

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

encourage colleagues to report use of the drug for all to benefit. We share the authors concern on the lack of an effective system of drug regulation and monitoring. The burden of regulation and off label use of drugs rests with the state and the laws of the land, as much as with the conscience of the practising physician. However we agree

that there should be some regulation to check and ensure safety of newborn care, our article clearly discourages the use of sildenafil by the individual practitioner other than in a research setting.

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Infant and Young Child Feeding Guidelines: 2010

We have following comments to submit in respect of the Infant and Young Child Feeding Guidelines: 2010 published in *Indian Pediatrics* [1].

1. While discussing HIV and infant feeding, the guidelines mention use of expressed, heat-treated breast milk as one of the alternatives to breastfeeding in infants less than six months of age. Guidelines need to mention a standardized method of heat-treatment of breast milk which should be fulfilling AFASS criteria. It should be borne in mind that it may not be possible to use a thermometer in a domestic setting to decide about the temperature to which the expressed breast milk should be heated.
2. While discussing HIV and infant feeding, the guidelines also mention introducing appropriate complementary foods after 6 months of life and continuing breast feeding for the first 12 months of life. This amounts to mixed feeding for second six months of life. In the same section, towards the end, the guidelines mention that mixed feeding should be avoided (except the short transition period of around a month when breast-feeding is being gradually stopped) as it causes a two fold increase in the risk of postnatal HIV transmission. This contradiction needs to be resolved.

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REPLY

1. Methods such as Pretoria Pasteurization or Flash Heat Treatment can effectively inactivate the virus in breastmilk from HIV-infected mothers [1,2]. These methods can also eliminate potential contaminants and adequately inhibit bacterial growth while retaining nutrients contained in breastmilk [3]. In a developing country set up where thermometer may not be available everywhere, it may be difficult to mention a standardized method, but breastmilk treated in this way is nutritionally adequate to support normal growth and development. However, it is difficult to sustain adhering to this method over a prolonged duration. The role of heat treatment as a truly feasible HIV prevention and child survival strategy is yet not clear [4]. However, this approach (heating to the boiling point) is useful as an 'interim' strategy to assist mothers over specific periods of time.
2. The term "Mixed feeding" is generally referred to feeding of breastmilk and other liquid/solids food prior to 6 months of age. It is hypothesized that when these infants are mix fed, the immature gastrointestinal tract is exposed to antigens and pathogens which may cause inflammation and facilitate acquisition of HIV infection [5] Exclusive breastfeeding may be healthier because it protects the integrity of the intestinal mucosa, a barrier to HIV. Another possible mechanism is that mixed feeding results in suboptimal breastfeeding practices which predisposes to mastitis and cracked nipples, consequently increasing the risk of transmission.

After six months the gut is more mature and better able to handle complex proteins and antigens significantly decreasing the risk of transmission. Thus after six months of age, the nutritional benefits of complementary feeding (which may or may not be milk based) and extended breastfeeding till 12 months outweigh the risk of transmission and is probably the best possible strategy for HIV-free survival. This is all the more true if the mother and baby are on antiretroviral prophylaxis or therapy as the