ESDPPP abstract submission

ADRIN 1 Methodology study: Adverse Drug Reactions in Neonates: What are the best ways to evaluate suspected adverse drug reactions in neonates?

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**Introduction:** There are 90,000 babies admitted to neonatal care units in the UK annually, and many of these require medications(1). Use of unlicensed and off-label medications is common in neonatal units, with accounting for up to 90% medicines (2). The incidence of adverse drug reactions (ADRs) in children is estimated to range between 0.6% and 16.8%, but the data specifically for neonates is limited(3). A number of tools exist to help clinicians to assess the causality of ADRs, but few have been validated in neonatal settings.

**Aims:** To compare three existing methods for assessing causality of ADRs in a neonatal setting and to compare the outcomes between tests and raters.

**Methods:** Following ethical approval, data were collected prospectively on suspected ADRs occurring in a tertiary neonatal care unit in the north of England over a five week period. Summaries of these cases were presented to two investigators who undertook three separate causality assessments of each case using the Karch and Lasagna algorithm(KL), the Liverpool ADR Causality Assessment Tool (LCAT), and the New Adverse Drug Reactions Algorithm for Infants in Neonatal Intensive Care Units(NAINICU) (4)(5)(6). Inter-rater and inter-test statistical analyses were performed.

**Results:** Causality assessments have been undertaken on 21 ADR cases reported from the unit to date. The KL algorithm rated 14.3% of cases as definite/likely, NAINICU 42.9% definite and LCAT 0% definite. Inter-rater reliability Kappa scores were 0.13, 0.136 and 0.294 for the 3 tools respectively. Inter-test reliability was greatest between the KL algorithm and the LCAT (Kappa 0.211) and least between NAINICU and LCAT (Kappa -0.149).

**Conclusion:** These three tools produced varied causality assessment outcomes when used on neonatal ADRs. Marked inter-test and inter-rater variability was noted. The study is continuing to collect cases to help determine the optimal way to assess causaility in this popualtion.

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