Author’s response to reviews

Title: A Qualitative Assessment of Factors Influencing Acceptance of a New Rotavirus Vaccine among Health Care Providers and Consumers

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Author’s response to reviews: see over
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Dear Editor,

Please accept the revised version of our manuscript entitled “A Qualitative Assessment of Factors Influencing Acceptance of a New Rotavirus Vaccine among Health Care Providers and Consumers.”

We have addressed the referees’ concerns in the subsequent pages (in bold) and are submitting a revised version of the manuscript. We look forward to your response.

Regards,

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**REFEREE 1:**

1. The MD sample was rather small (n=10). The authors made a point that the physician sample would have at least four individuals who had been in practice for >10 years, so that they would have been in practice during the time that RotaShield was recalled. Why include anyone who was not in practice during that time? Otherwise why make this point? Did those who were not in practice during that time differ in their opinions from those who were?

   Based on our prior discussions with pediatricians and family practice physicians, we suspected that most physicians (< 10 years and > 10 years practice) would be familiar with Rotashield. As we suspected, in the focus group all physicians expressed familiarity with Rotashield and its association with intussusception. We will include this finding in the results. Beyond familiarity with the topic, we did not further assess differences in opinions between the two groups.

2. Table 2 does not divide participants by education as is stated in the methods regarding college degrees. This lack of consistency is confusing to the reader.

   In the methods, we describe the process of forming the 4 focus groups at each site while the table provides overall characteristics of all participants at each site. For the 4 focus groups at each site, we ensured that each focus groups consisted of >2 participants with less than and more than a Bachelor’s degree of education. For this, we queried the participants informally and did not track their specific level of education. However, for our systematic data collection form on participant characteristics, we inquired on level of education as high school or less versus more than high school, which is presented in the Table.

3. For the Figure, there is no mention in the methods as to how these data were derived.

   We have amended the methods to include these two sentences:
   “After introduction to the project, each focus group began with a discussion of the general childhood health concerns that the participants regarded to be important. The discussion subsequently was directed to diarrhea and rotavirus disease and the participants’ perception of the importance of these diseases. **Participants were asked to rank the seriousness of rotavirus disease on a scale of one to seven, with one being “not serious at all” and seven being “very serious.”** Lastly, participants reviewed the rotavirus Vaccine Information Statement and discussed their knowledge, issues, concerns, and attitudes towards rotavirus vaccines. **On a scale of one to seven, where one was “definitely not get” and seven was “definitely get,” participants were asked to rank their likelihood of having their child vaccinated against rotavirus.** To facilitate and focus the discussion, throughout the session, the moderator used flipcharts and printed handouts relevant to rotavirus disease.”
4. Why did you assume that there would be empowerment in focus groups?
Sometimes group dynamics discourage people from saying what they truly believe. This may be especially true of consumers unaware of rotavirus.

We agree with the reviewer that it was inappropriate for us to assume this. We have revised the methods to reflect the actual steps of the study and retracted our personal opinions. The following was deleted:

“Because vaccine and child health issues have the potential to evoke strong emotions, we assumed that participants would likely feel empowered to discuss these issues in the presence of peers. Thus, we deemed that focus groups would be an appropriate forum for consumers and... We convened four 90-minute focus groups in each study site. “

5. Who were (what can you tell me about) the consumers who definitely would not have their children vaccinated? Did they differ from others?

*Because the groups were limited in number at each site, we did not further differentiate their characteristics.*

6. One half of your sample was not aware of the rotavirus before the focus groups; does it make sense to combine their responses with knowledgeable consumers?

This finding was a general note that was made by reviewing participants’ comments from the focus group. No formal quantitative assessment of this topic was undertaken as we did not anticipate such a high proportion of participants to be unaware of rotavirus disease (i.e., those with lack of awareness were not separately tracked). In our discussion, this was a finding that we do emphasize as a potential area of further focus, either through future quantitative surveys or studies determining factors to enhance immunization acceptance and coverage. The responses in our study could be associated with this lack of awareness, however we are unable to assess that through our data. We will acknowledge this in the limitations.

“The unique characteristics of our study sample may limit the application of these findings to a broader population. *For example, most of the participants in Sunnyvale were unaware of rotavirus disease prior to their involvement in the focus group.*”

7. How did those who were unaware, differ in response to the VIS from those who were aware of rotavirus?

Please see response to # 6.
1) At several points in the discussion/conclusion, the authors emphasize the need to disseminate rotavirus vaccine information to the general public in order to achieve adequate rotavirus immunization rates. The results suggest that most parents would immunize if a provider recommends it. This raises the question: to what extent is dissemination of information to the general public necessary to achieve adequate immunization rates?

This certainly is an important and complex question and we propose to modify some of the discussion to clarify this point. The aim of our study was not to answer this question and we have edited some of the language of the discussion to avoid over-interpretation of our results by suggesting dissemination of vaccine information to achieve adequate immunization rates. The answer to the question that the reviewer raises remains largely unanswered in the literature and is likely to be complex and possibly change over the course of a vaccination program. Many factors such as the disease and the vaccine (perceived risk/benefit) under question, financial mechanisms, region of use, and characteristics of the population, could all influence immunization rates. Identifying these barriers would be the first step, however, studies will ultimately be necessary to assess whether implementation of identified interventions tailored to specific groups actually impact vaccination rates.

The second paragraph has been modified:

“Unlike physicians, however, women who participated in these focus groups were considerably less aware of the health burden of rotavirus. In our study, many focus group participants, particularly those living in Sunnyvale, were completely unaware about rotavirus disease. Although these women initially did not perceive rotavirus diarrhea to be a high-priority health issue, a majority considered rotavirus to be a moderate to severe illness after reading the Vaccine Information Statement. Furthermore, they asked many pertinent questions about the epidemiology of rotavirus and risk factors for severe disease. Lack of disease awareness can/may be an important barrier to acceptance of the new vaccine, particularly if parents perceive the risks of vaccination to be greater. Our findings suggest that disseminating information to the public about the magnitude of the public health burden of rotavirus disease will help increase acceptance of the new rotavirus vaccine. Our data also suggests that regardless of rotavirus knowledge, if the provider recommends vaccination, parents would likely accept the vaccine. Since providers stated that they would follow recommendations from ACIP and their professional organizations, dissemination of rotavirus vaccine and disease information through these organizations would be important to increase vaccine uptake. However, further studies would be necessary to assess whether these interventions actually contribute towards increasing vaccination coverage rates.
2) The authors should describe the extent to which consumers’ comments differed based on previous childrearing (and immunization!) experience and on level of concern about vaccinations.

The results have been updated to reflect this:

Rotavirus knowledge: “However, in Kansas City, where a seasonal peak in rotavirus disease was ongoing at the time of the focus group, an increased awareness of rotavirus disease was noted among the participants. Perceived seriousness of rotavirus diseases was somewhat greater in Sunnyvale among women without childrearing experience. Interestingly, once participants reviewed the Vaccine Information Statement, most considered rotavirus disease to be a moderately serious condition.”

Rotavirus vaccines: “However, when asked to rank the likelihood of having their child vaccinated against rotavirus from 1 (‘definitely not get’) to 7 (‘definitely get’), 29% ranked between 1 to 2, 36% between 3 to 4, and 35% between 5 to 7 (Figure). Generally, those participants with previous child-rearing experience were less concerned about vaccinations. However, two respondents expressed increased level of awareness with regard to vaccine safety issues with their second child. Commonly expressed concerns about the vaccine included the administration of a live-vaccine to “young, vulnerable” infants, the newness of the vaccine, potential for adverse events as more data becomes available, and the narrow window of age when the vaccine is recommended.”

3) The authors state that providers showed a "keen interest" in post-licensure studies. Were these unprompted statements, or affirmative responses to a specific question?

This was their unaided response that they would feel more comfortable with the vaccine when post-surveillance would be available. We have amended the sentence to reflect this.

4) Did providers indicate that they would discontinue giving Rotatec if similar problems with intussusception occurred?

Providers were more interested in post-surveillance data as a factor that influence their acceptance of the vaccine, but no other specific comments were made with regard to whether they would or would not discontinue giving RotaTeq.

5) In the discussion, the authors state that lack of disease awareness is a barrier to vaccine acceptance. Is this true? Can the authors provide references?

Please also refer to our response to your question 1 above. We should be careful in stating that lack of disease awareness is a barrier to vaccine acceptance as a statement of fact. We hope to convey the importance of disease awareness in the
context of perceived vaccine safety, and are suggesting that this may be a barrier if parents perceive risks to be greater. Evidence does suggest that perceived risks of vaccination is an important predictor of parental intention to vaccinate (Meszaras et al. Jo Clin Epi. 1996:49;697-703) and an analysis of the National Immunization Survey also identified that perceptions of risk/benefit contributed to underimmunization of US children (Gust et al. Pediatrics 2004:114(1).

We have amended the 2nd paragraph of the discussion, as discussed under question 1 above. In addition, we also modified the conclusion:

“In conclusion, the findings of our survey indicate that US providers are aware of the health burden of rotavirus and are likely to adopt the new rotavirus vaccine, even though they were aware of the safety concerns with the earlier rotavirus vaccine. Parents were substantially less aware of rotavirus disease, although most expressed that they would get their child vaccinated if their physician recommended it. Future efforts to increase adoption of the new vaccine should focus on increasing awareness of rotavirus disease and the benefits of vaccination among the general public and rapidly communicating results of post-marketing surveillance for vaccine effectiveness and safety to providers and the public.”
Minor Essential Revisions

- First paragraph of results should present the response rate for each group.
  We typically do not track the response rates for focus groups and did not do so with this study.

- AAP is the American Academy of Pediatrics (not Association)  
  Amended

- Did providers comment on the narrow age range for Rotatec administration?
  This was not raised during the study.

- On pg 12 para 1, the response of "5" is assigned to two different categories (very serious and moderate). Please clarify.

  This was an error that has been rectified.
  “Based on a scale of 1 (“not at all serious”) to 7 (“very serious”), 59% consider the seriousness of rotavirus disease to be very serious (range 5 to 7), while 36% consider the disease to be moderate (range = 4 to 5) and only 5% consider it to be not at all serious (range = 0 to 1) (Figure).”