RESEARCH ARTICLE

Vaccine hesitancy among mothers of under-five children in Coastal South India: a facility-based cross-sectional study [version 3; peer review: 1 approved, 1 approved with reservations]

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Abstract

Background: Vaccine hesitancy (VH) has been identified by the World Health Organization as one among the top ten threats to global public health. There is limited literature regarding VH from developing countries like India.

Methods: In this facility based cross-sectional study, 172 mothers of under-five children were assessed regarding VH using the parental attitude towards childhood vaccination questionnaire (PACV).

Results: The prevalence of VH was 3.4% (n=6). Only 7.6% (n=13) of the study participants had ever refused vaccination for their child and the most common reason cited for their refusal was that they thought it was not safe (n=6). Government health facilities was the place of routine immunization for 60.5% (n=104) participants. Health care providers (n =79, 46%) were the major source of information regarding vaccines.

Conclusions: Our study highlights the presence of very low prevalence of VH in Mangalore compared to similar studies from India and other parts of the world. The limited number of participants had refused vaccination due to concerns related to vaccine safety.

Keywords
Vaccine Hesitancy, PACV, Mothers, Vaccination coverage, Mangalore
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Amendments from Version 2

The article has been further revised as per the suggestions of the reviewer. In the previous version of the article, in table 4 - Factors associated with vaccine hesitancy (N = 172), it was mentioned whether P value was <0.05 or >0.05 for each of the factors. The exact value of P was not mentioned. In the current version, the exact value of P has been mentioned as per the reviewer’s suggestion. Also, in the beginning of paragraph 8 of the discussion, the reviewer felt that the statement “In our study, mothers aged less than 30 years, educated up to high school and unemployed, residing in an urban area, belonging to Muslim religion, and availing immunization services from a government facility were found to be vaccine hesitant, though these factors were not significant (P>0.05)” was confusing. The reviewer suggested us a corrected version of the statement. We have incorporated the corrected version which reads as follows - “Vaccine hesitancy among the cohort was not significantly associated with factors such as maternal age, employment, mother’s educational status, religion, place of residence, place of immunization and socio-economic status (P>0.05).

Any further responses from the reviewers can be found at the end of the article

Introduction

One of the most effective and economical health interventions in recent times, immunization, has brought down the incidence of under-five morbidity and mortality. The effectiveness of a vaccine is subject to a significant number of people in the community being immunized. Unvaccinated children make those vaccinated susceptible to a disease due to waning herd immunity, as seen in poliomyelitis (Grassly et al., 2012). To achieve maximum immunization coverage, the Global Vaccine Action Plan 2011–2020 (GVAP) called for countries to achieve ≥90% immunization coverage by 2020 for all vaccines by incorporating it in their National Immunization Schedule (Peck et al., 2019). The highly ambitious Sustainable Development Goals (SDGs), to be achieved by 2030, includes immunization indicators to measure the progress made by countries in their journey towards ensuring healthy lives and promote well-being of all age groups. The percentage of children up to one year of age who have received three doses of diphtheria-tetanus and pertussis vaccine (DTP3) is taken as proxy indicator for full immunization (WHO, 2017). These estimates of DTP3 are used to monitor the performance of the health system, measure the effectiveness of the immunization program in terms of service delivery, and implement strategies for disease eradication and elimination (Measure Evaluation, n.d.). The global coverage for DTP1 and DTP3 in 2018 was estimated to be 90% and 86% and 86% for the first dose of measles-containing vaccine (MCV1). In India, even though maternal and neonatal tetanus has been eliminated and the country certified polio free, the coverage of routine immunization continues to remain low (UNICEF, n.d.). Only 62% of children were fully immunized, with the coverage of DTP3 and measles first dose estimated at 78.4% and 81.1%, respectively (Ministry of Health and Family Welfare, [MoHFW, 2015a]).

The lower vaccination coverage and dropouts may be attributed to populations who are either hard to reach or hard to vaccinate. Hard to reach are those residing in conflict zones or in difficult geographical terrain where vaccination is poor due to inadequate or irregular supply of vaccines. Hard to vaccinate population are those who despite having access to vaccination do not get their children immunized. This group poses a big challenge to immunization programs across the world (Peck, 2019).

“Vaccine hesitancy [VH] refers to the delay in acceptance or refusal of vaccinations despite availability of vaccination services” (WHO, 2014). Vaccine hesitant individuals may be those who have doubts about the vaccine but still get their children vaccinated, or individuals who either refuse or delay a vaccine but receive others, or individuals who reject all vaccines. VH is usually suspected to be present when the immunization coverage is low despite having adequate health services and provision of regular health communication by grass root level workers. This has threatened to reverse the progress made over the years in achieving adequate immunization coverage (WHO, n.d.1). VH has been identified by the WHO as one among the top ten threats to global public health (WHO, n.d.2), and was reported to be a significant problem by 74% of WHO member countries. These countries cited issues related to risk and benefits of vaccines as the most important reason for VH (MacDonald, Butler & Dube, 2018). However, VH is a complex and context specific phenomenon driven by behavioral and social factors which influence an individual’s decision of accepting a vaccine, and not just limited to the safety concerns regarding a vaccine (MacDonald, Butler & Dube, 2018, Thomson, Robinson & Vallee-Tourangeau, 2016). The reason for VH also varies across geographical regions and for different vaccines. The reasons for VH have been explained by the three “C’s” model - confidence, complacency and convenience. Lack of confidence in health systems and/or professionals regarding immunization services and provision of information complacency resulting in a belief that the vaccine is no longer needed once there is a decrease in incidence of disease,
Adverse effects of the vaccines, pain and fever following immunization, wrong and misleading information from mass media, unfavorable incidents following immunization reported by relatives and friends and lack of awareness and social factors are the reasons for VH in many countries (LaClair, Smith & Woodword, 2014).

There is limited literature regarding VH from Mangalore, where the proportion of children fully immunized (children between 12-23 months who have received measles, BCG and 3 doses of DPT and OPV) is 77.3% This is higher than the overall state average of 62.6% (Ministry of Health and Family Welfare, [MoHFW, 2015c]) and the National average of 62.9% (Ministry of Health and Family Welfare, [MoHFW, 2015a]). However, for a district with high literacy rate and, the immunization coverage rates are expected to be more than 80%.

With this background, we carried out this study to find the prevalence and reasons for VH among mothers of under-five children in Mangalore.

**Methods**

**Study area**

Mangalore, the major commercial and district headquarter of Dakshina Kannada in the South Indian state of Karnataka, India is known for its numerous educational institutes. It has a literacy rate of 93.4% with male literacy being 96.03% and female literacy 90.84%, which is better than the national urban average of 85% (Census, 2001). The performance of the district in achieving key health care indicators including immunization coverage is also better than the state and national average.

**Participants**

In this facility-based cross-sectional study, mothers of under-5 children visiting hospitals affiliated to Kasturba Medical College, Mangalore were assessed regarding VH. The study was carried out during the months of March and April 2017. Based on a previous study (Dubé et al., 2016), where VH was found to be 40.2%, the sample size was calculated to be 172 with a relative precision of 20%, confidence level of 95%, power 80% and adding a non-response error of 20%.

Participants were approached in the waiting area of the outpatient departments of the hospitals and were briefed about the purpose and objectives of the study. After obtaining a written informed consent, data was collected from the willing participants by interviewing them personally using a questionnaire. Mothers with at least one child visiting the obstetric and pediatrics outpatient departments were included in the study using non-random (convenient) sampling technique.

This study was approved by the Institutional Ethics Committee of Kasturba Medical College, Mangalore (IEC KMC MLR 03-17).

**Data collection**

Information was collected using a semi-structured questionnaire which had the following sections:

- **Section A:** Socio-demographic information of the participants (age, education, occupation, marital status, education and occupation of spouse, family income, number of family members, religion, place of residence, place of routine immunization, number of children, gender of the children);

- **Section B:** Core VH survey questions (Larson et al., 2015);

- **Section C:** Parental attitude towards childhood vaccination (PACV) (Opel et al., 2011). The PACV is a validated questionnaire which assesses the attitude of mothers towards vaccination under three domains: immunization behavior, beliefs about vaccine safety and efficacy and trust.

The questionnaire was translated to the local vernacular language, Kannada (Extended data (Rekha et al., 2021)) and was pretested and content validated for the language. The pretesting was done on 30 mothers visiting the outreach clinics of the department of community medicine. Based on the responses, the questionnaire was modified for the language without changing the content. The content validation of the questionnaire was done by the subject expert. Socioeconomic status was evaluated using Modified B.G Prasad scale (Singh, Sharma & Nagesh, 2017).
Questionnaires were checked for completeness and only the completed questionnaires were considered for final analysis.

Data management and analysis
The collected data was entered in and analyzed using IBM SPSS (Statistical Package for Social Sciences) Statistics for Windows Version 25.0. Armonk, NY: IBM Corp) and expressed using mean (Standard Deviation), and proportions. The calculated PACV scores ranged from 0-100: participants who scored between 0-49 were considered to have no VH, and those with scores from 50-100 were considered to be vaccine hesitant. The factors associated with VH was assessed using Chi-square test and P<0.05 was considered a statistically significant association.

Results
A total of 172 mothers were assessed regarding VH. The mean age of the participants was 29.4 (±5.2) years, with majority (n=112, 65.1%) in the age group between 26-35 years. A higher proportion (n=61, 35.5%) of the participants had completed high school and were from middle socio-economic status. (n=30, 30%) Government health facilities were the place of routine immunization for 60.5% (n=104) of the participants. The socio-demographic characteristics of the study participants is depicted in Table 1.

Health care providers (n =79, 46%) were the major source of information regarding vaccines, followed by the child’s primary doctor (n = 52, 30.2%). Family members, television, newspaper magazine and internet comprised the rest of the sources.

Table 2 shows the findings of the baseline VH survey among the study participants. Only 7.6% (n=13) of the study participants had refused vaccination for their child at some point of them and the most common reason cited for vaccine refusal was that they thought it was not safe (n=6).

The perception of the participants regarding vaccine safety and efficacy, trust and their immunization behavior as assessed by PACV is shown in Table 3. A lower proportion of the participants (14%, n=24) opined that children get more vaccines than that are good for them. A higher proportion (80.8%, n=139) of the participants worried about their child having serious side effects from the vaccine. However, the majority (91.8%, n=158) of the participants trust the information provided to them regarding vaccines. A very small proportion (n=6, 3.5%) of the study participants had refused getting their child immunized and 5.8% (n=10) were hesitant about childhood vaccination.

The median PACV score among participants was 10.0 with a total of 166 parents (96.5%). Only 6 (3.5%) participants were found to be vaccine hesitant. Among the participants who were found to have no VH, a higher proportion were under the age of 30 years, urban residents, belonged to Hindu religion and utilized government facility for immunization. Among the vaccine hesitant mothers, majority of them had studied up to high school (83.3%) and were unemployed (66.7%). No statistical significance association was observed between VH and mothers educational and employment status (P>0.05) (Table 4).

Discussion
The success of immunization programs relies on high vaccination coverage and vaccine uptake rates. Maintaining a high timely vaccination coverage has resulted in effective control of vaccine preventable diseases (VPDs), among those vaccinated, as well as the unvaccinated by virtue of herd immunity. However, recent outbreaks of VPDs like measles and diphtheria in both developed and developing countries, has undermined the progress made by immunization programs implemented all over the world. High vaccination coverage rates are misleading and do not reflect the number of under-vaccinated and unvaccinated section of the population (Kumar et al., 2016). The global vigilance on immunization programs in developed countries has attributed recent outbreaks of measles to VH (Shakla, 2019). However, the trend of VH is universal and not just limited to developed countries. The analysis of WHO/UNICEF Joint Reporting Form data for VH for the years 2015-2017 revealed that VH was reported by more than 90% of the WHO member countries (Lane et al., 2018).

In our study, a very low proportion (3.5%) of the participants were found to be vaccine hesitant. Though the immunization coverage rate of 77% of the study area is higher than the national average, it is still low. Being a health facility based study, the low VH in our study does not reflect VH in the general population. The lower VH among the participants could be due to high literacy rate, better immunization coverage and services, and creation of awareness by grass root level workers which has resulted in high vaccine uptake rates. With an educational index of 0.958 and an overall Human Development Index (HDI) of 0.830, Mangalore has always been one of the better performing regions in the State of Karnataka (Shodhganga. Profile of Dakshina Kannada, n.d.) There is huge variation in the estimates of VH reported in primary studies from various parts of the world. This variation may be attributed to the use of different questionnaires and cut-off scores to categorize VH among the population. Assessment of hesitancy for an individual vaccine or the entire
immunization schedule, as well as the age group of target population may also result in VH estimates of varying proportions. The VH reported in studies from different parts of India ranged between 14.1% to 83% (Krishnamoorthy et al., 2019, Agarwal et al., 2019, Narayanan, Jayaraman & Gopichandran, 2018, Dasgupta et al., 2018). Similar variation in the prevalence of VH is also observed in studies from other parts of the world. The VH was as low as 1.1% in a study in Guatemala (Domek et al., 2018) while in a study in Nigeria it was 76% (Larsen et al, 2015b). Other studies have reported VH in the range of 11.6% to 66% (Dubé et al, 2016, Lane et al., 2018, Mohd Azizi, Kew, Moy, 2017, Giambi et al., 2018, Ferrante et al., 2019, Napolitano, D’Alessandro & Angelilo, 2018, Ray et al., 2018, Paterson, Chantler & Larson, 2018).

Table 1. Socio-demographic characteristics of the study participants (N=172).

<table>
<thead>
<tr>
<th>Variables</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age of mother (years)</strong></td>
<td></td>
</tr>
<tr>
<td>≤25</td>
<td>40 (23.3)</td>
</tr>
<tr>
<td>26-35</td>
<td>112 (65.1)</td>
</tr>
<tr>
<td>&gt;35</td>
<td>20 (11.6)</td>
</tr>
<tr>
<td><strong>Education of mother</strong></td>
<td></td>
</tr>
<tr>
<td>Illiterate</td>
<td>13 (7.6)</td>
</tr>
<tr>
<td>Primary school</td>
<td>5 (2.9)</td>
</tr>
<tr>
<td>Middle school</td>
<td>50 (29.1)</td>
</tr>
<tr>
<td>High school</td>
<td>61 (35.5)</td>
</tr>
<tr>
<td>Post high school diploma</td>
<td>11 (6.4)</td>
</tr>
<tr>
<td>Graduate</td>
<td>25 (14.5)</td>
</tr>
<tr>
<td>Profession or Honors</td>
<td>7 (4.0)</td>
</tr>
<tr>
<td><strong>Occupation of mother</strong></td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>116 (67.4)</td>
</tr>
<tr>
<td>Unskilled worker</td>
<td>32 (18.6)</td>
</tr>
<tr>
<td>Semi-skilled worker</td>
<td>7 (4.1)</td>
</tr>
<tr>
<td>Skilled worker</td>
<td>3 (1.7)</td>
</tr>
<tr>
<td>Clerical/Shop-owner/Farmer</td>
<td>4 (2.3)</td>
</tr>
<tr>
<td>Professional</td>
<td>10 (5.8)</td>
</tr>
<tr>
<td><strong>Religion</strong></td>
<td></td>
</tr>
<tr>
<td>Hindus</td>
<td>132 (76.7)</td>
</tr>
<tr>
<td>Muslims</td>
<td>34 (19.8)</td>
</tr>
<tr>
<td>Christian</td>
<td>6 (3.5)</td>
</tr>
<tr>
<td><strong>Socioeconomic status (B.G. Prasad scale) [N=100]</strong></td>
<td></td>
</tr>
<tr>
<td>Upper class</td>
<td>19 (19.0)</td>
</tr>
<tr>
<td>Upper middle class</td>
<td>18 (18.0)</td>
</tr>
<tr>
<td>Middle class</td>
<td>30 (30.0)</td>
</tr>
<tr>
<td>Lower middle class</td>
<td>24 (24.0)</td>
</tr>
<tr>
<td>Lower class</td>
<td>9 (9.0)</td>
</tr>
<tr>
<td><strong>Place of residence</strong></td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>86 (50.0)</td>
</tr>
<tr>
<td>Rural</td>
<td>86 (50.0)</td>
</tr>
<tr>
<td><strong>Place of routine immunization</strong></td>
<td></td>
</tr>
<tr>
<td>Government hospital</td>
<td>104 (60.5)</td>
</tr>
<tr>
<td>Private hospital</td>
<td>41 (23.8)</td>
</tr>
<tr>
<td>Anganwadi</td>
<td>27 (15.7)</td>
</tr>
</tbody>
</table>
It is evident that irrespective of the measurement tool used, VH is widely prevalent across countries, having an impact on the coverage rates of immunization and vaccine uptake among the targeted population. Hence, it is imperative to first identify these vaccine hesitant groups, and strategically work towards restoring their trust and belief towards the health system in general and vaccination (Marti et al., 2017). Although by definition, it includes people who delay or refuse vaccination, people who chose to vaccinate in spite of having doubts about the same should also be identified and their concerns addressed. This will ensure a better immunization coverage in the future.

Identifying and overcoming the reasons for VH is one of the most important challenge faced by immunization and program managers. VH is usually limited to a subgroup of the population whose decision-making process is driven by their socio-cultural, religious, and political standing and cannot be overcome by strengthening the health system or increasing vaccination services alone. Studies have shown that there is not one particular reason for refusing or delaying vaccination. The reasons are diverse and can vary from one person to another in a vaccine hesitant population. Globally, the three most common reasons cited for VH during the year 2015, 2016 and 2017 were concerns related to vaccine safety (22%, 23%, 23%), lack of knowledge and awareness regarding immunization and its benefit (15%, 13%, 10%), and religious and cultural beliefs (10%, 9%, 12%) (Marti et al., 2017).

The reasons for VH varied across WHO regions and socio-economic status of the countries within these regions. In the European Region, South East Asian Region and Western Pacific Region, concerns about safety of vaccines and fear of side effects were predominant, while issues revolving around religion and cultural beliefs were common in the Americas. Inadequate knowledge or information regarding vaccines and their benefits as well as poor awareness were mainly reported from African Region and Eastern Mediterranean Region. Adverse events following immunization and safety of the vaccine were the most important driver for VH in upper-middle income countries, while inadequate knowledge and awareness regarding vaccines and immunization services were predominantly seen in lower-middle income countries. VH due to religious influences were seen across countries of all strata of income and in most of the WHO regions (The History of Vaccines. n.d.).

Apprehensions regarding the risks and benefit of vaccines were the most common reasons for VH in our study which was also reported by a study in Chennai. The other reasons for influencing VH cited in that study were lack of trust for the newer vaccines (Narayanan, Jayaraman & Gopichandran, 2108). In a study in Siliguri, unwillingness and having no

### Table 2. Baseline vaccine hesitancy survey findings among the study participants (N=172).

<table>
<thead>
<tr>
<th>Variable</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belief that vaccines can protect children from serious diseases</td>
<td>169 (98.3)</td>
</tr>
<tr>
<td>Belief that most parents get their children vaccinated with all recommended vaccines</td>
<td>167 (97.1)</td>
</tr>
<tr>
<td>Reluctant/hesitant to get a vaccination for the child</td>
<td>19 (11.0)</td>
</tr>
<tr>
<td>Refused a vaccination for the child</td>
<td>13 (7.6)</td>
</tr>
<tr>
<td><strong>Reasons for vaccine refusal (N=13)</strong></td>
<td><strong>%</strong></td>
</tr>
<tr>
<td>Did not think the vaccine was safe</td>
<td>6 (46.2)</td>
</tr>
<tr>
<td>Distance of the immunization clinic</td>
<td>4 (30.8)</td>
</tr>
<tr>
<td>Did not know where to get reliable information</td>
<td>4 (30.8)</td>
</tr>
<tr>
<td>Someone else told me that the vaccine was not safe</td>
<td>4 (30.8)</td>
</tr>
<tr>
<td>Long waiting period in the immunization clinic</td>
<td>3 (23.1)</td>
</tr>
<tr>
<td>Heard or read negative media</td>
<td>3 (23.1)</td>
</tr>
<tr>
<td>Someone else told me that their child had a bad reaction</td>
<td>3 (23.1)</td>
</tr>
<tr>
<td>Fear of needles</td>
<td>3 (23.1)</td>
</tr>
<tr>
<td>Time needed to get to the clinic</td>
<td>2 (15.4)</td>
</tr>
<tr>
<td>Did not know where to get vaccinated</td>
<td>2 (15.4)</td>
</tr>
<tr>
<td>Not possible to leave other work</td>
<td>2 (15.4)</td>
</tr>
<tr>
<td>Did not think the vaccine was effective</td>
<td>2 (15.4)</td>
</tr>
<tr>
<td>Timings of the clinic</td>
<td>1 (7.7)</td>
</tr>
<tr>
<td>Had a bad experience or reaction with previous vaccination</td>
<td>1 (7.7)</td>
</tr>
</tbody>
</table>

*Multiple responses.
reliable information on the vaccine were the major reasons cited for VH (Dasgupta et al., 2018). Primary studies from different part of the world have also reported a heterogeneous group of reasons. The most frequently cited reason leading to VH in a study in England were the presence of porcine gelatin in the vaccine and issues related to vaccine effectiveness and side effects (Lane et al., 2018). Meanwhile, in a study in Guatemala, health system related factors like distance of the clinic, cost incurred to get to the clinic and timing of the clinic and waiting at the clinic were the predominant reasons for VH (Domek et al., 2018). A study conducted in Quebec found that fear of adverse effects and low perceived vulnerability of the child or severity of the disease were the most common reasons for VH (Dubé et al., 2016).

Religious influences for VH are the most challenging to address in any immunization program since they arise out of individual’s core belief and driven by their faith. Use of human tissues in creating a vaccine or the belief that the body should be healed naturally by God and not by chemicals are some of the points for refusing vaccines (McKee & Bohannon, 2016). Unlike other reasons for VH, they do not arise out of lack of knowledge or awareness regarding

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### Table 3. Perception of the study participants regarding vaccine safety and efficacy, trust and their immunization behavior as assessed by PACV (N=172).

<table>
<thead>
<tr>
<th>Vaccine safety and efficacy</th>
<th>Strongly agree/ Agree</th>
<th>Not sure</th>
<th>Strongly disagree/ Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children get more shots than are good for them.</td>
<td>24 (14.0)</td>
<td>36 (20.9)</td>
<td>112 (65.1)</td>
</tr>
<tr>
<td>Many of the illness’s shots prevent are severe</td>
<td>133 (77.3)</td>
<td>28 (16.3)</td>
<td>11 (6.4)</td>
</tr>
<tr>
<td>Better for the child to develop immunity by getting sick than to get a shot</td>
<td>22 (12.8)</td>
<td>44 (25.6)</td>
<td>106 (61.6)</td>
</tr>
<tr>
<td>Better for children to get fewer vaccines at the same time</td>
<td>31 (18.0)</td>
<td>40 (23.3)</td>
<td>101 (58.7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Trust</th>
<th>Strongly agree/ Agree</th>
<th>Not sure</th>
<th>Strongly disagree/ Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>I trust the information I receive about shots</td>
<td>158 (91.8)</td>
<td>12 (7.0)</td>
<td>2 (1.2)</td>
</tr>
<tr>
<td>I can openly discuss my concerns about shots with my child’s doctor.</td>
<td>141 (82.0)</td>
<td>5 (2.9)</td>
<td>26 (15.1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Immunization behavior</th>
<th>Yes</th>
<th>No</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delayed getting vaccine for reasons other than illness or allergy</td>
<td>14 (08.1)</td>
<td>157 (91.3)</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Refused a vaccine for reasons other than illness or allergy</td>
<td>6 (3.5)</td>
<td>166 (96.5)</td>
<td>-</td>
</tr>
<tr>
<td>Follow the recommended schedule if the mother had another infant</td>
<td>149 (86.6)</td>
<td>19 (11.1)</td>
<td>4 (2.3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Overall hesitancy about childhood vaccination</th>
<th>Not at all hesitant/ Not too hesitant</th>
<th>Not sure</th>
<th>Somewhat hesitant / Very hesitant</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>153 (89.0)</td>
<td>9 (5.2)</td>
<td>10 (5.8)</td>
</tr>
</tbody>
</table>
immunization, but is a by-product of an individual’s or a group’s religious conviction thus making it difficult to change their attitude towards immunization (McKee & Bohannon, 2016).

Issues related to vaccine safety and side effects is one of the most important reasons for refusal of vaccines by the parents. Parents are bombarded with information on vaccine safety and adverse effects, and opinions on vaccination through mass media and social media. Such information can be overwhelming at times, creating enough doubts to make an informed decision, thus leading them to ultimately refuse vaccination (McKee & Bohannon, 2016).

Vaccine hesitancy among the cohort was not significantly associated with factors such as maternal age, employment, mother’s educational status, religion, place of residence, place of immunization and socio-economic status (P>0.05). Mother’s age (Krishnamoorthy et al., 2019), lower educational status of mother (Agarwal et al., 2019, Dasgupta et al., 2018) nuclear family (Agarwal et al., 2019, Dasgupta et al., 2018), and past history of incomplete immunization (Agarwal et al., 2019) were found to be significantly associated with VH in other studies from India. Some of the factors associated with VH reported in studies from other parts of the world include younger parents (Mohd Azizi, Kew & Moy, 2017), unemployed parents (Mohd Azizi, Kew & Moy, 2017), higher educational status (Ferrante et al., 2019), contact with parents of children who had experienced serious side effects (Giambi, 2018), not advised by a pediatrician to complete the full course of immunization (Giambi, 2018), and lack of trust on the pediatrician (Napolitano, 2018).

**Limitations**
This being a facility-based study, our findings cannot be extrapolated to the general population.
Conclusion
Our study highlights the presence of very low prevalence of VH in Mangalore compared to similar studies from India and other parts of the world. The limited number of participants who had refused vaccination, refused due to concerns related to vaccine safety.

Recommendations
Hesitancy to vaccines follows the iceberg phenomenon, with the tip of the iceberg representing the population who refuse vaccination, while the submerged proportion representing the vaccine hesitant population. Identifying these vaccine hesitant subgroups is important for the success of any immunization program. Population-based studies covering a larger sample and multicentric studies would throw more evidence towards the presence of VH as a reason for a lower vaccination. Such studies also give an insight into the various reasons for VH existing in different population groups.

Data availability
Underlying data

Extended data

This project contains the following extended data:
- Questionnaire as asked in the local language.

Data are available under the terms of the Creative Commons Zero "No rights reserved" data waiver (CC0 1.0 Public domain dedication).

Acknowledgements
We thank the Department of Community Medicine, Kasturba Medical College, Mangalore, and the Manipal Academy of Higher Education for their support for this research and its publication.

References
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Aida Kalok
Department of Obstetrics and Gynaecology, Faculty of Medicine, National University of Malaysia, Universiti Kebangsaan Malaysia Medical Centre, Selangor, Malaysia

Thank you for the revised version.

A couple more comments prior to my approval of this manuscript:
1. Please include the exact p-value of each chi-square test in Table 4.

2. This statement is quite confusing: "In our study, mothers aged less than 30 years, educated up to high school and unemployed, residing in an urban area, belonging to Muslim religion, and availing immunization services from a government facility were found to be vaccine hesitant, though these factors were not significant (P>0.05)". Please consider rephrasing it to "Vaccine hesitancy among the cohort was not significantly associated with factors such as maternal age, employment, religion, urban residence, etc."

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Maternal health, General Obstetrics.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 30 Aug 2021

Nithin Kumar, Kasturba Medical College, Mangalore, Manipal Academy of Higher Education, Manipal, Manipal, India

Thank you for taking time and reviewing our article. We have made the changes in the manuscript and uploaded the revised version. Kindly find the point-by-point
clarification/reply to your comments.

- Please include the exact p-value of each chi-square test in Table 4.

Thank you. The exact P value is incorporated in table 4 as per your suggestion.

- This statement is quite confusing: "In our study, mothers aged less than 30 years, educated up to high school and unemployed, residing in an urban area, belonging to Muslim religion, and availing immunization services from a government facility were found to be vaccine hesitant, though these factors were not significant (P>0.05)". Please consider rephrasing it to "Vaccine hesitancy among the cohort was not significantly associated with factors such as maternal age, employment, religion, urban residence, etc."

Thank you for your suggestion. We have rephrased the statement as per your suggestion.

Competing Interests: No competing interests were disclosed.
Discussion:

- Please discuss why with such a low VH rate, the proportion of immunised children in Mangalore is still around 77%.
- The study was conducted in a health facility; women who sought/received health care were most likely to demonstrate a lower level of vaccine hesitancy.

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Partly

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Maternal health, General Obstetrics.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 09 Jul 2021

Nithin Kumar, Kasturba Medical College, Mangalore, Manipal Academy of Higher Education, Manipal, Mangalore, India

We thank you for taking out your valuable time to review our article. We have incorporated all the changes and corrections suggested by you in the manuscript. Kindly find the response letter below.

The introduction is quite lengthy.
Thank you for the suggestion. We have made the introduction concise and specific, in line with the objectives of the study.

Sample size - please state the number of participants required based on the sample
size calculation. Did this study reach its required sample size?
Based on the sample size calculation, a total of 172 participants were required to be included in the study. We were able to achieve the sample size. The same has been added to the Methods section in the manuscript.

What was the study hypothesis?
Even though the study area has a good health system and a literacy rate that is higher than the national figures, the immunization coverage has consistently remained below 90 per cent. The study hypothesis was “Vaccine hesitancy is present in the study area”.

Data collection: Did the participants complete the questionnaire themselves? What about illiterate mothers?
All the participants were interviewed while they were waiting in the respective OPDs. The same has been included in the methods section of the manuscript.

Data analysis: Was there any association between VH and maternal employment/level of education/socio-economic status? Please include this in the results/discussion.
Crosstabulation between the presence of vaccine hesitancy and educational status, employment status and socioeconomic status is incorporated in the results and discussion section. However, no statistically significant association was observed between VH and maternal employment, level of education and socio-economic status.

Discussion: Please discuss why with such a low VH rate, the proportion of immunized children in Mangalore is still around 77%.
Being a health facility-based study, our finding of low VH among the study participants does not reflect the status of VH in Mangalore. Population-based studies covering a larger sample / multicentric studies would throw more evidence towards the presence of VH as a reason for a lower vaccination coverage in the study area. Also, since the study was conducted in a health facility; the women who sought/received health care were most likely to demonstrate a better health seeking behavior which is also reflected in a lower vaccine hesitancy among the participants.

The study was conducted in a health facility; women who sought/received health care were most likely to demonstrate a lower level of vaccine hesitancy.
Yes. we agree with the observation.

Competing Interests: NA
Giriyanna Gowda  
Department of Community Medicine, Kempegowda Institute of Medical Sciences, Bangalore, Karnataka, India

Comments:
1. The introduction is too lengthy; please make it specific and concise and based on the needs of the study.

2. In the abstract, it is mentioned that the prevalence of vaccine hesitance is 3.4% and also that 7.6% had refused vaccination for their child. Please clarify this.

3. Recommendations are not based on results. Kindly specify it.

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Yes

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: epidemiology, clinical trials

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 09 Jul 2021
Nithin Kumar, Kasturba Medical College, Mangalore, Manipal Academy of Higher Education, Manipal, Mangalore, India

We thank you for taking out your valuable time to review our article. We have incorporated all the changes and corrections suggested by you in the manuscript. Kindly find the response letter below.
Response to the Comments:
1. The introduction is too lengthy; please make it specific and concise and based on the needs of the study.
   Thank you for the suggestion. We have made the introduction concise and specific, in line with the objectives of the study.

2. In the abstract, it is mentioned that the prevalence of vaccine hesitance is 3.4% and that 7.6% had refused vaccination for their child. Please clarify this. One of the questions in the Core vaccine hesitancy Survey tool directed towards the mothers was “Have you ever refused a vaccination for your child? Yes/No”. Only 7.6% of the study participants had refused vaccination for their child at some point of time. The prevalence of vaccine hesitancy was calculated based on the scores obtained from the Parental Attitude Towards Childhood Vaccination Questionnaire (PACV). Participants who scored between 50-100 were vaccine hesitant. Only 3.4% of the study participants were vaccine hesitant. We have clarified it in abstract.

3. Recommendations are not based on results. Kindly specify it.
   Recommendations have been made specific to the conclusions drawn from the study.

Competing Interests: NA