Making Childbirth Safer

Through Promoting Evidence-Based Care

Towards an Evidence-Based Approach to Decision Making

Reducing Maternal Mortality Through Evidence-Based Treatment of Eclampsia

Reducing Postpartum Hemorrhage: Routine Use of Active Management of the Third Stage of Labor

The WHO Reproductive Health Library (RHL)

Better Births Initiative: A Programme for Action in Middle- and Low-Income Countries

Using Evidence to Save the Lives of Mothers

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Towards an Evidence-Based Approach to Decision Making

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Introduction

Thousands of mothers and babies die or become seriously disabled every year through complications of pregnancy and childbirth. These tragic events can, in many instances, be avoided through the application of relatively simple health-care interventions. While in poor countries these interventions may not be accessible, there are situations in which available treatments are used inappropriately or not all, because practitioners and policy makers do not consistently heed the results of the best available research when making decisions about health care. The limitations of expert opinion and traditional reviews as guides to current best practice have been well-documented.[1,2] For example, a study comparing expert advice with available evidence from research concluded that patients are often denied effective treatment while other interventions continue to be recommended years after research has shown them to be ineffective or harmful.[2] In this report, we highlight some recent efforts to strengthen the evidence base for the care of pregnant women. In addition, we draw attention to innovative methods that are being used in various parts of the world to promote evidence-based obstetric care.

Where is the evidence?

Too many health-care decisions are still made solely on the basis of tradition (what we've always done), anecdote (someone once told me), and clinical observations (in my hands this treatment works well) rather than the findings of carefully conducted clinical studies. Experience confirms that even reasoning from pathophysiological principles (what should work) is no guarantee for what does work in health care. While clinical impressions, uncontrolled case series or studies using non-randomized controls all have their place in generating hypotheses about what treatment might be useful, they suffer from the unfortunate disadvantage of not being able to control for differences in patient characteristics that influence outcomes. History is replete with examples of observed effects being erroneously attributed to new forms of treatment based on these approaches, sometimes with disastrous consequences for patients. The randomized controlled trial is currently the only means available for adjusting for known and unknown differences between patient groups and, therefore, constitutes the most reliable form of evidence for what does and does not work in health care.

An evidence-based approach in the field of obstetrics has evolved over the past two decades. In 1989, Chalmers, Enkin and Kierse published the first comprehensive collation of evidence concerning the effects of obstetric care. This two-volume compendium, entitled *Effective Care in Pregnancy and Childbirth (ECPC)*,[3] included 283 perinatal interventions. The authors concluded that of the nearly 300 interventions, only 100 were effective and 36 were promising, whereas 86 were of unknown benefit and 61 were ineffective and should be abandoned. In a discipline dealing with large numbers of essentially healthy people the potential for doing more harm than good on a grand scale was clearly apparent.

Since the publication of *ECPC* there have been steady improvements in the state of the science of obstetrics, with some particularly encouraging developments occurring recently. In this report, Lelia Duley discusses the implications of the Collaborative Eclampsia Trial. Published in 1995 and described as "the most important obstetric trial of the 20th century,"[4] the study finally put to rest a long-standing dispute about which treatment should be used for treating women suffering from a condition associated with an estimated 50,000 maternal deaths annually, almost all in developing countries. Prior to the publication of this study, no firm evidence existed to challenge the plethora of opinions on the management of eclampsia with recommendations from the World Health Organization further adding to the confusion.[5] Thanks to the Collaborative Eclampsia Trial, a multi-center, randomized study conducted almost entirely in developing countries, we finally know that magnesium sulphate is the drug of choice. The challenge now is to ensure that this life saving therapy reaches those affected by the condition.

In the next section of this report, Harshad Sanghvi, Barbara Kinzie and Melissa McCormick highlight evidence-based approaches for preventing postpartum hemorrhage (PPH), another significant cause of maternal morbidity and mortality. The authors describe the work of the Maternal and Neonatal Health Program, which promotes the "active management of the third stage of labor" (a set

Figure 1:
Opportunities for getting evidence from paper to policy and practice

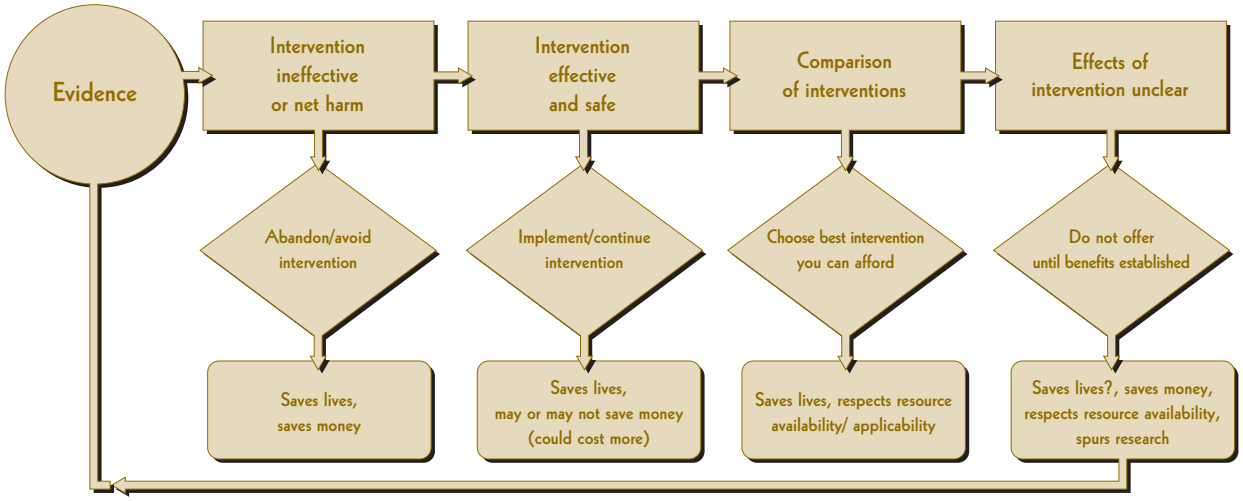
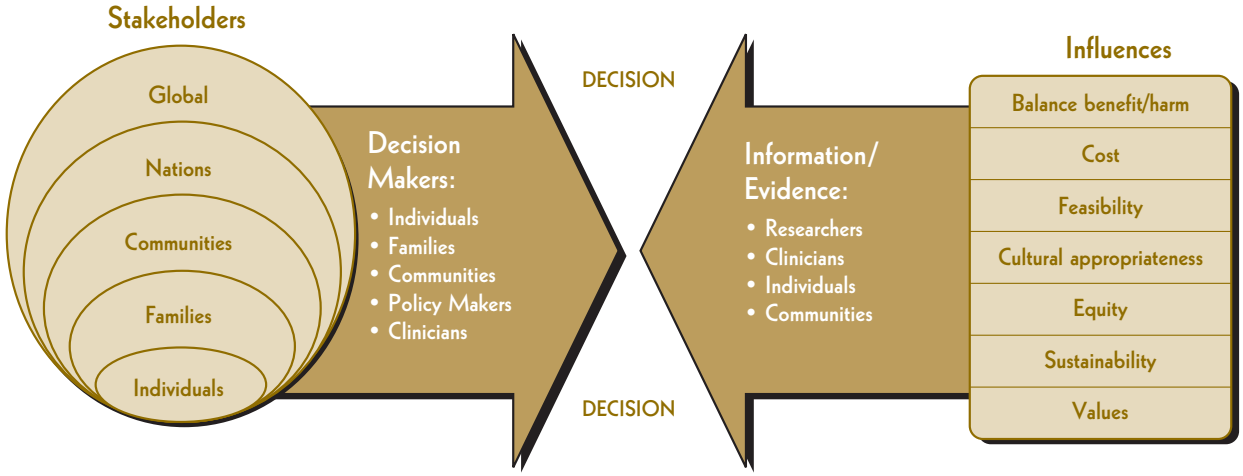


Figure 2:
Complexities of decision making



of procedures and drugs confirmed to be effective in randomized control trials). Importantly, this section demonstrates how scientific evidence can be integrated with information on feasibility and cost to arrive at decisions regarding best practice.

Synthesizing and disseminating the evidence

Even the most dedicated practitioners and policy makers fail to keep abreast of the burgeoning health-care literature. They, therefore, rely on others to summarize and distill important knowledge from primary research for them. Unfortunately, decision makers can and have been misled by reviews that have neglected to use scientific methods to limit systematic errors (biases) and random errors (the play of chance) thus reaching false conclusions regarding the effects of health care.[1,2,3] Systematic reviews aim to address these issues and are increasingly recognized as being more reliable than traditional reviews in communicating research evidence to decision makers. A systematic review is defined as: "a review in which bias has been reduced by the systematic identification, appraisal, synthesis, and, if relevant, statistical aggregation of all relevant studies on a specific topic according to a predetermined and explicit method."[6] The contribution by Metin Gülmezoglu and José Villar on the WHO Reproductive Health Library describes an innovative project involving the dissemination of systematic reviews on key topics in the field of reproductive health, together with expert commentaries and practical implementation strategies. A collaborative venture between the World Health Organization, the Cochrane Collaboration and others, this project targets practitioners in low- and middle-income countries and has shown potential for strengthening capacity for evidence-based decision-making.

From evidence to policy and practice

Informed decision-making does not only require knowledge of what works, but also what does not work, what could be harmful and what is unclear. Such information creates opportunities for decisions that can have a significant impact on health outcomes and expenditure (Figure 1).

However, getting research from paper (or PC) to practice and policy is a more complex process than is implied in the model depicted in Figure 1. Implementing change can be a difficult and overwhelming undertaking especially when the evidence is not in keeping with standard practice. As shown in Figure 2, decisions occur on many different levels involving various actors who are influenced by different types of information derived from a variety of sources. Promoting an evidence-based health-care approach, therefore, requires thoughtful analysis of the context in which decisions are made. This process should involve all relevant stakeholders with a view to identifying facilitators and barriers to evidence-based practice.[7] Helen Smith and Paul Garner discuss the Better Births Initiative, a project that grapples with these issues in a resource-constrained environment. Focusing on a few key procedures that are important to health and women's experience of labor, this initiative strives to introduce strategies to implement evidence-based obstetric care within the limits of existing resources.

Finally, this report is not intended to be a comprehensive account of what is happening in the field of evidence-based obstetric care; it focuses on only a limited number of case studies. However, we trust our readers will find the information provided in the report useful and that it will stimulate on-going dialogue that will influence the way obstetric care is practised with potentially large benefits for women and their children.

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Reducing Maternal Mortality Through Evidence-Based Treatment of Eclampsia

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Background

Globally, eclampsia is an important cause of maternal and perinatal mortality and morbidity. Although rare, eclampsia is estimated to be associated with 10% of maternal deaths.[1] It is defined as the occurrence of one or more convulsions superimposed on the syndrome of pre-eclampsia. Pre-eclampsia is a multi-system disorder usually associated with raised blood pressure and proteinuria. Eclampsia has especially serious consequences in low- and middle-income countries, where most cases occur, where maternal mortality is highest, and where there are limited resources and infrastructures to cope with acute medical or obstetric emergencies.

The aetiology of pre-eclampsia and eclampsia has yet to be unravelled. The occurrence of seizures during pregnancy has been noted since ancient Egyptian times, and in the mid-19th century were shown to be associated with proteinuria. When routine measurement of blood pressure began around 1910, the link with hypertension was established. In recent times, treatment for women with eclampsia has focused primarily on lowering blood pressure, trying to prevent further seizures, and delivery. Over the years, however, various theories about the pathophysiology of eclampsia have led to the unevaluated use of a wide range of interventions, many of which now sound bizarre or dangerous. Women were "blistered, bled, purged, packed, lavaged, irrigated, punctured, starved, sedated, anaesthetised, paralysed, tranquillized, rendered hypotensive, drowned, given diuretics, had mammectomy, dehydrated, forcibly delivered and neglected."[2]

In the early 1920s obstetric treatments (including delivery by forced dilatation of the cervix) were beginning to be recognised as more dangerous than doing nothing, and the multitude of medical treatments were judged to be sufficient "to reduce a parturient woman in good health almost to the point of death." Then, in 1925, an American obstetrician reported the use of magnesium sulphate for 20 women with eclampsia. Subsequent case series satisfied U.S. obstetricians that magnesium sulphate was the drug of choice for recurrence of convulsions and prevention of the first fit. Elsewhere, obstetricians preferred more conventional anticonvulants, such as diazepam and phenytoin. These again had been introduced into widespread obstetric practice based on opinion and case series, rather than on a reliable comparison of the effectiveness and safety of individual drugs. This absence of robust scientific evidence was reflected in striking geographical variation in favoured treatments. Thus, in the U.S., magnesium sulphate had been the anticonvulsant of choice for a large part of the 20th century whilst, in the U.K. and much of Africa diazepam has been favoured since the late 1960s. More recently many places were shifting to the use of phenytoin. The "lytic cocktail" (a combination of agents) remained popular in parts of India and Africa.

Rationale for project

In 1990, a systematic review of randomised trials for women with eclampsia identified just two trials into which a total of 73 women had been recruited. This compares with estimates that around 50,000 women die each year having had an eclamptic convulsion. The Collaborative Eclampsia Trial[3] was designed to estimate more reliably the differential effects of anticonvulsants commonly used for the care of women with eclampsia (magnesium sulphate, diazepam and phenytoin).

This study was the first large-scale, formal comparison of any intervention for women with eclampsia. A multinational, randomised controlled trial, it took place exclusively in low-middle income countries and has been described as "a landmark in the development of rational therapies for eclampsia."[4] It demonstrates that it is possible to overcome reluctance to test different management policies for women with eclampsia within randomised trials. The challenges facing those wishing to generate reliable evidence about health care are not just scientific, however. For example, funding for the Collaborative Eclampsia Trial

was delayed by 6 months whilst the research ethics committee of one funding agency attempted to impose impractical and potentially dangerous procedures for obtaining informed consent from unconscious or semi-conscious women.

Role of evidence

The trial has helped promote evidence-based care in several ways. It demonstrated that it is possible to conduct a large simple trial for an acute and relatively uncommon emergency, such as eclampsia. It produced a clear answer, and one that was relevant to clinical practice in a wide range of settings. The trial was pragmatic, aiming to evaluate policies of care based on the alternative anticonvulsant regimens within the constraints of the existing health services.

The trial recruited 1687 women. Ninety-seven percent of eligible women were randomised at participating centres, of which 99% received the allocated treatment and data were available for 99.6% of those women. Results were published in 1995 and show, together with the results of a few small trials, the clear superiority of magnesium sulphate over both diazepam and phenytoin in preventing further eclamptic seizures.[5,6] There is also evidence that magnesium sulphate is better and safer than lytic cocktail.[7]

As highlighted by Iain Chalmers and Adrian Grant[8], this trial also emphasised the need for evidence about the effects of health care. After decades of "vociferous if not vitriolic" debate, the collective efforts of clinicians from 27 hospitals in nine developing countries (Argentina, Brazil, Colombia, Ghana, India, South Africa, Uganda, Venezuela and Zimbabwe) achieved more than over half a century of small scale and poorly controlled research, largely by people in the developed world. When the original trial report was published in *The Lancet*, the editor commented "today's report is a triumph for the trialists, but what a scandal that we had to wait 70 years for the answer."

The Collaborative Eclampsia Trial helped to demonstrate the feasibility and importance of generating appropriate and relevant evidence to support maternal health services in low- and middle-income countries. Key principles in the design of the Collaborative Eclampsia Trial were that the results should be generalisable to places where maternal mortality was highest, that the study should be conducted within existing health services, and that treating a woman within the trial should be faster and easier than outside it, so that busy clinicians were not burdened and large numbers of women could be studied. That these aims were achieved is demonstrated by the low attrition, high compliance and completeness of the data collection. Implementation of these results remains a challenge, as magnesium sulphate is still not available in many low-income countries.

Most clinical trials evaluate new treatments or drugs. The Collaborative Eclampsia Trial compared existing and widely used treatments and demonstrated for the first time the unequivocal superiority of one these treatments. As a result, clinical care of women with this serious health problem became evidence-based.

Implementation

This trial demonstrated that magnesium sulphate is the drug of choice for women with eclampsia, clearly superior to either diazepam or phentytoin. To implement these results clinicians need to be aware of the evidence and understand or accept its value, and magnesium sulphate has to be easily available locally. Those who are unfamiliar with its administration will have to learn how to use magnesium sulphate safely. The trial demonstrated that safe monitoring could be achieved with simple clinical assessment of tendon reflexes, respiration and urine output, without measurement of serum magnesium levels.

Current barriers to implementation include language (the evidence is not known about in francophone Africa, for example), lack of access to up-to-date evidence, scarcity of magnesium sulphate (it is not available in many parts of Africa and Asia) and lack of training in administration and clinical monitoring.

Appropriate implementation must prevent unwarranted extrapolation of the results of the trial to prophylactic use of magnesium sulphate for pre-eclampsia. Currently there is little evidence that the potential benefits of prophylactic magnesium sulphate outweigh the potential risks. Findings of a further large international trial, the Magpie Trial, addressing this question will be published later this year.

An interesting aspect of the story of the Collaborative Eclampsia Trial is that a trial designed to address important practical problems in the developing world has led to a dramatic change in practice in the developed world. In the U.K., for example, magnesium sulphate was rarely used for eclampsia prior to 1995, whereas it is now in every labour ward protocol.[9] Anecdotally, since magnesium sulphate came into widespread use in the United Kingdom, maternal mortality associated with eclampsia has declined. A report from Bangladesh has also suggested a reduction in maternal deaths associated with eclampsia following the introduction of magnesium sulphate.[10]

The greatest challenge still remains — to ensure that the evidence generated by this trial has an effect on the care of the women in the developing world, as these are the women who have the most potential to benefit. Knowledge that magnesium sulphate is the anticonvulsant of choice must be shared.

Challenges/next steps: Implementing change in low-income settings

Magnesium sulphate is a cheap drug, and there is strong evidence that it is substantially better than alternative anticonvulsant drugs. Nevertheless, it continues to be unavailable in large parts of Africa and Asia. Removing barriers in the supply and appropriate use of magnesium sulphate should be a priority for those responsible for maternal health services in developing countries, including international agencies such as UNFPA, UNICEF and WHO. Key strategies in removing these barriers are facilitating easy access to the drug, increasing understanding of how to evaluate health care interventions and of levels of evidence, and raising awareness of the evidence supporting the use of magnesium sulphate. Once the drug is available and clinicians are convinced of the need to use it, they need training and support in its administration as they gain experience and confidence. Although it is usually the obstetrician who makes the decision to prescribe magnesium sulphate, it is often midwives who administer the drug, and they will also need training and support.

Generating the evidence is not enough. The greatest challenge is ensuring that it is properly implemented and benefits all women with eclampsia.

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Reducing Postpartum Hemorrhage: Routine Use of Active Management of the Third Stage of Labor

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Background

Immediate postpartum hemorrhage (PPH), defined as excessive blood loss within 24 hours after childbirth, is the single most important cause of maternal death worldwide, accounting for almost half of all postpartum maternal deaths in developing countries. Thus, the introduction of low-cost, evidence-based practices that can prevent PPH in countries with high maternal mortality is an important way to improve women's health.

Because two-thirds of PPH cases occur in women without any identifiable risk factors, every woman giving birth must be watched closely for signs of PPH. In addition, active management of the third stage of labor, a three-part process that helps prevent uterine atony, the most common cause of PPH, should be routinely used at all births attended by a skilled provider. The evidence-based protocol for active management of the third stage of labor is: 1) give a uterotonic drug within one minute of the birth of the baby; 2) clamp and cut the umbilical cord soon after birth; and 3) deliver the placenta by applying controlled downward tension on the umbilical cord during a strong uterine contraction, while at the same time applying counter pressure (toward the woman's head) on the uterus abdominally.

Role of Evidence

Three large randomized controlled trials studied the ability of active management of the third stage of labor to prevent PPH when compared to physiologic management.[1–3] The results of these studies are summarized in Table 1. In all three trials, active management reduced the risk of PPH, the incidence of prolonged third stage (longer than 30 minutes), and the need for blood transfusion or additional uterotonic drugs. Thus, there is strong and consistent support for the use of active management of the third stage of labor to prevent PPH due to uterine atony, thereby reducing maternal morbidity and mortality from this complication. Additional studies have shown that giving a uterotonic drug soon after the birth of the baby is the part of the active management protocol that has the greatest impact on the prevention of PPH. In fact, Prendiville et al.[4] found that giving a uterotonic drug reduced the risk of hemorrhage by approximately 40%.

The two most commonly used uterotonic drugs, oxytocin and syntometrine (a combination of oxytocin and ergometrine), are effective but they do have disadvantages. In addition to side effects, such as headache, nausea and vomiting, these drugs (especially ergometrine) must be handled and stored properly, and they must be given by injection. Use of these drugs, therefore, requires a cold chain, as well as an attendant who is trained and qualified to administer them. Sterile or high-level disinfected syringes and needles must also be available, and they must be handled and disposed of properly.

An alternative uterotonic drug is misoprostol (Cytotec®, Searle, Skokie, IL), a prostaglandin E1 analogue. Not only is misoprostol inexpensive and stable at room temperature, it also can be given orally, buccally, or rectally. These are important advantages over oxytocin and syntometrine. A large WHO multicenter study[5] found that oxytocin is preferable to oral misoprostol in hospital settings with skilled providers. However, in developing countries, 50–80% of births occur in the home and frequently are not attended by a skilled provider, or the provider may not have the necessary supplies to give an injectable uterotonic drug. In these circumstances, 400–600 µg misoprostol as a part of active management is clearly useful, even if it is less effective than injectable uterotonic drugs. Goldberg et al.[6] gave the use of misoprostol in these situations a category A recommendation (good and consistent scientific evidence to support the recommendation) based on their review of the literature.[7-10] In addition, prevention of PPH has recently been recommended as an acceptable indication for misoprostol by the United States Pharmacopeia, especially in settings where injectable uterotonic drugs are not available.[11]

Implementation

The Maternal and Neonatal Health (MNH) Program works to introduce active management and other evidence-based practices globally. In Nepal, for example, the MNH Program has collaborated with Patan Hospital to develop the hospital as a training site for nurses and auxil-

iary nurse midwives and to institute routine use of active management of the third stage at all births. The Program also collaborated in a similar fashion with the Centro Hospitalario Pereira Rossell in Montevideo, Uruguay. In Guatemala, where the majority of clinicians had never heard of active management, training of twelve nurses and four doctors from eight hospitals resulted in support of this life-saving practice. After participating in the update, the clinicians were convinced of its effectiveness and were eager to institute it in their home settings. As part of its Regional Expert Development Initiative (REDI), the MNH Program also trains experts who understand and can articulate the scientific basis for changes such as active management of the third stage of labor. The technical

TABLE 1: MATERNAL OUTCOMES IN THREE TRIALS COMPARING PHYSIOLOGIC AND ACTIVE MANAGEMENT OF THE THIRD STAGE OF LABOR

Outcome	Physiologic management	Active management	Significance	Reference
Blood loss > 500 ml	17.9% 16.5% 11%	5.9% 6.8% 5.8%	OR 3.13 (2.34–4.2) RR 2.42 (1.78–3) OR 0.50 (0.34–0.73)	(1) (2) (3)
Blood loss > 1000 ml	3.1% 2.6% 3.16%	0.8% 1.7% 0.72%	OR 3.22 (1.62–6.42) NS OR 0.22 (0.08–0.57)	(1) (2) (3)
Transfusion	5.7% 2.6% 0.49%	2.1% 0.5% 0.12%	OR 2.56 (1.57–4.19) RR 4.9 (1.68–14.25) OR 0.25 (0.01–2.33)	(1) (2) (3)
Low hemoglobin	6% 28.4%	3.2% 15.2%	OR 1.89 (1.2–2.99) RR 1.86 (1.51–2.3)	(1) (2)
Change in hematocrit (mean ± SD)	8 ± 1.7	2 ± 1.2	P < 0.001	(3)
Retained placenta	2.6% 1.7% 4.5%	1.9% 2% 1.58%	NS NS OR 0.31 (0.15–0.63)	(1) (2) (3)
Third stage > 30 minutes	26% 16.4%	3% 3.3%	OR 6.42 (4.9–8.41) RR 4.9 (3.22–7.43)	(1) (2)
Duration of third stage (min, mean ± SD)	14 ± 2.5	4 ± 2.5	P < 0.001	(3)
Therapeutic uterotonic drugs	29.7% 21.1% 5.17%	6.4% 3.2% 2.3%	OR 4.83 (3.77–6.18) RR 6.25 (4.33–9.96) OR 0.44 (0.24–0.78)	(1) (2) (3)
Increased diastolic blood pressure	0.9% 0.1%	0.9% 0.8%	NS NS	(1) (2)
Headache	0.9% 0.4%	1.5% 0.7%	NS NS	(1) (2)
Nausea	5.9%	11.5%	RR 0.51 (0.36–0.72)	(2)
Vomiting	6.5% 2.2%	12.1% 6.3%	OR .52 (0.37–0.72) RR 0.35 (0.21–0.61)	(1) (2)

OR = odds ratio, RR = relative risk, NS = not significant.

component of these training courses consists of the evidence-based practices contained in the manual *Managing Complications in Pregnancy and Childbirth*, produced by WHO and JHPIEGO and endorsed by UNFPA, UNICEF, World Bank, International Federation of Gynecology and Obstetrics, and the International Confederation of Midwives. The clinicians who have participated in this program have been responsible for implementing active management in their home institutions in several countries, including Indonesia, Bangladesh, Uganda and Uruguay, and the program will soon be expanded to Pakistan and other countries in South Asia.

The MNH Program also works with administrators and policy makers to ensure acceptance of active management and other evidence-based practices. For example, one hospital in Guatemala, Amatitlán Hospital, was hesitant at first to implement active management because of the increased cost of providing oxytocin routinely at all births. Ultimately, the hospital director was pleased to realize that although there was an increase in the hospital's use of oxytocin, significant savings resulted from the reduction in blood transfusions. Implementing active management conserved the hospital's blood supply, decreased labor costs, and decreased the risk of transmission of HIV/AIDS and hepatitis to women and hospital staff. Finally, in Bolivia, the MNH Program also played a role in the recent decision by the Ministry of Health to issue a Ministerial Resolution officially adopting MNH practices, including active management of the third stage of labor. As a result, oxytocin is now included on the national health insurance plan's list of routine drugs/supplies required for normal birth.

Next Steps

The MNH Program continues to work with health-care providers, administrators, and policy makers to implement routine use of active management of the third stage of labor. In addition, the Program continues to seek new evidence-based practices to reduce maternal morbidity and mortality. Among the program's planned activities is a project in Indonesia aimed at demonstrating the safety, acceptability, feasibility, and program effectiveness (SAFE) of self-administration of misoprostol in reducing PPH in areas where a large proportion of home births are not attended by a skilled provider. The project will involve educating women during the antenatal period about the benefits of taking 600 mcg misoprostol orally immediately following delivery of the baby and placenta, combined with offering misoprostol to the women after counseling during visits at the antenatal clinic or in their homes. It is expected that the results of this SAFE demonstration project will provide sufficient evidence to convince policy makers and administrators that the self-administration of misoprostol is effective in preventing PPH when the birth is not attended by a skilled provider.

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The WHO Reproductive Health Library (RHL)

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Background

The WHO Reproductive Health Library project was initiated in 1997 with the objective of providing access to the most up-to-date and reliable information about the effectiveness of reproductive health-care interventions. The underlying theme was to make Cochrane systematic reviews* available to health workers in under-resourced settings with additional contents to make the information easy to understand and apply. An important concern was the possibility of developed country bias that may appear in the review topics, the origin of the authors of the reviews and the available data included in the reviews. These biases could affect the applicability of the evidence as well as the readability of the reviews by health workers in developing countries. We invited health workers with knowledge and experience of the conditions typical to most under-resourced settings to write critical commentaries on the relevance of these reviews to their settings.

In order to achieve wide scale dissemination and targeted distribution in developing countries several a priori decisions were made that are summarized in Table 1. RHL contents gradually increased from 27 Cochrane reviews and original commentaries in 1997 to 70 Cochrane reviews, commentaries and other additional documents in 2002.

RHL is coordinated by a small secretariat located at WHO in Geneva and seven regional editors spread around the world (Table 2). There are RHL representatives in Cuba, Pakistan, Uruguay and the Philippines.

The RHL editorial team meets every year to select the Cochrane reviews that are available in the Cochrane Library for inclusion in RHL. In addition, questions that are not addressed by existing Cochrane reviews are identified and reviews to address these questions are initiated for inclusion in subsequent issues of RHL. Through this mechanism several important reviews addressing high priority reproductive health problems in developing countries have been initiated and completed.

The first issue of RHL was published in 1997 in English. Since 2000, RHL is published in English and Spanish and work for a Chinese version is currently ongoing. RHL subscriptions are increasing every day and as of October 2001 there were more than 9,000 RHL subscribers worldwide.

Role of evidence

RHL aims to provide the evidence in its original form while providing tools and means to make interpretation easier. Within the Cochrane reviews the characteristics of all studies contributing data to the review, the reasons for

* Cochrane reviews are systematic reviews prepared by the Cochrane Collaboration (www.cochrane.org). These follow a standard structure and are published electronically, which enables updating and revisions when new evidence emerges or in response to comments.

Table 1: RHL development and dissemination strategy

Provide access	Freely available (free subscription) in developing countries
Provide access	Use simple formats as long as possible (issue 1 on a floppy diskette, Windows 3.1 compatible)
Keep up-to-date	Annual publication that allows updates and revisions of all documents
Keep manageable	Small number of reviews to start with (27 in first issue) and gradually increase (10 –12 per issue)
Ensure widespread distribution	Use WHO mailing lists (medical school libraries and HRP newsletter mailing lists)
Encourage comments and feedback	Ongoing evaluations (qualitative and quantitative) and online feedback

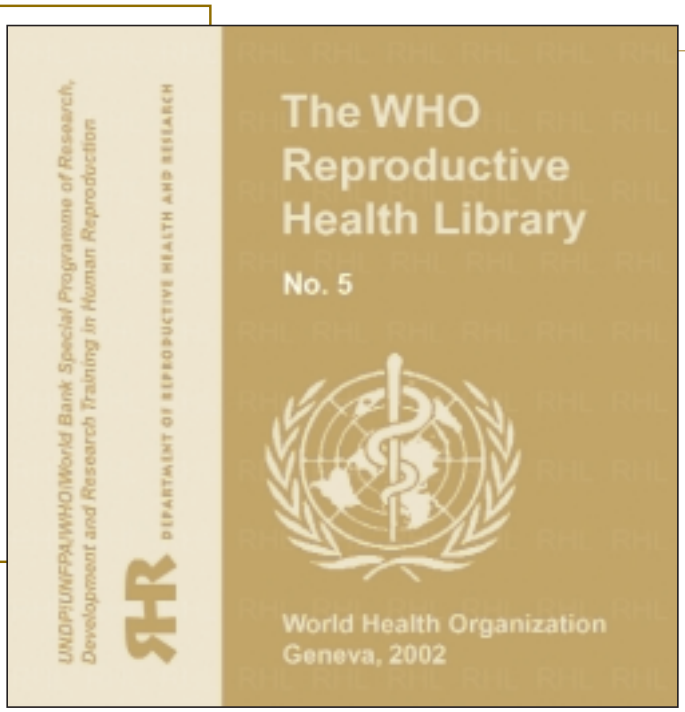
Table 2: RHL editorial organization

Coordinating editors

A. Metin Gülmezoglu and José Villar
HRP/WHO – Geneva, Switzerland

Regional editors

Guillermo Carroli — Rosario, Argentina
Linan Cheng — Shanghai, China
G. Justus Hofmeyr — East London, South Africa
Ana Langer — Mexico City, Mexico
Pisake Lumbiganon — Khon Kaen, Thailand
Suneeta Mittal — New Delhi, India
Kenneth F. Schulz — North Carolina, USA



exclusion of other studies, and the results of the studies can be found. RHL provides concise summaries for decision makers and the commentaries put the evidence into context. RHL includes methodological and educational articles for critical appraisal of systematic reviews. While we acknowledge the usefulness and practicality of looking at summaries and conclusions we also believe that the users should be given the opportunity to make this decision themselves by accessing original data.

Starting with the 2002 issue (RHL No.5), RHL now includes tools such as educational videos and implementation manuals to assist in the implementation of practices for which strong evidence of benefit exists.

RHL No.5 includes 70 Cochrane reviews related to all areas of reproductive health. The majority of the included reviews are on maternal and perinatal health. Within this category there is almost complete coverage of nutritional interventions during pregnancy, postpartum haemorrhage and hypertensive disorders of pregnancy. Mother-to-child transmission of HIV, sexually transmitted infections, and cervical cancer related interventions are also included.

All documents included in RHL are monitored, updated and revised as required every year.

Implementation

Two questions are pertinent to implementation:

1. How can RHL be implemented? That is, how can RHL become a routinely consulted source of evidence in developing countries?

Providing access is no doubt an important part of the solution. However, a critical mass of individuals who can effectively use (computer literate) and interpret (knowledgeable about critical appraisal, systematic reviews, meta-analysis) are necessary for RHL to be effectively used and incorporated into practices. To this end, the editors are conducting workshops and presenting RHL all-year round. Furthermore, projects to strengthen capacity in research synthesis are ongoing in Africa, Latin America and South-East Asia.

2. How can RHL facilitate the implementation of effective practices? The case of *Antenatal Care*.

Routine antenatal care models for women at low risk of complications have generally been based on a standard Western model of care developed in the early 20th century. This model consists of 9–10 antenatal visits with several repeated tests and examinations conducted in a ritualistic way. In the last two decades of the 20th century, this model was criticised and randomised controlled trials evaluating alternative models in terms of the type of care provider or the number of visits began to emerge. In the 1990s, WHO initiated a project to evaluate whether an antenatal visit schedule with less frequent visits but consisting only of evidence-based activities to prevent or treat specific conditions (goal-oriented) could be delivered without increasing adverse outcomes and in a cost-effective way. RHL included the Cochrane review[1] and abstracts of two reviews that were published in print media that formed the rationale for the trial.[2,3] In 2001, the main results of the trial were published back-to-back with the systematic review that included all evidence to date including the current trial.[4,5] RHL No.5 published recently includes the updated Cochrane review and the review of effectiveness of antenatal care as a whole[6] with the commentary that was revised according to the updated review. RHL No.5 has gone one step further by providing in full text "The Implementation Manual for the New WHO Antenatal Care Model" under a new section titled "RHL

Implementation Aids." This manual is linked to the Cochrane reviews included in RHL whenever reference is made to effective (or non-effective) practices.

In summary, RHL No.5 provides the evidence and the tools to implement the new evidence-based antenatal care model that is more cost-effective. It does not tell the user "how" they can or they should operationalize the new antenatal care model. We believe that barriers to changing practices are mostly multifactorial and contextual, therefore, programme managers and policy makers in the countries would be better placed to make these changes when armed with the evidence and other tools.

Box 1: RHL No.5 Implementation Aids

- WHO Antenatal Care Model Implementation Manual
- External cephalic version video
- Labour companionship video
- Better Births Initiative (PowerPoint presentation)

Impact of RHL

Has RHL made an impact? The ultimate goal is to change practices in the light of the most up-to-date and reliable evidence. RHL as a tool providing this evidence cannot be expected to improve practices in a short period of time. However, using effective strategies to improve practices utilizing RHL could be a rational approach. WHO is currently conducting a cluster randomized controlled trial in 40 hospitals in Thailand and Mexico to evaluate whether an active RHL dissemination strategy that includes three goal-oriented, interactive workshops to hospital managers and clinicians can improve obstetric practices. This active dissemination strategy (also called outreach) has been shown to be effective in improving individual practices but evidence regarding the use of a package (RHL) with multiple practices embedded is not clear. The results of this trial will be available by end of 2003 and, if effective, will provide clear guidance on how to influence clinical behaviour.

Future

As mentioned above, RHL No.5 (2002) contains 70 Cochrane reviews, original peer-reviewed commentaries and practical aspects documents and, for the first time "implementation aids" (Box 1). These contents gradually increase and existing contents are revised annually.

RHL project progresses in several directions with the following objectives:

1. Increase and improve the quality and amount of contents, making RHL the most comprehensive resource in reproductive health.

2. Stimulate and support the preparation of new relevant systematic reviews.

3. Through intensive dissemination workshops and capacity strengthening activities, contribute to creation of a critical mass of health workers knowledgeable about and able to synthesise research evidence.

To subscribe free to RHL from developing countries, send an e-mail to RHL@WHO.INT.

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Better Births Initiative: A Programme for Action in Middle- and Low-Income Countries

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Background

Reliable research evidence provides midwives and doctors with knowledge to improve services, but the challenge is helping health professionals to change their obstetric practice and institutionalise change.

The Better Births Initiative (BBI) developed from observational studies that demonstrated a gap between research evidence and actual practice on labour wards in China, South Africa and Zimbabwe. Practices are often out of date, and many procedures that hurt women have no demonstrable benefit. Obstetric care quality could be dramatically improved if health workers change what they do with respect to a small number of routine practices.

The Better Births Initiative was started in South Africa in 2000, and is being tested in a several countries. It is being developed and coordinated by the Better Births International Network, which is a small network of individuals that want to see obstetric care in developing countries change for the better.

Rationale for project

Better quality

The Better Births Initiative aims to ensure the clinical policies and procedures used in essential obstetric services are grounded in reliable research evidence, and is targeted at health-care providers. It assists them to understand research evidence, make decisions about best practice, and establish implementation procedures to assure change. It is aimed at middle- and low-income countries, where resources for health care are limited and better services will reduce maternal mortality.

Good quality obstetric care needs buildings, trained staff, equipment and drugs. Many governments and donors are striving to establish and maintain these services. The Better Births Initiative complements these efforts, and helps ensure staff use procedures that are based on the most reliable research evidence.

Policy makers, managers, midwives and doctors all have a role to play in effecting change towards evidence-based practice. We need to work collectively in the activities outlined here.

Better outcomes

Making clinical policies and practices more evidence based will improve quality, and will improve health outcomes in women and their babies. The Better Births Initiative encourages health workers to abandon practices that are painful and have no evidence of benefit. This means women will have a better experience of childbirth. It will help enhance the reputation of the provider, and encourage women to use the service, particularly those from disadvantaged groups who are often frightened to attend.

Role of evidence

Any health-care practice has benefits and harms, and researchers assess these effects through research – usually randomised controlled trials. Over the years, researchers throughout the world have carried out many such trials, and research synthesis is the method to bring together the totality of this research. Research is synthesised through systematic reviews, which are carefully conducted and updated regularly. With these results, policy makers, health professionals and users of health care can make more informed decisions about the best care appropriate for an individual.

Despite huge efforts by the Cochrane Collaboration and others in synthesising existing research evidence, there remains a gap between this information and health provider practice. It is not easy for individual health professionals or teams to change the way they have been taught to do things, and the way they are used to behaving. Research evidence has shown quite clearly that information about best practice is insufficient to initiate behaviour change. People need to be motivated to change and work together to organise how this actually is implemented in practice, and monitored over time.

Box 1: What practices does the Better Births Initiative target?

SAVING LIVES

Practices that can prevent maternal deaths, such as:

Routine oxytocic drugs given to the mother after the baby is born. It reduces the risk of postpartum haemorrhage.

Magnesium sulphate for women with eclampsia. It reduces the risk of further convulsions.

Antiretroviral drugs given to women who are HIV positive. They reduce the risk of mother-to-child transmission.

Prophylactic antibiotics during caesarean section. This reduces serious postpartum maternal infection.

Prophylactic antibiotics given to women who are HIV positive with prolonged rupture of membranes. They prevent maternal and neonatal infection.

IMPROVING QUALITY

Practices that can improve the health of women and the infants, such as:

Companionship provided by a lay carer during labour. This improves maternal satisfaction, shortens labour, and improves breastfeeding. It also reduces the need for pain relief and assisted delivery.

Being mobile during labour. This shortens labour and reduces the need for pain relief and assisted deliveries.

Routine antibiotics for preterm, prelabour rupture of membranes. They improve maternal and neonatal outcomes.

Prophylactic steroids given prior to preterm birth. They prevent respiratory distress syndrome and reduce neonatal mortality.

Keeping the umbilical cord clean at delivery. Poor hygiene is associated with neonatal tetanus and sepsis.

AVOIDING HARMS

Practices that are degrading or painful, and should be dropped, such as:

Routine episiotomy for all women is associated with more pain, poor healing, and longer hospital stays. Episiotomies should only be done where clinically required.

Enemas. They are uncomfortable, make a mess and are of no benefit.

Perineal shaving. Degrading and of no demonstrable benefit.

Withholding oral fluids. Uncomfortable and unjustified.

Artificial rupture of the membranes (AROM). Painful, and of no value unless progress in labour is abnormal.

The Better Births Initiative focuses on particular obstetric practices which are frequently used inappropriately, where it is reasonable to expect people to change, and where any resource implications of the change are probably realistic and affordable.

What practices does the Better Births Initiative target?

The Better Births Initiative has identified practices relevant to middle- and low-income countries where research evidence, available in the WHO Reproductive Health Library, provides some guidance on best practice. The interventions are grouped around three areas: saving lives, improving quality and avoiding harms (See Box 1).

Strategy for change

It is not easy to remove an entrenched practice, or change the way health professionals have been taught to do things. Behaviour change requires more than information about best practice; people need to be motivated, and develop locally relevant strategies to implement and monitor changes over time. The Better Births Initiative has developed the following strategy:

Political commitment

Discuss with policy makers, hospital managers, and senior midwives and doctors about international trends in evidence-based approaches, sources of evidence, how practice could be changed and its potential impact.

Evidence-based training

Arrange with health professionals in each unit to visit them. Communicate evidence-based concepts and use specific examples in evidence-based approaches, with trainers that understand evidence-based approaches and are familiar with Cochrane Reviews and the WHO Reproductive Health Library. Use learning materials to guide health workers through the process. All levels of staff should be encouraged to attend and discuss the feasibility of changing practice.

Design local implementation package

Health professionals at individual units need to agree on specific changes that are achievable, and could dramatically improve women's experiences during labour. A baseline study of current practice, using a patient note audit or survey method, can help identify gaps between evidence and practice and where change is needed most.

Agree on a strategy that will introduce the practice changes and encourage all levels of maternity staff to implement them. Methods that have been used to help health professionals change their practice include audit and feedback, small group workshops, opinion leaders and incentives. A combination of provider targeted approaches is more effective than formal educational methods alone.

Reinforcing change

For change to be implemented, all labour ward staff should be made aware of the strategy for change. Respected local opinion leaders can help to establish new norms and reinforce new practices. Selecting respected peer leaders at individual maternity units, and involving them in disseminating the agreed changes can help to institutionalise new practices.

Box 2: Materials included in the Better Births Initiative change package

Workbook	To guide group discussion around benefits and harms of procedures; exercises examine current practice, and identify ways to change practice.
PowerPoint presentation	An introduction to evidence-based practice, which summarises the evidence for obstetric procedures.
Reference booklet	A summary of the best evidence; concise, quick-reference style.
Journalistic-style video	Real experiences of implementing companionship in labour wards in South Africa.
Posters	Showing procedures that the Initiative promotes; designed to be displayed in labour wards and antenatal clinics.
Self audit	A method for monitoring practice and introducing change.

Monitor progress

Encourage staff to develop mechanisms to assure quality and monitor progress. Regular audit of maternity register entries or patient notes can help to monitor changes to practice over time. Establish a forum to feedback progress to all maternity staff; using existing meetings could facilitate this process.

Pilot project

The BBI International Network has developed a health provider targeted change package that introduces the evidence-based standards and encourages labour ward staff to consider potential benefits and harms of procedures they use. This has been piloted in hospitals in South Africa.

The rationale behind the package is to encourage labour ward staff to consider the potential benefits and harms of procedures used during childbirth; and to introduce a set of (evidence-based) changes that are achievable with existing resources. The package is presented as an interactive workshop with colourful materials including a workbook, reference booklet, posters, a presentation, video material and a self-audit mechanism (see Box 2).

The BBI was piloted in 10 government hospitals in Gauteng Province in 2000-1, and is now being implemented in hospitals in Gauteng, Eastern Cape and Kwazulu Natal.

Table 1: Number of hospitals with good practice at baseline and follow-up

Procedure	Good practice	Number of hospitals with good practice	
		Baseline	Follow-up
Mobility	40%+	4	7
Oral fluids	40%+	1	1
Companionship	40%+	0	3
Episiotomy	<40%	10	9
Enema	<20%	3	7
Perineal shaving	<20%	8	10
Supine position	<20%	0	0

Source: Analysis of baseline and follow-up exit interview data

Impact of pilot project

The pilot implementation study in Guateng (2000-1) evaluated the impact of the change package on provider behaviour and processes of change in government maternity units in South Africa. Evaluation used quantitative methods to assess impact on provider behaviour, and qualitative methods to understand social and individual change processes and identify conditions that determine change.

A pre-post comparison was used to evaluate the package at the 10 government maternity services. All sites received the educational programme in a two-hour workshop, and five sites were randomly allocated to receive a self-audit mechanism in addition to the workshop. Sites were randomised by a colleague not actively involved in data collection or analysis. Baseline data on actual practice were collected prior to workshops; baseline data collection was repeated and evaluated at follow-up, approximately six months later.

Exit interview data demonstrate changes in good practice from baseline to follow-up (Table 1). Good practice is defined as routine use (40%+) of mobility, oral fluids and companionship; selective use (<40%) of episiotomy; and low use (<20%) of enemas, perineal shaving and supine position.

The table shows that change was easier to institutionalise for some practices. Overall, the number of hospitals with good practice increased with BBI. For mobility during labour, the number of hospitals with good practice (defined as >40% of deliveries) increased with BBI. For companionship, the number of units with good practice (defined as >40% of deliveries) also increased. For enema and perineal shaving, good practice was defined as less than 20%, and the number of hospitals with good practice also increased with BBI. Supine position was routine in all hospitals, and none showed any change in this between baseline and follow up. The procedures that showed no change at all were oral fluids and supine position, and, for episiotomy the change was an increase in one hospital to undesirable behaviour.

Qualitative data explored the impact of the change programme on processes of behaviour change. Narrative data revealed that a combination of individual and social processes facilitated behaviour change at some hospitals, and the absence of some critical factors prevented change from occurring at others. Motivation was a key influence on practice change at the study sites, and hospitals where all staff worked well together implemented more changes to practice.

Challenges/next steps

Roll-out

The Better Births Initiative package helped to initiate change at some hospitals in the pilot study. A scaled up version of the study is planned for two other provinces in South Africa to determine wider impact.

Adaptation of the strategy

The Better Births Initiative package engaged providers in the process of change and encouraged critical thinking about current practice. It is important that clinicians have the capacity and capability to respond to change. The strategy has been adapted for use with clinicians in other settings.

China

Fudan School of Public Health, Shanghai, conducted an observational study to explore actual practice, women's preferences and provider's views.[1] The results showed variation in clinical practice at government hospitals in Shanghai, and highlighted important barriers to changing practice. On the basis of this study, and in response to the positive reaction of health professionals in China, the BBI materials will be translated and adapted for use as a training course in evidence-based childbirth care.

Zimbabwe

An observational study was used to explore actual practice, differences between evidence and practice, and women's views about childbirth at a government hospital in Harare. Using indicators of good obstetric care helped to identify the gap between knowledge and actual practice. The study also helped maternity staff identify barriers to implementing research findings at the organisational, social and individual level.

Tanzania

The African Midwives Research Network, Dar Es Salaam has designed an implementation study to promote the use of more upright positions for birth, and mobility during labour. The study builds on findings from the South Africa implementation, and will use adapted BBI materials in a training programme to enhance the skills and confidence of midwives in changing their practice.

Further information

The Better Births Initiative is a project that started in Coronation Hospital in South Africa in the Effective Care Research Unit. It is a component of the Effective Health Care Alliance Programme (EHCAP), supported by the Department for International Development. Funds for South Africa activities come from a variety of sources, including the government of South Africa.

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Better Births Initiative website: www.liv.ac.uk/lstm/bbimainpage.html

Using Evidence to Save the Lives of Mothers

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The charge of the practitioner – whether clinician or manager – is to use the best available information to do the best job possible for those in need, within the bounds of available resources. This report is intended both to further enable that decision-making at the programmatic level and to lay out a model which will advance the effective practice of global health.

The deaths of more than half a million women a year as a consequence of pregnancy and childbirth is an avoidable tragedy. Further, this demarcates the most striking health risk differential between developed and developing countries – a pregnant woman living in poverty in sub-Saharan Africa, Asia or Latin America faces a risk of death of up to 200 times the risk faced by a pregnant woman in America or Europe. Waiting for health systems to develop to the same level as in affluent societies is not a solution, particularly when there is available evidence that certain actions can be broadly undertaken that will make a difference.

However, the stark contrasts in the health of mothers between rich and poor societies has occasioned many efforts which, while well-intended, have been based more on concern and ideology than on evidence. As a result, despite the nearly two decades during which this issue has been highlighted there has been scarce progress in reducing maternal risks among the poor. It is high time to apply the evidence at hand.

The four leading contributors to high maternal mortality are postpartum hemorrhage, infection, post-abortion complications, and eclampsia. This report highlights two of these issues, hemorrhage and eclampsia, and provides clear evidence that several groups of interventions do work to save women's lives in under-resourced settings. First is the use of magnesium sulfate in the early treatment of eclampsia. Second is the application of a straightforward and limited set of activities, combined under the term "Active Management," which significantly reduce the risk of postpartum hemorrhage.

Notably, both of these interventions can be applied across a wide platform of health service delivery systems, including not only hospital settings but also community-based birthing which is the norm among the majority of the poor giving birth in developing countries. Therefore, this evidence is not only scientifically solid, it is eminently applicable.

In order to promote best practice in maternal care, dissemination and implementation of current best evidence play an equally important role. Ensuring that both practitioners and patients have access to reliable, up-to-date and relevant information is vital if evidence-based approaches are to be instituted and harmful practices avoided. However, in resource challenged settings, this is difficult – yet not impossible. This report looks at two projects (WHO Reproductive Health Library and Better Births Initiative) that have promise in promoting evidence-based obstetric care in low- and middle-income communities.

By highlighting evidence-based approaches as has been done in this report, the Global Health Council aims to help the tens of thousands of program managers and service delivery personnel who work on the front lines of global health to do their jobs more effectively and to enable them to carry out our common mission: to improve health and reduce health inequities around the world.

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