

Study Description/Protocol¹

Survey of the management of the third stage of labor in: ENTER COUNTRY NAME/S

Submitted to ENTER YOUR REVIEW BOARD, Ministry of Health

By
YOUR NAME

Date:

I. 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 (1). The Cochrane review 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 (ICM/FIGO) issued a joint statement in November 2003 (2) 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 WHO evidence-based manual *Managing Complications of Pregnancy and Childbirth* (3) also attests to the international acceptance of this practice as the standard of care.

Although the WHO manual is beginning the process of being incorporated into medical and midwifery pre and in-service training, the American College of Nurse Midwives and the 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 very 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.

¹ This document is a description of the study, but can also be modified for use in each country to serve as the protocol to be submitted for ethical approval for the study.

Apart from anecdotal information, a 2003 article by the Global Network for Perinatal and Reproductive Health (4) 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 (Dublin) consistently used all three components of the practice. Variation in the prophylactic use of oxytocins 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. Evidence is insufficient to permit conclusions about the effectiveness of this practice in its altered states.

II. Justification:

These results suggest that the use of AMTSL is quite low, and where it is 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 postpartum hemorrhage is a leading cause of maternal death in many countries with very high maternal mortality, there is an important and urgent need for information from these countries on current practices regarding AMTSL. As a complement to the work undertaken by the Global Network for Perinatal and Reproductive Health, this survey is proposed to advance our understanding of current AMTSL practices in:_____ . Many countries have relatively high institutional birth rates. It is in such settings that the potential for AMTSL should be the greatest and that low or inconsistent use of this practice represents the greatest missed opportunity.

Figure 1 below illustrates three main factors we have conceptualized to determine the routine use of AMTSL. These are:

Policy

At the national level, a number of influences determine the priority given to AMTSL. For example, given that AMTSL has been a standard of care for many years in the United Kingdom, it is hypothesized that AMTSL is more common in former British colonies and among providers who have trained in the UK. Likewise, charismatic leaders from national or international agencies may well influence national policies, standards of care and medical education regarding routine use of AMTSL, which in turn may influence facility-based policies and behavioral expectations.

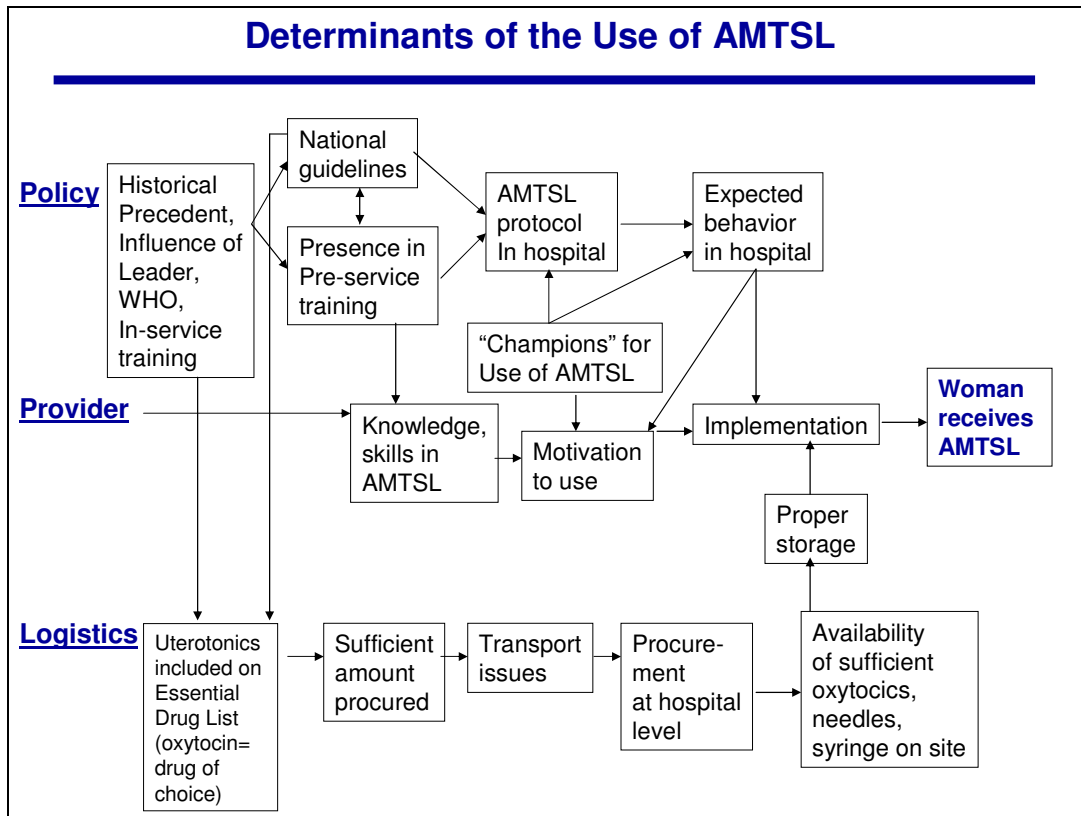
Provider-related factors

Knowledge and skills to perform AMTSL are clearly essential for routine use of the practice. However, provider motivation, influenced by facility-based behavioral expectations, is also key.

Supplies and logistics

The sufficient availability of quality uterotonic drugs, needles and syringes at national and local levels is essential for routine use of AMTSL. Effective use of AMTSL also implies appropriate conditions during transport and storage to assure the use of chemically active drugs and safe, sterile needles and syringes.

Figure 1: Determinants of the Routine Use of AMSTL



III. Objectives of the Study:

The aim of this proposed study is to provide Ministries of Health and their international partners the descriptive information necessary to assess current practices regarding AMTSL and to identify major barriers to its use. This information is needed to permit the development of interventions to improve adoption and implementation of the practice of AMTSL.

The specific research questions are:

1. 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?
2. Is AMTSL formally promoted in the Standard Treatment Guidelines (STGs) in each country at national level? Since when? How is AMTSL defined in the Standards?

3. How is the need for AMTSL drugs quantified at national and facility levels?
4. What drug is used (oxytocin, ergometrine, prostaglandins)? How is it stored?
5. At the facility level, is enough oxytocin available to allow for routine use of AMTSL?
6. What are the major barriers to correct use of AMTSL?

III. Study Design:

The study is strictly descriptive and is designed to answer the research questions stated above at national and/or facility levels. Four types of data collection are proposed: observations of deliveries, short interviews with key informants regarding a) procurement of AMTSL drugs and b) the content of pre and in-service medical and midwifery education; a document review of both the Standard Treatment Guidelines at the national level and medical curricula for midwives and physicians regarding AMTSL; verification of the availability and storage conditions of AMTSL drugs. Each component of data collection is described below and the study questionnaires are included on the PATH website.

Observations of deliveries:

Provider practice during vaginal deliveries will be observed and documented by study staff in selected facilities. A short, structured questionnaire will be completed which documents: the absence or presence of the various components of AMTSL; parity; gravidity; age of the woman; qualification of the provider and level of care provided by the health facility (tertiary care, hospital, health center, etc.). The questionnaire will not contain any identifiers for the woman or the provider. The questionnaire is an adaptation of the instrument used by Festin et al. in the only international survey on AMTSL to date. Data will be collected by skilled birth attendants who will have been trained for data collection.

Interviews with key informants:

Interviews will be conducted by study staff with key informants from the Ministry of Health regarding procurement of AMTSL drugs. Informants may include: chief pharmacists, heads of central and facility-based warehouses. Interviews will also be conducted with staff from the Ministries of Health and Education and obstetric and midwifery professional organizations who are knowledgeable of the content of medical/midwifery curricula regarding AMTSL. Data from these interviews will be used to provide contextual information to complement the quantitative analysis on facility-based births and to assist in locating documents needed for the document review, described below.

Document Review:

A short standardized questionnaire will be completed by a member of the study staff to identify the presence of AMTSL in national level Standard Treatment Guidelines, the presence of AMTSL drugs on Essential Drug Lists or National formularies and references to AMTSL in pre-service and in-service medical curricula/syllabus from the year preceding the study.

Verification of the availability and storage condition of AMTSL drugs:

Following interviews with key informants regarding drug procurement, study staff will verify the availability and storage conditions of AMTSL drugs. Data will be collected using a structured questionnaire.

Analysis:

Only descriptive analyses are required to respond to the research questions listed above. Quantitative analyses will include the reporting of: percentages, percent distributions, means and medians. All data will be presented in aggregated form at the country level, thus individual facilities will not be identified. Depending on the research question, the unit of analysis is births or facilities.

Sample Design:

A nationally, representative, sample of a minimum of approximately 200 vaginal 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 and births over a several day period will be observed (the duration of observation in each facility will depend on the expected number of births in facilities in each country). The sample size calculation assumes 30 percent use of AMTSL, a 90 percent response-rate, a design effect of 2.0 with a precision of +/-10 percent.

Data needed at the facility level will be collected in each facility selected for the observation of deliveries.

Key informant interviews will be conducted with three to five respondents at the national level, and one to three respondents at the facility levels.

The duration of data collection will depend on the number of facilities selected in the sample, the number of observers trained and the average number of births expected in these health facilities.

Ethical review, study approval and verbal consent

Ethical review board approval both in-country, and among concerned, supporting international agencies should be obtained. Signed approval for the study will also be obtained from the Ministry of Health. To request facility-level participation, the Ministry approval letter will be presented to health facility directors from all facilities selected for the study. Women should be asked at admission for verbal consent to be observed. However, no signatures should be obtained. A verbal consent form should be developed in each country.

Reference List

- (1) Prendiville WJ, Harding JE, Elbourne D, McDonald S. Active versus expectant management in the third stage of labour (Cochran review). The Cochrane Library 2001;(1).
- (2) International Confederation of Midwives and International Federation of Gyneacology and Obstetricians. Joint Statement: Management of the Third Stage of Labour to Prevent Post-partum Haemorrhage. internet . 2003.
- (3) WHO. Managing Complications in Pregnancy and Childbirth: A Guide for Midwives and Doctors. 2000. Geneva.
- (4) Festin MR, Lumbiganon P, Tolosa J, Finney K, Ba-Thike K, Chipato T et al. International survey on variations in practice of the management of the third stage of labour. Bull World Health Organ 2003; 81:286-291.