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Original Research

Caregivers' Willingness to Accept Expedited Vaccine Research During the COVID-19 Pandemic: A Cross-sectional Survey

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ABSTRACT

Purpose: This study determined the predictors of caregivers' willingness to accept an accelerated regulatory process for the development of vaccines against coronavirus disease 2019 (COVID-19).

Methods: An international cross-sectional survey was administered to 2557 caregivers of children in 17 pediatric emergency departments (EDs) across 6 countries from March 26, 2020, to June 30, 2020. Caregivers were asked to select 1 of 4 choices with which they most agreed regarding a proposed COVID-19 vaccine–approval process, in addition to questions regarding demographic characteristics, the ED visit, and attitudes about COVID-19. Univariate analyses were conducted using the Mann–Whitney *U* test for comparing non–normally distributed continuous variables, an independent *t* test for comparing normally distributed continuous variables, and a χ^2 or Fisher exact test for categorical variables. Multivariate logistic regression analysis was used for determining independent factors associated with caregivers' willingness to accept abridged development of a COVID-19 vaccine. A *P* value of <0.05 was considered significant.

Findings: Almost half (1101/2557; 43%) of caregivers reported that they were willing to accept less rigorous testing and postresearch approval of a new COVID-19 vaccine. 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 (odds ratio [OR] = 1.72; 95% CI, 1.29–2.31), caregivers' concern about having had COVID-19 themselves at the time of survey completion in the ED (OR = 1.1; 95% CI, 1.05–1.16), and caregivers' intent to have their children vaccinated against COVID-19 if a vaccine were to become available (OR = 1.84; 95% CI, 1.54–2.21). Compared with fathers, mothers completing the survey were less likely to approve of changes in the vaccine-development process (OR = 0.641; 95% CI, 0.529–0.775).

Implications: Less than half of caregivers in this worldwide sample were willing to accept abbreviated COVID-19 vaccine testing. As a part of an effort to increase acceptance and uptake of a new vaccine, especially in order to protect children, public health strategies and individual providers should understand caregivers' attitudes toward the approval of a vaccine and consult them appropriately. (*Clin Ther.* 2020;42:2124–2133) © 2020 Elsevier Inc.

Key words: COVID-19, drug approval, parental attitudes, vaccine.

INTRODUCTION

Since the genetic sequence of severe acute respiratory syndrome–coronavirus 2 (SARS-CoV-2), the virus that causes coronavirus disease 2019 (COVID-19), was published in January 2020,[1] >100 candidates for a vaccine have been developed. By establishing higher levels of herd immunity and preventing repeated or continuous epidemics, vaccination will be one of the most effective strategies of limiting the spread of the disease.[2] Findings from recent prediction modeling have suggested that, even with mitigation strategies, such as testing, isolation of cases, and social-distancing measures focused on shielding the elderly and slowing the transmission of SARS-CoV-2, the worldwide death toll may reach 20 million by the end of 2020 in the absence of an effective vaccine.[3] A wide spectrum of vaccine platforms are being developed,[4] with a recent report estimating that a COVID-19 vaccine may be available after 1 or 2 years,[5] much faster than the duration of conventional vaccine-approval processes.[6]

Prior to regulatory approval, the developers of novel vaccine candidates need to follow a well-defined process of surveillance.[7] However, during the COVID-19 pandemic, some vaccine candidates have

been given Fast-Track status by the US Food and Drug Administration (FDA),[8] and alternative vaccine-approval methods, such as human challenge studies, are being investigated to accelerate licensure.[9] The first COVID-19 vaccine candidate entered human clinical testing with unprecedented speed, on March 16, 2020,[1] and the first Phase III trials were begun just 4 months later.[10] Fast-Tracking the vaccine-licensure process has been explored in the past in other infectious diseases, including tuberculosis,[11] serogroup B meningococcal disease,[12] and Zika virus.[13]

In the United States, it has been estimated that only two thirds of people would be willing to undergo COVID-19 vaccination.[14] The hesitancy of parents to have their children vaccinated has been associated with safety concerns,[15] and positive public opinion and trust in expedited COVID-19 vaccine development is paramount to the success of the vaccine.[16] Understanding caregivers' willingness to accept an expedited vaccine-approval process may help to inform public health decisions and to support an effective rollout of a future COVID-19 vaccination program. The objective of the present study was to determine caregivers' perceptions and attitudes regarding vaccine-research regulations in the midst of the COVID-19 pandemic.

PARTICIPANTS AND METHODS

Sample and Procedures

This survey was a part of the larger-scale COVID-19 Parental Attitude Study (COVIPAS) of caregivers presenting with their children for emergency care during the era of COVID-19. Participants were recruited using posters placed in waiting areas and patients' rooms, as well as a direct approach by health care team members. Eligible participants were caregivers (mostly parents) of children aged <18 years who presented at 1 of 17 pediatric emergency departments (EDs) in cities in the United States (Seattle, Washington; Tacoma, Washington; Los Angeles, California; Dallas, Texas; and Atlanta, Georgia), Canada (Vancouver, Toronto, Saskatoon, Edmonton, and Calgary), Israel (Be'er Ya'akov), Japan (Tokyo), Spain (Barcelona), and Switzerland (Zurich, Bern, Geneva, and Bellinzona).

For infection-control purposes, caregivers used their own electronic devices (eg, smartphones, tablets) to complete the survey by logging onto a secure online platform based on REDCap metadata-driven software (Vanderbilt University), https://www.project-redcap.org/. Once caregivers selected their study site, they provided consent for participation in the online survey, as approved by each site's local institutional review board. Five institutional review boards (in Switzerland and Spain) provided a waiver of consent whereby responding to the survey was considered consent to participate.

The survey tool was available in English, French, German, Spanish, Japanese, Italian, and Hebrew. While sites began recruitment in a staggered fashion, surveys were obtained between March 26, 2020, and June 30, 2020. Due to restrictions to visitation at most sites, only 1 caregiver was in the room with each child. As such, only 1 caregiver completed the survey per visit.

Measures

The study-specific questionnaire was developed to include questions regarding demographic characteristics, information regarding the ED visit, and attitudes about COVID-19. The survey objective was to reflect caregivers' opinions and actions during the pandemic. Literature related to the SARS epidemic in 2002−2003 helped to inform survey development. Pilot testing for face and content validity of all items of the survey, including those presented in this report, was completed *a priori* by 10 individuals representing the target group of caregivers and by 10 health care providers working in the ED environment who provided feedback that led to revisions and development of the final survey.

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."

Table I. Demographic characteristics and survey responses for all caregivers that completed the survey (N = 2768 surveys).

Characteristic	n/N (%)*
Child	
Age mean (SD), y (n = 2764)	7.6 (5.1)
Female, no. (%)	1335/2728 (48.3)
Has chronic illness, no. (%)	384/2736 (14.0)
Long-term medication use, no. (%)	479/2736 (17.5)
Vaccinations up to date, no. (%)	2420/2729 (88.7)
Caregiver who completed the survey, no. (%)	
Father	662/2761 (24.0)
Mother	2025/2761 (73.3)
Other	74/2761 (2.68)
Age, mean (SD), y (n = 2724)	39.4 (7.86)
More than high school education, no. (%)	2081/2707 (76.9)
COVID-19 has led to a loss of income for caregiver, no. (%)	1076/2727 (39.5)
Caregiver attitudes	
Caregiver wants expedited COVID-19 vaccine approval, no. (%)	1101/2557 (43.1)
Caregiver would allow child to participate in a COVID vaccine trial, no. (%)	497/2708 (18.4)
Caregiver concerns, mean (SD) Likert scale score†	
Caregiver concerned their child has COVID-19 (n = 2688)	1.97 (2.91)
Caregiver concerned they have COVID-19 (n = 2675)	1.89 (2.77)
Caregiver concerned their child has influenza (n = 2662)	1.23 (2.37)
Caregiver concerned they have influenza (n = 2655)	0.92 (2.02)
Caregiver concerned about missing work (n = 2649)	2.65 (3.47)
Caregiver concerned about child missing school (n = 2641)	2.78 (3.49)

* Unless otherwise specified.
† Scale: 0 = not concerned at all to 10 = most concerned.

Statistical Analysis

Basic descriptive statistics and frequencies were used to describe all variables, comparing survey data from caregivers who would support abridged COVID-19 vaccine regulations and those who would not. To determine which factors were significantly associated with the decision to agree to expedited regulation processes, we used univariate analyses: the Mann–Whitney *U* test for comparing non–normally distributed continuous variables, the independent *t* test for comparing normally distributed continuous variables, and the χ^2 or Fisher exact test for categorical variables. We then used a multivariate logistic regression analysis to estimate the adjusted odds ratio (OR) of agreeing to abridged vaccine testing, using all of the variables that showed significance ($P < 0.1$) in the univariate analysis and other variables of interest. To compare caregivers' concern of their children having COVID-19 (Likert scale score, 0–10) and a willingness to agree with expedited regulations, we used the Mann–Whitney *U* test. All analyses were conducted with R software version 3.5.1. A *P* value of <0.05 was considered statistically significant.

RESULTS

A total of 2785 surveys were completed online. Seventeen surveys (0.6%) were excluded because they were completed by patients or were incomplete. Table I provides demographic information on the caregivers that completed the survey. We further excluded 159 surveys (5.7%) on which caregivers

Table II. Factors associated with caregivers' willingness to accept changes in vaccine regulatory standards for the COVID-19 pandemic. Data are given as number (%) of surveys unless otherwise specified.

	No. of Surveys (N = 2557)	All Caregivers (N = 2557)	No Change in Regulation (n = 1456)	Suggest Change in Regulation (n = 1101)	*P*
Child					
Age, mean (SD), y	2554	7.5 (5.1)	7.37 (5.1)	7.7 (5.0)	0.079
Female	2553	1235 (48.4)	689 (47.3)	546 (49.6)	0.272
Has chronic illness	2533	360 (14.2)	207 (14.2)	153 (13.9)	0.845
Chronic medication use	2534	444 (17.5)	248 (17.0)	196 (17.8)	0.647
Vaccinations up to date	2548	2275 (89.3)	1264 (86.8)	1011 (91.8)	<0.001
Caregiver who completed the survey	2552				<0.001
Father		622 (24.4)	297 (20.4)	325 (29.5)	
Mother		1866 (73.1)	1121 (76.9)	745 (67.7)	
Other		64 (2.51)	35 (2.40)	29 (2.64)	
Age, mean (SD), y	2527	39.4 (7.86)	38.8 (7.79)	40.2 (7.90)	<0.001
More than high school education	2507	1975 (78.8)	1109 (76.2)	866 (78.6)	0.171
COVID-19 has led to a loss of income for caregiver	2541	992 (39.0)	597 (41.0)	395 (35.9)	0.009
Caregiver attitudes					
Would vaccinate their child against COVID-19 if a vaccine existed today	2524	1707 (67.6)	875 (61.0)	832 (75.6)	<0.001
Caregiver believes that social distancing is worthwhile	2546	2405 (94.5)	597 (41.0)	395 (35.9)	0.009
Caregiver concerns, mean (SD) Likert scale score*					
Caregiver concerned their child has COVID-19	2514	1.97 (2.88)	1.69 (2.75)	2.34 (3.00)	<0.001
Caregiver concerned they have COVID-19	2504	1.90 (2.74)	1.57 (2.59)	2.34 (2.86)	<0.001
Caregiver concerned their child has influenza	2488	1.21 (2.33)	1.10 (2.28)	1.34 (2.39)	0.011
Caregiver concerned they have influenza	2486	0.89 (1.96)	0.77 (1.90)	1.06 (2.03)	<0.001
Caregiver concerned about missing work	2479	2.63 (3.44)	2.53 (3.46)	2.76 (3.42)	0.103
Caregiver concerned about child missing school	2476	2.75 (3.46)	2.62 (3.48)	2.93 (3.43)	0.03

* Scale: 0 = not concerned at all to 10 = most concerned.

did not provide an answer to whether they recommended a similar or faster approval process (n = 107) or responded "other" with no description of reasoning (n = 52). Another 52 surveys (1.9%) with "other" were excluded since caregivers provided descriptions suggesting that they were "against vaccines in general" (n = 19), suggested that they "do not know enough about the subject to

answer this question" (n = 19), indicated that "all vaccines need better testing processes" (n = 6), indicated that "Coronavirus is not real/not as bad as media portrays it" (n = 6), or that science needs to focus on "cure rather than vaccine" (n = 2). These exclusions resulted in a total of 2557 survey respondents included in the presently described study.

On surveys included (Table II), the mean (SD) age of the children was 7.5 (5.1) years, and the mean age of caregivers was 39.4 (7.86) years. The vast majority of surveys were completed by parents (97.5%) as opposed to other caregivers. A total of 360 respondents (14.2%) had children with a chronic illness.

There were 1456 caregivers (56.9%) who reported that standard vaccine regulations should not change for COVID-19 vaccine development and 1101 caregivers (43.1%) who indicated a preference for expedited regulations. Table II provides a comparison between families who completed the question on whether more expedited testing should be performed for COVID-19 vaccine approval. Over half of fathers (52.3%) were likely to suggest modifying the standards, while a greater proportion of mothers were likely to suggest continuing the current vaccine-research regulation scheme (60.1%) ($P < 0.001$). Caregivers of children with up-to-date vaccinations and those willing to have their children vaccinated against COVID-19 if a vaccine became available were more likely to accept shortening or changing of the vaccine-testing process (both, $P < 0.001$). Additional factors associated with a willingness to modify regulations included older age of caregivers ($P < 0.001$), caregivers' concern that they themselves or their children had COVID-19 (both, $P < 0.001$) or influenza ($P = 0.011$ and $P < 0.001$, respectively) when visiting the ED, caregivers' concern about their children missing school ($P = 0.03$), and caregivers' consideration that physical and social distancing were worthwhile actions ($P = 0.009$). Caregivers who reported that they lost income due to the COVID-19 pandemic were more likely to indicate a preference for maintaining the current regulations for vaccine research ($P = 0.009$).

On multivariate logistic regression analysis (Table III), factors predicting a willingness to change the regulations of COVID-19 vaccine research included having children who were up to date with their vaccination schedules (OR = 1.72; 95% CI, 1.29−2.31; $P < 0.001$), a willingness to have their children vaccinated against COVID-19 if a vaccine became available (OR = 1.84; 95% CI, 1.54−2.21; $P < 0.001$), and caregivers' worry that the caregivers themselves had COVID-19 infection (OR = 1.1; 95% CI, 1.05−1.16; $P < 0.001$). In general, mothers were less likely to support changes in the regulations regarding COVID-19 vaccine approval (OR = 0.641; 95% CI, 0.529−0.775; $P < 0.01$).

Table III. Predictors of caregivers' willingness to accept changes in vaccine regulatory standards for COVID-19 identified by multivariate logistic regression analysis.

Factor	OR	95% CI	*P*
Child's age	1	0.999−1	0.592
Survey completed by mother	0.641	0.529−0.775	<0.01
Survey completed by non-mother or non-father	0.7	0.404−1.2	0.197
Child's vaccinations are up to date	1.72	1.29−2.31	<0.001
Caregiver would vaccinate their child against COVID-19 if a vaccine existed today	1.84	1.54−2.21	<0.001
Caregiver is worried that their child has COVID-19	0.999	0.951−1.05	0.963
Caregiver is worried that they have COVID-19	1.1	1.05−1.16	<0.001

OR = odds ratio.

DISCUSSION

In our international sample of caregivers arriving with their children to 17 EDs in 6 countries, almost half of caregivers (43.1%) reported a willingness to accept expedited testing and approval of a COVID-19 vaccine during the pandemic, in order to make it available faster. Independent factors associated with an increased willingness to see a change in the approval process included caregivers being fathers, caregivers having children who had received vaccinations based on the recommended schedule, caregivers who would have their children vaccinated against COVID-19 if one became available, and caregivers who were concerned about having COVID-19 themselves at the time that the survey was conducted in the ED.

A safe and effective vaccine against COVID-19 would help countries to mitigate further morbidity and mortality and facilitate the return of people and economies to prepandemic activity. Overcoming challenges in vaccine development and increasing vaccine uptake are crucial, especially during the pandemic and among children.[17] The development of a vaccine against SARS-CoV-2 infection is expected to be relatively straightforward and attainable because the virus seems to be fairly stable.[18] Predicted vaccine coverage of 55%−82% of the population is needed in order to provide herd immunity to SARS-CoV-2 infection[19]; however, local health authorities such as those in the United States reported that it is unlikely that herd immunity will be achieved given the current state of COVID-19 vaccine refusal.[14]

Regulatory bodies in different countries have similar vaccine testing and approval processes,[20] and all are complex, often lasting 10−15 years and involving a combination of public and private involvement.[6] Developing and testing vaccine candidates to be used during the pandemic is imperative and, in an effort to facilitate research on a COVID-19 vaccine, the National Institutes of Health in the United States and other governments have developed networks to research and improve progress in vaccine development.[21] While we are in a new era in vaccine development that will expedite approval of the vaccine against SARS-CoV-2 infection, it may be many months before approval is granted.

The high number of caregivers in our sample who indicated that they would accept a change in the current standards of vaccine approval in the case of COVID-19, as well as an increase in those planning on having their children vaccinated against influenza next year,[22] are surprising findings since in the past parents have reported great importance in the safety of vaccines,[23,24] which necessitates extensive time for evaluation, and the perceived danger of vaccines has been associated with a reluctance to vaccinate children.[25] There are 70 independent barriers associated with vaccine hesitancy,[26] and parents' decision making regarding vaccination depends on trust in health care providers' advice, social network influences, knowledge about vaccines, and general views toward health.[27]

Several countries, such as the United States and Canada, have developed a Fast-Track process for drug approval, although not without controversy and increased safety warnings, compared to drugs approved through the usual regulatory process.[28] Yet, "cutting red tape" in Australia has been beneficial for bringing technologies and drugs to patients,[29] and some benefit of Fast-Tracking measures has been documented by the US FDA.[30] During the current pandemic, accelerated regulatory procedures for drug approvals have already been implemented, including the FDA's Emergency Use Authorization for remdesivir.[31] COVID-19 vaccine candidates are similarly being evaluated using an Investigational New Drug exemption mechanism in hopes of facilitating a quicker end to the pandemic.[31]

Caregivers reporting the concern that they may have had COVID-19 at the time of the visit to the ED, potentially reflecting a greater concern about transmitting the illness to their children, were more likely to want a vaccine to be ready faster. Similarly, caregivers who indicated that they were planning to vaccinate their children against COVID-19 also indicated that they were more comfortable with a faster testing and approval process for that vaccine.

Our surveys were administered during the peak of the COVID-19 pandemic (March to June 2020), with daily media reports of thousands of deaths and rapid new discoveries about the illness. It is possible that fear of the pandemic and its devastating consequences have shifted caregivers' acceptance to less rigorous regulation. Similarly, fear about the

H1N1 illness was associated with increased H1N1 vaccine uptake.[32,33] Emergency vaccine preparation and production and a change in risk/benefit ratio due to high morbidity and mortality have been suggested as acceptable.[11,34] While parents are concerned about the adverse events associated with vaccines, perhaps even more than the symptoms of illness itself,[35] more adverse events during a pandemic may be acceptable from a public health perspective.[34] Another important factor that may influence caregivers' willingness is the fact that COVID-19 infection in children is largely a self-limiting, benign disease.[36] On the other hand, recent reports of complications in children following COVID-19 infection, including a Kawasaki disease–like illness,[37] may influence caregivers to be more willing to allow for abridged vaccine-regulation standards.

We found that caregivers of children up to date with their vaccinations are likely to want a more relaxed COVID-19 vaccine–approval process. We surmise that these families trust the medical system and a rigorous testing and approval process, and have had positive experiences with vaccinations. Additionally, during the pandemic, they are willing to accept an abridged process. Similar to our findings, prior seasonal influenza vaccination experience was associated with H1N1 vaccine uptake.[33]

It is interesting that mothers were less likely than were fathers to choose abbreviated vaccine testing. This sex difference was seen among adults considering H1N1 vaccination[38] and among women who were never in favor of vaccination and made different trade-offs than did men who stated that they were (possibly) willing to get vaccinated.[39] Risk-taking behaviors of fathers may be different from those of mothers, similar to findings related to child play and pediatric trauma prevention.[40] Finally, families that reported a loss of income during this pandemic were not in favor of modifying regulations for COVID-19 vaccine approval, perhaps reflecting that caregivers want the best health for their children, before their own economic well-being.[41]

Limitations

Our study had some limitations. First, the population of parents and other caregivers who responded to the survey was not representative of all caregivers in the 6 countries where the survey was administered, as the survey was administered in a hospital ED setting during the peak of COVID-19. ED-access patterns by caregivers may have been influenced by the pandemic, resulting in delayed or omitted visits due to stay-in-place orders by local governments, or children who may not have ordinarily presented to the ED but did because their primary health care provider was unavailable. Moreover, not all parents completed the survey, and a few (2.5%) respondents were caregivers other than parents (eg, grandparents) who may not have been the decision makers. Also, requiring an electronic device such as a smartphone or tablet to complete the survey may have prohibited participation for some.

Second, caregivers shared their considerations with regard to vaccine-regulation standards at times of intense uncertainty during a period of major change in daily activities (no school, work at home), and their perceptions of an abridged vaccine-development process may be different when community life returns to a new normal of activity and the numbers of infected patients drop. Throughout the period of survey data collection, communications from local authorities had evolved, and factors including the availability of COVID-19 testing for children had changed over time. Given the unique stressors during this period of time when our understanding of this illness was limited and the amount of fear of harm from it was greatest, our findings may have overestimated the true acceptance of an expedited COVID-19 vaccine-research process. On the other hand, with schools beginning to reopen and the mental fatigue during the pandemic worsening, one may argue that caregivers will be more accepting in the coming months. Finally, the survey was administered before the regulatory approval of any COVID-19 vaccine, and once a vaccine has been tested and becomes available, caregivers may learn new information that may change their minds with regard to the acceptability of expedited vaccine licensure.

CONCLUSIONS

Almost half of caregivers in this worldwide sample were willing to accept less strict standards of the development and approval of a COVID-19 vaccine. The child's vaccination history, caregiver's sex, worry that they personally had COVID-19 at the time of survey completion, and an intention to have the child vaccinated against COVID-19 in the future were

independent factors associated with the acceptability of abbreviated vaccine testing. Understanding caregivers' attitudes toward an expedited COVID-19 vaccine testing and approval process is imperative in planning new vaccine uptake. This information may help to inform public health communication and strategies for improving vaccine acceptance, at the time that a COVID-19 vaccine is available.

AUTHOR CONTRIBUTIONS

R. Goldman has accepted full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish. Study concept and design were provided by R. Goldman, E. Klein, and J.C. Brown. Acquisition, analysis, and interpretation of data, and drafting of the manuscript, were provided by R. Goldman, T. Yan, and N. Shimizu. All of the authors provided critical revision of the manuscript for important intellectual content. Statistical analysis was provided by the statistician at the lead study site, working with R. Goldman.

The corresponding author has attested that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted. All of the authors have attested they meet the ICMJE criteria for authorship.

DISCLOSURES

The authors have indicated that they have no conflicts of interest with regard to the content of this article.

DATA STATEMENT

The data will not be shared or disseminated to study participants/patient organizations.

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