

However, most of the recent studies have reported the incidence of MAS as 5-8% [3,4]. Moreover, in the present study itself, the incidence of MAS is quite less (1.4% in intervention arm and 2.2% in control arm). The authors should have used information from these studies to calculate the sample size for adequate power of their study.

2. We clearly miss the definition of 'vigorous infant' in the entire manuscript. Also, whether the authors also included babies with respiratory distress soon after birth is not clear.
3. One of the exclusion criteria mentioned in the methodology is; mothers receiving methyl dopa. It is not clear why these babies were specifically excluded.
4. In this study, chest X-ray was done in all participants within 4 hours of birth, irrespective of symptoms. We feel that doing X-ray in an asymptomatic baby is not ethically justified. Also, MAS is defined based on presence of clinical symptoms and abnormal chest X-ray. Chest X-ray could have been done only in babies with respiratory distress.
5. For lavage, normal saline (10mL/kg) was used. As lavage was done before the baby was weighed, the clinician must have used approximations to estimate birth weight. It would have been better if volume used for lavage was weight independent.
6. Apart from the adverse effects studied, another potential harm of this intervention is being an hindrance to routine care. If, not for this intervention, a vigorous baby born through MSAF would have received immediate skin to skin contact and early initiation of breastfeeding. However, the need to perform gastric lavage before feeding hinders this practice. This adverse effect of performing this procedure should appear in the manuscript.

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#### AUTHORS' REPLY

We appreciate the interest of the readers in our research article. We have the following clarifications:

1. A very wide range in the incidence of meconium aspiration syndrome (MAS) from 1.62% to 34.4% has been reported in the literature [1-3]. We could not find the incidence of MAS in the vigorous infants only, and thus, we decided to go by the incidence (15%) observed in our institution. Another reason of considering our own institutional incidence of MAS was similar demographic profile of the mothers and infants.
2. A vigorous infant was defined at birth as: spontaneous breathing/crying; HR >10 in 6 seconds; and good muscle tone. All infants were monitored by Downe's scoring for the development of respiratory distress after birth until 72 hrs of age; the first assessment was done at 30-45 min of age. Infants who developed dyspnea during this period and had radiological evidence of meconium aspiration were diagnosed as MAS.
3. Intestinal peristalsis might be affected in the infants born to mothers receiving methyl dopa as anti-hypertensive medication. Therefore, these infants were excluded from this study where feed intolerance was being studied.
4. Meconium-stained amniotic fluid (MSAF) may be aspirated *in utero* in the majority of cases. However, it can also be aspirated after birth when an infant vomits out meconium stained liquor causing secondary MAS. The definition of MAS includes respiratory distress, radiological evidence of meconium aspiration and birth through MSAF. All infants who aspirate meconium do not develop MAS and we agree that in an asymptomatic infant there is no need to do X-ray chest. But our premise is that gastric lavage will prevent development of secondary MAS where meconium is aspirated after birth. The X-ray chest was, therefore, done in this study within 4 hrs in all infants to document any radiological evidence of the intrauterine aspiration of MSAF.

We agree with readers' suggestions regarding point 5 and 6.

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## Drug 'Control' or Drug 'Fixing'

National Pharmaceuticals Pricing Authority (NPPA) is an organization of the Government of India authorized to fix/revise the prices of controlled bulk drugs and formulations, and to enforce prices and availability of the medicines in the country, under the Drugs (Prices Control) Order, 1995 [1]. It is commendable that so far a total of 650-odd formulations have price caps. Of the total healthcare spending, 70% is on medicines. In India this cost is mostly borne by the patients. Controlling drug prices by administrative fiat may appear to be a correct initiative, but in reality it may not be so. We share our concern regarding impact of drug control on pediatric formulations.

Paracetamol oral formulation (125 mg/5 mL) is under price control. Several of the leading manufacturers have changed formulation to 120 mg, 150 mg, 500 mg per 5 mL or to 250 mg per 7.5 mL to overcome the price control without any drop in prices. Amoxicillin-clavulanic acid combination (Syrup 200+28.5 mg, Tablet 500+125 mg) is under price control. Several manufacturers have increased cost of other formulations (tablet 250+125 mg, drops 80+11 mg) as a compensatory process. Chlorpheniramine maleate (2 mg/5 mL), an anti-histaminic preparation, in isolation is difficult to procure in the market. Majority of manufacturers have clubbed it with a decongestant, mucolytic, antitussive or antipyretic agent to avoid price control. Cetirizine (5 mg/5 mL) is readily available as 2.5 mg/5 mL or in combination with a mucolytic agent, thus avoiding price control. Salbutamol

(2 mg/5 mL) has almost disappeared from the market once it came under price control. Majority of the manufacturers withdrew the molecule and changed the formulation to levo-salbutamol and modified the brand name. This led to a doubling of the cost. This is also true for respiratory solution for use in nebulizer. Several antibiotics (*e.g.* cefixime, azithyomycin) are also being marketed in strengths that are different from those under price control.

It is clear that the companies are modifying the strength, composition or format of the drug to avoid price control. This defeats the purpose as the drug either is difficult to procure or prescribe as laid down in the drug control list. There is no regulation on manufacturing a drug in various strengths or in combinations, which allows the companies to come with newer formulation overcoming the drug control. It is also a tragedy that majority of doctors are ignorant about this process, and there is a need to bring about awareness amongst the doctors and patients to prefer medicines in the drug control format. There is an urgent need for professional medical bodies to pressurize the Government to ensure strict implementation of the drug control; otherwise the entire purpose of making the medicines available, accessible, and affordable would be defeated.

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