Post COVID-19 vaccination: AusVaxSafety survey participation and adverse events – a community-based regional Queensland study

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Abstract

Objective: To describe adverse events following COVID-19 immunisation (AEFI) and participation in AusVaxSafety surveillance in a Queensland regional community.

Methods: Participants presenting for second dose COVID-19 vaccine at the Hervey Bay Wide Bay Hospital and Health Service (WBHHS) vaccine clinic in July 2021 completed a survey pertaining to their first COVID-19 vaccine. Data collected included participation in AusVaxSafety surveillance, vaccine type (BNT162b2 (Pfizer/BioNTech) or ChAdOx1-S(Oxford/AstraZeneca), AEFI experienced and impact on work/routine activities. Multivariable logistic regression related demographic factors to odds of surveillance participation and AEFI occurrence.

Results: Of 1,148 participants, 37.6% participated in AusVaxSafety surveillance and 44.8% reported an AEFI. Participation in surveillance was higher in older (≥50 vs <50 years: OR 1.36, 95%CI:1.04–1.78) and less-educated participants (university vs. high school/below: OR 0.68, 95%CI:0.48–0.95). Reporting an AEFI was higher in younger (≥50 years vs. <50 years: BNT162b2: OR 0.69, 95%CI:0.51–0.93; ChAdOx1-S: OR 0.42, 95%CI:0.10–1.89), female (female vs. male: BNT162b2: OR 2.28, 95%CI:1.67–3.12; ChAdOx1-S: OR 1.85, 95%CI:1.17–2.94) and more educated participants (university vs. high school/below: BNT162b2:OR 1.63, 95%CI: 1.08–2.45; ChAdOx1-S: OR 3.98, 95%CI:2.03–7.79). Of participants with an AEFI, 15% reported missing work/routine activities.

Conclusions: Participation in surveillance was modest in this regional population, despite AEFI being frequent, and impacts of absenteeism in this setting warrants further research.

Implications for public health: The findings can inform strategies to improve surveillance participation and inform workforce planning in regional areas.

Key words: COVID-19, vaccine surveillance, regional health, adverse event following immunisation

In December 2019 a cluster of pneumonia cases were reported in Wuhan, China which were later identified as the novel coronavirus SARS-COV-2 causing Coronavirus Disease 2019 (COVID-19).[1] In March 2020, COVID-19 was declared a global pandemic and there has been over 555 million confirmed cases and six million deaths to date.[2] In excess of six billion vaccine doses have been administered worldwide, which has been integral to the public health response of reducing transmission and the morbidity and mortality associated with COVID-19.[2] Australia had a different COVID-19 experience throughout the first two years of the pandemic compared to other countries, with comparatively lower numbers of infections and deaths. Furthermore, distinct geographic variation was evident,[3] where while Victoria underwent the world's longest continuous lockdown period (>37 weeks) to curb infection spread,[4] at the time of this study (July 2021), Queensland had minimal lockdown, low case numbers (n≈2,000) and seven deaths[3] and many communities in regional and remote Queensland had no exposure to COVID-19. In Wide Bay region where our study was based, prior to the opening of interstate borders in December 2021, 42 COVID-19 cases had been recorded, and zero deaths.[5] The uptake of vaccination in Queensland, particularly in regional and remote communities, was relatively slow compared to the national and state average,[6] related to higher rates of vaccine hesitancy,[7] barriers to access, lower perceived risks of infection and lack of culturally appropriate strategies.[8]

At the time of this study, two types of vaccines had been the mainstay of COVID-19 vaccination in Australia – BNT162b2 (Pfizer/BioNTech) mRNA vaccine and ChAdOx1-S(Oxford/AstraZeneca) viral vector vaccine. The vaccination rollout was conducted in three phases, prioritising frontline and healthcare workers in Phase 1a, elderly adults and those with vulnerable medical conditions in Phase 1b, adults aged 50–69 years in Phase 2a and subsequent phases included the remaining adult population.[9] At the time of this study the Australian Technical Advisory Group on Immunisation (ATAGI) recommended mRNA vaccines for those <60 years due to the age-related risk of rare adverse events associated with the ChAdOx1-S vaccine including higher rates of

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thrombosis with thrombocytopenia syndome (TTS) in younger recipients.[10] There was a large amount of negative media coverage surrounding the use of the ChAdOx1-S vaccine in this context.[11]

A crucial part of any vaccine program is monitoring safety – in Australia an active surveillance program called 'AusVaxSafety', introduced in 2014 to monitor adverse events following influenza immunisations. It is utilised in conjunction with passive surveillance systems to ensure the safety of COVID-19 vaccines and improve consumer and clinician confidence.[12] This includes monitoring of adverse events following COVID-19 immunisation (hereon referred to as AEFI) whereby participants can opt in by scanning a QR code in all State and Territory run vaccination clinics or if they receive their vaccine in a participating general practice. Brief surveys are sent by automated email or text message in the days following vaccination. Data is published regularly on a publicly available website. Participation in AusVaxSafety surveillance has varied over time and state.

We aimed to assess participation levels in AusVaxSafety surveillance post first dose COVID-19 vaccination, and describe AEFI and their impact on work, study or routine duties reported post COVID-19 vaccination in the Wide Bay region of Queensland.

Methods

Study design and participants

This study is based at the Hervey Bay vaccine clinic, part of the Wide Bay Hospital and Health Service (WBHHS), a regional area ≈300km north of the Queensland capital city, Brisbane. The WBHHS covers 37,000 square kilometres and services over 200,000 people. The Hervey Bay vaccine clinic was the single Queensland Health Hospital and Health Services (HHS) mass stand up vaccine clinic in this town. In July 2021 for three consecutive weeks, all adults aged ≥16 years presenting for their second dose of COVID-19 vaccination at the Hervey Bay COVID-19 Vaccination Clinic were eligible for inclusion in a self-administered survey. Consecutive sampling was used, where every eligible person was offered enrolment. Ethics approval was granted prior to study commencement (HREC/2021/QPCH/76672).

People eligible for vaccination over this timeframe were those in Phase 2a and above (i.e. frontline workers, elderly adults with vulnerable medication conditions and adults aged ≥ 50 years) and either BNT162b2 or ChAdOx1-S were administered based primarily on age-based eligibility criteria, where at the time the ATAGI preferred vaccine for <60 years was BNT162b2 vaccination.[10]

Survey assessment

The survey questions pertained to the participant's first dose of the vaccine. The questions collected data on broad demographic details: age (18–30 years/31–49 years/50–70 years/≥70 years), gender (male/female), education (year 12 or below/technical/certificate/diploma/bachelor and above) and being a health-service employee at the regional health service (yes/no). Employees included doctors, nurses, allied health, administrative, operational staff and other occupations in the healthcare setting. These were followed by eight questions pertaining to the participant's first dose COVID-19 vaccination, informed by questions utilised in the AusVaxSafety surveillance questionnaire. These questions included: vaccine type (BNT162b2/ChAdOx1-S), if the participant had registered and completed the AusVaxSafety surveillance questionnaire (yes/no/unsure), use of pain or fever medication at time of vaccination (yes/no/unsure), reaction after first dose COVID-19 vaccination (yes/no), and for participants reporting "yes" to a reaction to first dose COVID-19 vaccination, the day post-vaccination that reaction occurred (Day of vaccination/Days 1–3/Days 4–6/Days 7–13/Day 14+); needing to seek medical care/advice for any symptoms (yes/no); reaction(s) experienced (local reaction [pain, redness, swelling, itching at or near the injection site]; fever; rash [not at injection site]; chills; headache, muscle/body aches or joint aches/pain; gastrointestinal symptoms [nausea, vomiting, diarrhoea, abdominal pain]; fatigue; fainting/loss of consciousness or seizure); a free text question for any other reactions; and finally, if the vaccination caused missing work, study or normal daily activities (yes/no/unsure), and if "yes", the number of days missed (free text). For the type of reaction experienced multiple options could be selected.

Data collection

A participant information leaflet about the survey, which outlined the purpose of research and types of questions included in the survey, was provided by nursing staff in the monitoring period post vaccination. People wanting to participate in the survey were provided with a paper survey. Participants could choose to complete all, some or none of the fields and return the document to a collection tray. There was no encouragement or inducement to participate or review of the returned surveys by onsite healthcare teams. Paper surveys were data-entered into a preformed Microsoft excel spreadsheet by a study investigator.

Outcomes

The primary outcomes of interest were 1. participation in AusVaxSafety surveillance and 2. reporting an AEFI. Secondary outcomes reported among those reporting an AEFI included the type of AEFI, day it occurred, need to seek medical care and impact on work/daily activities (including duration).

Statistical analyses

Response rate was calculated using the total number of people eligible for study inclusion over the study timeframe – i.e. adults presenting for their second COVID-19 dose over the study period, obtained from Queensland Covid-19 Vaccine Management System (QCVMS). Descriptive analysis was conducted for the overall study cohort, and stratified by vaccine type, where categorical variables were summarised as numbers and percentages, and continuous variables were summarised as mean and standard deviation (SD) if normally distributed, or otherwise median and interquartile range (IQR). The number and percent of participants missing work/routine activities and seeking medical care are presented among participants reporting AEFI, and a chi-squared test used to compare these data by vaccine type. Missing data were presented in separate categories labelled "Not Reported" in descriptive data, and excluded for subsequent regression analyses.

To estimate the association between demographic variables and outcomes of 1. participating in the AusVaxSafety surveillance (in the overall cohort), and 2. reporting an AEFI (stratified by vaccine type), a two-step process was used. First, univariable logistic regression was used to relate demographic variables (age [<50, ≥50 years], sex [male, female], education [high school or below; certificate/technical; university or above; not reported], health-service employee [yes, no]) to odds of each outcome. Second, multivariable logistic regression was

conducted, including variables that were significantly associated with respective outcomes in univariable analyses ($p<0.05$). For participation in AusVaxSafety surveillance, participants reporting "unsure" were classified as "no". To examine if results were impacted by alternative classification of these participants reporting "unsure", a sensitivity analysis was conducted excluding them from this analysis. Subgroup analyses was performed to assess the age–AEFI association by gender, education and health-service employee status. R version 4.1.0 was used for statistical analyses and results were plotted in Microsoft Excel. Significance was set at p <0.05 (two-tailed test).

Results

Of 1,825 second dose vaccinations administered over the study timeframe, 1,256 people participated in the survey (response rate 69%). Of these surveys, 108 (8.5%) were excluded due to missing vaccine type data, leaving 1,148 participants in the cohort description. For regression analyses, a further 14 (1.2%) participants were excluded due to missing data leaving 1,125 participants. Given the proportion of participants with missing education level (n = 78, 6.9%), these participants were retained as a "not reported" category.

Most participants were aged between 50–70 years (55.2%), 61.3% were women, 14.8% were health-service employees of WBHHS and 24.8% reported attaining education of year 12 or below (Table 1). Among participants receiving BNT162b2 a lower proportion were aged ≥ 50 years compared to those receiving ChAdOx1-S, and 22.2% reported attaining year 12 or below, compared to 30.7% receiving ChAdOx1-S (Table 1).

Overall, 37.6% of participants reported participating in the AusVaxSafety surveillance after their first dose, with similar proportions among those receiving BNT162b2 (36.4%) and ChAdOx1-S (40.5%). A further 9.5% were unsure and 52.1% reported not participating (Table 1). Of participants, 44.8% reported an AEFI, including 43.6% and 47.4% for BNT162b2 and ChAdOx1-S respectively, and 14.6% overall reported taking fever or pain medication around the time of vaccination (BNT162b2: 14%, ChAdOx1-S: 16.1%) (Table 1). Of participants reporting an AEFI, 15% reported missing work, study or normal daily activities (Table 2), with a lower proportion in BNT162b2 (12.1%) than ChAdOx1-S (20.0%) recipients, however this difference was not statistically significant. Of these participants, most reported missing ≤ one day, with a median of two days (IQR 1-3) for BNT162b2 recipients and one day (IQR 1-2) for ChAdOx1-S recipients, while 20% of BNT162b2 recipients and 11.1% of ChAdOx1-S recipients reported being impacted for ≥ four days. Only 3% (n=16) of participants reported needing to seek medical care or advice for symptoms, which did not differ significantly by vaccine type (Table 2).

Types of AEFI reported included local reactions (of total participants: BNT162b2: 30.3%, ChAdOx1-S: 20.7%), headache (BNT162b2: 23%, ChAdOx1-S: 31.9%) and fatigue (BNT162b2: 29.6%, ChAdOx1-S: 19.8%) were the most frequently reported for both vaccines (Figure 1A). Among participants reporting an AEFI, a median of two were reported for both BNT162b2 (IQR 1-3) and ChAdOx1-S (IQR 1-4). Reported AEFI most frequently occurred on Day 1–3 post vaccine (BNT162b2: 62.9%, ChAdOx1-S: 64.7%), followed by the day of vaccination (BNT162b2: 30.7%, ChAdOx1-S: 28.7%) (Figure 1B).

For participation in AusVaxSafety surveillance (Table 3), after multivariable adjustment for age, education and whether an AEFI was reported, participants aged ≥50 years were 36% (95%CI: 4–78%) more likely to participate than those aged <50 years, while there was no significant association with gender, being a health-service employee, or vaccine type. For education, increasing levels of education were associated with lower likelihood of participating in the surveillance, where participants reporting university or

Table 1: Baseline characteristics of study participants.

Characteristic	Overall N=1,148 (%)	BNT162b2 N=800 (%)	ChAdOx1-S N=348 (%)
Age, years			
18–30	77 (6.71)	67 (8.4)	10 (2.9)
31–49	344 (30.0)	331 (41.4)	13 (3.7)
50–70	634 (55.2)	381 (47.6)	253 (72.7)
≥70	92 (8.0)	20 (2.50)	72 (20.7)
Not reported	1 (0.1)	1 (0.1)	0 (0)
Gender			
Female	704 (61.3)	517 (64.6)	187 (53.7)
Male	436 (38.0)	278 (34.8)	158 (45.4)
Not reported	8 (0.70)	5 (0.63)	3 (0.86)
Health-service employee[a]			
No	972 (84.7)	663 (82.9)	309 (88.8)
Yes	170 (14.8)	132 (16.5)	38 (10.9)
Not reported	6 (0.5)	5 (0.6)	1 (0.3)
Education level			
Year 12 or below	285 (24.8)	178 (22.2)	107 (30.7)
Certificate/technical	428 (37.3)	311 (38.9)	117 (33.6)
University or above	353 (30.7)	267 (33.4)	86 (24.7)
Not reported	82 (7.1)	44 (5.50)	38 (10.9)
Reported AusVaxSafety participation			
No	598 (52.1)	431 (53.9)	167 (48.0)
Yes	432 (37.6)	291 (36.4)	141 (40.5)
Unsure	109 (9.5)	72 (9.0)	37 (10.6)
Not reported	9 (0.8)	6 (0.8)	3 (0.9)
Fever medication use[b]			
No	974 (84.9)	683 (85.5)	291 (83.6)
Yes	168 (14.6)	112 (14.0)	56 (16.1)
Unsure	3 (0.3)	2 (0.3)	1 (0.3)
Not reported	3 (0.3)	2 (0.3)	0 (0)
AEFI (first vaccination)			
No	634 (55.2)	451 (56.4)	183 (52.6)
Yes	514 (44.8)	349 (43.6)	165 (47.4)

Notes:
a Health-service employee includes participants working for the Wide Bay Hospital and Health Service;
b: Fever medication use included paracetamol or ibuprofen at the time of vaccination.
Abbreviations: AEFI: adverse event following immunisation.

above were 0.68 (95%CI 0.48–0.95) times less likely to participate than those reporting high school or below. Reporting an AEFI was associated with a non-significant decrease in odds of participating in the surveillance (OR 0.79, 95%CI 0.61–1.02) compared to those who didn't. Sensitivity analysis (Supplementary Table 1) excluding 109 participants who reported they were "unsure" regarding participation in AusVaxSafety did not materially alter the results.

In univariable analyses of factors associated with reporting an AEFI, age, gender and education were significant for both vaccine types, while being a health-service employee was also associated with odds of reporting an AEFI with ChAdOx1-S vaccination (Table 4), and thus were retained in the multivariable model. After multivariable adjustment, women were more likely than men to report an AEFI (BNT162b2: adjOR 2.28, 95%CI 1.67–3.12; ChAdOx1-S: OR 1.85, 95% CI 1.17–2.94) and those with higher levels of education, where participants reporting attaining university or above, compared to those with high school or below were 1.63 (95%CI 1.08–2.45) and 3.98 (95%CI 2.03–7.79) times more likely to report an AEFI for participants receiving BNT162b2 and ChAdOx1-S respectively. Older age (≥50 years) was associated with a significantly lower risk of reporting an AEFI compared to participants aged <50 years (BNT162b2: OR 0.69, 95%CI 0.51–0.93; ChAdOx1-S: OR 0.42, 95%CI 0.10–1.89). Being a health-service employee was associated with a non-significant decrease in risk of reporting an AEFI for BNT162b2 recipients (OR 0.83, 95%CI 0.56–1.24) and non-significant increase in risk of reporting an AEFI for ChAdOx1-S recipients (OR 2.06, 95%CI 0.72–5.91), with a large attenuation in effect size after multivariable adjustment.

Examining the association between age (≥50 vs. <50 years) and odds of reporting an AEFI among other characteristics showed that there was no significant heterogeneity by gender or health-service employee status for those receiving BNT162b2 vaccination. For education status there was significant heterogeneity ($p_{heterogeneity}$=0.02), whereby there was a positive association with age among those reporting University or above (Supplementary Figure 1) and inverse association for other education levels, suggesting the effect of age on odds of AEFI may be modified by education level. Subgroup analyses for ChAdOx1-S recipients showed no significant heterogeneity by gender, education level of health-service employee status (Supplementary Figure 2).

Table 2: Select characteristics among those reporting an adverse event following first dose COVID vaccination (N = 514).[a]

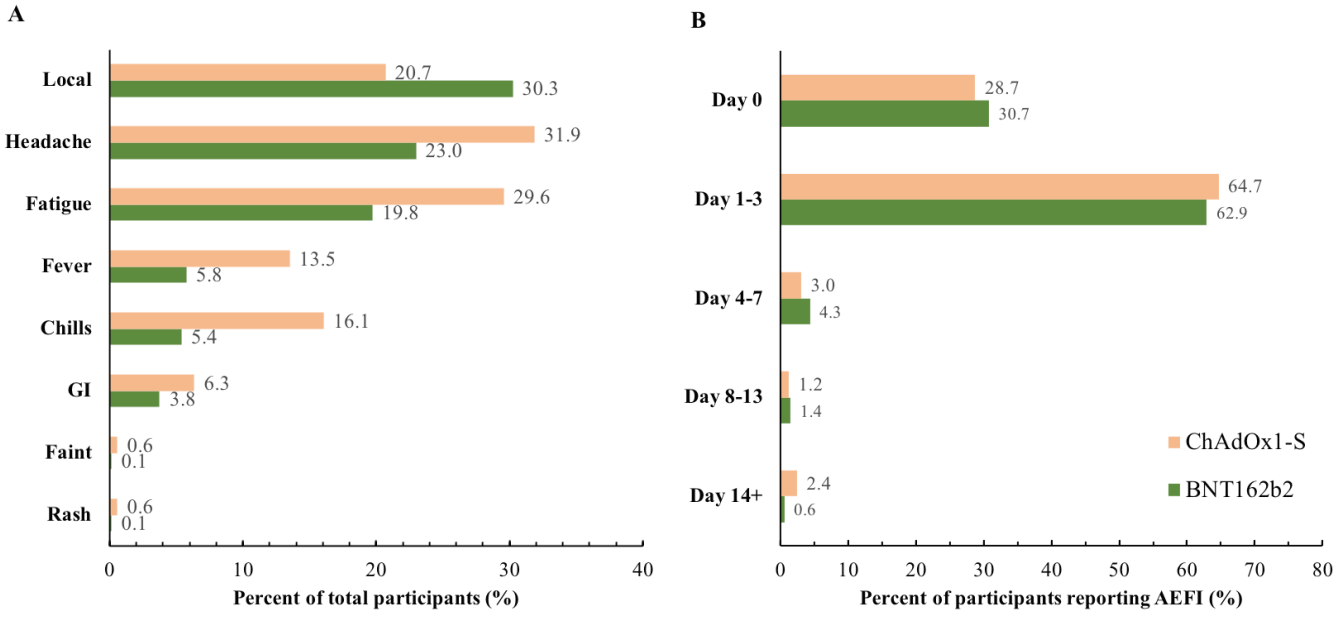
Characteristic	Overall N=514 (%)	BNT162b2 N=349 (%)	ChAdOx1-S N=165 (%)	P-value[a]
Missed work, study or routine activities				0.05
No	425 (82.7)	300 (86.0)	125 (75.8)	
Unsure	2 (0.4)	2 (0.6)	0 (0)	
Not reported	10 (1.9)	3 (8.6)	7 (4.2)	
Yes	77 (15.0)	44 (12.1)	33 (20.0)	
N. days missed (median, IQR)	2 (1–3)	2 (1–3)	1 (1-2)	
Medical assistance sought				
No	483 (94.0)	330 (94.6)	153 (92.7)	0.21
Yes	16 (3.1)	8 (2.3)	8 (4.8)	
Not reported	15 (2.9)	11 (3.2)	4 (2.4)	

Note:
a: Chi-squared test was performed to assess differences in characteristics (missed work, study or routine activities; medical assistance sought) by vaccine type.

Discussion

This study conducted in a regional community in Queensland, found that after first dose COVID-19 vaccination among 1,148 participants, approximately four in 10 people participated in the AusVaxSafety active surveillance, while ≈45% of participants reported AEFI, most frequently headache, local reactions and fatigue. Reported COVID-19 vaccination impacts on work, study

Figure 1: Adverse events reported post COVID-19 vaccination – type (A) and timing (B) of adverse events post vaccination.



and routine activities warrant consideration in workforce planning and policy in regional and remote areas with 15% of those reporting AEFI requiring time off work or routine activities.

To our knowledge, factors associated with participation in COVID-19 vaccine AEFI surveillance have not been described to date, and there is paucity of evidence relating to factors associated with participation in safety surveillance of other vaccines in a non-trial setting. In relation to surveillance more broadly, findings have been mixed. One study[13] among 1,400 pregnant women in the United States of America (USA) invited to enrol in an influenza surveillance program, reported that both commencing surveillance and completing more surveillance reports for influenza varied significantly by study site, race (higher in white race), ethnicity (higher in non-Hispanic) and if women had children at home (higher in women with no children at home) after multivariable adjustment. This could relate to geographic differences in socioeconomic status by site, while having children at home could relate to both time factors and past experience with influenza vaccination in pregnancy. One study[14] in a rural town in South Africa, found that participants of younger age and male gender were less likely to participate in HIV surveillance, while another study[15] reviewing the evidence on factors influencing patient participation and engagement in safety reporting more broadly, suggested younger, female and more educated participants, along with those with greater perceived vulnerability to safety incidents were more likely to participate than their counterparts.

In our study, we hypothesise that the trend observed with both higher education and younger age being associated with reduced likelihood of participating in surveillance may relate to convenience, and perceived risk of both COVID-19 vaccination and COVID-19. Older participants are more likely to be retired, less likely to have reached university level education and may have more time to complete the survey. Additionally, in the context of public concern surrounding ChAdOx1-S and TTS (which was used primarily in participants aged ≥60 years,

Table 3: Factors associated with participation in AusVaxSafety survey in 1,125 participants.

Characteristic	Participation in AusVaxSafety survey n=427 (%)	unadjOR (95%CI)	adjOR (95%CI)[a]
Age (years)			
<50 (ref)	131 (31.6)	1.00	1.00
≥50	296 (41.6)	1.54 (1.19–1.99)***	1.36 (1.04–1.78)*
Gender			
Male (ref)	170 (39.4)	1.00	1.00
Female	257 (37.0)	0.90 (0.71–1.16)	0.98 (0.76–1.26)
Education			
High school or below (ref)	119 (42.7)	1.00	1.00
Certificate/technical	167 (39.8)	0.89 (0.65–1.21)	0.94 (0.69–1.28)
University or above	105 (30.2)	0.58 (0.42–0.81)**	0.68 (0.48–0.95)*
Not reported	36 (46.2)	1.15 (0.70–1.91)	1.15 (0.69–1.91)
Health-service employee			
No (ref)	372 (38.8)	1.00	1.00
Yes	55 (32.9)	0.77 (0.55–1.10)	0.97 (0.67–1.40)
AEFI reported			
No (ref)	256 (39.7)	1.00	1.00
Yes	171 (35.6)	0.73 (0.57–0.93)*	0.79 (0.62–1.01)
Vaccine type			
ChAdOx1-S (ref)	140 (41.1)	1.00	1.00
BNT162b2	287 (36.6)	1.21 (0.93–1.56)	1.03 (0.77–1.38)

Notes:
a: Adjusted for age, education and AEFI reported
**p<0.05, **p<0.01, ***p<0.001*
Abbreviations: unadjOR: unadjusted odds ratio; adjOR: adjusted odds ratio; AEFI: adverse event following immunisation

Table 4: Factors associated with reporting an AEFI post first dose COVID-19 vaccination in 1,125 participants.

Characteristic	BNT162b2, n = 784			ChAdOx1-S, n = 341		
	AEFI reported (n, %)	unadjOR (95%CI)	adjOR (95%CI)[a]	AEFI reported (n,%)	unadjOR (95%CI)	adjOR (95%CI)[b]
Age (years)						
<50 (ref)	192 (49.1)	1.00	1.00	20 (87.0)	1.00	1.00
50+	150 (38.2)	0.64 (0.48–0.85)**	0.69 (0.51–0.93)*	143 (55.0)	0.12 (0.04–0.42)***	0.42 (0.10–1.89)
Gender						
Male (ref)	85 (30.9)	1.00	1.00	62 (39.7)	1.00	1.00
Female	257 (50.5)	2.28 (1.67–3.11)***	2.28 (1.67–3.12)***	101 (54.6)	1.82 (1.18–2.81)**	1.85 (1.17–2.94)**
Education						
High school/ below (ref)	64 (36.6)	1.00	1.00	34 (32.7)	1.00	1.00
Certificate/technical	128 (42.0)	1.25 (0.86–1.84)	1.25 (0.85–1.86)	52 (45.2)	1.70 (0.98–2.95)	1.84 (1.04–3.23)*
University or above	135 (51.5)	1.84 (1.25–2.73)**	1.63 (1.08–2.45)**	62 (72.1)	5.32 (2.85–9.93)***	3.98 (2.03–7.79)***
Not reported	15 (35.7)	0.96 (0.48–1.94)	0.96 (0.47–1.95)	15 (41.7)	1.47 (0.67–3.20)	1.65 (0.75–3.64)
Health-service employee						
No (ref)	283 (43.3)	1.00	1.00	133 (43.8)	1.00	1.00
Yes	59 (45.4)	1.09 (0.75–1.59)	0.83 (0.56–1.24)	30 (81.1)	5.51 (2.35–12.94)***	2.06 (0.72–5.91)

Notes:
a Adjusted for age, gender and education
b Adjusted for age, gender, education and, for ChAdOx1-S, health-service employee status.
**p<0.05, **p<0.01, ***p<0.001*
Abbreviations: unadjOR: unadjusted odds ratio; adjOR: adjusted odds ratio; AEFI: adverse event following immunisation

and the greater risk COVID-19 poses to older people), such participants may be more inclined to participate in vaccine safety surveillance.

Our findings about type and frequency of AEFI, and higher prevalence in younger participants, are consistent with a large existing body of literature, including the initial clinical trial reports and subsequent data published on vaccine use.[16-18] The observation that participants with higher education were more likely to report an AEFI may be related to higher health literacy than their counterparts. Moreover, in this research, younger participants in Phase 2a of the vaccine rollout were predominantly healthcare and frontline workers who may also have higher health literacy than the general population of a comparable age. Further research with greater power is required to further investigate any potential effect modification of education level on the association between age and AEFI. Our finding that younger and more educated participants were more likely to report AEFI, but less likely to participate in safety surveillance compared to their older and less educated counterparts, is of particular concern, whereby surveillance programs may be under-reporting AEFI in this age group due to non-participation.

Although the primary concern worldwide regarding COVID-19 and worker absenteeism has been related to the impacts of infection and disease, an important consideration in Wide Bay to date has been related to impacts of COVID-19 vaccination and absenteeism. Two studies[19,20] in the USA have reported the impact of COVID-19 vaccination on workplace absenteeism. One study[19] of healthcare personnel (HCP) in Phase one of their COVID-19 vaccination rollout, found that among ≈4,000 participants (12% response rate) 5% and 20% of participants required an average of 1.7 days and 1.4 days of unanticipated leave post-first and -second dose vaccination respectively. Another study[20] explored rates of workplace absence following receipt of COVID-19 vaccine in HCP, finding that 4.1% of COVID-19 vaccinations generated a short-term disability (STD) claim for lost work due to side effects, and found significant geographic differences in STD suggesting cultural and staffing factors may impact utilisation of STD claims. AusVaxSafety surveillance (as of 12 Dec 2021) reported that on Day three post-vaccination, among adult participants receiving ChAdOx1-S, 19% and 5% reported missing work, study or routine duties for their first and second dose respectively, usually due to lethargy, headache or joint pain.[21] For participants receiving BNT162b2, 8% and 21% of participants after their respective first and second dose reported missing work, study or routine duties for the same symptoms[22], and most participants reported missing one day or less for both BNT162b2 and ChAdOx1-S.[21,22]

While our findings are comparable to this, considering the distribution of days missed is important in regional and rural settings, as even modest increases in absence from the healthcare and wider workforce may have a significant impact on service provision compared to urban areas. In our study among those requiring time off work due to an AEFI, 1 in 5 participants receiving BNT162b2 and 1 in 10 receiving ChAdOx1-S needed at least four days off work or routine activities. Workplace planning and policy should take this into account and consider approaches to minimise disruption to the service provision, such as ensuring staff surge capacity is available around the time of vaccination, particularly in single doctor rural towns, staggered vaccination of key departments and access to specialised leave. Possible strategies to reduce workforce impacts of include education around expected side-effects post-vaccine and when it is safe to attend work, consultation sessions with staff and further research into interaction between broader workforce fatigue and COVID-19 vaccination related absenteeism.[20]

The strengths of our study include the generation of local data from a regional community, conducted in a pragmatic manner involving many local staff, with a reasonably high uptake facilitated by use of a short survey during the participant's post-vaccination monitoring period. We have a large study sample size and our survey included questions that align with questions used in AusVaxSafety survey. Making local data available can help to improve consumer and clinician confidence in COVID-19 vaccination,[23] which may be particularly relevant in areas where vaccination rates are lagging. There are several limitations of our study. First, we report response to first dose COVID-19 vaccination only, whereas surveillance programs (including the AusVaxSafety surveillance survey itself) conducted concurrently to our study, report both doses, with greater severity and frequency of AEFI after second dose mRNA vaccines. Second, our findings are impacted by differential recall bias, whereby participants receiving BNT162b2 may more accurately recall AEFI several weeks after first dose, compared to their counterparts receiving ChAdOx1-S, who are recalling events up to several months after their first dose. In contrast, AusVaxSafety receives reports usually at day three, day six and week six post-vaccination, with the data day three post-vaccination publicly available and referenced in this paper. Third, participants experiencing more severe AEFI and/or with greater health literacy and/or with greater concern about COVID-19 vaccination, may be more likely to report AEFI. This may be particularly relevant to participants receiving CHADOX1-S vaccination due the widespread concern in the media at the time of this study regarding TTS.[24] We also may have missed participants who did not present for second vaccination due to severe AEFI post-first vaccine, and there may be systematic differences between respondents and non-respondents to our survey. Four, this survey captures a cross-section of participants in Phase 2a and above – people in subsequent phases of the rollout and those who took longer to come forward for vaccination (particularly those being vaccinated after introduction of the mandatory vaccine policies) may report AEFI and impact on daily activities differently. Finally, this research was performed in a pragmatic manner in a local community setting, with at least one study investigator performing data entry of paper-based surveys, however ideally this would be performed by multiple people.

In summary, despite participants reporting a relatively low rate of participation in AusVaxSafety surveillance, we found that COVID-19 related AEFI to first dose vaccination were broadly similar to that described in clinical trial data and AusVaxSafety surveillance. Impacts of COVID-19 vaccination on missed work, study or routine duties should be contextualised in the planning of vaccine rollouts in regional or remote workforces, and further research is warranted into investigating factors associated with participation in COVID-19 vaccine safety surveillance.

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Supporting Information

Additional supporting information may be found in the online version of this article:

Supplementary Table 1: Factors associated with participation in AusVaxSafety surveillance excluding participants reporting "unsure".

Supplementary Figure 1: Subgroup analyses comparing participants aged ≥50 and <50 years and odds of reporting an adverse event following immunization (AEFI) with BNT162b2.

Supplementary Figure 2: Subgroup analyses comparing participants aged ≥50 and <50 years and odds of reporting an adverse event following immunization (AEFI) with ChAdOx1-S.