Letters

Nitric oxide is not licensed for preterm neonates

BMJ 2002; 325 doi: http://dx.doi.org/10.1136/bmj.325.7374.1244/a (Published 23 November 2002) Cite this as: BMJ 2002;325:1244

Charles E M Normand, head (charles.normand@lshtm.ac.uk), David Field, professor, Diana Elbourne, professor of healthcare evaluation, Ann Truesdale, INNOVO trial coordinator

Department of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, London WC1E 7HT
Neonatal Unit, Leicester Royal Infirmary, Leicester LE1 5WW
London School of Hygiene and Tropical Medicine

EDITOR—We agree with Pierce et al that attention should be drawn to the potential high cost of nitric oxide after the granting of its licence. The use of nitric oxide is not licensed for treating preterm neonates. The currently published evidence does not support the use of inhaled nitric oxide in preterm infants with hypoxic respiratory failure, and further randomised trials should be performed.

The increase in the cost of nitric oxide will be an important component in cost effectiveness studies as part of clinical trials of inhaled nitric oxide. Studies must be based on effectiveness data from long term follow up and the economic evaluation must take a broader account of costs, such as those to parents. It is also important to look at the cost (and not just the price from one supplier) of inhaled nitric oxide. Such a study is already at an advanced stage.

INNOVO (neonatal ventilation with inhaled nitric oxide versus ventilatory support without inhaled nitric oxide for severe respiratory failure) is an international randomised controlled trial funded by the Medical Research Council to investigate the clinical effectiveness and cost effectiveness of inhaled nitric oxide compared with conventional ventilatory care for preterm and for “mature” neonates with severe respiratory failure. The primary clinical outcome at 1 year of age (corrected for prematurity) is death or severe disability. The economic evaluation includes consideration of costs not only to the health services but also to parents. Recruitment is now closed, and follow up to age 4 is in progress. The results at 1 year of age should be available in 2003.

References
