Postmarketing Vaccine Safety Passive Surveillance: An exploratory study of parent and healthcare provider reporting of Adverse Events following Immunisation (AEFI)

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Abstract

Monitoring the safety of new and exisiting vaccines following licensure is a critical component of maintaining public confidence in immunisation and is an integral part of national immunisation programs. In Australia the process relies predominantly on the passive surveillance of adverse events following immunisation (AEFI) via spontaneous voluntary reports of AEFI by healthcare professionals, vaccine manufacturers and the public to state or federal health authorities. The aim of this thesis was to investigate factors that promote or inhibit parental and healthcare professional reporting of AEFI.

A mixed-methods sequential study design was employed, with three separate studies conducted: two quantitative and one qualitative. The first quantitative study involved telephone interviews of a representative sample of 469 South Australian parents, recruited from the general population about the previous occurrence of children's AEFI, safety opinions, awareness of surveillance and reporting AEFI to healthcare professionals and surveillance authorities. The second quantitative study interviewed 179 parents whose children had experienced an AEFI and had reported the events to the South Australian Immunisation Section, Department of Health. This study was conducted following the national suspension of a seasonal trivalent influenza (STIV) vaccine in 2010. Parental vaccine safety attitudes, reasons for reporting and impact on future vaccination intent were assessed. The qualitative study involved in-depth interviews with 29 healthcare professionals working in general practice, council immunisation clinics and a paediatric hospital emergency department (ED). The interviews sought to examine the experiences, knowledge and training of general practitioners (GPs), nurses and ED consultants in detecting AEFI and of reporting to surveillance authorities. The study was planned using a

social constructionist perspective and thematic analysis was used to analyse the interview data.

In the first study, 95% of all parents were confident in vaccine safety in general. Parental confidence in vaccine safety was significantly associated with higher levels of education (OR:2.58, p = 0.01) and being born in Australia, (OR:2.30, p = 0.004). Mothers, when compared with fathers, were less accepting of two vaccine risks: febrile convulsion (OR:0.57, p = 0.04) and anaphylaxis, (OR:0.55, p = 0.04). One in four parents stated that at least one of their children had previously experienced an AEFI: one third of these parents reported the symptoms to either a healthcare professional or the Department of Health. Parents of children who had experienced an AEFI were less likely to believe vaccines were safe (OR:0.53, $p \leq 0.01$) compared with parents of children who did not experience an AEFI.

In the second study, 88% of all parents were confident in the safety of vaccines in general. Parents reporting an AEFI to the 2010 STIV were more likely to state the event had influenced future vaccination intent than the National Immunisation Program (NIP) vaccine parent AEFI reporters (65% vs 14%, $p<0.001$), with 63% stating refusal or hesitance to re-vaccinate their children against influenza. Concern for their children's symptoms and media reports of the 2010 STIV program suspension were the most common reasons for reporting.

The qualitative study revealed that interpretations of a "serious" or "unexpected" AEFI and what would constitute a reportable AEFI varied according to the professional group. Common barriers to reporting included time constraints and unsatisfactory reporting processes. Nurses were more likely to have received formal training in vaccine safety and reporting than medical practitioners.

Collectively, these studies should inform future strategies aimed at improving AEFI reporting. These need to incorporate ongoing education and enhancing existing reporting processes for health professionals and investigation of alternate surveillance approaches that consumers will use.

Declaration

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university or other institution and affirms that to the best of my knowledge, the thesis contains no material previously published or written by another person, except where due reference is made in the text of thesis. In addition I certify that no part of this work will, in the future be used in a submission for any other degree or diploma in any university or other tertiary institution without the prior approval of the University of Adelaide and where applicable, any partner institution responsible for the joint-award of this degree.

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Signed .....

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Date.....

Publications contributing to this thesis

- Parrella A, Gold M, Marshall H, Braunack-Mayer A, Watson M, Baghurst P. Parental views on vaccine safety and future vaccinations of children who experienced an adverse event following routine or seasonal influenza vaccination in 2010. Human Vaccines & Immunotherapeutics May 2012, 8:5, 662–667

- Parrella A, Gold M, Marshall H, Braunack-Mayer A, Baghurst P. Parental perspectives of vaccine safety and experience of adverse events following immunisation. Vaccine April 2013, 31:16, 2067-2074

- Parrella A, Braunack-Mayer A, Gold M, Marshall H, Baghurst P. Healthcare providers' knowledge, experience and challenges of reporting adverse events following immunisation: A qualitative study. BMC Health Services Research. 2013 Aug 15;13(1):313

- Parrella A, Gold M, Braunack-Mayer A, Baghurst P, Marshall H. Consumer reporting of adverse events following immunisation (AEFI): identifying predictors of reporting an AEFI. Human Vaccines & Immunotherapeutics. [Published online ahead of print] 2014 Jan 09;10(3)

Conference presentations during candidature

- Public Health Association of Australia (PHAA) 12th National Immunisation Conference; 2010 Aug 17-19; Adelaide.

- Public Health Association of Australia (PHAA) 13th National Immunisation Conference; 2012 June 18; Darwin

Poster presentations:

- The University of Adelaide, Faculty of Health Sciences Postgraduate Research Conference; 2011 Aug 25; Adelaide, Australia.

- PHAA (SA branch) Conference 'Population Health: Working across sectors, settings and ages'; 2011 Oct 29; Adelaide, Australia.

Coverage of findings arising from this thesis in the media

- "Doctors urge jab as flu spreads" in The Advertiser, Adelaide, 28 February 2013, pg 5
- ABC local (Adelaide) radio interview, 27 February, 2013
- "University of Adelaide research finds most South Australian parents believe vaccines are safe for their children", Adelaidenow, 27 February, 2013
- Interview, VaxiPlace , 01 March, 2013

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Abbreviations

ABS	Australian Bureau of Statistics
ACSOM	Advisory Committee on the Safety of Medicines
ACSOV	Advisory Committee on the Safety of Vaccines
AEFI	Adverse Event(s) Following Immunisation
CATI	Computer-Assisted Telephone Interviewing
CDC	Centers for Disease Control and Prevention
CI	Confidence Interval
CYWHS	Children, Youth and Women's Health Service
ED	Emergency Department
GP	General Practitioner
IQR	Interquartile range
IRSD	Index of Relative Socio-economic Disadvantage
NCIRS	National Centre for Immunisation Research and Surveillance
NIP	National Immunisation Program
OR	Odds Ratio
PHAA	Public Health Association of Australia
SA	South Australia
SAEFVic	Surveillance of Adverse Events Following Vaccination in Victoria
SAIS	South Australian Immunisation Section
SEIFA	Socio-Economic Indexes For Areas
STIV	Seasonal Trivalent influenza vaccine
TGA	Therapeutic Goods Administration
UK	United Kingdom of Great Britain and Northern Ireland
US	United States of America

VPD	Vaccine Preventable Disease
WA	Western Australia
WCH	Women’s and Children’s Hospital

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