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Research Article

Adverse Events Following Measles and Rubella Vaccination Campaign in Children Aged 9 Months to 5 Years: Experience from An Urban Health Centre of Delhi

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A B S T R A C T

Background: Measles was responsible for an estimated 49,200 deaths among under-five- years- old children in India in the year 2015. In India, according to the National Family Health Survey-5 (NFHS-5 survey, 2019- 21), coverage of measles-containing vaccines (MCV), MCV-1 & MCV-2, at age 12-23 months was 88% & 59%, respectively. The MR (Measles & Rubella) vaccination campaign was launched to achieve the goal of measles elimination.

Aim: The study was aimed to record the various AEFIs among vaccine recipients during MR vaccination campaign through active surveillance.

Methodology: This was a prospective observational study. Five hundred forty children were vaccinated with the MR vaccine during the campaign. We included 530 children in our study as 10 children were lost to follow-up. All the patients were followed up for 30 days post-vaccination. A combination of door-to-door and telephonic surveys was adopted to find out AEFIs among the vaccine recipients. All information was noted on a predesigned case record form, and collected data were transferred to a Microsoft Excel spreadsheet for analysis.

Results: a total of 82 (15.47%) AEFIs were reported, of which 74 (90.24%) were in the initial 7 days and 8 (9.75%) were reported in the next 21days. Of the AEFIs reported, the most common was fever (36.6%), followed by local swelling at the injection site (30.5%), upper respiratory tract infection (21.9%), skin rash (6.1%), gastrointestinal symptoms including diarrhoea and vomiting (3.7%) and seizure (1.2%).

Conclusions: Active surveillance may help in finding and reporting the minor adverse events that could have been missed in the passive reporting of AEFIs by the parents. The MR vaccine introduced in the campaign is found to be largely safe for use among children aged 9 months to 5 years except for a few adverse reactions. We recommend further studies with a larger sample size along with prolonged follow-up to evaluate the delayed and rare AEFIs.

Keywords: Adverse Events Following Immunisation (AEFIs), Measles Rubella Vaccination Campaign, Children

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Introduction

Measles, also known as rubeola, is one of the most contagious infectious diseases, with almost a 90% secondary infection rate (SAR) in susceptible contacts. The disease burden of measles is high due to its higher infectivity and associated complications like encephalitis, pneumonia, diarrhoea, and otitis media.[1] Measles was responsible for deaths of about 134,200 children worldwide, mostly under 5 years of age, in the year 2015 and for an estimated 49,200 children in India. Many of these children were the ones who have not received two doses of the measles vaccine. Worldwide, measles vaccination has been attributed to a 73% decline in measles-related deaths between the years 2000 to 2008. Attainment and maintenance of more than 95% vaccination coverage will provide herd immunity and help in the elimination of disease.[2] According to the National Family Health Survey-5 (NFHS-5 survey, 2019– 21), coverage of the Measles Containing Vaccine-1 (MCV-1) at age 12–23months stands at 88% and for MCV-2 at a meagre 59% in India.[3] WHO and UNICEF estimates of immunisation coverage 2022 revision revealed MCV1 and MCV2 estimated coverage of 95% and 90%, respectively.[4]

Rubella infection during the first trimester of pregnancy may cause miscarriages, foetal death, and congenital rubella syndrome (CRS). Rubella infection has caused birth defects in almost 40,000 children nationwide.[5]

In this scenario, the Government of India launched one of the world's largest measles rubella (MR) vaccination campaigns in February 2017, as part of its national strategy to eliminate measles and rubella from the country by 2020. The phased MR campaign targeted to vaccinate more than 35 million children in the age group of 9 months to 15 years across the country with one dose of MR vaccine. The aim of the campaign was to rapidly build up immunity against measles and rubella in the community; therefore, it required 100% coverage.[6] The MR vaccination campaign dose was given to all targeted children, irrespective of prior measles-rubella immunisation or disease status. It was in addition to routine immunisation. The MR vaccine used in the campaign was found to be a safe and effective vaccine during routine vaccination, and it has been in use for over 40 years and in more than 100 countries across the world. The vaccine being given in the MR campaign was produced in India and is prequalified by the World Health Organisation.[6]

Since the adoption of the National Strategic Plan for Achieving and Sustaining Measles and Rubella Elimination in India, over 324 million children have been vaccinated between 2017 and 2020 through the MR vaccination campaign. The country is moving towards the MR elimination goal of achieving and sustaining vaccination coverage of 95% with two doses of a measles- and rubella-containing vaccine at the national and subnational levels.[7]

In Delhi, the MR vaccination campaign was supposed to start on 16 January 2019 but was deferred by the high court, stating that informed consent had not been sought from parents/wards of children.[8] Finally, the MR vaccination campaign was launched in Delhi on 6th Feb 2023, which lasted till 29th March 2023. All the children aged 9 months to 5 years were given one additional dose of MR vaccine, irrespective of their previous immunisation status, through fixed sessions in health facilities, i.e., dispensaries, maternity homes, hospitals, etc., and outreach sessions in the community.[9]

Like with any other vaccine, the MR vaccine can cause mild pain and redness at the injection site along with low-grade fever, rash, and muscle aches, which subside on their own. However, there are case reports of children in whom signs of both developmental regression and gastrointestinal symptoms developed shortly after measles, mumps, and rubella (MMR) vaccination.[10]

The measles virus used in the MMR vaccine is a live attenuated virus that normally causes no symptoms or only very mild ones. However, wild-type measles can infect the central nervous system and even cause postinfectious encephalomyelitis, probably as a result of an immune-mediated response to myelin proteins.[11]

Although the MR vaccine is proven to be safe, there is a potential risk of an adverse reaction, as with any other drug or medication. Adverse event following immunisation (AEFI) is defined by WHO/Council for International Organisation of Medical Sciences (CIOMS) as any untoward medical occurrence that follows the immunisation and which does not necessarily have a causal relation with the usage of the vaccine. The adverse events may be any unfavourable or unintended sign of an abnormal laboratory result, symptoms, or diseases.[12] AEFI is also defined as "a medical incident that takes place after immunisation, causes concern and is believed to be caused by the immunisation".[13] According to the AEFI 2015 guidelines of the Government of India, AEFIs are broadly classified into three categories: common minor AEFI, which includes fever, rash, and local reactions; serious AEFI, which results in hospitalisation, death, or significant disability; and severe AEFI, which includes any adverse event of increased severity.[14]

AEFI reporting in India has largely been passive, like in many other countries, but there are inherent limitations of passive surveillance, like underreporting, variable and often incomplete reports and a high frequency of inadequate follow-up of outcome information.[15] Further, passive reporting may not give a true idea about the AEFI's occurrence. In this context, we conducted this study to actively find out the AEFIs following MR vaccination during the campaign among children aged 9 month- 5years, at an urban health centre in Delhi.

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Material and Methods

This prospective observational study was conducted at a maternity & child welfare centre of Delhi for a duration of 3 months (February to April 2023). A sample size was calculated with the known incidence rates of 0.05 for fever and rash following the measles vaccine.[16] With a confidence interval of 95% and power of 80%, the minimum sample size was calculated to be 198. Considering a dropout rate of 20%, the sample size came to be 238. Children aged 9 months to 5 years were given one dose of MR vaccine and enrolled in the study after explaining the protocol and taking written informed consent from their parents. A total of 540 children were vaccinated during the study period; 10 children were lost to follow-up, so, finally, 530 children were enrolled in the study.

The MR vaccine used in the immunisation programme was a live-attenuated vaccine containing the Edmonston Zagreb strain of measles and the Wistar RA 27/3 strain of rubella, produced by the Serum Institute of India. The MR vaccine used in India is WHO prequalified. The vaccine was given subcutaneously in 0.5 ml to all the eligible children in the right arm. Children who were severely immunocompromised, had a previous severe allergic reaction to the vaccine constituents, or had a history of anaphylactic/anaphylactoid reactions to neomycin were excluded from the study.[17] All vaccinated children were kept under observation for 30 minutes to look for any anaphylactic/adverse reaction.

A case record form, similar to the Vaccine Adverse Event Reporting System form (VAERS)[18], was designed, which included details of basic demographic information and vaccine (batch number, manufacturing date, expiry date, and company) and adverse events.

A combination of door-to-door and telephonic surveys was adopted to find out AEFIs among the vaccine recipients. The post-vaccination surveys were conducted on day 7 and day 30. Both the surveys were conducted by the same researcher to avoid bias. Caregivers were first asked open-ended questions about any type of reaction. This was followed by closed-ended questions regarding possible adverse events such as pain, fever, and rash. If any positive response was found, the type of management sought for such events was also documented. Confidentiality of the data collected was ensured. All information was noted on a predesigned case record form, and collected data were transferred to a Microsoft Excel spreadsheet for analysis.

Ethical approval: Institutional ethical committee approval was obtained prior to the commencement of the study.

Results

All the children who were given the MR vaccine during the campaign period were included in the study. A total of 530 children were followed up for AEFIs. Out of 530 children, 270 (50.94%) were males and 260 (49%) were females (Table I).

A total of 82 (15.47%) AEFIs were reported, of which 74 (90.24%) were in the initial 7 days and 8 (9.75%) were in the following 21 days (Table II).

A total of 70 parents reported adverse events in their children, while 460 did not report any AEFIs. Of the AEFIs reported, the most common was fever (36.6%), followed by local swelling at the injection site (30.5%), upper respiratory tract infection (21.9%), skin rash (6.1%), gastrointestinal symptoms including diarrhoea and vomiting (3.7%) and seizure (1.2%) (Table II). Twelve children had more than one AEFI. The most common combination was fever and swelling at the injection site (9 children), followed by fever with URI (2 children), and one child had fever with a seizure. Patients with fever, swelling and URI were reassured and treated with appropriate doses of paracetamol. Patients with gastrointestinal symptoms were prescribed antiemetics, oral rehydration solution and oral zinc as per the clinical situation. Patients with skin rashes were reassured about their transient nature. A patient with a seizure was taken to a tertiary care hospital and discharged later.

Table 1.Age and gender distribution of children

Gender	Age Group		Total
	9 Months-1 year	2 years-5years	
Male	140	130	270
Female	132	128	260
Total	272	258	530

Table 2.Adverse events following immunization

AEFI reported		Number of AEFIs			
		Within 7 days post-vaccination, n (%)	7-30 days post-vaccination, n (%)	Total	
				Per 100 doses	n (%)
Local	Swelling	25 (30.5)	-	4.72	25(30.5)
	Other reactions (Abscess, Induration)	-	-	-	-

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Systemic	Fever	25 (30.5)	5 (6.1)	5.7	30(36.6)
	URI	15 (18.3)	3 (3.66)	3.4	18(21.9)
	Skin Rash	5 (6.1)	-	0.94	5(6.1)
	Gastrointestinal symptoms	3 (3.7)	-	0.57	3(3.7)
	Seizure	1 (1.2)	-	0.19	1(1.2)

AEFI: Adverse event following immunization, URI: Upper respiratory infection

Discussion

Vaccine-associated adverse events are more likely to be noticed and communicated and can often significantly impact immunisation programmes. AEFI surveillance has a very important role to guide vaccine safety, prompt management of adverse events, and reduce any negative effect on a vaccination programme.

Bhargava et al. demonstrated a good immunogenicity and safety profile of indigenously produced MMR vaccines produced by the Serum Institute of India Ltd, Pune.[19] While comparing the immunogenicity and side-effect profile of a new MMR vaccine (having the Hoshino mumps strain) with the existing Serum Institute MMR vaccine, authors found no difference in the side effect profile of the two groups. Interestingly, in both these studies, the components used for measles and rubella remain the same as in the MR vaccine introduced nationwide in India. Both the studies reported only minor adverse events, with the maximum reported event being fever.[19, 20] The methodology followed in our study was very similar to the study conducted by Joshi et al.[21] and Aherkar et al.[22]

AEFI incidence (15.47%) in our study is comparable to a study by Bhowmik et al. (15.5%) in which AEFIs with MR vaccine were assessed after routine vaccination at ages of 9-12 months.[23] AEFI incidences reported in our study were also comparable to the study by Joshi et al[21] in which a measles-only vaccine was used; and Bhargava et al[19] in which an MMR vaccine was used, reported AEFI incidences in these studies were 12.9% and 19.4%, respectively.

The mean age of the vaccinees in our study was 2.5 years. There was no gender predilection for AEFIs, which is in contrast to the study by Shohat et al[24], where higher rates of adverse effects like fever and rash were reported in females following routine MMR vaccination.

The most common adverse event reported in our study was fever, which is comparable to the study by Bhowmik et al.[23] Theirs was a study on AEFIs following routine MR vaccination at 9-12 months of age. Fever and rash were the most common reported adverse events following MMR vaccination in previous studies.[24, 25]

In our study, 3 patients reported vomiting, which is comparable to a study by Sharma R et al.[26] In our study one patient presented with fever and abnormal body movement/seizures. A few previous studies have also reported an association of measles-containing vaccines with febrile seizures.[16, 27, 28]

Probable mechanisms of development of AEFIs are postulated to be live viral activity, injection-related direct needle trauma, immune-mediated reaction, and cytokine production.[29]

Our study was unique as it was a prospective study evaluating AEFIs following the MR vaccination campaign in Delhi in 9 months–5 years age group. However, limitations of the study include the following: first, the short duration of the study, due to which long-term AEFIs could have been missed; second, the telephone survey, where minor ailments may have been missed; and third, cause-specific categorisation of AEFIs was not attempted. Lastly, the study was not powered to capture uncommon/rare adverse events. Further, the study covered only a limited population of vaccinees who resided around our health facility resulting in the findings being context-specific and may not be applicable in all situations.

Conclusion

Although there are studies reporting AEFIs following routine MR vaccination, there is hardly any study reporting AEFIs among children aged 9 months to 5 years, who have received an additional dose of the MR vaccine over and above the routine immunisation, especially from North India. Active surveillance helped us in finding and reporting the minor adverse events that could have been missed in the passive reporting of AEFIs. The MR vaccine introduced in the campaign is found to be largely safe for use among children aged 9 months to 5 years except for a few adverse reactions. We recommend further studies with a large sample size and with prolonged follow-up to evaluate the delayed and rare AEFIs.

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