Blood Loss Measurement

Technology Opportunity Assessment

Prepared for the Merck for Mothers Program
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Summary

Delayed diagnosis and poor management of postpartum hemorrhage (PPH) are associated with increased mortality and morbidity. Accurate measurement of the amount of blood lost after childbirth helps to quickly diagnose life-threatening hemorrhage. Innovations in measuring blood loss could improve the timely management of PPH.

Statement of Need

Obstetric hemorrhage is estimated to cause 25% of all maternal deaths and is the leading direct cause of maternal mortality worldwide. Postpartum hemorrhage (PPH), defined as vaginal bleeding in excess of 500 mL after delivery, is generally considered to account for a majority of the cases of obstetric hemorrhage, occurs in over 10% of all births, and is associated with a 1% case fatality rate.

Although active management of the third stage of labor can prevent up to 60% of PPH cases, PPH continues to have a devastating impact on women in resource-poor settings where home births are common and hospitals or health facilities are often inaccessible. Obstetric hemorrhage accounts for 34% of maternal deaths in Africa, 31% in Asia, and 21% in Latin America and the Caribbean, while only 13% of maternal deaths in developed countries are due to hemorrhage. Women who survive PPH can suffer from anemia postpartum.

Most births and maternal deaths occur in Africa and Asia where home deliveries are common, infrastructure and transportation are limited, and birth attendants are scarce or inadequately prepared to prevent and treat PPH. In such settings hemorrhage accounts for more than 30% of maternal deaths. The United Nation’s fifth Millennium Development Goal, to reduce 75% of maternal mortality by 2015, cannot be reached without addressing PPH.

Several factors influence PPH rates, such as how blood loss is measured at delivery, how the third stage of labor is managed (i.e., active management of the third stage of labor), or how obstetric interventions are carried out (i.e., episiotomy). Delayed diagnosis and poor management of PPH are associated with increased maternal mortality and morbidity. Clinicians continue to rely on visual assessment to determine the volume of postpartum blood loss even though studies have repeatedly shown visual estimates to be inaccurate (overestimating blood loss at low volumes and underestimating blood loss at high volumes).

Technologies that can help women and clinicians estimate postpartum blood loss more accurately could improve management of PPH, reduce cases of severe PPH (blood loss greater than 1,000 mL), and reduce
morbidity and mortality due to PPH. Methods to estimate postpartum blood loss include direct collection of blood in pans, gravimetric measurement of sponges (weighed before and after use), or blood collection drapes or mats. An ideal technology or method should estimate blood loss in real time, provide an accurate estimation of threshold volumes, permit early diagnosis of PPH (at least 500 to 1,000 mL of blood loss), have a high specificity and sensitivity, be practical and easy to use, be low cost, and require minimal equipment.

Technology Solutions Landscape

Over the years, different methods have been used to estimate blood loss. Several quantitative methods are described below, including visual assessment, direct methods of measurement, and laboratory-based methods of measurement.8

Visual assessment
The standard method of observation used for the visual estimation of blood loss is relatively straightforward and requires no expenditure. Despite its inaccuracy and variation from one caregiver to the next, birth attendants correlate it with clinical signs. The major advantage of this method is that it is a real-time assessment and enables the birth attendant to correlate findings, on an individualized basis, with the clinical presentation. However, significant differences between clinical estimates and actual measurements have been consistently demonstrated in several studies. A common error is underestimation of blood loss, with an average error of 46%, when estimates at the time of delivery are compared with more precise measurements.9 When losses are large, they are most often underestimated, and smaller losses tend to be overestimated.

Direct collection of blood

Bedpan and standard measuring jar: This approach was used in the World Health Organization (WHO) multicenter, randomized trial of misoprostol in the active management of the third stage of labor. In this trial, blood loss was measured from the time of delivery until the mother was transferred to postnatal care. This period was generally up to one hour postpartum. At that time, the collected blood was poured into a standard measuring jar provided by WHO and its volume measured. Immediately after the cord was clamped and cut, the blood collection was started by passing a flat bedpan under the buttocks of a woman delivering in a bed or putting in place an unsoiled sheet for a woman delivering on a delivery table. The errors in estimating blood loss arise from failure to collect or note all the blood in the stained linen, incomplete extraction from the collection device, ignoring maternal blood within the placenta (approximately 153 mL), confusion related to the mixing of blood contaminated with amniotic fluid and urine, and technical inaccuracies associated with the transfer of the collected blood to a measuring device.

Rubberized blood mat (Bangladesh): The International Centre for Diarrhoeal Disease Research, Bangladesh developed a rubberized blood mat which when saturated, is indicative that a woman is hemorrhaging. The mat holds approximately 500 mL of blood, with flowered plastic on one side and
rubber on the other side. The mat holds a maximum of 500 mL of blood, at which point the mat will begin
to leak onto plastic or onto the floor, signaling PPH. In a project implemented by Pathfinder International
Bangladesh, each pregnant woman received a PPH bag, consisting of a rubberized blood mat, misoprostol
tablets, and a clean delivery kit at 32 weeks gestational age. The mat was found to be well liked and
utilized by communities in Bangladesh. In the fall of 2010, Dr. Md Abdul Quaiyum, developer of the mat,
received a Grand Challenges in Global Health grant to enable further refinement of the mat to a
biodegradable form.10 This development would be important as medical waste is a challenge in many
developing-country settings.

*Kelly’s pad (India):* With funding from the John D. and Catherine T. MacArthur Foundation and
Pathfinder International, the Continuum of Care project was implemented in India using a rubberized mat,
called a Kelly’s pad, to measure blood loss. The Kelly’s pad is a simple medical device to funnel blood to
a collection device in order to help detect PPH. The device is widely used in India, though not elsewhere.
The Kelly’s pad funnels blood into a calibrated collection bowl which has a hemorrhage alert line at 500
mL. The pad is washable and sterilizable, making it far more cost-effective than a plastic collection drape.

*Kangas (Tanzania):* A study in Tanzania found that two kangas (large pieces of African cloth) provided an
approximate measure of PPH; when the two cloths were saturated with blood, they held approximately 500
mL of blood.11 The advantage of this method is the use of locally available measures that do not require
manufacturing, distribution, or waste disposal.

*Blood drape (Nigeria):* With funding from the John D. and Catherine T. MacArthur Foundation,
Pathfinder International implemented the Continuum of Care project using a blood drape. The blood drape
is a plastic sheet that is placed under the woman and siphons the blood into a calibrated measuring pocket
on the sheet. The sheet is decontaminated and then disposed of as medical waste or incinerated after use.
Stacie Geller with the University of Chicago and Richard Derman with the University of Kansas are the
principal investigators and developers of the BRASS-V® drape.12

*Gravimetric method:* This method involves weighing sponges before and after use. The difference in
weight provides a rough estimate of blood loss. The gravimetric method requires the weighing of materials
such as soaked pads on a scale and subtracting the known weights of these materials to determine the
blood loss. Inaccuracies can arise at several steps in this procedure, including lack of international
standardization of size and weight of gauze, sponges, and pads.

*Laboratory-based methods of measurement*

*Alkaline hematin method/Acid hematin method:* Another direct method of blood loss measurement is based
on mixing collected blood with a standardized solution which converts hemoglobin to acid hematin or
cyanmethemoglobin. This in turn can be measured by a spectrophotometer or colorimeter.
Spectrophotometric analysis can be performed by the methods described below: 13-15

1. Preparation of standard: 2 mL of peripheral blood are collected pre-delivery. The blood standard is prepared with 0.1 mL of the patient’s peripheral blood in 9.9 mL of 5% sodium hydroxide solution. The optical density (OD) is read at 550 nm after 30 minutes.

2. Preparation of sample: The collected sample is added to 2 L of 5% sodium hydroxide and left to stand for 15 minutes. One mL of the filtrate is diluted 10 times in 5% sodium hydroxide and left to stand for another 15 minutes. The OD is read with a spectrophotometer at 550 nm at 30 minutes after the addition of sodium hydroxide to the sample.

3. Calculations: OD sample × 2,000 mL × 10/OD blood standard × 100 = blood loss volume.

**Gap Analysis**

Currently, although there are no donors or projects with a $1 million investment in any of the above-mentioned technologies, there are many key stakeholders involved in the process of implementing blood loss measurement initiatives. These include patients, traditional birth attendants, health care providers, governments, funding sources, WHO, institutions specialized in research and implementation of methods, international and national nongovernmental organizations working in health fields, and manufacturers.

WHO recommends that blood loss and other clinical parameters after childbirth should be closely monitored. 16 According to WHO, there is insufficient evidence at present to recommend quantification of blood loss over clinical estimation. Thus, WHO has identified the following priority research areas:

- Define the quantity of blood loss that should be the marker for diagnosis of PPH (blood loss greater than 500 mL) and severe PPH (blood loss greater than 1,000 mL).
- Determine the role of quantifying blood loss in altering (or improving) clinical outcomes for the mother and her baby.
- Identify clinical consequences of blood loss that are of greatest value for the diagnosis and treatment of PPH.

Most of the technologies used to indirectly measure blood loss do not provide a real-time assessment or are difficult to implement in low-resource countries due to requirements for sophisticated laboratory equipment.

Among the quantitative technologies for blood loss measurement, the rubberized blood mat used in Bangladesh is the most promising in terms of its simplicity, low cost, and capacity to identify PPH quickly, especially in home deliveries. The rubberized mat was acceptable and well liked in selected communities in Bangladesh. 16
Investment Opportunity

The core investment for the rubberized mat should include designing a plan for introduction at the country level, identifying the health service providers who can use it, designing a guideline for its use or adapting it to existing guidelines, and developing a strategy to measure impact.

To understand impact and cost-effectiveness of the rubberized blood mat, operations research in representative countries and settings in sub-Saharan Africa and South Asia will be needed to recommend the use of services and evaluate maternal and perinatal outcomes from PPH. Careful documentation of implementation, disruptions, sustainability, lessons learned, and financial and service costs will help inform scale-up decision-making.

In addition, feedback should be collected from women, family members, providers, and managers on acceptability and perceptions of quality of care. These data should also inform scale-up decision-making.

Finally, this technology can effectively be incorporated into regional manufacturing as long as standardized and verifiable design specifications can be developed. Thus, PATH recommends investment in identifying the feasibility of regional manufacturing and also research and development of standardized product specifications.
References


