**Device – Target Product Profile (TPP)**

**Health/Disease Area: Postpartum haemorrhage**

**Intervention/Candidate: Tools for measurement of postpartum blood loss after vaginal birth**

# Version: <V3: 9 May 2024>

This is a draft document and is undergoing public consultation. It is anticipated that the contents and structure of this document may change during this process.

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# Background

## Postpartum Haemorrhage

Postpartum haemorrhage (PPH), characterized by excessive bleeding after childbirth, is a significant global health issue. An estimated 6% of women giving birth will experience PPH.1 With approximately 70,000 associated maternal deaths annually, equivalent to over 20% of all maternal deaths, PPH is the single largest contributor to maternal mortality globally.2 While PPH can affect postpartum women in any context, those in low-resource settings are disproportionately affected - the highest rates of PPH and PPH-associated mortality are observed in sub-Saharan African and South Asian countries.1,2 In addition to maternal mortality, PPH can result in a number of morbidities including hypovolemic shock, organ dysfunction, anemia and infection.3-5

The World Health Organization (WHO) defines primary PPH as 500 ml or more blood loss occurring within 24 hours postpartum, regardless of mode of birth.2 Severe PPH is characterized by a blood loss exceeding 1000 ml.6 Secondary PPH can occur up to 6 weeks following childbirth.7 PPH can occur after either vaginal or cesarean section births. It is most commonly caused by uterine atony, but can also be caused by lacerations, hematomas, uterine inversion, rupture, retained placental tissue, morbidly adherent placenta, or coagulopathy.8

In 2023, WHO issued a new recommendation in favour of early PPH detection and using care bundles for treatment.9 This care bundle should include multiple, effective interventions - uterine massage, administration of an oxytocic agent and tranexamic acid, intravenous fluids, examination of the genital tract and escalation of care.9 However, prompt initiation of these interventions relies upon early and accurate detection of PPH. Consequently, WHO also recommended routine, objective measurement of blood loss for all postpartum women, in order to ensure timely identification and treatment of PPH.9 Blood loss measurement should commence from the delivery of the infant and continue as long as active bleeding persists, or if the woman remains unstable after PPH.10 Failure to accurately measure postpartum blood loss will likely translate into delays in detecting PPH and commencing effective treatments – these delays can be life-threatening to the woman.

There are a number of different approaches used for estimation or measurement of blood loss and detection of PPH. Currently, subjective visual assessment of blood loss is widely practiced, which has proven to be unreliable. For example, visual estimation of blood loss often leads to overestimation when blood loss volume is low, and underestimation when blood loss volume is high.11-13 Other, more objective methods aim to quantitate the amount of blood loss, such as the use of gravimetric techniques (collecting and weighing) or uncalibrated drapes.14,15 More recently, calibrated drapes have been shown to be accurate for postpartum blood loss measurement.16,17 In a recent multi-country trial (E-MOTIVE trial) calibrated drapes were used to enable prompt identification of PPH in women giving birth vaginally.18 More complex technologies such as measuring haemoglobin (Hb) concentration in venous blood samples using spectrophotometry can also precisely measure postpartum blood loss.16 However, implementation of these technologies can be challenging and time consuming, particularly in resource-constrained settings.13

WHO has acknowledged the lack of advancement in PPH knowledge and technologies throughout the past decade, necessitating the development of innovative diagnostic strategies.2 While several blood loss measurement tools exist, there is yet to be global scale up of accurate, user-friendly and affordable tools for this purpose. This contributes to delays in identifying PPH and missed opportunities to implement effective treatment interventions that could prevent PPH-related morbidity and mortality. Given the significant impact of PPH on maternal health outcomes, particularly in low- and middle-income countries (LMICs), there is a pressing need for accurate, accessible, sustainable and affordable methods to be available, wherever women give birth.

## Purpose of this Target Product Profile

Target Product Profiles (TPPs) are strategic documents that outline the minimum and optimal characteristics required for new health products, including devices and medicines. TPPs are an important resource to guide key stakeholders (such as funders, researchers, product developers, manufacturers and regulators) on the requirements of new medicines, diagnostics and devices to meet pre-specified clinical and public health needs.19 They inform research and development strategies, help frame product dossiers, streamline communication with regulatory agencies and help funders set targets.20

There are currently no TPPs publicly available for PPH blood loss measurement devices.21 WHO have identified the need for TPPs for PPH interventions to create a shared understanding on ideal characteristics of innovative PPH products.2 Development of this TPP is intended to help drive innovation, research and implementation of effective and affordable devices that can accurately measure postpartum blood loss, particularly in low-resource settings. This will improve the timely detection of PPH, allowing for implementation of PPH care bundles as clinically necessary.

# Summary: Intervention Use Case and Target Users

A tool that can measure postpartum blood loss and detect PPH for vaginal births, from the third stage of labour up to 24 hours after birth. It will provide an objective measurement of direct blood loss, rather than a subjective visual estimate, to ensure accuracy. A user-friendly and inexpensive design will ensure it is a simple and effective tool that is suitable for use across all healthcare facilities globally, particularly in limited-resource settings. By enabling timely and accurate blood loss measurement, this tool will be crucial in optimising use of and adherence to treatment protocols for PPH.

# Executive Summary: TPP Core Variables

| **Variable** | **Minimum**  *The minimal target should be considered as a potential go/no go decision point.* | **Optimistic**  *The optimistic target should reflect what is needed to achieve broader, deeper, quicker global health impact.* | **Annotations / Actual Product Performance[[1]](#footnote-2)**  *For all parameters, include here the* ***source data used and rationale*** *for why this feature is important.* |
| --- | --- | --- | --- |
| **Indication** | Accurate measurement of blood loss and detection of PPH from the third stage of labour up to 1 hour after vaginal birth. | Accurate measurement of blood loss and detection of PPH from the third stage of labour up to 24 hours after vaginal birth. | In order to ensure accuracy of blood loss amounts, objective quantification should be used rather than subjective estimations, such as visual estimation.11-13  Large trials have measured blood loss over the first one hour postpartum.18 However, primary PPH can occur up to 24 hours after birth, including once women have left the delivery suite.  While PPH can also occur during caesarean section births, blood loss measurement tools will have different requirements compared to vaginal births, so are not included in this TPP. |
| **Target Population** | All pregnant women, girls, trans and gender-diverse people who are giving birth vaginally. | Same as minimum. | Postpartum blood loss and PPH can affect any person giving birth. While some risk factors for PPH are known, it is difficult to accurately predict which women are at higher risk of PPH.22 Because of these challenges in predicting PPH, blood loss measurement should be utilised for all women giving birth. |
| **Target Countries** | All countries, with a particular focus on limited-resource settings and countries with the highest burden of PPH. | Same as minimum. | PPH can occur in any country. Therefore, accurate measurement of postpartum blood loss is an important intervention globally. Rates of PPH and associated maternal mortality are highest in regions such as sub-Saharan Africa and South Asia.2 Therefore, blood loss measurement tools must be suitable for use in these contexts. |
| **Target Users and Settings** | Healthcare professionals providing intrapartum care and immediate postpartum care.  Suitable for use in different levels of healthcare facilities (primary, secondary and tertiary). | Same as minimum.  Plus:  Also suitable for use in home-or community-based settings where birth is attended by a health care professional. | The healthcare cadre responsible for using tools to measure postpartum blood loss may differ between countries, settings and health facilities. For example, this could include midwives, nurses, obstetricians, or community health workers.16,23-26 As such, the tool must be simple enough for any appropriately trained healthcare worker to use. |
| **Tool Design** | Single use.  Able to be used in multiple birth positions. | Single use or reusable.  Able to be used in multiple birth positions. | Whether tools are single- or multi-use can have impacts on cost-effectiveness, patient safety, cleaning requirements and environmental sustainability.  There are various birthing positions that women may choose during delivery.27 As such, it is necessary to have tools that can measure blood loss in different positions. |
| **Output and display of blood loss volume** | Volume of blood loss able to be clearly and quickly determined.  Produces a reliable, consistent, standardised and accurate measurement of blood loss volume.  Calibrated with indicators showing volumes that trigger detection, treatment and escalation of PPH. | Same as minimum.  Plus:  No additional equipment or specific technical expertise required to read results.  Digital or non-digital features for recording and/or documenting blood loss volume measurements to assist in clinical documentation. | Tools that clearly show volume of blood loss are necessary for accurate measurement.  Having indicators at certain blood loss volumes to trigger closer monitoring of other signs of blood loss and prepare to deliver interventions to treat PPH, facilitates more effective prevention and treatment of PPH-related mortality and morbidity. For example, calibrated drapes as used in the E-MOTIVE trial have indicators at 300 ml and 500 ml.18  If the device measures and notifies the care provider when a certain threshold is exceeded that may be an advantage.  The readings should not be dependent on the position or shape of the device. |
| **Time to result** | Real time, immediate results. | Same as minimum. | Accurate measurement of blood loss in real time is essential to monitor blood loss as it occurs.28 This also facilitates ongoing, cumulative blood loss measurement. In doing so, the rapid assessment of blood loss will facilitate timely detection of PPH and trigger treatment interventions. Tools (such as laboratory tests) that do not have real time results, but rather require a period of waiting time before reading results, would lead to a delay in detection of PPH. |
| **Training Requirements** | Some training required for any level of health care worker, with options for remote, video-based or simulation training. | Minimal or no training required. | Tools should be simple to use and not require extensive training. Ideally, no or minimal formal training would be required to operate the tool. It should be simple to use, so that any healthcare professional, with any level of training or qualification (including community health workers) can effectively use the tool. |
| **Instrument service, maintenance and warranty** | For single use tool, none required. | Same as minimum.  Plus:  For reusable tool, easily able to be cleaned and sterilized. | Tool should not require servicing or maintenance if a single-use product. No highly technical equipment or parts requiring specialist expertise to set up or maintain.  For reusable products, it is critical that reprocessing (i.e. cleaning and sterilization) of products is simple and effective.29 This must be achievable with easily accessible cleaning products. |
| **Accuracy** | Detects >70% of PPH. | Detects >90% of PPH. | Blood loss measurement tools should detect PPH to a high level of accuracy and precision. Ideally, the device should be validated against a precise measurement system for this claim. |
| **Complexity** | Set up in <3 steps  Requires one person to use | Set up in 1 step  Requires one person to use | The tool should be as simple as possible to unpack, set up, and use.  Regardless of which cadre is utilizing the device, it should be possible to set up and implement and read results by one person. In many settings, women give birth with only one healthcare professional present, so complexity of the tool must allow for this situation. |
| **Safety** | Safe for use by all postpartum women delivering vaginally. | Same as minimum. | There should be no safety concerns associated with use of the tool, including minimizing risk of infection or other potential adverse effects such as leakage. |
| **Environmental Stability** | Able to be transported and stored in a wide range of climatic conditions, including high humidity, dust and heat.  3-5 year shelf life in climatic zone IVb (simulated with 30°C and 75% relative humidity). | Same as minimum.  Plus:  Sustainable, biodegradable or reusable, and climate-friendly tool.  OR, easy to clean and re-use | In order to be implemented globally, the device must be suitable in all climate conditions, without affecting the quality or performance of the product. |
| **Regulation and Quality Management** | Approval by relevant national authority. | Approval by relevant national authority and at least one international regulatory authority.  WHO prequalification approval.  Quality certification through an international organization. | As with medical devices, blood loss measurement tools should be approved for use by the relevant national authority (e.g. government health department or administration) in the country of intended use.30  WHO prequalification, if granted, emphasizes the safety, quality, and efficacy of medical products.  Compliance with internationally recognised regulatory authorities ensures high quality and safety standards are met. For example, ISO 13485 for medical devices.31 |
| **Primary Target Delivery Channel** | Delivered by health workers in a range of public and private settings that provide intrapartum and postpartum care. This could include health centres, hospitals and birth centres. | Same as minimum.  Plus:  Settings including community-based outreach services and healthcare worker assisted homebirths. | Blood loss measurement should be conducted for all women giving birth. Therefore, blood loss measurement tools must be easy to use in any type of health facility, including primary and community-based facilities with varied staffing and resourcing capacities. |
| **Packaging** | Easily packable. | Same as minimum.  Plus:  Minimal environmental footprint with recyclable packaging. | Devices should be easy to pack to ensure efficiency throughout the supply chain, with mitigation of any damage to devices during transit.  Where possible, consideration should be given to the potential environmental impacts of medical devices. |
| **Price** | Affordable for use in low-resource settings, while maintaining high quality. Ideally no direct cost to women. | Affordable for use in low-resource settings, while maintaining high quality. Ideally no direct cost to women.  Unit cost is less than existing similar tools for objective blood loss measurement.  Discounts for bulk procurement available for governments, international health agencies, and large health facilities.  Able to be manufactured locally, with guaranteed quality assurance, to reduce costs. | Blood loss measurement tools must be low-cost and affordable to facilitate wide-spread use, particularly in limited-resource settings.  Where possible, costs should be less than existing tools for the same indication and pose no cost barriers to women. For example, calibrated drapes can currently be purchased for approximately USD 1.25.32 Reusable tools may be more expensive but should have a low cost-per-use.  Strategies to keep costs low, such as bulk procurement discounts and local manufacturing, may support in increasing the accessibility and availability of blood loss measurement tools.33 |
| **Procurement Volume Estimates** | Volumes compatible with global rate of vaginal births. | Same as minimum. | Approximately 134 million births occur each year.34 An estimated 21% of births globally are caesarean sections, therefore an estimated 105 million vaginal birth occur each year.35 However, the rates of caesarean section compared to vaginal births differ greatly among different countries.36 |

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1. [↑](#footnote-ref-2)