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Rapid cycle drug safety evaluations using routinely collected data

Ms Ximena Camacho[1], Dr Margaret Wilson[2], Professor Sallie Pearson[3], Professor David Henry[1]
[1]Melbourne School of Population and Global Health, The University of Melbourne, Melbourne, Australia, [2]Therapeutic Goods Administration, Department of Health, Woden, Australia, [3]Centre for Big Data Research in Health, University of New South Wales, Sydney, Australia

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[1] *Melbourne School of Population and Global Health, The University of Melbourne, Melbourne, Australia*
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Background
Although safety signals about medicines may come from sources such as product registration information and adverse drug reaction reports, it is important to perform population level confirmatory analyses to quantify harms and risk factors. Capacity to undertake this work has been limited in Australia.
Objectives
Many important drug safety questions can be addressed quickly using comprehensive population level datasets. The University of Melbourne and UNSW, with the Therapeutic Goods Administration (TGA), are developing a framework to undertake rapid initial assessment of drug safety questions using comprehensive linked administrative data from Canada and Australia.
Method
Queries will be identified and prioritised by the TGA and operationalised by scientific and analytic staff across the three organisations. Initial analyses will be limited to exposed cohorts to determine outcome frequencies. Exposure will be defined from dispensed medicines and outcomes of interest and basic demographics will be identified from medical consultations, hospital separations and registries. Where appropriate, studies will progress to fully adjusted comparisons of exposed and non-exposed cohorts.
Results
Pilot studies have yielded valuable information on two drug classes - psychostimulants in pregnancy and temozolomide to treat certain tumours. The initial data indicated the need for a fully adjusted model to assess harms of psychostimulants in pregnancy. With temozolomide, low frequencies of the outcomes and high competing risks from underlying disease negated the need for further analyses.
Conclusions
This framework aims to provide timely evidence to TGA while simultaneously building capacity within the government and academic communities