Real-Time Digital Feedback Device and Simulated Newborn Ventilation Quality

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abstract

OBJECTIVES: Effective bag-valve-mask ventilation is critical for reducing perinatal asphyxia-related neonatal deaths; however, providers often fail to achieve and maintain effective ventilation. The Augmented Infant Resuscitator (AIR) attaches to bag-valve-masks and provides visual feedback on air leaks, blocked airways, harsh breaths, and improper ventilatory rates. We evaluated the effect of this real-time-digital feedback on ventilation quality and the effective determination of airway integrity in a randomized controlled study in Uganda and the United States.

METHODS: Birth attendants trained in newborn resuscitation were randomized to receive either real-time AIR device feedback (intervention) or no feedback (control) during ventilation exercises. Intervention-arm participants received a 2-minute orientation on interpreting AIR feedback using a single-page iconography chart. All participants were randomly assigned to 3 blinded ventilation scenarios on identical-appearing manikins with airways that were either normal, significantly leaking air, or obstructed.

RESULTS: We enrolled 270 birth attendants: 77.8% from Uganda and 22.2% from the United States. Birth attendants receiving AIR feedback achieved effective ventilation 2.0 times faster: intervention mean 13.8s (95% confidence interval 10.6–17.1) versus 27.9s (21.6–34.3) for controls ($P < .001$). The duration of effective ventilation was 1.5 times longer: intervention mean 72.1s (66.7–77.5) versus 47.9s (41.6–54.2) for controls ($P < .001$). AIR feedback was associated with significantly more accurate and faster airway condition assessment (intervention mean 43.7s [40.5–47.0] versus 55.6s [51.6–59.6]).

CONCLUSIONS: Providers receiving real-time-digital AIR device feedback achieved effective ventilation significantly faster, maintained it longer, and determined airway condition faster and more accurately than providers in the control group.

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This trial has been registered at www.clinicaltrials.gov (identifier NCT04820504). The datasets generated and/or analyzed during the current study are not publicly available because (Continued)

WHAT'S KNOWN ON THIS SUBJECT: Breathing difficulties at birth are a significant contributor to newborn mortality worldwide. Effective bag-mask ventilation can prevent a large majority of these deaths. However, significant challenges exist to provider-level acquisition and retention of this life-saving skill after training.

WHAT THIS STUDY ADDS: In a randomized control trial in Uganda and the United States, clinicians receiving real-time-digital feedback from the Augmented Infant Resuscitator achieved effective ventilation significantly faster, maintained effective ventilation longer, and determined airway condition more accurately than controls during simulations.

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Hypoxic events around the time of birth result in 2 million intrapartum stillbirths and neonatal deaths annually.[1] Effective bag-mask ventilation (BMV) is a life-saving newborn resuscitation skill and has the potential to significantly reduce intrapartum-related complications, previously known as perinatal asphyxia, which are responsible for nearly one-quarter of neonatal deaths and one-half of stillbirths each year.[2–9]

Effective ventilation, including achieving adequate tidal volume and functional residual capacity, is an essential step in newborn resuscitation that requires a sufficient seal at the face-mask interface, a patent airway, and gentle adequate chest rise at a correct rate.[10–14] Achieving and maintaining effective provider-level ventilation skills after training has been a documented challenge in both resource-limited and resource-rich settings.[15–19] For example, in a 3-year national study in Tanzania among >13 000 providers, newborn resuscitation skill scores decreased by nearly 10% within 4 to 6 weeks and by more than 30% by 4 to 6 months, in large part due to deterioration of BMV skills.[17] In the United States, 20% of pediatric resident trainees were found to have inadequate ventilation skills immediately after training, with rapid further attrition of skills thereafter.[19] Delayed BMV can have severely detrimental impact on perinatal outcomes; for every 30-second delay in ventilation, there has been an associated 16% increase in mortality.[20] To improve these perinatal outcomes, post-training ventilation skills maintenance has been an important focus of quality improvement initiatives and new approaches, including low-dose high-frequency practice, clinical mentorship, training videos, and medical simulation.[21–23]

Real-time digital feedback has been shown to demonstrate objective ventilation feedback in animals, as well as improve BMV, in simulated and real-world newborn resuscitations.[24–26] Understanding the effect of real-time feedback on the time to achieve and duration of effective ventilation, as well as the ability to quickly determine airway problems, could inform its practical utilization in the design and implementation of ventilation skills training and skills maintenance programs.

With this goal in mind, the authors developed the Augmented Infant Resuscitator (AIR) (Fig 1), an add-on device to existing bag-valve-mask devices to provide clinicians with real-time digital feedback on BMV that is portable, lower-cost, intuitive to understand, and not reliant on a continuous source of power.[27] Human-Centered-Design cycles and 3 sequential feasibility and acceptability evaluations conducted with a total of 153 multinational participants in 2014 and 2015 informed the final device design (unpublished). The device's feedback works on the basis of flow, pressure, and rate parameters produced by the birth attendant during BMV as measured in the inline flow path sensors. If successful, the AIR device could be a valuable quality improvement tool.

FIGURE 1
The AIR device.

To evaluate the potential effect of real-time, digital feedback from the AIR device on the quality of ventilation achieved in simulated resuscitations by trained birth attendants, we conducted a multinational randomized controlled study in Uganda and the United States.

METHODS

The AIR Device

The AIR device is attached between the ventilation bag and the mask. In addition to providing digital feedback to the birth attendant, the AIR device records and automatically stores timestamped quality-of-ventilation data on 4 key parameters: ventilation rate, airway integrity (patent or blocked), gentle or harsh breaths, and the presence or absence of significant air leaks. The accuracy of the AIR device was independently assessed and determined to have 100% accuracy in determining these parameters in a respiratory mechanics laboratory.[27]

Trial Design and Participants

We performed a multinational, block-randomized trial among health facility-based birth attendants in greater Kampala, Uganda, as well as in Mbarara Regional Referral Hospital (Mbarara, Uganda) and Massachusetts General Hospital (MGH; Boston, MA, United States), from July 2016 through January 2017. Eligible participants were birth attendants (eg, nurses, nurse-midwives, respiratory therapists, pediatricians, and neonatologists) >18 years of age who could be expected to ventilate newborns as part of their current professional position. At MGH, participants were recruited through e-mail solicitations to the Department of Pediatrics. Successful completion within the past 2 years of the Neonatal Resuscitation Program (NRP) was required for MGH study participation.[28] Participants in Uganda were selected as a convenience sample immediately after completing a 1-day Helping Babies Breathe (HBB) newborn resuscitation training or refresher training.[16]

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Intervention

A standard newborn bag-valve-mask device (Laerdal, Stavanger, Norway) and NeoNatalie newborn manikin (Laerdal, Stavanger, Norway) were used for all ventilation sessions. After informed consent, each participant was instructed on the use of the bag-valve-mask device and the NeoNatalie manikin and how to attach the AIR device. The device's display icons were hidden by an opaque black paper sleeve during this orientation. A skilled HBB-trained study administrator demonstrated what adequate chest rise on the NeoNatalie would look like without otherwise commenting on technique.

Participants then completed a "familiarization session" in which they ventilated a NeoNatalie manikin for a period of 2 minutes and 15 seconds without AIR device visual feedback. During this session, the AIR device was digitally recording ventilation quality parameters as listed above but its visual feedback screen remained hidden. The purpose of this session was for participants to familiarize themselves with ventilating the manikin with the AIR device attached to the bag-valve mask. During this period, verbal feedback from a study administrator was limited to whether the health care provider was achieving adequate chest rise. Statements like "that is good chest rise" or "inadequate chest rise, try and achieve good chest rise" were used. The other parameters of ventilation, such as rate, airway, or mask positioning, were not commented on.

Subsequently, each participant underwent computer randomization using a 1:1 computer randomization program to either receive AIR device visual feedback (intervention arm) or continue without visual feedback (control arm). If randomized to the intervention arm, the cover sleeve was removed from the AIR device. The study administrator then trained intervention participants to interpret the device icons using a single-page iconography chart in up to 2 minutes.

A solid green light on the face-mask-seal icon represented a good seal, whereas a blinking red light signified significant air leakage at the face-mask interface. A solid green light on the airway icon implied airway patency, whereas a blinking red light signified high airway resistance or blockage (compliance <0.10 mL/cm H_2O or resistance >90 cm H_2O/L/s).[27] A blinking yellow light on the airway icon signified a harsh breath. We defined a harsh breath as having a maximum inspiratory flow rate greater than 22.5 L/minute. For reference, a triangular flow waveform having a peak value of 22.5 L/minute would inspire 30 mL in <0.1s. A significant air leak was defined as compliance of >4.0 cm/H_2O, which would prevent sufficient chest rise. Adequacy of the ventilation rate was conveyed by using a speedometer-inspired radial gauge icon that showed red on the left at rates <30 breaths per minute, green at the center at rates between 30 and 60 breaths per minute, and red on the right at rates >60 breaths per minute.

Participants in both the intervention and control arms were further sequentially computer randomly assigned to 2-minute ventilations of 3 blinded ventilation scenarios on identical-appearing manikins. These manikins had adapted airways that were either normal (ie, patent) or had 3-dimensional printed inserts that were partially leaking or partially obstructed such that it was impossible to achieve adequate chest rise. All ventilation sessions of participants randomly assigned to ventilate normal manikins with or without feedback from the AIR device were used to derive the time to and duration of effective ventilation during the 2-minute ventilation sessions. All 3 manikin airway conditions were to determine provider speed and accuracy in the recognition of varying airway conditions. Ventilation sessions were timed from when birth attendants first positioned the ventilation mask on the manikin's face.

Outcome Measures

Our primary outcomes were quality of ventilation as measured by (1) time to attain effective ventilation and (2) duration of effective ventilation using recordings from the AIR device. Effective ventilation was defined as having all 3 of the following conditions simultaneously and is indicated by all 3 icons on the AIR device being green: (1) correct rate (30–60 breaths per minute), (2) the absence of a significant leak (compliance >4.0 mL/cm H_2O), and (3) the absence of a significant airway blockage (defined as compliance <0.10 mL/cm H_2O or resistance >90 cm H_2O/L/s). Secondary outcome measures were the duration of ventilation in the correct rate range, time without airway blockage, time without significant face-mask air leak, absence of harsh breaths, and proportion of participants who correctly identified airway condition at 45 seconds and at 2 minutes. Additionally, we compared ventilation quality between Ugandan and US providers, with and without real-time feedback from the AIR device.

Sample Size

We powered the study to detect a 20% higher frequency in intervention-arm participants correctly identifying manikin airway conditions in all 3 manikins at 45 seconds. Based on our previous work with training >1000 providers in newborn resuscitation, we predicted $\sim$40% to 60% of participants would correctly identify manikin airway conditions in all 3 scenarios in the control arm. Consequently, with a 2-sided α of 0.05%, we determined to enroll up to 140 participants in each study arm to have 90% power to detect a 20% improved rate of detection in the intervention arm.

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Statistical Methods

AIR device data files contained a time-stamped record of ventilation quality measurements in CSV format for every participant's ventilation session were aggregated with a Python (Wilmington, DE, United States) analysis script.[29] Data were sequentially downloaded to a secure laptop by using a USB to Micro-USB cable.

The primary outcomes of interest (time until effective ventilation and total duration of effective ventilation) were extracted from the subset of records in which the manikin being ventilated had a normal airway. As the distribution of outcome data could be skewed and invalidate assumptions required for Student's t tests, we used randomized permutation testing for hypothesis testing between the intervention and control arms. Using $n = 500\,000$ random permutations, the mean, median, and interquartile range were compared with a significance level of $P = .05/m$, where $m = 6$ is a Bonferroni correction for the 2 primary outcomes and 3 measures per outcome.

This study was approved by the Institutional Review Boards of Mbarara University of Science and Technology (Mbarara, Uganda) and Mass General Brigham (Massachusetts General Hospital, Boston, MA, United States) and is registered at ClinicalTrials.gov (NCT04820504; March 29, 2021).

RESULTS

We screened a total of 271 providers for enrollment in the study (Fig 2). One provider was not enrolled as a result of not having recently completed HBB or NRP. The remaining 270 providers (210 [77.8%] from Uganda and 60 [22.2%] from the United States) were randomly assigned. Of these, 204 were randomly assigned to ventilate at least 1 normal manikin, for a total of 293 normal manikin ventilation sessions because some randomly received >1 normal manikin session: 62.7% of participants ventilated 1, 30.9% ventilated 3, and 6.4% ventilated 3 normal manikins. All 293 normal manikin sessions were analyzed for the primary outcome measure. Our study participants included nurses and nurse-midwives (78.4%), physicians (18.6%), respiratory therapists (2.5%), and a clinical officer (0.5%; Table 1). A large majority of participants (81.4%) had received HBB or NRP training within the past 6 months.

Quality of Ventilation

Birth attendants who ventilated manikins with real-time feedback from the AIR device attained effective ventilation 2.0 times faster (mean 13.8s [95% confidence interval 10.6–17.1] versus 27.9s [21.6–34.3], $P < .001$) and sustained effective ventilation 1.5 times longer than the control arm (mean 72.1s [66.7–77.5] versus 47.9s [41.6–54.2], $P < .001$)

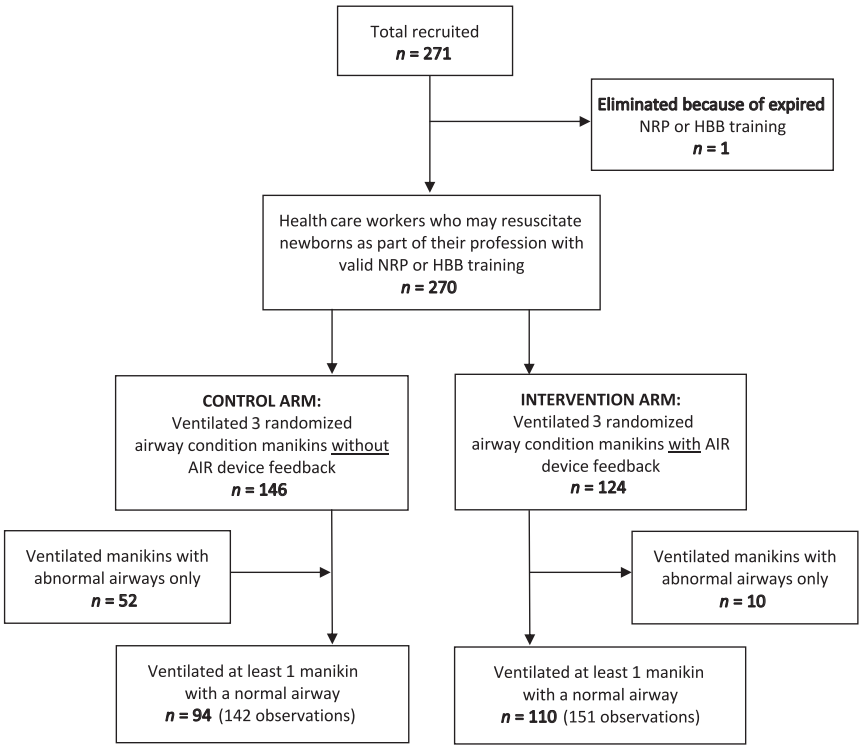

FIGURE 2
Study flow diagram.

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TABLE 1 Characteristics of Study Participants Who Were Randomly Assigned to Ventilate at Least 1 Manikin With Normal Airway Condition

Characteristic	Control (n = 110)	Intervention (n = 94)	Total (n = 204)
Sex, *n* (%)			
Female	102 (92.7)	78 (83.0)	180 (88.2)
Male	7 (6.4)	10 (10.6)	17 (8.3)
Not disclosed	1 (0.9)	6 (6.4)	7 (3.4)
Profession, *n* (%)			
Nurse/nurse-midwife	88 (80.0)	72 (76.6)	160 (78.4)
Physician	19 (17.3)	19 (20.2)	38 (18.6)
Respiratory therapist	2 (1.8)	3 (3.2)	5 (2.5)
Clinical officer	1 (0.9)	0 (0.0)	1 (0.5)
Facility ownership, *n* (%)			
Government	67 (60.9)	49 (52.1)	116 (56.9)
Private not for profit	43 (39.1)	42 (44.7)	85 (41.7)
Private for profit	0 (0.0)	3 (3.2)	3 (1.5)
Health facility level, *n* (%)			
Hospital	57 (51.8)	58 (61.7)	115 (56.4)
Health Centre III	37 (33.6)	19 (20.2)	56 (27.5)
Health Centre IV	16 (14.5)	17 (18.1)	33 (16.2)
Duration since previous resuscitation training, *n* (%)			
<6 mo	91 (82.7)	75 (79.8)	166 (81.4)
6–12 mo	7 (6.4)	5 (5.3)	12 (5.9)
>12 mo	12 (10.9)	14 (14.9)	26 (12.7)

(Table 2). Receiving feedback from the AIR device was also associated with significantly decreased variance (Fig 3). The factors preventing sustainment of effective resuscitation when real-time feedback was not provided during the 2-minute timed ventilation sessions were, in descending order of frequency, incorrect rate, significant face-mask air leak, harsh breaths, and airway blockage.

Ventilation Quality Between Ugandan and US Providers

Without real-time ventilation feedback, there were no significant differences in the time to attain effective ventilation between providers in Uganda (mean 27.4s [20.7–34.2]) and the United States (mean 30.5s [11.6–49.4]; $P = .76$) or in the duration of effective ventilation (mean 46.9s [40.2–53.6] and 52.5s [34.0–70.9]), respectively ($P = .57$).

However, with real-time feedback, providers in the United States achieved effective ventilation much sooner (mean 6.2s [3.3–9.1]) compared with providers in Uganda (mean 16.6s [12.4–20.8]; $P < .001$; Fig 4). The duration of effective ventilation was also longer among US providers (mean 88.5s [79.5–97.5]) compared with Ugandan providers (mean 66.1s [59.7–72.5]; $P < .001$).

Determination of Airway Integrity

Real-time feedback from the AIR device was also associated with significantly faster (Fig 5) and more accurate determination of airway integrity (Table 2). With feedback, participants correctly assessed the airway condition in a mean time of 43.7s (40.5–47.0), compared with 55.6s (51.6–59.6) among controls ($P < .001$). Among those with feedback, 25.0% (17.3–32.7) and 61.3% (52.7–69.8) correctly assessed all 3 airway conditions by 45 seconds and by the 2-minute ventilation simulation, respectively. This contrasts with only 5.5% (1.8–9.2) and 24.7% (17.7–31.6) among participants not receiving real-time feedback from the AIR device ($P < .001$).

DISCUSSION

Studies have indicated that trainees are frequently unable to achieve effective ventilation immediately after training and that there is a significant decline in these skills soon thereafter.[17–19] Effective ventilation in this study was defined by parameters critical to both NRP and HBB training.[16,30,31] These parameters included gentle chest rise at the correct rate without significant airway leakage or blockage of a degree that would impede air entry into the lungs. This study indicates that, with the display of objective feedback, the quality of ventilation that previously trained providers administered on manikins was significantly improved.

Specifically, compared with controls, providers receiving real-time AIR-device feedback achieved effective ventilation in less than half the time and sustained it >50% longer during a 2-minute ventilation assessment with newborn manikins. Providers receiving AIR-device feedback also significantly outperformed controls by identifying manikin airway conditions faster and with greater accuracy, with 25.0% correctly assessing all 3 airways by 45 seconds and 61.3% by 2 minutes versus only 5.5% and 24.7%, respectively, of participants not receiving AIR feedback.

TABLE 2 Ability and Time to Correct Assessment of Airway Conditions Among All 270 Study Participants Who Ventilated 3 Randomly Assigned Manikins With or Without Visual Feedback From the AIR Device

	Control (n = 146)	Intervention (n = 124)	P
Mean time to correct airway assessment(s), mean [95% CI]	55.6 [51.6–59.6]	43.7 [40.5–47.0]	<.001[a]
Percentage of participants correctly assessing all 3 airways within 45s, % [95% CI]	5.5 [1.8–9.2]	25.0 [17.3–32.7]	<.001[b]
Percentage of participants correctly assessing all 3 airways within 2-minute ventilation session, % [95% CI]	24.7 [17.7–31.6]	61.3 [52.7–69.8]	<.001[b]

CI, confidence interval
[a] Student's t test
[b] Pearson (chi2) test with Yates Correction

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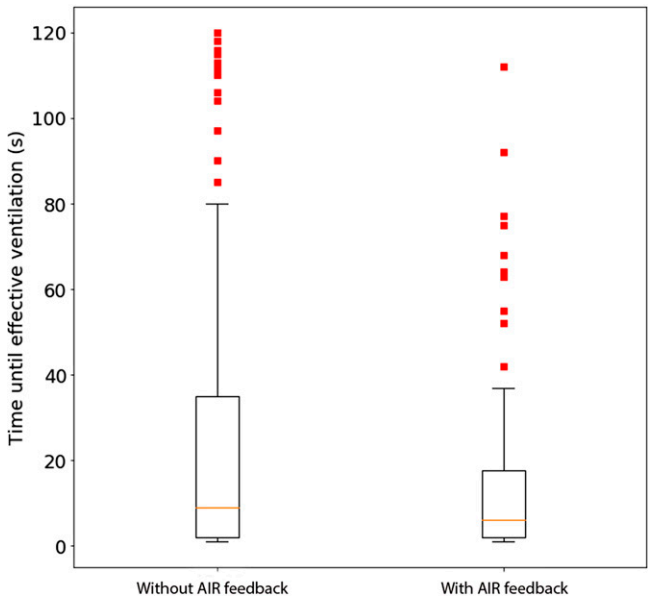

FIGURE 3
Time until effective ventilation, without and with feedback from the AIR device. Outcomes are presented as a box-and-whisker plot with a median red line, box representing the interquartile range (25th to 75th percentile), whiskers representing 150% of the interquartile range, and red dots representing outliers beyond the whiskers.

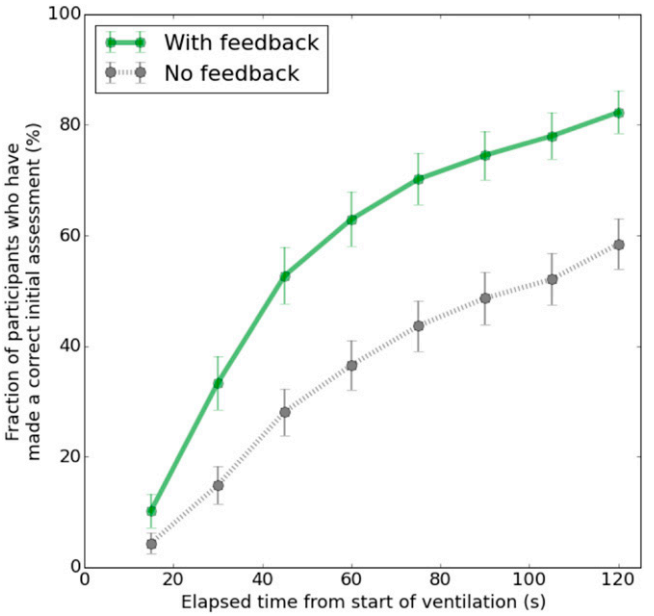

FIGURE 5
Time to correct assessment of airway integrity among 270 birth attendants ventilating externally identical manikins with altered airway integrity, with or without visual feedback from the AIR device.

These benefits were obtained with <2 minutes of instruction on the AIR device and were apparent among both Ugandan and US providers, revealing benefit-generalizability across geographies. However, with real-time feedback from the AIR device, providers in the United States achieved effective ventilation sooner and sustained it for longer compared with Ugandan providers, although the effect of real-time feedback was significant in both Uganda and the United States. These differences between the 2 locations may be a result of inequity in previous training opportunities or in technological trust.

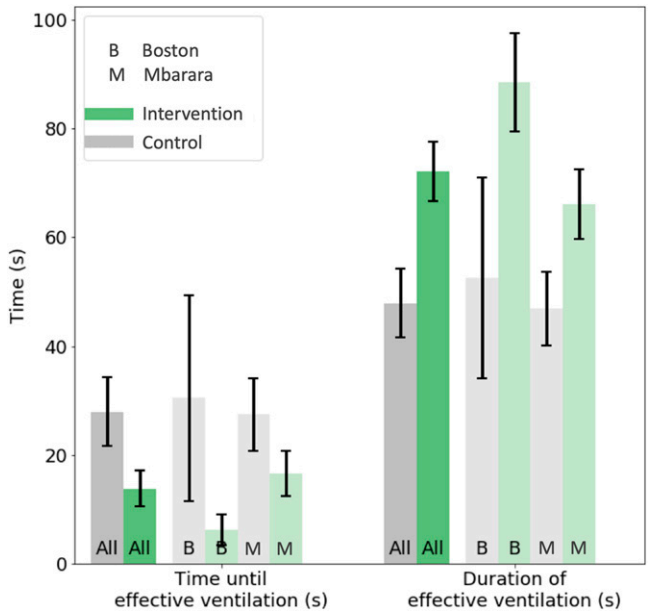

FIGURE 4
Comparisons for time until effective ventilation and duration of effective ventilation, by intervention arm and site.

To date, there has not been a portable add-on device for objectively determining the primary skill parameters of effective ventilation during training. Gurung et al used an external monitor to provide clinicians in Nepal with real-time ventilation data during simulated newborn resuscitations and found that ventilation quality and provider confidence improved with the use of the external monitor.[25,32] However, most evaluations of ventilation skills have been relatively subjective and based on either objective structured clinical examinations (OSCEs) with newborn manikins before or after training or observation of BMV in delivery rooms.[16,33] As a result of the AIR device used in this study, the type and frequency of provider-level ventilation errors were precisely measurable and included, from most frequent to least frequent, incorrect ventilation rates, air leakages, harsh breaths, and airway blockages. Although there was marked individual variability between providers, variability was significantly lower among participants who received real-time feedback compared with participants who did not. In comparison, in their 2010 study using a tablet-based, nonintegrated, respiratory function monitor to assess BMV quality during live newborn resuscitations, Schmölzer et al found that face-mask

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leaks were the most common challenge and occurred in 51% of clinical resuscitations.[12]

This study has several limitations. First, the convenience sampling may have contributed to bias in the attributes of participants as perhaps not representative of participants at other sites in each country. However, block randomization of birth attendants in both a low- and high-income country setting across a range of specialties is expected to minimize the likelihood of participants being nonrepresentative. As per Table 1, each site's participants represented the range of birth attendants present at each site. In addition, after consent, randomization is expected to have bolstered the internal validity of our findings. Another limitation is that this was a single-day intervention study using a simulation manikin and, as such, does not demonstrate the ability of real-time feedback to contribute to the retention of these skills and, ultimately, translation into clinical practice. Subsequent studies are underway to reveal the effect of such feedback longitudinally. In addition, few episodes of provider-caused blockage were apparent in either study arm, which is likely an attribute of the manikin used. Finally, this is one of the first studies to assess these combined ventilation technical skills in real-time, and as such, there is no standard with which to compare. Standardized resuscitation simulation evaluations such as HBB's OSCE B are able to only subjectively assess "looks for chest movement," "ventilates at 40 breaths/minute (30–50 acceptable)," and "improves ventilation," as 3 of the OSCE's 18 total evaluation points focus specifically on mechanical ventilation. Alignment of the quality parameters measured by the AIR device with NRP and HBB, as well as a previous study of the accuracy of the AIR device buttress confidence in this study's findings.[27] Additional research is underway to evaluate the device's potential impact on skills retention over time.

We are optimistic that the real-time feedback and objective data on ventilation quality from the AIR device and platform will (1) drive self-skills improvement and maintenance, (2) better prepare health care providers to resuscitate newborns, a task that is performed infrequently yet, if not performed within minutes, has tremendous implications, and (3) enable collaborative learning and quality improvement across geographies.[34]

CONCLUSIONS

We have demonstrated that providers in Uganda and the United States who received real-time quality-of-ventilation feedback from the portable AIR device achieved effective ventilation of a newborn manikin significantly sooner, sustained effective ventilation significantly longer, and determined abnormal airway conditions significantly more quickly and correctly compared with providers ventilating without feedback. We believe the AIR device could be a valuable tool for improving the acquisition and retention of effective newborn resuscitation skills, facilitating quality improvement initiatives, as well as, possibly one day, improving direct patient care.

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ABBREVIATIONS

AIR: Augmented Infant Resuscitator
BMV: bag-mask ventilation
HBB: Helping Babies Breathe
MGH: Massachusetts General Hospital
NRP: Neonatal Resuscitation Program
OSCE: objective structured clinical examination

of ongoing processes to complete securing intellectual property for the Augmented Infant Resuscitator technology, but data are available from the corresponding author on reasonable request.

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