So I think that is the one aspect. I think also the fact that many of the people who then came into government, came from underprivileged communities. So it was important and necessary to try and change the conditions of those communities." (DoH 2 pp. 3-4)

This new cadre of staff, who were being appointed into key positions within the national department, also had long standing affiliations with the Priorities in Peri-Natal Care Conferences and the South African Society of Obstetrics and Gynaecology. Given this context and these networks, respondents described how a small group of researchers within the country who had played a leading role within these same networks, were able to convince the national department and in particular the incoming minister of health (Dlamini-Zuma) of the need to make maternal death notifiable. Information gathered through this notification process would allow for an assessment of the leading causes of mortality through a confidential enquiry into maternal death. Thus in 1996 the first National Committee for the Confidential Enquiry into Maternal Death was appointed, chaired by Prof. Jack Moodley, a leading figure within the national obstetric networks (he was a member of the College of Medicine, the South African Society of Obstetrics and Gynaecology and attended the Priorities in Peri-Natal Care Conferences). Respondents describe the outcome of this enquiry as significant for policy development, particularly as related to this case study. Firstly, it found that hypertension was the leading cause of maternal mortality

(prior to the escalation in AIDS related deaths). Secondly, it recommended that a national policy be written. In 1998, the national department began drafting the 'Guidelines for Maternity Care in South Africa'. At the launch of the first report of the Confidential Enquiry entitled 'Saving Mothers', members of the College of Medicine volunteered to write the management guidelines for the treatment of the ten most common causes of maternal death as found through the enquiry. Thus, within a year of each other, two national guidelines were published.

Respondents had varied answers as to why two national guidelines, covering some of the same areas and both making explicit use of evidence from systematic reviews and randomised controlled trials were written. One respondent suggested that the people who wrote 'Saving Mothers' felt the 'Guidelines for Maternity Care' to be a waste of time (Acad 4). He suggested that they felt that there was a need to concentrate on the common causes of maternal death identified by the first Confidential Enquiry into Maternal Death. In this light, the 'Guidelines for Maternity Care' were regarded as too broad, 'Saving Mothers' hence attempting to be more specific. Others suggested that these two guidelines are aimed at different levels of care. They claim that 'Saving Mothers' is inclusive of guidelines for care at level 3 (specialist referral) institutions, since it was established that maternal mortality was occurring at this level too. The 'Guidelines for Maternity Care', according to respondents, are aimed at levels 1 and 2. As one respondent explained, there is a shortage of staff at this level, particularly a shortage of trained obstetric specialists (DoH 1). These guidelines, she suggested, would allow for medical staff, midwives and doctors, not trained as specialists, and specialists who had not trained within the country, all to be able to deliver the same care that a woman being treated by a specialist would receive.

Furthermore, one of the spin offs hoped for in involving academics in the writing and reviewing of these guidelines was that they would then take these back to their training institutions and begin incorporating it into their teaching. Thus it was hoped, that standardisation of care within the country would be achieved.

But where within this picture did the use of evidence fit in? We knew from our early interviews and from our reading of the guidelines that explicit use of evidence had been made and thus we questioned respondents as to how this had come about. Several interlinked reasons emerge from the data.

Firstly, respondents repeatedly emphasised that throughout this process the "same names" appear. They explained that the academic obstetric fraternity within South Africa is small and that members of this fraternity met regularly through the Priorities in Peri-Natal Care Conferences, the South African Society of Obstetrics and Gynaecology and the College of Medicine. Some respondents felt very positively about the influence of this group, others not so, calling them the "big bosses" (Acad 5) and an "enfranchised clique" (Acad 8). Whatever their opinion, respondents were clear that it was members of this group who had successfully lobbied for the conducting of the confidential enquiries into maternal deaths and who then led the committee. They also took lead roles in the writing of the 'Guidelines for Maternity Care' and similarly for 'Saving Mothers'. Staff appointed to the national department, if not leaders within this group, were certainly closely affiliated to it and felt it appropriate to draw on their assistance because they knew through association which areas members of this group held expertise in. The importance of their influence on the use of evidence in the guidelines was that members of this group had been

cultured within the philosophy of evidence based medicine and they carried this with them into the writing of the guidelines.

Secondly, as explained by the person who was responsible for writing the first draft of the 'Guidelines for Maternity Care', using evidence was not just a reflection of the values of the national department, but it was a reflection of the "world that we live in":

> "But I mean, in the world we live today, it is the world of evidence based practice, evidence based medicine. So one had to be careful about… cognizant of the fact that one had to use the best available evidence. Because I mean, this would be national… it would be a reflection of us as a country." (DoH 3 p. 11)

Furthermore, he explains that when he was appointed to start this process he had just finished his registrarship and as a consequence of this training, for him, evidence based medicine was "the truth I knew, that's how I was cultured." (DoH 3 p. 11)

Finally and very importantly, as explained by former members of the department of health, the use of evidence leant credibility to the guidelines. The department of health was attempting to standardise practice through the national guidelines. However a perceived challenge to standardisation was the felt tendency of institutions to pursue their own identities in terms of treatment protocols. At the same time these guidelines needed to be acceptable to a small but highly influential lobby of academic obstetricians who were sold on evidence based medicine. In other words, in order to get institutions to adopt a national standard, the guidelines would have to be seen to

be above questioning, and basing them on credible evidence was seen as a means to achieving this:

> "As I indicated, that we want to, the aim of maternal and child health at national is to improve the health of women and children, and for anything to be used, especially if you include academics and everybody. For anything to be utilised, then people want to be convinced that this actually is of benefit and it can work. So you then need to have evidence. If you come and say that magnesium sulphate works to stop eclampsia and to further prevent people from fitting. You see people will say, "where do you get that from", and you cannot say, "I heard somebody saying it works". You need evidence, and therefore, you have then to rely on the research that has been done. And without that information it would be very difficult to convince anybody to actually buy into what you are doing." (DoH 1 pp. 6-7)

> "So this (guideline) then starts saying, this is what is accepted as practice in South Africa. So that even if you come from Cape Town and you decide you're going to give 20 drops, and another one comes from Medunsa and say we give 30 drops, then this will say: these are the drops that you must give. So that the nurse, who is working with the doctor, knows that this is what has to be done. Not to be shouted at because she's running with 25 drops and at Medunsa they say "not giving enough", Cape Town says this "you're giving more than enough" ... So it is very important then to take the research findings and get them into policy. And even get the research to say what is the best way ..." (DoH 2 p. 14)

Evidence then gave power to these guidelines. The authors of the guidelines were keenly aware of the social context in which these guidelines were written. They used

evidence not only because they believed that it offered the best possible treatment solution, but also because they believed that those reading the guidelines would be more convinced of the strength of the recommendation if it were supported by evidence. These guidelines are a product of their historical era. They reflect the values of this era in academic obstetrics. They were written by an authorship cultured in evidence based medicine for an audience primed in the same culture.

Chapter Five

5. Discussion

The data collected for this study has revealed a long tradition of utilisation, production and critical reflection on research evidence amongst academic obstetricians in South Africa. It also shows that during the time when policies and guidelines for maternal health were being written in South Africa, those responsible for these documents were open to incorporating research evidence into them. This is reflected in the use of evidence in contemporary policies and guidelines. It suggests congruence between the opinions of those persons in academic obstetrics and those responsible for policy making and guideline development for maternal health. This study shows a positive example of research utilisation in policy making and guideline development.

The literature suggests that although the idea of using evidence to inform policy making has come into favour, actualising this idea in practice is complex. In the past theoretical approaches and models have been used to understand the process of research utilisation. These models evolved from their analysis of research utilisation as linear. In the knowledge driven and problem solving models, research is utilised because results exist and in addition there is a problem that needs to be addressed (Weiss, 1979). With time the complexity captured in these models has increased (Kothari et al., 2005). More recent literature suggests that research utilisation is contextually influenced by many factors such as the social and political environment in which policy making is taking place (Bowen & Zwi, 2005). The literature suggests that research is not always utilised in the same manner, i.e. it can be used in an

instrumental, conceptual and symbolic manner (Hanney et al., 2003, Lavis et al., 2003, Innvaer et al., 2002). Furthermore the literature points out that there are different stages in policy making (Bowen & Zwi 2005; Lavis et al., 2002). Research can be utilised at any or all of these stages.

If we look at this study against these arguments, it does not seem at first that a similar picture of complexity emerges. Looking at the policy and guideline documents outside of the interview data the process appears to be linear. It seems that policy makers adopted the most recent evidence available at the stage of guideline development. This evidence they used instrumentally in an attempt to solve the problem of maternal mortality. Reading these documents alone offers little indication as to the possible influence of the social and political context in which they were written. But given that the literature continuously suggests that research utilisation can be complex, the picture of simplicity emerging from the document analysis seemed unusual. Triangulating the data sources however presented a different picture. Reading the policy and guideline documents against reflections from the interview data suggests that these documents were indeed a product of their time. Applying some of the analytical approaches suggested in the literature as different lenses on the same data helped to explore this complexity.

5.1. Three analytical lenses

5.1.1. The "Two Communities" Theory

Let us consider the findings from this study against the "two-communities" theory (Innvaer et al., 2002; Kothari 2005; Lavis et al., 2002). Researchers and policy makers have been likened to two communities with different perspectives and different functions but who are required to understand each other and interact. This theory suggests that researchers and policy makers operate separately from each other, thus creating challenges for research utilisation. In contrast it has been informally suggested that in developing country settings academics are called upon to both conduct research and to write policies. This raises questions about the appropriateness of the two communities theory for developing countries as researchers and academics do not seem to be so separate here.

Looking at the data generated in this study there appeared to be no clear distinction between policy makers and researchers, particularly after the change in government. Our respondents suggested that before the change in government, the opportunity for engaging policy makers was limited or did not exist. But after the elections in 1994, there was a new administration with space in it for new people. At least some of the people who were appointed to positions in maternal health were from within the close and influential network of academic obstetricians and midwives. When consulting outside of government, these new incumbents drew on the assistance of others within that circle: - all of them researchers. Furthermore, a fluidity of roles was observed with people moving between academia and government within a short space of time.

Thus for example, one of the respondents was initially an academic. He then held a key post at the National Department of Health and now again returned to academia. This movement was observed in the main study too where several respondents followed a similar career path as that described above. In another scenario, respondents maintained their academic positions but were often called upon in a consultative manner to work with the National Department of Health, serving on committees, writing policies and guidelines or offering advice, etc. In this instance it would appear that researchers and policy makers were never required to draw closer as their close relationships were already formed prior to the consideration of developing policies and guidelines, evidence based or not.

But the closeness between policy makers and researchers observed here, serves to hide a deeper level of complexity in the process of research utilisation. The committees set up for writing and developing both the "Guidelines for Maternity Care" and the "Saving Mothers" guidelines were chaired by academics. In addition several of the members of these committees were academics who were also responsible for writing chapters of the guidelines. If researchers are writing policies and guidelines, then their attitude to research utilisation and the quality of the evidence is very important. In this instance it was fortunate that these academics shared a belief that policies and guidelines should be evidence based. This could have been different, as we cannot assume that all academics share this belief. It suggests that advocates hoping to encourage research utilisation in policy need to map out carefully who is responsible for writing the policy. Then they need to target their marketing appropriately, not just at policy makers or government officials since they are only one part of the process along with researchers. This study suggests that the

distinction between policy makers and researchers may not be as clear in developing countries[8] as it can be in more affluent countries. Furthermore, it suggests that researchers working close to government are as important to the research utilisation process as are government officials and policy makers.

5.1.2. The Kingdon Framework

Another useful framework against which to view data from this study is that which is suggested by Kingdon (1995). Kingdon's framework is not so much focused on policy making as it is on understanding how issues get onto the policy making agenda. Key within this framework, is the role of policy entrepreneurs in taking advantage of rare windows of opportunity to push their issues onto the policy making agenda. These windows of opportunity occur when various streams of activity, namely problem solving, policy making and general politics, interact with each other at a governmental level. This framework can be used to explain how the need for maternal health care policy came to be on the agenda of the National Department of Health.

Prior to the change of government in 1994, little attention was given to maternal health at a national level and there were no national policies for this area. This was the case despite continuous attempts by advocates, some of whom where respondents in this study, to bring the problem of maternal health to the attention of the national government. These advocates were also themselves involved in national and

[8] Of course this could be a transient occurrence given that South Africa is in the early stages of its democracy, and the capacity of government officials to write policy independently may soon increase coupled with the possibility of a decrease in willingness on the part of the administration to directly involve researchers. Given that a very different scenario is occurring in terms of the debates and controversies around anti-retroviral treatment, this case study may be unique even within this setting.

international research networks, which sought to find solutions to the problem of maternal health. In other words, they believed that there was a problem; they believed that there were potential solutions to this problem and they sought an opportunity to bring government attention to this. Using Kingdon's framework (Kingdon, 1995), these advocates can be seen to be policy entrepreneurs.

The political climate however, did not allow these policy entrepreneurs to bring any of this to the attention of the national government in a way that would affect meaningful change at a policy level. This climate changed dramatically, when in 1994 South Africa held its first democratic elections and a new national administration came into being. Following this change the National Department of Health amongst other things employed a new cadre of health officials. Appointed in key positions within this process were persons who had strong links to the networks of policy entrepreneurs and researchers who sought a change in approach to maternal health. These new government employees opened up the space for the policy entrepreneurs and researchers to engage with the National Department of Health. As a result of the continued advocacy and the new openness, a decision was made to conduct a national confidential enquiry into maternal mortality. This enquiry established that maternal mortality was a problem and recommended that a national policy for maternal health was needed as part of the solution. Only once the need for maternal health care policy was expressed did the opportunity for drawing research evidence into that policy arise.

Much of the research utilisation literature is focused on getting research into policy. Applying the Kingdon framework (1995) to this data set shows that there may be a

prior step. The processes observed here suggest that researchers may need to become policy entrepreneurs and point out to government that it needs a policy in the first place. What this model does is to show how the development of policy and guidelines for maternal health came to be on the agenda of the National Department of Health and how policy entrepreneurs were important in this process. It does not explain the reason why, when these policies and guidelines were being developed, evidence from randomised controlled trials came to be utilised.

5.2.3. The "three I's" framework

The 'three I's framework as applied by Lavis et al. (2002) is helpful in illuminating the influences on policy making. This framework suggests that in order to understand the policy making process at any one moment in time, one needs to take into consideration three key influences. It suggests that the process is influenced by prevailing ideas (e.g. values, available information). It is also influenced by those people or bodies whose interests are affected by shifts (or not) in the policy and it is influenced by legacies (e.g. a scheduled review of the policy) that inform policy. The suggestion of key events as influential (such as major political change) has also been proposed. Within this framework all of these influences operate in relation to each other.

One can apply this framework to understanding research utilisation in the Guidelines for Maternity Care. As alluded to already twice above, a key event preceding the writing of this document was the election in 1994, which brought in a new dispensation. Linked to this event the institution of the National Constitution had

changed. The constitution of the country now recognised the right to health services with attention to the needs of children and women. A prevailing idea at the time was that women's health was important. Attending to this need in turn was in the interest of the new government in the process of reforming old structures. Another event, the outcome of the findings of the first confidential enquiry, suggested that in order to attend to this need, policy making for maternal health was required. An idea held very strongly by those persons now charged with the responsibility of writing these policies was that policies and guidelines had to be scientifically grounded. They believed that policies and guidelines should be based on the best available evidence. The best available evidence was believed to be the results from systematic reviews and randomised controlled trials. Fortuitously at the time that these ideas were strong and the desire for policy was great, a randomised controlled trial showing the effectiveness of magnesium sulphate as a treatment was published. Furthermore, some of the interests representing the new government felt that this new administration needed to be seen to be keeping abreast of the trends. Given the strength of the belief in evidence based medicine at the time, using the best available evidence was seen to be an expression of keeping abreast in this way.

Use of this lens gives further suggestion to the idea that the process of research utilisation observed in this study was more complex than first meets the eye. There were multiple influences on the process of developing the "Guidelines for Maternity Care". It was fortuitous that the results from the Collaborative Eclampsia Trial (ETCG, 1995) were published only a few years before this guideline was developed. However the mere availability of this evidence did not automatically ensure its uptake. This framework suggests that this evidence was received in a context which

was open to research utilisation, a context which linked best care to best evidence. It was published at a time when those developing the policies and guidelines wanted to offer the best possible care to women. This framework shows that at the time when the "Guidelines for Maternity Care" were being developed all the influences seemed to be in agreement with each other. It also shows the interdependency of these influences on each other and the precarious nature of the policy and guideline making process. If any of these influences had not been in agreement, would the guideline have looked similar or even come into existence? We don't know. It does suggest that the arguments presented in the literature that context is very important to research utilisation are correct. The difficulty for those wishing to influence research utilisation is that they may not always have the power or authority to influence this context. Coming back to Kingdon (1995) this would suggest that policy entrepreneurs need to be vigilant of when the influences are in alignment and when a window of opportunity opens so that they can take advantage of the moment.

5.2. Networks of influence

In this study a serious attempt was made to find as many respondents as possible who had been involved in the policy making and guideline development process and then also to find respondents with divergent views. However, it was not that easy to find respondents who disagreed absolutely. Instead the interview data suggested that most respondents seemed to be in agreement around the concept of evidence and the importance of evidence based policies and guidelines[9]. One respondent (Acad 4), suggested that the people in government, those writing the policies and guidelines and

[9] Of the 15 respondents only 2 could be said to have held a different perspective.

those in academia all belonged to the same "club". This opinion that policy making and guideline development was dominated or strongly influenced by a small but strong network of senior academics was shared by several of the respondents (Acad 1, Acad 2, Acad 4, Acad 5, Acad 7, Acad 8, DoH 1). As is to be expected some respondents were more positive about the influence of this group than others. The important issue though, is that this group met regularly through their collaborative work, through their various society meeting and through the College of Medicine. Influential members of this group were also tied into international networks, which strongly promoted evidence based medicine, such as the Cochrane Collaboration and the National Perinatal Epidemiology Unit at Oxford. Within this network, the idea of evidence based medicine had been well diffused. The opinion that policy making should be based on best available research evidence was strongly held. Best evidence was understood to be that which was derived from randomised controlled trials and systematic reviews. Working together so closely, sharing many of the same ideas and having "members" now placed at the National Department of Health, meant that this group had a very strong influence over the final policies and guidelines which were produced. In this instance the idea of needing to base policy on evidence was clearly a strongly held value amongst members of this group. However, the policies (if produced at all) could well have been formulated very differently if this group held a different set of values. This suggests firstly that networks of influence are very important and secondly research utilisation can be unpredictable if dependent on the values of these networks.

5.3. Building on previous research: Barriers and Facilitators

Previous research has identified barriers and facilitators to research utilisation (Aaserud et al., 2005; Innvaer et al., 2002). This study identified no barriers. Facilitators to the uptake of evidence included:

- The availability and credibility of the evidence from randomised controlled trials.
- The timeliness of the evidence in relation to policy and guideline development.
- The close relationship between the policy makers and researchers.
- A positive attitude towards research utilisation, particularly evidence from randomised controlled trials and systematic reviews, in policy making. This was shaped by the growth of evidence based medicine and evidence based obstetrics.
- An amenable or open political context.

It is important to remember though that both facilitators and barriers are time specific. For example, at another moment in time the political context may have been closed thus hampering potential research utilisation. Alternatively it may have been open but the evidence may not have been available. Relationships can also be fickle. So while relationships were good at the time, it could very easily change, especially if the evidence suggests something that the policy makers do not like, while the researchers are convinced by it. Describing barriers and facilitators is useful but limited. It may be more useful to offer a thick description of the full process surrounding the moment when research was or could have been utilised. This allows for us to explore the process within its full context thus enhancing the possibility that we may learn from the experience of others.

5.4. Limitations of this study

This study has adequately covered the research question it set out to answer. There are however some limitations.

The lessons learnt in this study are very useful and the research process and results can both be said to be valid and reliable. The depth of the interview process along with the depth of analysis and the triangulation with other data sources suggests that this study does meet the requirement of presenting "probable truth" (Thorne, 1997). However, as this is only one case study, the lessons are very specific and not generalisable. The transferability of the insights, which are drawn here, will be enhanced when reflected upon in triangulation and in comparison with the insights drawn from the other five case studies, which make up the main study.

One of the objectives of this study has been to develop out of this data set a conceptual model of the relationship between research and policy making. This idea came from an early reading of the literature, where this kind of modelling was attempted in other studies (Kothari et al., 2005). In this study, this has not been possible. There were two methodological barriers in this regard. Firstly, the design of this study would have had to be far more sophisticated in order to build such a model. It would have required that an approach such as grounded theory (Dellve et al., 2002) be taken from the outset. In using such an approach the student would have been required to pay more attention to the relationship between different issues emerging from the data. Instead, this study has taken a very general qualitative approach and therefore remains largely descriptive. Secondly, as mentioned above, this is only one

case study. Even if a model were developed out of this data, it would be an arbitrary exercise as the possibility for transferability would be limited. A more credible model would build upon patterns observed and compared within more settings and over a longer period of time. However, the literature does offer empirically based models and an attempt has been made to apply at least some of these models to this data. As the discussion tries to show, using these models enhances our understanding of the processes.

A criticism of this study could be that it simply collected and reports on the accounts of respondents. However, the strength of these accounts is that they are the opinions of people who have actually contributed to the formulating of contemporary policies and guidelines. Because of their closeness to the process, in reflecting upon their accounts and the contradictions between and within them, we are able to reflect on the thinking behind the policies and guidelines. In other words we are able to compare our document analysis of the policies and guidelines against the policy writers' opinions about evidence based guidelines and research utilisation. This data shows congruence between what is reflected in the policies and guidelines and the accounts, which respondents shared.

This study has not addressed the issue of implementation. Some respondents suggested that this may be a required. Respondents suggested that there may be problems at facility level (hospitals and clinics) around availability of the policies and guidelines, access to the drug, confusion around whether or not midwives are able to administer the drug, etc. However, problems of implementation were never a part of the research question. This question remains open for exploration in a further study.

A further limitation of this study has been that it was difficult in the context of the interviews to tease out the difference between respondents' acceptance of the evidence for the treatment of eclampsia and their acceptance of the treatment of pre-eclampsia. Some respondents suggested that the results from the Collaborative Eclampsia Trial (ETCG, 1995) were easier to implement than that from the Magpie Trial (MTCG, 2002), but in this study that difference was insufficiently explored. We suspect that the nature of specific evidence may be of similar importance to research utilisation as openness to the use of evidence in general, unfortunately the current data set does not allow further exploration of this possibility.

Although, the data raises many issues around the culture of evidence based medicine, in this discussion I have limited my comments to how this affected policy making and guideline development. Thus, for example, the fact that some respondents held very strongly the view that evidence was important yet at the same time believed that evidence was not needed if experience already showed one the "correct" way, is very interesting. The phenomenon under investigation however was not the building of an evidence based culture, but how different thinking paradigms ultimately influenced research utilisation in policy making and guideline development.

5.5. Implications for research utilisation in policy making

It is difficult to make recommendations on the basis of this study. However the following factors has a positive influence on research utilisation:

- The existence of a strong *network* who held influence over decision making at a national level
- The *strongly held belief* within this network that policy should be based on research evidence
- The willingness of certain individuals to act as *policy entrepreneurs* pushing forward the need for policy and the need to utilise research in that policy.
- The *readiness* of those policy entrepreneurs to take advantage of the *window of opportunity*, which opened with the change of administration.
- The *availability* of the evidence from randomised controlled trials at the time of writing the policies and guidelines.

Researchers may not be able to influence events such as a window of opportunity opening. However, researchers can ensure that the best evidence is constantly being produced and is accessible, they can organise themselves into networks in order to enhance their influence, and they can be willing to act as policy entrepreneurs when the opportunity arises.

5.6. Further research

A key area for further research is that of implementation. This data has shown that if the conditions are conducive then the utilisation of evidence from randomised controlled trials in policy making is possible. However, what happens after policy making? Are these policies being implemented? What influences this implementation or not? What are the health systems issues that facilitate or inhibit this process? How does the attitude of clinicians, doctors and midwives, interact with their willingness to follow these guidelines? To what extent does their sense of

agency impact upon this process? These are but some of the questions that could still be asked.

6. Conclusions

The seeds for evidence use in the recent policies and guidelines were already planted in the 1970's. This suggests that changing thinking around policy making and research utilisation takes a long time and a lot of work. This has to be done without the assurance that that things will change and that the opportunity will arise. It needs to be based on the hope of change. The people seeking a treatment solution to eclampsia and pre-eclampsia and the proponents of evidence based medicine were not assumingly doing so with the idea that South Africa would undergo great political change, they were simply working in their streams. We learn from this study that policy is indeed politics. The processes observed here suggest that the literature is correct in pointing out that an amiable political context is indeed necessary to promote the uptake of research information into policy making.

This case study is a positive example of research utilisation. As has been argued through this dissertation, the fact that research had been taken up so easily into policy does not imply that the process was not complex. What has been argued is that the opportunity to influence policy making can be erratic and out of the researchers' control. However, researchers can take on the role of policy entrepreneurs and push for their issue to come onto the policy making agenda and push for research to be utilised in that policy. The lesson is that when the opportunity arrives the researchers need to be ready, the research needs to be available and the researchers need to be

willing to engage with the policy making process to ensure that good research is appropriately utilised.

Very little in this study suggests that any of the observed processes were developing country specific. The focus however has been exclusively on the policy and guideline development stage without exploration of policy and guideline implementation. It is likely that the issues of resource limitation which are key to developing country settings are more likely to affect whether or not evidence based policies are implemented and acted upon than whether the evidence gets into the policy and guidelines or not.

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Appendices

Appendix One

Alliance for Health Policy and Systems Research Proposal

Alliance for Health Policy and Systems Research Alliance

RESEARCH TO POLICY GRANTS

Health System Development and Scaling-Up Priority Services

THIRD ROUND 2003-2004

RESEARCH PROPOSAL

THIS FORM SHOULD BE PREFERABLY SUBMITTED BY E-MAIL

alliance-hpsr@who.int

1.5 Abstract: (120 words maximum)

Well informed decisions about scaling-up priority services require at least three types of information: on local needs and resources (epidemiological and health services data); on the relative effects of alternative services; and on local values. This proposal focuses on access to and use of the second type of information in scaling-up priority services. It aims to improve the uptake by policy makers in low- and middle-income countries of findings from randomized controlled trials by describing the barriers and facilitators to the use of such findings. Qualitative case studies of two selected health policies will be undertaken in three Southern African countries: Mozambique, South Africa and Zimbabwe. The study will contribute to ensuring that scaling up utilises evidence based policies and programmes.

PART II. PROJECT INFORMATION

2.1 Aim: benefit expected from project for policy process or health system development (75 words maximum)

To improve the uptake by policy makers in low- and middle-income countries of findings from randomized controlled trials (RCTs) by describing the barriers and facilitators to the use of such findings.

2.2 Objectives: measurable project outputs in a logical, sequential order (220 words maximum):

In three different countries and for two selected health policies:

i. To describe the formal and informal structures; the political, economic and social context; and the processes through which health policy is developed.
ii. To compare and contrast the demographic, networking and organizational characteristics of the key (formal and informal) policy-makers.
iii. To describe the various interested parties at international, regional, and national level, the extent of their influence and their position regarding each policy.
iv. To explore policy makers' perceptions of what evidence is and the value attributed to different kinds of evidence; their knowledge of evidence from RCTs for the selected policies; their accounts of the use of different forms of evidence in policy making; and their position (for, against, neutral) regarding the use of evidence from RCTs for policy-making.
v. To examine how best to ensure that scaling up is based on policies and programmes that are evidence-based.
vi. To report the study findings at national, regional and international fora and in various journals and publications.

2.3 Background and justification

2.3.1 Health problems addressed and their ranking within national health priorities (180 words maximum):

This project addresses the translation of evidence from RCTs into health policy making. This will be explored through case studies of policies for two important health interventions: magnesium sulphate (MgSO4) for the control of preclampsia/eclampsia among pregnant women and insecticide impregnated bed-nets for malaria control.

Case study 1:
Pre-eclampsia and eclampsia are important contributors to maternal and infant morbidity and mortality in low-income countries (WHO 1988). Strong evidence is available of the effectiveness of MgSO4 for women with eclampsia and pre-eclampsia (Eclampsia Trial 1995; Duley 2003a; Duley 2003b; Magpie Trial 2002; Duley 2003c). However, there is concern that this safe, inexpensive drug may still not be available in many countries (Magnesium 2002; Mahomed 1998). Many women could benefit from these RCT results, provided they are scaled up into appropriate policies and actions.

Case study 2:
Malaria remains a major contributor to the burden of disease in low-income countries (WHO 2002). Trials have demonstrated the effectiveness of insecticide-impregnated bednets in reducing malaria incidence in endemic regions (Lengeler 2003). However, there are still controversies regarding the sustainability of bednet programmes and their relative effectiveness compared to traditional household spraying with insecticides (Curtis 2000; Lengeler 2001; Curtis 2001). Decision-makers need to assess these uncertainties in developing policies and scaling up interventions for malaria prevention.

2.3.2 Current structure and situation of the health system (270 words maximum):

Mozambique: Mozambique has a National Health Service based on the primary health care approach. This service provides the bulk of health care, although the numbers of both private providers and non-governmental organizations are increasing. The Ministry of Health produces a national formulary and an essential drugs list and determines which medicines are included in them. Within the Ministry of Health, the Departments of Reproductive Health Epidemic and Endemic Diseases make policy on use of antenatal/obstetric care and malaria control, respectively.

South Africa: South Africa has extensive public and private health systems. Public sector primary care is free and most antenatal care and malaria treatment are delivered within the public sector system. National guidelines for the treatment of eclampsia and pre-eclampsia have been formulated (DOH 1998; DOH 2003) and include the use of MgSO4. MgSO4 is widely available and previous studies suggest that it is used extensively for treating eclampsia but less extensively for pre-eclampsia (Aaserud 2003 – see abstract in section 2.10). National guidelines for malaria prevention recommend the use of both insecticide treated bednets and household spraying.

Zimbabwe: Zimbabwe has a national health system based on the primary health care approach. Over 90% of care is provided by government services and the missions, with the private-for-profit sector serving 8% of the population. The Ministry of Health and Child Welfare (MoHCW) produces a national formulary and an essential drugs list for public sector facilities. There is a long history of effective household spraying for malaria control, though recently insecticide-impregnated bed-nets have been piloted. MgSO4 is not used in public facilities for the management of eclampsia/pre-eclampsia, and in recent years, its availability has decreased. The MoHCW Planning Pool, (consisting of all department heads) is responsible for policy development.

2.3.3 Scaling-up or health system integration issues /problems addressed (400 words maximum):

Effective and affordable interventions are available for many of the health problems contributing to the burden of disease in low- and middle-income countries (WHO 2002). However, these interventions are often not implemented at national level, or are discarded in favour of unproven interventions. For example, research has indicated that in many settings MgSO4 is not recommended or available for the treatment of eclampsia and pre-eclampsia, despite strong evidence for its effectiveness (Aaserud 2003). This problem occurs even within the countries that generated the evidence of effectiveness. Good evidence of effectiveness from local or international studies is therefore not necessarily or consistently scaled up to national level or implemented as national policy. National policies promoting ineffective interventions are an inefficient use of scarce resources and may do harm.

In other circumstances, clear evidence is not available on the most effective and appropriate interventions to address a health problem. For example, insecticide impregnated bednets have been shown to be effective in experimental conditions but there are still questions regarding the sustainability of this intervention in low income communities, particularly if individual households have responsibility for maintaining nets and purchasing insecticide. Furthermore, debate continues on the relative effectiveness of treated bednets and house spraying with insecticide (Curtis 2000; Lengeler 2001; Curtis 2001). In these circumstances, the scaling up of interventions may be more problematic and policy makers may need to take judgements on the applicability of the evidence to particular settings. How policy makers weigh different types of evidence in making such decisions is not clearly understood.

Well informed decisions about scaling-up priority services require at least three types of information: information about local needs and resources (epidemiological and health services data); information about the relative effects of alternative services; and information about local values. This proposal focuses on access to and use of the second type of information in scaling-up priority services. Maternal child health and malaria are priority problems in all three countries. There is a significant avoidable disease burden from malaria and eclampsia, in part because the results of rigorous evaluations of the effects of interventions to address these problems have not been used to inform policy decisions. The gap between the production of rigorous evidence and development and implementation of evidence based policies is therefore a key factor in the pathway towards scaling up research findings and interventions.

2.3.4 Policy/health system actors and processes to be addressed by the project (330 words maximum):

There are two groups of actors who are key to addressing the gap between the production of evidence and its uptake into policies in low- and middle-income countries: policy makers at regional and national levels and researchers. This study plans to focus on the first group and will explore the barriers and facilitators experienced by policy makers to the uptake of findings from RCTs. Understanding these barriers and facilitators experienced by policy makers will, we anticipate, facilitate the development of interventions to increase the uptake of RCT evidence into policy making at national and regional levels. These interventions might include training or materials for policy makers. Such interventions contribute to ensuring that scaling up is based on policies and programmes that are evidence based. A model for this process can be found in the extensive body of research on the promotion of evidence-based clinical practice. This research has explored the barriers to implementation and tested a range of interventions such as academic detailing; training; and audit and feedback (Grimshaw 2001).

The complexity of the policy making environment, in terms of actors, content, context and process (Walt 1994a), suggests, firstly, that the development of interventions at this level will be a considerable challenge and, secondly, that the interventions are themselves likely to be complex and multi-faceted (Campbell 2000; Innvaer 2002). Because policy making is a profoundly political process, the case studies will locate the use of evidence within the political, economic and social contexts in which policy making occurs and explore the processes through which policy making occurs.

In each of the three case study settings (Mozambique, South Africa, Zimbabwe), the research teams are already working closely with national and regional departments of health. This should facilitate access to policy makers as well as subsequent uptake of the study findings.

2.3.5 Expected benefits of research project for policy/health system development (120 words maximum):

This research will have important benefits for policy development because it is about policy making, and how to ensure that scaling up is based on policies and programmes that are evidence based. More evidence-based policies will contribute to health system development by reducing the inefficient use of resources on ineffective interventions. These resources may then be available for interventions that have been shown to impact positively on service delivery and on health and well-being. The research process itself and the dissemination of the findings may draw the attention of policy makers to the important role of evidence in policy making. The study will also contribute to a better understanding of health policy making in the southern African region.

2.4 Conceptual framework and bibliographic review (580 words maximum)

Low and middle-income countries are faced with a number of difficulties in providing equitable, appropriate and accessible health care. One of these challenges is reconciling health needs with available resources. Interventions of proven effectiveness and affordability need to be identified, piloted and scaled up to national level.

There is a growing body of evidence on interventions that are efficacious, affordable and appropriate (Cochrane Library 2003; WHO 2002). Nonetheless, these interventions are often not implemented or scaled up. It is not clear what factors affect the uptake of evidence regarding the effectiveness of interventions into policy making. A recently completed systematic review (Innvaer 2002) and case study (Aaserud 2003) showed the following:

- There is only limited evidence supporting the many views in the literature on how policy makers use research evidence. Barriers and facilitators of the use of research evidence in policies are still poorly understood. This is a particular problem with regard to the uptake of evidence from RCTs into policy making in low- and middle-income countries. Only 4 of 24 eligible studies in the review were conducted in such settings (also see Garner 1998).
- The relationships between the production of evidence and the development and implementation of evidence-based policies are complex, variable and poorly understood. It is therefore not clear how best to ensure that priority health problems are addressed in an evidence-based way when programmes are scaled up to national level.

A related question is what constitutes 'evidence' in the eyes of policy makers? This may include findings from RCTs as well a wide range of other 'evidence', including the views of important stakeholders (Rosen 2000). Further investigation is needed of how these different forms of evidence are utilised, both directly and indirectly (Elliott 2000), in policy making.

To address these questions, this study will explore the factors affecting the uptake of evidence into policies. A case-study approach will be used. Rather than testing any one of the large number of policy making theories (Walt 1994b; Sutton 1999), this study will use an inductive approach and will draw on the data collected to develop an understanding of how evidence is used in policy making. The model derived from this process will then be related to relevant theories.

Policy making for two different types of intervention will be examined: community-based (bed-nets as against insecticide spraying), compared with hospital (magnesium sulphate). These cases also represent two different priority health areas: reproductive health and infectious diseases. Studying two different conditions from different areas will allow for important differences in evidence use to be elucidated. The case studies will be drawn from three countries: Mozambique, South Africa and Zimbabwe. Although there are some similarities between countries, there are differences in health systems and resources; in current and past policies with regard to malaria control and the treatment of preclampsia/eclampsia; and in their relationships to national and international policy networks. Including three countries will help to illuminate the similarities and differences in policy making across different settings, thereby improving the generalisability of the study findings.

We have focused in particular on the use of evidence from RCTs as these are widely accepted as producing the most robust evidence of the effectiveness of health care interventions. However, we acknowledge that RCTs are not always feasible and that, in some instances, observational studies may provide better evidence. Moreover, the results of randomized trials may not always be applicable, if for example, the participants are highly selected and motivated relative to the population of interest. Hence this study looks at the range of evidence used by policy makers in their decision making.

2.5 Project design and methods

2.5.1 Research questions and/or hypotheses (240 words maximum):

Main research question: What are the barriers and facilitators to the use of findings from RCTs by policy makers in low- and middle-income countries?

Specific sub-questions:

1. What are the formal and informal structures and the processes through which health policy is developed in each setting?
2. What are the political, economic and social contexts in which policies are being made?
3. What are the demographic, networking and organizational characteristics of the key (formal and informal) policy-makers?
4. How do policy makers perceive 'evidence' and what values do they attribute to different kinds of evidence?
5. What is policy makers' knowledge of evidence from RCTs for the selected interventions?
6. How do policy makers use different forms of evidence in policy making?
7. What are policy makers' views regarding the use of evidence from RCTs for policy-making?
8. How do other stakeholders at international, regional, and national level influence policy making for the selected interventions?
9. How can it be ensured that scaling up is based on policies and programmes that are evidence-based?

2.5.2 Population and/or actors to be studied (260 words maximum):

Health policy makers:

- The study will focus on national level policy makers (Ministry of Health) in 3 countries (Mozambique, South Africa and Zimbabwe) as well as selected provincial policy makers in South Africa.
- Policy makers will be selected on the basis of being currently, or in the recent past, involved in developing policies, firstly, for the use of magnesium sulphate for the control of pre-eclampsia / eclampsia and, secondly, for the control of malaria using insecticide impregnated bednets and / or household insecticide spraying. The informants need to be of sufficient seniority to be able to take policy decisions, for example on programme specifications. These individuals will generally be Directors or Deputy-directors of units in the ministries of health. The majority can be expected to be health professionals.

Other policy actors:

- We will also include informants from relevant non-governmental, international and regional organisations operating in the three study countries.
- The informants will be selected on the basis of having been directly or indirectly involved in policy development for the case study policies. Direct involvement might include participation on a committee developing management guidelines or the provision of advice directly to the primary policy makers. Indirect involvement might include formal or informal lobbying of policy makers regarding policy decisions or the submission of materials to inform policy making on a particular topic.

As we will be using a qualitative approach, it is not possible to indicate in advance precisely the number of actors that will be included (see section 2.5.5). Data collection will rather continue until theoretical saturation is reached (Brewer 2000).

2.5.3 Key variables and indicators (260 words maximum):

Objective (see section 2.2)	**Verifiable Indicators***
Objective 1	Structures, context and processes of health policy described by month 3.
Objective 2	Characteristics of key policy makers compared by month 6.
Objective 3	Policy actors at various levels described by month 7.
Objective 4	Use of evidence in policy making explored by month 8.
Objective 5	Implications for scaling up examined by month 8.
Objective 6	Study findings reported in various fora by month 12.

* Please note that it is not possible to identify dependent and independent variables for qualitative research. Verifiable indicators of project progress have therefore been listed here.

2.5.4 Bibliographic and documentary research strategy (150 words maximum):

A literature review will be conducted of the factors associated with the uptake of research findings into policy. This will complement and update an existing systematic review on health policy-makers perceptions of their use of evidence in which one of the research team was involved (Innvaer 2002). This review included studies published up to June 2000.

Search strategy:
Using combinations of index terms and text words developed for the earlier review, we will search the following databases from July 2000 to December 2003: Medline, EMBASE, International Bibliography of the Social Sciences; PsycInfo; ISI Web of Science; United Kingdom NHS National Research Register; and the International Political Science Abstracts.

Selection criteria:
We will include interview studies and surveys with health policy decision-makers regarding their use of research evidence in health policy decisions. Studies of clinical decision-making for individual patients will be excluded (Innvaer 2002). Data on the study characteristics, methods used and key findings will be extracted from each included study.

2.5.5 Empirical data sources and observation methods, including sampling and measurement techniques (330 words maximum):

A qualitative case-study methodology is useful to explore this topic given the complexity of the issues involved. This approach involves '...the investigation of a *relatively small* number of *naturally occurring* (rather than researcher-created) cases' (Hammersley 1992 p185, original italics). The selected social units (in this instance, a particular policy making process) are viewed as a whole, allowing relationships and processes to be examined (Mitchell 1983).

The methods will include the following:

1. A literature review of the factors associated with the uptake of research findings into policy (see above).
2. A brief document review of the history, structure and processes of policy making for the two policies in each country. Relevant documents from regional organizations (e.g. SADC) and the WHO will also be examined.
3. Review of the use of RCT evidence in existing policies on the treatment of pre-eclampsia / eclampsia in pregnancy and on the use of bednets / household spraying to prevent malaria.
4. In-depth, semi-structured qualitative interviews with policy makers and other policy actors (see section 2.5.2) exploring the following issues:
   - the structure and process of policy making
   - individual's perceptions of what evidence is; the value attributed to different kinds of evidence, and how this has changed over time
   - individual's knowledge of evidence related to the selected policies and their accounts of the use of this evidence, including evidence from RCTs, in policy making
   - factors facilitating/inhibiting the use of data from RCTs to inform policy
   - other stakeholders in the policy making process; their position on various policy and policy options: the reasons for their position; and the extent of their influence.

A copy of the draft interview guide is included in section 2.10.

Informants will be purposively selected to represent the range of policy actors identified above. Analysis of data from the early interviews will inform subsequent data collection, allowing emerging themes to be further explored (Brewer 2000). We estimate that approximately ten to twenty individuals will be interviewed in each country.

2.5.6 Methods to ensure validity and reliability of observations (160 words maximum):

- An iterative approach to data collection will allow emerging themes to be further explored in later interviews.
- Interviews will be taped, transcribed verbatim and (where necessary) translated into English. Interviewers will keep fieldnotes of their thoughts and responses during the interview. These will inform data analysis.
- Systematic and comprehensive analysis of the data will be undertaken.
- The research team will work collaboratively to develop the coding frame (researcher triangulation [Denzin 1989]). A sample of transcripts will be coded by two researchers to ensure that the coding frame is being applied consistently.
- The constant comparative method, in which the codes emerging from the data are constantly compared to new data and thereby refined and elaborated, will be used (Brewer 2000). Deviant cases, i.e. informants whose opinions are different to the majority, will be examined to ascertain the generalisability of the emerging themes.
- Preliminary findings will be fedback to stakeholders for comment and their responses used to inform subsequent work.

2.5.7 Ethical issues and protections (150 words maximum):

An application for ethics approval will be submitted to the appropriate Institutional Review Board (or Ethics Committee) in each country. Permission to interview Ministry of Health staff will be requested from Directors of the appropriate units (e.g. Maternal and Child Health; Malaria Programme).

For in-depth interviews, informed consent will be obtained in writing from each informant. Informants will be provided with an information sheet summarising the objectives of the study; the purpose of the interview; and their rights as interviewees. They will be assured that non-participation will not compromise their employment in any way. All informants will be also assured of anonymity and confidentiality in the writing of the project report. Pseudonyms or generic terms (such as "programme manager") will be used to identify informants in project outputs.

Original interview transcripts will be kept in locked filing cabinets and will be accessible only to the research team.

2.5.8 Main conceptual challenges in project design/methodology, and expertise required to overcome them (180 words maximum):

Conceptual challenge	Expertise required
Developing a coherent coding frame for qualitative data from multiple research settings.	Analysis of large qualitative datasets generated from multiple settings and in different languages.
Developing an understanding of the country- and policy-specific contextual factors that influence the uptake of RCT findings into policy.	Policy analysis, particularly in low- and middle-income settings.
Developing an understanding of policy makers' constructions of 'evidence' and how these constructions influence the ways in which policies are made and implemented.	Familiarity with the sociology of science and technology.
Moving from an understanding of the barriers and facilitators to using RCT evidence in policy making to the development of interventions to promote evidence based policy making.	This will need to be the subject of further studies, but expertise in this area would probably add depth to this project.

2.6 Data analysis methods

2.6.1 Processing of data and construction/development of databases (150 words maximum):

All interviews will be audiorecorded and transcribed. This will be done by a transcriber employed for this purpose. Approximately 8 hours is required to transcribe 1 hour of audiorecording. A sample of transcripts will be checked for accuracy against the original audiorecordings. Features in the interview that may identify specific individuals will be changed or removed to maintain the anonymity of informants.

The transcripts will then be uploaded into the NUD*IST qualitative analysis package in each country. NUD*IST requires a PC with the following specifications: 100MHz or better processor; 128 MB RAM; 15MB of free hard disk space for installation; a monitor with a minimum 800 x 600 resolution (1024 x 768 recommended); and a CDROM drive.

A master file of all transcripts will be held in a secure location by the principal investigator.

2.6.2 Statistical methods (220 words maximum):

Not applicable

2.6.3 Qualitative interpretation methods (200 words maximum):

Preliminary coding of each transcript will be done in NUD*IST, allowing a database of codes and, subsequently, themes, to be developed. Use of NUD*IST will facilitate the sharing of coding frames between country teams. Initial data analysis will be undertaken at country level, thereby drawing on each country team's familiarity with the local setting. The country teams will 'open code' the transcripts by reading through the data and noting ideas about the issues raised by informants (Strauss 1990). A coding frame, divided into major themes and sub-themes, will then be built. The analysis will focus on identifying key themes and issues with regard to the roles of evidence, and particularly evidence from RCTs, in policy making.

The preliminary coding frames will be circulated between the country teams and a joint coding frame then developed during a meeting of the research team. This will facilitate cross-country and cross-case comparisons. The interviews will then be re-coded according to this coding frame. The themes will later be framed within relevant theoretical perspectives and examined in relation to the empirical work of others, as identified in the literature review. In writing up the study, the key themes will be illustrated by relevant data extracts.

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Appendix Two

Draft interview guide

Draft of 27 April 2004

Introduction:
Our study is exploring the use of different kinds of information in the process of policy making. We are doing this by examining policy making for the treatment and prevention of eclampsia and pre-eclampsia and for the use of insecticide treated nets or insecticide spraying in the prevention and control of malaria. I am here today to talk to you as someone who has experience with the research and policy making for eclampsia and pre-eclampsia. What we would like to know more about is the factors that led up to this policy, and we can go back as far as you like. We are developing a timeline in this regard, which I would appreciate your comments on. We would also like to know about your specific role in this process and how you understand the role of the other actors.
Probe:

- role players / interest groups
- significant events / ideas
- significant institutions
- use of different types of evidence
- previous policies

Questions for magnesium researchers	Reminder notes
Background of respondent • Official position • Background and training	
What is the *current* official national *policy* with regards to the management of eclampsia? (What the DoH says clinicians should do). What is the *current* official national *policy* with regards to the management of pre-eclampsia? (What the DoH says clinicians should do). [In what way is this different from the provincial policy(ies)?] Are there 'unofficial' policies or understandings of how eclampsia should be managed? Are there 'unofficial' policies or understandings of how pre-eclampsia should be managed?	• Eclampsia is always treated, but drugs may include MgSO4, phenytoin or diazepam. • Pre-eclampsia is not always treated.
Would you describe the *process* by which the policy(ies) was arrived at?	
To what extent were *you* involved in this process? To what extent has your research been used in policy? (If they were involved themselves then ask) To what extent have you used other people's research in your contribution to the policy making process?	
Introduce the timeline and ask the respondent to comment on it and suggest changes / additions. Probe on: • When and how the management of eclampsia / pre-eclampsia got on to the policy agenda • When MgSO4 was licensed in the country [For Zim: why not licensed] • Whether it is locally produced or imported	• Timeline • MgSO4 has been on the WHO EML from 1996

• Whether it is on the essential medicines list for the country and, if so, when it was added to the list • 'Landmark' events with regard to policies on the management of eclampsia / pre-eclampsia e.g. meetings of networks; visits of international experts; publication of papers; evaluations	
I would like to talk about the other *stakeholders* involved in this process of policy making with regard to the management of eclampsia and pre-eclampsia. Tell me about the individuals and groups who were particularly influential in initiating the process. (Probe international agencies, donors, international NGO's as groups). What were their specific roles? For each, what was the level of influence? How were they able to influence the policy process? Who has been responsible for formulating or drafting the policies on the management of eclampsia / pre-eclampsia? What were their specific roles? What role if any did you play in this process? (probe for networks in which they are / were involved)	
What sort of information or evidence was drawn upon in formulating policy on the management of eclampsia / pre-eclampsia? How were these different kinds of evidence or information obtained? How useful were they? Earlier we discussed the different people and groups involved in the process of policy making. In what ways were they responsible for providing and generating information or evidence? (Probe for use of expert opinion).	
Of the information and evidence gathered, what contribution did evidence from randomised control trials and systematic reviews [or systematic summaries] make? Could you tell us more about which trials and reviews were referred to and if any of these were more or less influential than the rest? What factors influenced the use of RCT and systematic review evidence in policy making for eclampsia / pre-eclampsia?	Prompt using timeline
Still staying with our discussion on information, what value would you say was placed on these different kinds of evidence or information? Why? Was there any process of validating information and evidence from all of the different sources? How was the strength of evidence for different policy options assessed? Were there any differences of opinions / controversies among those drawing up these policies? How did you decide how to weight these different opinions? Were there any uncertainties with regard to the information during policy formulation? If so, how were these dealt with?	Have there been any shifts over time in the types of evidence and information used in policy making? Has the way in which evidence and information is used changed over time?
Did the way in which evidence was used in this case differ from other policy processes in which you have been involved? If so, how?	

How is eclampsia / pre-eclampsia currently treated? If a treatment policy is available, how has it been distributed and implemented? Is there any monitoring of the implementation of the policy / guidelines? Who is responsible for monitoring?	
? probe confidence in recollection of the events discussed above	
Suggestions of other policy actors who should be interviewed. Suggestions of documents that should be examined.	

Appendix Three

Extended Timeline

This unabbreviated timeline is a working document. It should be read in the same way that an interview transcript is read. The timeline, like an interview has been used as a means to collect data.

Year	Key Events and Processes	Source
Egyptian times till Prior to 1970's	Long history of attempts to find suitable treatment for eclampsia and pre-eclampsia. There is disagreement as to how to best to do so and several different regimes were followed. However the publication of Pritchard case series (1955) on the use of MgSO4 for eclampsia was very influential. This updated every 10 years for 30 years (1967, 1975, 1984). "Despite the lack of any control group for comparison these reports have had a huge influence on the clinical practice of several generations of obstetricians, both in the United States and in many other parts of the world." (Duley, L., thesis) In 1968 a research group of British physicians in Hong Kong suggested the use of diazepam (conventional anticonvulsant) for the treatment of eclampsia. By 1970's diazepam used widely in UK.	Duley, L., Evidence and Practice: The MgS04 story Duley, L. Thesis Duley, personal communication
1970s	Oxford database of peri-natal trials set up (see further details below)	
	Change from Valium to MgSO4 at Stellenbosch Med School, based on evidence from Pritchard case series, and introduced by Paul de Villiers from Harare. Changed to MgSO4 at UCT based on reading of American literature. Attention to eclampsia/ pre-eclampsia as cause for maternal mortality. At least three articles in SAMJ refer (1973 & 1977)	Interviews PubMed
1974	Card file of references to controlled trials in perinatal medicine established; MEDLINE search strategy designed and implemented monthly	Copied from: Starr M, Chalmers I. The evolution of The Cochrane Library, 1988-2003. Update Software: Oxford (www.update-software.com/history/clibhist.htm). Accessed Thursday 5 May 105 .
1978	Grant provided by Maternal and Child Health Unit, WHO, Geneva, enabling systematic hand-search for reports of perinatal trials to begin World Health Organisation and English Department of Health fund work at National Perinatal Epidemiology Unit, Oxford, UK to assemble a register of controlled trials in perinatal medicine (Copied from: Chronology of the Cochrane Collaboration http://www.cochrane.org/docs/cchronol.htm Accessed Thursday 5 May 2005)	
1979	First overview (meta-analysis) of perinatal trials published (Chalmers 1979). Archie Cochrane publishes an essay in which he suggests that *"It is surely a great criticism of our profession that we have not organised a critical summary, by specialty or subspecialty, adapted periodically, of all relevant randomised controlled trials."* He also designates obstetrics the least scientific medical specialty! (Copied from: Chronology of the Cochrane Collaboration http://www.cochrane.org/docs/cchronol.htm Accessed Thursday 5 May 2005)	
1980	Introduction of pilot classification system for perinatal trials	
	Paper by in SAMJ by Moodley discusses drugs commonly used for hypertension in pregnancy and reviews recent literature, Moodley J, The management of hypertension in pregnancy: A review, S Afr Med J. 1980 Jul 19;58(3):103-9	Pubmed

	Suggests early attention to seeking out evidence. Moodley continues to publish extensively in area, up until present. Growing attention given by South African researchers to eclampsia, pre-eclampsia and it's treatment, continues to present. 1990's even more studies than 1980's	
1980s	Phenytoin introduced in the UK for the management of eclampsia.	?
1982	"The Perinatal Conferences were established in 1982 by Alan Rothberg, formerly Head of the Division of Neonatology at the Johannesburg Hospital and Professor and Head of the Department of Paediatrics and Child Health, University of the Witwatersrand. The Conference serves to bring together a range of health professionals involved in and committed to maternal and perinatal health. Through some of the darkest years of South Africa's history, contacts were established and maintained between universities, medical and allied disciplines, urban and rural areas and academic and non-academic centres. Important international links were also forged with many experts in the field of perinatology."	Copied from: http://www.perinatalpriorities.co.za/ Accessed 6 May 2005
1983	Links established between SA researchers and Oxford Database of perinatal trials and Iain Chalmers	
1985	Grant from Oxford University Press to develop database for eventual release as an electronic publication.	Copied from: Starr M, Chalmers I. The evolution of The Cochrane Library, 1988-2003. Update Software: Oxford (www.update-software.com/history/clibhist.htm). Accessed Thursday 5 May 105
1986	Development of database of perinatal trials documented in *Controlled Clinical Trials* and *WHO Chronicle*	
1988	Publication of *'Oxford Database of Perinatal Trials (ODPT)'* (Version 1.0, Disk Issue 1) Publication of the first in a series of overviews (meta-analyses) in the *Br J Obstet Gynaecol*	
Late 1980s	Controversy among clinicians regarding the relative benefits and harms of MgSO4, phenytoin and diazepam. Duley started working on hypertension - with Chalmers as supervisor. Also worked closely with Godfrey Walker (Director of the Safe Motherhood Programme) at WHO. This was the period when there was a lot of focus on maternal mortality – Lancet paper – 'where is the M in MCH' etc. The rationale for focusing on hypertension was to understand how much maternal mortality was due to hypertension. (Although infection and haemorrhage are the main causes of maternal mortality in poor countries).	
1986	First presentation on pre-eclampsia at Perinatal Conference by HJ Odendaal, between then and 2003 48 papers are presented on eclampsia & pre-eclampsia collectively covering range of related issues	Database of Proceedings of the Priorities in Perinatal Care Conferences (PPCC)
1988	Murray Enken from Oxford Database attends PPCC, presents paper entitled Effective Care in Pregnancy and Childbirth	Ibid
1989	Iain Chalmers first presents at PPCC paper entitled Obstetric prevention of morbidity associated with preterm birth of normally-formed babies following spontaneous labour	Ibid
Early 1990s	MgSO4 used in management of pre-term labour in the USA – passionate belief that tocolytic, although no evidence for this.	

	South African starts to shift towards the use of phenytoin for the management of eclampsia.	
1990	Dommisse RCT of MgSO4 vs phenytoin for eclampsia published in BJOG 1990 Feb;97(2):104-9(22 patients).	? & PubMed
1991-2	Duley report to WHO and paper in BJOG shows that hypertension in pregnancy probably responsible for 10-15% of maternal deaths in developing countries, almost all due to eclampsia.	
1991	Duley systematic review on treatments for eclampsia published. Concluded that insufficient evidence regarding the relative effectiveness of 3 commonly used drugs - only three trials, all comparing drugs, and with small numbers of women. Commonly believed that an RCT of treatments for eclampsia was not ethical or feasible as the patients could not consent to participate. Also a sense in WHO and among NGOs that the problem would be addressed by better access to care. There seemed to be antipathy to RCTs within many sections of WHO. Godfrey Walker important to changing this.	
1992	Duley first presents at PPCC entitled Anticonvulsants in the management of eclampsia Chalmers presents paper entitled: Clinicians and researchers don't seem to care very much about maternal morbidity. Quote from abstract, "It is time for clinicians and researchers to make it clearer to women that they do care about maternal as well as child health".	Database of the proceedings of PPCC
Feb 1992	Encouraged by the reception given to the systematic reviews of care during pregnancy and childbirth, Michael Peckham, first Director of Research & Development in the British National Health Service, approves funding for 'a Cochrane Centre' 'to facilitate the preparation of systematic reviews of randomised controlled trials of health care'	(Copied from: Chronology of the Cochrane Collaboration http://www.cochrane.org/docs/cchronol.htm Accessed Thursday 5 May 2005)
Oct 1992	'The Cochrane Centre' opens in Oxford, UK Pregnancy and Childbirth Group registered	
1992	Eclampsia Trial protocol written. This eventually funded by WHO, although against huge resistance – on ethical grounds. The whole thing nearly fell apart when WHO insisted on getting informed consent, which the researchers argued would be impossible from women who could be unconscious. Godfrey Walker was key in turning around the reluctance, and Lelia started with 300 women in S America, and then it expanded to 800 women in Argentina, Colombia and Venezuela – with funding from Dfid (then ODA for extension to Africa and India) The trial treatment protocol was very clearly designed and left choice of drugs (comparing 2 out of 3 [phenytoin, diazepam, MgSO4]) to the countries concerned. Centres in Africa included Harare (Kassan Mohomed); Durban (Moodley); Jo'burg (Hofmyer); Pretoria (Pattinson)	
	Naidu S, Moodley J, Botha J, McFadyen L, The efficacy of phenytoin in relation to serum levels in sever pre-eclampsia and eclampsia, Br J Obstet Gynaecol, 1992 Nov;99(11):881-6	Pubmed
Apr 1993	Update Software reissues *'The Oxford Database of Perinatal Trials (ODPT)'* as a redesigned pilot electronic journal entitled *'The Cochrane Pregnancy and Childbirth Database (CCPC)'*	(Copied from: Chronology of the Cochrane Collaboration http://www.cochrane.org/docs/cchronol.htm Accessed Thursday 5 May 2005)
	At the same time, the then recently established Research and Development Programme of the UK National Health Service had recognised the value of the work being done at the National Perinatal Epidemiology Unit and provided funds for a new centre, the UK Cochrane Centre, to promote an extension of the process to other areas of healthcare.	Copied from: Starr M, Chalmers I. The evolution of The Cochrane Library, 1988-p2003. Update Software: Oxford

	The development and launch of *CCPC* thus coincided with the opening of the UK Cochrane Centre in October 1992, and planning for the launch of the international Cochrane Collaboration in October 1993. *CCPC* was designed in part as a pilot to show how Cochrane Reviews in all areas of healthcare could be published electronically.	(www.update-software.com/history/clibhist.htm). Accessed Thursday 5 May 105
1994	Change of government in South Africa **PEP started, Manuals updated in 1998 & 2000** South African Constitution guarantees equality for women, right to health care including reproductive heath care, right to dignity. Free health care for pregnant women and children under the age of 6	Penn-Kekana & Blaauw
1995	Collaborative Eclampsia RCT findings published. Showed MgSO4 to be the most effective drug for treating eclampsia. Rapid and extensive changes to eclampsia management in the UK follow.	
	An article in Safe Mother (1995, (18):3, 13) suggests that as a result of the Collaborative Eclampsia Trial findings, "the World Health Organisation plans to ensure that magnesium sulphate is readily available in all countries, possibly through inclusion on the Essential Drugs List."	PubMed Abstract
	Senior obstetricians publish editorial on implications of eclampsia trial for SA. Moodley J, Hofmeyr, GJ, Howarh G., Pattinson B, The eclampsia trial—implications for South Africa, S Afr Med J 1995 Aug; 85(8): 746-7	
	First papers on maternal mortality presented at PPCC, three under section entitled Safe Motherhood: Iliff, VF: Maternal mortality in Harare: Trends, causes and concerns Larsen, JV, Janowski, K, Kronlikowski, A: Maternal mortality in Zululand Hospitals Moodley, D, Moodley J, Adhikari, M: Perinatal and maternal mortality in some urban and rural South African hospitals Theron, GB, Maternal mortality in the Cape Province, South Africa (61 presentations with maternal mortality in keywords between 1995-2003)	PPCC proceedings database
1996	MgSO4 added to WHO's Essential Medicines List. **Maternal Child and Women's Health Policy Committee- MCWH organised in its own directorate with a National Director.**	Penn-Kekana & Blaauw
	Moodley, D., Payne AJ, Moodley J., Maternal mortality in Kwazulu/Natal: need for an information database system and confidential enquiry into maternal deaths in developing countries, Trop Doct 1996 Apr;26(2)50-4 * Academic Advocacy for confidential enquiry	Pub Med
Oct 1996	• Appointment of the NCCEMD Appointment of the NCCEMD in October 1996 • First committee appointed from October 1996 to 31 March 1999 **Chairman** Prof. Jack Moodley **Editor of Reports** Prof. Bob Pattinson **Members** Ms D Nyasulu, Dr RE Mhlanga, Dr R Mulumba, Dr G Theron, Ms L Mangate, Prof. H van Coeverden de Groot, Dr N Simelela, Mrs E Retief, Dr Makiwane, Prof. H Cronje **Hon. Member** Prof. JO Drife	http://www.doh.gov.za/department/subdir_maternal.html accessed 24/2/04 2:59 pm

	South African Cochrane Centre registered	Chronology of Cochrane Collaboration
1997	All maternal deaths made notifiable & National Committee on Confidential Enquiries in Maternal Deaths appointed	Penn-Kekana & Blaauw
	Announcement to make maternal deaths a notifiable event from the 1st December 1997 as appeared in the October 1997 Government Gazette	http://www.doh.gov.za/department/subdir_maternal.html accessed 24/2/04 2:59 pm
1998-2001	Duley et al., recruit for Magpie RCT of MgSO4 for treatment of pre-eclampsia i.e. for prevention of eclampsia. Recruited patients from 33 countries. Trial stopped earlier (2002) because the drug was so effective	
	Coetzee EJ, Dommisse J, & Anthony J, publish trial set in SA: A randomised controlled trial of intravenous magnesium sulphate versus placebo in the management of women with severe pre-eclampsia, Br J Obstet Gynaecol 1998 Mar, 105(3):300-3	PubMed
1999	No national guidelines. Provinces and others doing their own things, using varied sources of evidence including expert opinion, research etc.	Interviews, Penn-Kekana & Blaauw
	National Committee on Confidential Enquiries into Maternal Deaths (NCCEMD), **Saving Mothers: Report on Confidential Enquiries into Maternal Deaths in South Africa, 1998**, Chairman- Prof. Jack Moodley, Editor of Report- Prof. Bob Pattinson, National Department of Health, Pretoria, South Africa	Documentation, Penn-Kekana & Blaauw
	• Second committee appointed from 1 April 1999 to 31 March 2001 **Chairman:** • Prof. J Moodley, Director MRC/UN Pregnancy Hypertension Research Unit, Head Department of Obstetrics and Gynaecology, University of Natal. (From 1996) **Editor of the reports:** • Prof. RC Pattinson, Director MRC Maternal and Infant Health Strategies Research Unit, Clinical Head, Department of Obstetrics and Gynaecology, University of Pretoria. (From 1996)	http://www.doh.gov.za/department/subdir_maternal.html accessed 24/2/04 2:59 pm
	National Maternity Case Record	Penn-Kekana & Blaauw
	Magpie Trial pilot results from SA centre presented at PPCC:- Pattinson, RC, Magnesium sulphate for the treatment of pre-eclampsia: A trial to evaluate the effects on women and their babies (The Magpie Trial). Results of the pilot study at Kalafong	PPCC proceedings database
2000	Magpie Trial presented at PPCC:- Duley, L., The Magpie Trial: Magnesium sulphate versus placebo for women with pre-eclampsia Abstract suggests the presentation was an attempt at further recruitment of researchers/ research centres	PPCC Proceedings Database
	National Maternity Care Guidelines Committee (NMCGC) of the Department of Health, Chairperson, Prof. EJ. Buchmann, **Guidelines for Maternity Care in South Africa: A manual for clinics, community health centres and district hospitals**, Pretoria	Documentation
	Manyemba, J. Magnesium Sulphate for Eclampsia: Putting the evidence into clinical practice, Central Afr J Med 2000 Jun;46(6):166-9 "This paper seeks to encourage African governments, teaching hospitals, the pharmaceutical industry and the regional Cochrane Collaboration Centre in South Africa to co-operate in order to facilitate the practice of evidence-based medicine in this aspect of maternal health in the region."	Pub Med

Oct 2000	8th Cochrane Colloquim in Cape Town 11th Meeting of elected Steering Group in Cape Town	Chronology of the Cochrane Collaboration
2001	NCCEMD, **Saving Mothers: Policy and Management Guidelines for Common Causes of Maternal Deaths**, National Department of Health, Pretoria, South Africa, **(2001)**	Documentation
	Presentation of by NCCEMD at PPCC:- Changing patterns in maternal mortality in South Africa: 1998-2000	PPCC database
2002	Magpie RCT findings published, Lancet.	
	NCCEMD, **Saving Mothers: Second Report on Confidential Enquiries into Maternal Deaths in South Africa, 1999-2001**, Chairman, Prof. Jack Moodley, Editor of Report- Prof. Bob Pattinson, National Department of Health, Pretoria, South Africa National Maternity Care Guidelines Committee (NMCGC) of the Department of Health, Chairperson, Prof. EJ. Buchmann, **Guidelines for Maternity Care in South Africa: A manual for clinics, community health centres and district hospitals, 2nd Edition**, Pretoria	Documentation
2003	Clinical practice article in SAMJ on implications of Magpie trial for poor countries. Recommends the use of MgSO4 for women with moderate to severe pre-eclampsia where it can be administered safely	
	South African researcher/ senior obstetrician (John Anthony) co-publishes on a trial comparing nimodipine with magnesium sulphate. Not clear if trial or part of trial is set in SA.	PubMed
2004	Moodley, J Maternal deaths associated with hypertensive disorders of pregnancy: a population-based, Hypertens Pregnancy Nov;23(3):247-56 *This paper raises the need for clear management protocols at all levels (i.e. suggesting these are not yet in place)	Pubmed

The student used colour coding in the timeline as a means of organising or group key events for later narrative description. Below is a key to this coding:

Treating eclampsia and pre-eclampsia: Research and practice

Growing a culture of evidence based medicine in obstetrics

Political change in South Africa

Maternal Mortality Monitoring

Policies and Guidelines