

Exhibit 541

COVID-19 Illness and Vaccination Experiences in Social Circles Affect COVID-19 Vaccination Decisions

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Article

COVID-19 Illness and Vaccination Experiences in Social Circles Affect COVID-19 Vaccination Decisions¹

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Abstract

Policymakers have communicated that COVID-19 vaccination programs need to be accepted by a large proportion of the population to allow life to return to normal. However, according to the Center for Disease Control and Prevention, about 31% of the United States population had not completed the primary vaccination series as of November 2022 and since that time booster uptake has declined. The primary aim of this work is to identify factors associated by American citizens with the decision to be vaccinated against COVID-19. The proportion of fatal events from COVID-19 vaccinations was also estimated and compared with potential fatalities reported in the Vaccine Adverse Events Reporting System. An online survey of COVID-19 health experiences was conducted to collect information regarding reasons for and against COVID-19 inoculations, including experiences with COVID-19 illness and COVID-19 inoculations by survey respondents and their social circles. The survey was completed by 2,840 participants between December 18 and 23, 2021. Logit regression analyses were carried out to identify factors influencing the likelihood of being vaccinated. Those who knew someone who experienced a health problem from COVID-19 were more likely to be vaccinated (OR: 1.309, 95% CI: 1.094-1.566), while those who knew someone who experienced a health problem following vaccination were less likely to be vaccinated (OR: 0.567, 95% CI: 0.461-0.698). Thirty-four percent (959 of 2,840) reported that they knew at least one person who experienced a significant health problem due to the COVID-19 illness. Similarly, 22% (612 of 2,840) indicated that they knew at least one person who experienced a health problem following COVID-19 vaccination. With these survey data, the total number of fatalities due to COVID-19 inoculation may be as high as 289,789 (95% CI: 229,319 – 344,319). The large difference in the possible number of fatalities due to COVID-19 vaccination that emerges from this survey and the available governmental data should be further investigated.

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Keywords

Pandemic, COVID-19, return to normal, SARS-CoV-2, survey, vaccination

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1 Introduction

Around the world, policymakers have made clear to their fellow citizens that the SARS-CoV-2: Severe acute respiratory syndrome coronavirus (COVID-19) vaccination programs need to be accepted by a large proportion of the population to allow life return to normal. However, according to the Center for Disease Control and Prevention (CDC) as of November 2022 about 31% of the United States (US) population had not completed the primary vaccination series, and a portion of the US population is resistant to being vaccinated. Recent studies that have examined the issue of vaccine hesitancy in the context of COVID-19, have highlighted concerns about vaccine safety as the main contributor to vaccine hesitancy [2, 3, 4, 5]. A variety of factors such as age, education, political leaning, and misinformation have also been examined. Older people are at greater risk of severe disease and death from COVID-19 and thus may be more inclined to accept treatments such as the COVID-19 inoculation. Given the history of medical experimentation on African American populations [6], African American respondents may be less likely to be vaccinated. Information sources about COVID-19 may also influence the decision to be vaccinated.

A largely unexplored factor is the degree to which serious health problems arising from the COVID-19 illness or the COVID-19 vaccines among family and friends influences the decision to be vaccinated. Serious illness due to COVID-19 would make vaccination more likely; the perceived

benefits of avoiding COVID-19 through inoculation would be higher. On the other hand, observing major health issues following COVID-19 inoculation within one’s social network would heighten the perceived risks of vaccination. Previous studies have not evaluated the degree to which experiences with the disease and vaccine injury influence vaccine status. The main aim of this online survey of COVID-19 health experiences is to investigate the degree to which the COVID-19 disease and COVID-19 vaccine adverse events among friends and family, whether perceived or real, influenced inoculation decisions. The second aim of this work is to estimate the total number of COVID-19 vaccine induced fatalities nationwide from the survey.

2 Methods

2.1 Design of the National Survey of COVID-19 Health Experiences

The survey instrument and recruitment protocol of the National Survey of COVID-19 Health Experiences was approved via exemption determination by the Institutional Review Board (IRB) of the Michigan State University Human Research Protection Program (file number: STUDY00006960, date of exemption determination: November 17, 2021). All methods were carried out in accordance with relevant guidelines and regulations. The sample was obtained by Dynata, the world’s largest first-party data platform, and is representative for the US American population [7]. The sampling using Dynata is based on opt-in sampling, respondents deliver high quality data, they are diverse and have community norms of honesty and accuracy [8]. The survey was opened to the Dynata panel until the required number of responses was obtained from each category of the stratification variables age, sex, and income, as required for a balanced response set. With opt-in sampling there is no response rate as classically defined in survey research.

2.2. Development of questionnaire and pre-test

The questionnaire was developed in November 2021. A team that included a medical doctor and survey research specialist helped to validate the survey. The survey design was based on Shupp et al. [7]. Of relevance are questions that ask respondents about the health status of people in their social circles. Shupp et al. [7] included a similar question in their survey but in the context of prescription drug abuse. A pre-test was conducted with 1,110 respondents December 6-9, 2021. The questionnaire was finalized using the responses from the pre-test.

The questionnaire is composed of five sets of questions: 1) questions about respondents' experiences with COVID-19 illness, 2) questions about respondents' experiences with COVID-19 inoculation, 3) questions about experiences with COVID-19 illness in respondents' social circles, 4) questions about experiences with COVID-19 vaccination in respondents' social circles, and 5) questions to obtain standard socioeconomic information, political affiliation, approximate size of social network, and views on COVID-19 policies, such as lockdowns and vaccine mandates. The questionnaire is provided in Supplementary Material 1.

2.3. Statistical analysis of the survey data

Means and standard deviations are provided for continuous variables, and absolute numbers (percentages in parenthesis) for categorical variables. Socioeconomic characteristics of survey participants were compared with those from the United States (US) Census and the US American Housing Survey [9, 10, 11] after adjustment for age and sex.

Logistic regression was used to identify factors associated with the chance of being vaccinated with at least one shot. The two primary independent variables of interest were: 1) knowing someone who suffered from the COVID-19 disease; and 2)

knowing someone who has been injured by the COVID-19 vaccine. Adjustments were made for the following confounders: age, sex, political affiliation (Democrat, Republican, Independent), degree of urbanization using respondents' self-assessment of whether they live in urban, suburban or rural areas, race (Caucasian, African American, Hispanic, Asian, Native American/Pacific Islander, Other), educational attainment as defined by the US Census [12], sources of information about COVID-19 (mainstream news, alternative news/other, peer-reviewed scientific literature, official government sources), COVID-19 illness problems in social circles, and COVID-19 inoculation problems in social circles. Social circles, as defined in the survey, include "family, friends, church, work colleagues, and social networks". Among those in social circles who experienced health problems, respondents were asked to provide a description of the person they know best.

2.4. Comparing serious adverse events between publicly available data and the survey

Several steps are required to compare data on COVID-19 vaccine adverse events from the survey with publicly available government data. In the first step, public data on COVID-19 fatalities from the CDC [13] is combined with COVID-19 vaccine-related adverse events from VAERS [14] to create the ratio of COVID-19 vaccine-related fatalities to fatalities from the COVID-19 illness. An important limitation of VAERS is that reports often lack details and may contain errors. Further, reporting of vaccine adverse events does not prove the vaccine caused the health problem described. At present, the government reports that there are nine verified fatalities from the COVID-19 vaccines. The same ratio from the survey data is calculated so that a comparison can be made. To examine differences, the null hypothesis (H_0) is defined such that the True Ratio, X , is equal to the CDC ratio which is in turn equal to the survey ratio:

$$X = \text{CDC Ratio} = \text{Survey Ratio.}$$

$$\text{Survey Ratio} = \frac{\text{Survey COVID-19 Vaccine Fatalities}}{\text{Survey COVID-19 Illness Fatalities}}$$

$$\text{Pop. Ratio} = \frac{y}{\text{CDC COVID-19 Illness Fatalities}}$$

$$\text{Fatality Ratio} = \frac{\text{Estimated Pop. COVID-19 Vaccine Fatalities}}{\text{Survey COVID-19 Vaccine Fatalities}}$$

$$\text{Adverse Event Ratio} = \frac{a}{\text{Survey Adverse Events}}$$

The alternative hypothesis, H_a , is:

$$X = \text{CDC Ratio} < \text{Survey Ratio}.$$

This hypothesis is tested using state-by-state VAERS data on reported COVID-19 vaccine fatalities and CDC data on COVID-19 illness fatalities. If there is a statistically significant difference, the two ratios can be used to estimate nationwide COVID-19 vaccine fatalities under the assumption that the survey is accurate.

Solving for y generates the estimated number of nationwide vaccine fatalities. Through the end of 2021, reported COVID-19 vaccine fatalities from VAERS [14] for the US states and the District of Columbia was 8,023, and the CDC [13] reported 839,993 fatalities attributed to COVID-19. These data were downloaded on January 16, 2022. The ratio of vaccine-associated fatalities to COVID-19 fatalities is $8,023 / 839,993 = 0.0096$, or about 1%. A bootstrap method is used to obtain the 95% confidence interval, which is a non-parametric approach that does not assume an underlying distribution of the data. The procedure is as follows. First, resample the original dataset with replacement to obtain the same number of "pseudo-observations" where some of the original observations are counted multiple times. The new

dataset serves as a pseudo-survey sample, which is used to recalculate the point estimate. This process is repeated 1,000 times to compute the 95% confidence interval.

In the second step, the fatality calculation from above is used to estimate the number of non-fatal adverse events. The ratio of estimated population-wide fatalities to reported fatalities in the survey is used to calculate nationwide adverse events, a , as per the two equations above. "Severe" and "less severe" adverse events are calculated separately, where "severe" is determined by the author as potentially life threatening or life shortening (cardiac, pulmonary, neurological, thrombosis). A full list of adverse events that were categorized as severe is available upon request.

Additional analysis is conducted wherein CDC data on deaths per 100,000 people for pre-pandemic 2019 are used to calculate the expected number of fatalities by age group, which is subtracted from reported COVID-19 vaccine fatalities in the survey to obtain COVID-19 vaccine-related fatalities net of deaths that might have occurred regardless of vaccination status.

One important issue regarding the CDC estimates of COVID-19 fatalities requires

discussion. Ealy et al. [15] documents how CDC changed the COVID-19 death reporting requirement and offer evidence that CDC data on COVID-19 fatalities are overcounted. According to Ealy, et al. [15], in just 6% of recorded deaths was COVID-19 the only cause mentioned, and there was an average of 2.6 additional health conditions connected with COVID-19 fatalities. However, the CDC overcount should not affect the results of this examination because medical authorities are charged with reporting cause of death based on CDC requirements. Further, medical personnel will also likely tell loved ones that COVID-19 was the cause of death, even though the cause of death may have been associated with other underlying health conditions. Some of the respondent comments reveal complicating conditions. For example, some respondents reported that a person they know died from COVID-19, but they also noted that the person had cancer, had a heart condition, etc. In summary, medical personnel have the charge of reporting COVID-19 fatalities as per CDC requirements as well as tell loved ones that COVID-19 was cause of death. In turn, survey respondents who report knowing someone who died from COVID-19 are likely repeating explanations on cause of death from medical personnel.

The survey dataset and corresponding Stata code are available from the author upon request.

3 Results

3.1. Characteristics of survey participants representativeness of the survey

The National Survey of COVID-19 Health Experiences was administered online between December 18 and 23, 2021. A total of 2,840 participants completed the survey after removing the 216 respondents (6.5%) who opted out of the survey by not consenting to participate, 60 missing responses on age which is used to weight the data (1.9%), and 105 incomplete surveys (3.2%).

Twenty-seven additional respondents did not answer the question about race; in portions of the evaluation where race is considered, there are 2,813 observations. Item non-response for the following variables is considered negligible: age 1.9% (age), 0.9% (race), and 0.28% (number of people in social circles). The other questions used in this evaluation did not have a single missing item.

The survey instrument is available in Supplementary Material 1. Table 1 provides descriptive statistics for the survey sample with comparison to data from the US Census [11, 14] and the American Housing Survey [17]. Forty-nine percent of both the survey participants and the US population were male. Age of participants 46.9 (CI 95% \pm 0.640) years. There were also some minor differences in political affiliation, race, degree of urbanization and education. The data on urbanicity are comparable to data from the American Housing Survey [17] with small differences in percent urban (30.8% vs. 27%), percent suburban (46.7% vs. 52%), and percent rural (22.5% vs. 21%). For educational attainment, the survey had a higher percentage with “some college” (35.4% vs. 27.6%) but a lower percentage of “college graduates” (18.9% vs. 22.1%), and a higher percentage with “more than a college degree” (14.2 vs. 12.7).

Though a person may report that someone they know experienced a COVID-19 vaccine adverse event, it does not mean that vaccination was the cause of injury. As shown in the Table 4 and Supplementary Material 3, some respondents indicated that a person they know had a heart attack after being vaccinated, though the heart attack could have been unrelated to the inoculation. To address this issue, an estimate of the number of people within respondent social groups who are expected to die regardless of inoculation is calculated and subtracted from reported COVID-19 vaccine fatalities. The phrasing of the survey question with respect to potential vaccine-related health problems made it clear to respondents that

Table 1: Demographic characteristics of survey participants compared to the US Census and the American Housing Survey 2020

Variable	Adjusted Survey	US Census/AHS
Age in adult population (years)	46.9	47.6
Sex (male)	48.7%	49.2%
Political affiliation		
Democrat	32.7%	33%
Republican	32.1%	29%
Independent	35.3%	34%
Race		
Caucasian	68.3%	71.0%
African American	15.4%	14.2%
Urbanization		
Urban	30.8%	27%
Suburban	46.7%	52%
Rural	22.5%	21%
Education		
Some College/2-Year Degree	35.4%	27.6%
College Degree	18.9%	22.1%
College Above Bachelors	14.2%	12.7%

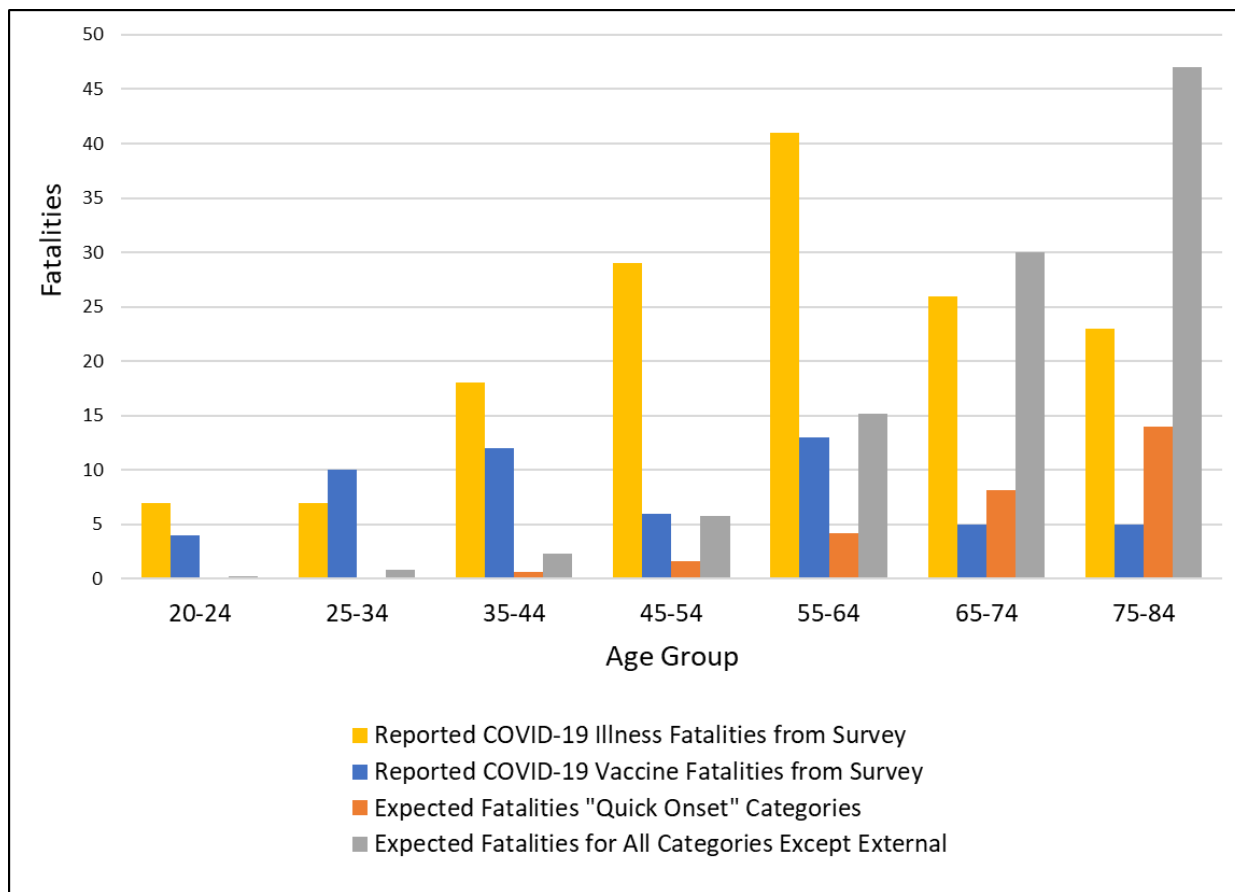
unexpected health events that occurred following vaccination should be reported. This suggests that it may be most appropriate to subtract fatalities that occur relatively quickly and not fatalities resulting from ongoing chronic conditions or other ongoing illnesses that would likely be known by survey respondents. Supplementary Material 4 presents a detailed explanation of the calculation of expected fatalities using CDC data for pre-pandemic 2019 [18] deaths per 100,000 that are the result of 1) relatively quick onset conditions (diseases of the heart and cerebrovascular diseases), and 2) all deaths except those from external causes (self-harm, assault, accidents). These calculations are examined by age group to account for differences in rates of death by cause across the age distribution. Figure 1 presents a comparison of reported COVID-19 illness fatalities and COVID-19 vaccine fatalities from the survey with expected

“quick onset” fatalities and total fatalities except those from external causes.

Figure 1 shows that the pattern of COVID-19 vaccine fatalities in the survey is very different than would be expected from “quick onset” and expected all cause deaths (except external causes). Reported COVID-19 vaccine fatalities from the survey occur more often in the younger age groups whereas expected fatalities are much higher in the older age categories. In contrast, reported COVID-19 illness deaths occur more often in the older age categories, as expected.

Also, from the survey about 51% of respondents reported being vaccinated. It is assumed that same proportion applies to those in respondents’ social circles. Finally, the survey included a question about the size of respondent social circles:

Figure 1: Survey COVID-19 Illness Fatalities, COVID-19 Vaccine Fatalities and Expected Fatalities



Q32 Think about your social circles (family, friends, church, work colleagues, social networks, etc.). About how many people in your circles do you know well enough that you would typically learn about a significant emerging health condition? (numerical answer only please)

On average, respondents indicated that they know about 10 people well enough to learn about a significant emerging health condition. The estimated total number of people in respondents’ social circles is therefore about 28,400. However, the sensitivity analysis includes calculations and discussion using larger social circle sizes of 15 and 23.

To calculate an estimated number of fatalities that might have occurred regardless of inoculation

status, the expected number of fatalities for 1) sudden onset deaths, and 2) all deaths except those from external causes all are multiplied by the proportion of people who are vaccinated (0.51) and the proportion of people in social circles out of 100,000 (0.284).

Direct respondent experiences regarding the COVID-19 illness or the COVID-19 vaccine are informative but incomplete because potential respondents who are very ill or died due to COVID-19 illness or the COVID-19 vaccine could not participate in the survey. For this study, the most important information comes from the questions about the experiences of those within respondents’ social circles because these health experiences can be reported by survey respondents.

3.2. Descriptive statistics for primary endpoints

Table 2 presents summary statistics for the relevant questions answered by respondents with differences and p-values between those who had the COVID-19 illness and not, and those who were vaccinated and not. The survey questionnaire is provided in Supplementary Material 1. Twenty-three percent of respondents report that they have had the COVID-19 illness, of which 28% experienced lingering health issues; most indicated they had ongoing respiratory/ breathing or taste/smell issues. About 8.6% of those who had health problems experienced more severe health problems resulting from COVID-19. Fifty-one percent of respondents indicated that they had been vaccinated of which 15% indicated that they experienced a health issue after vaccination, and 13% of those indicated that a severe adverse event had occurred. The respondents' comments describing the nature of health issues from the COVID-19 illness and COVID-19 vaccine adverse events are available from the author upon request. There are statistically significant differences across groups, with notable differences across the vaccinated/unvaccinated groups in income (\$70,919 vs. \$48,903), knowing someone who experienced a vaccine adverse event (0.157 vs 0.277), as well as with the education, race, information sources, and political affiliation categorical variables.

3.3. Factors related to vaccination decision and vaccine injury

The Logit regressions for vaccination and knowing someone who experienced a vaccine adverse event are shown in Table 3, which reports the odds ratios with confidence intervals. All regressions are estimated using the unweighted data due to the inclusion of socio-economic controls used by Dynata to recruit a balanced sample. Starting with socioeconomic factors, age is positively associated with inoculation (OR: 1.025, 95% CI: 1.019–1.031), but negatively associated with knowing someone who has been injured from inoculation

(OR: 0.979, 95% CI: 0.973-0.985). Higher income is also positively associated with inoculation (OR: 1.000005, 95% CI: 1.000004-1.000007). Relative to Democrats, those who self-identify as Republican have lower odds of being vaccinated (OR: 0.595, 95% CI: 0.477-0.742) and have greater odds of knowing someone who has experienced an adverse event (OR: 1.388, 95% CI: 1.089-1.769). Those who identify as Independent also have lower odds of being vaccinated (OR: 0.631, 95% CI: 0.514-0.773). There is evidence of an urban-rural divide, where rural residents have lower odds of being vaccinated (OR: 0.744, 95% CI: 0.587-0.943). Race is an important factor in vaccination status. African Americans (OR: 0.655, 95% CI: 0.513-0.835), Hispanics (OR: 0.647, 95% CI: 0.469-0.893), and Asians (OR: 0.599, 95% CI: 0.387-0.927) have lower odds of being vaccinated relative to the White population. African Americans are also more likely to know someone who has experienced a health problem post-vaccination (OR: 1.376, 95% CI: 1.066-1.776). Educational attainment is positively associated with inoculation. Those with doctoral (OR: 3.835, 95% CI: 1.759-8.358) or professional degrees (OR: 3.2821, 95% CI: 1.601-6.729) have higher odds of being inoculated. Those with doctoral (OR: 4.263, 95% CI: 2.009-9.043) or professional degrees (OR: 3.525, 95% CI: 1.755-7.079) also have higher odds of reporting that they know someone who has experienced a health problem after inoculation, respectively. Information sources are also associated with inoculation status. Those who report reliance on mainstream news and official government sources have higher odds of being vaccinated (OR: 1.394, 95% CI: 1.165-1.669). However, use of alternative news sources reduces the odds of inoculation (OR: 0.669, 95% CI: 0.557-0.802). Also, reliance on alternative news (OR: 1.481, 95% CI: 1.217-1.801) and peer-reviewed scientific publications (OR: 1.430, 95% CI: 1.143-1.789) increases the odds that a respondent knows someone who experienced a health problem post-vaccination.

Table 2: Key Summary Statistics for COVID-19 Health Survey

Question/Variable*	Obs	Overall Mean	COVID-19 Illness				Vaccinated			
			Yes Mean	No Mean	Diff	P-Value	Yes Mean	No Mean	Diff	P-Value
Have you had COVID?	2,840	0.230	0.230				0.208	0.253	-0.046	0.005
Health issues after COVID	690	0.284	0.284				0.341	0.236	0.105	0.004
Severe health issues after COVID	188	0.086	0.086				0.080	0.093	-0.013	0.759
Vaccinated against COVID?	2,840	0.511	0.461	0.526	-0.064	0.005	0.511			
Health issues after vaccine	1,365	0.146	0.258	0.116	0.142	0.000	0.146			
Severe health issues after vaccine	205	0.134	0.145	0.128	0.017	0.752	0.134			
Average income	2,840	60,152	63,957	59,014	4,943	0.033	70,919	48,903	22,015	0.000
Gender (male=1, female=0)	2,840	0.487	0.507	0.481	0.026	0.253	0.510	0.463	0.047	0.017
Social circle - # people respondents know	2,432	10.601	10.598	10.602	-0.004	0.997	12.487	8.443	4.044	0.000
Social circle health issues after COVID)	2,840	0.338	0.416	0.314	0.101	0.000	0.353	0.322	0.031	0.097
Social circle health issues after vaccine	2,840	0.216	0.286	0.195	0.091	0.000	0.157	0.277	-0.121	0.000
Education										
Less than high school	2,840	0.038	0.047	0.035	0.012	0.198	0.016	0.061	-0.045	0.000
High school/GED	2,840	0.276	0.247	0.285	-0.038	0.054	0.217	0.338	-0.121	0.000
Some college	2,840	0.242	0.269	0.234	0.035	0.079	0.232	0.253	-0.022	0.201
2-year college degree	2,840	0.112	0.096	0.117	-0.021	0.129	0.109	0.114	-0.005	0.684
4-year college degree	2,840	0.189	0.173	0.195	-0.022	0.217	0.248	0.128	0.121	0.000
Master's degree	2,840	0.097	0.103	0.095	0.008	0.583	0.123	0.070	0.054	0.000
Doctoral degree	2,840	0.019	0.022	0.018	0.004	0.552	0.024	0.014	0.010	0.069
Professional degree (JD, MD)	2,840	0.026	0.044	0.021	0.023	0.010	0.030	0.022	0.008	0.226
Race										
White/Caucasian	2,813	0.683	0.662	0.690	-0.028	0.192	0.755	0.608	0.147	0.000
African American	2,813	0.154	0.127	0.162	-0.035	0.020	0.116	0.193	-0.078	0.000
Hispanic	2,813	0.071	0.116	0.057	0.059	0.000	0.051	0.092	-0.041	0.000
Asian	2,813	0.035	0.033	0.036	-0.003	0.722	0.032	0.038	-0.006	0.388
Native American/Pacific Islander	2,813	0.024	0.030	0.023	0.007	0.341	0.018	0.031	-0.013	0.026
Other/more than one race	2,813	0.033	0.032	0.033	-0.001	0.948	0.028	0.037	-0.009	0.179
Urbanicity										
Urban	2,840	0.308	0.320	0.305	0.015	0.475	0.299	0.318	-0.019	0.294
Suburban	2,840	0.467	0.459	0.469	-0.010	0.664	0.504	0.427	0.077	0.000
Rural	2,840	0.225	0.221	0.227	-0.005	0.786	0.197	0.255	-0.058	0.000

Notes:

* Variable is (yes=1, no=0) unless otherwise noted.

Table 2 continues overleaf.

Table 2 Continued: Key Summary Statistics for COVID-19 Health Survey

Question/Variable*	Overall		COVID-19 Illness				Vaccinated			
			Obs	Mean	Yes Mean	No Mean	Diff	P-Value	Yes Mean	No Mean
Information sources about COVID-19										
Mainstream news sources	2,840	0.603	0.540	0.621	-0.081	0.000	0.700	0.501	0.198	0.000
Alternative news sources	2,840	0.350	0.385	0.340	0.045	0.041	0.270	0.434	-0.165	0.000
Peer reviewed scientific literature	2,840	0.182	0.195	0.179	0.016	0.368	0.177	0.188	-0.010	0.485
Official gov't sources such as the CDC	2,840	0.382	0.361	0.388	-0.027	0.222	0.458	0.302	0.156	0.000
Political affiliation										
Democrat	2,840	0.327	0.300	0.335	-0.035	0.091	0.389	0.261	0.128	0.000
Republican	2,840	0.321	0.360	0.309	0.051	0.021	0.300	0.342	-0.042	0.024
Independent/Other	2,840	0.353	0.341	0.356	-0.015	0.475	0.311	0.397	-0.086	0.000

* Variable is (yes=1, no=0) unless otherwise noted.

Turning to the primary hypothesis, a respondent’s observations within his/her social circles have a significant influence on the decision to be vaccinated. Those who know someone who experienced a significant health problem from the COVID-19 illness have higher odds of being vaccinated (OR: 1.309, 95% CI: 1.094-1.566). Conversely, those who know someone who had a health problem following inoculation have lower odds of being vaccinated (OR: 0.567, 95% CI: 0.461-0.698). The impact of COVID-19 vaccine injury is larger than the impact of COVID-19 illness.

3.4. Comparison of serious adverse events between publicly available data and the survey

One result of the survey is that many participants who decided not to be vaccinated reported that an event among friends or family members, which they recognized as adverse vaccination effect, was a reason for their hesitance to be vaccinated. If COVID-19 vaccine adverse events are rare, then they would not be captured in the survey and would not influence inoculation decisions. The high proportion motivated a closer examination of data

from the CDC Vaccine Adverse Events Reporting System (VAERS) [14].

Table 4 presents a summary of COVID-19 illness and COVID-19 vaccine health experiences among respondents’ social circles. Thirty-four percent (959 of 2,840) of respondents indicated that they knew at least one person who had experienced significant health problems from the COVID-19 illness, including 165 people who had died as tallied after the survey weighting adjustment. Supplementary Material 2 provides a word-cloud of respondent descriptions of COVID-19 illness experiences in social circles along with respondent comments. Twenty-two percent (612 of 2,840) of respondents indicated that they knew at least one person who experienced a health problem after COVID-19 vaccination. After the survey weighting adjustment, 57 people indicated that among the people they knew who had experienced a vaccine adverse event, the person they knew best had died. Supplementary Material 3 provides respondent descriptions of COVID-19 vaccine health problems in social circles in a word-cloud along with respondent comments. Respondents report a variety of problems including heart attacks and other heart-

Table 3. Logit Regression on COVID-19 Inoculation and Social Circle Inoculation Adverse Events

	Have you been inoculated against Covid-19?					Has anyone in your social circles experienced a significant health problem after they received the Covid-19 vaccination?				
	OR	SE	95% CI		P	OR	SE	95% CI		P
Age	1.025	0.003	1.019	1.031	0.000	0.979	0.003	0.973	0.985	0.000
Combined income	1.000005	0.000001	1.000004	1.000007	0.000000	0.999999	0.000001	0.999997	1.000001	0.229544
Democrat	REF	REF	REF	REF	REF	REF	REF	REF	REF	REF
Republican	0.595	0.067	0.477	0.742	0.000	1.388	0.172	1.089	1.769	0.008
Independent/Other	0.631	0.066	0.514	0.773	0.000	1.098	0.129	0.872	1.381	0.426
Urban	REF	REF	REF	REF	REF	REF	REF	REF	REF	REF
Suburban	0.967	0.096	0.797	1.175	0.738	1.004	0.110	0.809	1.245	0.973
Rural	0.744	0.090	0.587	0.943	0.015	1.255	0.167	0.967	1.630	0.088
White	REF	REF	REF	REF	REF	REF	REF	REF	REF	REF
African American	0.655	0.081	0.513	0.835	0.001	1.376	0.179	1.066	1.776	0.014
Hispanic	0.647	0.106	0.469	0.893	0.008	1.115	0.193	0.794	1.565	0.531
Asian	0.599	0.133	0.387	0.927	0.022	0.666	0.179	0.393	1.129	0.131
Native American/Pacific Islander	0.803	0.212	0.479	1.346	0.405	1.244	0.340	0.728	2.126	0.425
Other/More than one	0.760	0.174	0.485	1.191	0.232	0.811	0.213	0.485	1.357	0.425
No high school completion	REF	REF	REF	REF	REF	REF	REF	REF	REF	REF
HG/GED	1.700	0.420	1.047	2.760	0.032	1.083	0.275	0.659	1.781	0.754
Some college	2.133	0.533	1.308	3.480	0.002	1.248	0.321	0.754	2.067	0.389
2-year CD	2.208	0.589	1.309	3.726	0.003	1.827	0.499	1.070	3.121	0.027
4-year CD	3.535	0.918	2.125	5.880	0.000	1.355	0.365	0.800	2.296	0.259
Master's	2.941	0.827	1.695	5.102	0.000	2.010	0.579	1.143	3.536	0.015
Doctoral	3.835	1.524	1.759	8.358	0.001	4.263	1.636	2.009	9.043	0.000
Professional (JD, MD)	3.282	1.202	1.601	6.729	0.001	3.525	1.254	1.755	7.079	0.000

Table 3 continues overleaf.

Table 3 Continued: Logit Regression on COVID-19 Inoculation and Social Circle Inoculation Adverse Events

	Have you been inoculated against Covid-19?					Has anyone in your social circles experienced a significant health problem after they received the Covid-19 vaccination?				
	OR	SE	95% CI		P	OR	SE	95% CI		P
No news source	REF	REF	REF	REF	REF	REF	REF	REF	REF	REF
Mainstream news sources	1.394	0.128	1.165	1.669	0.000	1.026	0.105	0.840	1.254	0.800
Alternative/ Other news sources	0.669	0.062	0.557	0.802	0.000	1.481	0.148	1.217	1.801	0.000
Peer reviewed scientific literature	1.069	0.117	0.862	1.326	0.544	1.430	0.163	1.143	1.789	0.002
Official government sources such as CDC	1.594	0.140	1.341	1.894	0.000	0.845	0.085	0.694	1.028	0.092
Female	REF	REF	REF	REF	REF	REF	REF	REF	REF	REF
Male	1.172	0.101	0.990	1.387	0.065	1.006	0.096	0.833	1.213	0.954
Social circle-no health problem	REF	REF	REF	REF	REF					
Social circle-health problem after Covid-19	1.309	0.120	1.094	1.566	0.003					
Social circle-health problem after vaccine	0.567	0.060	0.461	0.698	0.000					
Constant	0.135	0.039	0.076	0.238	0.000	0.354	0.106	0.197	0.636	0.001
Obs	2813					2813				
LR Chi2	563.42					158.68				
Pseudo R2	0.145					0.053				

related problems, blood clots and strokes, and neurological problems. Many of the descriptions such as “heart attack,” “stroke,” or “blood clot” are consistent with Food and Drug Administration [19] and Pfizer [20] documentation about the potential risks of the COVID-19 vaccine.

The ratio of COVID-19 vaccine deaths to COVID-19 illness deaths of the people respondents knew best who had health problems is $\frac{57}{165} = 0.345$, whereas the ratio of vaccine-associated fatalities to COVID-19 fatalities from government sources is $\frac{8,023}{839,993} = 0.0096$.

Table 4: Summary Statistics for Health Problems in Social Circles

Question/Variable	Obs	# People	Mean
Social circle health issues after COVID-19 (yes=1, no=0)	2,840	959	0.338
One person - health issue after COVID-19 (yes=1, no=0)	980	379	0.387
Two people -health issue after COVID-19 (yes=1, no=0)	980	355	0.362
Three people - health issue after COVID-19 (yes=1, no=0)	980	156	0.159
≥ three people - health issue after COVID-19 (yes=1, no=0)	980	91	0.092
Death after COVID-19 (yes=1, no=0)	980	165	0.168
Severe issues after COVID-19 (yes=1, no=0)	980	354	0.361
Less severe issues after COVID-19 (yes=1, no=0)	980	471	0.480
Average age of people with COVID-19 issues	980	-	44.95
Social circle health issues after vaccination (yes=1, no=0)	2,840	612	0.216
One person - health issues after vaccination (yes=1, no=0)	649	268	0.413
Two people - health issues after vaccination (yes=1, no=0)	649	230	0.354
Three people - health issues after vaccination (yes=1, no=0)	649	90	0.138
≥ three people - health issues after vaccination (yes=1, no=0)	649	62	0.095
Death after vaccine (yes=1, no=0)	649	57	0.088
Severe health condition after vaccine (yes=1, no=0)	649	197	0.303
Less severe health condition after vaccine (yes=1, no=0)	649	400	0.616
Heart condition after vaccine (yes=1, no=0)	649	42	0.065
Blood condition after vaccine (yes=1, no=0)	649	22	0.034
Nervous condition after vaccine (yes=1, no=0)	649	14	0.021
Covid related conditions after vaccine (yes=1, no=0)	649	45	0.069
Average age of people with vaccine adverse events	649	-	41.16

The null hypothesis (H_0) that the true ratio, X , is equal to the CDC ratio which is also equal to the survey ratio: $X = \text{CDC Ratio} = \text{Survey Ratio}$. This hypothesis is tested using state-by-state Vaccine Adverse Events Reporting System (VAERS) data on reported COVID-19 vaccine-associated deaths and COVID-19 illness fatalities. The alternative hypothesis (H_a) is: $X = \text{CDC Ratio} < \text{Survey Ratio}$. The mean (μ) and standard deviation (σ) of the ratio of vaccine fatalities to COVID-19 fatalities from the state-by-state data are $\mu = 0.0136$ and $\sigma = 0.0111$. The probability that the Survey Ratio $>$ CDC Ratio = X [$P(\text{CDC Ratio} > 0.345)$]. With

$P(\text{CDC Ratio} > 0.345) = 0$ and a Z-score = 28.86; the null hypothesis is rejected.

Assuming the experiences captured in the survey represent the true ratio, the survey ratio is used to estimate nationwide COVID-19 vaccine fatalities: Estimated fatalities are 289,789 (95% CI: 229,319 – 344,319). Estimated nationwide deaths combined with other survey data on adverse events are also used to estimate total adverse events. “Severe” adverse events, as defined earlier as potentially life threatening or life shortening, are estimated to be about one million nationwide, and “less severe” adverse events are about 2.1 million. Estimated

nationwide fatalities, “severe injuries” and “less severe” injuries tally to 3.4 million.

This evaluation is conducted under the assumption that the reported vaccine-related fatalities and injuries are caused by the COVID-19 vaccine but is now relaxed by reducing the number of reported fatalities by the deaths due to other causes that would be expected to have occurred anyway. Subtracting expected fatalities from “quick onset” conditions (diseases of the heart and cerebrovascular diseases) generates estimated nationwide COVID-19 vaccine fatalities of 205,737. If all expected fatalities except those from external causes are subtracted, estimated nationwide COVID-19 vaccine fatalities are 126,407. More detail on these calculations is provided in Supplementary Material 4.

The size of social circle used in the core evaluation is based on reported social circle size from the survey, where respondents indicated that, on average, they know about 10 people well enough to be aware of health status (see Supplementary Material 1 for the survey question 32). As described by Stiller and Dunbar [20], the average size of the social network a person sees at least once a month is 12-15. If a social network size of 15 is used in the calculation of expected fatalities, estimated nationwide COVID-19 vaccine fatalities is about 189,000 after subtracting “sudden onset” fatalities and 103,000 after subtracting all expected fatalities except those from external causes.

To get agreement between reported COVID-19 illness deaths in the survey with CDC COVID-19 death estimates, a social circle size of 23 is needed. If this larger social circle is used in the calculation of expected fatalities, estimated nationwide COVID-19 vaccine fatalities is about 162,000 after subtracting “sudden onset” fatalities and 66,000 after subtracting all expected fatalities except those from external causes.

Supplementary Material 4 also uses social circle size to calculate a nationwide estimate of COVID-19 vaccine fatalities using a different method based directly on social circle size instead of the ratio of reported COVID-19 deaths to COVID-19 vaccination fatalities. This approach generates a COVID-19 vaccine fatality figure that is similar to the baseline calculation presented in the body of this article.

Also included in Supplementary Material 4 is an analysis of respondent bias as reflected by political affiliation and vaccination status as well as several other sensitivity analyses. Estimated nationwide COVID-19 vaccine fatalities based on the Democrat, Republican and Independent subsets are 109,564, 463,444 and 247,867, respectively. With the vaccinated and unvaccinated subgroups, estimated COVID-19 vaccine fatalities are 110,942 and 659,995. Other sensitivity analyses include: 1) potential sample selection bias due to low vaccination rate in the survey as compared to CDC data on the nationwide vaccination rate; and 2) omission of death reports where underlying cause is questioned.

At the time of the survey, the vaccination rate reported by the CDC was 72% but the vaccination rate in the survey is 51%. As described in Supplemental Material 4, due to counting second shots as first shots the CDC reported vaccination rate may be overcounted. Nevertheless, reweighting the survey in accordance with the vaccination rate reported by the CDC to account for potential selection bias resulting from a low vaccination rate generates an estimated 216,000 COVID-19 vaccine fatalities.

Supplementary Material 2 and 3 provide reports of COVID-19 illness problems and COVID-19 vaccination problems among respondents’ social circles, respectively. An inspection of these reports reveals that among COVID-19 vaccine fatalities there was a case where cancer was described, two cases where Covid-illness post-vaccination was

noted, and one case of spontaneous abortion. For reported COVID-19 illness fatalities, there were three cases of deaths related to cardiac arrest, five deaths from pneumonia, two from cancer, and one by suicide. If all these cases are removed, the recalculated nationwide estimate of COVID-19 vaccine fatalities is about 287,000. Supplementary Material 4 also reports estimated fatalities generated by removing subgroups of these questionable reported fatalities.

4 Discussion

The primary contribution of this study is to examine the role that observed health experiences within social circles play in COVID-19 vaccination decisions. Findings indicate that knowing someone who experienced a major health problem from the COVID-19 illness as well as knowing someone who experienced an COVID-19 vaccine adverse event are important factors. The large number of respondents who reported that they knew someone who had experienced a vaccine adverse event motivated further examination of how many people nationwide may have experienced an adverse event from the COVID-19 vaccine. Estimates from the survey indicate that through the first year of the COVID-19 vaccination program vaccine induced fatalities are between 126,407 and 289,789 in the baseline calculations, depending on assumptions about how many people may have died regardless of vaccination status. The analyses offer new evidence that the health experiences with the COVID-19 illness and vaccination within social circles play an important role in the decision to be vaccinated. Further, the reported COVID-19 vaccine adverse events within respondent social circles in the survey are substantial, suggesting that this effect is an important factor in vaccine hesitancy, whether perceived or real. Consistent with previous research, findings show that personal characteristics are also associated with vaccination status. As summarized in Nguyen et al. [22] and

Prematunge et al. [23], a number of studies have examined vaccine hesitancy in the context of influenza outbreaks. Among the factors that influence vaccination status are perceptions of vaccine safety, effectiveness in the prevention of infection to self and others, and the seriousness of the illness.

The research on COVID-19 vaccine hesitancy also shows the importance of perceptions and beliefs regarding the safety and effectiveness of the vaccines as well as concerns about the severity of the COVID-19 illness [9, 21, 22, 23] in vaccination decisions. Important factors also include vaccine-specific concerns, the need for more information, antivaccine beliefs/attitudes, and lack of trust, which are also correlated with lower educational attainment [24, 25]. In addition, there is a positive correlation between general trust in science and COVID-19 vaccination intentions [29]. As highlighted earlier, socioeconomic characteristics are also associated with vaccination status [1, 2, 3, 4].

The findings confirm other research on vaccine hesitancy that show the importance of various personal characteristics [1, 2, 3, 4] and builds on this earlier work by demonstrating that experiences with health problems from the COVID-19 illness and the COVID-19 vaccine in respondent social circles are also important factors. Knowing someone who had health issues with the COVID-19 illness increases the odds of vaccination, whereas knowing someone who experienced a vaccine injury reduces the odds of vaccination. This research suggests that those who know someone who is COVID-19 vaccine injured will be resistant to vaccination. Future research with a larger sample validated in a clinical setting is needed.

The strengths of this research are that it is based on a sample that closely matches the US population and that it provides new information regarding how experiences with the COVID-19 illness and COVID-19 vaccine adverse events, real or

perceived, influence COVID-19 vaccination decisions. These findings increase our understanding of vaccine hesitancy.

The limitations of the study are fourfold: 1) The sample of 2,840 respondents is small; 2) reported COVID-19 illnesses and COVID-19 vaccine adverse events are not diagnosed in a clinical setting; and 3) health survey responses are biased. For example, there are limitations with using a survey to collect COVID-19 health information, particularly for a politicized health issue. Respondents often interpret events with bias due to perceptions based on history, beliefs, culture and family background. For example, a respondent who self identifies as Republican may offer a report that is different than a person who identifies as Democrat. As discussed in the results section, I examine response differences across sub-samples based on reported political affiliation and vaccination status. These alternative calculations provide evidence of bias; Democrats perceived fewer vaccine adverse events than Republicans and Independents, and the vaccinated perceived far fewer vaccine adverse events than the unvaccinated. The latter finding suggests significant bias in the sense that each subgroup (vaccinated and unvaccinated) is inclined to validate personal health decisions. Finally, social circle size is an important factor in subtracting fatalities that might have occurred regardless of COVID-19 vaccination status. Willingness to share health issues within social circles may differ depending on the nature of the health issue. In the context of the COVID-19 crisis, people may have been willing to share health status updates regarding the COVID-19 illness, but some may have been less willing to share potential vaccine adverse effects due to “taboo”. For example, sharing information on a vaccine adverse event might be perceived as potentially generating vaccine hesitancy and thus reticence in discussing that topic. Also, while the analysis includes evaluation using differing social circle sizes (10, 15,

and 23) caution is warranted because social circle sizes are likely to differ depending on age, gender, marital status, and other factors.

5 Conclusion

The survey provides useful information about the decision for or against getting vaccinated for COVID-19. The evaluation also showed that those who perceive that loved ones were harmed by the COVID-19 illness were more likely to be vaccinated, but the opposite was true for those who knew someone who they believe had been injured by the COVID-19 vaccine. The large difference in the possible number of fatalities due to COVID-19 vaccination that emerges from this survey and the available governmental data should be further investigated.

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7 Author Statements

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Conflicts of Interest

The author declares no conflict of interest.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The survey instrument and recruitment protocol of the National Survey of COVID-19 Health Experiences were approved via exemption determination by the Institutional Review Board (IRB) of the Michigan State University Human Research Protection Program (file number: STUDY00006960, date of approval: November 17,

2021, name of IRB: Michigan State University Human Research Protection Program). All participants gave written informed consent via reading a written consent statement and clicking “I Agree” before being allowed to take the online survey. All methods were carried out in accordance with relevant guidelines and regulations.