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The Aboriginal gap in online active vaccine safety surveillance

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Introduction

Vaccine safety monitoring is an essential component of immunisation programs that aims to provide reassurance to the community and health care workers of the safety of vaccines and to enable potential safety signal detection. Pre-marketing vaccine safety studies are generally conducted on healthy participants; post-marketing surveillance should include groups who are underrepresented in vaccine clinical trials. This may include younger and older age-groups, people with underlying health conditions and minority groups. Participant-centred active Adverse Event Following Immunisation (AEFI) surveillance is increasingly recognised as an efficient way of contacting vaccine recipients and directly gathering data on their near real-time vaccine experience (Cashman et al., 2017; Pillsbury et al., 2017).

In Australia, there have been substantial and long-standing gaps in health outcomes between Aboriginal and Torres Strait Islander People (hereafter respectfully called Aboriginal People) and the rest of the population (Holland, 2018). This is well described for vaccine-preventable diseases (Naidu et al, 2013). During the 2009 influenza pandemic, Aboriginal people, particularly those in regional and remote communities, were found to experience higher morbidity and mortality than non-Aboriginal people in Australia (Kelly, Mercer and Cheng, 2009). The primary barrier for Aboriginal people receiving the influenza vaccine is concern about the potential side effects (Wolstenholme, Duffy and Smith, 2017). Thus, concerns about safety, which might hamper vaccine uptake, should be actively allayed.

It is essential to ensure Aboriginal involvement in active AEFI surveillance, so that trust can be built. Supporting Aboriginal involvement in AEFI surveillance is an important component in building trust in vaccination. The advent of improved personal communication and access to smartphones and email has enabled active engagement and direct involvement with community members before (such as pre-call systems) and after immunisation. Immunised individuals or their carers are actively canvassed for their own experience following immunisation, which has facilitated adverse event data collection but also has the potential to make vaccine safety more transparent for consumers. To enhance AEFI surveillance, we developed an active web-based participant-centred vaccine safety monitoring system called Vaxtracker, which is an active member of the AusVaxSafety

consortium. Vaxtracker aims to detect signals indicating a possible vaccine safety issue by sending a SMS (short message service) and/or email three days after immunisation. Clicking or tapping on the embedded link allows completion of an online survey.

In 2015, Aboriginal children aged six months to less than five years of age became eligible for funded seasonal influenza vaccine under the Australian National Immunisation Program (NIP) and in 2016 a diphtheria, tetanus and acellular pertussis (DTPa) booster vaccine was introduced for all 18-month-old children. Both changes were accompanied by enhanced vaccine safety surveillance through the national AusVaxSafety consortium, in which Vaxtracker participates. These changes to the NIP provided the opportunity to better understand participation of Aboriginal people in the active AEFI surveillance and explore factors that may impact on their participation.

Methods

At the time of immunisation with either the influenza or DTPa vaccine, children's parents or carers were asked by practice or clinic health staff if they would like to participate in the Vaxtracker program. Links to the online survey were sent via the contact method chosen by the parent or carer (email and/or SMS). Written information describing the Vaxtracker program was available for parents. A welcome message was sent one day after the immunisation and the link to the survey followed three days after the immunisation. If there was no response to the survey after three days, then two automated reminders were sent three days apart on days six and nine post immunisation. Twenty-three general practices, four Aboriginal Medical Services (AMS) and one Community Health Centre in the Hunter New England Local Health District, New South Wales, Australia, enrolled parents and carers of vaccinated children into the study.

To explore potential barriers to participation in automated active AEFI surveillance, Aboriginal Immunisation Officers attempted to interview all parents or carers of children who did not respond to the Vaxtracker surveys. Families whose children had a vaccination date from 5 April to 24 October 2016 were included in this study.

Two questionnaires were used during the follow-up interviews by the Aboriginal Immunisation Officers. Firstly, the Vaxtracker AEFI questionnaire was

used only with Aboriginal parents who did not respond to the influenza vaccine online survey. This AEFI survey was modified to ensure the language was more suitable for a person to person telephone interview. The demographic and AEFI data gathered telephonically were manually entered by the study interviewer into the Vaxtracker web-based program to add to the data already collected from the web-based influenza vaccine questionnaire from the online parental responders. The second person-to-person telephone questionnaire (Evaluation Questionnaire) explored possible barriers to accessing Vaxtracker for Aboriginal and non-Aboriginal participants for both the influenza and DTPa vaccines. These responses were collated separately in an MS Excel spreadsheet.

Training was provided for two Aboriginal Immunisation Officers on interviewing people using the two questionnaires, data entry on the Vaxtracker and MS Excel, and the referral process to a public health clinician for appropriate follow up if an adverse event was reported.

Aboriginal Immunisation Officers attempted to contact parents and carers who had not completed the online automated survey ten days after their vaccination date with three phone call attempts and/or three email attempts made for each family. These contact attempts were made over a one-week period, at different times of the day. Messages were left if there was a voice mail service available. Once 28 days had lapsed since vaccination, no further contact was attempted. Phone calls were made from an 'unblocked' land line number so that the phone number was visible to phone call recipient. The protocol used for this study is available from the authors.

Data collected as part of the study was analysed in Stata 15 Statistical Package. Basic descriptive analysis was conducted on each vaccine program individually.

In Australia, health professionals are required to report adverse event following immunisation to the Therapeutic Goods Administration (TGA) and State and Territory Health Departments. The follow-up of people who did not respond to the automated survey was considered a quality improvement activity to assess the impact of AEFI surveillance and was authorised as a non-research activity by the Hunter New England Human Research Ethics Committee Authorisation Number AU201506-3.

Results

There was a differential response rate for both vaccines between Aboriginal and non-Aboriginal enrolees, with statistically significantly lower responses from Aboriginal parents for both vaccines (Table 1). The methods of response were similar for Aboriginal and non-Aboriginal families using the link to the online survey from both email and SMS (Table 1).

For Aboriginal children, those enrolled through a general (family) practice were more likely to respond than those enrolled through an Aboriginal Medical Service. There was no significant difference in the age distribution of the children from six months to under five years for families who responded.

Aboriginal immunisation officers were able to contact the non-responding parents or carers of 25 of the 53 Aboriginal children in 50 Aboriginal families (47.2%) and 31 of the 122 non-Aboriginal children (25.4%) in 105 non-Aboriginal families. The parents or carers of 119 children (Aboriginal children n=28 in 26 families, non-Aboriginal children n=91 in 77 families) were either unable to be contacted or 28 days had elapsed since the vaccination. The most common reason for not being contacted was that 28 days had passed since the vaccination (Aboriginal n=13/28, non-Aboriginal n=75/91). Other reasons included that the phone number was incorrect (Aboriginal n=7, non-Aboriginal n=3) and lost to follow-up by having three unanswered calls (Aboriginal n=6, non-Aboriginal n=4).

One of the 12 interviews of parent/carers who did not respond to the online survey after influenza immunisation of an Aboriginal child reported a localised reaction (8.3%) during this follow-up study. This rate was low compared to 22% (36/167) of people responding to the automated online influenza vaccine AEFI survey.

During the follow-up telephone interviews regarding reasons for non-response, the interviewers allocated responses into categories. The most common reason provided by both Aboriginal and non-Aboriginal parent/carers for not completing the survey was being “too busy” (50.0% and 75% respectively) (Table 2). Technological issues such as problems with the mobile telephone or the network were more common among Aboriginal non-responders 33.3% compared to 7.1%.

Table 1: Vaxtracker AEFI survey responses by Parents and Carers of Aboriginal and non-Indigenous children, for Influenza and DTPa vaccine in 2016

	Influenza		DTPa	
	No. (%)	P value ⁴	No. (%)	P value ⁴
No. of parents/carers agreeing to participate in Vaxtracker:	193		568	
• Representing Aboriginal children	55 (28.5)		78 (13.7)	
• Representing non-Indigenous children	138 (71.5)		490 (86.3)	
No of surveys completed (by parents and Aboriginal Immunisation Officers)	150 (77.7)		432 (76.1)	
No of surveys completed (by parents)	137 (71.0)		426 (75.0)	
Survey completion by Aboriginality¹				
• Parents/carers: Aboriginal children	31 (56.4)	0.005	43 (55.1)	<0.001
• Parents/carers: non-Indigenous children	106 (76.8)		383 (78.2)	
Preferred contact method selected by participants				
• Parents/carers: Aboriginal children				
Both	21 (38.2)		33 (42.3)	
Email only	2 (3.6)		0 (0.0)	
SMS only	32 (58.2)		45 (57.7)	

• Parents/carers: non-Indigenous children	Both	83 (60.1)		396 (80.8)	
	Email only	7 (5.1)		27 (5.5)	
	SMS only	48 (34.1)		67 (13.7)	
Response rate by method¹					
• Parents/carers: Aboriginal children	Email	10 (30.3)	0.381	12 (52.2)	0.289
	SMS	21 (39.6)		31 (39.7)	
• Parents/carers: non-Indigenous children	Email	52 (57.8%)	0.015	176 (41.6)	0.352
	SMS	54 (41.2%)		207 (44.7)	
Response rate by clinic type: Aboriginal children¹					
• Aboriginal Medical Service		12 (52.2)	0.595	14 (36.9)	
• General Practice		19 (59.4)		8 (100.0)	0.001
• Community Health		N/A ⁴		21 (65.6)	
Response rate by clinic type: non-Indigenous children¹					
• General Practice		106 (76.8)		147 (87.0)	0.001
• Community Health		N/A ³		236 (73.5)	

Notes: 1. Surveys completed by parents only, does not include surveys completed by Aboriginal Immunisation Officers

2. DTPa Vaxtracker is an ongoing program. Children with a vaccination date from 5/4-24/10/2016 were included in this study

Table 2: Reasons provided for not responding to the Vaxtracker AEFI surveys elicited during follow-up interview, by Aboriginality

	Parents/carers of Aboriginal children (N=24)	Parents/carers of non-Aboriginal children (N=28)	RR (95% CI)	P value
	n (%)	n (%)		
Too busy	12 (50.0)	21 (75.0)	0.58 (0.33- 1.02)	0.062
Forgot	4 (16.7)	15 (53.6)	0.35 (0.14- 0.87)	0.006
No credit available	3 (12.5)	1 (3.6)	1.71 (0.89- 3.29)	0.228
No specific reason	4 (16.7)	2 (7.1)	1.53 (0.80- 2.95)	0.284
Too busy/forgot	13 (54.2)	23 (82.1)	0.53 (0.30- 0.91)	0.029
Technical issues (user/device/network)	8 (33.3)	2 (7.1)	2.1 (1.28- 3.44)	0.017
Technical issues (all) ¹	10 (41.7)	3 (10.7)	2.1 (1.28- 3.58)	0.010

Multiple responses per participant possible

1. Includes all user and device technical issues including no credit

Discussion

There are many gaps in health outcomes between Aboriginal people and the rest of the Australian population, which we also found in this study of the early use of participant-centred AEFI surveillance. There was a differential response rate for both vaccines' online AEFI surveys between Aboriginal and non-Aboriginal enrolees.

In interpreting these findings, it is important that the following limitations are considered. The sample size was small, and the interviewers were not blinded. Responses to telephone surveys may have provided relatively superficial reasons rather than when these are explored in-depth in person and some people may have found the telephone survey confronting. As there was naturally a delay before seeking reasons for not completing the survey, potentially up to 28 days, recall bias may have been a factor. The study had no additional resourcing and delays in making the telephone calls excluded a number of participants, in order to limit the potential for recall bias.

We found that parents/carers were more likely to respond if they provided both an email address and mobile phone number to the vaccination clinic. As parents/carers of non-Aboriginal children were more likely to provide both contact options when compared to the parents/carers of Aboriginal children, they would have received twice the number of survey prompts and reminder messages, which may have increased the opportunity of responding to a message (Australian Ministers' Advisory Council, 2017). When Aboriginal people nominated both SMS and email, they were more likely to respond from the link sent by email (50%). Both technologies are worth exploring to enable Aboriginal people to access health information services, however, their preference should be monitored over time, as this may be influenced by cost and availability of emerging technologies.

Response rates of the parents/carers of Aboriginal children who received their vaccination at an Aboriginal Medical Service (AMS) were lower when compared to those visiting a General Practice. We were unable to identify why this difference exists. The Aboriginal and Torres Strait Islander Health Performance Framework 2017 Report (Australian Ministers' Advisory Council, 2017) found that most Aboriginal and Torres Strait Islander people went to a doctor if they had a health problem (54%), followed by Aboriginal Medical Services (AMS) (17%),

with use of AMS and community clinics increasing from 13% in major cities to 66% in very remote areas. Aboriginal participants in this AEFI surveillance followed a similar pattern with more outer regional and remote area participants serviced by AMSs. Over 50% of Aboriginal people live in major cities or regional centres (Marles, Frame and Royce, 2012). Our study area in the HNELHD in NSW covers the city of Newcastle and regional areas of NSW but not very remote areas. The relative geographic isolation of some Aboriginal families may explain the more frequent mention of technical issues impacting on their ability to respond to online surveys. Although general (family) practice may not have a high proportion of Aboriginal clients it is an important place of care where active surveillance is potentially useful and informative for Aboriginal people (Australian Ministers' Advisory Council, 2017). Further strategies may be required to reach and canvas Aboriginal people living in remote and very remote areas to ensure inclusion in appropriately designed AEFI surveillance.

Although telephone credit was mentioned as a barrier by four respondents (3 Aboriginal and 1 non-Aboriginal) it appears to be less of a barrier than was anticipated following discussions with health professionals prior to the study. Aboriginal people did report technology difficulties more than non-Aboriginal people (41.7% cf 10.7%, p value 0.010), however, care should be taken when interpreting these data, as numbers of participants are small. However, in a 2015 survey of Aboriginal women about immunisation during pregnancy in Western Australia, over half of the 400 women sampled had a phone number that was incorrect or not functional (Lotter et al., 2018). Mobile phones are an increasingly efficient means of involving people in health and health data collection, but care is required to ensure Aboriginal people are not excluded and are able to contribute their experiences, in this case, vaccine adverse events. In 2017, the Aboriginal and Torres Strait Islander participation in the national AusVaxSafety database was 2.0%, whereas Aboriginal and Torres Strait Islander people comprise 3.3% of the Australian population (Pillsbury et al., 2018).

Young Aboriginal people are rapid adopters of new technologies, including smartphones, which can facilitate participation in culturally important activities, such family and community connectivity, but factors such as socioeconomic status and remoteness may impact on uptake. A review of social media use by young Aboriginal people concluded that future use could bridge health and education gaps (Rice et al., 2016). The Menzies School of Health Research has successfully

demonstrated the use of an app to prevent overconsumption of sugary drinks in remote Communities in the Northern Territory (Tonkin et al., 2017). These case studies suggest that use of new technology alone does not necessarily exclude Aboriginal people. We recognise that deeper understanding is required on how to best engage Aboriginal families in active AEFI surveillance and a qualitative study using a “yarning circle” methodology may be worthwhile to ensure that current inequality in health service provision is not perpetuated (Dunleavy, 2013).

Conclusion

There is growing recognition that active automated participant-based surveillance is an important contributor to assess the post-marketing safety of vaccines (Pillsbury et al., 2017). This method likely improves vaccine safety signal detection and potentially contributes to better confidence in vaccines (Cashman et al., 2017; Crawford et al., 2014). The response rates to the active AEFI surveillance in this study were generally good in both non-Aboriginal and Aboriginal families, but lower in the latter. Involving Aboriginal people in active AEFI surveillance is critical to the surveillance of safety as new vaccines, for example pandemic vaccines, are introduced in higher risk subpopulations, including First Nations Peoples. Vaccine safety is a concern for some Aboriginal people (Wolstenholme, Duffy and Smith, 2017) so all the more important that Aboriginal people have the opportunity to participate in active AEFI surveillance and thus it is important that barriers to their participation are better understood and overcome.

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