



RACP Foundation Research Awards

FINAL REPORT

Project / Program Title	Population-level vaccine safety monitoring: risk assessment and policy implications	
Name	Dr Anastasia Phillips	
Award Received	2018 RACP NHMRC J J Billings Scholarship	
Report Date	March 2021	
Administering Institution	University of Sydney	
Funding Period	Start Date:	16/01/2017
	Finish Date:	30/11/2020

PROJECT SUMMARY

This PhD thesis assesses Australia's vaccine safety surveillance systems, examining data from several different systems and describing their benefits and limitations, in the context of safety assessment for specific vaccines. The thesis concludes with a qualitative study examining the views of vaccine safety experts on Australia's vaccine safety systems over the past 10 years and in preparation for a pandemic immunisation program.

PROJECT AIMS / OBJECTIVES

The project aims to determine whether vaccine pharmacovigilance systems in Australia are sufficiently robust to identify, investigate and communicate a vaccine safety signal.

The objectives are to:

1. Assess the value and limitations of specific pharmacovigilance systems
2. Evaluate improvements over the past ten years
3. Examine Australia's preparedness to monitor pandemic vaccine safety

Objective (1) has been achieved through three studies (all published or in press in peer reviewed journals):

a) Phillips A, Hickie M, Totterdell J, Brotherton J, Dey A, Hill R, Snelling T, Macartney K.

Adverse events following HPV vaccination: 11 years of surveillance in Australia. *Vaccine*. 2020; 38 (38): 6038-6046

b) Phillips A, Glover C, Leeb A, Cashman P, Fathima P, Crawford N, Snelling T, Durrheim D, Macartney K. Safety of live attenuated herpes zoster vaccine in Australian adults 70 to 79 years of age: an observational study using active surveillance. (in press: *BMJ open*)

c) Totterdell J, Phillips A [joint first author], Glover C, Chidwick K, Marsh J, Snelling T, Macartney K. Safety of live attenuated herpes zoster vaccine in adults 70 to 79 years: a self-controlled case series analysis using primary care data from the MedicineInsight program. *Vaccine*. 2020; 38 (23): 3968-3979.

Objective 2 and 3 have been achieved through a qualitative study (submitted for peer review) entitled 'From program suspension to the pandemic: a qualitative examination of Australia's vaccine pharmacovigilance system over 10 years', and through further examination as part of the main thesis, to be submitted mid 2021.

SIGNIFICANCE AND OUTCOMES

The three important papers above have been published in peer reviewed journals, in addition to a Review article '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'.

The findings of these papers are significant, particularly in the context of COVID-19 vaccines and the need for Australia and other countries globally to have robust, responsive, multi-faceted pharmacovigilance systems in place. Australia has developed an innovative, active cohort event monitoring system for vaccine adverse events, which has now been adapted by the US for COVID-19 vaccine safety monitoring. However, it is important to evaluate Australia's systems against comparable countries nationally, particularly in relation to

the analysis of later onset vaccine adverse events. This thesis provides an important examination of this topic.

PUBLICATIONS / PRESENTATIONS

The published papers have been presented at annual at the Public Health Association of Australia Communicable Disease or Immunisation conferences during the candidature (apart from the 2020 conference, which was postponed due to COVID-19). These projects have also increased collaboration between the host organisation (the National Centre for Immunisation Research and Surveillance, University of Sydney) and the national Therapeutic Goods Administration, as well as State and Territory health departments. They have also increased my networks in the field of vaccine safety, both nationally and internationally. These collaborations are likely to lead to future, related projects over time and in the post-doctoral phase.