Aftermath of a Clinical Trial: Evaluating the Sustainability of a Medical Device Intervention in Ghana

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Summary

A randomized controlled trial recently demonstrated that continuous positive airway pressure (CPAP) effectively decreases respiratory rate in children presenting to Ghanaian district hospitals with respiratory distress. A follow-up study 16 months later evaluated the extent to which the skills and equipment necessary for CPAP use have been maintained. Seven of eight CPAP machines were functional, but five of eight oxygen concentrators and three of four electric generators were non-functional. Nurses trained by US study personnel (first-generation) and nurses trained by Ghanaian nurses after the study (second-generation) were evaluated on CPAP knowledge and skills. Twenty-eight nurses participated in the study, 9 first-generation and 19 second-generation. First-generation trainees scored significantly higher than second-generation trainees on both skills and knowledge assessments ($p = 0.003$). Appropriate technical support and training must be ensured to address equipment maintenance. Protocolization of the training program, in conjunction with skills and knowledge assessment, may improve acquisition and retention among second- and future-generation trainees.

Key words: nasal continuous positive airway pressure, training, pediatrics, ethics, developing countries.

Introduction

Medical devices have the potential to greatly improve health in resource-limited settings [1]. However, demonstrating that an intervention is effective in the course of a research study may not be sufficient to prove that it will be effectively incorporated into the health care system. There is an acute need for research that extends beyond effectiveness to include broader issues affecting sustainability of technology transfer [2,3].

The authors of this article and colleagues recently conducted a randomized controlled trial evaluating the effectiveness of nasal continuous positive airway pressure (CPAP) for children with respiratory distress in four district hospitals in Ghana. The study was referred to as '*CPAP in Ghana*'. The study demonstrated that nurses in emergency wards were able to safely apply CPAP to children with respiratory distress, and that the device decreased respiratory rate in these children [4]. All of the equipment and training materials used in the study were donated to the participating hospitals at the conclusion of the study.

The results of the *CPAP in Ghana* study were encouraging, and a larger-scale study to determine the impact of CPAP use on mortality in children

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with respiratory distress is due to begin enrollment soon. However, the efficacy of CPAP when used in the context of a research study with external oversight and funding may not translate into effective and ongoing use of the technology. Little information is available about how well medical device interventions are sustained after the completion of a research study, particularly in low- and middle-income countries.

This project was undertaken to evaluate the sustainability of CPAP use in the four hospitals in Ghana that participated in *CPAP in Ghana*. We evaluated the state of the CPAP equipment and the competence and knowledge of the health care providers in each hospital. We hypothesized that each hospital would have a minimum of one complete, functioning set of equipment necessary for CPAP use in children. We hypothesized that the nurses who were trained by US study personnel (termed 'first-generation trainees') would have higher levels of knowledge and competency with CPAP use than nurses trained by local Ghanaian nurses after the end of the CPAP study (termed 'second-generation trainees').

Methods

Parent Study

Before the *CPAP in Ghana* study, none of the hospital sites had the capacity for long-term mechanical ventilation and CPAP was not used. Full details of the study protocol have been previously published [4]. The timeline of the initial and follow-up study is presented in Fig. 1. Seventeen nurses from the four district hospitals underwent the CPAP training program outlined in Table 1. A team leader was identified at each site. This individual underwent additional training as a super-user, received supplemental one-on-one training on CPAP application and troubleshooting and was directly observed initiating CPAP on a pediatric patient. The leadership at each hospital committed to providing a stable cadre of nurses in the emergency ward for the duration of the study.

A nasal bubble CPAP system was used in the study as shown in Fig. 2. Each site was provided with two oxygen concentrators, a back-up electrical generator, CPAP equipment and vital sign monitors. During *CPAP in Ghana*, CPAP was used on 70 patients, (range 6–29 per site). Mean respiratory rate of children

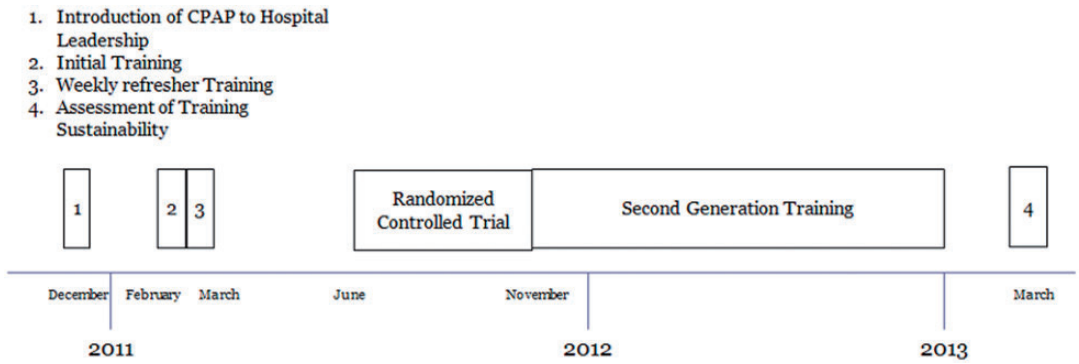

FIG. 1. Timeline of the CPAP in Ghana study.

TABLE 1
CPAP training program

Training session: 4-hour session lead by two experienced Neonatal ICU nurses and a Pediatric Critical Care fellow from Columbia University	
45 minutes	Power Point: US physician-lead presentation of: recognition of respiratory insufficiency, indications, risks and physiology
15 minutes	Break
2 minutes	Video of nasal bubble CPAP being applied to an infant in the United States demonstrated the proper application of the device
45 minutes	Demonstration of CPAP application to training dolls by US ICU nurses
15 minutes	Break
45 minutes	Small group sessions (≤5 trainees), hands-on practice with mannequins. Each nurse was observed successfully placing CPAP on the training mannequin
10 minutes	Trainees together set up CPAP and initiated nasal bubble CPAP on an adult volunteer

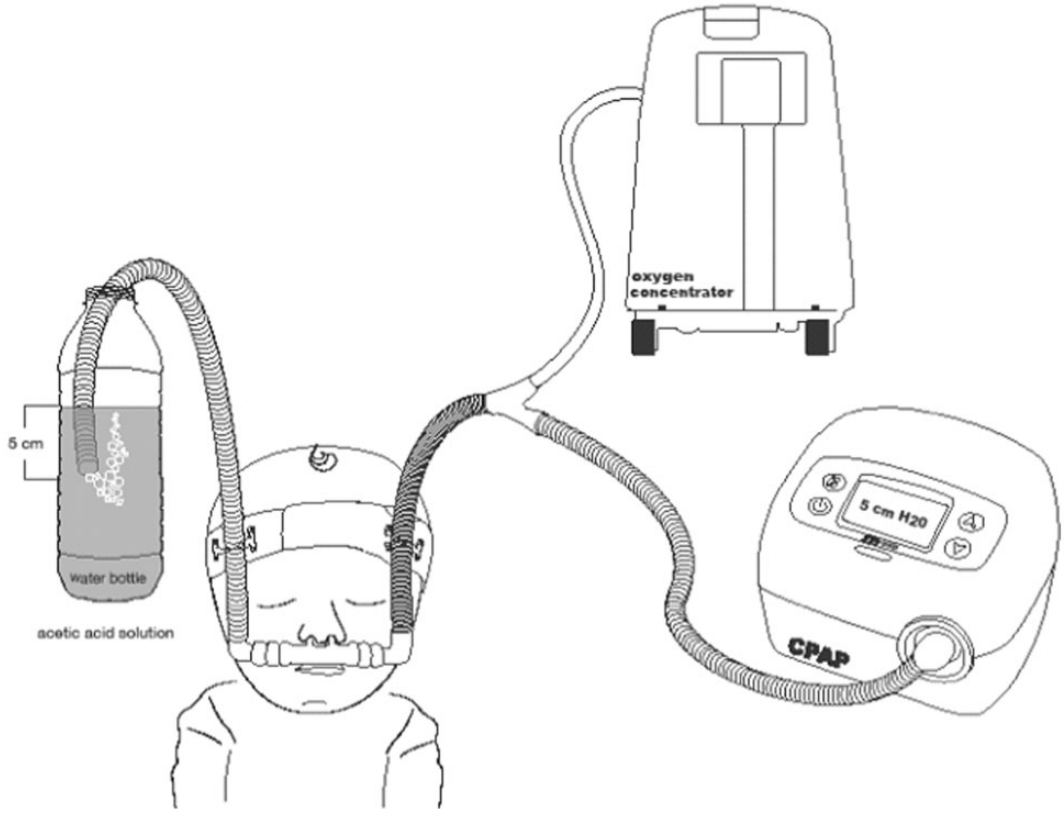

FIG. 2. Nasal bubble CPAP set-up.

managed with CPAP fell by 16 breaths/minute (95% CI 10–21) in the first hour compared with no change in children managed with usual care ($p < 0.01$).

At the conclusion of the study, equipment maintenance was reviewed with super-users, and laminated pages detailing equipment maintenance were affixed to the equipment or to the wall where the equipment was stored. Nursing leadership at each site was provided with all of the training materials (training mannequins, laminated written training information and video of CPAP application). A laptop computer containing detailed instructions was also provided for initial and refresher training, as needed. All four super-users trained colleagues at their respective hospitals after the study finished. No formalized plan for training, measuring competency and follow-up was made.

Follow-up Study

The initial CPAP study was completed in November 2011. In March 2013, investigators returned to each participating site to inventory equipment and assess the CPAP skills and knowledge among nurses who had been trained on CPAP. Two investigators visited each emergency ward and attempted to locate all pieces of donated equipment. All equipment that was still found in the emergency ward was tested for functionality.

A skills and knowledge assessment took place at all four hospitals from 4 to 7 March 2013. Nurses were eligible for inclusion if they self-reported that they had undergone CPAP training. Verbal consent was sought and anonymity assured; a pen was given to each participating nurse as a token of appreciation. All nurses who were identified as eligible agreed to participate. Because there was no record-keeping regarding CPAP training, it is not possible to report how many eligible nurses were not identified.

Nurses were defined as 'first-generation trainees' if they had been trained in CPAP use by US researchers for the *CPAP in Ghana* study. Nurses were defined as 'second-generation trainees' if they were trained subsequent to the parent study, by local personnel.

The assessments included three stages: skills assessment, knowledge assessment and a brief verbal survey regarding experiences with and opinions about CPAP. A blinded research assistant conducted the skills testing. During the skills assessment, each nurse was asked individually and privately to set up the CPAP system on the training mannequin. If a

TABLE 2
Open-ended questions

1	What are the barriers to using CPAP?
2	What could make using CPAP easier for you?
3	How were you trained to use CPAP?
4	Do you feel you were adequately trained?
5	What is the best way to train other nurses how to use CPAP?
6	Do you feel confident in your ability to use the CPAP machine correctly each time a patient presents with respiratory distress?
7	Do you have any other comments or suggestions regarding the use of CPAP at your hospital?

satisfactory seal is formed on the mannequin's nares, bubbles will be seen in acetic acid solution in which the expiratory limb is immersed (Fig. 2). The investigator judged whether each of eight steps was accomplished successfully. The written knowledge assessment included 10 multiple-choice questions covering indications, methods of use and complications of nasal CPAP in children. After skills and knowledge assessments, each nurse was asked a series of open-ended questions (Table 2). The investigator noted the responses verbatim.

Both studies were approved by the Institutional Review Board at the Columbia University; the Committee on Human Research, Ethics and Publications of the School of Medical Sciences, Kwame Nkrumah University of Science and Technology and the medical superintendents at each hospital.

Statistical analysis

Two independent investigators evaluated and categorized responses to open-ended questions using thematic analysis. Themes were developed on the basis of a priori hypotheses and review of the responses. Any discrepancies were resolved to the satisfaction of both investigators. The Mann–Whitney U test was used to compare non-parametric data.

Results

Equipment

A summary of the equipment donated to the study sites and its presence and functionality in the emergency ward is found in Table 3.

Skills and knowledge assessments

Twenty-eight nurses participated in the study, including 9 first-generation and 19 second-generation (range 6–8 per site).

First-generation trainees scored significantly higher than second-generation trainees on both skills and knowledge assessments (Figs 3 and 4 and Tables 4 and 5).

TABLE 3
Status of equipment

Item	Number provided	Present and functional *n* (%)
Automated patient monitors[a]	7	7 (100)
Temperature probes	7	7 (100)
CPAP training mannequins	4	4 (100)
CPAP written training materials	4	4 (100)
CPAP machines	8	7 (88)
Blood pressure cuffs	7	5 (71)
Pulse oximeters	7	5 (71)
Manual suction devices	8	4 (50)
Generators	4	1 (25)
Oxygen concentrators	8	2[b] (25)
Portable pulse oximeters	4	1 (25)

[a]Blood pressure, heart rate and oxygen saturation monitors.
[b]One additional oxygen concentrator was functional, but was in use in the newborn nursery at the time of our inventory.

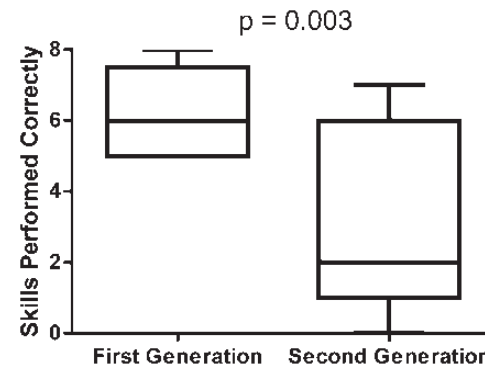

FIG. 3. Performance of first- and second-generation trainees on CPAP skills (highest possible score = 8).

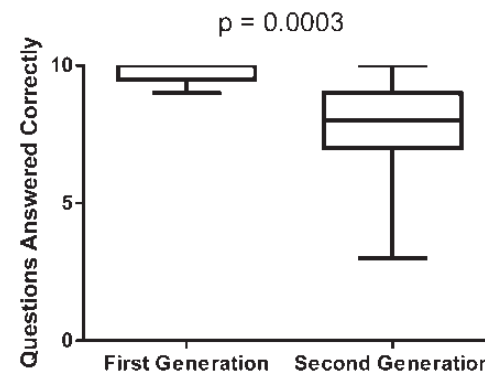

FIG. 4. Performance of first- and second-generation trainees on knowledge assessments (highest possible score = 10).

TABLE 4
Number of nurses correctly performing each step of CPAP application

CPAP application skill	First-generation n (%)	Second-generation n (%)
Water/acetic acid solution mixed properly	6 (67)	7 (37)
5-cm line marked on water bottle (±1 cm)	7 (78)	5 (26)
Expiratory limb immersed 5 cm (±1 cm)	4 (44)	2 (11)
CPAP machine plugged in and turned on	8 (89)	11 (58)
Nasal prongs positioned and secured correctly on mannequin[a]	7 (78)	8 (42)
Head dressing secured on mannequin	9 (100)	11 (58)
Subject checked for bubbles to confirm intact circuit	8 (89)	7 (37)
Bubbles visualized by assessor	8 (89)	7 (37)

[a]Prongs were considered incorrectly placed if they were placed backward (prongs curved outward rather than inward, or if the prongs were below the nares rather than inserted into the nares).

TABLE 5
Number of nurses correctly answering each knowledge question

Text of question[a]	First-generation n (%)	Second-generation n (%)
How does CPAP work?	9 (100)	16 (84)
What type of patient does CPAP help?	9 (100)	10 (53)
How much pressure is delivered with CPAP?	8 (89)	12 (63)
What should be added to the water to prevent bacterial growth?	9 (100)	17 (89)
How do you confirm that CPAP was set up properly?	9 (100)	18 (95)
How far should the expiratory limb be immersed?	9 (100)	13 (68)
When should oxygen be used with CPAP patients?	8 (89)	16 (84)
Which is not a possible adverse effect of CPAP?	8 (89)	11 (58)
When should CPAP be removed?	9 (100)	19 (100)
Which patients should not receive CPAP?	9 (100)	11 (58)

[a]All questions were multiple-choice. Available choices are included in Supplementary data.

Nurses' perceived competence with CPAP was discordant with assessed competence. In response to the question 'Do you feel confident in your ability to use the CPAP machine correctly each time a patient presents with respiratory distress?', all first-generation trainees and 15 of 19 second-generation trainees responded yes. Among the second-generation trainees who responded that they were confident in their ability to apply CPAP properly, 8 of 15 scored less than 50% on the skills assessment. In response to the question, 'Do you feel you were adequately trained in CPAP use?', 7 of 9 first-generation trainees replied yes, and 2 replied equivocally. Nine of 19 second-generation nurses replied yes, 5 replied no and 5 replied equivocally ($p = 0.2$).

In response to the open-ended questions, 16 of 28 participants expressed a desire for more robust training or retraining. Thirteen nurses made statements in support of CPAP use ('It is effective'), 10 cited patient discomfort ('Sometimes the child is so irritated he does not cooperate') and one cited the potential for CPAP to cause harm ('It may do harm to those patients who don't need it'). Eight nurses complained about the cumbersome nature of the CPAP set-up, particularly securing the tubing to the headdress. Six commented that often too few personnel are in the emergency ward to monitor a child on CPAP. Two cited dysfunctional equipment, and three that they will run out of nasal prongs.

Discussion

We found that limitations in equipment maintenance and limitations in training of personnel impede sustainable use of nasal CPAP in district hospitals in Ghana.

Equipment

Lack of durable medical equipment is recognized as a major impediment to advancing medical care in resource-limited settings [2,5–8]. We found that seven of eight CPAP machines were present and functional 16 months after the conclusion of the parent study. However, five of eight oxygen concentrators and three of four generators donated were non-functional at follow-up. An informed choice between oxygen cylinders and the use of oxygen concentrators is critical and appropriate technical support and staff

training must be ensured [9]. The generators chosen for use in the CPAP study were available locally, and all had functioned well throughout the initial study period. Although locally available equipment may help ensure that equipment can be serviced locally, it does not ensure durability, nor does it ensure proper care and use. Detailed plans for care and maintenance of donated equipment should be developed in collaboration with local providers before donation.

We found that CPAP machines were durable, with seven of eight functioning at follow-up, but the problem of ongoing provision of consumables has not been solved. The *CPAP in Ghana* study was begun in full knowledge that single-use nasal prongs are not affordable on an ongoing basis. We found that at least one hospital is washing and reusing prongs to circumvent this problem. Ongoing research into the use of CPAP in the resource-limited settings should include research into inexpensive, safe and effective disinfection processes.

Training

Skills retention of first-generation nurses was considered good, with a median of 9 of 10 answers correct on the knowledge assessment and 6 of 8 skills correctly performed on the skills assessment. First-generation trainees underwent a single 4-hour training session, with investigator availability for follow-up questions once weekly for the next 4 weeks. Our training curriculum is much shorter and much less comprehensive than the 11-day Integrated Management of Childhood Illness training program [10,11], but reinforces the effectiveness of formal training programs and need for refresher training. If CPAP use is found to be broadly effective and sustainable, we believe CPAP training could be integrated into the Integrated Management of Childhood Illness training program.

Nurses who were trained by local staff after the study concluded did not acquire or did not retain adequate knowledge and skills. All of the materials for training were left with the nursing leadership at the end of the study, but no formalized plan for programmatic training of second-generation nurses was developed. We believe that protocolization of the training program, in conjunction with skills and knowledge assessment, will significantly improve acquisition and retention among second- and future-generation trainees. High turnover rate of medical professionals was identified as a particular challenge for effectively integrating medical devices into resource-poor health systems [2]. Training plans need to specifically accommodate this fact.

Need for sustainability research

The Reasonable Availability Standard posits that it is not ethical to do research in the resource-limited settings if a successful intervention will not be available to the community after the research is completed [12,13]. With medical devices, research is needed to determine how to incorporate beneficial therapies into the existing health care system. Successfully incorporating medical devices into resource-poor settings is predicated on appropriate personnel training and equipment maintenance. Our study revealed deficiencies to be addressed in both training and equipment maintenance.

As progress is incremental, it may not always be possible for researchers to ensure that all barriers to intervention implementation are addressed before a study begins. We believe that studying the effectiveness of CPAP in low-income settings is appropriate, despite some persistent barriers (e.g. cost of cannulae, sustainability of training). However, the ethical conduct of research in resource-poor settings requires that investigators consider how these barriers will be addressed. Attention to these issues will facilitate the goal of moving away from a donor-recipient paradigm toward a framework in which medical advances can be sustained locally [14].

Study limitations

The skills and knowledge assessments used in this study are not validated tools, and therefore, our assessments of skills and knowledge should not be interpreted as the gold standard. Further, nurses' responses to the open-ended questions could have been biased by a desire to please the researchers. We did not ask nurses the extent to which use and maintenance of CPAP may have detracted from the care of other patients. We would have liked to ascertain how often CPAP is used in each of the participating hospitals. Due to extremely scanty medical records, this was not possible.

Conclusions

Investigators conducting research in resource-limited settings have an ethical obligation to facilitate incorporation of successful interventions into the local health care system. With medical devices, this task is particularly challenging. We found that a formal 4-hour training session resulted in good skills and knowledge retention among first-generation nurses. However, an informal system of personnel training was not sufficient to ensure that second-generation providers remained proficient in the use of CPAP.

Supplementary Data

Supplementary data are available at *Journal of Tropical Pediatrics* online.

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