UNLICENSED AND OFF-LABEL MEDICATION USE IN THE NEONATAL INTENSIVE CARE UNIT: A PROSPECTIVE COHORT STUDY

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E Kieran, N O Callaghan, CP O Donnell. 'Neonatology, The National Maternity Hospital; 2The National Children’s Research Centre, Crumlin; 3School of Medicine and Medical Sciences, University College Dublin; 4Pharmacy, The National Maternity Hospital, Dublin, Ireland

Background Many medications have not been extensively studied in children. Medications may be prescribed for indications for which their use has not been approved (unlicensed use); or may be given for an approved indication, but to an age group or at a dose or frequency by a route that has not been approved (off-label use). We wished to determine the extent of unlicensed and off-label prescription in our NICU.

Methods We prospectively studied infants admitted to our tertiary level NICU over 2 months. We recorded demographic data and all medications prescribed for all infants. We compared the use of each medication to their licensed indications as contained in the Summary of Product Characteristics.

Results 110 infants were admitted. All infants received a prescribed medication. 79 different medications were prescribed to these 110 infants, a median (IQR) of 4 (3, 12) each. 41% of prescribed medications were given in an unlicensed manner and 15% in an off-label manner. 12 (11%) infants received an unlicensed medication, 5 (4%) infants received an off-label medication and 38 (35%) infants received both an unlicensed and off-label medication. Of infants <32 weeks, 91% received unlicensed and 85% off-label medications. 100% of infants <28 weeks received an unlicensed and an off-label medication. Adverse events appear uncommon.

Conclusions Our study suggests that clonidine may be a useful adjunctive treatment of NAS in infants who respond incompletely to PB. Cardiovascular side effects were not common in our study.