Oxygen Supply

Technology Opportunity Assessment

Prepared for the Merck for Mothers Program
Oxygen Supply

Summary

Oxygen is vital for treatment in many obstetric emergencies, including cardiac arrest, acute blood loss, shock, dyspnea (breathlessness), pulmonary edema, unconsciousness, convulsions (eclampsia), and fetal distress during labor. There are two main viable sources of oxygen in hospitals in low-resource settings, oxygen in cylinders and oxygen produced from oxygen concentrators.

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). Skilled care at primary health centers 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. 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. 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. 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. Lack of basic facilities and the need for more comprehensive facilities contributes to the inability to meet the fifth United Nations Millennium Development Goal, to reduce maternal mortality. Constraints are numerous and are often due to lack of equipment, inadequate equipment maintenance, poor training, and insufficient infrastructure.

There is a need for EmOC technologies that are reliable, cost-effective, and easy to implement in both basic and comprehensive facilities.

Oxygen is indicated for the treatment of many obstetric emergencies including cardiac arrest, acute blood loss, shock, dyspnea, pulmonary edema, unconsciousness, convulsions (eclampsia), and fetal distress during labor. These acute care treatments typically require high-flow delivery (from 4–6 up to 6–8 liters per minute [LPM] by mask or nasal cannulae) of oxygen for a duration that is measured in hours, rather than days. Oxygen is also needed for use during administration of anesthesia for surgery and in case of complications with use of local anesthesia. Other uses for oxygen include treatment of cyanosis or
breathing difficulty in newborns (0.5 LPM) and acute respiratory infection (ARI), principally pneumonia, for children under the age of five (0.5–1.5 LPM). Treatment duration for newborns is measured in hours, while ARI treatment duration averages three days.⁶

Oxygen is included on the WHO list of essential medicines. Although it is a treatment that is a basic requirement to save the lives of seriously ill patients, oxygen is rarely available in community health centers (primary care facilities) and is often lacking in district hospitals. In 2010, it was reported that only 44% of the 231 health centers, district hospitals, and provincial/general hospitals surveyed in 12 African countries had access to oxygen on a continuous basis.⁷ Reasons include transportation difficulties for refillable cylinders, power outages for concentrators, malfunctioning concentrators, leaking cylinders, and lack of capital investment. Another major hurdle to achieving continuous supply at all point-of-care facilities is the misperception that oxygen therapy is palliative and therefore not essential.⁸ This is despite evidence to the contrary, medical communities’ long experience with oxygen use, and oxygen’s inclusion on the WHO list of essential medicines.

As part of treatment for obstetric care emergencies (and for other indications), oxygen supply is essential. There is a need for equipment that supplies oxygen on demand, 24 hours per day, regardless of power availability, at an economical cost. Administration of oxygen at the point of care requires a source, such as an oxygen concentrator or cylinder, and equipment for delivery, such as tubing, face mask, or nasal prongs. Electrical power may or may not be available. Oxygen treatment, however, must be made available all hours of the day to treat emergencies and provide ongoing therapy. The supply should provide for flow rates up to 8 LPM and should be available at multiple locations within the facility (i.e., emergency room, operating room, labor and birthing rooms, antepartum and postpartum ward, and recovery room). The equipment must be safe, reliable, easy to maintain, affordable, easy to use, and appropriate for use in the environmental operating conditions found in low-resource settings. Ideally, oxygen supply would not rely on replenishing agreements from outside the point-of-care facility.

**Technology Solutions Landscape**

There are two main viable sources of oxygen in hospitals in low-resource settings: 1) oxygen in cylinders and 2) oxygen produced from oxygen concentrators. Many sources discuss the pros and cons of cylinders vs. concentrators and have reported on the economics, challenges, successes, recommended models, and patient outcomes when a steady supply is made available for their institutions and patients.⁵, ⁶, ⁹-¹⁴

Oxygen for cylinders is typically produced by fractionally distilling liquefied air using industrial equipment at low temperatures (below -180 °C). The nearly pure (>99%) liquid oxygen is collected and stored under pressure in cylinders. Because of the very low temperatures required, this process is restricted to large manufacturing plants. Oxygen cylinders can also be charged using filling machines that are integral to an oxygen concentrator.
Oxygen from concentrators is produced by devices that entrain air from the environment and separate the oxygen and nitrogen by way of a pressure swing adsorption (PSA) process. An air compressor pushes the room air into a sieve bed or column filled with a regenerative molecular sieve made of zeolite, a beaded inert ceramic material. The sieve material allows the oxygen to pass freely through while the nitrogen is retained under pressure. The cycle alternates between two sieve beds, allowing one bed to make oxygen while the other is depressurized, freeing the nitrogen to exit the system through the exhaust muffler. Most concentrators supply oxygen at a concentration of 90%–96%. When concentrators are used to fill oxygen cylinders, an additional compressor is required. The 90%–96% pure oxygen is compressed into the cylinders where it remains in a gaseous phase. Compressed oxygen in cylinders provides approximately one-tenth the volume of oxygen compared to liquefied oxygen stored in the same size cylinder.

Production of oxygen on site from other sources such as fractional distillation of liquefied air and electrolysis of water is not practical because of industrial equipment and power consumption requirements. Chemical oxygen generators, used for emergencies in airplanes and submarines and in breathing apparatus for firefighters, generate significant heat upon reaction, provide a relatively short duration of supply, and are costly. These technologies will not be discussed further because they are not appropriate for low-resource settings.

The decision to implement a cylinder-based strategy vs. a concentrator-based strategy is largely driven by the reliability of power at the facility under consideration. A typical decision tree algorithm used for analysis is shown in Figure 1.

![Decision Tree](image)

*Figure 1. Algorithm for determining the most suitable main oxygen supply method.¹¹*
A comparison of oxygen cylinders vs. oxygen concentrators is provided in Table 1.

Table 1. Comparison of oxygen cylinders vs. oxygen concentrators*

<table>
<thead>
<tr>
<th>Power source requirement</th>
<th>Oxygen cylinders (delivered)</th>
<th>Oxygen concentrators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transport requirement</td>
<td>Yes, frequent replenishment of exhausted tanks</td>
<td>Only at time of installation.</td>
</tr>
<tr>
<td>Exhaustible supply</td>
<td>Yes, standard cylinders last up to 2–3 days with continuous use.</td>
<td>No, continuous supply as long as power remains uninterrupted.</td>
</tr>
<tr>
<td>Establishment equipment costs</td>
<td>Oxygen flow meter (about US$400) and regulator (about US$200) per cylinder.</td>
<td>Equipment cost (about US$1,000) per concentrator, plus installation, commissioning, and training.</td>
</tr>
<tr>
<td>Ongoing costs</td>
<td>Refill costs (US$30) per tank, cylinder leakage and transport costs.</td>
<td>Minimal costs for electricity, maintenance, and spare parts.</td>
</tr>
<tr>
<td>Maintenance</td>
<td>Minimal.</td>
<td>Moderate, both preventative maintenance and intermittent repairs; spare parts are needed.</td>
</tr>
<tr>
<td>Training (2009)</td>
<td>In-clinic use of oxygen and pulse oximetry, and day-to-day troubleshooting of cylinders and connectors.</td>
<td>In-clinic use of oxygen and pulse oximetry, day-to-day troubleshooting of cylinders and connectors, and preventive maintenance for concentrators and training for hospital engineers/technicians.</td>
</tr>
</tbody>
</table>

* Criteria in this table are as reported by WHO in 1993 and updated by WHO (Trevor Duke) in 2009.

The algorithm and comparison analysis indicate that the preferred solution for oxygen supply depends on multiple factors; however, lack of reliable power drives decision-makers from selecting oxygen concentrators to selecting oxygen cylinders. One solution that may be appropriate for hospitals with unreliable power is installation of oxygen concentrators that also function as filling stations for oxygen cylinders. These devices, known as oxygen generators, are large oxygen concentrators with integrated oxygen compressors capable of filling cylinders to over 2,000 pounds per square inch pressure. Another solution may be to install large bulk oxygen tanks on site and fill cylinders using a filling station.

Oxygen generators may be preferable due to the low initial capital costs and the ability to eliminate the replenishment supply that bulk tanks require. Although bulk oxygen tanks can provide oxygen in concentrations greater than 99%, generators will meet WHO’s oxygen concentration guidelines for concentrator use (concentration greater than 85% at a rate of 10 LPM). Oxygen generators also offer advantages over oxygen concentrators that include an integral battery backup. Battery back-up systems may become exhausted during long duration therapy in the event power is disrupted for multiple days. Battery back-up systems will also lose capacity over time and will eventually need to be replaced. Replacement of batteries is a challenge in low-resource settings. Although generators require routine maintenance and may require spare parts at some point, their performance and capacity should be reliable and consistent over time.
Oxygen generators could potentially ensure a continuous supply of oxygen in settings where the power source is not reliable and where there is need for a mechanism to refill oxygen cylinders for facilities without reliable power. Oxygen generators can be used when power is available, and the oxygen cylinders filled by the oxygen generators can be used when power is not available. Oxygen generators can be used to treat patients directly with patient feed lines, thus acting in place of an oxygen concentrator. Excess filling capacity at facilities that install oxygen generators could be used to fill oxygen cylinders that are deployed to rural clinics that have little or no power.

Gap Analysis

Oxygen generators have the potential to ensure continuous supply of oxygen in settings where oxygen concentrators or cylinders cannot and can provide a decentralized mechanism for supplying oxygen to peripheral health centers. To date, implementation and use of oxygen generators in low-resource settings is limited. The current state of technology for oxygen cylinders, oxygen concentrators, oxygen generators, and oxygen bulk storage tanks is mature and in commercial distribution. Projects in the Gambia, Malawi, the Philippines, Egypt, and Papua New Guinea have all implemented national-level introduction of oxygen concentrators after careful evaluation of advantages and disadvantages of oxygen cylinders vs. concentrators. While it is significant that these countries have successfully implemented an oxygen delivery system using concentrators, oxygen concentrators are vulnerable to breakdown and interruption of power supply and do not ensure a sustainable supply on their own.

Hospitals may need to consider an oxygen supply strategy that includes a combination of technologies: oxygen generators, oxygen concentrators, and refillable oxygen cylinders (to be filled by the oxygen generator). The number of generators, concentrators, and cylinders can be calculated based on historical demand for oxygen and historical availability of power. While power is available, the concentrators and generators would be used to treat patients and fill the cylinders. When power is not available, the cylinders would be used to treat the patients.

Generators, however, bear a significant capital expense compared to oxygen concentrators. Three manufacturers, all from the United States, offer oxygen generators that produce medical-grade oxygen. Research conducted for this technology landscape did not identify oxygen generators produced in other regions of the world (i.e., China, Europe, India, South America) where equivalent functionality might be purchased for a much lower cost. However, PSA technology is quite mature, and filling technologies are used in all regions of the world. A more exhaustive search will likely identify regional manufacturers of such systems; if a suitable system is not identified, the investment opportunity may include work with a regional manufacturer to develop a suitable system at an appropriate cost to the purchasing facility.

Implementation of a sustainable oxygen supply strategy that includes purchase and placement of oxygen generators will require local ownership and participation, as well as involvement of policymakers to ensure that adequate funding mechanisms are in place for initial capital expenditures and for ongoing
maintenance and purchase of accessory supplies and equipment. It will also necessitate the involvement of end-users such as clinicians, nurses, and maintenance staff, and the public, whose levels of expectations of public services help shape those services. In settings where oxygen has not been readily available, national guidelines will need to be established to ensure rational, correct use of oxygen and promote the purchase of oximeters to assist in decision-making around oxygen use. Finally, training activities will be required for people responsible for maintaining the equipment and for providers who will use it. There are no known currently donor-funded projects aimed at improving oxygen supply equipment or for developing new oxygen supply technology.

**Investment Opportunity**

To date, implementation and use of oxygen generators in low-resource settings is limited. An investment in oxygen generator technology should focus on the use of commercially available oxygen generators in conjunction with oxygen concentrators and oxygen cylinders. The goal of evidence-based pilot operations would be to alter the algorithm presented in Figure 1 and generate a method for determining appropriate numbers of generators, concentrators, and cylinders to ensure a continuous supply of oxygen.

Commercially available generator manufacturers, such as OGSI, currently offer their products to developing-world facilities at a discount (specific prices unknown). Selection of a preferred manufacturer’s product could be included in a reliability study prior to initiation of a pilot program. Alternatively, oxygen generators from a variety of manufacturers could be included in the study in an effort to generate actual use data.

A facility with complete records regarding oxygen availability and power availability should be identified. Data for facility selection are available from the surveys completed between 2007 and 2009 by 12 sub-Saharan African countries and 231 health facilities. The survey respondents completed the WHO Tool for Situational Analysis to Assess Emergency and Essential Care, and results were summarized by Belle et al.

Pending facility selection and agreements, oxygen supply equipment including oxygen generators, oxygen concentrators, and oxygen cylinders should be procured in appropriate quantities and installed. Training, including use and maintenance, should be conducted. Oxygen availability and power availability should be recorded and compared to previous records. If the facility is capable of providing oxygen on a continuous basis, regardless of power status, the primary goal for the pilot program will have been met. Other goals (equipment reliability, equipment costs, community clinic support, etc.) should be identified and evaluated to determine if a pilot program should be replicated at a larger scale.

Another investment opportunity would be to identify a regional manufacturer for the oxygen generator. The three oxygen generators identified in the technology landscape are, even at a discounted price, a significant capital expense. Oxygen concentrators are manufactured in countries outside the United States
(China, Europe, and India), and these regional manufacturers may have oxygen generators available for purchase. If there are currently no regional manufacturers of generators outside the United States, an investment could be made to develop such a product with a willing collaborator. It is unknown if there is currently a sub-Saharan oxygen concentrator manufacturer and if they would be capable of developing oxygen generators.
References


