Knowledge and Attitudes Towards Rotavirus Diarrhea and the Acceptance of Rotavirus Vaccination Amongst Primary Caregivers in Yogyakarta, Indonesia: A Qualitative Study

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Knowledge and attitudes towards rotavirus diarrhea and the acceptance of rotavirus vaccination amongst primary caregivers in Yogyakarta, Indonesia: a qualitative study

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ABSTRACT

Background: Rotavirus is the leading cause of hospitalized diarrhea in Indonesia. Rotavirus vaccine has not been included on the Indonesian National Immunization Program (NIP). There are some key issues must be considered before introducing a new vaccine into a NIP. Our study aimed to explore the knowledge and attitudes of rotavirus diarrhea and barriers to the acceptance of the vaccine.

Methods: We conducted 26 in-depth interviews in two districts (rural and urban areas) of Yogyakarta Province, Indonesia. Participants included pregnant women in their third trimester and mothers of infants aged less than 14 weeks. We conducted a thematic analysis.

Results: Participants did not perceive diarrhea as being a priority health problem. Very few had heard of rotavirus diarrhea or were aware of the availability of the vaccine. While participants would accept a vaccine their children against rotavirus, some key barriers impacted the use of the vaccine. As the rotavirus vaccine is not included in the Indonesian National Immunisation Program (NIP), parents perceived it as not essential. Parents were concerned regarding the safety and benefit of the vaccine due to the perceived newness of the vaccine. Other concerns were the vaccine was too costly and the *halal* issue. Participants expressed a need for more information on the vaccine's effectiveness and safety, with their primary health care providers (HCPs) nominated as playing an important role in vaccine acceptance.

Conclusions: There was low awareness of rotavirus being a serious disease and the availability of the rotavirus vaccine in Indonesia. The vaccine is not on the Indonesian NIP, the newness, the safety and efficacy, the cost, and the *halal* status of vaccine were barriers to vaccine acceptance. Information and recommendation by HCPs play an essential role in vaccine acceptance

Key Words: vaccine acceptance, knowledge, primary caregiver, rotavirus

57 **Background**

58 Diarrhoeal diseases are one of the leading causes of morbidity and mortality in children
59 younger than five years, cause more than half a million deaths per year globally, with most of
60 them, live in low-middle income countries[1],[2]. A large proportion, 55% in Asia, and 32% in
61 Africa, of acute watery diarrhea hospitalizations and 28% of watery diarrhea deaths are due to
62 rotavirus[3]. The Indonesian Rotavirus Surveillance Network (IRSN) conducted hospital-based
63 surveillance studies across Indonesia from 1978 -2015 and found 38% -62% of watery diarrhea
64 was caused by rotavirus[4],[5],[6],[7]. The estimated total direct medical costs of rotavirus
65 outpatient and inpatient hospitalizations in Indonesia amount to US$16.7million per year[8].
66 Reinfections with rotavirus are common throughout life, although the disease severity is reduced
67 with repeat infections[9]. The repeated infection at a younger age leads to growth faltering and
68 subsequent, resulting in stunting[10], which is associated with a decrease in cognitive
69 development[11],[12].

70 Due to the high transmissibility of rotavirus, improvements in sanitation and hygiene are
71 not sufficient to prevent rotavirus disease, and vaccination is the most effective prevention[9]. In
72 2013, World Health Organization (WHO) recommended the inclusion of a rotavirus vaccine into
73 all national immunization programs (NIP), especially in regions with a high mortality rate of
74 rotavirus-associated diarrhea, including South-East Asia[13]. To date, ninety-nine countries have
75 introduced the vaccine, including 73 Gavi-eligible countries[14]. Rotavirus vaccination has the
76 potential to prevent nearly 600 000 deaths and to save approximately $484·1 million from the
77 government perspective and $878·0 million from the societal perspective[15]. A recent systematic
78 review (2019) on rotavirus vaccines showed evidence of the vaccine's effectiveness in preventing
79 death caused by rotavirus diseases and vaccine safety, both in developed and developing
80 countries[16].

Since 2011, two commercial rotavirus vaccines, RotaTeq® (Merck Vaccines, USA) and Rotarix® (GlaxoSmithKline Biologicals, Belgium), have been licensed in Indonesia and has been recommended by the Indonesian Pediatric Society, however to date, it has not been included on the Indonesian NIP schedule. According to the WHO, some key issues should be considered before introducing a new vaccine into a NIP, including the communities' perceptions of disease severity and susceptibility, vaccine efficacy, and safety[17]. Another issue is the use of porcine trypsin in the manufacturing process. For Indonesia, which has the largest Muslim population in the world, the exploration of cultural and religious aspects of vaccination will inform the national vaccination program and has broader implications for policy development in other Islamic communities [18]. We conducted a qualitative study in Yogyakarta, Indonesia, to explore the knowledge and attitudes to rotavirus diarrhea and barriers to the acceptance of the vaccine of community members, health care providers (HCPs), and other stakeholders. This study reports on the findings from the pregnant women and primary caregivers of infants.

METHODS

Study design and setting

This qualitative study is a part of a more extensive study exploring the rotavirus vaccine acceptance among three groups: parents (pregnant women in their third trimester and primary caregivers of infants aged less than 14 weeks), HCPs,[19], and key community-religious leaders [18]. This article focuses on pregnant women and parents. We conducted in-depth interviews between August and Octobers 2013 in two districts of Yogyakarta Province: Yogyakarta and Sleman (representing urban and rural areas). Each district consists of several sub-districts, and each sub-district has at least one Primary Health Centre (PHC) responsible for providing primary health care to the surrounding villages. Each village has at least one midwife responsible for

105 mother and child health services at the village level, including providing NIP vaccines.

106 **Participants and recruitment**

107 We purposely invited pregnant women in their third trimester and primary caregivers of
108 infants aged less than 14 weeks to participate in the study. The infant age limit reflects the
109 specified cut-off period for the first dose of the rotavirus vaccine. Midwives identified potential
110 participants from the registries of community members and offered them invitation letters and
111 supporting documents at the time of attending the clinic. Follow-up telephone calls were made by
112 the research staff to ascertain if they were interested in participating. Before the interview, they
113 did not know each other.

114 **Data collection**

115 The authors developed an interview guide based on the literature review. We conducted
116 a weekly team meeting to discuss preliminary findings, and we modified and revised the interview
117 guides as needed. Questions related to the following topics: (1) knowledge and attitudes
118 towards diarrhea, (2) perceptions of susceptibility and disease severity, (3) awareness and
119 acceptance of the rotavirus vaccine; (4) barriers impacting on vaccination and (5) information
120 needs and strategies for the provision of information (Supplementary file). We conducted
121 paraphrasing and asked additional questions to seek clarification during the interviews to ensure
122 that the study included most of the question topics. We provided a brief, standard written
123 explanation of rotavirus diarrhea and the vaccine after ascertaining participant baseline
124 knowledge about rotavirus. Debriefing was done at the end of each interview. We re-contacted
125 participants if further clarification was required. We recruited participants until data was saturated,
126 where no new ideas or issues were raised in subsequent sessions. Two trained and experienced
127 researchers, who were familiar with the data collection method, from the Faculty of Medicine,

Public Health and Nursing, Universities Gadjah Mada (FK-KMK UGM) conducted the interviews in the participants' house for an average of 45 minutes per interview. No observers were present.

The Medical and Health Research Ethics Committee (MHREC) FK-KMK UGM ((KE/FK/689/EC) and University of New South Wales, Australia (HC13079) approved the study. We obtained informed consent from all participants at the time of the interview, and we assured confidentially. We conducted and reported the study according to Consolidated criteria for reporting qualitative studies (COREQ). (Additional file 1: Table S1: COREQ checklist)[20]

Analysis

All interviews were conducted in the local language and then translated into English by a professional translator. Interviews were digitally recorded and professionally transcribed verbatim. Two experienced researchers, S Padmawati, Ph.D., Medical Anthropologist, and Dr. M Sitaresmi, Ph.D. Pediatrician- public health researcher, independently analyzed the transcript manually and constructed it, cross-checked, and finalized a code list of major themes. We analyzed and coded all of the 26 transcripts using the final thematic framework.

RESULTS

All of 26 invited respondents (100% response rate) consisted of 17 primary caregivers, and nine pregnant women participated in in-depth interviews. Two of 17 parents (11%) had vaccinated their child with rotavirus vaccine. The mean ages of participants were 31 years (range: 22 to 44 years old), 20 (77%) of participants had completed at least senior high school, while 17 (65%) were unemployed.

General knowledge and attitude towards diarrhea

The general knowledge of participants regarding diarrheal disease was fair. Changes in

151 stool consistency, frequent defecation, abdominal pain, and dehydration were frequent symptoms
152 cited by participants. Participants recognized poor hygiene and sanitation, irregular eating
153 schedules, and eating the "wrong food" as causes of diarrhea. Improved sanitation and hygiene
154 behavior were reported as effective approaches to prevent diarrheal disease. They perceived the
155 use of Oral Rehydration Solution (ORS), increasing fluid intake, and continued breastfeeding as
156 effective treatments for diarrhea.

157 "*Give Oralit [ORS] first. When still a baby, just give him enough breast milk because the*
158 *baby has to breastfeed to prevent dehydration.....If her condition becomes more severe,*
159 *then consult the doctor" (Pregnant woman)*

160 **Not a high health priority**

161 The low risk of acquiring diarrhea was a common emergent theme with diarrhea not
162 perceived as a high-priority health issue for children. However, if not managed appropriately,
163 participants did recognize that diarrhea could become a severe condition.

164 *"I have already kept clean; my children do not get diarrhea. Just last time during the*
165 *earthquake when it was dirty, now it is clean" (Mother of three children)*

166 '*Diarrhea is a mild disease. "Old people" said, if children get diarrhea, it's called ngenteng-*
167 *ngentengi (lighter), because he will be smart. However, it can also be severe diarrhea... If*
168 *it continues, it will be serious"* (Mother of two children).

169 Severe diarrhea was perceived as diarrhea presenting with vomiting, frequent watery
170 stool, fever, or bloody stool. Most participants were aware of the need to present to HCPs if
171 diarrhea persisted or accompanied by vomiting, fever, or bloody stool.

172 *"If no fever, it means mild, if defecation watery and frequently more than five times it is*
173 *severe, very severe if with blood, (child) should be brought to HCPs)" (Mother of two*
174 *children).*

175 After receiving information on the signs and symptoms of rotavirus diarrhea, the local term
176 *muntaber* (frequent vomiting and diarrhea) was associated as being rotavirus diarrhea. There was
177 a perception that *muntaber* was associated with serious diarrhea. However, the perception that
178 *muntaber* could be prevented by high sanitation and hygiene remained.

179 *"Yes, muntaber is dangerous.. It will make the body weak and dehydrated" (Mother of a*
180 *child aged)*

181 *"I am really worried about mutaber, but if we keep healthiness and clean, it will prevent*
182 *the children from the disease." (Pregnant woman)*

183 **Low awareness of the rotavirus vaccine**

184 Aside from the two mothers who had vaccinated their children against rotavirus, only one
185 participant had heard of the rotavirus vaccine. In this case, the respondent had a family member
186 who had participated in a clinical trial for the RV3 rotavirus vaccine. After receiving information on
187 the rotavirus vaccine, most participants perceived that the vaccine is an important method to
188 prevent severe diarrhea. However, when asked about their intention to vaccinate their child, over
189 half indicated that they would vaccinate their child with rotavirus vaccine. Participants commonly
190 highlighted that they need to discuss it with their HCP before accepting the vaccine. Most
191 participants mentioned that they trust their HCP and will vaccinate their children according to their
192 HCP recommendation.

193 **Barriers to rotavirus vaccination**

194 We identified some concerns regarding the vaccine with consistently emerging themes
195 summarized in Table 2. The most common issue raised was that the vaccine was not included
196 in the Indonesian NIP. The parents perceived the vaccine as not being important as it is not
197 included in NIP.

198 *"If (vaccine) is not obligatory, it means it is not important, right?" (Pregnant women)*

199 *"... I will take the basics first (NIP vaccines), and I do not know about the other vaccines*
200 *because it is not obligatory. If it is included in the basic vaccination, I will follow the*
201 *recommendation" (Mother of two children)*

202 Participants were concerned that the vaccine was too new and that there needed to be more
203 evidence of the vaccine's effectiveness and safety

204 *"Yeah, for the new vaccines, we are still confused about whether to give it or not. We do*
205 *not know, because it is new. Will the baby respond to the vaccine well, or will it lower their*
206 *immune system. So, I only give the obligatory ones." (Mother of a child)*

207 We also identified that the cost of the vaccine was also a significant barrier. When asked
208 how much money they are willing to pay for the vaccine, the responses varied from US$1 to
209 $US25. In regards to the issue of the use of porcine trypsin, most participants stated that they are
210 willing to accept it as long as the vaccine has been 'washed' correctly, and it has been labeled as
211 *halal* (permitted) by the Indonesia Islamic organization, Council of Islam, Indonesia (MUI).

212 *"I think if it had been stated as halal by MUI the community would receive it" (Mother of*
213 *three children)*

214 **Desire to receive information**

215 Vaccine information and recommendations were mainly from primary HCPs, especially midwives.
216 However, they mentioned that their HCP provided limited information and only the recommended
217 vaccines on the NIP due to long waiting times and short consultations.

218 *"…in the primary health center, if we do not ask, they do not give any information" (Mother*
219 *of two children)*

220 *"No, there was no explanation about immunization, yesterday was so crowded it was*
221 *already at ten o'clock and the queue was a lot, felt like in a hurry" (mother of a child)*

222 Other sources of information mentioned included healthcare volunteers (cadres), relatives,
223 friends, maternal-child health books, leaflets, and the Internet.

224 *"I read from the maternal-child health book. I know it (rotavirus vaccine) from the leaflet,*
225 *and then I asked to doctor" (Mother of a rotavirus vaccinated child)*

226 Participants expressed a desire to receive more information about rotavirus disease and the
227 vaccine. Suggested methods for disseminating the information included a personal consultation
228 by primary HCPs, leaflets, and a group education session for pregnant women/new mothers.
229 Islamic leaders were also identified as an essential source for disseminating the information.

230

231 **DISCUSSION**

232 This study was exploring knowledge and attitudes towards rotavirus diarrhea and the
233 acceptance of the vaccine amongst primary caregivers in Yogyakarta, Indonesia. We found that
234 participants were not aware of the burden of rotavirus disease and the availability of the vaccine.
235 Diarrhea was perceived as not being a high health priority. Most of our parents believe their
236 children had a low susceptibility to the disease. They perceived that they could protect their child
237 from diarrhea if they maintained strict sanitation-hygiene behaviors and breastfed. This finding
238 was similar to the more recent multi-countries survey (2018), which involved 1500 participants,
239 including 250 parents from Indonesia. They reported that only 36% of Indonesian parents aware
240 that every child will be infected rotavirus by the age of 5 years[21]. Another study from a developed
241 country, Italy, assessed parent's knowledge, belief, and behavior toward rotavirus, and found that
242 less than half of their participants had heard about rotavirus infection and aware of the availability
243 vaccine[22]. Prioritizing the importance of rotavirus disease is the first step towards the successful
244 implementation of the vaccine[17]. Our participants perceived diarrhea as an accepted and
245 manageable disease. Increasing fluid intake and use of ORS were considered to be simple

246 methods to manage diarrhea. While it appears that past efforts to educate the community about
247 the importance of preventing and managing classic diarrhea appear to have been successful,
248 renewed efforts are needed to establish the importance of rotavirus as a causative agent of
249 diarrhea. Compared to classic diarrhea, rotavirus diarrhea is significantly more severe due to the
250 increased risk of vomiting and difficulties in the administration of ORS. Besides, improvements in
251 sanitation and hygiene are not sufficient to prevent rotavirus disease; thus, vaccination is the most
252 effective prevention [9].

253 As the vaccine was not listed on the NIP, it was devalued by parents. This was intrinsically
254 linked to the idea that if the vaccine was not listed on the NIP, then the Indonesia Government
255 must not consider that the disease is essential. This concern was also raised by our HCPs[19]
256 and has been previously reported in connection with other vaccines, namely the pneumococcal
257 vaccine [23].

258 Concern regarding "the newness", safety, efficacy, and the cost of the vaccine were raised
259 by our participants as potential barriers for accepting the vaccine. These concerns have also been
260 cited as important barriers to the acceptance of other new vaccines [24], [25]. Other barriers are
261 the *halal* status and the use of porcine trypsin in the vaccine production process. This issue has
262 been previously reviewed by Grabenstein [26]. For most Muslims in Indonesia, *halal* is a
263 significant factor influencing their decision to vaccinate. Both Rotarix® and RotaTeq® have yet to
264 been approved as *halal* vaccines by MUI. Previous experience with obtaining approval for the
265 polio vaccine highlights the importance of MUI endorsement of the rotavirus vaccine as a halal
266 vaccine[27]. Advocacy for the endorsement of new vaccines by Islamic Organizations should be
267 a critical component of an immunization strategy as parents need assurances that the vaccine is
268 halal[18].

269 Similar to a qualitative review by Ames HMR et al.[28], our participants expressed a desire
270 to receive more information about rotavirus disease and the vaccine. Knowledgeable of the

disease and the vaccine will influence the acceptance of the vaccine. As with previous studies, our study found that primary HCPs have an essential role in parental vaccine decisions[21], [29]. Clear communication between parents and their trusted HCP will influence vaccine acceptance. Most participants reported that they received their information on vaccines from their primary HCPs and that their primary HCPs influenced their decisions. However, the limited time spent discussing the issue of immunization with parents (especially given that is a tendency to focus on the vaccines listed on the NIP) along with the provider's lack of knowledge has been identified as potential barriers in promoting the rotavirus vaccine[19]. In Indonesia, midwives provide most childhood vaccines. However, according to Indonesian regulation, midwives are only permitted to provide vaccines on the NIP[30]. Non-NIP vaccines are only available through hospitals or private pediatricians[31]. The limited availability of the vaccine will continue to be a significant barrier for parents who wish to vaccinate their children against rotavirus.

To our knowledge, no research focusing on the attitudes of Indonesian parents towards the rotavirus vaccine. Using in-depth interviews to elicit a greater depth in the information is a key strength of our work. Our study can identify the barriers of rotavirus vaccine acceptance. We acknowledge that this result should not be generalized to a broader population due to the unique characteristics of our study sample. We conducted interviews with a limited number of participants, so other important themes in other populations cannot be ruled out. This qualitative study should be complemented with a quantitative study with a representative sample of parents to provide a comprehensive assessment of barriers to the implementation of the rotavirus vaccine in Indonesia.

CONCLUSION

294 There was low awareness of rotavirus being a serious disease and the rotavirus vaccine
295 availability in Indonesia. The vaccine is not on the Indonesian NIP, the newness, the safety and
296 efficacy, the cost, and the *halal* status of the vaccine were barriers to vaccine acceptance.
297 Information and recommendation by their HCP play an essential role in accepting the vaccine.
298 Discussion regarding rotavirus disease and the vaccine availability needs to be conducted with
299 communities, religious leaders, and HCPs
300

301 **List of abbreviations**

302 HCP: Health Care Provider; IRSN: Indonesian Rotavirus Surveillance Network, MUI: Majelis
303 Ulama Indonesia; MHREC: The Medical and Health Research Ethics Committee, NIP: National
304 Immunization Program; ORS: Oral Rehydration Solution; PHC: Primary Health Centre; WHO:
305 World Health Organization

306 **Declarations:**

307 **Ethics approval and consent to participate**: The Medical and Health Research Ethics
308 Committee (MHREC) FK-KMK UGM ((KE/FK/689/EC) and University of New South Wales,
309 Australia (HC13079) approved the study. We obtained informed consent from all participants at
310 the time of the interview, and we assured confidentially. We conducted and reported the study
311 according to Consolidated criteria for reporting qualitative studies (COREQ).

312 **Consent for publication: not applicable**

313 **Availability of data and materials:** The datasets used and/or analysed during the current
314 study are available from the corresponding author on reasonable request

315 **Conflict of interests**

HS has received grant funding for investigator-driven research from bioCSL, GSK, and Sanofi Pasteur. AEH has received grant funding for investigator-driven research from GSK and Sanofi Pasteur. CRM has received funding from GSK for investigator-driven research on vaccines.

The other authors have no competing interests to declare.

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Author's Contributions

MNS, AEH, RSP, HS, and CRM developed the study design. MNS, RSP, JAT, and YS performed data collection. MNS, RSP, HS contributed to the interpretation and data analysis. MNS developed the main draft manuscript. All authors reviewed, gave comments, and approved the final manuscript.

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445

446 **Table 1: Consolidated criteria for reporting qualitative studies (COREQ): 32-item**

447 **checklist**

448

449 Developed from:

450 Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ):

451 a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health*

452 *Care*. 2007. Volume 19, Number 6: pp. 349 – 357

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	Methods: data collection page 6, paragraph 1
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	Methods: analysis page 6, paragraph 2
3. Occupation	What was their occupation at the time of the study?	Methods: analysis page 6, paragraph 2.
4. Gender	Was the researcher male or female?	Methods: data collection & analysis page 6, paragraph 1& 2.
5. Experience and training	What experience or training did the researcher have?	Methods: data collection & analysis page 6, paragraph 2.
Relationship with participants		

6. Relationship established	Was a relationship established prior to study commencement?	Methods: participants and recruitment page 5, paragraph 3.
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Methods: participants and recruitment page 5, paragraph 3.
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Methods: data collection page 6, paragraph 2.
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Methods: analysis page 6, paragraph 2.
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Methods: participants and recruitment page 5, paragraph 3.
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Methods: participants and recruitment page 5, paragraph 3.
12. Sample size	How many participants were in the study?	Results

		page 7, paragraph 1
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Results page 7, paragraph 1
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Methods: data collection page 6, paragraph 1.
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	Methods, data collection page 6, paragraph 1.
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Results page 7, paragraph 1.
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Methods: data collection page 6, paragraph 1.
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	Repeat interviews were not carried out.
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Methods: analysis page 6, paragraph 2.
20. Field notes	Were field notes made during and/or after the inter view or focus group?	Methods: analysis page 6, paragraph 2.
21. Duration	What was the duration of the inter views or focus group?	Methods: data collection page 6, paragraph 1.
22. Data saturation	Was data saturation discussed?	Methods: data collection page 6, paragraph 1.
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	Methods: data collection page 6, paragraph 1.

Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	Methods: analysis page 6, paragraph 2.
25. Description of the coding tree	Did authors provide a description of the coding tree?	N/A
26. Derivation of themes	Were themes identified in advance or derived from the data?	Methods: analysis page 6, paragraph 2.
27. Software	What software, if applicable, was used to manage the data?	NA
28. Participant checking	Did participants provide feedback on the findings?	Methods: data collection page 6, paragraph 1.
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Results
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	Themes are outlined in the discussion section
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes included in the Results and Discussion.

455 **Table 2. Consistently emerging themes**

• Respondents were not aware of the burden of diarrheal disease.
• Respondents did not perceive their child susceptible of acquiring diarrhea. Improving sanitation-hygiene behaviors and providing breastfeeding were believed to protect from diarrhea sufficiently.
• Rotavirus diarrhea is an almost unknown disease. After receiving information about rotavirus, it was perceived as a serious disease.
• Rotavirus vaccine was acceptable especially if the vaccine is included in the NIP
• Concerns regarding rotavirus vaccine included not being on the Indonesian NIP, the "newness" of the vaccine, the potential for adverse events, the cost of vaccine, and the use of trypsin porcine in the vaccine production process.
• Respondents conveyed their desire for the Halal label to be clearly stated in the vaccine information sheet provided to parents
• Respondents reported the need for more information on rotavirus disease and the vaccine and that further discussion with primary health providers was essential before accepting the vaccine for their children.

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UNIVERSITAS GADJAH MADA

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Research Project Title: Rotavirus Vaccine Acceptability Study
Principal Researcher: Dr Mei Neni Sitaresmi and Dr Jarir At Thobari (Indonesia)
Dr Holly Seale and Dr Anita Heywood (Australia)

What is an Information Statement?

Thank you for taking the time to read this Information Statement. It provides information about a new study that is being conducted by the Universitas Gadjah Mada and the University of New South Wales.

The information provided in this document is to help you to decide whether or not you would like to take part in the research.

Please read this information statement carefully. If you have any questions about the study, please ask the study team member.

Once you have understood what the project is about you will be asked whether you wish to take part. If you agree, you will be asked to sign the consent form on page 4. By signing the consent form you indicate that you understand the information and want to participate in the research project.

You will be given a copy of this information and consent form to keep.

---

1. What is the research about?

Background

Rotavirus is the most common cause of severe gastroenteritis and dehydration in young children in both low and high resource countries. Efforts to prevent disease by improving sanitation alone have not reduced the rotavirus disease burden and it remains a significant cause of child mortality and hospitalisation in Indonesia. A vaccine to prevent rotavirus is available and the first dose is given to infants between 6 and 14 weeks of age.

2. What is the purpose of this study?

This study aims to identify the attitudes and barriers to acceptance of rotavirus vaccine among parents/primary caregivers, vaccine providers, community/village leaders, policy makers and Religious Leaders in Yogyakarta, Indonesia.

3. How many people will be involved in this study?

Participants will consist of parents, grandparents, healthcare workers, community/village leaders, policy makers and Religious Leaders.

4. Which institutions are supporting this research project?

The study is being run by the Paediatric Research Office Dr. Sardjito Hospital/Faculty of Medicine Gadjah Mada University (Yogyakarta, Indonesia) and The University of New South Wales (Sydney, Australia). The funding for this study is provided by GlaxoSmithKline, a vaccine manufacturer.

5. Why am I being asked to be in this research project?

Based on information from the primary health centre or from publically availably information, you have been identified as being eligible for our study.

6. What do I need to do to be in this research project?

If you agree to participate, you will be asked to complete a short (5 minute) survey that will collect general demographic information. This information will be used to generally describe the study population and their level of experience in any published work. After that, we would like to complete one interview with you to examine your views on the disease and the vaccine. The interview will take 30 minutes to complete and will be scheduled at a time which is convenient to you. You can stop the interview at any time or can leave questions you don't want to answer.

7. What are my alternatives to taking part in this study?

It is up to you to decide whether or not to take part and no one force you to do so. Your consent and participation in this study is voluntary. You are free to withdraw at any time, without giving a reason. If you decide to withdraw, please let me know. Deciding not to take part in the study or withdrawing during the study will have no impact on your or your children's care through your Primary Health Centre or your relationship with The University of New South Wales or Universitas Gadjah Mada, Indonesia.

8. What are the possible benefits for me?

We cannot and do not guarantee or promise that you will receive any benefits from this study.

9. What are the benefits to other people in the future?

We hope that the rotavirus vaccine will be accepted by the community and prevent many of deaths and hospitalisations caused by rotavirus every year.

10. What are the possible risks?

We do not anticipate any risks to you from being in this study. Some questions ask about your attitudes towards rotavirus and the vaccine in a way that you may not have considered before. Thinking about some of these issues may make you worry or feel uncomfortable. If you do feel this way, please speak to the study investigator.

11. What will be done to make sure my information is confidential?

Any information that is obtained in connection with this study and that can be identified will remain confidential and will be disclosed only with your permission, except as required by law. We plan to publish the outcomes of the research in peer-reviewed journal papers. In any publication, information will be presented in such a way that you will not be able to be identified.

12. Will there be any financial cost or reimbursement for participating in this research project?

There will be no compensation provided to you, but transportation costs will be reimbursed.

13. Who can I contact about the study?

If you would like more information about the project or if you need to speak to a member of the research team, you can contact the research team as follows:

Complaints may be directed to:
Indonesia: Ethics Secretariat, Faculty of Medicine Gadjah Mada University (Tel. 9017225 or 0274-7134955, email mhrcc_fmugm@ugm.ac.id

Australia: Ethics Secretariat, The University of New South Wales, SYDNEY 2052 AUSTRALIA (Tel: 61 2 9385 4234, fax 9385 6648, email ethics.gmo@unsw.edu.au).

Any complaint you make will be investigated promptly and you will be informed out the outcome.

Principal Investigators

Indonesia

Name: Dr. Mei Neni Sitaresmi, Ph.D, SpA(K) or Dr. Jarir At Thobari, Ph.D.
Office name: Paediatric Research Office
Addres: jl. Kesehatan No. 1, Sekip, Yogyakarta, Indonesia
Phone: (0274)561616 or (0274) 587333 ext 543.
Email: msitaresmi@yahoo.com or j.atthobari@gmail.com

Australia

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Office name: School of Public Health and Community Medicine, University of New South Wales
Address: Level 3, Samuels Building, UNSW, Sydney, NSW 2052
Phone: +61 2 9385 3667
Email: h.seale@unsw.edu.au or a.heywood@unsw.edu.au

THE UNIVERSITY OF NEW SOUTH WALES
SYDNEY, AUSTRALIA

UNIVERSITAS GADJAH MADA
YOGYAKARTA, INDONESIA

PARTICIPANT INFORMATION STATEMENT

Rotavirus Vaccine Acceptability Study

I have read the information provided above. I understand the purpose, extent and possible effects in this project. I understand that participation in this project is voluntary and that I can withdraw myself from further participation at any time. I understand the procedure of this study. I understand that the researcher has agreed not to reveal my identity and personal details if information about this project is published or presented in any public forum.

By signing this form, I decide to participate.

Date : ……

Signature : ……

Name : ……...

Signature of witness : ……..

Name of witness : ……

THE UNIVERSITY OF NEW SOUTH WALES
SYDNEY, AUSTRALIA

UNIVERSITAS GADJAH MADA
YOGYAKARTA, INDONESIA

PARTICIPANT INFORMATION STATEMENT

Rotavirus Vaccine Acceptability Study

I hereby wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** jeopardize any relationship with The University of New South Wales or Universitas Gadjah Mada, Indonesia.

....

Signature Date

.....

Name

The section for Revocation of Consent should be forwarded to: Dr Mei Neni Sitaresmi, Pediatric Research Office, Pediatric Department, Faculty Medicine, Universitas Gadjah Mada, Jl, Kesehatan No. 1 Yogyakarta 55284, Indonesia.

Interview guide

Knowledge and attitudes towards rotavirus diarrhea and the acceptance of rotavirus vaccination amongst primary caregivers in Yogyakarta, Indonesia: a qualitative study

Mei N. Sitaresmi[a,g], Holly Seale[b], Anita E. Heywood[C], Retna S. Padmawati[d], Yati Soenarto[a], C Raina MacIntyre[e], Jarir Atthobari[f]

What do you know about diarrhoea? (Probes: symptoms, diagnosis, treatment, complications, prevention) What are the reasons for developing diarrhoea? How serious can the consequences of diarrhoea be? What should be done to prevent diarrhoea in children?

Have you ever heard about diarrhoea caused by RV (If no, the interviewer should explain about the symptom, to understand whether there are local concepts on the illness)? Is there any other word that you use to describe or call the symptoms in your local terminology/ language?

How concerned are you about your child becoming infected with rotavirus?

[Skip for women pregnant with 1st child] Have your child(ren) ever had RV diarrhoea? (please mention the symptoms in case the informant does not know about RV). If yes, how did you know it was RV diarrhoea? (by HCP, leaflet, other media?)

646 Have you ever heard about rotavirus vaccine? If your child's doctor recommended a
647 vaccination for your child against a virus that causes diarrhoea (RV), how likely would
648 you be to vaccinate your child? Would you accept your health care provider
649 recommendations for vaccination of your child/children? Why or why not? What would
650 you want to know about the virus or the vaccination? From whom would you prefer this
651 information from?
652 What issues would concern you when deciding whether or not to vaccinate your child
653 against this virus that causes diarrhoea? What would convince that this vaccine is very
654 important for your child/children? What would influence you to refuse having your
655 child/children vaccinated against this virus?
656 How much would you be willing to pay for the vaccine?
657
658 Have you ever looked for information about rotavirus or about the rotavirus vaccine
659 from any source?
660 If yes, on the most recent time you looked for information, where did you go first? What
661 did you think about the quality of the information?
662 If no, imagine then that you had a strong need to get information about rotavirus. Where
663 would you go first? Which additional information would you like most to have on rotavirus
664 or the vaccine?
665
666 Is there any other information regarding this topic you would like to add?
667
668

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- InterviewguideBMC.docx
- Informationstatement.docx