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Maternal and Child Survival Program

Improving care for newborns with respiratory distress in Nigeria through use of bubble continuous positive airway pressure devices

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Background and Objectives

Auxiliary nurse, Patricia Ajibo, is attending to Catherine Mbam's four-day old baby. Photo by Karen Kasmauski/MCSP

Preterm birth complications (31%), intrapartum related events including birth asphyxia (31%) and infection including pneumonia and sepsis (26%) are the three leading causes of newborn death in Nigeria[1] and often result in respiratory distress – a significant cause of neonatal mortality in the developing world. Bubble continuous positive airway pressure (bCPAP) reduces neonatal mortality in newborns with respiratory distress by supporting more normal breathing in infants. The bCPAP maintains a constant stream of pressurized, blended air and oxygen into the infant's lungs to keep the lungs inflated. There is a widespread use of bCPAP in developed countries, however due to its high cost, unavailability of comprehensive newborn special care and adequately trained providers; it has not yet been widely scaled in low-resources settings.

To address this need, Hadleigh Health Technologies and Rice University developed the low-cost and user-friendly Pumani bCPAP. Results from a non-randomized controlled trial conducted in the neonatal ward of Queen Elizabeth Central Hospital in Blantyre, Malawi showed a 27% improvement in neonatal survival when the Pumani bCPAP was used, compared with the control group. Several studies have demonstrated the efficacy of using bCPAP in low resource settings; however, to further maximize its success and

[1] Healthy Newborn Network. Newborn Numbers Database. Washington, DC: Save the Children; 2018 [Available from: https://www.healthynewbornnetwork.org/hnn-content/uploads/Newborn-Numbers-excel-30-Jan-2018-FINAL.xlsx accessed August 15, 2018].

sustainability, Nigeria and other countries need additional evidence on the acceptability, feasibility and cost of implementing this intervention. [2]

From August 2016 through June 2018, USAID's flagship Maternal and Child Survival Program (MCSP) in collaboration with the Federal Ministry of Health (FMoH), members from the American Academy of Pediatrics (AAP), as well as select professional associations in Nigeria, namely PAN (Pediatric Association of Nigeria) and NISONM (Nigeria Society of Neonatal Medicine), conducted a pilot study on the introduction of Pumani bCPAP in seven hospitals across three States of Nigeria. This study helped to achieve MCSP's overall Nigeria MNCH objectives of increasing the utilization of life-saving innovations and improving the quality of facility-based maternal, newborn, and child health services.

Methodology

The Intervention

Pumani bCPAP was initially implemented in five hospitals in Ebonyi and Kogi— two Federal hospitals (including one teaching hospital) and three mission hospitals. Due to low recruitment of eligible patients, USAID requested extending the intervention to two additional hospitals in Cross River States—one Federal teaching hospital and one General Hospital. The study was determined to be exempt research by the Committee for the Protection of Human Subjects, Dartmouth College. Facilities were selected according to the following criteria: volume of deliveries; availability of oxygen; electricity; and doctors and nursing staff 24 hours per day.

Study Questions

- Assess service providers' compliance with Pumani bCPAP standard operating protocols
- Assess the feasibility and acceptability of Pumani bCPAP in selected hospitals
- Identify challenges and facilitators to implementation of bCPAP services in selected hospitals

MCSP conducted the following activities during the implementation period:

- Reviewed and adopted the Malawi bCPAP training materials, and developed protocol for the use of the Pumani bCPAP to manage infants with moderate to severe respiratory distress
- Trained doctors and nurses on bCPAP protocols to identify, treat, monitor, and wean newborns who need bCPAP
- Monitored service providers' adherence to bCPAP protocols and equipment maintenance protocols
- Tracked treatment coverage and clinical outcomes for babies treated with bCPAP, including any adverse outcomes.

Study Implementation

A two-day training workshop on the use of Pumani bCPAP and care of patients was conducted for clinicians and nurses selected as "champions" from each hospital. All Neonatal Intensive Care Units (NICUs)/special newborn care unit clinicians and nurses were required to complete on-the-job, competency-based training led by the champions at each participating hospital. One nurse trained in bCPAP was to be assigned for each shift per hospital.

Data Collection

To assess the feasibility of the use of the Pumani device at the selected hospitals in Nigeria, the Program interviewed a total of 30 healthcare workers comprising of physicians, nurses ,and administrative leadership about human resources for health, equipment, leadership, and facility-level facilitators and challenges to implementation. Physicians in selected facilities used the bCPAP monitoring sheet and an outcome data form

[2] Kawaza K, Machen HE, Brown J, Mwanza Z, Iniguez S, et al. (2014) Efficacy of a Low-Cost Bubble CPAP System in Treatment of Respiratory Distress in a Neonatal Ward in Malawi. PLoS ONE 9(1): e86327. doi: 10.1371/journal.pone.0086327

to record patient clinical status while on the Pumani device and measure clinical outcomes. Eligibility criteria for treatment with bCPAP as part of the study included neonatal age (<28 days old), severe respiratory distress, birth weight >1000g, breathing spontaneously, and neurologically viable. Exclusion criteria included specific congenital anomalies, severe cardiac instability, and severe asphyxia.

Findings

Effectiveness of Capacity Building for Providers

The planned step-down competency-based training led by champions at their home institutions in Ebonyi State were reported by both learners and trainers to be ineffective. Challenges included very limited time (as little as one hour) assigned for the training, only one trainer for a large group of staff, and limited opportunities for hands on learning. To address this critical gap in capacity building, a series of intensive, competency-based workshops were conducted by champions, with support from MCSP, at facilities in Ebonyi that resulted in strengthened staff capacity to implement bCPAP.

In Kogi State, the Federal Medical Center hospital conducted a series of bCPAP trainings as part of their resident physician ongoing education. Clinical staff agreed that the trainings were effective in building their capacity to implement bCPAP.

In Cross River State, the planned step-down training of nurses by a champion (doctor) did not take place since the champion was busy with other responsibilities and did not have time to conduct the step down training. MCSP staff stepped in to train the nurses in both facilities on the use of bCPAP and care for eligible patients.

Treatment with bCPAP for eligible newborns

A total of 76 neonates were treated with the Pumani bCPAP device from all seven facilities – significantly lower than the planned participation size (the estimated sample size needed was 245 neonates). At three of the study facilities, improvised bCPAP (ibCPAP) was available in addition to the Pumani bCPAP device. Data presented in this brief is based on only babies treated with the Pumani bCPAP device. Availability of ibCPAP was a limitation to enrolling eligible babies on the bCPAP device, as clinicians tended to put patients on this alternate equipment in the face of severe and erratic power outages. ibCPAP uses easily accessible, locally available supplies for setup and requires no electricity to operate. Babies that were transferred to ibCPAP from Pumani bCPAP were considered ineligible for the study. At least 40 babies were put on ibCPAP when Pumani bCPAP was available at the same facility. MCSP did not follow-up on the babies that were placed on the ibCPAP machine. The project did not support the use of ibCPAP for fear of the potential risk of retinopathy leading to blindness in infants because it delivers pure oxygen at 100% instead of blended oxygen and air to achieve desired levels of oxygen in the blood. Table 1 presents the final number of newborns treated by facility.

Table 1: Number of newborns treated with bCPAP by facility from August 2016 to June 2018 (n=7 facilities)

State	Name and type of hospital	Number
Ebonyi	Federal Teaching Hospital Abakaliki/ FETHA (Federal)	20
	Mile Four Mission Hospital (Mission)	23
	Mater Misericordiae Hospital (Mission)	4
Kogi	Federal Medical Center (Federal)	13
	ECWA Hospital (Mission)	3
Cross River	University of Calabar Teaching Hospital (Federal)	13
	General Hospital	0**
Total		**76**

** Even though a small number of babies were placed on the Pumani device since data monitoring forms were not completed.

The Program found four categories of challenges with applying bCPAP to eligible newborns: **human resources for health**, **facility infrastructure**, **equipment** and **financing**.

Human Resources for Health factors:

- Many healthcare workers deviated from the protocol or do not consistently use the TRY CPAP algorithm, which was developed to help identify newborns that need bCPAP. As a result, they may not recognize or enroll all eligible newborns who would benefit from bCPAP.
- The quality of step-down trainings varied across champion providers, which impacted the quality of the bCPAP services rendered and number of patients enrolled.
- Facilities had high staff turnover and nurse rotation off the neonatal unit, so there were a limited number of staff trained on the use of bCPAP equipment to assign to each shift. The lack of mechanisms to train new staff resulted in inconsistent application of the protocol.
- Multiple workers' (both clinical and non-clinical staff) strikes resulted in only skeletal services available at the hospitals, particularly in Kogi State, during the pilot period. The incessant strikes affected the enrolment of patients and quality of service.
- At some facilities, providers started eligible neonates on Pumani bCPAP but switched to improvised bCPAP (ibCPAP) during power outages instead of following the protocol of connecting the nasal cannula directly to oxygen cylinder at a low rate of two liters per minute (LPM), and when power returns, they did not resume Pumani bCPAP. While the ibCPAP is lower in cost and easy to assemble, as mentioned earlier it puts the neonate at greater risk of retinopathy and blindness.

Facility infrastructure factors

- Some facility infrastructure factors that have affected use of bCPAP include erratic power supply, limited availability and high cost of oxygen. Although patients did not have to pay for Pumani use they did, however, pay for oxygen (cost varied by facility).

Equipment factors

- Prongs and tubings were lost or incompatible, rendering providers unable to start babies on the device. In some cases, the size of the nasal prongs were too big for the small babies, thus resulting in some challenges. However, facilities still used the prongs with the support of adhesive tape.
- The Pumani device broke down in some cases due to technical faults. MCSP provided the needed technical support when contacted by the facilities. The study did not establish a link between the breakdown of the device and clinical outcomes. In cases where the machines broke down the baby was placed on the ibCPAP machine.

Financing factors

- Data on acceptability or cost of treatment was difficult to collect, but one of the Mission hospitals reported that cost of care ranged from N17, 000 to N65, 000 (approximately USD $50- $180) depending on length of stay and co-morbidities of the patient. In October 2017, study team members from AAP conduct a review of the bCPAP implementation study. The review revealed that the high cost and limited availability of oxygen was a significant limitation during program implementation. This is an important finding to keep in mind particularly when thinking of scalability of this intervention.

Clinical outcomes

Overall, there was a low complication rate among newborns treated with bCPAP. There was no report of pneumothorax (abnormal quantity of air between the lungs and the chest wall) in the 76 patients. One patient experienced abdominal distention (1.3%), while 6 patients experienced nosebleeds (7.9%) and 2 patients (2.6%) were reported to have nasal trauma. A total of 23 newborn deaths (30.3%) were recorded among those treated with bCPAP. Of these, 39% of deaths were due to sepsis, 30% were due to respiratory failure, 13% were from necrotizing enterocolitis (a condition where part of the baby's intestines is damaged and begins to die). Tables 2 and 3 (below) displays clinical outcomes and causes of death of enrolled patients.

Table 2: Clinical outcomes for enrolled patients (N=76)

Outcome		Number	Percent
Complications	Pneumothorax	0	0
	Abdominal distention	1	1.3
	Nasal bleeding	6	7.9**
	Nasal trauma	2	2.6**

** The rates of complications from nasal prongs were high due to ill-fitting prong and dry gases.

Table 3: Causes of death among enrolled patients (N=23)

Outcome		Number	Percent (n=23)
Cause of death	Sepsis	9	39.1
	Respiratory failure	7	30.4
	Necrotizing enterocolitis (NEC)	3	13
	Other	4	17.4
Total number of deaths		**23**	**100**

Recommendations and Conclusion

For bCPAP to become a feasible and viable technology across Nigeria, solutions to the challenges identified above must be introduced.

Recommendations

- **Infrastructure:** To protect the equipment from power fluctuations, each facility bCPAP device should have a dedicated power supply by connecting alternative back up sources. An uninterrupted power supply device (UPS) should be in place. An electricity current stabilizer is also necessary to protect the equipment from power surges. Furthermore, given the challenges with identifying a reliable source of oxygen in the country, facilities should work towards having oxygen in the form of cylinders readily available, along with a backup option (i.e. an oxygen concentrator). The oxygen concentrators that were purchased had a compatible interface with the Pumani device.

Here, attendants set up a bubble continuous positive airway pressure machine, which helps provide oxygen to infants having trouble breathing.
Photo by Karen Kasmauski/MCSP

  Additionally, erratice power outages are common in Nigeria and the cost of fuel is high. A sustainable, cost-effective energy alternative must be identified to address the challenge posed by unreliable electricity supply. To ensure sustainability, it is recommended that districts or facilities invest in reliable power sources such as solar energy.

- **Financing**: Findings from the review of the bCPAP study revealed the high cost of oxygen limiting the implementation of the activity. Facilities should develop strategies to make oxygen affordable to the patient population through subsidies. For facilities with low patient volume, it might be less costly to use oxygen concentrators. This will address a key limitation identified in the program review and will improve the flow of patients placed on the machine.

- **Health worker motivation and capacity:** To ensure a prepared and motivated health workforce, an engaged, innovative, and effective leader or champion should be identified at each facility. Facility administrators can play a role in provider buy-in by championing the new intervention. Facilities should build and maintain the capacity of providers through sustainable and cost-effective methods of instruction to ensure that adequate number of staff know how to use the device. Such methods include low-dose, high-frequency practice sessions on equipment setup and use, in situ team education by unit champion, and peer mentoring. MCSP provided facilities with poster size graphics of the TRY CPAP algorithm for the NICU's to serve as a visual reminder and an education tool for NICU staff. In addition, facilities should train existing staff in the NICU on the program algorithm and establish clear mechanisms for training new staff as they come in.

  Competency-based training sessions should focus not only on technology and equipment use, but also on delivery of care and patient monitoring. Monitoring patient clinical outcomes is vital to assessing safety and quality. Training and ongoing support during the introduction phase can help increase acceptance and use of the device by providers.

- **Equipment**: It is vital that customer service and repair services be available for timely troubleshooting and repair of malfunctioning devices. During the budgeting and planning period, a cost benefit analysis that factors in maintenance and consumable costs should be conducted. A WhatsApp group was established during the pilot to allow for peer-to-peer troubleshooting of problems with the bCPAP device among trained service providers.

  Most facilities were using ibCPAP, instead of the Pumani bCPAP device, which was deemed to be unsafe and poses various risks to the neonates resulting in complications. In order to avoid these risks, it is advised that facilities replace ibCPAP machine with the appropriate bCPAP device with blended air and oxygen, thus avoiding the risk retinopathy.

- **Recordkeeping**: To collect data on patient outcomes and safety, providers should fill out a simple, user-friendly data collection and patient monitoring tool every four hours. Hospital administrators should ensure that consent and monitoring forms are consistently stocked at all NICUs to ensure all bCPAP services are documented.

In conclusion, the implementation of the bCPAP study has had mixed results at the various sites. There is a potential for future research as the institutions already have the technology and materials needed. However, the technology has not been used to its optimal potential. The goal for the future is for facilities to use lessons learned from this program to successfully establish and sustain a bCPAP program that will ultimately lead to improvements in neonatal morbidity and mortality. Countries seeking to introduce or expand the use of bCPAP will need to ensure there is continuing education through various mechanisms including onsite supportive supervision, WhatsApp communication or peer supported periodic mentorship for both doctors and nurses, in order to maintain their skills and confidence to identify and care for eligible babies using the bCPAP.

Additionally, programs should have in place a system to ensure routine maintenance, replacement and repair of the bCPAP equipment and its accessories. Although not included in this study, incorporating selected indicators related to the care of babies using bCPAP as part of the hospital quality improvement review process will contribute to strengthening care of newborns with respiratory distress. Auditing bCPAP related deaths to determine avoidable factors that contributed to the deaths is another process likely to contribute to increasing survival for newborns and reduce the number of deaths attributable to respiratory distress in hospitals.

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