Original Research Article

Delay for pentavalent vaccine: a hospital based cross sectional study

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ABSTRACT

Background: Young children are often at increased risk for illness and death related to infectious diseases, and vaccine delays may leave them vulnerable at ages with a high risk of contracting several vaccine-preventable diseases. This study examined delay for each pentavalent vaccine in the universal immunization programme and the factors that influence untimely vaccinations.

Methods: This was a hospital based cross sectional study done on 45 days to-12 months aged children attending the immunisation clinic held at government medical college and hospital Aurangabad, Maharashtra. Data was collected from the records on health card as well from mother with the help of pretested pre-structured questionnaire for predictors of delay.

Results: Total 411 children aging 45 days to 12 months were enrolled in the study. For pentavalent 1 vaccine, 83.69% received vaccine without delay and 16.31% were delayed. 43.53% were delayed for pentavalent 2 vaccine, 224 children received pentavalent 3 vaccine, out of them 80.35% received within time whereas 19.65% were delayed. We found birth order, parent’s education, working status of mother, mother’s age below 18; parity had statistically significant association with delay. Unawareness about the right timings of vaccination and immunization schedules held at periphery, parents delaying vaccine for minor sickness of baby, were the main reasons observed for delay.

Conclusions: A total 83.69% children received vaccine within the recommended time. Still 16.31% children experience delay for the vaccination. Reasons for delay observed can be overcome by appropriate counselling of mother by health care workers at the first time of vaccination which will improve the adherence and avoid delay in future to immunisation schedule.

Keywords: Penta-pentavalent vaccine, Vaccine preventable disease, Immunization

INTRODUCTION

Immunization is one of the most cost-effective interventions to prevent the suffering that comes from avoidable sickness, disability and death. With the implementation of the Universal Immunization Programme (UIP) by the Government of India, significant achievements have been made in preventing and controlling vaccine-preventable diseases (VPDs). Introduction of pentavalent vaccine will further reduce the incidence of pneumonia and meningitis caused by Haemophilus influenzae type b (Hib) bacteria. Pentavalent vaccine provides protection to a child from 5 life-threatening diseases - Diphtheria, Pertussis, Tetanus, Hepatitis B and Hib. Pentavalent vaccine is given to any child aged more than 6 weeks and up to 1 year of age in India.1

Despite being operational for the past more than 30 years, only 65% of children in India receive all vaccines during their first year of life, thus contributing to continued high burden of morbidity and mortality in children from...
vaccine preventable diseases (VPDs), India has the highest number (approximately 10 million) of such children in the world.  

Any delay in vaccination i.e., administering vaccine doses later than the national recommended schedule, predisposes children to risk of a vaccine-preventable disease (VPD) in the period when they have not acquired protective immunity through vaccinations. Young children are often at increased risk for illness and death related to infectious diseases, and vaccine delays may leave them vulnerable at ages with a high risk of contracting several vaccine-preventable diseases.  

Timely vaccination is defined as administration of vaccine doses at a schedule recommended by India’s national immunization schedule. Age-appropriate and timely vaccinations are an important indicator of vaccination program performance, as timely vaccinations maximize the protection and decrease the time for which children are at risk for various VPDs.

There are wide variations in the proportion of unvaccinated and partially vaccinated children within states and districts. Recent evaluations have indicated that the major reasons for inability to reach with all vaccines to children in the entire country are lack of awareness among parents about the benefits of vaccination, fear of adverse events following immunization (AEFI) and operational reasons such as non-availability of vaccines or vaccinators during vaccination sessions.

Understanding the multi-dimensional determinants of delays is crucial in improving services for routine immunization in any country. There is distinct gap in the vaccination literature and a notable lack of studies on vaccination timeliness in India. This study examined delay for each pentavalent vaccine in the universal immunization programme and the factors that influence untimely vaccinations.

The objectives of this study were to study delay for pentavalent vaccine in children attending immunization clinic, and to study factors influencing delay for pentavalent vaccine.

METHODS

Sample size for the study is calculated by taking 65% prevalence for immunization coverage in India, 95% confidence interval and 5% allowable error, sample size came 365 adding 10% more came to 401, we included 411 children of 45 days to 1 year age.

This was a hospital based cross sectional study done during November 2018 to February 2019 on 45 days to 12 months aged children attending the immunization clinic held at government medical college and hospital Aurangabad, Maharashtra. This immunization clinic runs three days a week and children from all over Aurangabad city as well residing outskirts of the city visit the clinic for immunization. As this clinic is run as outpatient department, flow of the patients is different every time so beneficiaries from this clinic are not same and could not followed. Children between 45 days to 12 months of age and eligible for recommended vaccine as per age were enrolled in the study. Children who were younger than recommended age for each vaccine were excluded.

Data was collected from the records on health card as well from mother. Dates of previous vaccination are recorded from child’s health cards and mother of child was interviewed with the help of pretested pre-structured questionnaire for predictors of delay such as parents education, working status, mother ‘s age, parity, birth weight, birth order and sex of child, social factors like religion, residence, migration and reason for delay.

Delay is considered if the child had received vaccine after the 45 days than the recommended time of vaccine i.e. for pentavalent 1 vaccine after the 45 days from 6th week of child’s birth date similarly for pentavalent 2 and pentavalent 3, 45 days later than 10th and 14th week of child’s birth date respectively.

Statistical analysis

Data was coded and entered in Microsoft excel 2010, data was analyzed using IBM SPSS software 24 trail version. Quantitative data is expressed in terms of frequencies and percentage. Delay and its determinants were assessed with the help of box whisker plot and its statistical association is tested with chi square test. In order to determine the length of delay, the age at immunization was calculated with the help of age calculator by subtracting the vaccination received date from the birth date. By these calculations the day when child received vaccine from his birth is calculated and categorized into two groups for the purpose of this study. First group was considered age appropriate for those who receive vaccine within timeline. Second group considered delayed for those who received beyond timeline.

RESULTS

Total 411 children aging 45 days to 12 months were enrolled in the study (Table 1). 20.46% children were in 45-74 days age group 17.03 were in 75-104 days age group and 55.50% were more than 104 days.

| Age in days | No . of children | Percentages |
|------------|------------------|-------------|
| 45-74      | 117              | 28.46       |
| 75-104     | 70               | 17.03       |
| ≥105       | 224              | 54.50       |

It is observed from Table 2 that 411 children received pentavalent vaccine 1, 294 received pentavalent vaccine 2 and 224 received pentavalent vaccine 3. For pentavalent
vaccine 1,344 (83.69%) received vaccine without delay and 67 (16.31%) were delayed. 66 (22.94%) were delayed for pentavalent 2 vaccine, however amongst these 66 children 34 (51.51%) were delayed because of the previous pentavalent vaccine delay. 224 children received pentavalent 3 vaccine, out of them 180 (80.35%) received within time whereas 19.65% were delayed.

**Table 2: Distribution of children according to their immunization status.**

| Received vaccine | No. children received vaccine without delay (%) | No. of children received vaccine with delay (%) | Total |
|------------------|-----------------------------------------------|-----------------------------------------------|-------|
| PENTA1           | 344 (83.69)                                   | 67 (16.31)                                    | 411   |
| PENTA2           | 128 (43.53)                                   | 66 (22.94)                                    | 294   |
| PENTA3           | 180 (80.35)                                   | 44 (19.65)                                    | 224   |

Note- figures in parenthesis are percentages.

**Table 3: Distribution of delay factors related to mother and child to pentavalent 1 vaccine.**

| Determinant                | Sub class            | No delay | Delay | Total | df  | X² value | P value |
|----------------------------|----------------------|----------|-------|-------|-----|----------|---------|
| Sex                        | Male                 | 181      | 39    | 220   | 0.705| 1        | 0.401   |
|                            | Female               | 163      | 28    | 191   |     |          |         |
| Birth weight               | Normal               | 284      | 51    | 335   | 1.951| 1        | 0.377   |
|                            | LBW                  | 60       | 16    | 76    |     |          |         |
| Birth order                | ≤2                   | 289      | 48    | 337   | 5.812| 1        | 0.023*  |
|                            | ≥3                   | 65       | 19    | 84    |     |          |         |
| Mother’s Education         | Illiterate           | 4        | 3     | 7     | 10.279| 3        |         |
|                            | 1-5 years schooling  | 6        | 3     | 9     |     |          |         |
|                            | 6-12 years schooling | 209      | 47    | 256   |     |          |         |
|                            | >12 years schooling  | 125      | 14    | 149   |     |          |         |
| Working status of mother   | Not working          | 287      | 62    | 349   | 9.927| 1        | 0.007*  |
|                            | Working              | 57       | 4     | 61    |     |          |         |
| Mother’s age               | <18 years            | 55       | 16    | 72    | 4.039| 1        | 0.044*  |
|                            | ≥18 years            | 289      | 51    | 340   |     |          |         |
| Parity                     | ≤3 children          | 289      | 47    | 336   | 5.541| 1        | 0.019*  |
|                            | >3 children          | 56       | 19    | 75    |     |          |         |
| Father’s education         | Illiterate           | 3        | 0     | 3     | 11.466| 3        | 0.009*  |
|                            | 1-5 years schooling  | 9        | 5     | 14    |     |          |         |
|                            | 6-12 years schooling | 186      | 46    | 232   |     |          |         |
|                            | >12 years schooling  | 146      | 16    | 162   |     |          |         |

Figure 1: Distribution of duration of delay according to type of pentavalent vaccine. Figure 1 depicts the duration of delay with the Its Box and Whisker plot. It was observed that for pentavalent 1 vaccine was median delay was 79 days and IQR (59-79-106 days) similarly median delay for pentavalent 2 vaccine was 78 days with IQR (60-78-111 days) with minimum 46 days to maximum 334 days whereas median delay for pentavalent 3 vaccine was 98 days with IQR (62-98-113 days) with minimum 47 days to maximum 319 days were observed in our settings.

Table 3 and 4 describes the multiple factors responsible for vaccination delay. It is obvious that if the child receives first pentavalent vaccine beyond the recommended time, next two doses of the pentavalent vaccine will be delayed subsequently. So, the factors responsible for the for very first pentavalent vaccine delay are explored out in present study. It was observed from Table 3 there are factors related to mother and child which can be predictors of delay. We found birth order,
parent’s education, working status of mother, mother’s age below 18; parity had statistically significant association with delay.

Social determinants like religion, residence, migration, type of family were asses for the delay. Table 4 shows that no statistically significant association observed between social factors and delay.

It is observed from Figure 2 that 26.87% mothers were unaware about the timings of immunization session held at periphery, while 7.46% mothers visited the session but didn’t received vaccine due to some reasons like, being late to the session, long waiting period, etc. 22.39% of mothers delayed vaccination on their own as the baby had some kind of minor sickness while 13.33% were delayed with medical advice for sick child, 7.46% children did not received vaccine due to unavailability of vaccine at the peripheral session site whereas 8.96% mothers were not aware of the right time of vaccination was observed.

Table 4: Distribution of social determinant of delay to pentavalent 1 vaccine.

| Determinant      | Sub class          | No delay | Delay | Total | df  | X² value | P value |
|------------------|--------------------|---------|-------|-------|-----|---------|---------|
| Religion         | Hindu              | 213     | 37    | 250   | 3.197 | 3       | 0.362   |
|                  | Muslim             | 123     | 30    | 153   |     |         |         |
|                  | Buddhist           | 6       | 0     | 6     |     |         |         |
|                  | Other              | 2       | 0     | 2     |     |         |         |
| Social class     | Higher             | 60      | 6     | 66    | 5.685 | 4       | 0.224   |
|                  | Upper middle       | 79      | 14    | 93    |     |         |         |
|                  | Middle             | 74      | 16    | 90    |     |         |         |
|                  | Lower middle       | 78      | 23    | 101   |     |         |         |
|                  | lower              | 37      | 7     | 44    |     |         |         |
| Residence        | Within city        | 267     | 56    | 323   | 1.105 | 1       | 0.293   |
|                  | Outside city       | 83      | 5     | 88    |     |         |         |
| Type of family   | Nuclear            | 150     | 24    | 175   | 0.035 | 1       | 0.851   |
|                  | Joint              | 192     | 43    | 235   |     |         |         |
| Migration        | No                 | 267     | 53    | 320   | 9.927 | 1       | 0.851   |
|                  | Yes                | 75      | 14    | 89    |     |         |         |

Figure 2: Reasons of delay for pentavalent vaccine 1 among the study participants.

DISCUSSION

Present study was hospital based carried out to determine delays and socio demographic factors influencing delay for pentavalent vaccine of children attending immunization clinic. In India immunization schedule of a new borne child starts at birth, but if the child miss at birth dose, the next dose is at 6th week at the 45th day from the birth from where pentavalent vaccine schedule starts It is obvious that if the child receive first pentavalent vaccine beyond the recommended time , next two doses of the pentavalent vaccine will be delayed subsequently. Whereas immunization at 6th week is a best opportunity to health care worker to counsel the mother about further immunization schedule of her baby and importance of adherence to it So the factors responsible for the very first pentavalent vaccine delay are explored out in present study so as to avoid them in future delay.

In present study we defined delay as more than 45 days from the recommended date for pentavalent vaccine 1,2,3 doses. Same delay was defined in studies done at Delhi and Goa, whereas studies done out of India had different definition of delay.⁶,⁷ A vaccine was defined as delayed if it was received later than 1 month (31 days) after the recommended age in study conducted at Norway and in UK is > 12 weeks Sheikh N et al, studied timelines for vaccination in Bangladesh study classified delay as 2 months late, 3-6 months late, and more than 6 months late, respectively and observed average delay for 26.77% Pentavalent 1, 40.52% Pentavalent 2, 14.13% for Pentavalent 3 vaccine.⁸,¹⁰
It was difficult to compare the duration of delay as the delay dependent upon the local socio-cultural and local health infrastructure in that specified area. However, factors responsible for delay are similar with studies conducted all over India and across the country. We found birth order, mother’s education, father’s education, working status of mother, mother’s age below 18 had statistically significant association with delay. NFHS 4 has shown increased birth order, mother’s age, mother’s education has significant impact on the immunization coverage. Similar findings are observed in present study.

The timelines are more followed where respondents were educated parents. This finding is similar to that found in study conducted by Wadgave et al. Study conducted in urban slums of Delhi observed socioeconomic status of the household, female illiteracy, health awareness and gender inequality were important determinants of coverage we did not found any gender in equality for delay. Tiwari et al, in their case control study found the common causes for delayed immunization were negligence on part of parents, unawareness about the use of vaccine and sickness of child. Kadam et al study in the urban slums areas of Pratiksha Nagar, Sion found children who were partially immunized reported that child was ill so they did not take the child to health care facility for immunization, followed by the other common reason that family had been to native place. This finding are similar to present study. Gupta et al in Pune by wherein the main reason for partial immunization was timing of immunization was inconvenient. In our study majority of the mothers were unaware of the timings of immunization session held at periphery reflecting the communication gap between peripheral health worker and community. Wadgave et al in Solapur reported lack of knowledge of immunization, ignorance about immunization of child and revisits for the immunization sessions were two main reasons findings are in line with present study Smith in his study found intentionally delay by parents for vaccine administration because of vaccine safety or efficacy concerns.

Immunization is frequently postponed if children are ill or malnourished. This is not acceptable in light of present knowledge. In fact, it is particularly important to immunize children with malnutrition. Low grade fever, mild respiratory illnesses should not be considered as a contraindication to immunization. We observed 22.39% children were delayed to pentavalent 1 vaccine due to minor illnesses, which is avoidable delay if the mother is counselled.

Limitation of this study was the study is hospital-based study carried out in immunization clinic of government medical college and hospital Aurangabad. Clinic serves as an outpatient department and the flow of children attending the clinic is not fixed to one geographic area. It was not possible to follow up the children for their further doses however best counselling was done to adhere to immunization schedule

CONCLUSION

Present study found that 83.69% children received vaccine within the recommended time. Still 16.31% children experience delay for the vaccination. Delayed vaccination leads to decreased levels of protection against disease. Parent’s education, birth order, mother’s age, working status of mother and parity had found significant association with delay. Unawareness about the right timings of vaccination and immunisation schedules held at periphery, parents delaying vaccine for minor sickness of baby, were the main reasons observed for delay and this can be easily overcome by appropriate counselling of mother by health care workers at the first time of vaccination which will improve the adherence and avoid delay in future to immunisation schedule.

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