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

**Health/Disease Area: Postpartum haemorrhage**

**Intervention/Candidate: Tools for blood loss measurement during caesarean delivery**

# Version: <V1.0: 14 October 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 in Caesarean Delivery

Birth via caesarean delivery is becoming increasingly common throughout the world, with a global caesarean delivery rate of 21%.1 Countries with the highest rates of caesarean deliveries include the Dominican Republic (58.1%) and Brazil (55.7%), whereas the lowest rates are found in Chad (1.4%), Niger (1.4%) and Ethiopia (1.9%).1 Caesarean delivery is indicated when vaginal delivery may increase the risk of poor maternal and/or neonatal outcomes. Indications for caesarean delivery can include fetal distress, antepartum hemorrhage, obstructed labour, severe pre-eclampsia or eclampsia, abnormal fetal presentation, and uterine rupture.2 While many caesarean deliveries are essential, a growing number of women undergo caesarean delivery without a clear medical indication.3 A caesarean delivery procedure itself has short- and long-term risks, including surgical risks (e.g. haemorrhage, blood transfusion, anesthesia complications, injury to organs), post-operative risks (e.g. infection, blood clots), and risks in future pregnancies (e.g. uterine rupture, abnormal placentation).4 Additionally, prevalence of maternal mortality and morbidity are higher following caesarean delivery compared to vaginal delivery.5 Performing a caesarean delivery also requires more resources than a vaginal delivery,6 and given that an estimated 15-20% of pregnancies will require a caesarean delivery, health systems must be able to provide safe and standardized surgical services and manage associated complications.7

Women undergoing caesarean delivery are, in general, at higher risk of intrapartum and postpartum haemorrhage (PPH).8,9 This can be due to common causes of haemorrhage such as the underlying indication for the caesarean delivery itself (such as uterine rupture), postpartum causes (such as uterine atony), as well as the risk of bleeding caused by surgical incision or surgical trauma.10,11 The World Health Organization (WHO) defines PPH as 500ml or more blood loss occurring within 24 hours postpartum, regardless of mode of delivery.12 However, some organizations such as the American College of Obstetrics and Gynaecology (ACOG), define PPH as 1,000mL or more blood loss with signs or symptoms of hypovolemia regardless of route of delivery.13

In 2023, WHO issued new recommendations in favour of early PPH detection, and care bundles for PPH treatment.14 Tools for the accurate and timely measurement of blood loss are needed to help healthcare professionals detect PPH early, and trigger PPH treatment promptly. However, much of the available evidence on methods of blood loss measurement focus on blood loss after vaginal delivery only. WHO’s recommendations emphasized that, despite a current lack of trial evidence on PPH detection and use of care bundles for caesarean deliveries specifically, it is nonetheless clinically important to accurately measure postpartum blood loss in women undergoing caesarean delivery.14

Ideally, a tool for measuring blood loss during caesarean delivery should be accurate, simple to use, safe, affordable and environmentally sustainable. A number of methods and tools are described in the literature for measuring blood loss during caesarean delivery. Visual estimation, with or without visual aids, may be conducted by obstetricians, general surgeons, anesthetists, nurses, midwives, or other staff attending caesarean deliveries.15-17 Gravimetric methods involve all relevant materials (e.g. towels, pads, sponges, drapes) being weighed before and after use, with the difference in weight representing the calculated blood loss.18-20 Volumetric methods, commonly suction canisters, are used to collect and measure blood loss volume.21 Some innovative methods utilize colorimetric techniques through use of photography and smartphone applications.22,23 Preoperative and postoperative calculations of blood loss based on haemoglobin or hematocrit level changes can also be used.16,17,20 However, no current method is considered a ‘gold-standard’ for accurately measuring blood loss, while several methods pose practical challenges (e.g. cost, complexity, training requirements) for global scale up.16,19

Further research and development (R&D) is required to improve on these tools, or develop new tools. Doing so would help ensure excessive blood loss occurring during caesarean delivery is detected early, leading to timely intervention with effective treatments, and reducing haemorrhage-associated morbidity and mortality.

## 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.24 They inform research and development strategies, help frame product dossiers, streamline communication with regulatory agencies and help funders set targets.25

A new TPP for postpartum blood loss measurement for vaginal births has undergone public consultation. Expert stakeholder feedback as part of this consultation identified the need for a TPP to be developed for tools for blood loss measurement during caesarean delivery. Additionally, WHO’s PPH Roadmap identified the need for TPPs for PPH-related interventions.12

This TPP is intended to guide R&D of new tools to measure blood loss during caesarean delivery. This will facilitate timely and consistent detection of excessive blood loss during caesarean delivery and help improve maternal health outcomes.

# Summary: Intervention Use Case and Target Users

A tool that can accurately measure blood loss during caesarean delivery. The tool will provide an objective, rather than a subjective, estimate of caesarean delivery blood loss. It is also able to differentiate between blood loss and other body fluids (e.g. amniotic fluid, irrigation fluids).

The tool will be used by appropriately trained healthcare providers attending caesarean deliveries, in hospital settings where planned or emergency caesarean deliveries take place. The tool is feasible to use and acceptable to women and providers.

Vaginal blood loss following a caesarean delivery is beyond the scope of this TPP. This is addressed in the soon to be published TPP for postpartum vaginal bleeding.

# 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 during caesarean delivery. | Same as minimum.  | Accurate tools to measure blood loss during caesarean delivery can aid in the early detection of PPH, allowing for timely initiation of PPH management.14 Objective quantification of blood loss is more accurate than subjectively estimating blood loss, such as through visual estimation.26 |
| **Target Population** | All pregnant people who undergo caesarean delivery. | Same as minimum.  | Women undergoing caesarean delivery have higher rates of excessive blood loss and PPH.11 Blood loss volume should be measured and monitored at every caesarean delivery. |
| **Target Countries** | All countries where caesarean deliveries occur, with a particular focus on countries with high rates of caesarean delivery. | Same as minimum. | Caesarean deliveries occur in many settings around the world; however the rates vary between countries and regions. The global caesarean delivery rate is estimated at 21%,1,3 varying from 1.4% to 58.1% across different countries.1 |
| **Target Users and Settings** | Healthcare professionals conducting caesarean deliveries.Suitable for use in facilities equipped to conduct caesarean deliveries. | Same as minimum.  | Healthcare professionals must be suitably trained to conduct and support caesarean delivery. This may include obstetricians, surgeons, surgical nurses, midwives, surgical technicians and anesthesiologists. Caesarean delivery is a major surgery which requires the appropriate infrastructure, equipment and capacity.27 Therefore, caesarean deliveries will take place in suitably equipped hospital settings.  |
| **Tool Design** | Able to differentiate between blood loss and other fluids (e.g. amniotic fluid).Can be integrated with existing surgical/anesthetic equipment and processes. User-friendly design and operation. | Same as minimum. Plus: Lightweight and portable for ease of operation.Single use or reusable options as relevant depending on the tool design and context of use.Consideration of environmentally sustainable options. *If powered:*Battery life for at least 5 hours with rechargeable battery and/or able to be plugged into mains power. If imaging technology is used, high-resolution imaging required. | It is important to distinguish between volume of blood loss and volume of other fluids (amniotic fluid, irrigation, etc.) to ensure volume measurements are accurate. ACOG guidelines recommend suction of all amniotic fluid before or separate to measurement of blood loss.28  |
| **Output and display of blood loss volume** | Clear display of blood loss volume through visual and/or numerical means. | Same as minimum. Plus: Alarm (visual and/or audible) for thresholds of excessive blood loss.Options for printable and exportable reports/results, including ability to integrate with electronic patient record systems. | Blood loss volume amounts should be simple and quick to read without needing complex interpretation. This may include calibration with indicators at blood volume increments. Tools that notify health professionals when certain blood volume thresholds are met (such as 300mL, 500ml or 1000ml) would be advantageous. Methods to share blood loss volume amounts with post-operative and maternity wards, including through printouts or integration with electronic medical record systems, would facilitate documentation and cumulative blood loss measurement.  |
| **Time to result** | Real-time results of blood loss volume. Continuous monitoring of ongoing blood loss. | Same as minimum. Plus:*If machine learning or algorithms required:*Real-time data processing.  | Real-time data provides information necessary to inform timely clinical decision-making. Cumulative blood loss measurement facilitates accurate indication of the overall blood loss volume.  |
| **Training Requirements** | Less than 2 hours of training for proficiency. Training on use of the tool can be easily incorporated into health professional training on PPH awareness, prevention and management, and surgical care. | Less than 1 hour of training for proficiency. Training on use of the tool can be easily incorporated into health professional training on PPH awareness, prevention and management, and surgical care. | All healthcare workers involved in caesarean delivery should be trained in effective use of the tool. A range of training delivery methods should be considered (e.g. face-to-face, videos, simulation, written/pictorial instructional information) depending on what is most appropriate and feasible for different settings. Training materials (and language/s used) must be relevant to the context in which they will be used.  |
| **Instrument service, maintenance and cleaning** | Minimal maintenance requirements. Software updates available if required. Materials are durable for containing blood. *For reusable tools:*Designed for ease of cleaning and disinfecting.  | Same as minimum. Plus: Consideration of single-use components or tools for parts in contact with blood. Ongoing technical support available.   | The instrument requirements will vary depending on the design of the tool. Where appropriate, consideration should be given to the benefits and costs of single use tools compared to reusable tools, or a combination of both.  |
| **Accuracy**  | ±10% of actual blood loss. | ±5% of actual blood loss. | Accuracy of blood loss measurement tools is important to aid early detection and management of PPH. While tools do not require accuracy to the exact mL, they should measure blood loss within a reasonable margin of error.  |
| **Complexity** | Less than 5 minutes to set up and calibrate. | Less than 1 minute to set up. No steps to calibrate tool.  | The tool must be ready to use without a lengthy set up period. This is particularly important for emergent caesarean delivery. |
| **Safety** | Safe for use during caesarean delivery, with no risk of injury from the tool.Safe for use by healthcare professionals conducting or assisting in caesarean deliveries.Safe for the neonate.  | Same as minimum.  | There should be no risk of injury to the woman, health care workers, or neonate as a result of using the tool. Particular consideration must be given to infection prevention and personal protective equipment.  |
| **Environmental Stability** | Suitable for use in surgical operative room temperatures and conditions. | Same as minimum.  | The tool should be able to be used in conditions of the local operating theatre standards.  |
| **Regulation and Quality Management**  | National authority approval in the country of use. Meets ISO standards. | Same as minimum Plus: Meets international regulatory standards for medical devices.Recommended for use in WHO guideline or recommendation. | Regulatory approval must be gained before medical tools or devices are used. If international regulatory approval is granted (e.g. FDA, WHO), this can accelerate national level approval processes.  |
| **Packaging and Disposal** | Minimal packaging. Blood and other fluids able to be easily and safely disposed of.  | Same as minimum.  | Packaging should be reduced where possible, to aid in improving environmental sustainability and reducing storage space requirements. Safe and simple disposal of the tool, including collected blood, is necessary to reduce the risk of infection and spills or leakage.  |
| **Price** | Affordable for use in low-resource settings, while maintaining high quality.  | Same as minimum.  Plus:  Unit cost is less than existing 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 or regionally, with guaranteed quality assurance, to reduce costs.  | Price of medical tools and devices is a critical consideration for all health systems, especially those in limited-resource settings. Lower prices are preferrable. However, cheaper tools must maintain a high level of quality and accuracy. Visual estimation and gravimetric methods are free or very low cost, but are highly inaccurate.  |
| **Procurement Estimates** | Procurement quantity compatible with global or regional rate of caesarean deliveries. | Same as minimum.  | Approximately 134 million births occur each year.29 An estimated 21% of births globally are caesarean deliveries. Fewer blood loss measurement tools will be required if they are reusable compared to single use. |

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1. [↑](#footnote-ref-2)