Flawed Data Render Findings Meaningless

"A Pacifier-Activated Music Player . . ." has 2 fatal errors in methodology, rendering the findings meaningless, and is based on the questionable assumption that the quantity ingested reflects an infant's feeding maturity.

First, the concealment (masking) of group assignment is badly flawed; unmasked nurses and parents could have influenced study outcomes of feeding intake and advancement. Infants receiving the plainly visible and audible bedside intervention (ie, multiple, pacifier-controlled exposures to recordings of mother's voice) and control infants (ie, ad libitum use of a typical pacifier) were enrolled simultaneously. All nurses and parents had unlimited mutual contact and fed study infants. They were unmasked by free access to the intervention in progress. Additionally, intervention parents had full training and voice recording but control parents had only partial training. Obvious safeguards (eg, a sham control intervention and sham control parent training and pacifier-voice recording) were not used. The investigators themselves admit that an unknown number of nurses saw infants receiving the intervention. Yet there are no data about infant feeding by unmasked nurses and parents. Any NICU nurse can attest to the ease of "making" a preterm infant suck and ingest formula. An unmasked nurse could "push" an intervention infant toward the hoped-for study results (the ethics and quality of care of this practice, aside).

Second, signal (mother's voice recording) and ambient (ongoing NICU sound/noise) sound levels were neither measured nor reported.[1] The levels of pacifier-voice recordings during training may have been undetectably low or exceeded the infant's threshold of physiologic or behavioral self-regulation. Either condition would eliminate training effects.

An infant's ability to detect a signal in noise changes inversely with age: the younger the infant, the higher the signal level necessary for reliable detection against ambient background.

> 6-month-olds do not detect a signal in noise until it [the signal] is about 15 dB more intense than that needed by adults to make the same discrimination. . . . Children do not reach adult thresholds for detecting a signal in noise until age 10. . . Noisy environments may interfere with newborns' and infants' abilities to discriminate important signals such as mother's voice and music. . . . In hospitals . . . the singular example of the mother's voice, although intelligible to adults, may be indistinct or lost to her infant.[2] (p. S70)

The AAP Recommended Standards for NICU include sound-level limits.[3] Without sound-level data, conformity with AAP Standards and effective signal-to-noise ratios during pacifier-voice training are unknown. An unplanned effect of high pacifier-voice levels could be infants perceiving their mothers' voice as aversive.[4]

Lastly, the study is based on the unexamined premise that the quantity ingested and not the quality of feeding behavior is the valid measure of feeding maturity. Are fast advancement goals as beneficial for infants as for third-party payers? Evidence suggests that feeding for quantity produces atypical neurobehavioral feeding development and the perception of feeding as aversive, both of which contribute to the large percentage of preterm infants with feeding problems.[5]

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In Reply

We write to address the concerns raised by Dr Philbin regarding the masking, measurement, and outcomes used in our randomized controlled trial in preterm infants of a pacifier-activated music player using mother's voice.

Her first concern was inadequate masking. In our study, our NICU nurses, although not part of the research team, were masked to their patient's group assignment.[1] The music therapist visited all enrolled infants with the pacifier-activated lullaby (PAL) device, regardless of study assignment. Infants are cared for in single-patient rooms (or semiprivate if multiples), and the study visits, conducted behind closed doors in these rooms, were neither visible nor audible. Nursing staff rarely entered the patient room during the study visit, although they were obviously not excluded; entry was only for necessary patient care. Thus, masking of nurses to study group assignment was within the limits of standard of care. Parents in both groups received identical books, were exposed to similar sound environment recommendations, and were not aware of the treatment other infants received, a process facilitated by the yearlong recruitment process and the mostly single-patient rooms.

Concern was raised regarding potential attempts by unmasked nurses to skew the results toward the desired outcome. We consider this highly unlikely for many reasons. As stated previously, we attempted to mask the nurses to their patient's study group to the extent possible. Multiple nurses typically gave the 8 feedings during a 24-hour period, and the music therapist never fed the infant. We recorded feeding volume for 24 hours before the first and after the last intervention or visit, making it unlikely for an individual nurse to influence the outcome, especially given that the specific outcome variables were not known to the nursing staff during the study, only that we were measuring effect on feeding. We are surprised and disappointed at the writer's implication that highly trained NICU nurses would change their feeding practices because their patient was enrolled in a study.

We incorporated the American Academy of Pediatrics recommendations for appropriate NICU decibel level into the design and implementation of our study because these are routine in our NICU. Before the interventions, the music therapist equalized each recording to a constant gain level. In addition, the settings of the device used in this study conformed to sound-level guidelines appropriate for preterm infants at 34 to 36 weeks' postmenstrual age. Behavioral cues and monitors were closely watched for desaturations, bradycardic or tachycardic events, and state instability because these signs of overstimulation are the primary response to sound or noise levels that are noxious to preterm infants.

We agree that feeding quality is also important, although adequate assessment would require continued observation by study personnel, which was not feasible. However, conduct of our randomized controlled trial required assessment of quantitative measures,[2] even though these measures may not represent the full complex spectrum of oral feeding characteristics. As a result, we recorded measurable and objective data including volume, duration, and frequency of feeds as well as suck strength. Feeding tube removal is based on achieving full feeds orally, a quantitative and functional although indirect measure of newborn feeding ability used in many NICUs. The achievement of full oral feedings more rapidly in our intervention group makes it highly unlikely that the PAL promotes oral aversion.

Finally, a growing body of literature supports the use of rigorous study design to evaluate pediatric rehabilitation therapies in infants to provide evidence for their role.[3] Our trial of PAL adds to this evidence base.

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