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RESEARCH PAPER

Factors associated with parents' willingness to enroll their children in trials for COVID-19 vaccination

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ABSTRACT

The coronavirus disease 2019 (COVID-19) pandemic has taken an unprecedented global toll and vaccination is needed to restore healthy living. Timely inclusion of children in vaccination trials is critical. We surveyed caregivers of children seeking care in 17 Emergency Departments (ED) across 6 countries during the peak of the pandemic to identify factors associated with intent to participate in COVID-19 vaccine trials. Questions about child and parent characteristics, COVID-19 expressed concerns and parental attitudes toward participation in a trial were asked.

Of 2768 completed surveys, 18.4% parents stated they would enroll their child in a clinical trial for a COVID-19 vaccine and 14.4% would agree to a randomized placebo-controlled study. Factors associated with willingness to participate were parents agreeing to enroll in a COVID-19 vaccine trial themselves (Odds Ratio (OR) 32.9, 95% Confidence Interval (CI) (21.9–51.2)) having an older child (OR 1.0 (1.0–1.01)), having children who received all vaccinations based on their country schedule (OR 2.67 (1.35–5.71)) and parents with high school education or lower (OR 1.79 (1.18–2.74)). Mothers were less likely to enroll their child in a trial (OR 0.68 (0.47–0.97)). Only one fifth of families surveyed will consider enrolling their child in a vaccine trial. Parental interest in participation, history of vaccinating their child, and the child being older all are associated with parents allowing their child to participate in a COVID vaccine trial. This information may help decision-makers and researchers shape their strategies for trial design and participation engagement in upcoming COVID19 vaccination trials.

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Introduction

The novel coronavirus (COVID-19) started spreading in humans toward the end of 2019 and became a global pandemic affecting millions of families. Public health authorities worldwide implemented specific actions to reduce physical encounters, as the virus spreads mainly among people who are in close physical contact. While some therapies are currently in trials, vaccines are likely to provide the best protection from contracting the illness and there are currently more than 100 projects centered on the development of a vaccine.[1] At the time of conducting this study, at least eight candidate vaccines were entering clinical trials.[1]

Parents focus on the best interests of their children, and consenting for a child to enter a vaccination trial is a complex decision. Developing an effective and safe vaccine is crucial for protection from COVID-19, since treatments have not proved effective thus far. Clinical trials are a key step in vaccine development prior to widespread dissemination.

The objective of our study was to determine factors associated with parents' intent to enroll their children in a COVID-19 vaccination trial. Information from this survey may enable sponsors of studies, investigators and decision makers to better tailor study design and recruitment strategies for prospective COVID-19 vaccine clinical trials. Developing strategies for successful recruitment will ensure that parents will have the

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information and confidence to allow their children to be enrolled in clinical trials, facilitating timely vaccine efficacy studies.

Methods

Sample and procedures

This study is part of a larger COVID-19 Parental Attitude Study (COVIPAS) of caregivers presenting for emergency care for their children in the era of COVID-19. The aim of the larger study is to assess parental attitudes toward COVID-19 during the peak of the pandemic. Using posters placed in waiting areas and patient rooms, as well as direct approach by a healthcare team members, caregivers who arrived to 17 pediatric emergency departments (ED) in the USA (Seattle, Tacoma, Los Angeles, Dallas, Atlanta), Canada (Vancouver, Toronto, Saskatoon, Edmonton, Calgary), Israel (Shamir), Japan (Tokyo), Spain (Barcelona), and Switzerland (Zurich, Bern, Geneva, Bellinzona) were asked to participate, using posters in waiting areas and patient rooms. For infectious control purposes, respondents used their own smartphones to complete the survey by logging into a secured online platform based on REDCap metadata-driven software (Vanderbilt University). Several IRBs (in Switzerland and Spain) provided a waiver of consent such that responding to the survey was considered consent to participate.

Languages available to complete the study were English, French, German, Italian, Spanish, Hebrew and Japanese. While sites joined recruitment in a staggered fashion, surveys were obtained between March 27 and June 30, 2020. Only one caregiver completed the survey during the visit, and due to restrictions to visitation in most sites, only one caregiver was in the room with the child.

Measures

The study-specific questionnaire was developed to include questions on demographic characteristics, information on reason for the ED visit and attitudes around COVID-19. The survey was developed to reflect parental opinions and actions during the pandemic. Literature related to the Severe Acute Respiratory Syndrome (SARS) epidemic in 2002–2003 helped inform questions in the survey. All items of the survey, including those presented in this report were evaluated a priori by 10 individuals representing the target group and 10 healthcare providers working in the ED environment. Feedback led to revisions. The survey was tested for clarity and then was loaded online.

We asked parents to answer four questions about participation in a theoretical vaccine trial without explanation of what such a trial might entail: (1) "If there was a research study in the emergency today for a new vaccine/immunization for Coronavirus (COVID-19) and your child was to receive the new vaccine/immunization in the study – would your child participate?" (2) "For the same study would you participate?" (3) "If there was a study in the emergency today for a new vaccine/immunization for Coronavirus (COVID-19) and your child had a 50% chance of getting the new vaccine/immunization and 50% chance of receiving PLACEBO (not an active immunization, chances like a flip of a coin) would your child participate?" (4) "For the same study would you participate?"

Data analysis

Descriptive statistics and frequencies were used to describe all variables, comparing survey data from parents who would enroll their children in a trial for COVID-19 vaccination to those who would not. To determine which factors were significantly associated with the decision to enroll their child in a vaccine trial, we used univariate analyses: Mann-Whitney test for comparing non-normal continuous variables, independent *t*-test was used for comparing normally distributed continuous variables, and Chi-square or Fisher's exact test for categorical variables. We then used multivariable logistic regression analysis to estimate the adjusted odds ratio of agreeing to participation in a vaccination trial, using all the variables that showed significance ($p < .05$) in the univariate analysis. All analyses were conducted with R version 3.5.1. A p value less than 0.05 was considered statistically significant.

Results

A total of 2775 surveys were completed online. Seven (0.3%) were excluded because they were completed by the patient (n = 3) or the survey was only partially completed (n = 4).

Median age of children was 7.5 (Standard Deviation (SD) = 5.1) years and parent's median age was 39.3 (SD = 7.9) years. Table 1 provides demographic information including a comparison between families who would or would-not enroll their children in a COVID-19 vaccine trial. Many more mothers completed the survey compared to fathers or other caregivers (73.3%, 24.0%, and 2.7%, respectively).

A total of 497/2708 (18.4%) parents stated they would enroll their child in a clinical trial for a COVID-19 vaccine. When asked about participating in a placebo controlled vaccine trial, 389/2693 (14.4%) parents would agree to enroll their child (78.3% of the caregivers that agreed to a clinical trial), a meaningful reduction in rate of approval. Table 2Table 3 represents vaccine trial design and the rate of anticipated participation of children and parents per parent report.

In the univariate analysis, factors associated with anticipated participation were having older children ($p < .001$), child being vaccinated based on the recommended schedule ($p < .001$), older parents ($p < .001$), if the mother completed the survey ($p < .001$), and if parent willing to participate themselves in the same trial ($p < .001$). Level of concern about contracting COVID-19 on a scale of 0–10 was not associated with willingness to participate in a potential vaccine trial.

In a logistic regression analysis to determine factors associated with enrolling children, we found that five factors that were associated in a multivariate model with parents' willingness for their child to participate. The most significant was parental willingness to participate in a similar trial (OR 32.9, 95% CI 21.9–51.2). The other factors were child's age, child's vaccination status up-to-date, if the mother completed the survey, and parental education at a level of high school or lower.

Table 1. Factors associated with child participating in a COVID-19 vaccine trial. SD- Standard Deviation.

	Will not have child participate (n = 2211)	Will have child participate (n = 497)	P value
Child's Mean Age in months (SD)	7.36 (5.06)	8.33 (5.02)	<.001
Child's Gender Female	1069 (48.5%)	241 (48.9%)	.903
Child has Chronic Illness	306 (14.0%)	70 (14.1%)	.994
Chronic Medication Use by Child	377 (17.3%)	89 (17.9%)	.767
Child Vaccinations Up to Date	1919 (87.4%)	467 (94.5%)	<.001
Who is completing the survey			<.001
Father	490 (22.2%)	160 (32.3%)	
Mother	1662 (75.3%)	320 (64.6%)	
Other*	55 (2.49%)	15 (3.03%)	
Parent's age in years (SD)	39.1 (7.71)	40.7 (8.16)	<.001
Parents with post-secondary education	1676 (77.4%)	374 (76.6%)	.757
Parent willing to participate themselves in the same trial	504 (23.1%)	442 (89.7%)	<.001
Mean score Likert scale – parents concerned their child has COVID-19	1.92 (2.88)	2.11 (2.97)	.192
Mean score Likert scale- parents concerned they are sick with COVID-19	1.84 (2.73)	2.05 (2.87)	.147

(*) Grandparents or siblings

Table 2. Level of concordance between parents' participation and their willingness to enroll their children in a COVID-19 in a vaccination trial. Complete answers were received by 2679 parents on "vaccine trial" question, and 2673 on "RCT Vaccine trial" question RCT = Randomized Controlled Trial.

VACCINE TRIAL (N)	Parent will participate themselves (946)	Parents will not participate (1733)
Parent will allow child to participate (493)	442 (89.7%)	51 (10.3%)
Parent will not allow child to participate (2186)	504 (23.1%)	1682 (76.9%)
RCT VACCINE TRIAL (50% chance of getting vaccine) (N)	Parent will participate Themselves (761)	Parents will not participate (1912)
Parent will allow child to participate (385)	366 (95.1)	19 (4.9)
Parent will not allow child to participate (2288)	395 (17.3)	1893 (82.7)

Table 3. Predictors of parents agreeing for their child to enroll in a COVID-19 vaccination trial identified by multivariate logistic regression analysis.

Factor evaluated	Odds ratio	OR 95% CI	P value
Mean Child's Age in months	1	(1–1.01)	.009
Gender – Male	0.985	(0.718–1.35)	.926
Child has a chronic illness	1.09	(0.682–1.72)	.719
Child is Up to Date with Vaccinations	2.67	(1.35–5.71)	.007
Mother completing the survey	0.677	(0.472–0.972)	.034
Mean Parent's Age in years	0.986	(0.963–1.01)	.271
Parent Education high school or less	1.79	(1.18–2.74)	.007
Parent concerned the child has COVID	1.03	(0.974–1.1)	.27
Parent plan to enroll themselves in a similar trial	32.9	(21.9–51.2)	<.001

Discussion

With limited therapies available for either prevention or treatment of COVID-19, vaccine researchers and public health officials aim to expedite vaccine development.[1] The parent's role in decision-making for their child differs from an adult deciding about their own participation in a vaccine trial, exercising their individual autonomy.[2] Determining parental considerations during the peak of a pandemic can help optimize the study design and recruitment strategies for prospective COVID-19 clinical trials involving children. This is especially important in order to ensure successful and time-sensitive completion of a trial.[1]

We found that only one fifth of parents bringing their children to the ED would be willing to have their child participate in a COVID-19 vaccine study. Of those who would enroll their child in a vaccine trial, only 78.3% will still consent to participate if the study was a randomized controlled trial (RCT) including a placebo arm. With the sample size of this study, we were unable to assess differences in willingness by country.

Parents approached in the ED about a potential COVID-19 vaccine trial expressed low willingness to have their child participate. Rapid enrollment in trials can offer a faster and more efficient vaccine research program, leading to expedited evidence of efficacy and approval, benefitting individuals everywhere. There seems to be a large gap between views of the importance of research in public health and medicine, and the willingness of patients or parents to participate in research studies, especially with minors.[3] When a placebo-controlled trial was presented to parents as an option, an even larger proportion suggested they will not agree to have their children partake in the trial. One reason for unwillingness to allow participation of a child could be lack of understanding of clinical trials and that children are only enrolled in these trials after initial research with adults. Clear explanations and education about clinical trials is essential to garner parental support.

Factors influencing agreement

Parental willingness to include their child in a clinical trial is complex and factors strongly associated with the decision include health of the child,[4–8] positive perceptions and trust in the research team,[1,4,9–11] understanding of the study,[4,5,10] and altruistic motives.[4,12,13] In our cohort from 17 pediatric EDs in 6 countries we found that parents who would agree to participate in a COVID-19 vaccine trial were likely to also allow their child

to participate in a similar vaccine trial (89.7%). Parents were more comfortable with a trial when their children were older. We found that having a chronic illness or taking medications on a regular basis were not associated with willingness to participate, so frequent interaction with the medical establishment did not add to parental willingness to have their children join a trial. Parents who had their child complete the immunization schedule in their country were more likely to agree to participate in a new vaccine trial, likely reflecting their trust in the medical system that vaccines entering trials are safe and will provide their children with protection from an illness. We also determined that mothers were less likely to agree to child participation, when adjusting the prediction model. This needs to be further examined, and may be similar to findings from a discrete choice experiment from the Netherlands, when pandemic vaccination decision making by females who stated that they were never in favor of vaccination made different trade-offs compared to males who stated that they were possibly willing to get vaccinated.[14]

Other factors cited in the literature suggest that higher socioeconomic status,[15] having a private health insurance,[4] and the possible interference with standard of care[4] were associated with likelihood of refusal to participate in a trial. Among adults with cancer a higher level of education resulted in higher research participation[16] and parents with a medical or scientific background may be more open to research.[17]

In our cohort association was found, with lower education as a predictor for willingness to have their child participate in a trial. This is consistent with other pediatric studies that found higher education was a factor associated with not consenting to participate in research: a clinical trial on vesicoureteral reflux,[4] a survey on research participation in emergency,[18] and a study reviewing psychological profiles of parents who volunteer their children for research studies.[19]

Placebo-controlled trial

RCTs provide the most reliable information about the effectiveness and safety of health care interventions such as vaccines, and the World Health Organization (WHO) suggests cases in which RCT design is appropriate for vaccine trials.[20] RCTs of vaccine efficacy may struggle to enroll the number of patients needed in a timely manner, which can reduce investigators' ability to measure the effect of a new vaccine. British parents who declined consent in a survey suggested randomization design to be one of the factors for refusal,[21] a systematic review of 37 RCTs with over 18,000 adult participants reported that consent rates are higher for nonblinded trial designs[5] and understanding randomization and blinding were associated with consenting in a pediatric trial.[4]

In our global cohort of parents, the rate of likely participation dropped further (from 18.4% to 14.4%) when a proposed study was offered as a RCT with the possibility of receiving placebo. The psychological properties of parents is different for those consenting to randomized pediatric trials[19] and agreeing to participate in a RCT is associated with understanding of the health problem being studied and how it may impact the parent or child's own health.[5] Significant uncertainty surrounding COVID-19 when caregivers completed the surveys may have affected willingness to consider RCT methodology.

Concern about COVID-19

We hypothesized that if parents are concerned about getting sick with COVID-19 or considering their child to be sick with COVID-19, they would be more likely to agree to a vaccine trial. We found an overall low rate of concern among parents, and no correlation between level of concern and the decision to participate in a vaccine trial.

In one questionnaire study at a tertiary hospital, parents' primary concern about emergency research was that it could delay therapy or distract physicians' attention from the child's needs and parents were much less likely to endorse research during an emergency than at a nonemergency time.[18] An invitation to participate in a study, especially a RCT, may add to the intense emotional strain associated with the unprecedented COVID-19 public emergency state and impact willingness to consider a trial.

Limitations

Our study has several limitations. First, the population of parents responding to the survey does not represent all parents in the countries or hospitals where the survey took place, and we can also not determine a response rate as we administered the survey in a hospital ED setting and parents responded to an advertisement or a member of the medical team telling them about the study. Also, using smartphones may prohibit participation for some. Secondly, as in any survey, parents may share their opinions based on a hypothetical trial, trial but act differently once a more detailed description of the clinical trial is offered through an informed consent form. Finally, differences between parental attitudes and progress of the pandemic in different countries may account for some of our findings, though if there was heterogeneity in response by country, we did not have the power to detect that difference in this study. Public health organizations should consider local concerns when implementing vaccine trial methods based on our findings.

In summary, parents are more likely to consent for their children to participate in a COVID-19 vaccine trial if they are willing to be subjects in a similar trial, so adult participants in upcoming trials should be approached first for research involving their children. Only one fifth of families will consider enrolling their child in a vaccine trial, and trial design involving placebo-controlled arms is less likely to gain parental approval. This information may help decision-makers and researchers shape their strategies for trial design and implementation of upcoming COVID-19 vaccination trials.

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Author contributions

Dr Goldman had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis

Study concept and design: Drs. Goldman, Klein

Acquisition, analysis, or interpretation of data- Dr. Goldman's lab

Drafting of the manuscript: Drs. Goldman, Klein, Brown, Ali

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