Pulse Oximeter

Technology Opportunity Assessment

Prepared for the Merck for Mothers Program
Pulse Oximeter

Summary

Pulse oximeters are devices that offer a noninvasive method for monitoring the oxygen saturation of a patient’s hemoglobin. This is important to ensure the safety of patients under anesthesia or sedation during surgery associated with emergency obstetric care.

Statement of Need

Around 15% of all pregnant women develop a potentially life-threatening complication that calls for skilled care from a facility that provides emergency obstetric care (EmOC).¹ Skilled care is needed to provide basic EmOC services (defined as parenteral administration of antibiotics, uterotonic drugs, and anticonvulsants; manual removal of the placenta and retained products; assisted vaginal delivery; and basic neonatal resuscitation) to be performed at community health centers (basic facilities).² Additional skills are needed to provide comprehensive EmOC services, defined by the additional signal functions of cesarean delivery and blood transfusion, to address certain complications such as obstructed labor, severe hemorrhage, and complications from abortion. The World Health Organization (WHO) recommends there should be four basic EmOC facilities and at least one comprehensive EmOC facility per every 500,000 population.² Facilities with comprehensive EmOC services must be equipped with anesthetic machines, monitors, respirators and oxygen supply, sterilizing equipment, and other equipment suitable for the level of service.³

A recent analysis of 24 national or near-national needs assessments showed that all but two countries met the minimum acceptable level of one comprehensive EmOC facility per 500,000 population, and in countries with high maternal mortality ratios, the number of basic facilities was insufficient.² Lack of basic facilities and the need for more comprehensive facilities contributes to the inability to meet the fifth United Nations Millennium Development Goal, which is to achieve a 75% reduction in maternal mortality between 1990 and 2015. Constraints are numerous and are often due to lack of equipment, inadequate equipment maintenance, poor training, and insufficient infrastructure.⁴ There is a need for EmOC technologies that are reliable, cost effective, and easy to implement in both basic and comprehensive EmOC facilities.

Pulse oximetry (SpO₂) is a noninvasive method allowing the monitoring of the oxygen saturation of a patient’s hemoglobin. SpO₂ is required for safe monitoring of patients under anesthesia or sedation during surgery. Assessing oxygen saturation by SpO₂ can also aid in the assessment of risk in women with preeclampsia. A SpO₂ value less than or equal to 93% confers particular risk, and the symptom complex of chest pain and/or dyspnea* adds strength to the association⁵ and may be a valuable early warning of

* Shortness of breath.
pulmonary edema in women with preeclampsia if there is a downward trend in oxygen saturation.\textsuperscript{6} \textit{SpO}\textsubscript{2} can also be used to screen newborn infants for congenital heart defects and for other hypoxemic conditions such as acute respiratory infection, chronic obstructive pulmonary disease, and shock due to acute blood loss or sepsis.

Pulse oximeters are devices used for assessing oxygen saturation and consist of a probe, processor, display, and power source. The technology was developed in the 1970s and commercialized in the early 1980s. Despite the relative maturity of the technology and the general acceptance of the pulse oximeter’s role in safe surgery, estimates suggest that more than half of the operating rooms in the developing world are not equipped with pulse oximeters.

Anesthesia death rates are reported to be 100 to 1,000 times higher in the developing world as compared to anesthesia death rates in the developed world where pulse oximeters are applied in nearly every procedure that involves anesthesia or sedation.\textsuperscript{7} The reasons for this disparity are numerous and include the severity of patients’ conditions, inadequate clinical training, poorly developed infrastructure, and the inability to monitor patients during surgery. To address these issues and improve safety of surgery, WHO launched the Safe Surgery Saves Lives program in 2007 that resulted in the creation of the WHO Surgical Safety Checklist.\textsuperscript{8} The checklist includes a set of basic steps to follow before, during, and after surgery; one of the steps is to check for pulse oximeter use and proper functioning of the \textit{SpO}\textsubscript{2} equipment.

Equipment to measure the oxygen saturation level of a patient’s blood must be\textsuperscript{7}:

- Safe.
- Reliable.
- Easy to use and maintain.
- Affordable.
- Unaffected by skin pigmentation.\textsuperscript{9}
- Produced to International Safety Organization (ISO) standards.
- Manufactured under Good Manufacturing Practices according to an external assessment.
- Certified to meet electrical and other health product certifications.
- Appropriate for use in the environmental operating conditions found in low-resource settings.

Ideally, pulse oximeters should include:

- Reusable, long-lasting probes that fit infants, children, and adults.
- A display for peripheral oxygen saturation (\textit{SpO}\textsubscript{2}), pulse rate, and plethysmograph (either waveform or bar graph).
- Alarms for low \textit{SpO}\textsubscript{2}, high and low pulse rate, and weak or irregular signals.
- An integral rechargeable battery and ability to run on mains power.
- \textit{SpO}\textsubscript{2} accuracy within 2% that tracks reasonably to changes and is maintained in the face of some patient movement.
The device should also be portable, and replacement probes should be readily available.

**Technology Solutions Landscape**

Commercial pulse oximeters operate on the technology platform developed in the 1970s by Nihon Koden, a Japanese maker of medical electronic equipment. The basic principle of operation involves light absorption through a thin part of a patient’s body, usually a peripheral digit or earlobe. Two light sources are used: (1) red light at approximately 650 nm and (2) infrared light at 950 nm. A photodetector is placed opposite the sources (in transmittance SpO\textsubscript{2} setups vs. reflectance) and detects the light that passes through the body part.

Some of the light is absorbed by the body part as it travels through the skin, tissue, blood vessels, bone, etc. An assumption is made that all absorbing materials in the light’s path except arterial blood will produce a constant level of absorption. Arterial blood, on the other hand, regularly changes the amount of light absorbed due to the pulsatile nature of its flow. Sophisticated algorithms within the pulse oximeter’s processor subtract out the constant absorption levels (as well as stray room light, light that bypasses the body part, and other sources of noise) and analyze the pulsatile changes in absorption. Hemoglobin, a protein in red blood cells that carries oxygen to tissues throughout the body, will absorb light differently depending on the presence or absence of the oxygen it is transporting.

Absorption curves for oxygenated and deoxygenated hemoglobin have been developed over a wide range of light wavelengths. If most of the hemoglobin in the arterial blood is saturated with oxygen, then the ratio of red light absorbed to the infrared light absorbed will closely resemble the absorption curve for oxygenated hemoglobin. The less saturated the hemoglobin in arterial blood is, the more the ratio resembles the deoxygenated curve.

The quality and accuracy of pulse oximeters vary based on how well they process the signals generated by the light transmittance and resulting absorption. Standards exist (IEC 60601-1, ISO 9919:2005) to guide manufacturers on the minimum acceptable safety and performance for oximeters. Successful clinical use of pulse oximeters will depend on the proper selection of probe size, good probe placement, and ensuring the probe and control unit are in good working condition. Equipment checks can be made by operating the device on a healthy human such as the caregiver before using the oximeters on the patient. Pulse oximeters are commonly found in the following three types of packages:

**Finger probe pulse oximetry units**

These are controllers with integrated probes as opposed to tethered probes. These devices are economical (as low as US$10\textsuperscript{7}) and provide basic SpO\textsubscript{2} functionality. Device comparisons by various manufacturers tend to highlight the units’ ability or inability to minimize lag time to display oxygen saturation as a patient’s oxygen saturation level changes. Because SpO\textsubscript{2} is an indirect method for measuring oxygen saturation, if an oximeter is unable to indicate true events regarding saturation level changes, the value of
the device becomes questionable. Manufacturers that meet ISO 9919:2005 must address these requirements; however, not all manufacturers claim to meet the ISO requirements.

**Handheld pulse oximetry units**

These include an interface for a probe assembly to connect to a control unit. In the event that a probe malfunctions, a new probe assembly can be used. These devices tend to have larger displays than finger probe units and include features for setting alarm limits, operating directly from mains power supply or a rechargeable battery, printing logged data by universal serial bus (USB) or infrared (IR) data transfer, and various audible indicators for monitoring operation and in the event of an alarm. They also tend to include a plethysmograph display of the pulse (i.e., indication of circulatory volume).

**Stand-alone pulse oximetry units**

These include tabletop controllers with one or more interfaces for probe assemblies to connect. These devices tend to be more sophisticated than handheld units and often include additional functionality such as the ability to report blood pressure and monitor EKG and capnography (CO$_2$ gases). These devices are the most expensive type of pulse oximeters.

In 2008, WHO initiated the Global Pulse Oximetry Project to improve the safety of anesthesia care throughout the world by providing affordable, robust SpO$_2$ devices for every operating room in the developing world that does not have one. The nonprofit organization Lifebox Foundation was developed to address the goals of the Global Pulse Oximetry Project. They designed and contracted a manufacturer, Acare Technology Co., Ltd (New Taipei City, Taiwan), to produce handheld pulse oximeters. The pulse oximeters from Acare are available through the Lifebox.org website for US$250. To date, they have distributed over 1,500 Lifebox pulse oximeters to hospitals and health care workers worldwide. They estimate that 77,000 pulse oximeters are needed to fill the operating room gap in low-resource countries and many more to equip areas of health care facilities that are not operating rooms. The device appears to meet the requirements outlined in the Global Pulse Oximetry Project. Long-term reliability, general acceptability, and effect on patient outcomes are yet to be determined.

**Gap Analysis**

There is not a technology gap with respect to affordable, reliable, accurate, and easy-to-use pulse oximeters suitable for use in the developing world. Lifebox pulse oximeters meet these requirements. The challenge is in fulfilling the 77,000 needed units in operating rooms and the additional units needed by postoperative recovery rooms, birthing centers, pediatric wards, and other areas of the health care centers. The Lifebox Foundation provides a direct purchase service option that allows individuals and institutions to purchase the Lifebox pulse oximeter for US$250 and replacement probes for US$25 each. Even at this price point, some individuals and institutions may still not be able to afford the pulse oximeter. The Lifebox Foundation also provides a donation service option that allows individuals and organizations the opportunity to donate funds on behalf of those in need. The donated funds are used to provide Lifebox
pulse oximeters to donor-specified locations or are used to provide Lifebox pulse oximeters to recipients identified by the Lifebox Foundation.

Although the financial challenges regarding pulse oximeter access have been mitigated by the Lifebox Foundation, additional challenges remain. To ensure access and availability of pulse oximeters, distribution systems must be capable of supplying units and replacement probes in a timely manner without damaging the items during shipment. In-country customs and levies and the overall handling costs associated with distribution must not undermine the cost reduction efforts of the Lifebox Foundation.

Training on proper use of pulse oximeters is being addressed by WHO. Training is important for correct use of SpO\textsubscript{2} and also for monitoring and maintaining the oximeters and the probes. Because of the strong support by WHO (e.g., the Surgical Safety Checklist, the Global Pulse Oximetry Project, training manual), there will likely be a strong demand-side response for pulse oximeters. Because of efforts by the Lifebox Foundation and others, there will likely be an equally strong supply-side response. Currently, however, there is a gap.

**Investment Opportunity**

There is an opportunity to accelerate the closure of the gap for pulse oximeter use by providing direct donor funds to the Lifebox Foundation. Many of the hurdles typically encountered when trying to increase access and availability of certain technologies in developing countries have been addressed by WHO and the Lifebox Foundation. Country-specific hurdles (distribution, service, national standards) may exist. These country-specific hurdles must be understood and addressed on a case-by-case basis. Specifically, an investment opportunity should include the following:

- Direct donor funds to the Lifebox Foundation.
- Country-specific analysis of existing access hurdles and funds to mitigate them.
- Country-specific analysis of SpO\textsubscript{2} training protocols and funds to standardize them to WHO standards.
- Donor funds for a replacement probe bank that can be accessed over years to come.
- Additional training to ensure health care providers are making appropriate decisions based on SpO\textsubscript{2} information and to convey the importance of oxygen as an essential medication.
- Global effort (where appropriate) to buy back unused, malfunctioning, or substandard pulse oximeters and replace them with Lifebox pulse oximeters and probes. Standardization will provide for regional economies with respect to distribution, service, and training, and should provide for accelerated regional adoption and use.
- Funding to support pre-introduction vs. post-introduction SpO\textsubscript{2} use studies and how patient outcomes (surgical, pediatric, neonatal) are affected.
References


