



RACP Foundation Research Awards

PROGRESS REPORT

Project / Program Title	Population-level vaccine safety monitoring: risk assessment and policy implications	
Name	Dr Anastasia Phillips	
Award Received	2018 RACP NHMRC JJ Billings Scholarship	
Report Date	4 February 2019	
Chief Investigator / Supervisor	Professor Kristine Macartney	
Administering Institution	The University of Sydney	
Funding Period	Start Date:	1 April 2018
	Finish Date:	31 March 2021

PROJECT SUMMARY

Immunisation has been hugely successful in reducing vaccine-preventable diseases and deaths. As these diseases become less common, there is increasing focus on any potential risks of immunisation. While vaccine safety is tested in clinical trials before vaccines become available, ongoing safety monitoring is important. Many different methods may be used in Australia and internationally to monitor and investigate vaccine safety. These methods have some limitations and findings can be taken out of context, leading to errors in assumptions about the safety of vaccines. This PhD is examining the usefulness of both existing and novel safety data and methodology to monitor vaccine safety. The best approach to interpreting this information and balancing risks and benefits will be examined.

PROJECT AIMS / OBJECTIVES

1. To evaluate the usefulness and quality of Australian data sources for vaccine safety monitoring through the manipulation of existing and novel data sources, focusing on specific vaccines.

This objective is being achieved through review of the usefulness and limitations of traditional and novel data sources including analysis of Therapeutic Goods Administration (TGA) and general practice (GP) data.

2. To assess the impact of safety data on immunisation program policy and develop a framework for assessment by policy-makers of the risk-benefit profile of Australian immunisation programs.

This objective will be achieved through a qualitative research methodology in the later stages of the PhD program.

SIGNIFICANCE AND OUTCOMES

The HPV review article and conference presentation were well received internationally and identified a large volume of robust scientific evidence that supports the safety of the HPV vaccine. The review brought together published evidence supporting the position of expert groups in finding no evidence of any safety issue that should impact the use of this vaccine in immunisation programmes worldwide. It highlighted the importance of communication given that assumptions based on insufficient evidence may lead to unjustified loss of confidence in vaccine safety.

As Australia was the first country to implement a nationally funded HPV program, the next piece of research analysing 11 years of post-marketing Please also list any data on HPV vaccine from the TGA will provide robust and valuable safety proposed future information.

PUBLICATIONS / PRESENTATIONS

Macartney K, Phillips A, Patel C, Pillsbury A, Brotherton J. Authors' reply: Safety of human papillomavirus vaccines. *Drug Saf.* 2018; 41(5):541-543. Available from <https://doi.org/10.1007/s40264-018-0655-1>

Phillips A, Beard F, Macartney K, Chan J, Gilmour R, Saravanos G, McIntyre P. Vaccine-preventable child deaths in New South Wales from 2005 to 2014: How much is preventable? *J Paediatr Child Health.* 2018; 54(4): 356-364. Available from <http://onlinelibrary.wiley.com/doi/10.1111/jpc.13835/full>

Phillips A, Patel C, Pillsbury A, Brotherton J, Macartney K. Safety of Human Papillomavirus Vaccines: An Updated Review. *Drug Saf.* 2017; 41 (4): 329-346. Available from <https://doi.org/10.1007/s40264-017-0625-z>

Phillips A, Patel C, Pillsbury A, Brotherton J, Macartney K. Safety of Human Papillomavirus Vaccines: An Updated Review. In: PHAA 16th National Immunisation Conference, 2018: Adelaide, Australia.

Hiam R, Gowland A, Behm C, Phillips A, Macartney K. Live vaccine administration to immunocompromised patients: use of active surveillance data to enhance vaccine signal investigation. In: Asian Conference on Pharmacoepidemiology (ACPE); 2017: Brisbane, Australia.

Phillips A, Beard F, Macartney K, Chan J, Gilmour R, Saravanos G, McIntyre P. Child deaths from vaccine preventable infectious diseases, New South Wales, 2005 to 2014. In: PHAA Communicable Disease Conference; 2017: Melbourne, Australia.