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Evaluation of mortality risk after COVID-19 vaccination, Utah 2021

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ABSTRACT

Introduction: In order to evaluate trends in death after COVID-19 vaccination we analyzed the timing of death relative to vaccination date and the causes of death in vaccinated Utahns in 2021.
Methods: We matched people in the Utah immunization registry with documented COVID-19 vaccinations between December 18, 2020 and December 31, 2021 to Utah's 2021 vital statistics death records. Vaccinated people were categorized as having one, two, or ≥ three COVID-19 vaccine doses in a time-updated metric. We examined crude mortality rates by dosing groups in two-week intervals for all deaths, and by COVID-19 versus non-COVID-19 causes, within the 44 weeks following receipt of the most recent vaccine.
Results: We identified 2,072,908 individuals who received at least one dose of COVID-19 vaccine of whom 10,997 died in 2021. Only 17.5 % of the total vaccinated population was age 65+, while 80.9 % of those who died were over 65. In the four weeks following the first or second vaccination, all-cause mortality was low and then stabilized for the remainder of the evaluation period at a bi-weekly average of 33.0 and 39.0 deaths/100,000 people for one and two doses, respectively. Typical seasonal variation in death was observed among those with two doses. Small sample size precluded analysis of those with ≥ three doses, but trends were similar.
Conclusions: Mortality rates in the 44 weeks following the COVID-19 vaccination did not show trends suggesting an increase in mortality related to COVID-19 vaccination, reinforcing the safety of COVID-19 vaccines. This represents an accessible approach for local evaluation.

1. Introduction

Vaccines against COVID-19 are highly effective at preventing deaths and are a critical tool to prevent severe disease [1–3]. Data from vaccine safety systems show acceptable vaccine safety profiles for currently available U.S. vaccines against COVID-19 [4]. Yet vaccine distrust in the general population and among policymakers continues, in part due to concerns of severe adverse reactions, long-term side effects, and a lack of data perceived to be trustworthy [5–7].

The Centers for Disease Control and Prevention (CDC) monitors vaccine safety using a number of different systems, including the Vaccine Adverse Event Reporting System (VAERS), the Vaccine Safety Datalink, and v-safe [8]. Data from these systems are evaluated on an ongoing basis and have identified a number of safety signals for COVID-19 vaccines, including menstruation disorders, thrombosis with thrombocytopenia syndrome, and myocarditis [9–12]. One specific area of ongoing attention is related to cardiovascular side effects. Nationwide analysis using VAERS data found an increased risk of myocarditis following the administration of mRNA vaccines [12]. The vast majority of these cases respond well to treatment and recover fully [13]. An October 2022 announcement from the Florida Department of Health observing an increase in cardiac death in young men who received the mRNA vaccines gained much attention [14]. Analyses in other states and by other organizations have not found a similar risk of death [15–17].

These vaccine safety data systems are robust; however, it is also important for local authorities to understand data from their own jurisdictions. Data from state and local public health surveillance systems directly influence local policy and reviewing this data for safety signals is vital to assure local trust. However, in sub-national populations, only a small number of people will experience rare

Abbreviations: CDC, Centers for Disease Control and Prevention; VAERS, Vaccine Adverse Event Reporting System; USIIS, Utah Statewide Immunization Information System; DOHMPI, Department of Health and Human Services Master Person Index.

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vaccine adverse events. Analyses of local safety data can be challenging and have not been widely implemented.

Here we used routinely collected immunization and death data to examine mortality trends following the receipt of a COVID-19 vaccination in Utah. We assessed the time interval from vaccination to death for all vaccinated people in 2021 and estimated COVID-19 and non-COVID-19 crude mortality rates by the number of vaccine doses received.

2. Methods

2.1. Study population

We included all Utah residents who were vaccinated from December 18, 2020 through December 31, 2021.

2.2. Immunization records

Utah Statewide Immunization Information System (USIIS) is a voluntary, secure, confidential, electronic immunization registry that enables healthcare providers to submit immunization records for vaccinations administered in Utah, consolidating those from multiple providers into one patient-based record. Name, date of birth, sex, zip code, and date(s) of COVID-19 vaccination are routinely collected. We included records of individuals with one to four doses of COVID-19 vaccinations, of which at least one dose was administered between December 18, 2020 and December 31, 2021.

2.3. Mortality data

The Utah Office of Vital Records and Statistics maintains a record of all deaths that take place in Utah. Death certificates include information on the person's name, age, race, sex, zip code, date of death, and underlying cause of death. We used records of deaths that occurred in 2021 among Utah residents for our analysis. We considered possible immediate effects of the vaccine by evaluating deaths in the first 4 weeks post-vaccination as well as the possible long-term effects over the following months.

2.4. Record linkage

We linked immunization and death data using the Department of Health and Human Services Master Person Index (DOHMPI) system. The DOHMPI provides ongoing linkage of multiple Utah public health data sources using a proprietary hybrid (probabilistic and deterministic) method to match on demographic information [18]. This linking algorithm is flexible enough to accommodate typos in the data fields and still produce an accurate match. Immunizations data and Death Registry data are existing data sources currently integrated into DOHMPI and the linkages between the two data sets are established.

After reviewing the linked data, we curtailed our analysis to death within 44 weeks of the last vaccine due to small sample size and the observed low likelihood of the death being attributable to vaccination.

2.5. Statistical analysis

We created distinct populations for analysis based on the number of COVID-19 vaccine doses the person had received. We calculated the crude mortality rate among people with one, two, and three or four doses in two-week increments following the date of vaccination. This mortality rate was calculated using a denominator consisting of the people who were at risk of death in each two-week period post-vaccine dose (i.e., alive during the evaluation period). People moved between dose groups when they received additional doses. For example, a person was counted in the one dose group for as long as they had received exactly-one dose but then moved into the two dose group as soon as they received their second dose. Similarly, they moved to the three dose group when they received their third dose. Numerators were the number of people in the vaccine dose group who died during that two-week period. We used the Clopper-Pearson exact method to calculate 95 % confidence intervals using the beta.inv function in Microsoft Excel (Redmond, WA). We tested for statistically significant differences between mean rates in different time periods using conditional binomial tests.

We calculated rates for all deaths and by COVID-19 or non-COVID-19 cause of death. We used ICD-10 code U07.1 to determine the underlying cause of death as COVID-19. Additionally, we categorized the cause of death according to the National Center for Health Statistics categories [19]. We compared the 10 leading causes of death among vaccinated people in 2021 to the 10 leading causes of death among Utahns in 2019 and 2020 when the vaccine was largely unavailable.

This project was determined by the Utah Department of Health Ethics/Institutional Review Board to be non-research.

3. Results

3.1. Population description

USIIS included 2,072,908 residents who received at least one dose of COVID-19 vaccine between December 18, 2020 and December 31, 2021. The majority of vaccinated people were female (51.5 %, n = 1,068,269) and a plurality were aged 18–34 (28.2 %, n = 584,630) (Table 1). Relatively few were $\geq$ 65 years (17.5 %, n = 362,509).

In 2021, 22,124 deaths were recorded among Utah residents, of which 10,997 were matched to immunization records of people receiving between one and four doses of the COVID-19 vaccine. The majority of deaths were among males (50.7 %, n = 5,570), people over the age of 65 (80.9 %, n = 8,901), and people identified as white (95.8 %, n = 10,423), and non-Hispanic (94.7 %, n = 10,368). Deaths attributed to COVID-19 accounted for 4.2 % (n = 460) of all deaths among vaccinated people in 2021; 6.3 % (n = 136) of deaths following a single dose and 3.8 % (n = 297) of deaths following a second dose.

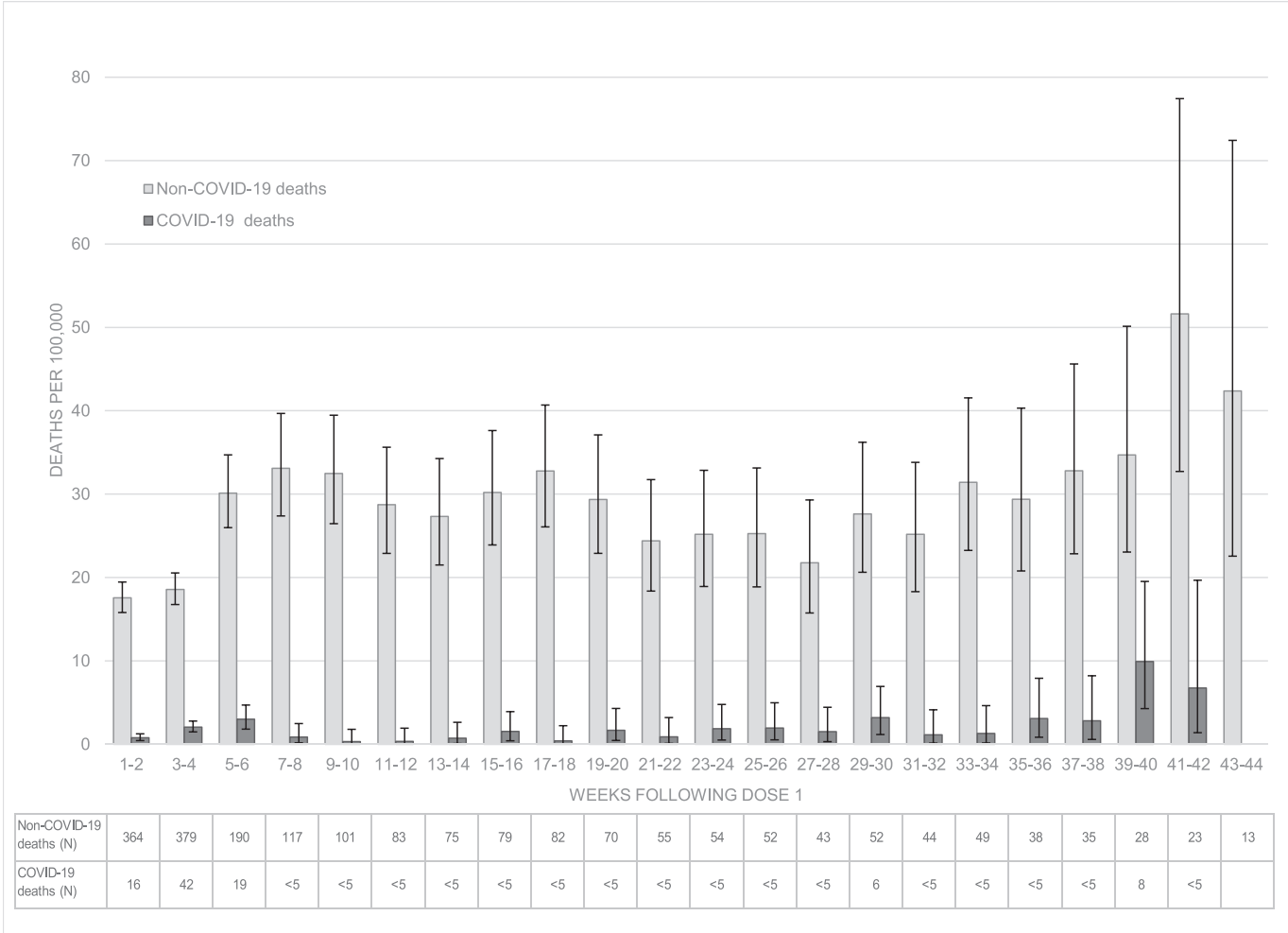
3.2. Deaths observed following each dose of COVID-19 vaccine

The population at risk (i.e., the denominator) among those that had received one dose of COVID-19 vaccine was over two million individuals for the first four weeks and then dropped dramatically after that as most people received the second dose in their primary COVID-19 series three to four weeks after the first dose. For the remaining weeks of the evaluation period, the dose one population at risk declined gradually. Among those who received exactly-one dose of COVID-19 vaccine, 2,160 deaths occurred in the 44 weeks following vaccination. The overall bi-weekly mortality rate in those people who received only one vaccine dose was 31.7 deaths per 100,000 population (Fig. 1). Very few deaths (n = 134, 6.2 %) were attributed to COVID-19; the large majority (93.7 %) were attributed to other causes. Mean mortality during the two bi-weekly periods immediately following vaccination (19.5/100,000 vaccinated people) was lower than that observed in the following 40 weeks (33.0/100,000, $p < 0.0001$). In addition, non-COVID-related mortality was lower (bi-weekly mean 18.1 deaths/100,000) in the four

Table 1
Characteristics of vaccinated Utahns overall and among those who died, Utah 2021.

	Vaccinated Utahns (n = 2072908)		Dead among vaccinated Utahns (n = 10997)	
Sex*	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Female	1,068,269	51.59	5427	49.35
Male	1,002,395	48.41	5570	50.65
Age group (years)				
0–17	273,550	13.20	29	0.26
18–34	584,630	28.20	174	1.58
35–49	470,909	22.72	488	4.44
50–64	381,310	18.39	1405	12.78
≥ 65	362,509	17.49	8901	80.94
Race*				
American Indian	24,227	1.27	123	1.13
Asian	66,159	3.47	144	1.32
Black	26,018	1.37	85	0.78
Pacific Islander/Native Hawaiian	22,086	1.16	102	0.94
White	1,766,681	92.73	10,423	95.83
Hispanic Origin*				
Yes	253,388	12.97	576	5.26
No	1,700,175	87.03	10,368	94.74

* Less than 1% were missing or unknown among vaccinated persons overall and 0% missing among those who died.
** Race was missing for 8% of vaccinated Utahns and 1% of those who died.
*** Ethnicity was missing for 5 % of vaccinated Utahns and < 1 % of those who died.



	1-2	3-4	5-6	7-8	9-10	11-12	13-14	15-16	17-18	19-20	21-22	23-24	25-26	27-28	29-30	31-32	33-34	35-36	37-38	39-40	41-42	43-44
Non-COVID-19 deaths (N)	364	379	190	117	101	83	75	79	82	70	55	54	52	43	52	44	49	38	35	28	23	13
COVID-19 deaths (N)	16	42	19	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	6	<5	<5	<5	<5	8	<5	

Fig. 1. COVID-19 and non-COVID-19 mortality rates in two-week intervals among people with one COVID-19 vaccine dose, Utah 2021.

weeks after vaccination compared to the following 40 weeks (bi-weekly mean 30.8 deaths/100,000, p < 0.0001).

Most individuals who received one dose of COVID-19 vaccine went on to receive a second dose and were switched into the two dose follow-up group. This population at risk remained large throughout the first 28 weeks of the evaluation period with a two-week average of approximately 1.5 million individuals and declined rapidly after that. During the 44-week follow-up period 7,779 deaths occurred (an average of 37.1 per 100,000 people for each two-week period) among individuals who received two doses of COVID-19 vaccine. There were on average 18.8 deaths bi-weekly per 100,000 population in the first four weeks; significantly lower than the mean bi-weekly mortality rate observed in the next 40 weeks (39.0/100,000, p < 0.0001). Like the one dose group, few deaths caused by COVID-19 disease were observed (3.8 %, n = 293) (Fig. 2). Mortality attributable to both COVID-19 and non-COVID-19 causes increased in weeks 35–44 following vaccination (p < 0.0001).

Many fewer individuals in this population received three or four doses of COVID-19 vaccine. The population at risk after dose three was only 20 % of the population at risk after dose two through the first 14 weeks of the examination period and declined rapidly thereafter. Only 8.9 % of the deaths in this evaluation occurred in individuals who had three or four doses of COVID-19 vaccine. Trends in mortality rates were similar to those with only one or two doses, remaining relatively stable throughout follow-up (data not shown) and comprising relatively few COVID-19 cases (n = 27, 2.8 %).

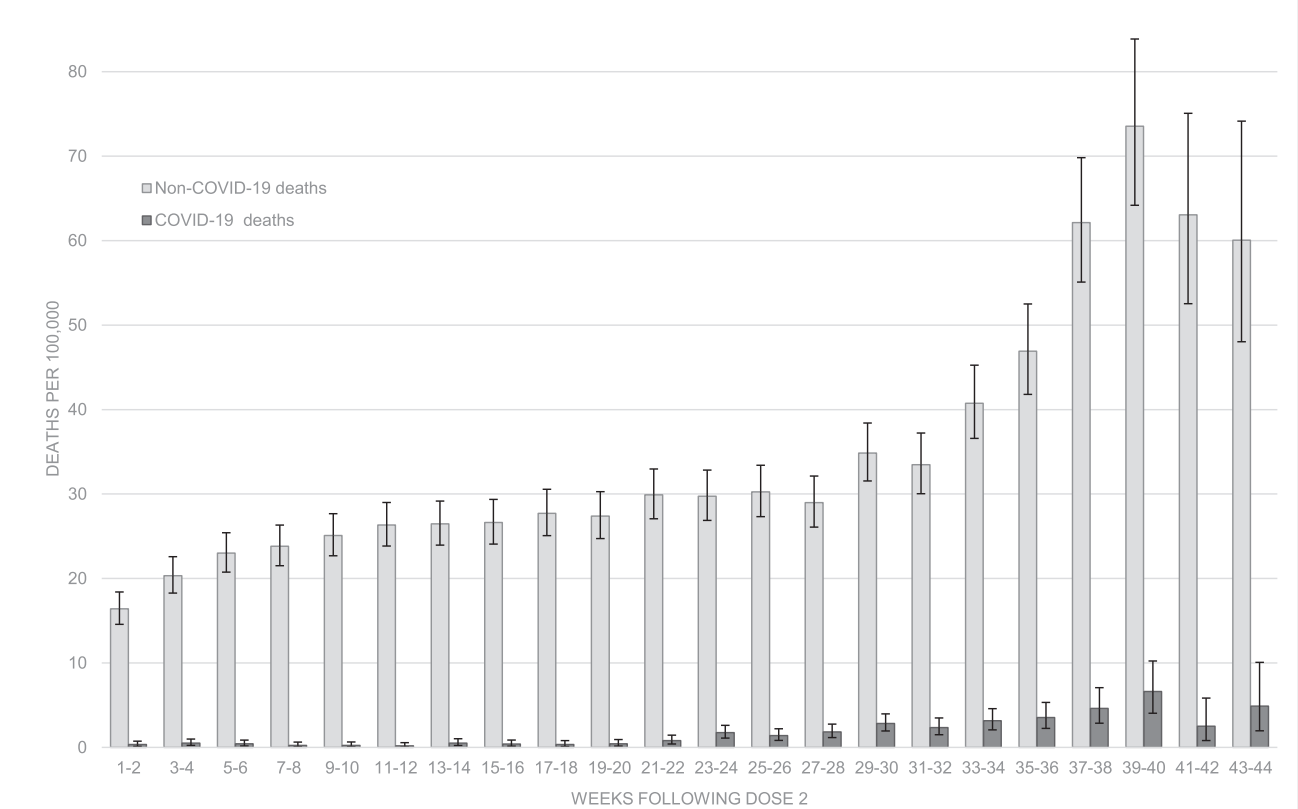
3.3. Causes of death after vaccination

The top causes of death in Utah were due to the same etiologies regardless of the year (pre-pandemic or pandemic) or vaccine status when COVID-19 is excluded (Table 2). Overall, the most common causes of death were diseases of the heart and malignant neoplasms. The COVID-19 mortality rate was 42.0 per 100,000 people in 2020 compared to 22.2 per 100,000 vaccinated people in 2021, dropping in rank from 4 to 6.

Heart disease was rarely the primary cause of death in young adults, but these deaths did occur. From 2017 to 2020, there were an average of 69 heart disease-related deaths among 18–39 year old Utahns, of which 63 % were among males. Among 2379 deaths caused by diseases of the heart among the vaccinated in 2021, only 27 (1.1 %) were among people 18–39 years; 21 (78 %) in men and 6 (22 %) in women. These heart disease-related deaths in young adults did not show any time association with the vaccine administration being distributed across the 44 weeks of follow-up; 4 occurred within 4 weeks of receipt of vaccine.

4. Discussion

In the first year of COVID-19 vaccine delivery in Utah, non-COVID-19-related mortality rate remained stable among the vaccinated population. Importantly, there was no increase in mortality observed either immediately or in the months following administration of the COVID-19 vaccine. In addition, we did not find an



	1-2	3-4	5-6	7-8	9-10	11-12	13-14	15-16	17-18	19-20	21-22	23-24	25-26	27-28	29-30	31-32	33-34	35-36	37-38	39-40	41-42	43-44
Non-COVID-19 deaths (N)	290	352	384	387	400	411	406	399	402	384	406	393	390	363	407	343	349	304	282	222	126	86
COVID-19 deaths (N)	6	9	7	<5	<5	<5	8	6	5	6	11	23	18	23	33	24	27	23	21	20	5	7

Fig. 2. COVID-19 and non-COVID-19 mortality rates in two-week intervals among people with two COVID-19 vaccine doses, Utah 2021.

Table 2
Leading 10 causes of death in Utah among vaccinated persons in 2021 and overall in 2019 and 2020.

All deaths, Utah, 2019			All deaths, Utah, 2020			Deaths among vaccinated Utahns, 2021		
Rank	**Cause of death**	**Crude mortality rate, deaths per 100,000 population**	**Rank**	**Cause of death**	**Crude mortality rate, deaths per 100,000 population**	**Rank**	**Cause of death**	**Rate per 100,000 population among the vaccinated**
1	Diseases of heart	121.2	1	Diseases of heart	130.9	1	Diseases of heart	114.8
2	Malignant neoplasm (cancer)	102.7	2	Malignant neoplasm (cancer)	106.4	2	Malignant neoplasm (cancer)	84.0
3	Unintentional injuries	40.6	3	Unintentional injuries	45.0	3	Alzheimer's disease	29.4
4	Alzheimer's disease	30.6	4	COVID-19	42.0	4	Unintentional injuries	28.7
5	Cerebrovascular diseases	28.5	5	Alzheimer's disease	34.3	5	Cerebrovascular diseases	23.0
6	Chronic lower respiratory diseases	26.3	6	Chronic lower respiratory diseases	28.6	6	COVID-19	22.2
7	Diabetes mellitus	21.6	7	Cerebrovascular diseases	28.2	7	Diabetes mellitus	22.1
8	Intentional self-harm (suicide)	20.4	8	Diabetes mellitus	23.9	8	Chronic lower respiratory diseases	22.0
9	Nephritis and nephrosis	11.1	9	Intentional self-harm (suicide)	20.0	9	Nephritis and nephrosis	10.5
10	Parkinson's disease	9.4	10	Nephritis and nephrosis	11.2	10	Nutritional deficiencies	10.5

increase in cardiac mortality in young men. These findings reinforce the nationally established safety of COVID-19 vaccine. In 2021, only 460 deaths were due to COVID-19 infection in this vaccinated population of over 2 million, while more than 2,000 COVID-19 deaths were recorded in the unvaccinated population of approximately 1.1 million individuals [19].

For people who received a single dose of COVID-19 vaccine, mortality rates were stable throughout the 10 months following vaccine receipt. For those who received two doses of COVID-19 vaccine, similar levels of non-COVID-19 mortality were seen for the first eight months of follow-up, after which an increase in overall mortality was observed. On further analysis we found that this increase coincided with the onset of the winter season, approximately-eight months after peak vaccine uptake in April 2021. Evaluation of data from prior years found that deaths routinely increased around this same time period and are likely due to a variety of factors including seasonal variation in viral transmission and air quality. There was also a small increase in the COVID-19 mortality rate during this period, which coincides with the Delta and Omicron waves and possibly waning vaccine-induced immunity.

Unsurprisingly, few deaths caused by COVID-19 were observed in the vaccinated population. Overall Utah's COVID-19 mortality in 2021 was recorded as 2,447 deaths [19]. Only 460 of those deaths matched vaccine records in our matching procedure. Deaths caused by COVID-19 disease represented only 4.2 % of all deaths among vaccinated people in 2021; 6.3 % for deaths following a single dose and 3.8 % for deaths following a second dose. For comparison, deaths caused by COVID-19 disease represented 27.2 % of deaths among unvaccinated people in Utah in 2021. This finding underscores the established effectiveness of currently available vaccines at preventing death from COVID-19 disease [1–3].

The leading causes of death observed in this analysis among the vaccinated Utah population in 2021 did not differ substantially from leading causes of death for the entire population in Utah for 2019 with the notable exception of deaths from COVID-19. The top causes of death became even more similar in 2020, when COVID-19 deaths appear, but the vaccine was not available [20]. The similarities of ranked causes of death in these groups provide additional confidence that widespread administration of COVID-19 vaccines did not appear to have an impact on mortality trends. In addition, we did not observe a difference in cardiac mortality for young adult men, differing from what was reported by Florida in October 2022.

This work is an example of locally driven data analyses that are particularly helpful to state and local health departments. While national data is essential, local citizens, media, and politicians may believe that national data is not representative of their own population. The results of this analysis provided an additional level of reassurance regarding vaccine safety that was needed in Utah and has helped Utah promote COVID-19 vaccination in accordance with federal guidance. Quality surveillance data and epidemiologically sound analyses in conjunction with active feedback loops between policy makers and public health officials are essential for the protection and promotion of sound public health policy. Our data structure and formulas are available in Supplemental Appendix 1.

4.1. Strengths and limitations

Our evaluation has several strengths. We utilized well-developed immunization and vital statistics registries with built in data quality control systems, providing comprehensive immunization and mortality data for Utah residents. Additionally, given the public health importance of COVID-19, determinations of COVID-19 as the cause of death were carefully adjudicated by the Office of Vital Records and Statistics so we have high confidence they are true COVID-19 deaths. Finally, this analysis was accomplished using data routinely collected in many state and local health departments. We provide a low-barrier method others can use to provide locally derived data on mortality trends after COVID-19 vaccination.

There are also several limitations. First, our analysis uses data from two established surveillance systems so there is limited ability to control for confounding and data quality and completeness can vary. For these analyses, the number of doses a person received

is probably undercounted since additional doses would not be captured when a person moves in or out of the state, potentially inflating the denominator primarily in the one dose group. Second, we did not manually verify matches across the death and vaccine databases and there may be false matches. Compared to a separate disease surveillance process that involved manual review, we identified approximately 40 additional COVID-19 deaths among vaccine breakthrough cases. However, there is unlikely to be any systematic bias over time that would impact our findings. Third, people vaccinated in the last two weeks of December 2021 would not have a full two weeks of time at risk and therefore could inflate the numerator (deaths) without having an opportunity to contribute to the denominator (time at risk). This is of limited concern as only 2.7 % (n = 55,489) of people received their first or second vaccine during this two-week time period. An additional 78,009 people received their third shot (12.4 % of all booster shots) during this period, however this had limited impact on our analysis as we focused on deaths after the first and second dose. Fourth, we were not able to examine rare outcomes due to small sample size. Finally, small numbers and lack of data on co-morbidities limited our ability to examine waning immunity among those with one or two doses after 44 weeks and among those with three doses after about 20 weeks.

5. Conclusions

Our data demonstrates that people were not at increased risk of COVID-19 or non-COVID-19 death over a 44 week period following COVID-19 vaccine receipt. COVID-19 deaths were rare in this vaccinated population and the COVID-19 mortality rate was nearly half the COVID-19 mortality among unvaccinated people in 2020. The methodology used for these analyses is straightforward and uses data widely available at state and local levels.

6. Conflict of interest and funding statement

The conclusions, findings, and opinions expressed by the authors do not necessarily reflect the official position of the Utah Department of Health and Human Services, the CDC Foundation, and other affiliated institutions. The authors report no conflicts of interest in connection with the evaluation reported in this article. The authors are employees of the Utah Department of Health and Human Services and the CDC Foundation and completed this work as part of their regular job duties. No other funding was obtained for this study.

7. Financial disclosure

No financial disclosures are reported by the authors of this paper.

Data availability

The data that has been used is confidential.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.vaccine.2023.03.072.

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