Comprehensive Emergency Obstetric Care

Technology Opportunity Assessment

Prepared for the Merck for Mothers Program
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Summary

Implementation of comprehensive emergency obstetric care guidelines has been difficult in low-resource settings because of lack of supplies, equipment, and staff essential to providing lifesaving care to women with obstetric emergencies. The Deliverable Comprehensive Care Unit aims to deliver all emergency obstetric care components in a standardized, modular package that can be scaled for broader use.

Statement of Need

While most pregnancies and births are uneventful, all pregnancies are at risk. Around 15% of all pregnant women develop a potentially life-threatening complication that calls for skilled care, and some will require a major obstetrical intervention to survive. About 1,000 women die from pregnancy- or childbirth-related complications around the world every day; of these, 99% occur in low-resource countries. Improving maternal health is one of the eight Millennium Development Goals (MDGs) adopted by the international community in 2000. The fifth MDG is to achieve a 75% reduction in maternal mortality between 1990 and 2015. Emergency obstetric care (EmOC), access to family planning, and skilled attendance at birth are three key interventions that have been implemented globally to reduce maternal mortality.

Three Crucial Delays

In settings where maternal mortality is highest, three crucial delays are associated with elevated rates of maternal death:

1. Delay in seeking health care (delay in recognizing the problem and delay in making a decision to seek care).
2. Delay in reaching a health facility.
3. Delay in obtaining appropriate care upon reaching a health facility.

The first two delays are issues of access, which are dependent on the patient, her family, her community, and safe and reliable transport. The third delay relates to factors in the health facility. While clinical interventions and technologies may be available to manage obstetric emergencies, several factors may contribute to suboptimal outcomes, including:

- Delay in diagnosis.
- Outdated clinical protocols.
• Inadequately trained staff.
• Failure to employ sufficient medical and surgical staff.
• Lack of essential medications, equipment, and supplies.

Although any intervention program must address all three delays to have any chance at sustainable, scalable success, the United Nations Population Fund (UNFPA) has provided the following prioritization of the development of EmOC services: “In practice, it is crucial to address the third delay first, for it would be useless to facilitate access to a health facility if it was not available, well-staffed, well-equipped and providing good quality care.”

Standards and guidelines for EmOC have existed for decades and should guide implementation of basic EmOC (bEmOC) and comprehensive EmOC (cEmOC). The World Health Organization, the United Nations Children’s Fund, and UNFPA recommend the following guidelines for the minimum acceptable level of EmOC services:

• There must be at least four bEmOC facilities and one cEmOC facility per 500,000 population.
• The minimum facility level must also be met in subnational areas.
• At least 15% of all births in the population should take place in EmOC facilities.
• 100% of women expected to have obstetric complications should be treated in EmOC facilities.
• Cesarean sections should account for neither less than 5% nor more than 15% of the total births.
• Case fatality rate among women with obstetric complications in EmOC facilities should be less than 1%.

Standards and guidelines for EmOC have been enormously difficult to implement. Since 1997, experience in more than 40 countries has shown that while health systems often have at least one facility providing cEmOC per 500,000 people, fully functioning facilities providing bEmOC are much less common. As a first step in EmOC, it is essential for women to have access to a bEmOC facility where they can receive care for some emergencies and first aid for others until they can reach a cEmOC facility. Combined with adequate referral networks and safe, reliable transport, it is at this junction where equally distributed, well-staffed cEmOC units are essential to provide definitive lifesaving care. The survival of women with obstetric emergencies depends on access to quality care once they arrive at a cEmOC facility. Many units have been described as obstetric units but have a dire lack of supplies, equipment, and staffing. Even when facility numbers are sufficient, the locations and staffing often mean the poorest or most destitute populations are not served.

Encouraging data have emerged from rural Mali that suggest institution of cEmOC programs has significantly reduced the maternal and perinatal mortality rates over a three-year period in a cost-effective manner without significant external grant funding. Furthermore, cost-effective reductions in morbidity and mortality were observed in work performed in Burkina Faso where general medical practitioners (physicians) were trained with advanced obstetric skills for cEmOC.
One of the most compelling arguments for cEmOC originates in Mexico where Hu and colleagues describe their most effective strategy of reducing maternal mortality as that of enhancing access to cEmOC. Their strategy reduced mortality by 75%, morbidity by 47%, cost less than previous practice, and had an incremental cost-effectiveness ratio of $300 per disability-adjusted life year (DALY) averted relative to the next best strategy. The Deliverable Comprehensive Care Unit (DC2U) aims to build on the successes of these programs while focusing on efficiencies to be gained from standardization, modularity, and scalability.

The Deliverable Comprehensive Care Unit

To meet the fifth MDG, cEmOC facilities must have the following:

- Water.
- Electricity.
- Shelter.
- A sterile environment (clean air, clean linens, refrigeration).
- Equipment for delivering safe anesthesia (monitors, oxygen, suction, ventilator, medications, intravenous supplies).
- Appropriate surgical instruments and supplies (cautery, gowns, gloves, suture).
- Neonatal resuscitation equipment and supplies.
- Basic laboratory capabilities.
- Capacity for delivering blood transfusion when necessary.

The primary focus of the DC2U is to deliver all of these components in a standardized, modular, scalable package. What sets the DC2U apart from existing deliverable health care solutions is its specific focus on cEmOC services, the surgical capabilities it provides, and the blueprint for sustainable expansion of host-country cEmOC services.

A stable, reliable, in-country supply chain for supplies, consumables, and medications is required to successfully implement cEmOC services. Advocacy at the host governmental level is required to ensure that the local ministries of health take responsibility for ongoing supplies at all cEmOC centers. While the DC2U is not intended as a substitute for permanent facilities, it can serve as an interim solution to definitively boost local capacity until host governments complete facility improvements necessary to incorporate DC2U (or similar) components into existing structures.

Hospitals in high-income countries consider technology repair services just as essential as surgeons themselves, yet donors often send complex technologies to under-resourced hospitals, magnifying technology challenges. The result is a kaleidoscope of expensive and complex, but nonfunctioning, medical equipment lying unused and taking up space. Conversely, stripped-down technologic solutions
for low-income countries often remain unused due to a perception that these are substandard technologies.\textsuperscript{11}

The DC2U will break away from these wasteful cycles in multiple ways, including:

- Standardizing care through effective, reliable, and easily repairable and replaceable devices.
- Bolstering local health care capacity by adding infrastructure and physical treatment space.
- Expanding biomedical technician training.
- Delivering standardized training modules for appropriate technology implementation.
- Providing communication equipment for accessing decision support and technical support services.

**DC2U Simulation, Mock-Up, and Testing**

The anchor of the DC2U’s initial operating capacity will be the technology in a box (a refurbished shipping container) that can be set up in a remote location, either freestanding or as an annex to an existing unit. It can be installed and commissioned with all accompanying equipment and power supplies in the span of five days with minimal construction and support. For cEMOC services, additional specialized tools, equipment, and medications required for anesthesia and surgical care as well as facilities for blood transfusions will be required.

To verify the appropriateness of DC2U contents and feasibility, it will be important to simulate its implementation. All component parts will be staged and secured in a DC2U in a manner that will ensure safe transport and delivery. The prototype will then be engineered, furnished, and installed in a central warehouse location.

Relevant cEmOC clinical scenarios will also be simulated in a dedicated medical simulation lab with a matching floor plan to the DC2U. Layout, ergonomics, and staff and patient flow patterns during these simulations may prompt revisions of the floor plan, equipment list, and/or equipment locations within the module.

**Landscape Analysis and Planning**

A thorough political and demographic survey as well as needs assessment will guide site selection for DC2U deployment. Baseline health statistics will also help guide site selection. This pilot implementation of the DC2U will be incorporated into existing host medical center infrastructure. At this stage, it is not intended to function as a stand-alone health care facility. It is estimated that a fully operational DC2U will be able to initially provide for five assisted or cesarean deliveries per day. Assuming that half of these procedures are cesarean sections and the recommended maximum 15% of mothers receive cesarean sections, then the DC2U would reach its maximum capacity at a facility that provides care for 6,000
deliveries per year. Though productivity is expected to increase with time, pilot site selection will need to consider the volume of deliveries as a selection criterion.

Health metrics that will be collected at each site should include the following:

- Maternal mortality ratio (MMR).
- Number of deliveries by the health facility.
- Number of cesarean sections and assisted deliveries.
- Estimated blood loss for each delivery.
- Maternal age.
- Prevalence of obstetric complications.
- Estimated gestational age at time of delivery.
- Fetal mortality rate.
- Fetal weight.
- Apgar scores.

Selection criteria for a pilot site will include the combination of demonstrated need (higher MMR and higher prevalence of obstetric complications) and host government factors (enthusiasm for the DC2U system and willingness/ability to implement necessary changes to improve existing facilities to provide cEmOC services). The remainder of the metrics will serve as baseline measures by which the performance of the DC2U will be monitored on an ongoing basis.

Additional data on costs will be collected at baseline and in an ongoing manner. These data will include facility costs, operation costs, human resource expenses, and consumable expenditures for three entities: the host country health facility, the DC2U module, and for a comparable health facility in the host country. These data will allow for comparative and direct assessment of cost-effectiveness of this program. Cost-effectiveness of the DC2U is expected to compare favorably with other cEmOC programs. The benchmarks that will be used to define cost-effectiveness will be cost per delivery (for the entire health center), cost per assisted or cesarean delivery, cost per death averted, and cost per DALY averted.

Upon selection of possible pilot sites for DC2U implementation, site surveys will be completed. These surveys will include comprehensive assessments of the following:

- Availability of critical resources (land, electricity, clean water).
- Availability and engagement of the local medical community.
- Availability of appropriate local transportation resources.
- Logistical capabilities for establishment of a reliable supply chain.

Additionally, representatives from the local population will be interviewed to gain perspective on seasonal, geographic, and other unknown factors that may impact DC2U installation and operation.
In addition to addressing clinical needs, the goals of the pilot studies will include the following:

- Concept development and testing of the overall assumptions of cEMoC.
- Designing research/data collection protocols.
- Refining resource needs for staffing, equipment, and training.
- Development of program engagement with stakeholders including the host country, the donor community, and humanitarian organizations.

Through existing partnerships and ongoing professional collaborations with the Ministry of Health, the Department of Obstetrics and Gynaecology, and the Department of Anaesthesia, several sites in Uganda are likely pilot site candidates. These sites are located in Kampala, Mbarara, and Soroti and will be ideal for providing a comprehensive review of assumptions in operating environments in urban and rural sites:

- Kampala is situated near the shore of Lake Victoria and is served by Entebbe International Airport. It presents an urbanized site with access to international transportation, a steady supply of water and power, and a large local population with medically trained personnel readily available.
- The western city of Mbarara provides a more modest infrastructure and population base with a semi-developed professional services sector, including a tertiary referral center.
- Soroti offers the most rural site with minimally developed infrastructure, power supply, and transportation facilities.

**Construction and Deployment**

The DC2U pilot program will be implemented concurrently in collaboration with host country ministries of health. After selection of pilot sites, DC2U modules will be delivered and installed by local groups with supervision and guidance from trained DC2U engineers. Local biomedical engineers and/or technicians will be trained and equipped to routinely service and maintain all relevant biomedical equipment and facilities. Trained DC2U physicians, nurses, and midwives will train local medical providers on operation of any equipment with which they are not familiar. DC2U staff will remain at the pilot site for the initial four weeks of deployment to continue training host country staff, initiate safety checklists, and help facilitate establishment of data collection systems. Following the initial deployment period, a DC2U staff member will be available for consultation, and representatives will return to visit the site on a monthly basis. During these visits, any new challenges can be addressed. An ongoing training and education curriculum will be implemented to steadily maximize the capacity of the local population to provide for its own needs. Furthermore, during the pilot study engagement period, host country ministries of health will also be engaged to coordinate further expansion of cEmOC services and permanent facilities.
Post-Deployment Follow-Up and Metrics

The pilot period will be planned for 24 months. During this time, utilization metrics and health metrics (as described above) will be collected on an ongoing basis. Data will be collected and managed by the host institution with guidance from DC2U staff. All data will be jointly accessible by the host institution and DC2U staff, and each group will have full publication rights. Detailed analysis of trends and performance on all metrics will be provided to the host institution on no less than a quarterly basis through the entire project period.

Dissemination

Upon successful completion of the pilot projects described above, additional sites with demonstrated cEmOC needs will be identified. DC2U modules will be delivered, installed, and local medical and engineering staff will be similarly trained. Mileposts of capacity-building will be established with the end goal of transferring the leadership and staffing of the medical team to local talent within 24 months in each case.

The DC2U creates a system that provides immediate obstetric care coupled with a basic, yet comprehensive, training program that attracts local medical talent back to serve its own underserved populations. By enabling them with the equipment, skills, training, and long-term support needed to develop a sustainable, small-scale medical facility, the overall DC2U program helps these practitioners address their own unique medical needs in the best way possible through local knowledge and expertise.

This model of health care is undoubtedly expensive, especially when considering initial investment costs, but this is the only sustainable, scalable, long-term solution to reducing maternal mortality. The DC2U program embraces this philosophy, reiterating that comprehensive approaches to health care are far superior to individualized technologies or condition-based approaches. This model will serve as a fulcrum for dissemination or expansion of cEmOC services with the goal of facilitating sustainable and scalable progress toward the fifth MDG for the critically underserved.
References


