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Original Research

Willingness to Accept Expedited COVID-19 Vaccine Research for Children Aged <12 Years After Adult Vaccine Approval

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ABSTRACT

Purpose: The goal of this study was to assess if caregivers' attitudes toward the regulatory process of approving the vaccine against coronavirus disease 2019 (COVID-19) for children aged <12 years changed after a vaccine was approved for adults.

Methods: This was a larger scale COVIPAS (COVID-19 Parental Attitude Study) survey of caregivers presenting with their children aged ≤12 years for emergency care in 12 hospitals in the United States, Canada, and Israel. The study compared willingness to support abridged research into COVID-19 vaccines for children between the peak of the pandemic (March–May 2020) and after a COVID-19 vaccine became available for adults (December 2020–March 2021).

Findings: A total of 1956 surveys were included in the analyses. Overall, 385 (30.9%) caregivers in the pre–vaccine approval period and 250 (35.3%) caregivers in the post–adult vaccine phase supported abridged research into COVID-19 vaccines ($P < 0.001$). In both phases, mothers were less likely to favor abridged approval. Those with children who were fully vaccinated based on the pediatric schedule in their country favored abridged approval in phase 1 (odds ratio, 1.98; 95% confidence interval, 1.31–3.08) but less so in phase 2. In both phases, age and concerns of parents that they had COVID-19 or their child had COVID-19 were not associated with changes in response between phases.

Implications: Willingness to expedite vaccine approval increased after the emergency approval of COVID-19 vaccine for adults. Mothers are much less likely to approve expedited approval. No significant changes have been found in the composition of caregivers willing to forego regulatory demands on vaccine approval. (*Clin Ther.* 2022;44:e1–e10.) © 2021 Elsevier Inc.

*Members of the international COVIPAS (COVID-19 Parental Attitude Study) Group are listed in the Acknowledgments.

Accepted for publication November 7, 2021
https://doi.org/10.1016/j.clinthera.2021.11.003
0149-2918/$ - see front matter

Keywords: COVID-19, parental attitudes, vaccination, vaccine hesitancy, vaccine research.

INTRODUCTION

Vaccinating children against coronavirus disease 2019 (COVID-19) is critical as a public health strategy to reach herd immunity and prevent illness among children and adults.[1] In the first stages of the COVID-19 pandemic (mid-2020), before any vaccine was available and when parents of children of all ages (0–18 years old) completed a survey, close to one half (43%) of caregivers reported that they were willing to accept less rigorous testing and post–research approval of a new COVID-19 vaccine.[2]

With the progress of the pandemic 1 year later, several vaccines have been approved and delivered to millions of adults, and clinical trials are ongoing for evaluation of the same vaccines among children 6 months to 11 years of age. Recently, the American Academy of Pediatrics and pediatricians in the United States have been pushing the US Food and Drug Administration (FDA) to review trial data and to facilitate approval of pediatric vaccines,[3] and the FDA asked vaccine manufacturers to test their vaccines in more children to help rule out safety issues that were discovered in adolescents.[4]

The aim of the present study was to assess if caregivers' attitudes toward the regulatory process of approving the vaccine against COVID-19 for children aged <12 years has changed over the course of the pandemic, specifically after a vaccine was approved for adults.

PARTICIPANTS AND METHODS

Sample and Procedures

This survey was part of the larger-scale COVIPAS (COVID-19 Parental Attitude Study) of caregivers presenting with their children for emergency care during the era of COVID-19. In this analysis, we included caregivers (mostly parents) of children aged ≤12 years who presented at 1 of 12 pediatric emergency departments (EDs) in cities in the United States (Denver, Los Angeles, Dallas, Seattle, and Atlanta), Canada (Vancouver, Saskatoon, Edmonton, and Calgary) and Israel (Zerifin, Hedera, and Safed).

One parent for each child was asked to complete an online survey while in the ED. Once a caregiver selected their study site from the online platform, consent for participation was considered completed. This study was approved by each site's local institutional review board.

Measures

The study-specific questionnaire was developed to include questions regarding demographic characteristics, information on symptoms leading to the ED visit, and caregiver attitudes about vaccinating against COVID-19. The objective of this substudy was to determine caregivers' perspectives about the approval process of vaccines for children aged <12 years. The survey took ~15 minutes to complete. We have previously described the development and validation of the original survey.[5]

We asked caregivers to answer the question, "It usually takes several months or years to perform scientific studies before a vaccine/immunization is approved for use. Which one do you agree with?" followed by 4 choices: (1) "In a pandemic (disease that spreads across the world) like Coronavirus (COVID-19) there is no need to wait for the usual research process, a vaccine/immunization should be approved immediately"; (2) "In a pandemic (disease that spreads across the world) like Coronavirus (COVID-19) vaccine/immunization research should be more limited than the usual approval process (for example, limited to several hundred people) and then approved for everyone"; (3) "In a pandemic (disease that spreads across the world) like Coronavirus (COVID-19) we still need all the same research as for other vaccines/immunizations before approval"; or (4) "Other."

The initial phase of the survey was conducted during the peak of the pandemic (March–May 2020) before vaccine availability, and the revised survey, after a COVID-19 vaccine became available for adults through emergency authorization in all 3 countries (phase 2), was conducted from December 2020 to March 2021. The changes to the survey included updating language of questions related to the availability of a vaccine (no vaccine was available during the initial phase of this study; several were available and approved during this phase of the study).

Statistical Analysis

Basic descriptive statistics and frequencies were used to report demographic characteristics and compare survey data from caregivers who would support

abridged COVID-19 vaccine regulations and those who would not during each study phase. To assess variables that may be associated with willingness to support abridged vaccine regulations, we fit a multivariable logistic regression model including *a priori* selected variables. Variables describing who completed the survey, child's age, and immunizations status, as well as parental level of concern about the child or the caregiver having COVID-19, were included. These models were stratified according to study phase (pre–COVID vaccine approval and post–emergency use COVID-19 vaccine approval for adults) by including interactions between phase and each variable of interest. We tested these interactions with the likelihood ratio test, comparing univariable models with and without interactions. Because there were changes in the responses according to country between study periods, these models were further adjusted according to country of response.

Results are presented as adjusted odds ratios (ORs) and 95% confidence intervals (CIs). All analyses were conducted by using R statistical software version 4.0.3 (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

A total of 2889 surveys were completed online; 2096 (72.5%) were completed by caregivers of children aged ≤12 years. Four were excluded because they were completed by patients, and 136 (6.5%) did not provide an answer to whether they recommended the currently regulated approval process or a facilitated process. In total, 1956 (67.8%) surveys were included in the analyses, 627 (32.1%) from the United States, 1103 (56.4) from Canada, and 226 (11.6%) from Israel.

A total of 385 (30.9%) caregivers of children aged ≤12 years in the pre–vaccine approval period and 250 (35.3%) caregivers in the post–adult vaccine phase supported abridged research into COVID-19 vaccines ($P < 0.001$).

Table I describes demographic characteristics and survey responses for all caregivers who completed the survey in the preapproval and postapproval periods. The majority of children were brought to the hospital by their mothers (74.7% of respondents); the caregivers were mostly educated (82% with higher than high school education); a large proportion (41.4%) of caregivers had lost income due to COVID-19; and parents were in general more concerned about the child having COVID-19 than the parent having the viral illness (3.15 of 10 and 2.91 of 10 on average, respectively). The mean age of children was 5.13 years, and the rate of chronic illness (11.9%) and use of chronic medications (13%) were similar to findings in the pediatric population. Finally, the rate of fully vaccinated children was high (87.7%).

Table II provides comparisons of characteristics or caregivers and between phases 1 and 2 of the study. Table III presents the results for possible associations between explanatory variables and willingness to see an abridged approval process by phase. Those in phase 2 were more likely to favor abridged approval (OR, 2.33; 95% CI, 1.05–5.12; $P = 0.036$). In both phases, mothers were less likely to favor abridged approval. Those with children who were fully vaccinated based on the pediatric schedule in their country favored abridged approval in phase 1 (OR, 1.98; 95% CI, 1.31–3.08) but less so in phase 2 (OR, 1.22; 95% CI, 0.71–2.19), although these CIs were compatible, and there was no significant effect modification ($P = 0.29$). In both phases, age and concerns of parents that they had COVID-19 or their child had COVID-19 were not associated with changes in response between phases.

DISCUSSION

We found that after receiving emergency approval of COVID-19 vaccines for adults, and the commencement of a national vaccine program in the 3 countries included in our analysis, more caregivers of children aged <12 years were willing to forego the anticipated vaccine approval process. Mothers were less likely to approve an abridged process in both the preapproval and the postapproval phase, but in general, there was no significant difference in the characteristics of caregivers willing to forego the traditional regulatory framework.

Effective herd immunity will require pediatric vaccination,[6] and we previously reported that independent factors associated with caregivers' willingness to accept expedited COVID-19 vaccine research included having children who were up to date on the vaccination schedule, caregivers' concern about having had COVID-19 themselves, and caregivers' intent to have their children vaccinated against COVID-19 if a vaccine were to become available. Compared with fathers, mothers completing the prior survey including all ages of children, similar to our findings in the post–

Table I. Characteristics of caregivers and children for those completing the survey before adult coronavirus 2019 (COVID-19) vaccine approval as well as after vaccine emergency approval (phases 1 and 2). Comparisons are made of the group supporting current regulation of vaccine approval process versus those supporting abridged vaccine approval. Data are given as mean (SD) unless otherwise indicated.

Characteristic	All Caregivers (N = 1956)	Pre–Vaccine Approval: Regular Vaccine Research (n = 862)	Pre–Vaccine Approval: Abridged Vaccine Research (n = 385)	Post–Vaccine Approval: Regular Vaccine Research (n = 459)	Post–Vaccine Approval: Abridged Vaccine Research (n = 250)	N
Country						1956
Canada	1103 (56.4%)	454 (52.7%)	205 (53.2%)	287 (62.5%)	157 (62.8%)	
Israel	226 (11.6%)	52 (6.03%)	21 (5.45%)	94 (20.5%)	59 (23.6%)	
United States	627 (32.1%)	356 (41.3%)	159 (41.3%)	78 (17.0%)	34 (13.6%)	
Child's age, y	5.13 (3.63)	5.02 (3.56)	5.32 (3.58)	5.28 (3.78)	4.93 (3.62)	1956
Child's sex (female)	920 (47.1%)	400 (46.5%)	199 (51.7%)	208 (45.3%)	113 (45.2%)	1954
Child has chronic illness	232 (11.9%)	96 (11.1%)	42 (10.9%)	64 (13.9%)	30 (12.0%)	1955
Child uses chronic medication	254 (13.0%)	106 (12.3%)	48 (12.5%)	69 (15.0%)	31 (12.4%)	1955
Child's immunizations up to date	1708 (87.7%)	721 (84.3%)	350 (91.1%)	408 (89.1%)	229 (91.6%)	1947
Survey completed by						1956
Father (percentage of fathers)	457 (23.4%)	166 (61.3%)	105 (38.7%)	104 (55.9%)	82 (44.1%)	
Mother (percentage of mothers)	1461 (74.7%)	679 (71.4%)	272 (28.6%)	348 (68.2%)	162 (31.8%)	
Other (percentage of others)	38 (1.94%)	17 (68.0%)	8 (32.0%)	7 (53.8%)	6 (46.2%)	
Caregiver's age, y	36.8 (7.15)	36.3 (7.21)	37.1 (7.57)	36.9 (6.94)	37.5 (6.58)	1922
Caregiver has higher than high school education	1577 (82.0%)	672 (79.4%)	318 (84.1%)	375 (82.6%)	212 (86.9%)	1922
Caregiver had lost income due to COVID-19	791 (41.4%)	366 (42.8%)	157 (41.2%)	170 (38.4%)	98 (42.2%)	1912
Caregiver believes social distancing is effective	1777 (92.6%)	779 (90.9%)	370 (96.9%)	404 (90.6%)	224 (95.7%)	1919
Likert scale scores (range, 0–10)						
Level of concern about child having COVID-19	2.08 (3.15)	1.60 (2.82)	2.31 (3.14)	2.43 (3.41)	2.83 (3.55)	1899
Level of concern about caregiver having COVID-19	1.87 (2.91)	1.44 (2.62)	2.11 (2.85)	2.16 (3.18)	2.50 (3.26)	1888
Level of concern about losing work	2.89 (3.62)	2.57 (3.55)	2.92 (3.58)	3.21 (3.72)	3.41 (3.67)	1871
Level of concern about child losing school	2.69 (3.54)	2.47 (3.45)	2.83 (3.58)	2.86 (3.61)	2.96 (3.61)	1855

Table II. Comparison of characteristics of caregivers and children for phases 1 and 2 of the study. Data are given as mean (SD) unless otherwise indicated.

Characteristic	All Caregivers (N = 1956)	Phase 1 (n = 1247)	Phase 2 (n = 709)
Country			
Canada	1103 (56.4%)	659 (52.8%)	444 (62.6%)
Israel	226 (11.6%)	73 (5.85%)	153 (21.6%)
United States	627 (32.1%)	515 (41.3%)	112 (15.8%)
Child's age, y	5.12 (3.63)	5.11 (3.57)	5.16 (3.73)
Child's sex (female)	920 (47.1%)	599 (48.1%)	321 (45.3%)
Child has chronic illness	232 (11.9%)	138 (11.1%)	94 (13.3%)
Child uses chronic medication	254 (13.0%)	154 (12.4%)	100 (14.1%)
Child's immunizations up to date	1708 (87.7%)	1071 (86.4%)	637 (90.0%)
Survey completed by			
Father (percentage of fathers)	457 (23.4%)	271 (21.7%)	186 (26.2%)
Mother (percentage of mothers)	1461 (74.7%)	951 (76.3%)	510 (71.9%)
Other (percentage of others)	38 (1.94%)	25 (2.00%)	13 (1.83%)
Caregiver's age, y	36.8 (7.15)	36.6 (7.33)	37.1 (6.81)
Caregiver has higher than high school education	1577 (82.0%)	990 (80.9%)	587 (84.1%)
Caregiver had lost income due to COVID-19	791 (41.4%)	523 (42.3%)	268 (39.7%)
Caregiver believes social distancing is effective	1777 (92.6%)	1149 (92.7%)	628 (92.4%)
Likert scale scores (range, 0–10)			
Level of concern about child having COVID-19	2.08 (3.15)	1.82 (2.94)	2.56 (3.46)
Level of concern about caregiver having COVID-19	1.87 (2.91)	1.65 (2.71)	2.27 (3.21)
Level of concern about losing work	2.89 (3.62)	2.68 (3.56)	3.28 (3.71)
Level of concern about child losing school	2.69 (3.54)	2.58 (3.50)	2.90 (3.61)

COVID-19 = coronavirus 2019.

vaccine approval, were less likely to approve of changes in the vaccine development process.[2]

The present analysis, after a COVID-19 vaccine became available under emergency authorization and vaccination of the population in Israel, the United States, and Canada began, shows a modest increase in willingness to accept an abridged process. This finding parallels views that COVID-19 vaccine acceptance is influenced by vaccine efficacy and perceptions of disease risk.[7] In one cross-sectional survey from Indonesia in March to April 2020, almost all (93%) participants agreed to receive a COVID-19 vaccine that was 95% effective, and only two thirds (67%) accepted a 50% effective vaccine.[8] With initial findings of effectiveness of the vaccine during our study, and reduction in COVID-19 burden of illness due to immunization, more caregivers among our cohort may have been willing to accept an abridged regulatory process.

In a survey of a national sample of 1971 US adults from July 2020, when offered a hypothetical COVID-19 vaccine, the FDA approval process, national origin of vaccine, and endorsements, as well vaccine efficacy, adverse effects, and duration of protection, were associated with preferences for choosing a vaccine. An FDA Emergency Use Authorization was associated with a lower probability of choosing a vaccine (coefficient, −0.03; 95% CI, −0.04 to −0.01) compared with a full FDA approval.[9] In Taiwan, with a 52.7% rate of willingness to be vaccinated, those who had previously refused other vaccinations were 2.44 times more likely to refuse the COVID-19 vaccines, and the most common vaccine refusal reason was "the Emergency Use Authorization process is not strict

Table III. Multivariable logistic regression model for caregivers' support of abridged vaccine approval before and after the adult coronavirus 2019 (COVID-19) vaccine became available. The *P* value for effect modification was computed from likelihood ratio tests comparing models with and without interaction term.

Pre–Vaccine Approval	Pre–Adult Vaccine Approval			Post–Adult Vaccine Approval			*P* for Effect Modification[†]
	Odds Ratio	OR 95% CI[*]	*P*	Odds Ratio	OR 95% CI	*P*	
Child's age	1.00	(1.00–1.00)	0.270	1.00	(1.00–1.00)	0.234	0.07
Who completed survey							0.79
Father	Ref	Ref	Ref	Ref	Ref	Ref	–
Mother	0.60	(0.45–0.81)	<0.001	0.63	(0.44–0.92)	0.016	–
Other	0.73	(0.28–1.76)	0.50	1.44	(0.43 – 4.83)	0.55	–
Child's immunizations up to date	1.98	(1.31–3.08)	0.002	1.22	(0.71–2.19)	0.48	0.29
Level of concern about child having COVID-19 (Likert scale 0–10)	1.06	(0.96–1.12)	0.13	1.06	(0.96–1.16)	0.282	0.77
Level of concern about caregiver having COVID-19 (Likert scale 0–10)	1.04	(0.96–1.12)	0.36	0.982	(0.89–1.09)	0.72	0.11

CI = confidence interval; COVID-19 = coronavirus 2019.
[*] Odds ratio from multivariable model including all predictors as well as country.
[†] Computed from likelihood ratio test comparing models with and without interaction term.

enough" (48.7%).[10] With the approval of COVID-19 vaccine for young children, special emphasis is needed to convince parents that it is safe to have their child vaccinated based on robust research and clinical trials.

Caregivers' decision on willingness to administer vaccines to children depends on numerous factors.[11] Some of those include fear of an imminent infection,[12] the availability of the vaccine to the adult population, media reporting of generally safe administration to the vast majority of adults, potential inclusion in community activity or ability to travel if vaccinated, and the ongoing course of the pandemic. One study from Turkey reported that 83.9% of parents were willing to have their children vaccinated with the COVID-19 vaccine if the mortality rates associated with COVID-19 in children increased following a mutation.[13] Those factors may also be associated with further eagerness of caregivers to see an approved vaccine for children aged <12 years to reach herd immunity in the population.

Although vaccine hesitancy, recognized as one of the top 10 threats to global health in 2019,[14] has been hampering efforts to vaccinate the population against COVID-19, the majority of parents planned to vaccinate their children,[5] and one third seemed to be enthusiastic to have the vaccine approved, even if not all regulatory requirement stages have been achieved.

Willingness to vaccinate children has been assessed in different countries and varied widely across samples, ranging from 51% to 88%; in some jurisdictions, parents were even willing to enroll their children in vaccine trials for the chance of receiving a vaccine before approval.[15] The analyses of Kerr et al[16] found that sex (female OR, 0.59; 95% CI, 0.55–0.64), trust in medical and scientific experts (OR, 1.28; 95% CI, 1.22–1.34), and worry about the COVID-19 virus (OR, 1.47; 95% CI, 1.41–1.53) are the strongest correlates of stated vaccine acceptance. In our initial report on >1500 families during the peak of the pandemic in March to May 2020, 65% of

caregivers reported that they intend to vaccinate their child against COVID-19 once a vaccine is available.[5] In Turkey, 36% of parents were willing to have their children receive the COVID-19 vaccine, and almost 60% were willing to receive it themselves.[13] Among families in Germany, 58% of parents stated their intention to get vaccinated against COVID-19, and 51% declared their intention to have their child vaccinated.[17] In the United Kingdom, parents of children aged <18 months were more hesitant to have their child vaccinated than to get vaccinated themselves,[7] and in Germany fluctuations in rate of willingness to vaccinate over time were recorded with increase or decrease in rate of infections.[18] In Canada, parents of children aged 9 to 12 years recorded safety and efficacy as the most important factors influencing decisions to vaccinate.[19] Finally, in China, 44.5% of >1300 parents who were health care workers reported they are likely or very likely to have their children aged <18 years take up COVID-19 vaccination in the next 6 months.[20]

We found that mothers are much less likely than fathers to approve abridged research and approval (64.8% in the post–adult vaccine approval period). This follows previous findings showing that mothers are less likely to vaccinate their children.[2,5,21–23] In prior work, our group found lower willingness to vaccinate among mothers in an international sample.[5] In Bologna, Italy, higher vaccine hesitancy was found among mothers/female guardians of children aged 6 to 10 years,[23] and Skjefte et al[21] reported that a major reason for mothers' refusal of a COVID-19 vaccination for their child was concerns about insufficient data collection during the approval process. Furthermore, findings from the pre–adult approval phase of COVIPAS revealed that >40% of parents would accept shortcuts to speed the approval process for children.[2] A range of social and contextual factors was offered to explain gender pattern of vaccination intentions.[22]

The approval of new drugs is an increasingly complicated process,[24,25] and the success of vaccination programs is contingent on irrefutable scientific safety data combined with high rates of public acceptance and population coverage.[26] Trust in the process of vaccine approval rests on the shoulders of the scientific community and regulatory bodies. As research of vaccines for children aged <12 years is likely to be available soon, and approval and rollout of vaccines will then ensue, it is critical to enhance trust in the government and regulators.

The rapid pace of vaccine development, misinformation in popular and social media, the polarized sociopolitical environment, and the inherent complexities of large-scale vaccination efforts may undermine vaccination confidence and increase complacency about COVID-19 vaccination. A comprehensive post-efficacy strategy is essential for building trust and should include assessment of optimization of vaccination regimens, dosage for children, booster doses, safety, and enhanced surveillance.

The present study has limitations. First, the cohort that completed the survey was not a representative sample of families visiting the EDs or the entire population in these countries. Rate of vaccinating the adult population (partially or fully vaccinated) differed between the countries included in the study. There could be bias in responses due to social desirability and several confounders such as traditional as well as social media interactions, variable and changing public health recommendations during the study period, and the rate of morbidity and mortality due to COVID-19. Furthermore, there was variation in the rate of response as well as the outcome by country between the 2 study periods. Israel comprised a greater proportion of responses in phase 1 versus phase 2, whereas the opposite was true for the United States. To account for this difference, we adjusted our analyses by country, and findings were relatively unchanged from an unadjusted analysis. Finally, additional factors that go into making a decision on whether to get a child vaccinated were not included in the survey.

CONCLUSIONS

The rate of willingness to expedite vaccine approval increased after the emergency approval of COVID-19 vaccine for adults. In both phases, mothers were much less likely to approve expedited approval. We found similar characteristics of caregivers who were willing to forego regulatory demands on vaccine approval after approval of adult vaccines. Ongoing public health education efforts should include documentation on measures taken to ensure that a vaccine is safe and effective as well as on the regulatory process that leads to COVID-19 vaccine approval for children.

ACKNOWLEDGMENTS

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. All authors had full access to all of the data (statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

Dr Goldman accepts full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish. Dr Goldman and Mr Bone were responsible for the acquisition, analysis, and interpretation of data, with contribution from all authors. Mr Bone was the statistician at the lead study site, working with Dr Goldman. All authors contributed to drafting of the manuscript and critical revision of the manuscript for important intellectual content.

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DISCLOSURES

The authors have indicated that they have no conflicts of interest regarding the content of this article.

DATA AVAILABILITY

Data are available from Dr Goldman, who may be contacted by e-mail at rgoldman@cw.bc.ca. The data will not be shared or disseminated to study participants/patient organizations.

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