

STRENGTHENING MONITORING OF MEDICINES IN AUSTRALIA

**Submission to the Therapeutic Goods
Administration**

from the Population Health Research Network

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NCRIS
National Research
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1. INTRODUCTION

The Population Health Research Network¹ (PHRN) is a national data linkage infrastructure network funded by the Australian Government's National Collaborative Research Infrastructure Strategy (NCRIS) with support from government agencies and partner organisations. The PHRN's primary purpose is to build and facilitate the operation of collaborative, national data linkage infrastructure capable of securely and safely linking data collections from a wide range of sources and providing access to linked data.

With support of the PHRN, Australia now has the capacity to link and provide access to linked data in all jurisdictions. This infrastructure is of international significance. PHRN achievements include:

- Establishment of new data linkage units in Queensland, Victoria, Tasmania and South Australia and an accredited Commonwealth Integrating Authority at the Australian Institute of Health and Welfare;
- New online application and secure data delivery systems which facilitate access to data; and
- Establishment of a remote access data laboratory that enables researchers to access linked datasets in a secure environment from anywhere in Australia.

The PHRN infrastructure supports the linkage of data collections from both the public and private sectors across a range of disciplines including health, education and social services. There are usually few technical barriers to the linkage of data from a variety of sources but a range of legal, policy, resourcing and cultural barriers remain.

2. SUBMISSION

This submission addresses the 'Improved collection and use of data section' of the Consultation Paper.

The PHRN strongly supports the proposal for the TGA to use linked data for pharmacovigilance monitoring and compliance activities. This approach has a number of advantages including whole of population coverage, timely results and cost effectiveness. The proposal to use linked Pharmaceutical Benefits Scheme, Medical Benefits Scheme and hospital data collections is supported. However, the proposed approach seems limited and does not leverage Australia's extensive data linkage infrastructure and expertise in the analysis of linked data, including analysis of linked prescribing information. The inclusion of death, emergency department and cancer registry data in pharmacovigilance activities should definitely be considered in the first instance. The inclusion of other linked data collections including perinatal, congenital abnormalities, mental health and other national disease registries would enhance the quality of pharmacovigilance in Australia.

It is somewhat surprising that the TGA is currently seeking to establish the feasibility of advanced data linkage. Australia has a long and world leading history of data linkage. The first specialist data linkage unit was established in Western Australia more than twenty years ago. The PHRN was established in 2009 and Australian governments, universities and research institutes have already invested \$70m in this internationally significant research infrastructure. PHRN data linkage units routinely link a wide range of population level administrative data collections (<http://www.phrn.org.au/for-researchers/data-collections-available/>) including all

¹ The Population Health Research Network. Perth WA (Aus). 2016 [cited 27/06/2016]. Available from <http://www.phrn.org.au>

of the collections mentioned above. Approximately 80% of all research conducted using linked data in Australia uses PHRN funded facilities. There are highly skilled researchers across Australia with specialist skills in analysis of linked prescribing data who could contribute to a comprehensive approach to pharmacovigilance in Australia. Partnering with the academic sector will enhance Australia's ability to monitor medicines. Examples of research publications resulting from the analysis of linked Pharmaceutical Benefits Scheme data that are relevant to medications monitoring/safety are provided below.

The PHRN has a national network of facilities and services and has extensive experience with data linkage which can help the TGA. Australian researchers have considerable experience with use of linked data for medications monitoring and TGA can leverage that experience. Australia would benefit from a broader approach that supports use of linked data for pharmacovigilance/medicines monitoring outside of as well as within the TGA.

We believe there is an opportunity to work together with the TGA to leverage existing government investments in linked data and build an internationally significant national pharmacovigilance program in Australia.

3. References

1. Skinner A, Havard A, Tran DT, Jorm LR. Access to Subsidized Smoking Cessation Medications by Australian Smokers Aged 45 Years and Older: A Population-Based Cohort Study. *Nicotine Tob Res.* 2017;19(3):342-50.
2. Karanges EA, Blanch B, Buckley NA, Pearson SA. Twenty-five years of prescription opioid use in Australia: a whole-of-population analysis using pharmaceutical claims. *Br J Clin Pharmacol.* 2016;82(1):255-67.
3. Price SD, Holman CD, Sanfilippo FM, Emery JD. Does ongoing general practitioner care in elderly patients help reduce the risk of unplanned hospitalization related to Beers potentially inappropriate medications? *Geriatr Gerontol Int.* 2015;15(8):1031-9.
4. Price SD, Holman CD, Sanfilippo FM, Emery JD. Association between potentially inappropriate medications from the Beers criteria and the risk of unplanned hospitalization in elderly patients. *Ann Pharmacother.* 2014;48(1):6-16.
5. Price SD, Holman CD, Sanfilippo FM, Emery JD. Impact of specific Beers Criteria medications on associations between drug exposure and unplanned hospitalisation in elderly patients taking high-risk drugs: a case-time-control study in Western Australia. *Drugs Aging.* 2014;31(4):311-25.
6. Price SD, Holman CD, Sanfilippo FM, Emery JD. Are older Western Australians exposed to potentially inappropriate medications according to the Beers Criteria? A 13-year prevalence study. *Australas J Ageing.* 2014;33(3):E39-48.
7. Kemp A, Preen DB, Saunders C, Boyle F, Bulsara M, Holman CD, et al. Women commencing anastrozole, letrozole or tamoxifen for early breast cancer: the impact of comorbidity and demographics on initial choice. *PLoS One.* 2014;9(1):e84835.
8. Price SD, Holman CD, Sanfilippo FM, Emery JD. Use of case-time-control design in pharmacovigilance applications: exploration with high-risk medications and unplanned hospital admissions in the Western Australian elderly. *Pharmacoepidemiol Drug Saf.* 2013;22(11):1159-70.
9. Colvin L, Gill AW, Slack-Smith L, Stanley FJ, Bower C. Off-label use of ondansetron in pregnancy in Western Australia. *Biomed Res Int.* 2013;2013:909860.
10. Colvin L, Slack-Smith L, Stanley FJ, Bower C. Dispensing patterns and pregnancy outcomes for women dispensed selective serotonin reuptake inhibitors in pregnancy. *Birth Defects Res A Clin Mol Teratol.* 2011;91(3):142-52.

11. Colvin L, Slack-Smith L, Stanley FJ, Bower C. Linking a pharmaceutical claims database with a birth defects registry to investigate birth defect rates of suspected teratogens. *Pharmacoepidemiol Drug Saf.* 2010;19(11):1137-50.