Neonatal CPAP for Respiratory Distress Across Malawi and Mortality

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OBJECTIVES: Our aim in this observational study was to monitor continuous positive airway pressure (CPAP) usage and outcomes in newborn wards at 26 government hospitals in Malawi after the introduction of CPAP as part of a quality-improvement initiative. CPAP was implemented in 3 phases from 2013 through 2015.

METHODS: Survival to discharge was analyzed for neonates treated with nasal oxygen and/or CPAP with admission weights of 1 to 2.49 kg at 24 government hospitals with transfer rates <15%. This analysis includes neonates admitted with respiratory illness for 5.5 months before (621 neonates) and 15 months immediately after CPAP implementation (1836 neonates). A follow-up data analysis was completed for neonates treated with CPAP at all hospitals during an additional 11 months (194 neonates).

RESULTS: On implementation of CPAP, survival to discharge improved for all neonates admitted with respiratory distress (48.6% vs 54.5%; \( P = .012 \)) and for those diagnosed with respiratory distress syndrome (39.8% vs 48.3%; \( P = .042 \)). There were no significant differences in outcomes for neonates treated with CPAP during the implementation and follow-up periods. Hypothermia on admission was pervasive and associated with poor outcomes. Neonates with normal mean temperatures during CPAP treatment experienced the highest survival rates (65.7% for all neonates treated with CPAP and 60.0% for those diagnosed with respiratory distress syndrome).

CONCLUSIONS: A nurse-led CPAP service can improve outcomes for neonates in respiratory distress in low-resource settings. However, the results show that real-world improvements in survival may be limited without access to comprehensive newborn care, especially for small and sick infants.

WHAT'S KNOWN ON THIS SUBJECT: Preterm birth is the leading cause of global child mortality, and respiratory distress syndrome is the most common cause of death in preterm infants. In Malawi, improvements in the management of neonatal respiratory failure are needed to reduce neonatal mortality.

WHAT THIS STUDY ADDS: This study shows that a nurse-led continuous positive airway pressure service can be implemented and sustained in district-level hospitals on national scale in Malawi. The introduction of continuous positive airway pressure reduced neonatal mortality, but improvements were limited by pervasive hypothermia.
Every year, 15 million infants are born preterm. Preterm birth is the leading (and still growing) cause of global child mortality, currently accounting for >1 million deaths per year. Eighty percent of newborn deaths are of small infants, two-thirds of whom are preterm. Premature infants are susceptible to infection, especially pneumonia, and to respiratory distress syndrome (RDS). Indeed, RDS is the most common cause of death in preterm infants. Malawi has the highest rate of premature live births (18.1 in 100) worldwide.

The World Health Organization states in Sustainable Development Goal (SDG) 3.2.2 that by 2030, neonatal mortality should be <12 in 1000 live births per year across all countries. In 2016, 80% of neonatal deaths were considered to be preventable or treatable. Neonatal mortality in Malawi is 23 in 1000 live births, and for Malawi to achieve SDG 3 for newborns, it is important to improve the care and management of respiratory failure.

Bubble continuous positive airway pressure (CPAP) is 1 of the most effective and safest ways to treat neonatal respiratory distress. CPAP helps optimize lung volumes for better gas exchange and reduces the effort of breathing and lowers the risk of morbidity and death. CPAP is widely used in high-income countries but is rarely available in low-income countries because of cost and infrastructure limitations. Low-cost, rugged CPAP machines have recently been developed for use in low-resource settings. These devices have been evaluated to treat neonatal respiratory distress in low-resource settings; results have shown comparable clinical efficacy to that of standard CPAP devices. In the last decade, use of neonatal CPAP at nontertiary hospitals has increased. There is need, however, to monitor clinical outcomes, resources required, implementation challenges, and longer-term effects as neonatal CPAP is implemented routinely in resource-limited settings.

In 2013, we began a phased implementation of a low-cost CPAP to treat neonates with respiratory illness in all government district and central hospitals in Malawi, where antenatal steroids were rarely available and surfactant and mechanical ventilation were not available. We monitored CPAP usage and the resultant impact on clinical outcomes.

METHODS

Ethics Statement

The protocol was approved by the National Health Sciences Research Committee (No. 1180) of Malawi and the Institutional Review Board of Rice University (13-102X). Deidentified patient information was collected from standard Ministry of Health (MOH) acute respiratory illness (ARI) forms.

Quality-Improvement Program Overview

Our aim in this observational study was to introduce and monitor CPAP usage and outcomes in newborn wards at all 24 government district and 2 central hospitals in Malawi where CPAP was not available. CPAP was implemented in 3 phases as part of a quality-improvement program (Table 1).

Baseline training for maternity and pediatric staff was conducted at each hospital to ensure ARI forms were completed for each hospitalized neonate with respiratory illness. Baseline data were collected for ~6 months at each facility.

Pumani CPAP devices, along with oxygen concentrators, suction machines, pulse oximeters, all necessary disposable supplies, a storage cabinet, and wall job aids, were installed at each site.

Initially, CPAP was implemented at central hospitals. In phase 1, 1-day trainings were conducted by an MOH representative and a physician familiar with CPAP. Trainings consisted of presentations, videos, and hands-on practice. Trainings covered patient identification, CPAP device operation, initiation and monitoring of CPAP, and weaning patients from CPAP. Because chest radiographs were rarely available, a simple, validated algorithm using a combination of vital signs, tone, and birth weight was introduced to assist nurses in determining the need for CPAP.

Before phases 2 and 3, 6 health care workers from each district hospital were trained at central hospitals. These 2-day trainings allowed participants to see successful implementation of CPAP before installation in their own hospital's newborn ward. Additional 1-day trainings were conducted at each hospital for 10 to 15 health care workers.

Clinical supervisory visits were conducted quarterly by the MOH ARI team. Beginning in phase 2, a guided mentorship approach was used to assist facilities with observed difficulties in identifying and treating CPAP candidates. Clinical staff showing exceptional ability with CPAP were trained as mentors, who conducted week-long visits to hospitals to address these concerns, which were often associated with high turnover or staff rotations.

Data Collection

In the baseline and implementation phases, ARI forms were used by the admitting staff member and updated at 6-hour intervals by the attending nurse or clinician until discharge or death of each hospitalized neonate presenting with respiratory illness. An on-site ARI coordinator ensured completion of forms for every qualifying patient, and each facility maintained a CPAP registry
TABLE 1 Eligible Neonates With Admission Weight 1 to 2.49 kg Admitted With Respiratory Distress and Treated With Nasal Oxygen and/or CPAP by Hospital

<table>
<thead>
<tr>
<th>Phase</th>
<th>Hospital</th>
<th>First Date of Baseline</th>
<th>Date of Implementation</th>
<th>Last Date of Analysis</th>
<th>Total No Neonates Admitted (Baseline)</th>
<th>Total No Neonates Admitted (Implementation)</th>
<th>No. Neonates Treated With CPAP (Implementation)</th>
<th>No. Neonates Treated With CPAP (Follow-up)</th>
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<tr>
<td>1</td>
<td>Mzuzu</td>
<td>February 11, 2013</td>
<td>July 25, 2013</td>
<td>October 18, 2014</td>
<td>74</td>
<td>268</td>
<td>29</td>
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<tr>
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<td>Bwaila</td>
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<td>July 11, 2013</td>
<td>October 4, 2014</td>
<td>141</td>
<td>489</td>
<td>45</td>
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<tr>
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<td>January 21, 2013</td>
<td>July 4, 2013</td>
<td>September 27, 2014</td>
<td>12</td>
<td>22</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>Ruphia</td>
<td>March 10, 2013</td>
<td>August 21, 2013</td>
<td>November 14, 2014</td>
<td>12</td>
<td>20</td>
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<td>October 2, 2013</td>
<td>March 15, 2014</td>
<td>June 8, 2015</td>
<td>19</td>
<td>71</td>
<td>7</td>
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<tr>
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<td>Chikwawa</td>
<td>September 22, 2013</td>
<td>March 5, 2014</td>
<td>May 29, 2015</td>
<td>37</td>
<td>25</td>
<td>18</td>
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<td>April 1, 2014</td>
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<td>40</td>
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<td>October 11, 2013</td>
<td>March 24, 2014</td>
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<td>47</td>
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<td>20</td>
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<tr>
<td>2</td>
<td>Mangochi</td>
<td>October 1, 2013</td>
<td>March 14, 2014</td>
<td>June 7, 2015</td>
<td>40</td>
<td>105</td>
<td>20</td>
<td>10</td>
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<tr>
<td>2</td>
<td>Mulanje</td>
<td>October 19, 2013</td>
<td>April 1, 2014</td>
<td>June 25, 2015</td>
<td>24</td>
<td>44</td>
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<td>2</td>
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<td>October 5, 2013</td>
<td>March 18, 2014</td>
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<td>June 6, 2015</td>
<td>August 29, 2016</td>
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<td>August 16, 2015</td>
<td>November 8, 2016</td>
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<td>57</td>
<td>21</td>
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<td>Karonga</td>
<td>March 21, 2015</td>
<td>September 1, 2015</td>
<td>November 24, 2015</td>
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<td>2</td>
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<tr>
<td>3</td>
<td>Mchinji</td>
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<td>August 15, 2015</td>
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<td>95</td>
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<td>March 14, 2015</td>
<td>August 25, 2015</td>
<td>November 17, 2016</td>
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<td>August 26, 2015</td>
<td>November 18, 2016</td>
<td>13</td>
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<td>August 17, 2015</td>
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<td>Salima</td>
<td>March 16, 2015</td>
<td>August 27, 2015</td>
<td>November 19, 2016</td>
<td>20</td>
<td>28</td>
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<td>0</td>
</tr>
<tr>
<td>Total</td>
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<td></td>
<td></td>
<td></td>
<td>623</td>
<td>2464</td>
<td>366</td>
<td>257</td>
</tr>
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documenting CPAP use. A central team made weekly phone calls to ARI coordinators and collected patient details after discharge or death, including dates of birth and admission, admission temperature and weight, days on oxygen and/or CPAP treatment, days in the hospital, discharge diagnosis, and outcome. Deidentified ARI forms were scanned monthly and cross-checked against data gathered from phone calls. Quarterly chart audits to cross-check information in ARI forms against patient case files and CPAP registries were conducted by the MOH ARI team to ensure the completion and accuracy of ARI forms for all patients.
Analysis of Neonatal Outcomes

Patient eligibility criteria for this analysis were as follows: neonates with a recorded admission weight between 1 and 2.49 kg treated for respiratory illness with nasal oxygen and/or CPAP at 26 hospitals where CPAP treatment was not previously available. Two central hospitals were not included because they had CPAP treatment available before this study. Data were analyzed for eligible neonates treated with nasal oxygen during the 5.5 months before CPAP was introduced (baseline) and for eligible neonates treated with either nasal oxygen or CPAP in the 15 months immediately after CPAP implementation (implementation). To monitor continued use of CPAP beyond the implementation period, a follow-up data analysis was completed for eligible neonates treated with CPAP at all hospitals for 11 months between December 1, 2016, and October 1, 2017 (follow-up).

Although transfer criteria varied by facility, the decision to transfer small and sick neonates was generally determined by proximity to a referral facility because no organized transportation system existed between facilities. Transfer rates for eligible neonates were calculated at each facility; hospitals with transfer rates exceeding 15% during baseline or implementation were excluded. Demographics and survival at the remaining hospitals were compared during the baseline, implementation, and follow-up periods. Eligible neonates with known outcomes who died or survived to discharge were included. Rate of survival was defined as the fraction of eligible neonates with known outcomes who survived to discharge. Neonates were not included if they were transferred to another hospital, they left against medical advice, or a power outage during treatment was noted in their chart. Differences in survival between baseline, implementation, and follow-up were compared by using a 2-sided Fisher’s exact test. Differences between continuous variables were assessed by using a 2-sided t test for equality of means (unequal variances assumed). Kaplan-Meier survival curves were calculated during baseline and implementation; cumulative survival was compared with a log-rank test. Results were considered significant at the 5% level.

RESULTS

Table 1 summarizes the number of eligible neonates treated for respiratory illness with nasal oxygen and/or CPAP at each hospital during baseline and implementation and the number of eligible neonates treated with CPAP during implementation and follow-up. Transfer rates at the Bwaila and Neno District Hospitals exceeded the 15% threshold set for inclusion (Supplemental Fig 6); therefore, data from these facilities were excluded from further analysis. Table 2 shows demographic information and survival rates for neonates during baseline, implementation, and follow-up for the 24 facilities included in the analysis.

Implementation of CPAP was associated with a significant increase in survival for all eligible neonates treated for respiratory illness (Fig 1A) and for the subset diagnosed with RDS (Fig 1B). During baseline, 48.6% of eligible neonates treated for respiratory distress survived to discharge; the rate of survival
improved to 54.5% after the implementation of CPAP \( (P = .012) \). There was a larger increase in survival for neonates diagnosed with RDS; survival rose from 39.8% in baseline to 48.3% after the implementation of CPAP \( (P = .042) \).

Admission weights were similar for neonates admitted during baseline and implementation. During both periods, roughly equal proportions of neonates were admitted within the weight bands of 1 to 1.49, 1.50 to 1.99, and 2.0 to 2.49 kg (Supplemental Fig 7A). Neonates with RDS had lower admission weights when compared with all neonates admitted with respiratory illness, but admission weights for neonates with RDS were distributed similarly during baseline and implementation (Supplemental Fig 7B). Supplemental Fig 7 shows the distribution of admission weights for neonates treated with CPAP. As expected, neonates treated with CPAP were generally smaller than those receiving only nasal oxygen.

CPAP training emphasized the criteria for diagnosis of RDS and the importance of initiating respiratory therapy as soon as possible for neonates with RDS. After the implementation of CPAP, rates of RDS diagnosis approximately doubled, from 25% to 50%, whereas diagnosis rates of birth asphyxia and sepsis generally remained constant (Supplemental Fig 8A). Throughout implementation, ~17% of eligible neonates treated for respiratory illness were treated with CPAP; rates were highest for those with RDS (Supplemental Fig 8B). There was a significant decrease in age of admission after CPAP implementation for all eligible neonates treated for respiratory distress as well as for the subset with RDS (Supplemental Fig 9).

Of the 2457 eligible neonates treated for respiratory illness during baseline and implementation, 8 did not have a documented length of hospitalization. Kaplan-Meier survival curves for the remaining 2449 neonates are shown in Fig 2A. After the implementation of CPAP, there was a significant increase in survival for neonates with respiratory illness \( (P = .004) \). The length of hospitalization was not documented for 3 of 1010 neonates with RDS. Kaplan-Meier survival curves for the remaining 1007 neonates with RDS are shown in Fig 2B; CPAP implementation was associated with a significant improvement in survival \( (P = .009) \).

Figure 3 compares rates of survival for eligible neonates treated with CPAP during implementation and follow-up. There were no significant differences in rates of survival between implementation and follow-up for all neonates admitted with respiratory distress and treated with CPAP (Fig 3A; \( P = .9 \)). Similarly, there were no significant differences in survival between implementation and follow-up for the subset diagnosed with RDS and treated with CPAP (Fig 3B; \( P = .6 \)).

Admission temperatures were similar during baseline and implementation (Fig 4). In both periods, approximately one-fourth of eligible neonates did not have a documented admission temperature. The majority of eligible neonates with a documented admission temperature...
FIGURE 2
A, Kaplan-Meier curve for all neonates admitted with respiratory distress weighing 1 to 2.49 kg and treated with oxygen and/or CPAP. B, Kaplan-Meier curve for the subset of neonates diagnosed with RDS during baseline and after the implementation of CPAP. In both cases, there was a significant improvement in the survival time after the implementation of CPAP ($P = .004$ and $P = .009$, respectively).

were hypothermic, including the group treated with CPAP. During follow-up, temperatures for eligible neonates treated with CPAP were documented throughout treatment; survival rates for these neonates are shown in Fig 5A, stratified by mean temperature during treatment. Only 40.5% of neonates with hypothermic mean temperatures ($<36.5^\circ C$) during CPAP treatment survived. In comparison, 65.7% of neonates with normothermic mean temperatures (36.5–37.5°C) during CPAP treatment survived during the same period. Only 30.0% of neonates with hyperthermic mean temperatures (>37.5°C) during CPAP treatment survived during follow-up. Figure 5B shows survival rates for neonates with RDS stratified by mean temperature during treatment. Sixty percent of neonates with RDS and mean normothermic temperatures during CPAP treatment survived compared with survival rates of 37.4% and 22.2% for those with mean hypothermic and hyperthermic temperatures, respectively.

DISCUSSION
Previously, we reported results from a quasi-randomized study of CPAP versus standard nasal oxygen conducted in the neonatal unit of the referral hospital of southern Malawi. Dedicated research nurses provided care and monitored progress, supervised by ward clinicians. A low-cost CPAP was found to be highly efficacious with survival of 71% vs 44% in controls. There was a 41% improvement in survival of infants with RDS.22 Here, we report findings of an observational study within a quality-improvement program of the feasibility and efficacy of national implementation of the same, low-cost CPAP system into 26 public hospitals in Malawi. Survival increased for all neonates, from 48.6% during baseline to 54.5% during implementation ($P = .012$). Survival in infants with RDS was 39.8% at baseline versus 48.3% in implementation ($P = .042$). These improvements were achieved in the
“real world” of normally staffed health units and were not as dramatic as those previously reported when research nurses provided care and monitored progress. This is not unexpected; proving that something can work has always been easier than embedding it in daily practice. There are inevitable limitations of studies being undertaken in routine care; missing data, staffing, physical space, and inpatient numbers differed between hospitals. Information on maternal complications was rarely detailed in paperwork accompanying the neonate on admission to the nursery and was therefore not available for our study. Our assessments were before versus after implementation of CPAP, and circumstances may have changed between each time period. Nevertheless, overall numbers are large, making the findings convincing; and these are the hospitals where most infants are born and receive care.

**Lessons Learned**

The benefits of introducing CPAP were greater than merely providing CPAP. Firstly, it was feasible to train, introduce, mentor and monitor, and sustain CPAP use successfully in the routine care of neonates in district and central hospitals. This was done with and by the MOH, providing increased awareness of challenges and system-wide action to improve newborn care. Existing government paperwork in all hospitals was used so extra forms were not required, and data continue to be collected routinely after implementation ceased. Secondly, care was initiated, given, and monitored by ward nurses. Our experience emphasized the importance of a broader approach to teaching the use of CPAP at training institutions, in-service trainings, and supportive supervision and mentorship. Mentoring visits have ensured continued use of CPAP. Despite this success, high staff turnover and staff rotations negatively impacted CPAP usage. Thirdly, there was more careful identification of premature infants and better diagnoses made after training and the introduction of CPAP. Many more infants <2.5 kg were identified in the implementation.
phase than in the baseline, and diagnosis of RDS increased substantially. Fourthly, hypothermia was ubiquitous and harmful. It is clear that measures to improve survival, including the provision of CPAP, should be introduced as part of a package of good essential newborn care that must address hypothermia, which is harmful for all infants and especially for premature neonates. Infants with a core temperature of <35.0°C have a sixfold greater mortality rate than those with warmer core temperatures. Hypothermia is recognized as occurring in many low- and middle-income countries but is often not perceived as a major problem. This may be because we speak of “not letting infants get cold,” and it is assumed that “cold” means a temperature well below normal. In our program, admission hypothermia is a constant problem, but there was a decrease in the number of neonates with undocumented admission temperatures during follow-up (11.9% vs 23.2% in implementation), which implies improved identification of hypothermia on admission. Before the implementation of CPAP, 35.1% of infants with RDS and admission temperatures of 34°C to 36°C survived, but 61.3% with admission temperatures ≤36.0°C survived. After implementing CPAP, 58.4% of all neonates with admission temperatures ≤34.0°C survived. Thermal care before and after admission to the nursery must be improved if more premature and sick infants are to survive. Finally, training for hospital technicians to service and repair CPAP equipment facilitated continued usage despite harsh environmental conditions.

The Experience of Others

Ours is not the first report of a successful nurse-led CPAP service, but to our knowledge, it is the most extensive. Reports of the introduction of CPAP in low- and middle-income countries have been mainly from single secondary- or tertiary-level hospitals. In the referral hospital for the eastern half of the island of Viti Levu in Fiji, nurses led the use of CPAP and reduced the need for mechanical ventilation from 10.2% to 5.1%. The referral system is good, and transport is funded by the government; at best, the ratio of nurses to patients is 1:3. Where mechanical ventilation was not available in Ghana, research nurses managed undifferentiated respiratory distress with CPAP in children aged 1 month to 5 years in 2 district hospitals. When follow-up was done 16 months after that study closed, it was clear that several pieces of equipment needed servicing or repair and skills had waned.

There are many examples of good ideas and practices that struggle to become routine. This may be because a project has relied on extra staff, research nurses, and data managers to ensure its success. By contrast, we worked with the MOH, especially for training and data collection, and relied on ward nurses for clinical care and documentation. This was not without difficulty. Nurses in public hospitals are rotated frequently to other wards, and new staff require training and mentoring. A stable ward workforce would be a great asset to any neonatal care program.

The Wider Picture

Careful thought must be given to selecting hospital equipment. Hospital technicians must receive training and undertake simple repairs. Spare parts should be easily sourced, and consumables should not be costly. Equipment should be robust and able to withstand unpredictable power surges, heat, dust, and humidity. Not least, equipment must be easy to clean and simple to use. In Malawi, CPAP training had 2 themes; 1 was clinical and the other involved hospital technicians. Power outages were not infrequent in Malawi, and an energy source such as solar power could help provide seamless care to CPAP- and oxygen-dependent infants.

Adverse Effects

In a review of reports from low- and middle-income countries on the use of CPAP, pneumothoraces were found to be uncommon (0.0%–7.2%), nasal trauma was frequent but usually limited to hyperemia, and 2 studies that looked for retinopathy of prematurity did not find it. Adverse events in the early development of our program were limited to nasal and/or facial irritation and epistaxis and occurred with similar frequency among neonates treated with CPAP and oxygen. We have not reported adverse events here, but anecdotally, they were few and limited to nasal bleeds or nasal hyperemia.

CONCLUSIONS

The SDGs have set a global goal of 12 neonatal deaths per 1000 live births by 2030. At the present rate of progress, it will be 2124 before this goal is achieved in sub-Saharan Africa. Malawi has done well to reduce the neonatal mortality rate from 50 to 22 per 1000 live births during the Millennium Development Goals (1990–2015). However, there is still a long way to go. To meet the SDG for newborn survival, facilities need space, equipment, and trained staff to provide comprehensive newborn care, especially for small and sick infants. Sustainability must be ensured by in-service and preservice training of biomedical engineers and medical and nursing staff and supported by a procurement scheme for robust, low-cost equipment and materials.

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### ABBREVIATIONS

- ARI: acute respiratory illness
- CPAP: continuous positive airway pressure
- MOH: Ministry of Health
- RDS: respiratory distress syndrome
- SDG: Sustainable Development Goal

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