

subgroup with reasonable confidence. Only 3 of the survivors in this cohort had BPD and one developed NEC. Differential analysis of growth pattern in these infants could not have been inferential due to very small number. We observed a lag in head growth despite management based on current nutrition guidelines and aggressive PN. Similar lag in head growth in VLBW infants during hospital stay has been reported in other studies [1,2]. This fact emphasizes the need for finding predictors of poor head growth and optimizing postnatal care of VLBW infants.

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Sildenafil, Neonates and Regulation

I read with interest the perspective on the emerging role of Sildenafil in neonatology [1]. I was disappointed with the authors' statement, "We could not find any Indian data or case report on use of sildenafil in PPHN". I have published my use of sildenafil in two term neonates with PPHN which was missed by authors [2]. I also feel disappointed by the lack of studies emerging from Indian subcontinent on use of sildenafil in neonates (especially with PPHN) as my belief is that developing countries are in a unique situation to conduct such research [3]. In developed countries, ethical dilemmas will arise as inhaled nitric oxide has become standard treatment for PPHN in term neonates.

I completely agree with Malik and Nagpal that all experiences with sildenafil in neonates must continue to be monitored and reported. However, it reads like a wishful superficial statement with no suggestions of who is going to monitor and report and how. In India, almost three-quarters of pediatricians are in private practice and it is very likely that this cohort is more likely to use this drug as an off label use. Doctors using it will be highly uncomfortable reporting it if they meet out with adverse events or mortality. This would be because of lack of access to Institutional ethics committees or ethicists for consultations, reliance on their conscience and potential for causing controversy. The journals will be critical and hesitant to publish due to lack of evidence and ethical concerns.

Sildenafil is a Schedule 4 drug in Australia meaning it is a prescription only drug. However, for indications other than where it is approved, hospitals seek approval of drug committees comprising experts in field and consultation with ethicists if such dilemmas arise. For medications not available in Australia, provisions exist using Special

Access Scheme of Therapeutic Good Administration, for procuring and using off-label drugs [4]. This results in monitoring of the drug and outcomes.

Off label use of drugs including sildenafil is an unfortunate reality in neonatology [5]. Mechanisms and regulatory bodies on regional basis for monitoring this needs to be developed to ensure safe neonates in myriad neonatal units mushrooming in India, especially in the private sector.

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REPLY

We would like to thank the author for the interest shown in our article. We were able to access the article mentioned but as no abstract was available, neither was there a link to the full text of the article; hence, the inadvertent error.

The aim of writing this article was to acknowledge the emerging role of sildenafil in neonatology and to