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Parental perspectives of vaccine safety and experience of adverse events following immunisation

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ABSTRACT

Introduction: We aimed to determine demographic predictors of parental vaccine safety and risk perceptions, and assess the relationship between the occurrence of children's perceived adverse events following immunisation (AEFI) on parents' opinions.
Methods: Computer-assisted telephone interviews (CATI) were conducted in 2011 with a cross-sectional, random general population sample of rural and metropolitan residents in South Australia. Multivariate ordinal logistic regression analyses examined associations between parental vaccine safety attitudes and socio-demographic factors, adjusting for whether children had ever experienced a previous suspected AEFI.
Results: Of 469 parents interviewed, 95% were confident in vaccine safety in general, but almost half expressed concern for pre-licensure testing of vaccines. Of all parents, 41% responded that at least one of their children had experienced an AEFI. Almost one third of the AEFI parent group indicated they reported their children's symptoms to either a healthcare professional or the Department of Health. Parental acceptability of the risks of febrile convulsion and anaphylaxis were 73% and 76% respectively. Ordinal logistic regression analyses showed parents of children who had experienced a suspected AEFI were associated with greater concern for vaccine safety (OR:0.53, $p \leq 0.01$) and more were likely to expect either a mild or a serious AEFI. After adjusting for demographics, 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 the two vaccine risks presented: febrile convulsion (OR:0.57, $p = 0.04$) and anaphylaxis, (OR:0.55, $p = 0.04$).
Conclusions: Parents commonly perceive and report that their child has experienced an AEFI. In this group of parents the subsequent expectation of an AEFI and vaccine safety concerns may be heightened. Further research should investigate parental understandings of differentiating an expected event from an adverse event as this could inform immunization risk communication and consumer AEFI reporting strategies.

1. Introduction

It is widely acknowledged that the success of immunization programs in eliminating vaccine preventable diseases (VPD) has resulted in less public fear of disease but increased concerns for vaccine safety [1–3]. Community acceptance of both the benefits of immunization and potential vaccine risks is crucial to achieving high immunization coverage rates [4]. As immunizations are administered to healthy individuals to prevent illness, expectations of vaccine safety are high. Several factors have contributed to heightened concerns for vaccine safety, including the increasing number of vaccines in immunization schedules, limited or no experience of VPD, and the increasing presence and influence of conflicting safety information in online or news media [2,3,5,6]. Parental concerns such as the fear of potential adverse effects, refusal of recommended vaccines, concern for safety of new vaccines, misconceptions such as vaccines causing autism or too many vaccines weaken the immune system have been reported in published research [7–11].

An adverse event following immunization (AEFI) is defined as "any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine" [12]. Although most vaccine reactions

Abbreviations: VPD, vaccine preventable diseases; AEFI, adverse event following immunisation; STIV, seasonal trivalent influenza vaccine.

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are common and usually mild, the occurrence of an AEFI can negatively influence attitudes towards revaccination and impact on vaccine coverage. In Australia, increased concerns about influenza vaccination have been identified in parents notifying an AEFI to surveillance authorities [13] following the temporary suspension of seasonal trivalent influenza vaccination (STIV) on 23rd April 2010, due to an increase in expected rates of febrile convulsion [14]. Decreased paediatric uptake of influenza vaccination has been observed as a result of the safety signal [15]. Studies elsewhere have also reported negative parental attitudes towards vaccine safety and immunization associated with the experience of a child's AEFI [16,17]. Although AEFI status has been shown to influence safety views, other determinants may be associated with vaccine safety attitudes.

Monitoring parental confidence in vaccine safety and safety concerns are important to inform immunization strategies and maintain high coverage rates. Although our study of parents reporting an AEFI to surveillance authorities found concerns for a specific vaccine as a result of a real safety signal [13], in order to better understand parental vaccine safety perceptions, it is necessary to examine the views of parents in the general population. The purpose of the present study was to examine (1) vaccine safety attitudes, (2) perceptions of experiencing mild and serious AEFI, (3) differences in attitudes according to whether a child had experienced a perceived AEFI and (4) demographic predictors associated with concern, from a random community sample of parents residing in South Australia (SA).

2. Methods

We conducted a cross-sectional telephone survey of adults randomly selected from electronic residential telephone listings, between March and May 2011, from metropolitan and rural SA (population 1.6 million). The study was part of the Health Monitor program of the Population Research and Outcomes Studies Unit, University of Adelaide [18]. The Health Monitor program conducts surveys of 2000 South Australian households three times a year. It is used by health professionals and policy makers for research and policy planning. In addition to the vaccination questions, other health-related topics were also included in the survey.

Selected households were sent a letter introducing the survey. Following initial telephone contact, the adult in the household (aged $\geq$18 years) who most recently had a birthday was identified. The Computer Aided Telephone Interviews (CATI) were conducted by trained marketing researchers, with up to 10 call-backs made to interview the selected adult. Respondents with poor or no English were excluded from participating. A pilot survey of 50 respondents was conducted in order to refine survey question format and sequence.

Respondents who identified as a parent or legal guardian of children aged birth – 18 years were asked their views on vaccine safety; pre-licensure safety testing; acceptability of two vaccine safety risks, anaphylaxis and febrile convulsion; and awareness of a system for vaccine safety surveillance. Parents were asked whether an AEFI had ever occurred for each child and if so, to describe the symptoms experienced. To examine vaccine safety risk perceptions and assess parental expectations of potential adverse reactions, we asked parents to recall their beliefs regarding the likelihood of their youngest child experiencing a mild AEFI (described as fever, irritability and injection site swelling) and a serious AEFI (requiring medical attention), at their last immunization.

We compared the responses of two subgroups: parents who indicated any of their children had previously experienced an AEFI ("AEFI parents") and parents for whom all children had not experienced AEFI symptoms ("no-AEFI parents"). In this study, the term "AEFI" does not imply causality, but only a temporal relationship to an immunization that the parent judged to be vaccine related.

Statistical analyses were performed using data weighted to the age, gender, probability of selection within a household and geographical area profile of the South Australian population. Individual data were weighted by the inverse of the individual's probability of selection and then reweighted by age, gender and area, derived from the Australian Bureau of Statistics estimated resident population for 30 June, 2009 [19,20]. Survey response frequencies were tabulated with analyses for clustered, weighted survey data. Differences in survey response proportions between AEFI- and no-AEFI parent sub-groups were examined with χ^2 tests. Ordinal logistic regression analyses were used to examine the association between AEFI-parent status and response to survey questions, adjusting for evidence of any potential confounders among the demographic variables collected in the survey. Preliminary checks confirmed the proportional odds assumption was not violated [21]. The demographic covariates included: parent age, gender, total children (1, 2, 3 and >3), education (secondary school, certificate/trade and university), income and country of birth (Australia or other). We used the Index of Relative Socioeconomic Disadvantage (IRSD) as a measure of socio-economic status [22]. All variables of interest, regardless of statistical significance in univariate analysis were included in the multivariate regression analyses. Statistical tests were two-tailed, with a significance level of 5%. The study was approved by the Human Research Ethics Committees of the South Australian Department of Health and the University of Adelaide.

3. Results

3.1. Description of study sample

The sample (n = 469) in this study comprised parents or legal guardians of 929 children aged $\leq$18 years and was a sub-group of respondents identified in a household community sample of 2002 randomly selected adults, in which the response rate was 55.6% [23]. Table 1 summarises the demographics of all respondents and two sub-groups of parents: AEFI parents (n = 191, 40.7%), and no-AEFI parents (n = 278, 59.3%), weighted for both numbers and proportions. Of all parents, 165 (35.2%) were males and 304 (64.8%) were females. The mean age of the parent interviewee was 40.2 years (95% confidence interval (CI): 39.4–41) and a range of 18–66 years. The median number of children per parent was two, with a range of one to seven children. The respondents' households were situated in both metropolitan (n = 345, 73.6%) and rural Adelaide (n = 124, 26.4%).

3.2. Parental demographic differences

There were no statistically significant differences in age, gender, income, total children, employment, education and marital status between the AEFI parent and the no-AEFI parent sub-groups. Significant differences were found by gender in the AEFI parent group ($p \leq 0.01$), with a greater proportion of mothers stating their children had experienced an AEFI (68%) compared to the no-AEFI parents (46%).

3.3. Previous AEFI and reporting

Of all children, 97.6% (n = 913) were fully or partially immunized compared to coverage estimates of 89% for South Australian children up to 5 years of age [24]. Of all parents, 41% (n = 191) stated 28.8% of all children (n = 269) had previously experienced an AEFI (Fig. 1). The children's age at time of interview who had experienced an AEFI was 0–2 years (18.9%), 3–5years (21.4%), 6–10 years (26.7%)

Table 1
Household demographics of survey respondents ($n = 469$): South Australia, 2011.

Respondent characteristics	All Parents raw N (weighted N)	All Parents weighted %	AEFI Parents[a] weighted N (weighted %)	No AEFI Parents[b] weighted N (weighted %)	SA population[c] (%)
Age (years)					
18–34	89 (125)	26.8	55 (28.9)	70 (25.3)	21.5
35–44	220 (217)	46.2	98 (51.3)	119 (42.7)	14.5
45 +	160 (127)	27.0	38 (19.8)	89 (32.0)	33.6
Sex					
Male	165 (209)	44.6	61 (31.7)	149 (53.6)	48.6
Female	304 (260))	55.4	131(68.3)	129 (46.4)	51.4
Residence					
Metropolitan	345 (350)	74.6	139 (72.5)	211 (76.1)	73.7
Rural	124 (119)	25.4	53 (27.5)	66 (23.9)	26.3
Country of birth					
Australia	382 (386)	82.2	155 (81.1)	230 (83.0)	69.2
Other	87 (83)	17.8	36 (18.9)	47 (17.0)	24.7
Main language spoken at home					
English	453 (450)	96.1	184 (96.3)	266 (95.9)	82.5
Other	16 (19)	3.9	7 (3.7)	11 (4.1)	13.0
Educational attainment					
Secondary school/studying	141(134)	28.5	49 (25.7)	85 (30.5)	52.8
Trade/certificate/diploma	190 (187)	40.0	79 (41.5)	108 (38.9)	24.8
Bachelor degree or higher	138 (148)	31.5	63 (32.8)	85 (30.5)	13.6
Annual household income ($AU)[d]					
≤ 20 000 (<18 148)	21 (15)	3.3	5 (2.8)	10 (3.6)	20.3
20 001–40 000 (18 200–41 548)	37 (30)	6.4	12 (6.4)	18 (6.4)	18.7
40 001–60 000 (41 600–62 348)	70 (69)	14.7	26 (13.7)	43 (15.4)	19.5
60 001–80 000 (62 400– 88 348)	75 (76)	16.2	37 (19.6)	39 (14.0)	17.4
80 001–100 000 (88 400 – 103 948)	86 (87)	18.6	39 (20.6)	48 (17.2)	7.3
> 100 000 (>104 000)	141(151)	32.2	50 (26.1)	101 (36.5)	16.7
Not stated	39 (40)	8.6	21 (10.9)	19 (7.0)	1.8
Employment					
Full or part time	388 (396)	84.4	157 (82.0)	239 (86.1)	57.2
Not in workforce	81 (73)	15.6	34 (18.0)	39 (13.9)	37.6
Socioeconomic quintile[e]					
1 (Least disadvantaged)	93 (88)	18.9	32 (16.5)	57 (20.5)	17.7
2	79 (78)	16.7	35 (18.1)	44 (15.8)	18.2
3	98 (99)	21.1	47 (24.6)	52 (18.8)	18.3
4	114 (110)	23.4	41 (21.4)	69 (24.8)	21.4
5 (Most disadvantaged)	85 (93)	19.8	37 (19.4)	56 (20.2)	24.4

[a] AEFI parent subgroup are parents who indicated any of their children aged ≤18 years had previously experienced a suspected adverse event following immunization (AEFI).
[b] no-AEFI parent subgroup are parents who indicated any of their children aged ≤18 years had not previously experienced a suspected AEFI.
[c] Australian Population Census, 2006, persons aged ≥18 years, Australian Bureau of Statistics (ABS), http://www.abs.gov.au/cdataonline.
[d] The 2006 ABS Census income categories are not directlycomparable in terms of income ranges. The SA population income category percentages relate to income of family households with one or more children. (Cat.(No. 2068.0 – 2006 Census Tables). Percentages do not equal 100 due to rounding.
[e] Socio-Economic Indexes for Areas (SEIFA) area-based index of relative socioeconomic disadvantage (IRSD) derived from residential postcode and based on the Australian census data.

and >10 years (33.0%). Fever was the most commonly experienced AEFI (59%), followed by injection site swelling (36%); injection site rash (24%); other, described as fatigue, irritability (17%), rash over part or whole body (6%); diarrhea (3.%); vomit (2%); convulsion (0.4%) and anaphylaxis (0.4%) (Table 2).

One third of the AEFI parent group (32%, $n = 62$) reported their children's symptoms to either a healthcare professional or the Department of Health (Fig. 1). Of the 66 children who had an AEFI reported, 59 children's AEFI were reported to one person only, and 7 were reported to more than one person.

General Practitioners (family physicians) received the majority of reports (53%). Fever was the most common symptom reported (Table 2).

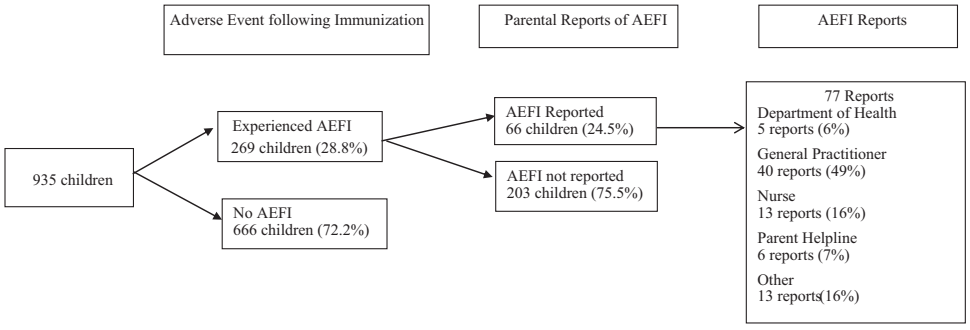

Fig. 1. Children's experience of AEFI and total parental AEFI reports.

Table 2
Children's AEFI symptoms and AEFI reported.

Symptom	Total AEFI	AEFI reported *N* (%)	AEFI not reported	(*P* value)[a]
Fever	158	44 (28)	114 (72)	0.14
Injection site swell	97	17 (18)	80 (82)	0.06
Injection site rash	64	17 (28)	47 (72)	0.27
Rash over body	15	13 (87)	2 (3)	<0.01
Diarrhea	9	4 (44)	5 (55)	0.34
Vomit	6	5 (83)	1 (17)	<0.01
Convulsion	1	1 (100)	0	0.04
Anaphylaxis	1	1 (100)	0	0.08
Other	45	13 (30)	12 (15)	0.12
Total	396	115	281	

[a] *P* value compares proportion of AEFI symptoms reported with those not reported.

3.4. Vaccine safety opinion

The majority (95%) of all parents stated that vaccines given to children in general were "safe" or "very safe", although half stated concern for the adequacy of pre-licensure safety testing (Table 3). The AEFI parents were more likely to expect a mild (fever, irritability or injection site reaction, $p \leq 0.01$) and serious AEFI (requiring medical treatment, $p = 0.03$) at their children's last immunization.

3.5. Predictors of survey response

Table 4 presents the regression results. The adjusted analyses show that the AEFI parents were significantly more concerned for vaccine safety in general than the no-AEFI parents, and were more likely to expect a mild or serious AEFI at their youngest child's last immunization, (although the result for the serious AEFI was not significant, $p = 0.09$). The odds of stating confidence in vaccine safety, compared to the no-AEFI parents were lower, OR = 0.53 [$p < 0.01$, 95% CI(0.34, 0.84)]. The odds of stating mild reactions were unlikely to occur at their children's last immunization were OR = 0.18, [$p \leq 0.01$, 95% CI, (0.12, 0.28)].

There were few demographic predictors that were significant in the adjusted models. Of those that were, mothers, Australian born and university qualified respondents expressed greater confidence in vaccine safety in general, OR = 1.59 [$p = 0.05$, 95% CI (1.00, 2.51)], OR = 2.31 [$p \leq 0.01$, 95% CI,(1.31, 4.06)], and OR = 2.28 [$p = 0.01$, 95% CI,(1.24, 4.19)] respectively. Likewise, mothers, compared with fathers, were less accepting of febrile convulsion, OR = 0.57 [$p = 0.04$, 95% CI,(0.33, 0.97)] and anaphylaxis risk, OR = 0.55 [$p = 0.04$, 95% CI,(0.31, 0.97)].

Parents of two and three children, compared with parents of one child, were less concerned about pre-licensure safety testing but the results showed marginal significance, OR = 1.63 [$p = 0.05$, 95% CI,(0.99, 2.67)] and OR = 1.85 [$p = 0.05$, 95% CI,(1.00, 3.42)] respectively. Similarly, parents of two and three children believed a serious AEFI at their youngest child's last immunization was unlikely, OR = 1.80 [$p = 0.03$, 95% CI,(1.05, 3.07)] and OR = 2.48 [$p = 0.01$, 95% CI,(1.28, 4.83)] respectively.

Household incomes of (AUD) 20,001–40,000 and 80,001–100,000, compared with the lowest income category were associated with the belief that a mild AEFI was unlikely, OR = 4.81 [$p = 0.03$, 95% CI,(1.96, 19.98)] and OR = 4.13 [$p = 0.04$, 95% CI,(1.09, 15.58)] respectively.

Parents aged 35–44 and 45+ years, compared with parents aged 18–34 years, were most likely to not expect a serious AEFI at the time of their children's last immunization was, OR = 1.72 [$p = 0.05$, 95% CI,(0.99, 2.98)] and OR = 2.22 [$p = 0.01$, 95% CI,(1.23, 4.04)] respectively.

3.6. Awareness of vaccine safety surveillance

Of all parents, 55% were aware of the existence of a surveillance system for vaccine safety (Table 3). There was greater awareness of a surveillance system among the AEFI parents (57.5%) than no-AEFI parents (53.4%), $p = 0.03$. Of all demographic variables, mothers were more aware of a surveillance system, (OR = 1.77, $p = 0.01$, 95% CI,(1.14, 2.76).

4. Discussion

In this representive sample of the South Australian population, the majority (95%) of parents believed that vaccines were safe, indicating high overall confidence in vaccine safety. This finding is encouraging because false claims about vaccine safety are frequently cited in media reports and on the internet [25,26]. In addition, this study was conducted 12 months following the unprecedented vaccine suspension of an Australian manufactured seasonal influenza vaccine, due to an increase of febrile convulsions, and during a time when media reports regarding the safety of the 2011 influenza vaccines were circulating [27]. There were no consistent socio-demographic predictors of vaccine safety concerns evident from the analyses we conducted, although we did find that mothers, when compared with fathers, expressed greater concerns. This is the first Australian study, to our knowledge, that examined parental perceptions of experiencing a defined mild or a serious AEFI. We found half of all parents expected common vaccine side effects, such as fever or injection site reaction, and 10% thought a serious AEFI would occur at their youngest child's last immunization.

Although vaccines were regarded as safe, half of all parents expressed concern about prior testing of vaccines and one in four was not aware of a system in Australia for monitoring vaccine safety. This may suggest that consumers accept the safety of vaccines without knowledge of or consideration of systems to track their ongoing safety. All parents of vaccinated children in South Australia are meant to be provided with vaccine safety information at the time of immunization which outlines how vaccine safety is monitored and how to report adverse events [28]. Our findings would indicate that either parents are not being provided with this information, or that it is not readily recalled. Thus, it would seem that current community education regarding the measures taken to monitor vaccine safety and ensuring public awareness of AEFI reporting processes requires comprehensive evaluation by health authorities.

Almost one in four parents indicated that at least one child had an AEFI, a similar rate reported in a study conducted in the United States of America [29]. The majority of the events in our study were expected side effects of vaccination (fever and injection site reactions) and of all AEFI parents, one-third notified the symptoms to a healthcare provider or health authorities. Of all

Table 3
Parental opinions on vaccine safety and the probability of experiencing an adverse event following immunization ($n = 469$).

	Respondents		*N*			
	AEFI parents		191			
	No AEFI parents		278			
	Total parents		469			
Survey Question			Response, weighted *N* (%)			(*P*)[a]
In general, how safe would you say the vaccines given to children are?	Very unsafe	Unsafe	Undecided	Safe	Very safe	
AEFI parent	2 (1.3)	3 (1.8)	5 (2.8)	83 (43.6)	97 (50.6)	
No AEFI parent	2 (0.05)	8 (2.8)	2 (0.05)	95 (34.1)	172 (62.1)	0.08
Total parents	4 (0.8)	11 (2.4)	7 (1.5)	178 (38)	269 (57.4)	
How concerned are you that new vaccines have been adequately tested for safety before they are released to the public in Australia?	Very concerned	Somewhat concerned	Undecided	Not too concerned	Not at all concerned	
AEFI parent	46 (23.8)	54 (28.4)	1 (0.4)	52 (27.4)	38 (19.9)	
No AEFI parent	76 (27.2)	61 (21.8)	4 (1.5)	84 (30.4)	53 (19.1)	0.48
Total parents	121 (25.8)	115 (24.5)	5 (1.0)	137 (29.2)	91 (19.5)	
How likely did you think he/she would experience a reaction such as fever, irritability or redness at the injection site?[b]	Very likely	Somewhat likely	Undecided	Not too likely	Not at all likely	
AEFI parent	61 (32.8)	77 (41.8)	0 (0)	33 (17.9)	14 (7.5)	
No AEFI parent	14 (5.5)	72 (27.7)	6 (2.2)	114 (44.3)	52 (20.3)	<0.01
Total Parents	75 (16.9)	149 (33.6)	6 (1.3)	148 (33.3)	66 (15.0)	
How likely did you think he/she would experience a reaction that would need medical treatment from a hospital or GP?[c]	Very likely	Somewhat likely	Undecided	Not too likely	Not at all likely	
AEFI parent	7 (3.7)	18 (10.2)	0	75 (41.6)	80 (44.5)	0.03
No AEFI parent	1 (0.5)	13 (5.0)	1 (0.6)	95 (37.2)	145 (56.7)	
Total parents	8 (1.8)	31 (7.2)	1 (0.3)	170 (39.0)	225 (51.7)	
Acceptability of febrile convulsion risk[d,e]	Not acceptable		Undecided	Acceptable		
AEFI parent	39(20.3)		12 (6.3)	140 (73.4)		0.20
No AEFI parent	68 (24.5)		9 (3.1)	200 (72.4)		
Total parents	106 (22.8)		21 (4.4)	340 (72.8)		
Acceptability of Anaphylaxis risk[f]	Not acceptable		Undecided	Acceptable		
AEFI parent	31 (16.4)		14 (7.3)	146 (76.3)		0.93
No AEFI parent	47 (17.1)		18 (6.4)	213(76.5)		
Total parents	79 (16.8)		32 (6.8)	359 (76.4)		
Are you aware that a system for checking and assessing vaccine safety exists in Australia?	No		Undecided	Acceptable		
AEFI parent	67 (34.8)		15 (7.7)	110 (57.5)		0.03
No AEFI parent	121 (43.7)		8 (2.9)	148 (53.4)		
Total parents	188 (40.1)		23 (4.9)	258 (55.0)		

Table notes.
[a] χ^2 *P* value compared AEFI parents with no-AEFI parents.
[b] 21 (4.4%) missing cases, excludes 5 (1.2%) "did not consider". Parents were asked to respond to this question for their youngest child only.
[c] 21 (4.4%) missing cases, excludes 12 (2.5%) "did not consider". Parents were asked to respond to this question for their youngest child only.
[d] 2 refusal.
[e] The risk of febrile convulsion was stated as 1 per 12,000.
[f] The risk of anaphylaxis was stated as 1 to10 per 1,000,000.

symptoms described, skin rash and vomiting were most likely to have been reported, as were the two serious events (convulsion and anaphylaxis). We presume this is because parents may have regarded the events as "unexpected". Since up to 10% of children may experience a skin rash after the MMR vaccine, [30] there is a need to educate parents about differentiating expected mild events from adverse events (of any severity) which should be reported.

Parents who perceived that their children had experienced an AEFI were more concerned about vaccine safety in general when compared with those whose children were not perceived as having had an AEFI, which is consistent with the study by Gust et al. [16]. This trend towards concern is difficult to interpret, as the regression analyses demonstrated no statistically significant differences when compared with the no-AEFI group for most of the other survey items, (except for perceptions of mild AEFI). The AEFI parents were more likely to expect both mild and serious AEFI than parents of children who did not experience an AEFI, (although the adjusted analyses were not significant for serious AEFI). This may indicate, (but not prove), that the AEFI parents were more concerned about vaccine safety prior to immunization. However, other factors, such as knowledge and experience of expected events following immunization may play a part in the perception of whether these events are adverse or not, and whether they should be reported.

Table 4
Odds ratios for the association between socio-demographic, AEFI status variables and vaccine safety opinions.

	Vaccine safety in general	Concern about safety testing	Likelihood of a mild reaction	Likelihood of a serious reaction	Acceptability of Anaphylaxis Risk	Acceptability of febrile convulsion risk	Awareness of a surveillance system
	Univariate OR (95% CI) Adjusted OR (95% CI)	Univariate OR (95% CI) Adjusted OR (95% CI)	Univariate OR (95% CI) Adjusted OR (95% CI)	Univariate OR (95% CI) Adjusted OR (95% CI)	Univariate OR (95% CI) Adjusted OR (95% CI)	Univariate OR (95% CI) Adjusted OR (95% CI)	Univariate OR (95% CI) Adjusted OR (95% CI)
Sex							
Male[a]	referent	referent	referent	referent	referent	referent	referent
Female	1.15 [0.77, 1.73]	1.05 [0.73, 1.52]	0.64 [0.45, 0.90][a]	0.68 [0.44, 1.04]	0.50 [0.30, 0.84][a]	0.59 [0.36, 0.95][a]	1.61 [1.07, 2.42][a]
	1.59 [1.00, 2.51][a]	1.20 [0.79, 1.85]	0.88 [0.58, 1.38]	0.79 [0.47, 1.32]	0.55 [0.31, 0.97][a]	0.57 [0.33, 0.97][a]	1.77 [1.14, 2.76][a]
Age							
18–34	referent	referent	referent	referent	referent	referent	referent
35–44	1.19 [0.71, 1.99]	0.46 [0.30, 0.70][a]	1.25 [0.80, 1.95]	1.61 [0.95, 2.70]	1.45 [0.81, 2.60]	1.23 [0.70, 2.14]	0.83 [0.50, 1.40]
	1.09 [0.61, 1.95]	0.42 [0.26, 0.69][a]	1.32 [0.81, 2.14]	1.72 [1.00, 2.98][a]	1.29 [0.70, 2.39]	1.10 [0.60, 2.02]	0.74 [0.42, 1.31]
45+	1.23 [0.73, 2.07]	0.66 [0.41, 1.09]	1.73 [1.09, 2.73][a]	1.97 [1.15, 3.38][a]	1.88 [0.98, 3.60]	1.97 [1.06, 3.70][a]	1.16 [0.66, 2.03]
	1.36 [0.75, 2.48]	0.78 [0.46, 1.34]	1.59 [0.96, 2.62]	1.22 [1.23, 4.04]a	1.89 [0.89, 4.01]	1.93 [0.93, 4.10]	1.19 [0.62, 2.27]
Country of birth							
Overseas born	referent	referent	referent	referent	referent	referent	referent
Australian born	1.87 [1.16, 3.02][a]	1.25 [0.78, 1.99]	1.06 [0.65, 1.73]	1.59 [0.91, 2.78]	1.33 [0.74, 2.39]	1.15 [0.67, 2.00]	0.78 [0.46, 1.33]
	2.30 [1.31, 4.06][a]	1.36 [0.80, 2.33]	1.11 [0.59, 2.11]	1.61 [0.84, 3.09]	1.73 [0.93, 3.25]	1.40 [0.78, 2.52]	0.92 [0.50, 1.69]
Total children							
1 child [a]	referent	referent	referent	referent	referent	referent	referent
2 children	1.27 [0.79, 2.03]	1.36 [0.91, 2.01]	1.13 [0.75, 1.70]	1.64 [1.04, 2.57][a]	1.16 [0.67, 1.99]	0.81 [0.49, 1.35]	0.97 [0.60, 1.56]
	1.20 [0.71, 2.03]	1.63 [0.99, 2.67][a]	1.50 [0.90, 2.47]	1.80 [1.05, 3.07][a]	0.96 [0.51, 1.81]	0.73 [0.40, 1.32]	1.08 [0.63, 1.86]
3 children	1.11 [0.62, 1.96]	1.45 [0.82, 2.58]	1.28 [0.76, 2.14]	1.93 [1.07, 3.49][a]	1.63 [0.76, 3.50]	2.37 [1.09, 5.11][a]	1.22 [0.67, 2.24]
	1.02 [0.54, 1.94]	1.85 [1.00, 3.42][a]	1.73 [0.95, 3.14]	2.48 [1.28, 4.83][a]	1.23 [0.53, 2.86]	2.31 [0.97, 5.52]	1.25 [0.65, 2.44]
>3 children	1.03 [0.44, 2.43]	0.99 [0.52, 1.92]	0.75 [0.25, 2.26]	0.59 [0.19, 1.85]	1.06 [0.43, 2.66]	0.99 [0.40, 2.48]	0.90 [0.42, 1.94]
	1.16 [0.43, 3.15]	1.42 [0.60, 3.35]	0.94 [0.29, 3.10]	0.69 [0.20, 2.44]	1.33 [0.41, 4.33]	1.05 [0.38, 2.90]	0.86 [0.36, 2.05]
Education							
Secondary school	referent	referent	referent	referent	referent	referent	referent
Trade/certificate/diploma	1.21 [0.76, 1.90]	1.12 [0.72, 1.74]	1.04 [0.65, 1.64]	1.22 [0.75, 1.97]	1.46 [0.85, 2.52]	1.04 [0.65, 1.64]	1.17 [0.72, 1.89]
	1.50 [0.90, 2.50]	1.28 [0.79, 2.06]	0.98 [0.58, 1.64]	1.17 [0.70, 1.97]	1.47 [0.79, 2.73]	1.46 [0.80, 2.67]	1.45 [0.84, 2.51]
Bachelor	1.60 [0.93, 2.70]	1.64 [1.04, 2.59][a]	0.98 [0.63, 1.52]	1.20 [0.73, 1.98]	1.69 [0.92, 3.10]	0.98 [0.63, 1.52]	1.48 [0.88, 2.49]
degree/higher	2.58 [1.24, 4.19][a]	1.68 [0.99, 2.86]	0.99 [0.57, 1.70]	1.20 [0.67, 2.14]	1.70 [0.82, 3.53]	1.77 [0.90, 3.47]	1.76 [0.96, 3.24]
Household income							
≤20,000	referent	referent	referent	referent	referent	referent	referent
20,001–40,000	1.04 [0.30, 3.66]	0.97 [0.22, 4.25]	3.20 [0.96, 10.63]	0.90 [0.19, 4.30]	1.25 [0.37, 4.22]	3.20 [0.96, 10.63]	1.64 [0.46, 5.89]
	1.01 [0.28, 3.66]	0.89 [0.22, 3.72]	4.81 [1.96, 19.98][a]	1.32 [0.25, 6.94]	1.04 [0.31, 3.56]	0.54 [0.14, 2.02]	1.38 [0.33, 5.00]
40,001–60,000	1.86 [0.59, 5.94]	0.94 [0.24, 3.72]	3.11 [0.91, 10.65]	0.97 [0.23, 4.10]	1.17 [0.41, 3.35]	3.11 [0.91, 10.65]	0.99 [0.31, 3.15]
	1.50 [0.47, 4.82]	0.84 [0.26, 3.38]	3.78 [0.93, 15.25]	1.01 [0.22, 4.66]	0.96 [0.34, 2.68]	1.06 [0.31, 3.65]	0.84 [0.25, 2.85]
60,001–80,000	1.23 [0.38, 3.92]	1.04 [0.26, 4.21]	2.08 [0.62, 6.93]	1.08 [0.26, 4.26]	3.85 [1.18, 12.55][a]	2.08 [0.62, 6.93]	1.46 [0.47, 4.53]
	1.10 [0.35, 3.46]	0.89 [0.24, 3.30]	2.84 [0.70, 11.51]	1.00 [0.21, 4.66]	2.78 [0.87, 8.86]	0.82 [0.24, 2.84]	1.13 [0.33, 3.86]
80,001–100,000	1.55 [0.50, 4.79]	0.94 [0.24, 3.65]	3.05 [0.96, 9.68]	1.04 [0.25, 4.26]	1.15 [0.41, 3.24]	3.05 [0.96, 9.68]	1.11 [0.36, 3.48]
	1.23 [0.40, 3.76]	0.84 [0.25, 2.83]	4.13 [1.09, 15.58][a]	1.00 [0.23, 4.40]	0.80 [0.29, 2.19]	0.57 [0.17, 1.89]	0.87 [0.26, 2.95]

Table 4 (*Continued*)

	Vaccine safety in general	Concern about safety testing	Likelihood of a mild reaction	Likelihood of a serious reaction	Acceptability of Anaphylaxis Risk	Acceptability of febrile convulsion risk	Awareness of a surveillance system
>100,000	2.06 [0.68, 6.19]	1.47 [0.39, 5.54]	3.07 [0.98, 9.62]	1.10 [0.27, 4.43]	2.55 [0.89, 7.31]	3.07 [0.98, 9.62]	1.36 [0.45, 4.10]
	1.43 [0.47, 4.31]	1.30 [0.38, 4.47]	3.48 [0.87, 13.92]	0.91 [0.20, 4.18]	1.48 [0.51, 4.34]	0.83 [0.25, 2.78]	1.00 [0.30, 3.38]
IRSD[b]							
Least disadvantaged (tiers1-2)	referent	referent	referent	referent	referent	referent	referent
Middle (tier3)	0.95 [0.58, 1.55]	0.77 [0.47, 1.26]	0.77 [0.50, 1.18]	0.65 [0.39, 1.07]	0.60 [0.31, 1.18]	0.77 [0.50, 1.18]	0.79 [0.47, 1.35]
	1.04 [0.62, 1.76]	0.93 [0.54, 1.60]	0.93 [0.56, 1.54]	0.73 [0.41, 1.28]	0.63 [0.30, 1.32]	0.85 [0.44, 1.63]	0.73 [0.40, 1.32]
Most disadvantaged (tiers 4–5)	0.64 [0.33, 1.23]	0.72 [0.39, 1.31]	1.03 [0.57, 1.84]	0.71 [0.35, 1.47]	0.46 [0.21, 0.99][a]	1.03 [0.57, 1.84]	0.65 [0.34, 1.28]
	0.79 [0.39, 1.62]	0.79 [0.42, 1.69]	1.14 [0.58, 2.23]	0.72 [0.32, 1.61]	0.53 [0.22, 1.23]	0.59 [0.27, 1.31]	0.66 [0.31, 1.40]
AEFI parent							
No	referent	referent	referent	referent	referent	referent	referent
Yes	0.63 [0.42, 0.94][a]	1.02 [0.71, 1.46]	0.17 [0.11, 0.26][a]	0.57 [0.38, 0.85][a]	1.00 [0.63, 1.60][a]	1.10 [0.71, 1.72]	1.28 [0.87, 1.90]
	0.53 [0.34, 0.84][a]	1.04 [0.68, 1.60]	0.18 [0.12, 0.28][a]	0.67 [0.42, 1.07]	1.07 [0.64, 1.79]	1.39 [0.84, 2.30]	1.21 [0.77, 1.89]

Table notes.
[a] Significant p value.
[b] SEIFA IRSD quintiles.

Interestingly, similar proportions of both AEFI and no-AEFI parents believed the risks of a rare AEFI (convulsions) and a very rare AEFI (anaphylaxis) were unacceptable, with almost equal proportions who were undecided about the risks presented. This perhaps reflects the difficulty in understanding the concept of relative risk regarding vaccine reactions and the manner in which they are communicated [31–33]. As the addition of new vaccines to immunization schedules creates the opportunity for an increase in the number of AEFI to occur [34], the relative risk of a vaccine reaction compared to perceptions of VPD may impact further on the confusion.

Immunization providers and healthcare professionals are influential sources of vaccine safety information and advice to parents [3,10,11,35] and are often contacted for medical advice following a suspected AEFI [29]. The parents in this study reported their children's AEFI most commonly to general practitioners, whereas only 6% of all AEFI were notified directly to the Department of Health. We would suggest that it is likely that parents would seek medical advice from their general practioner, rather than make a formal AEFI notification to health authorities. We did not verify whether reports were made to general practitioners or the Department of Health, as this was out of this study's scope. Similarly we do not know if the healthcare providers subsequently reported the children's AEFI to the local Department of Health or the national surveillance authority.

Our findings are subject to several limitations. The analyses presented are based on cross-sectional data and from a relatively small sample and sample sub-groups, which may have reduced our statistical power to detect differences. This study design cannot measure causality, that is, if the children's AEFI experience negatively influenced parental beliefs about vaccine risk perception, as parents were interviewed after immunizations had occurred, and up to several years following immunization. The children's AEFI were self-reported by parents and not verified through medical records, leading to the possibility of recall bias. The questions regarding the likelihood of mild and serious AEFI were asked only for the youngest child. It is possible that the vaccination experience of older children, or earlier vaccinations of the youngest child may have influenced parents' response regarding the expectation of a serious/mild AEFI. As we included children aged up to 18 years in the study, it is important to consider that changes in vaccines and immunization schedules may have resulted in differing rates and types of AEFI experienced and that vaccination of older children would have occurred several years ago, which could have affected parents' recollection of AEFI. We did not ask parents to recall specific vaccines associated with their children's AEFI or the timeframe of reporting to health authorities. Furthermore, we could not assess whether parents' concerns or perceptions of an AEFI differed by children's age. The generalisability of these findings is limited also to the beliefs of parents fluent in English, as interviews were conducted only in English. The timing of this study, 12 months after a major, highly publicised safety signal and vaccine suspension may affect generalisability of results. Finally, we did not collect information on children's health status or parents' beliefs about specific vaccines, although these factors have been associated with parents reporting that their children have experienced an AEFI [36].

Although our results cannot determine whether the experience of an AEFI caused higher vaccine safety concerns or whether parents with higher vaccine safety concerns were more likely to believe their children experienced an AEFI, we believe that our findings provide useful information about Australian parental vaccine safety views, perceptions of children's AEFI and reporting to healthcare providers. Further research should investigate parental understandings of reportable events to inform immunization risk communication education and consumer AEFI reporting strategies.

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