

EXECUTIVE SUMMARY

Birth asphyxia accounts for nearly 25% of all newborn deaths, with nearly 99% of these deaths occurring in low-resource settings. With access to basic resuscitation skills and equipment, newborn resuscitation can be successfully accomplished in 30% of cases for full-term neonates and 5-10% of cases for pre-term neonates. In excess of 100 neonatal resuscitation devices currently exist, however, less than 25% of these devices are feasible for use in low-resource settings due to challenges with cost and distribution. Existing devices are also limited by the use of materials that degrade quickly, permanent assemblies that cannot be taken apart for proper sterilization, and excessive parts that prevent functionality when misplaced.

The overall goal of the project was to reduce neonatal mortality due to birth asphyxia by designing an effective neonatal resuscitation device for use by traditional birth attendants in low-resource settings. User requirements for a low-resource resuscitation device were developed through consideration of project stakeholder recommendations and a thorough review of subject literature. In rank order of importance, the device must be effective, safe, easy to use, affordable, reusable, sterilizable, and portable.

Functional decomposition was used to identify critical modules of air delivery, air-lung interface, air retention and safety. Concepts were generated to address each of these modules. The highest scoring concept was a dual tidal volume bag and variable size mask attached to a valve housing with a pressure relief valve and one-way valves to control airflow. Engineering analyses primarily used benchmarking and anthropometric data to determine appropriate geometries and materials of the bag and mask.

A prototype bag and mask representing the final form and function of the device were manufactured through silicone compression molding with 3D printed molds. Most user requirements were validated through the use of a neonatal resuscitation simulator at the University of Michigan Hospital. The remaining user requirements were satisfied through design. The prototype demonstrated the ability to deliver an appropriate pressure and volume of air at an acceptable rate. The fit of the mask and the range of deliverable volumes were found suitable for 5th to 95th percentile neonates. The estimated manufacturing cost for the final design is \$10 based on the cost of materials, tooling, and process equipment. The prototype also meets the requirements for portability. Additional validation may be necessary to ensure that the device is easy to use and reusable for 60 patients.

The flipping functionality and the quality of seal achieved by the variable size mask present the greatest areas of opportunity. The current mask requires modifications after molding to flip correctly. This should be reduced to a single manufacturing step when the final design is injection molded. The geometry of the dual tidal volume bag should be modified to increase the stiffness between the sections while shortening the overall length of the bag.

It is recommended that future work be focused on optimizing the effectiveness of the variable size mask as it is likely the most feasible component for use in low-resource settings. The dual tidal volume bag seems to have limited advantages over existing resuscitation technologies in its current form and should be further refined. If the shortcomings of the current design are addressed, future studies within low-resource settings are warranted.