Original Article

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Paediatrics Section

Study of Severe Adverse Events Following Immunisation in Children of Jamnagar District with Follow-up at Tertiary Care Hospital

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ABSTRACT

Introduction: The World Health Organisation (WHO) defines Adverse Effects Following Immunisation (AEFI) as a medical incident that takes place after an immunisation, causes concern, and believed to be caused by immunisation.

Aim: To study the patterns of serious adverse events following immunisation among children in Jamnagar district in tertiary care centre.

Materials and Methods: The study was conducted at Paediatrics Department at Shree M. P. Shah Medical College, Jamnagar, Gujarat, India along with two primary health centers, one community health centre and four private clinics of Jamnagar district. There were 26 children included in the study that lasted for one year, from April 2013 to April 2014. The numbers of adverse event reports were calculated in five age groups: 0-1 month (neonates), 1-12 months (infants), 1-3 years (toddler), 3-6 year (preschool) and 6-14 years (school going). Vaccination details had been taken from place of immunisation. The variables were assessed for normality using the Kolmogorov-Smirnov test. Descriptive statistics were calculated.

Results: From the one year of events reported of AEFI, most commonly AEFI noted was due to immunisation of Pentavalent vaccine. Most serious adverse events found were swelling, pain and tenderness, redness and persistent crying. Remaining were local requiring primary support in the hospital.

Conclusion: The most common age group affected was infants. Regular follow-up should be done for all participants, so that focus should be done in this population for reducing AEFI.

Keywords: Community health, Convulsion, Pentavalent, World health organisation

INTRODUCTION

Immunisation constitutes one of the most effective modern public health measures for preventing serious diseases. It has been estimated that under Universal Immunisation Programme (UIP), 2.7 crore children are eligible for receiving vaccines in India. Immunisation currently, saves 3 million lives per year throughout the world and is one of the most cost effective health intervention that exists [1-4]. Safety regarding vaccines had been questioned because of cases reported at many places as a result certain misconception about the safety of the vaccines has arisen in many communities [5]. The WHO defines AEFI as a medical incident that takes place after an immunisation, causes concern, and believed to be caused by immunisation. An AEFI is an unpleasant medical incidence following immunisation and does not essentially have a contributory association with the practice of the vaccine [6]. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. Healthcare providers at all levels should be equipped with technical and communication skills to address public concerns about vaccination and respond rapidly, clearly and effectively to protect the beneficiaries and preserve the integrity of the immunisation program. The AEFI surveillance supervises immunisation protection, identifies and reacts to adverse events following immunisation, decreases the harmful impact of the occasion on health and adds to the eminence of immunisation behaviours.

In the natural process of developing immunity, a vaccine may cause fever, erythema, local pain etc. The AEFI may distress community to the extent that they may decline vaccination for children. Hence, AEFI surveillance assists in building public assurance and helps in the overall success of the immunisation program [7,8]. Although most of the AEFIs are mild, resolve without management and has no significant economic impact; seldom serious adverse reactions can happen. When the vaccination reporting augments and disease load decreases severely, extra cases of AEFI draws awareness

of the population more than the disease among the public; no vaccine is 100% safe [9].

The AEFI surveillance in India was started in 1985 along with the UIP, but AEFI reporting is still suboptimal in the country, with almost no participation from the private sector [8]. The Pharmacovigilance Program of India (PvPI) follows a spontaneous surveillance method and collects all AEFIs irrespective of the healthcare setting via Adverse drug reaction Monitoring Centers (AMCs) across the country, and further transmits this information to a national AEFI committee for investigation and communication as required [9,10]. However, spontaneous reporting system might possibly not collect all AEFIs due to factors such as under-reporting, incomplete reports due to lack of time to fill out forms, healthcare professionals' tendency to report serious events more frequently than other events, lack of denominator data to calculate incidence rates [11,12]. The present study was done with the aim to study patterns of adverse events following immunisation among children in Jamnagar district (Gujarat state), in a tertiary care centre.

MATERIALS AND METHODS

The present surveillance study was conducted at Department of Paediatrics, M. P. Shah Medical College, Jamnagar, Gujarat, India affiliated with Shree Guru Gobind Singh Hospital (GGGH) and also few private clinics, community health centre and primary health centre situated in Jamnagar district.The study spanned from April 2013 to April 2014 and included 26 children.

From the records available from Gujarat Hospital Management Information System (GHMIS) Jamnagar District, Gujarat, India fully immunised child at that point of time were: 40000. From the records, with limitations of private clinic data, 26 children were included in the study. This sample size comprised of children from all the health centers who had reported adverse event to Paediatrics Department in Shree M. P. Shah Medical College, Jamnagar.

Ethical clearance was obtained from the Institutional Human Ethics Committee of Shree MP Shah medical college Jamnagar (GG/2312/pedia) and verbal consent of the guardian of child was taken in vernacular language. The adverse event reports were divided into five age groups: 0-1 month (neonates), 1-12 months (infants), 1-3 years (toddler), 3-6 year (preschool) and 6-14 years (school going).

Inclusion criteria: All children that came for immunisation and having adverse events following immunisation were included. An AEFI was measured serious, if it lead to death, needed in-patient hospitalisation or lead to a noteworthy disability/ incapacity.

Exclusion criteria: Parents who did not give consent for participation.

Each child's detail record book was maintained, which contained detailed history from the informant (mainly mother) about name, age, sex of child and regarding his/her residence. Every participant was observed in the waiting locale of the immunisation center at the research place for the event of any unwanted systemic reactions, for duration of 30 minutes subsequent to vaccination.

Parents were offered with a patient data brochure in the local language which had guidance on vaccination, probable AEFIs and the contact details of the research team. On day eight subsequent to the vaccination, a telephonic follow-up was carried out.

The proforma was drafted that had details on demographic information of the child, allergic status, medical history and AE details. The AEFI section was developed on the basis of WHO's AEFI core variables [6]. Brighton collaboration case definitions were utilised for the suitable diagnosis of AEFIs. Causality assessment of AEFIs was executed utilising WHO's new causality evaluation algorithm by inspecting the eligibility, and utilising the checklist and algorithm. Lastly, the AEFIs were classified as per the causality assessment classification [7].

STATISTICAL ANALYSIS

The data were analysed using Statistical Package For The Social Sciences (SPSS) version 15 (SPSS Inc., Chicago, Illinois, USA). For all tests, confidence level and level of significance were set at 95% and 5%,respectively.The variables were assessed for normality using the Kolmogorov-Smirnov test. Descriptive statistics were calculated. One sample t-test is applied for statistical comparison of data.

RESULTS

In the present study, the most common affected age group of children with AEFI was 1 month to 12 months (80%) [Table/Fig-1].

Age	Male	Female	Total
0-1 month	-	-	-
2-12 months	10 (38.4%)	11 (42.3%)	21 (80.7%)
2-3 years	02 (7.7%)	02 (7.7%)	04 (15.4%)
4-6 years	01 (3.84%)	-	01 (3.84%)
7-14 years	--	-	
Total	13 (50%)	13 (50%)	26 (100%)

[Table/Fig-1]: Demographic data of study participants.

Out of the 26 patients, the most common immunising agent found was the first does of Pentavalent. One sample t-test was applied between pentavalent vaccine (73.07%) and other vaccines (26.91%). The result was significant statistically ($p \leq 0.05$) [Table/Fig-2].

According to various symptoms of patients, most serious adverse events found were swelling, pain and tenderness,

Immunising agent	No. of AEFI Noted
Pentavalent	19 (73.07%)
DTwP	5 (19.23%)
Measles	1 (3.84%)
BCG	1 (3.84%)

[Table/Fig-2]: Distribution of events according to immunising agent.
DTwP: Diphtheria and tetanus toxoids and whole-cell pertussis vaccine; BCG: Bacille calmette-guérin (tuberculosis) vaccine; AEFI: Adverse effects following immunisation

redness and persistent crying. Remaining were local requiring primary support. The most common adverse event was injection site inflammation [Table/Fig-3]. Most of the causality was due to program error (42.3%) and owing to unknown causes (42.3%) [Table/Fig-4].

Presenting complains	No. of patients
Swelling	17
Pain and tenderness	15
Fever	2
Redness (Erythema)	11
Difficulty in walking	2
Persistent crying	4
Convulsion	2
Others	6

[Table/Fig-3]: Distribution according to various symptoms at the time of admission.

Type of AEFI	No. of patients identified
Vaccine Reactions	1 (3.84%)
Program Error	11 (42.3%)
Coincidental Events	1 (3.84%)
Injection Reaction	2 (7.7%)
Unknown	11 (42.3%)

[Table/Fig-4]: Causality-wise classification.
AEFI: Adverse effects following immunisation

Most of the patients having AEFI were immunised at Shree Guru Gobindsingh Government hospital. Total number of AEFI observed from government facilities was 84.6% [Table/Fig-5]. In Shree Guru Gobindsingh hospital (GGGH), total number of AEFI observed in pentavalent was 8, among which 75% were due to open vial system [Table/Fig-6].

DISCUSSION

The method of the present study was similar to a study done by Carrasco-Garrido P et al., in Spain but it was for six months on 946 cases [13]. There was no significant difference between AEFI in males and females in this study (50% males and 50% females, total children=26). These findings are similar to a study by Carrasco-Garrido P et al., and Zhou W et al., in USA

Place of Immunisation	No. of patients affected
Shree guru gobindsingh hospital (GGGH)	14 (53.84%)
CHC/PHC of Jamnagar	08 (30.76%)
Private hospital	04 (15.38%)
Total	26 (100%)

[Table/Fig-5]: Events according to centre of immunisation.
PHC: Primary health care; CHC: Community health center

Paramaters	GGGH	Others	Total
Open	6 (75%)	8 (73%)	14
Fresh	2 (25%)	3 (27%)	5
Total	8	11	19

[Table/Fig-6]: Distribution According to vial policy.
(in Pentavalent) GGCH: Shree guru gobindsingh hospital

[13,14]. The most common adverse event was injection site inflammation which was also the case in other studies from Spain, New Zealand and USA [15-18].

The most common vaccines causing AEFI was with pentavalent vaccine, followed by Diptheria, Tetanus toxoids and Pertussis (DTP) booster dose, followed by measles and Bacille Calmette-Guérin (Tuberculosis) Vaccine (BCG). In a study by Carrasco-Garrido P et al.,(Spain), it was DPT + Haemophilus influenzae type B (Hib) followed by Measles, Mumps and Rubella (MMR) [13]. In another study done by Mansoor O and Pillans PI. (New Zealand), it was reported that DPT+Hib was the most common vaccines followed by Haemophilus (H) influenza [16]. Similar findings were observed in a study performed in US [19]. Joshi ND et al. showed that 71% of AEFI were 'certain' due to vaccines followed by 21% of AEFI which were 'possible' and 8% of AEFI which were 'probable' [20]. In this study, patients suffering from serious AEFI had taken immunisation (84%) from the study hospital and Community Health Center (CHC) and Primary Health Care (PHC) of Jamnagar district. As all national immunisation scheduled vaccines and since last few years pentavalent vaccine is available in government hospital free of cost, most AEFI was found here. So, by training health personnel in government set-up and improving reporting system, incidence of AEFI can be decreased.

Limitation(s)

Under-reporting or impenetrability in collecting a causal relationship between the manifestation of the adverse reaction and the management may have affected the study outcome.

CONCLUSION(S)

Most common immunising agent causing AEFI was pentavalent, in this study. The most common age affected group was infants. Regular follow-up should be done for all participants, so that focus should be in this population to reduce AEFI. All AEFI (serious/minor) should be reported by specific reporting system

available.Healthcare workers should be trained regarding type of AEFI, its prevention and management.

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