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## Assessment of parental acceptance of a potential cytomegalovirus vaccine for adolescent females

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### Abstract

The development of a vaccine against cytomegalovirus (CMV) has been designated as a high priority and adolescent females are a likely target population for CMV vaccination. A self-administered, internet-based survey was developed using constructs from the Health Belief Model to identify factors that may be associated with parental acceptance of a CMV vaccine for their adolescent daughters. Data from 516 parents were analyzed, the majority of whom were female, white, and college educated. Parental acceptance of a CMV vaccine was generally high. Perceived benefits of vaccine were independently associated with vaccine acceptance while history of previous vaccine refusal, concerns about safety and cost of the vaccine were negatively associated. These findings provide initial data on factors that are likely to influence parental acceptance of a CMV vaccine for adolescent girls.

### Keywords

Acceptance; Cytomegalovirus; Adolescents; Parents

## 1. Introduction

Cytomegalovirus (CMV) is the most common congenital infection among children in developed nations. In the United States, approximately 40,000 neonates are born each year with congenital CMV infection, resulting in nearly 400 deaths and many more infants with neurological and developmental deficits, such as mental retardation, sensorineural hearing

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loss, and cerebral palsy [1,2]. Congenital CMV causes a greater number of serious disabilities than other well-known childhood conditions including Down Syndrome, Fetal Alcohol Syndrome, and Spina Bifida [3]. Worldwide, the incidence of congenital CMV infection is 0.2–2.3% of live births [1].

In 1999 an Institute of Medicine (IOM) report stated that the development of a CMV vaccine should be of the highest priority in the US considering the potential economic costs and years of productive life that might be saved [4]. The report estimated the annual cost of congenital CMV infection in the US at \$1.86 billion, with nearly \$300,000 spent on each infected child [5]. The success of recent phase 1 and 2 clinical trials of CMV vaccine highlights the potential of these vaccines to reduce the burden of congenital disease [6–10]. There is debate regarding the optimal target populations for a CMV vaccine with proponents advocating for vaccinating toddlers, adolescents (including males and females) and women of reproductive age. If the goal of a CMV vaccine is to reduce congenital CMV infection, adolescent females represent a logical target population with the goal of inducing immunity to CMV prior to pregnancy [11]. In fact, the IOM analysis was based on a hypothetical model of CMV vaccine administered to adolescent females [4].

Because those <18 years of age require parental consent to receive vaccines, the success of a potential CMV vaccine program for adolescent females will depend on parental acceptance of the vaccine. Studies of parental acceptance of other vaccines suggest that several factors are important in their decisions including recommendations of health care providers, social norms, and parental perceptions of the likelihood and severity of the disease to be prevented through vaccination [12–14]. To date, the factors that may be associated with parental acceptance of a CMV vaccine have not been studied. The objective of this study was to identify factors that might influence parental acceptance of a future CMV vaccine for their adolescent daughters.

## 2. Methods

### 2.1. Study population

Eligible participants were parents (ages 18 years or older) participating in Vanderbilt's Volunteer for Research (VFR) registry with at least one daughter. The VFR registry is a searchable database that included 4739 individuals who responded, online or by phone, to community-wide advertisements seeking individuals who would voluntarily agree to be contacted for future participation in a variety of research studies conducted at the institution. To identify eligible participants, adults in the VFR registry were sent a communication via electronic mail that contained the purpose of the study, a request to complete the survey, and a link to the survey. Respondents who reported that they had at least one daughter were eligible to complete the remainder of the survey. Respondents whose daughters were not between ages 11 and 17 years were asked to answer the questions as though their daughter was within that age range. Respondents with two or more daughters were asked to respond to the questions considering one daughter who was within the age range or the daughter closest to the age range. Non-responders received two additional e-mail requests to complete the survey over a 2-month period.

### 2.2. Survey instrument

The survey instrument was a self-administered, 36-item questionnaire about CMV disease and a potential CMV vaccine that was modeled after a previous survey exploring parental attitudes about the Human Papillomavirus (HPV) vaccine [15]. Consistent with many other studies of parental attitudes about vaccines [15–17], the survey was developed using constructs from two well-validated models of health behavior: the Health Belief Model and

the Theory of Reasoned Action [18,19]. By these models, vaccination “intent” is considered the decision state immediately upstream of actual vaccine receipt. Thus, parental vaccination intention/acceptability is considered a reasonable proxy measure for parents actually having their child vaccinated. In the Health Belief Model, four psychological domains contribute to vaccination intention: the *perceived susceptibility* to illness (i.e., how much is a daughter at risk for becoming infected with CMV), the *perceived severity* of illness (i.e., how bad would it be if a daughter or her unborn child contracted CMV), the *perceived barriers* to vaccination (how difficult would it be to get the CMV vaccine) and the *perceived benefits* to vaccination (what are the expected health benefits of having a daughter vaccinated against CMV). As in other studies, we also included a fifth domain in our study, *normative beliefs*, derived from the Theory of Reasoned Action to investigate the influence of peers and family on vaccine acceptance [15,17]. To aid those with limited knowledge about CMV, respondents were given information about the prevalence and modes of acquisition of CMV and about the sequelae of congenital CMV infection.

### 2.3. Outcome measure

The primary outcome measure in this study was parental acceptance of a potential CMV vaccine as determined by parental response to the statement “I would allow my daughter to receive the CMV vaccine between the ages of 12–17 years old.” Responses were quantified using a 0 (corresponding to very unlikely) to 100 (corresponding to very likely) sliding scale.

### 2.4. Primary independent variables

The primary independent variables included summary scores, comprised of survey items developed to measure the same construct and demonstrating acceptable internal consistency, and individual items. Cronbach’s alpha (  $\alpha$  ) was used to assess internal consistency of the individual survey items assessing the same construct. It has been suggested that Cronbach alpha values greater than 0.7 suggest acceptable internal consistency [20]; therefore, when the Cronbach alpha score for items evaluating a construct was  $\geq 0.75$ , summary scores averaging the responses to those items were included in models. If an item was missing for a respondent (<3% of respondents), the summary score was the average of the non-missing items. For Cronbach’s  $\alpha$  score <0.75, individual items, rather than a summary score, were included in the model. Our primary variables included four summary scores assessing perceived susceptibility of a future grandchild to CMV infection (three items, e.g., “I am concerned that my daughter’s future baby may become infected with CMV,”  $\alpha = 0.89$ ), perceived severity of congenital CMV infection [three items, e.g., “Hearing problems can make learning to talk difficult for children,” Cronbach’s  $\alpha$  (  $\alpha$  ) = 0.91], perceived vaccine benefits (three items, e.g., “I believe the vaccine would help to protect my daughter’s baby from getting infected with CMV,”  $\alpha = 0.92$ ) and normative beliefs about CMV (three items, e.g., “Most people I know would think that it is a good idea to vaccinate girls of ages 12 to 17 against CMV,”  $\alpha = 0.75$ ), as well as three individual items assessing potential barriers to vaccine receipt (concerns about safety of the vaccine, cost of the vaccine, and the adherence to the proposed three shot vaccination schedule).

### 2.5. Other independent variables

Other independent variables included sociodemographic characteristics, self-reported awareness of CMV (assessed via the question “Have you heard of CMV?”), and prior experiences related to other vaccines offered to their children. Sociodemographic factors included age and gender of the study participants, ages and genders of other children in the family, marital status, race ethnicity, and education level. Finally, an item asked if the subject had ever refused a vaccine recommended for his or her child.

## 2.6. Statistical analysis

Demographic and survey questions were summarized using median and interquartile range. The associations between vaccine acceptability and predictor variables were assessed using the Wilcoxon rank sum or Kruskal–Wallis test. Multivariable linear regression models were constructed to study independent variables associated with parental CMV vaccine acceptance. Variables included in the models were the four summary scores for perceived susceptibility, perceived severity, perceived vaccine benefits, and normative beliefs; three individual items assessing potential barriers to vaccine receipt, and prior vaccine refusal. Given the homogeneity of the respondents in terms of gender, race/ethnicity, and education, these sociodemographic variables were not included in the regression analysis. We hypothesized *a priori* that responses from parents whose daughters were already adults (42% of respondents) might differ from those whose daughters were minors; therefore, we created two multivariable models (parents with daughters ≥ 18 years or <18 years) to assess this. Results were not substantially different between the two models; therefore, in this manuscript we report the responses from all participants combined into a single model. A two-sided *P*-value of less than 0.05 was considered to indicate statistical significance. All analyses used the statistical software package R 2.9.1 9 (<http://www.r-project.org/>).

The study was approved by the Institutional Review Board of Vanderbilt University Medical Center.

## 3. Results

Of the 3467 individuals with a valid email address in the VFR, 1268 individuals replied to the invitation to complete the survey [response rate = 36.6%, though the proportion of the original sample that were actually eligible for the study (i.e., had a daughter) is unknown]. Of these, 516 individuals met study inclusion criteria (i.e., they were at least 18 years of age and had one or more daughters) and were included in the analyses. Baseline characteristics of these participants are shown in Table 1. The majority of the participants were female (85%), white (86%), had attended college (91%), and were married (67%). Only 53% of the participants reported that they had knowledge of CMV disease. Six percent of parents reported refusing one or more vaccines for their daughter (3% refused vaccine for HPV, 2% refused the combined vaccine for diphtheria, tetanus, and pertussis [DTP/DTaP], 1% each refused vaccines for hepatitis B, meningococcus, varicella, Influenza and the combined vaccine for measles, mumps, and rubella [MMR]).

Parental acceptance of a potential CMV vaccine was generally high with a median acceptance score of 91 (out of a maximum acceptance score of 100). In univariate analyses (Table 2), we found no significant differences in acceptance of CMV vaccine by gender, race, education, or marital status, although the homogeneity of the sampled subjects limited our ability to detect differences.

In the multivariable linear regression model (Table 3), two constructs were independently associated with increased parental acceptance of the CMV vaccine. These included parental perceptions of the benefits of a potential CMV vaccine ( $\beta = 9.18$ ,  $P < 0.001$ ) and normative beliefs, including their assessment of the opinions of physicians, family members, and peers regarding vaccination of adolescent girls against CMV (normative beliefs construct:  $\beta = 7.52$ ,  $P < 0.001$ ). The other two psychological constructs, perceived severity of congenital CMV infection and perceived susceptibility to CMV infection were not associated with vaccine acceptance.

Parental vaccine acceptance was negatively associated with concerns about vaccine safety ( $\beta = -2.55$ ,  $P = 0.03$ ) and concern about expense ( $\beta = -3.68$ ,  $P = 0.005$ ), and a prior history of

vaccine refusals ( $\beta = -15.4$ ,  $P = 0.005$ ). CMV vaccine acceptance was not significantly associated with concerns about the number of injections.

#### 4. Discussion

Adolescent females represent an important potential target population for future CMV vaccination. To our knowledge, this study is the first to assess the acceptability of adolescent female CMV vaccination by parents. Parental acceptance for CMV vaccination was high in our study (median of 91 on a 100-point scale). We found that parental perception of the benefits of CMV vaccination was the most influential factor affecting parental CMV vaccine acceptance. This finding is consistent with studies examining parental views of HPV vaccines and other vaccines against sexually transmitted infections in adolescents and suggests that parental education about CMV and congenital CMV infection is likely to be an important target for future interventions aimed at maximizing adolescent vaccination rates [12,15]. As in studies of HPV vaccine, we also found the advice of physicians and perceived beliefs of family members (i.e., normative beliefs) were important predictors of parental CMV vaccine acceptance [12,15,21,22]. Future CMV vaccines are likely to have similarities to HPV vaccines in terms of target populations (preferentially females) and dosing strategies (3 injections administered over 6 months) [23,24]. However, there are important differences between these two viruses in terms of disease transmissibility and sequelae, and the fact that, in contrast to HPV, the primary beneficiary of a CMV vaccine is not the vaccine recipient, but the future child of that recipient. Since there may also be an increasing number of vaccines that are recommended for indirect benefit, more work will be needed to determine how health care providers can best educate parents and the public about the potential benefits of vaccine against CMV or similar vaccines.

Concerns about safety were negatively associated with parental CMV vaccine acceptance in our study. This finding is in keeping with that of a systematic review that found that concerns about vaccine safety were negatively associated with HPV vaccine acceptance; with qualitative studies on a variety of vaccines that demonstrate safety concerns are often the primary barriers to vaccination for parents; and with several published reports indicating that parents are reluctant to try “new vaccines” because of the lack of long-term safety data [25–28]. A concern about the cost of a CMV vaccine was negatively associated with parental CMV vaccine acceptability in our study. The price of future CMV vaccines has not yet been determined, but the likelihood that a CMV vaccine will require three visits to complete the injection series only adds to the potential financial burden of the vaccine.

Prior vaccine refusal was also significantly and negatively associated with parental CMV vaccine acceptance. Previous work demonstrates that less than 1% of parents refuse all vaccines, but that a much larger percentage have refused at least one recommended vaccine for their children in the past [29,30]. Omer et al. demonstrated that the proportion of parents opting out of recommended vaccines for non-medical reasons has been climbing steadily over the past decade [31]. Developing mechanisms to reverse the trend of parental vaccine refusal will be critical for ensuring high vaccination rates among adolescents in the future.

The high acceptance of CMV vaccines by parents in our study is encouraging given that recent reports demonstrate relatively low uptake of adolescent-targeted vaccines like HPV, meningococcal conjugate vaccine and tetanus-diphtheria-pertussis vaccine (Tdap) [32]. As demonstrated by recent experience with the HPV vaccine in the US, vaccine uptake may lag behind pre-availability assessments of acceptance. While acceptance is an important prerequisite, there are many other factors that may affect vaccine uptake, including socioeconomic factors and acceptance by providers and society [33,34].

Our study findings should be interpreted in the context of several limitations. First, the sample population was relatively homogeneous in terms of race, gender, and level of education and study results may therefore not be generalizable to a broader population. Indeed, 53% of respondents in our study had some knowledge of CMV which is substantially higher than those reported in other studies (14–22%) and is likely a reflection of the education level and increased prevalence of health care workers in our study population [35,36]. Prior studies suggest that when poor vaccine uptake is related to acceptance, it may be more prominent among children of parents with higher education, suggesting that highly educated populations are important groups to study [29,37]. Second, since we used a self-administered questionnaire, subjects did not have the opportunity to ask questions to health care providers about CMV and a potential CMV vaccine. Interactions with health care providers and the opportunity to independently obtain information about a vaccine may positively or negatively influence vaccine acceptance. Third, CMV vaccines are not publicly available, thus we were only able to measure acceptability of a hypothetical vaccine. Vaccine acceptability could be different if parents were making a choice about a licensed vaccine and were considering actual costs and reported side effects. For this reason we chose to base our survey questions on well-validated theories of health behavior (Health Belief Model and the Theory of Reasoned Action) that have been shown in other studies to be a reasonable proxy measure for future vaccine receipt [25]. Fourth, a CMV vaccine trial was ongoing in our institution's Adolescent Medicine clinic. Though parents for our study were recruited from an unrelated registry, there is a remote chance that a few parents in our study may have had a daughter in the vaccine trial. However, given the small numbers enrolled in the vaccine trial compared to the relatively large size of the VFR, it is unlikely that this would have occurred, or could have biased the results of our study. Finally, we focused our survey primarily on the major constructs of the Health Belief Model (susceptibility, severity, benefits, and barriers), and were therefore not able to assess associations between CMV vaccine acceptability and other potentially important factors such as parent or child demographic characteristics. Since health care decision-making is a complex process, qualitative and quantitative research that is informed by heterogeneous populations of parents is needed to understand the many factors that may contribute to parental acceptance of a CMV vaccine and to assist clinicians and public health officials in effectively communicating risks and benefits of a CMV vaccine when it is licensed.

## 5. Conclusion

In the first study to examine parental acceptance of adolescent CMV vaccination, we found that among a highly educated population, parents were very accepting of a potential vaccine for their adolescent daughters. Perceptions of the opinions of peers and the physician, as well as perceived benefits to vaccination were associated with increased CMV vaccine acceptance while concerns about cost/safety and a history of prior refusal for other vaccines were associated with decreased parental CMV vaccine acceptance. Although additional studies in more heterogeneous populations are needed, our data add to the growing literature detailing factors that are likely to influence parents' acceptance of vaccines for their adolescent children.

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### Conflict of Interest

KE has received funding for laboratory studies related to pertussis vaccine from Sanofi Pasteur. AD has served on an advisory board for Merck related to HPV vaccination.



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**Table 1**

Baseline characteristics of study sample.

Variable	(N = 503)
Age (mean), y	45.5
Gender, %	
Male	15
Female	85
Race, %	
Black	11
Caucasian	86
Other	2
Education, %	
Some high school	1
High school diploma	8
Some college	28
College degree	33
Some graduate school	8
Graduate degree	21
Relationship status, %	
Married	67
Divorced/widow	24
Single	9
Awareness, %	
Yes	53
No	38
Maybe	9

**Table 2**

Level of acceptance of CMV vaccine by select sociodemographic characteristics.

Variable	Median	Interquartile range	P-value
Gender			
Male	89.0	(76.0, 99.8)	0.456
Female	89.0	(72.0, 99.0)	
Race			
Black	85.0	(59.0, 96.3)	0.234
Caucasian	89.5	(74.5, 99.5)	
Other	75.0	(58.3, 99.6)	
Education			
Some high school	85.5	(79.0, 92.0)	0.944
High school diploma	88.0	(76.8, 99.8)	
Some college	88.5	(74.9, 99.0)	
College degree	87.8	(70.8, 99.5)	
Some graduate school	88.3	(73.0, 97.4)	
Graduate degree	89.5	(73.0, 99.0)	
Relationship status			
Married	87.8	(69.3, 99.0)	0.125
Divorced/widow	93.5	(79.8, 99.5)	
Single	86.5	(76.0, 99.0)	
Awareness			
Yes	89.0	(73.0, 99.0)	0.968
No	88.8	(70.9, 99.5)	
Maybe	86.5	(75.3, 99.3)	
Past vaccine refusal			
Yes	21.0	(1.50, 57.0)	0.00
No	90.0	(75.0, 99.5)	
Maybe	72.0	(71.5, 86.0)	

**Table 3**

Standardized coefficients from multivariate linear regression model of independent predictors of CMV vaccine acceptance among parents.

Variable	Standardized coefficient	P-value
Past vaccine refusals	−15.4	0.005
Perceived susceptibility of baby to CMV	−0.610	0.6
Perceived severity of congenital CMV	−1.34	0.3
Perceived benefits of CMV vaccine	9.18	<0.001
Perceived barriers of CMV vaccine		
Safety of CMV vaccine	−2.55	0.03
Expense of CMV vaccine	−3.68	0.005
Adherence to CMV vaccine schedule	−0.0461	1.0
Normative beliefs <sup>a</sup>	7.52	<0.001

<sup>a</sup>Parent's assessment of the opinions of physicians, family members, and peers regarding vaccination of adolescent girls against CMV.