

not the effect of community health workers on neonatal mortality. We accept the error that the abstract has it wrong (vide the full text of the manuscript for the correct objective).

2. While it is true that overall effect size combining different community level neonatal interventions could have difficulties in interpretation, it may be pointed out that the systematic review also provides a sub group analysis by type of interventions (Fig.3) [1]. It may also be pointed out that health interventions are never “pure” interventions and there are bound to have overlaps with multitude of other interventions in varying proportions. Realizing this complexity, the review used the best possible categorization of the

interventions with least possible of overlaps (Table 1 and Figure 2 of the manuscript).

3. We accept that the abstract does not do justice to all the community based neonatal interventions, but the full text does.

We do not believe that the review would confuse policy makers. The review clearly underscores the complexity of neonatal care interventions especially at the community level and provides (as summarized by the authors of this correspondence) the possible strategies, likely impact and the conditions that are required to make these interventions work.

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## Whole Body Cooling in Newborn Infants with Perinatal Asphyxial Encephalopathy

It is encouraging to see trials in progress addressing hypothermia in resource poor settings. I compliment the team at Vellore for this study [1]. There are some points in the study which the authors might want to clarify for their readers.

The rectal temperatures in this study are mean temperatures over time. What is difficult to infer from the paper is the duration that their subjects were outside the target temperature range, and further what extremes of temperature were encountered below the target temperature of 33 degree C. This is very important for understanding the safety of this method. A study published by Hoque, *et al* comparing different methods of cooling shows that the target rectal temperature of between 33.5 +/- 0.5 was within target temperature( +/-0.5 degree C), for 81% in infants cooled using a mattress for cooling manually, and 74% in infants who were cooled with gloves. Mean overshoot was 0.3 degree C for servo controlled whole body cooling, 1.3 degrees C for whole body cooling using a manually controlled mattress [2]. The variation in the mean rectal temperature from target temperature during the period of cooling was 0.08 ± 0.04°C in this study, which betters the servo controlled device used in Hoque’s study. Considering this was possible with 1:3 nursing support using a passive cooling method is exceptional.

A further point to emphasize is that Western trials for therapeutic hypothermia have kept very strict criteria for

recruitment. 11 of the 20 neonates were outborn who were recruited on criteria which don’t meet definite criteria for perinatal asphyxia such as in the TOBY trial [3]. It is mentioned there was significant acidosis among inborn babies at admission, not the outborn. This raises a slight question of the representativeness of the sample in this trial. Why were outborn neonates recruited at all? If these neonates had neonatal encephalopathy due to other causes they might not have shown the complications that moderately to severely asphyxiated neonates display when cooled?

The surface temperatures correlated with the rectal temperatures very well in this study, probably a reflection of the narrow range of environmental temperatures. A recent study using passive cooling as part of a strict protocol showed there is poor correlation between the two. Continuous rectal temperature monitoring remains the standard for monitoring during therapeutic hypothermia and should be the standard whether using active or passive cooling methods [4].

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## REPLY

We appreciate the interest shown in our study [1] and the opportunity to clarify the important points raised by the author of this letter.

We had a total of 1514 rectal temperature recordings in the 20 babies during the 72 hours maintenance phase of hypothermia. During this time, 90.4% of the temperature recordings were within the target temperature range. Five percent of the temperatures were below and 4.6% above the target range. Of the lower temperature readings, only 1% was below 32°C. The lowest recorded temperature was 30.8°C. In addition to this, we have temperature data on the babies we have cooled since the study. Of 1200 temperature recordings in a further 18 babies, 92% of the temperature recordings were in the target range. We agree that this degree of temperature maintenance is exceptionally good compared to other studies including the ICE trial which used a similar cooling method [2]. We believe that good nursing and careful monitoring can achieve these results even with low technology methods. It is our experience that with adequate training and careful monitoring, the desired temperature range can be easily maintained.

The study design did not have blood gas criteria as inclusion criteria for outborn babies. This being so, we had mentioned that “there was significant acidosis among inborn babies at admission”. This was not supposed to preclude the presence of acidosis in outborn babies. All the outborn babies recruited had a blood gas at admission (mean time, 3.7 hours of life). All but one of the outborn babies were acidotic at admission (mean base excess -11; mean bicarbonate 14.8).

Further, if we look at the western trials, the criteria for recruitment were neonatal encephalopathy with the presence of 1 of 4 criteria (low pH or elevated base excess on cord gas, low APGAR score or need for ventilation at 10 minutes) and not the presence of all 4 [2-5]. We fail to see why the criteria for a trial cannot be designed to suit a local population but must always follow a Western precedent! We had strict criteria for study entry which was followed to the letter. The ground reality in India is that most of the asphyxiated babies admitted into a neonatal unit are outborn where a cord pH or early blood gas will

not be available. For example, during the 6 months of our trial, there were 53 outborn babies as compared to only 15 inborn babies with HIE. We recruited outborn babies with encephalopathy who had needed prolonged resuscitation at birth and this is representative of babies who would benefit from cooling as per the Western data. It is worth noting that out of the 53 outborn babies with HIE, only 8 reached before 6 hours and could be cooled. This is a major issue that needs to be addressed if cooling is to reach those babies who need it most.

We would like to point out to the authors that Kendall, *et al* looked at correlation of rectal and skin temperature among transported babies who were passively cooled [6]. They also had only 152 paired rectal and skin temperature readings. This is unlike our cohort, who were actively cooled in a neonatal unit and about 1745 paired temperature readings were analysed. Similar to our findings, good correlation between rectal and skin temperature was seen in the study published by Horn, *et al.* [7]. However, at this point of time, the standard of care is to monitor rectal temperature continuously and we do not advocate or follow only skin temperature when we cool babies.

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