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

Goldman, Ran D ; Marneni, Shashidhar R ; Seiler, Michelle ; Brown, Julie C ; Klein, Eileen J ; Cotanda, Cristina Parra ; Gelernter, Renana ; Yan, Tyler D ; Hoeffe, Julia ; Davis, Adrienne L ; Griffiths, Mark A ; Hall, Jeanine E ; Gualco, Gianluca ; Mater, Ahmed ; Manzano, Sergio ; Thompson, Graham C ; Ahmed, Sara ; Ali, Samina ; Shimizu, Naoki

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.

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Caregivers' willingness to accept expedited vaccine research during the COVID-19 pandemic – a cross sectional survey

Ran D. Goldman, MD, FRCPC, Shashidhar R. Marneni, MD, FAAP, Michelle Seiler, MD, Julie C. Brown, MD, Eileen J. Klein, MD, MPH, Cristina Parra Cotanda, MD, Renana Gelernter, MD, Tyler D. Yan, Julia Hoeffe, MD, Adrienne L. Davis, MD, MSc, FRCPC, Mark A. Griffiths, MD, FAAP, FACEP, Jeanine E. Hall, MD, Gianluca Gualco, MD, Ahmed Mater, MD, FRCPC, FAAP, Sergio Manzano, MD, Graham C. Thompson, MD, FRCPC, Sara Ahmed, MD, Samina Ali, MDCM, FRCPC, Naoki Shimizu, MD, PhD, For the International COVID-19 Parental Attitude Study (COVIPAS) Group

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Caregivers' willingness to accept expedited vaccine research during the COVID-19 pandemic – a cross sectional survey

Ran D. Goldman, MD, FRCPC

The Pediatric Research in Emergency Therapeutics (PRETx) Program, Division of Emergency Medicine, Department of Pediatrics, University of British Columbia, and BC Children's Hospital Research Institute, Vancouver, BC, Canada

Shashidhar R. Marneni, MD, FAAP

Department of Pediatric Emergency Medicine, Children's Medical Center of Dallas, UT Southwestern Medical Center, Dallas, TX, USA

Michelle Seiler, MD

Emergency Department, University Children's Hospital Zurich, Zurich, Switzerland

Julie C. Brown, MD

Seattle Children's Hospital and University of Washington School of Medicine, Seattle, WA, USA

Eileen J. Klein, MD, MPH

Seattle Children's Hospital and University of Washington School of Medicine, Seattle, WA, USA

Cristina Parra Cotanda, MD

Hospital Sant Joan de Déu Barcelona, Pediatric Emergency Department, Barcelona, Spain

Renana Gelernter, MD

Pediatric Emergency Medicine Unit, Shamir Medical Center, and Sackler Faculty of Medicine, Tel Aviv University, Israel

Tyler D. Yan

The Pediatric Research in Emergency Therapeutics (PRETx) Program, Division of Emergency Medicine, Department of Pediatrics, University of British Columbia, and BC Children's Hospital Research Institute, Vancouver, BC, Canada

Julia Hoeffe, MD

Pediatric Emergency Medicine, Inselspital University Hospital of Bern, Bern, Switzerland

Adrienne L. Davis, MD, MSc, FRCPC

Pediatric Emergency Medicine, Hospital for Sick Children and University of Toronto, ON, Canada

Mark A. Griffiths, MD, FAAP, FACEP

Division of Pediatric Emergency Medicine, Children's Healthcare of Atlanta, Emory School of Medicine, Atlanta, GA, USA

Jeanine E. Hall, MD

Division of Emergency and Transport Medicine, Children's Hospital Los Angeles, USC Keck School of Medicine, Los Angeles, CA, USA

Gianluca Gualco, MD

Pediatric Emergency Department, Pediatric Institute of Italian part of Switzerland, Ticino, Switzerland

Ahmed Mater MD, FRCPC, FAAP

Pediatric Emergency Medicine, Jim Pattison Children's Hospital, and University of Saskatchewan, Saskatoon, SK, Canada

Sergio Manzano, MD

Department of Pediatric Emergency Medicine, Geneva Children's Hospital, Geneva University Hospitals, and Faculty of Medicine, University of Geneva, Geneva, Switzerland

Graham C. Thompson MD, FRCPC

Pediatrics and Emergency Medicine, Alberta Children's Hospital and University of Calgary, Calgary, AB, Canada

Sara Ahmed, MD

Department of Emergency Medicine, Mary Bridge Children's Hospital, Tacoma, WA, USA

Samina Ali, MDCM, FRCPC

Department of Pediatrics, Faculty of Medicine & Dentistry, Women and Children's Health Research Institute, University of Alberta, Edmonton, AB, Canada

Naoki Shimizu MD, PhD

Department of Pediatrics, St. Marianna University School of Medicine, Kawasaki, Japan

For the International COVID-19 Parental Attitude Study (**COVIPAS**) Group

Correspondence: Ran Goldman, MD, FRCPC, Department of Pediatrics, University of British Columbia, BC Children's Hospital, BC Children's Hospital Research Institute 4480 Oak St, Vancouver, BC Tel: 604-875-2345 ext 7333 rgoldman@cw.bc.ca

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International COVID-19 Parental Attitude Study (COVIPAS) Group Information (alphabetic):

Dr. Sarah Ahmed, MD, Tacoma, USA
Dr. Samina Ali, MDCM, FRCPC, Edmonton, Canada
Dr. Julie C. Brown, MD, Seattle, USA
Dr. Adrienne L. Davis, MD, MSc, Toronto, Canada
Dr. Nathalie Gaucher, MD, FRCPC, PhD, Montreal, Canada
Dr. Gualco Gianluca, MD, Ticino, Switzerland
Dr. Ran Goldman, MD, Vancouver, Canada
Dr. Mark Griffiths, MD, Atlanta, USA
Dr. Jeanine E. Hall, MD, Los Angeles, USA
Dr. Matt Hansen, MD, MCR, Portland, USA
Dr. Tomohiro Katsuta, MD, PhD, Tokyo, Japan
Dr. Christopher Kelly, MD, New York, USA
Dr. Eileen J. Klein, MD, MPH, Seattle, USA
Dr. Eran Kozer, MD, Be'er Yakov, Israel
Dr. Shashidhar-R. Marneni, MD, Dallas, USA
Dr. Ahmed Mater, MD, FRCPC, FAAP, Saskatoon, Canada
Dr. Rakesh Mistry, MD, MS, Colorado, USA
Dr. Cristina Parra, PhD, Barcelona, Spain
Dr. Naveen Poonai, MD, FRCPC, London, Canada
Dr. David Sheridan, MD, MCR, Portland, USA
Dr. Naoki Shimizu, MD, PhD, Kawasaki, Japan
Dr. Esther L. Yue, MD, Portland, USA

Author Contributions:

Guarantor: Dr. Ran 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.

Study concept and design: Drs. Ran Goldman, Eileen Klein, Julie C. Brown

Acquisition, analysis, and interpretation of data: Ran Goldman, Tyler Yan, Naoki Shimizu

Drafting of the manuscript: Ran Goldman, Tyler Yan, Naoki Shimizu

Critical revision of the manuscript for important intellectual content: All authors

Statistical analysis: Statistician in lead site for the study, working with Dr. Ran Goldman

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

Caregivers' willingness to accept expedited vaccine research during the COVID-19 pandemic – a cross sectional survey

ABSTRACT

Purpose: To determine predictors associated with caregivers' willingness to accept an accelerated regulatory process for Coronavirus disease 2019 (COVID-19) vaccine development.

Methods: An international cross-sectional survey of 2557 caregivers arriving with their children to 17 pediatric Emergency Departments (ED) across six countries from March 26 to June 30, 2020. Caregivers were asked to select one of four choices they agreed with the most regarding a proposed COVID-19 vaccine approval process, in addition to questions regarding demographics, the ED visit, and attitudes about COVID-19. Univariate analyses were conducted using the Mann-Whitney test for comparing non-normal continuous variables, independent t-test for comparing normally distributed continuous variables, and Chi-square or Fisher's exact test for categorical variables. Variables of interest subsequently underwent a multivariable logistic regression analysis to determine independent factors associated with caregivers' willingness to accept abridged COVID-19 vaccine development. A p-value less than 0.05 was considered significant.

Findings: Almost half (1101/2557; 43%) of caregivers reported that they are willing to accept less rigorous testing and post-research approval for a new COVID-19 vaccine. Independent factors associated with willingness to expedite COVID-19 vaccine research included children that were up-to-date on their vaccination schedule (Odds Ratio (OR) = 1.72, 95% Confidence Interval (CI) = 1.29-2.31), caregivers concerned that they had COVID-19 at the time of survey completion in the ED (OR = 1.1, 95% CI 1.05-1.16), and caregivers that intend to vaccinate their children against COVID-19 if a vaccine becomes available (OR = 1.84, 95% CI 1.54-2.21). Mothers completing the survey were less likely to approve changes in the vaccine development process (OR = 0.64, 95% CI = 0.53-0.78).

Implications: Less than half of caregivers in a global sample are willing to accept abbreviated vaccine testing during the COVID-19 pandemic. As part of an effort to increase acceptance and uptake of the new vaccine, especially in order to protect children, public health strategies and individual providers should understand caregivers' attitudes towards approval of the vaccine and consult them appropriately.

Keywords: COVID-19; Vaccine; Drug approval; parental attitudes

30 INTRODUCTION

31 Over 100 different vaccine candidates have been developed since the genetic sequence for SARS-CoV-2,
32 the virus that causes coronavirus disease 2019 (COVID-19), was published in January 2020.[1]
33 Vaccination will be one of the most effective strategies in limiting the spread of the disease by
34 establishing higher levels of herd immunity and preventing repeated or continuous epidemics. [2]
35 Recent prediction modelling has suggested that even with mitigation strategies such as testing and
36 isolation of cases and social distancing measures focused on shielding the elderly and slowing the
37 transmission of SARS-CoV-2, the global death toll may reach 20 million this year in the absence of an
38 effective vaccine. [3] A wide spectrum of vaccine platforms are currently under development, [4] with
39 recent reports estimating that a COVID-19 vaccine may be available after 1-2 years, [5] much faster than
40 conventional vaccine approval processes. [6]

41 Prior to regulatory approval, novel vaccine candidates need to follow a well-defined process with post
42 marketing surveillance. [7] However, during the COVID-19 pandemic, some vaccine candidates have
43 gained fast-track status from the US Food and Drug Administration (FDA) [8] and alternative means of
44 vaccine approval methodologies such as human challenge studies are being investigated to accelerate
45 licensure. [9] The first COVID-19 vaccine candidate entered human clinical testing with unprecedented
46 speed on March 16, 2020, [1] and the first Phase 3 trials began just four months later. [10] Fast-tracking
47 the licensure process for vaccines has been explored in the past for other infectious diseases including
48 tuberculosis, [11] serogroup B meningococcal disease, [12] and Zika virus. [13]

49 In the United States (US), it was estimated that only two thirds of people would be willing to get a
50 COVID-19 vaccine [14]. Parental vaccine hesitancy is associated with safety concerns, [15] and positive
51 public opinion and trust in an expedited COVID-19 vaccine is paramount to its success. [16]
52 Understanding caregivers' willingness to accept an expedited vaccination approval process may help
53 inform public health authorities and support effective rollout of a future COVID-19 vaccination program.
54 The objective of this study was to determine caregiver perceptions and attitudes regarding vaccine
55 research regulations, in the midst of the COVID-19 pandemic.

56 PARTICIPANTS AND METHODS

57 Sample and procedures

58 This study is part of a larger COVID-19 Parental Attitude Study (COVIPAS) of caregivers presenting for
59 emergency care for their children during the era of COVID-19. Using posters placed in waiting areas and
60 patient rooms, as well as direct approach by healthcare team members, caregivers (mostly parents) of
61 children 0 to 18 years of age who arrived to 17 pediatric emergency departments (ED) in the US (Seattle,
62 Tacoma, Los Angeles, Dallas, Atlanta), Canada (Vancouver, Toronto, Saskatoon, Edmonton, Calgary),
63 Israel (Be'er Ya'akov), Japan (Tokyo), Spain (Barcelona), and Switzerland (Zurich, Bern, Geneva,
64 Bellinzona) were asked to take part in the survey.

65 For infectious control purposes, caregivers used their own electronic devices (e.g. smartphones, tablets)
66 to complete the survey by logging into a secure online platform based on REDCap metadata-driven
67 software (Vanderbilt University). Once a caregiver selected their study site, they provided consent for
68 participation in the online survey, as approved by each site's local Institutional Review Board (IRB). Five
69 IRBs (in Switzerland and Spain) provided a waiver of consent whereby responding to the survey was
70 considered consent to participate.

71 The survey tool was available in English, French, German, Spanish, Japanese, Italian, and Hebrew. While
72 sites began recruitment in a staggered fashion, surveys were obtained between March 26 and June 30,
73 2020. Due to restrictions to visitation in most sites, only one caregiver was in the room with the child. As
74 such, only one caregiver completed the survey per visit.

75

76 Measures

77 The study-specific questionnaire was developed to include questions regarding demographic
78 characteristics, information regarding the ED visit, and attitudes about COVID-19. The survey objective
79 was to reflect caregiver opinions and actions during the pandemic. Literature related to the SARS
80 epidemic in 2002-2003 helped inform survey questionnaire development. Pilot testing for face and
81 content validity for all items of the survey, including those presented in this report, was completed a
82 priori by 10 individuals representing the target group of caregivers and by 10 healthcare providers

83 working in the ED environment who provided feedback that led to revisions and development of the
84 final survey.

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

94

95 Data analysis

96 Basic descriptive statistics and frequencies were used to describe all variables, comparing survey data
97 from caregivers who would support abridged COVID-19 vaccine regulations and those that would not.
98 To determine which factors were significantly associated with the decision to agree to expedited
99 regulation processes, we used univariate analyses: Mann-Whitney test for comparing non-normal
100 continuous variables, independent t-test for comparing normally distributed continuous variables, and
101 Chi-square or Fisher's exact test for categorical variables. We then used a multivariable logistic
102 regression analysis to estimate the adjusted odds ratio of agreeing to abridged vaccine testing, using all
103 the variables that showed significance ($p < 0.1$) in the univariate analysis and other variables of interest.
104 To compare caregiver concern of their child having COVID-19 (score 0-10) to willingness to expedited
105 regulations, we used the Mann-Whitney U test. All analyses were conducted with R version 3.5.1. A p-
106 value less than 0.05 was considered statistically significant.

107 RESULTS

108 A total of 2785 surveys were completed online. Seventeen (0.6%) were excluded because they were
109 completed by patients or were incomplete. Table 1 provides demographic information for the caregivers
110 that completed the survey. We further excluded 159 (5.7%) surveys since the caregivers did not provide
111 an answer to whether they recommend a similar or faster approval process ($n=107$) or responded

112 “other” with no description of reasoning (n=52). Another 52 (1.9%) surveys with “other” were excluded
113 since caregivers provided descriptions suggesting they are ‘against vaccines in general’ (n=19),
114 suggested they ‘do not know enough about the subject to answer this question’ (n=19), thought that ‘all
115 vaccines need better testing processes’ (n=6), that ‘Coronavirus is not real/not as bad as media portrays
116 it’ (n=6) or that science need to focus on ‘cure rather than vaccine’ (n=2). This resulted in a total of 2557
117 survey responses included in the currently described study.

118 For surveys included (Table 2), the median age of children was 7.5 (Standard Deviation (SD) = 5.1) years
119 and the median age of caregivers was 39.4 (SD = 7.86) years. The vast majority of surveys were
120 completed by parents (97.5%) as opposed to other caregivers. Three hundred and sixty (14.2%)
121 respondents had children with a chronic illness.

122 There were 1456 (56.9%) caregivers who reported that standard vaccine regulations should not change
123 for COVID-19 vaccine development and 1101 (43.1%) caregivers who prefer expedited regulations.
124 Table 2 provides a comparison between families who completed the question on whether more
125 expedited testing should be performed for COVID-19 vaccine approval. Over half of fathers were likely
126 to suggest modifying the standards (52.3%) while a greater proportion of mothers were likely to suggest
127 continuing the current vaccine research regulation scheme (60.1%, $p < 0.001$). Caregivers of children with
128 an up-to-date vaccination schedule and those willing to vaccinate their children against COVID-19 if a
129 vaccine became available were more likely to accept shortening or changing the vaccine testing process
130 (both $p < 0.001$). Additional factors associated with greater willingness to modify regulations included
131 older caregivers ($p < 0.001$), caregivers who were concerned they themselves or their child had COVID-19
132 (both $p < 0.001$) or influenza ($p = 0.011$ and $p < 0.001$, respectively) when visiting the ED, caregivers
133 concerned about their child missing school ($p = 0.03$), and caregivers that consider physical and social
134 distancing a worthwhile action ($p = 0.009$). Caregivers who reported that they lost income due to the
135 COVID-19 pandemic were more likely to prefer to maintain current regulations for vaccine research
136 ($p = 0.009$).

137 In the multivariate logistic regression analysis (Table 3), factors predicting willingness to change the
138 regulations around COVID-19 vaccine research included having children who were up-to-date with their
139 vaccination schedules (Odds Ratio (OR)=1.72, 95% confidence interval (CI) 1.29-2.31, $p < 0.001$),
140 willingness to vaccinate their child against COVID-19 if a vaccine was available (OR=1.84, 95% CI 1.54-
141 2.21, $p < 0.001$), and being worried that the caregivers themselves were sick with COVID-19 (OR=1.1, 95%

142 CI 1.05-1.16, $p < 0.001$). In general, mothers were less likely to support changes in the regulations
143 regarding COVID-19 vaccine approval (OR=0.641, 95% CI 0.53-0.78, $p < 0.01$).

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145 DISCUSSION

146 In our international sample of caregivers arriving with their children to 17 EDs in six countries, almost
147 half (43.1%) of caregivers reported willingness to accept expedited testing and approving a COVID-19
148 vaccine during the pandemic, in order to make it available faster. Independent factors associated with
149 an increased willingness to see a change in the approval process included fathers, caregivers of children
150 that received vaccinations based on the recommended schedule, caregivers who would like to vaccinate
151 their children against COVID-19, and caregivers who were concerned about having COVID-19 themselves
152 at the time the survey was conducted in the ED.

153 A safe and effective vaccine against COVID-19 would help countries to mitigate further morbidity and
154 mortality and facilitate the return of people and economies to pre-pandemic activity. Overcoming
155 challenges in vaccine development and increasing vaccine uptake are crucial, especially during the
156 pandemic and among children. [17] Developing a vaccine against SARS-CoV-2 is expected to be relatively
157 straightforward and attainable because the virus seems to be fairly stable.[18] Predicted vaccine
158 coverage of 55% to 82% of the population is needed in order to provide herd immunity to SARS-CoV-
159 2,[19] however local health authorities such as those in the US reported that it is unlikely herd immunity
160 will be achieved given the current state of COVID-19 vaccine refusal. [14]

161 Regulatory bodies in different countries have similar vaccine testing and approval processes, [20] and all
162 are complex, often lasting 10-15 years, and involving a combination of public and private involvement.
163 [6] Developing and testing vaccine candidates to be used during the pandemic is imperative and, in an
164 effort to facilitate research into a COVID-19 vaccine, the National Institutes of Health in the US and other
165 governments have developed networks to research and improve progress in vaccine development. [21]
166 While we are in a new era in vaccine development [4] that will expedite approval of the vaccine against
167 SARS-CoV-2, it may take many months until an approval is granted.

168 The high number of caregivers in our sample accepting a change in the current standards for approval of
169 a COVID-19 vaccine, as well as an increase in those planning on vaccinating their child against influenza
170 next year, [22] are surprising findings since parents report great importance in the safety of vaccines,
171 [23, 24] which necessitate extensive time for evaluation, and the perceived danger of vaccines is
172 associated with reluctance to vaccinate children. [25] There are 70 independent barriers associated with
173 vaccine hesitancy [26] and parental vaccine decision-making depends on trust in healthcare providers'
174 advice, social network influences, knowledge about vaccines, and general views towards health. [27]

175 Several countries such as the US and Canada have developed a fast-track process for drug approval,
176 though not without controversy and increased safety warnings, compared to drugs approved through
177 the usual regulatory process. [28] Yet, “cutting red tape” in Australia has been beneficial to bring
178 technologies and drugs to patients [29] and some benefit of fast-tracking measures has been
179 documented by the US Food and Drug Administration (FDA). [30] During the current pandemic,
180 accelerated regulatory procedures for drugs have already been implemented including the FDA’s
181 Emergency Use Authorization for remdesivir. [31] COVID-19 vaccine candidates are similarly being
182 evaluated using an Investigational New Drug exemption mechanism in hopes of facilitating a quicker end
183 to the pandemic. [31]

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

189 Our surveys took place during the peak of the COVID-19 pandemic (Mar-June 2020) with daily media
190 reports of thousands of deaths and rapid new discoveries about the illness. It is possible that fear of the
191 pandemic and its devastating consequences have shifted caregiver acceptance to less rigorous
192 regulation. Similarly, fear about the H1N1 illness was associated with increased H1N1 vaccine uptake.
193 [32, 33] Willingness to accept emergency vaccine preparation and production and change in risk/benefit
194 ratio due to high morbidity and mortality has been suggested as acceptable [11, 34]. While parents are
195 concerned about adverse events associated with vaccines, perhaps even more than the symptoms of
196 illness itself, [35] more adverse events during a pandemic may be acceptable from a public health
197 perspective. [34] Another important factor that may influence caregiver willingness is the fact that
198 COVID-19 infection in children is largely a self-limiting, benign disease. [36] On the other hand, recent
199 reports of complications in children following COVID-19 infection including Kawasaki-like illness [37] may
200 influence caregivers to be more willing to allow for abridged vaccine regulatory standards.

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

206 It was interesting that mothers were less likely than fathers to choose abbreviated vaccine testing.
207 These gender differences were seen among adults considering H1N1 vaccination [38] and among
208 females who were never in favor of vaccination and made different trade-offs than males who stated
209 that they were (possibly) willing to get vaccinated [39]. Risk taking behaviours of fathers may be
210 different than those of mothers, similar to findings related to child play and pediatric trauma
211 prevention. [40] Finally, families that reported a loss of income during this pandemic were not in favour
212 of modifying regulations for COVID-19 vaccine approval, perhaps reflecting that caregivers want the best
213 health for their children, before their own economic well-being. [41]

214

215

216 **LIMITATIONS**

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

226 Secondly, caregivers shared their considerations in regards to vaccine regulatory standards at times of
227 intense uncertainty during a period of major change in daily activities (no school, work-at-home), and
228 their perceptions on an abridged vaccine development process may be different when community life
229 returns to a new normal activity and the numbers of infected patients drop. Throughout the period of
230 survey data collection, communications from local authorities had evolved and factors including the
231 availability of COVID-19 testing for children had changed over time. Given the unique stressors during
232 this period of time when our understanding of this illness was limited and the amount of fear of harm
233 from it was greatest, our findings may overestimate the true acceptance of an expedited COVID-19
234 vaccine research process. On the other hand, with schools beginning to reopen and the mental fatigue
235 of the pandemic worsening, one may argue that caregivers will be more accepting in the coming

236 months. Finally, the survey was administered before the regulatory approval of any COVID-19 vaccine,
237 and once available and tested, caregivers may learn new information that may change their mind with
238 regards to acceptability of expedited vaccine licensure.

239 Conclusions

240 Almost half of caregivers in a global sample were willing to accept less strict standards for the
241 development and approval of a COVID-19 vaccine. The child's vaccination history, caregiver's gender,
242 worry that they personally had COVID-19 at the time of survey completion, and intention to vaccinate
243 their child against COVID-19 in the future, were independent factors associated with the acceptability of
244 abbreviated vaccine testing. Understanding caregiver attitudes to an expedited COVID-19 vaccine is
245 imperative in planning new vaccine uptake. This information may help inform public health
246 communication and strategy to improve vaccine acceptance, at the time that a COVID-19 vaccine is
247 available.

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253 **Declaration of Interest:** none

254

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256 organizations

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257 **References**

- 258 1. Thanh Le T, Andreadakis Z, Kumar A, et al. The COVID-19 vaccine development landscape. *Nat*
259 *Rev Drug Discov* **2020**;19:305-6
- 260 2. Graham BS. Rapid COVID-19 vaccine development. *Science* **2020**;368:945-6.
- 261 3. Walker PGT, Whittaker C, Watson O, et al. The global impact of COVID-19 and strategies for
262 mitigation and suppression. London (UK): Imperial College London (UK); 2020. Available from:
263 <https://doi.org/10.25561/77735>.
- 264 4. Lurie N, Saville M, Hatchett R, Halton J. Developing Covid-19 Vaccines at Pandemic Speed. *N*
265 *Engl J Med* **2020**;382:1969-73.
- 266 5. Amanat F, Krammer F. SARS-CoV-2 vaccines: Status report. *Immunity* **2020**;52:583-9.
- 267 6. The College of Physicians of Philadelphia. The history of vaccines: Vaccine development, testing,
268 and regulation [Internet]. 2018 January 17 [cited 2020 Sept 10]. Available from:
269 [https://www.historyofvaccines.org/content/articles/vaccine-development-testing-and-](https://www.historyofvaccines.org/content/articles/vaccine-development-testing-and-regulation)
270 [regulation](https://www.historyofvaccines.org/content/articles/vaccine-development-testing-and-regulation)
- 271 7. Singh K, Mehta S. The clinical development process for a novel preventive vaccine: An overview.
272 *J Postgrad Med* **2016**;62:4-11.
- 273 8. Maddipatla M. Pfizer, BioNTech's coronavirus vaccine candidates get FDA's 'fast track' status.
274 The Globe and Mail [Internet]. 2020 July 13 [cited 2020 Sept 10]. Available from:
275 [https://www.theglobeandmail.com/business/international-business/us-business/article-pfizer-](https://www.theglobeandmail.com/business/international-business/us-business/article-pfizer-biontechs-coronavirus-vaccine-candidates-get-fdas-fast/)
276 [biontechs-coronavirus-vaccine-candidates-get-fdas-fast/](https://www.theglobeandmail.com/business/international-business/us-business/article-pfizer-biontechs-coronavirus-vaccine-candidates-get-fdas-fast/)
- 277 9. Eyal N, Lipsitch M, Smith PG. Human challenge studies to accelerate Coronavirus vaccine
278 licensure. *J Infect Dis* **2020**;221:1752-6.
- 279 10. Chung E. How close are we to a vaccine for COVID-19? CBC News [Internet]. 2020 July 17 [cited
280 2020 Sept 10]. Available from: <https://newsinteractives.cbc.ca/coronavirusvaccinetracker/>
- 281 11. Rustomjee R, Lockhart S, Shea J, et al. Novel licensure pathways for expeditious introduction of
282 new tuberculosis vaccines: A discussion of the adaptive licensure concept. *Tuberculosis*
283 **2014**;94:178-82.
- 284 12. Lennon D, Jackson C, Wong S, Horsfall M, Stewart J, Reid S. Fast tracking the vaccine licensure
285 process to control an epidemic of serogroup B meningococcal disease in New Zealand. *Clin Infect*
286 *Dis* **2009**;49:597-605.

- 287 13. Vannice K, Casetti MC, Eisinger RW, et al. Demonstrating vaccine effectiveness during a waning
288 epidemic: A WHO/NIH meeting report on approaches to development and licensure of Zika
289 vaccine candidates. *Vaccine* **2019**;37:863-8.
- 290 14. Cohen E. Fauci says COVID-19 vaccine may not get US to herd immunity if too many people
291 refuse to get it. CNN [Internet]. 2020 June 28 [cited 2020 Sept 10]. Available from:
292 [https://www.cnn.com/2020/06/28/health/fauci-coronavirus-vaccine-contact-tracing-
294 aspen/index.html](https://www.cnn.com/2020/06/28/health/fauci-coronavirus-vaccine-contact-tracing-
293 aspen/index.html)
- 294 15. Dubé E, Laberge C, Guay M, Bramadat P, Roy R, Bettinger J. Vaccine hesitancy: an overview.
295 *Hum Vaccin Immunother.* **2013**;9(8):1763-1773.
- 296 16. Fadda M, Albanese E, Suggs LS. When a COVID-19 vaccine is ready, will we all be ready for it? *Int*
297 *J Public Health* **2020**.
- 298 17. Nicholson A, Shah CM, Ogawa VA. Exploring Lessons Learned from a Century of Outbreaks:
299 Readiness for 2030: Proceedings of a Workshop. Washington (DC): National Academies Press
300 (US); 2019. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK544048/>
- 301 18. Mahase E. Covid-19: What do we know so far about a vaccine? *BMJ* **2020**;369:m1679
- 302 19. Schaffer DS, Pudalov NJ, Fu LY. Planning for a COVID-19 vaccination program. *JAMA*. Published
303 online May 18, 2020. <https://jamanetwork.com/journals/jama/fullarticle/2766370>
- 304 20. World Health Organization. Immunization standards: Vaccine regulation [Internet]. 2020 [cited
305 2020 Sept 10]. Available from:
306 https://www.who.int/immunization_standards/vaccine_regulation/en/
- 307 21. National Institutes of Health. NIH launches clinical trials network to test COVID-19 vaccines and
308 other prevention tools [Internet]. 2020 July 8 [cited 2020 Sept 10]. Available from:
309 [https://www.nih.gov/news-events/news-releases/nih-launches-clinical-trials-network-test-
311 covid-19-vaccines-other-prevention-tools](https://www.nih.gov/news-events/news-releases/nih-launches-clinical-trials-network-test-
310 covid-19-vaccines-other-prevention-tools)
- 311 22. Goldman RD, McGregor S, Marneni SR, et al. Willingness to vaccinate children against influenza
312 after the Coronavirus Disease 2019 pandemic. *J Pediatr*. Published online Aug 6, 2020.
313 [https://www.jpeds.com/article/S0022-3476\(20\)30987-2/fulltext](https://www.jpeds.com/article/S0022-3476(20)30987-2/fulltext)
- 314 23. Salmon DA, Moulton LH, Omer SB, DeHart MP, Stokley S, Halsey NA. Factors associated with
315 refusal of childhood vaccines among parents of school-aged children: A case-control study. *Arch*
316 *Pediatr Adolesc Med* **2005**;159:470-6.
- 317 24. Miton H, Mercier H. Cognitive obstacles to pro-vaccination beliefs. *Trends Cogn Sci* **2015**;19:633-
318 6.

- 319 25. Wilson RS, Arvai JL, Arkes HR. My loss is your loss ... Sometimes: loss aversion and the effect of
320 motivational biases. *Risk Anal* **2008**; 28:929-38.
- 321 26. Schmid P, Rauber D, Betsch C, Lidolt G, Denker ML. Barriers of influenza vaccination intention
322 and behavior - A systematic review of influenza vaccine hesitancy, 2005 - 2016. *PLoS One*
323 **2017**;12:e0170550.
- 324 27. Dubé E, Gagnon D, MacDonald N, Bocquier A, Peretti-Watel P, Verger P. Underlying factors
325 impacting vaccine hesitancy in high income countries: a review of qualitative studies. *Expert Rev*
326 *Vaccines* **2018**;17:989–1004.
- 327 28. Lexchin J. Post-market safety warnings for drugs approved in Canada under the Notice of
328 Compliance with conditions policy. *Br J Clin Pharmacol* **2015**;79:847-59.
- 329 29. Martin J, Shenfield G. The hazards of rapid approval of new drugs. *Aust Prescr* **2016**;39:2-3
- 330 30. Woodcock J. Expediting drug development for serious illness: Trade-offs between patient access
331 and certainty. *Clinical Trials*. **2018**;15:230-4.
- 332 31. Beninger P. COVID-19: Regulatory landscape of medicinal and medical device products for
333 human use. *Clin Ther*. Published online June 28, 2020.
334 <https://doi.org/10.1016/j.clinthera.2020.06.014>
- 335 32. Setbon M, Raude J. Factors in vaccination intention against the pandemic influenza A/H1N1. *Eur*
336 *J Public Health* **2010**;20:490-4.
- 337 33. Rubin GJ, Potts HWW, Michie S. Likely uptake of swine and seasonal flu vaccines among
338 healthcare workers. A cross-sectional analysis of UK telephone survey data. *Vaccine*
339 **2011**;29:2421-8.
- 340 34. Sjøborg C, Mølbak K, Doherty TM, et al. Vaccines in a hurry. *Vaccine* **2009**;27:3295-8.
- 341 35. Brown KF, Kroll JS, Hudson MJ, et al. Omission bias and vaccine rejection by parents of healthy
342 children: Implications for the influenza A/H1N1 vaccination programme. *Vaccine* **2010**;28:4181-
343 5
- 344 36. Goldman RD. Coronavirus disease 2019 in children. *Can Fam Physician* **2020**;66:332-4.
- 345 37. Cheung EW, Zachariah P, Gorelik M, et al. Multisystem Inflammatory Syndrome Related to
346 COVID-19 in Previously Healthy Children and Adolescents in New York City. *JAMA*. Published
347 online June 08, 2020. <https://jamanetwork.com/journals/jama/article-abstract/2767207>
- 348 38. Bish A, Yardley L, Nicoll A, Michie S. Factors associated with uptake of vaccination against
349 pandemic influenza: A systematic review. *Vaccine* **2011**;29:6472-84.

- 350 39. Determann D, Korfage IJ, Lambooj MS, et al. Acceptance of vaccinations in pandemic outbreaks:
351 A discrete choice experiment. *PLoS One* **2014**;9:e102505.
- 352 40. Brussoni M, Olsen L. Striking a balance between risk and protection: fathers' attitudes and
353 practices toward child injury prevention. *J Dev Behav Pediatr* **2011**;32:491-8.
- 354 41. Elliot S, Powell R, Brenton J. Being a good mom: low-income, black single mothers negotiate
355 intensive mothers. *Journal of Family Issues* **2015**;36:351-70.

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356 Legend:

357 **Table 1.** Demographic characteristics and survey responses for all caregivers that completed the survey

358 **Table 2.** Factors associated with caregivers' willingness to change vaccine regulatory standards for the
359 COVID-19 pandemic

360 **Table 3.** Predictors of caregivers' willingness to change vaccine regulatory standards for COVID-19
361 identified by multivariate logistic regression analysis

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Table 1. Demographic characteristics and survey responses for all caregivers that completed the survey.

SD-Standard Deviation

Entire cohort	Number of Surveys (2768)	N (%) / SD
Child		
Mean age in years (SD)	2764	7.6 (SD 5.1)
Gender (female)	2728	1335 (48.3%)
Has chronic illness	2736	384 (14.0%)
Chronic medication use	2736	479 (17.5%)
Vaccinations up to date	2729	2420 (88.7%)
Caregiver		
Who completed the survey	2761	
Father		662 (24.0%)
Mother		2025 (73.3%)
Other		74 (2.68%)
Age in years (SD)	2724	39.4 (7.86)
More than high-school education	2707	2081 (76.9%)
COVID-19 has led to a loss of income for caregiver	2727	1076 (39.5%)
Caregiver Attitudes		
Caregivers want expedited COVID19 vaccine approval	2557	1101 (43.1%)
Caregiver would allow child to participate in a COVID vaccine trial	2708	497 (18.4%)
Caregiver concerned their child has COVID-19 Mean score 10 point Likert scale (SD)*	2688	1.97 (2.91)
Caregiver concerned they have COVID-19 Mean score 10 point Likert scale (SD)*	2675	1.89 (2.77)
Caregiver concerned their child has influenza Mean score 10 point Likert scale (SD)*	2662	1.23 (2.37)
Caregiver concerned they have influenza Mean score 10 point Likert scale (SD)*	2655	0.92 (2.02)
Caregiver concerned about missing work Mean score 10 point Likert scale (SD)*	2649	2.65 (3.47)
Caregiver concerned about child missing school Mean score 10 point Likert scale (SD)*	2641	2.78 (3.49)

(*) 0 = not concerned at all, 10 = most concerned

Table 2. Factors associated with caregivers' willingness to change vaccine regulatory standards for the

	Number of Surveys (2557)	Population	No Change in Regulation (N=1456)	Suggest Change in Regulation (N=1101)	P- Value
Child					
Mean age in years (SD)	2554	7.5 (5.1)	7..37 (5.1)	7.7 (5.0)	0.079
Gender (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 in years (SD)	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 caregivers	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 concerned their child has COVID-19 Mean score 10 point Likert scale (SD)*	2514	1.97 (2.88)	1.69 (2.75)	2.34 (3.00)	<0.001
Caregiver concerned they have COVID-19 Mean score 10 point Likert scale (SD)*	2504	1.90 (2.74)	1.57 (2.59)	2.34 (2.86)	<0.001
Caregiver concerned their child has influenza Mean score 10 point Likert scale (SD)*	2488	1.21 (2.33)	1.10 (2.28)	1.34 (2.39)	0.011
Caregiver concerned they have influenza Mean score 10 point Likert scale (SD)*	2486	0.89 (1.96)	0.77 (1.90)	1.06 (2.03)	<0.001
Caregiver concerned about missing work Mean score 10 point Likert scale (SD)*	2479	2.63 (3.44)	2.53 (3.46)	2.76 (3.42)	0.103
Caregiver concerned about child missing school Mean score 10 point Likert scale (SD)*	2476	2.75 (3.46)	2.62 (3.48)	2.93 (3.43)	0.03

COVID-19 pandemic. SD-Standard Deviation

(*) 0 = not concerned at all, 10 = most concerned

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Table 3. Predictors of caregivers' willingness to change vaccine regulatory standards for COVID-19 identified by multivariate logistic regression analysis

	Odds ratio	OR 95% CI	P value
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-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

HIGHLIGHTS

- Half of caregivers accept an abridged process for rapid COVID-19 vaccine approval
- Seeking fast approval associated with caregiver's gender, intent to vaccinate child
- Concern about own COVID-19 infection associated with preferring expedited approval

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Declaration of interests

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

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

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