

Study Proposal:

Survey of the Management of the Third Stage of Labor

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Management Sciences for Health, Rational Pharmaceutical Management (RPM) Plus in support of the Prevention of Postpartum Hemorrhage Initiative (POPPHI).



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About RPM Plus

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

About POPPHI

The Prevention of Postpartum Hemorrhage Initiative (POPPHI) is a three-year project awarded to a partnership of PATH, RTI International, Engender Health, the International Confederation of Midwives (ICM) and the International Federation of Gynecology and Obstetrics (FIGO) on July 29, 2004.

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ACRONYMS

AMTSL	Active management of the third stage of labor
JHSPH	Johns Hopkins Bloomberg School of Public Health
MoH	Ministries of Health
POPHI	Prevention of Post partum Hemorrhage Initiative
RPM Plus	Rational Pharmaceutical Management Plus (Program)
STG	standard treatment guidelines
USAID	U.S. Agency for International Development
WHO	World Health Organization

BACKGROUND

Active management of the third stage of labor (AMTSL) involves the use of an uterotonic agent immediately following the birth of the baby and delivery of the placenta by controlled cord traction. Definitions vary as to the inclusion of immediate cord clamping and fundal massage. Clinical trials in developed countries have shown that, relative to AMTSL, physiologic management of the third stage of labor (in which oxytocics are not used and the placenta separates spontaneously and is delivered by gravity and maternal effort) substantially increases the risks of postpartum hemorrhage and severe postpartum hemorrhage, the need for blood transfusion, the need for therapeutic oxytocics and increases the duration of the third stage of labor (Prendiville 2001). The Cochrane Database of Systematic Reviews (Buchmann et al. 2002) of these trials concludes by recommending active management of the third stage of labor for all women delivering in hospital and anticipating the vaginal birth of a single infant.

Based on this body of evidence, the International Confederation of Midwives and the International Federation of Gynecologists and Obstetricians issued a joint statement in November 2003 stating that every woman should be offered AMTSL “as a means of reducing the incidence of postpartum hemorrhage due to uterine atony.” The inclusion of AMTSL in the recent World Health Organization (WHO) evidence-based manual *Managing Complications in Pregnancy and Childbirth* (WHO 2000) also attests to the international acceptance of this practice as the standard of care.

Although the WHO manual is beginning to be incorporated into medical and midwifery pre-service and in-service training, the American College of Nurse-Midwives and the U.S. Agency for International Development (USAID)-sponsored Maternal and Neonatal Health Program, to name just a few, have been actively promoting this practice in developing countries for the past decade. Evidence regarding adoption of this practice, however, is limited. Evaluation of donor-funded projects incorporating this practice tends to be limited to reporting on the numbers of providers trained and the percent achieving competence following training. Apart from anecdotal information, an article by the Global Network for Perinatal and Reproductive Health (Festin 2003) offers the best glimpse into the adoption of this practice. Their results from 15 university-based referral obstetric centers in developed and developing countries show substantial variation between and within hospitals. Overall, only 25 percent of observed deliveries included AMTSL. However, only one hospital (Dublin) consistently used all three components of the practice. Variation in the prophylactic use of oxytocin ranged from zero to 100 percent; in the practice of controlled cord traction from 13 to 100 percent; in the number of women who received additional dosages of oxytocin during the third stage of labor from five to 100 percent. Therefore, there is insufficient evidence to permit conclusions about the effectiveness of this practice in its altered states.

JUSTIFICATION

The small amount of results-based evidence suggests that the use of AMTSL is quite low, and where practiced, the definition varies within and between countries. Since at least 1997, the Safe Motherhood Initiative has proclaimed that maternal mortality is an issue of “health infrastructure.” AMTSL is one highly measurable, evidence-based, life-saving aspect of this health infrastructure. Given that in many countries with high maternal mortality postpartum hemorrhage is a leading cause of maternal death, there is an urgent need for information from these countries on current AMTSL practices.

As a complement to the work undertaken by the Global Network for Perinatal and Reproductive Health, the USAID-funded Prevention of Post-partum Hemorrhage Initiative (POPPHI), has proposed this survey to advance our understanding of current AMTSL practices. The survey has already been initiated in Tanzania, and Ethiopia. As a partner with POPPHI, the Management Sciences for Health, Rational Pharmaceutical Management (RPM) Plus Program is proposing to support the study in two W. African countries.

OBJECTIVES OF THE STUDY

The aim of this proposed study is to provide Ministries of Health (MoH) and their international partners the information necessary to assess current practices regarding AMTSL and to identify major barriers to its use. A complementary component of the study includes a qualitative assessment of perceptions and practices with regard to serious postpartum bleeding at home-based births among community leaders, traditional birth attendants, and recently delivered mothers. This information is needed to permit the development of interventions to improve adoption and implementation of the practice of AMTSL and to provide policy makers with information needed to promote institutional birth. A secondary aim is to produce public domain tools and a methodology which could be employed by others in the future to document change in the practice of AMTSL.

The specific research questions are—

- For what proportion of deliveries is AMTSL used at a national level? Which components of AMTSL are practiced (prophylactic use of oxytocic agents, early cord clamping, controlled cord traction, fundal massage), and how consistently are they practiced?
- Is AMTSL formally promoted in the standard treatment guidelines (STGs) in each country at national, and/or facility levels? Since when? How is AMTSL defined in the standards?
- How is the need for AMTSL drugs quantified at national and facility levels?
- What drug is used (oxytocin, ergometrine, prostaglandins)? How is it stored?
- At the facility level, is enough oxytocin available to allow for routine use of AMTSL?
- What are the major barriers to correct use of AMTSL?

STUDY DESIGN

The study is strictly descriptive and is designed to answer the previously stated research questions at national and/or facility levels. Four types of data collection are proposed.

1. Observations of deliveries
2. Short interviews with key informants regarding—
 - a) Procurement of AMTSL drugs and
 - b) The content of pre and in-service medical and midwifery education;
3. Document review of both the STGs at all existing levels and medical curricula for midwives and physicians regarding AMTSL
4. Verification of the availability and storage conditions of AMTSL medicines

Analysis

All data will be presented in aggregated form at the country level, thus individual facilities and providers will not be identified. Depending on the research question, the unit of analysis is births or facilities.

Sample Design

A nationally, representative, self-weighting sample of approximately 200 facility-based births will be selected in each country. Selection of births will result from a two-stage process in which facilities will be selected with equal probability and births over a two-day period will be observed.

Facilities eligible for selection are those with 10 births per week or more, for practical and logistical reasons. The sample size calculation is adequate to detect differences between groups or over time of 10 percent and assumes 30 percent use of AMTSL, a 90 percent response-rate, a design effect of 2.0.

Key informant interviews will be conducted with 3-5 respondents at the national level, and 1-3 respondents at the facility levels. Data collection is anticipated to last 20–25 days and is anticipated to be completed during July 2006.

Ethical Review, Study Approval, and Verbal Consent

Ethical review board approval from each country included in the study is required. An exempt status is being requested from the Johns Hopkins Bloomberg School of Public Health (JHSPH). MSH/RPM Plus, with which JHSPH is contracted for this study, will defer to JHSPH on issues of human subjects approval.

To request hospital participation, a MoH approval letter will be presented to the facility directors from all study facilities. Women and health care providers will be asked for verbal consent to be observed in sites where this is required. However, no signatures will be obtained. The verbal consent form for women/providers is attached.

REFERENCE LIST

1. Prendiville W.J., J.E. Harding, D. Elbourne, et al. 2001. Active versus expectant management in the third stage of labour. The Cochrane Library, Issue 3. Oxford, Update Software.
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3. World Health Organization (WHO). 2000. Managing Complications in Pregnancy and Childbirth: A guide for midwives and doctors. Geneva, WHO.
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ANNEX 1. SUMMARY OF DATA COLLECTION AT NATIONAL AND FACILITY LEVELS

Subject/data	Levels at which to collect data	
	National level	Individual Facility level
Questions on AMTSL drugs on the National Essential Drug List or national formulary; including questions regarding restrictions on the level of facility where these medicines are allowed and the type of provider allowed to use them	x	x
Are AMTSL medicines registered?	x	
Is public-use procurement of AMTSL medicines restricted to those on NEDL/formulary?	x	
Any quality assurance of medicines at purchase/receipt?	x	x
Is AMTSL specifically promoted in STGs?	x	x
How is quantification of AMTSL medicines done for procurement purposes?	x	x
Storage conditions	x	x
Stock		x
Supplies other than drugs		x
Cost		x

ANNEX 2: VERBAL CONSENT FORM FOR HOSPITAL DIRECTORS IN SELECTED HEALTH FACILITIES

The Ministry of Health has agreed for a sample of hospitals in [country] to participate in a study that documents practices during labor and delivery. Your hospital has been randomly selected to participate in the study. Participation in the study involves allowing our medically trained study staff to observe health care providers during labor, delivery and the immediate postpartum period for a period of two days. The study also involves a brief interview with the Chief Pharmacist and a visit to the hospital pharmacy to document the stock of uterotonic drugs and syringes. As hospital director, you have the right to refuse participation and there will be no consequences should you decide not to participate. There is neither benefit nor risk to your participation in this study. We are not recording the name of any of your staff nor of their patients. The information that is collected here will be analyzed along with observations from hospitals all over the country. The results from your hospital will never be identified in the analysis nor published separately. The results of the *national* study will be made available to the staff of all participating hospitals. We anticipate that these results will be available in December 2006.

Do you agree to have your hospital participate in this study of the management of labor, delivery and the immediate postpartum period?

YES _____

NO _____

Signature of the observer: _____

Date (dd/mm/yy): _____

**ANNEX 3: VERBAL CONSENT FORM FOR PROVIDERS OF OBSTETRIC CARE IN
SELECTED HEALTH FACILITIES**

The director of this hospital has agreed for this hospital to participate in a study that documents practices during labor and delivery. You are being asked to participate by allowing us to observe you during labor, delivery and the immediate postpartum period on this shift today. You have the right to refuse participation and there will be no consequences should you decide not to participate. There are neither benefits nor risks to your participation in this study. We are not recording your name or the name of any of your patients. The information that is collected here will be analyzed along with observations from hospitals all over the country. The results from your hospital will never be identified in the analysis nor published separately. The results of the *national* study will be made available to the staff of all participating hospitals. We anticipate that these results will be available in December 2006.

Do you agree to allow me to observe your work during labor, delivery and the immediate postpartum period during this shift?

YES _____

NO _____

Signature of the observer: _____

Date of the observation (dd/mm/yy): _____

ANNEX 4: VERBAL CONSENT FORM FOR PARTURIENT WOMEN IN SELECTED HEALTH FACILITIES

The director of this hospital has agreed for this hospital to participate in a study that documents health care during labor and delivery. You are being asked to participate by allowing us to observe you and your health care providers during labor, delivery and the immediate postpartum period. You have the right to refuse to be observed and there will be no consequences should you decide that you do not want your birth observed. There are neither benefits nor risks to your participation in this study. We are not recording your name. The information that is collected here will be analyzed along with information on births in hospitals all over the country. The results from this hospital will never be identified in the analysis nor published separately.

Do you agree to allow me to observe you and your health care providers during your birth and immediately after your birth?

YES _____

NO _____

Signature of the observer: _____

Date of the observation (dd/mm/yy): _____