Abstract: Introduction The objective was to scrutinise the completeness of safety reporting in randomised controlled trials evaluating pharmacological interventions for the treatment of pre-eclampsia. Methods We searched Cochrane Central Register of Controlled Trials (CENTRAL), Cumulative Index to Nursing and Allied Health Literature (CINAHL), EMBASE, MEDLINE and PsycINFO from inception to January 2016. Randomised trials evaluating any therapeutic intervention for pre-eclampsia were included. We systematically extracted and categorised safety reporting in the included trials. Results Seventy-nine randomised trials, including data from 31,615 maternal participants were included. Twenty-two trials stated the frequency of withdrawals within each study arm and three trials adequately reported these events. Adverse events were inconsistently reported across trials. When considering the 21 trials evaluating magnesium sulphate for the prevention or treatment of eclampsia, 19 trials reported at least one severe or life-threatening adverse events and two trials reported laboratory-defined toxicity. A single trial adequately reported these events. When considering the 12 trials evaluating beta-adrenoceptor blockers for the treatment of hypertension in women with pre-eclampsia, seven trials reported at least
one severe or life-threatening adverse event and six trials reported mild or moderate adverse events. Conclusion Pre-eclampsia trials contain significant deficiencies in safety reporting. Developing and implementing a minimum data set, in future pre-eclampsia trials could help to address these issues. Improvements in safety reporting would permit a more balanced assessment of interventions and enhance informed decision-making when considering the trade-off between the benefits and harms.