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ORIGINAL RESEARCH

Adverse Effects Following Immunisation and Vaccine Hesitancy: A Qualitative Study in a South Indian District

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Background: Parental perceptions and concerns about vaccine safety and 'adverse effects following immunisation' (AEFI) are the reasons for vaccine hesitancy. This study aimed to understand how these vaccine-related concerns have become significant determinants of vaccine decision-making among non-vaccinating parents in the Alappuzha district of Kerala, India. The healthcare providers' views in this regard are also reported.

Methods: This is a qualitative study. In-depth interviews were conducted with informants from 110 households having non-immunised/partly-immunised children. In addition, 18 healthcare providers were interviewed. Thematic analysis using the reflective thematic method was carried out.

Results: Parents reported incidences of minor events of AEFI and are hesitant to continue vaccination in circumstances when children need medical treatment. AEFI incidents within the family have seriously hampered the trust in vaccines. Parents have concerns about multiple vaccinations and have misconceptions about the content of vaccines. Other concerns that lead to hesitancy are vaccine-related infertility, polio infection after polio vaccination and autism due to vaccination. Healthcare providers reported that there were no serious incidents that needed hospitalisation. Health workers opined that informing parents about AEFIs and preparing them is better.

Conclusion: The study reported that AEFIs are a barrier to vaccine acceptance. It warrants the need to build trust in vaccines and the vaccination process. Transparent communication with the beneficiaries is crucial. AEFI monitoring and reporting should be an essential component of efforts to minimise vaccination hesitancy.

Keywords: adverse effects following immunisation, vaccine hesitancy, parental perceptions, qualitative research

Introduction

Vaccination has had a profound impact on contemporary public health and medicine. Until the invention of vaccinations, people were constantly at risk of contracting fatal infectious illnesses such as smallpox, polio and hepatitis. Having more than 116 million children in the world getting immunised yearly, vaccines are estimated to save 2–3 million lives yearly from more than 20 life-threatening diseases.[1] However, trust in vaccinations and the healthcare system is critical in providing lifesaving immunisations to the general population. Understanding the factors contributing to and threatening trust is critical to understanding vaccination acceptance and hesitance.[2]

Parental perceptions, attitudes and concerns about vaccine safety and the risk of vaccine-preventable diseases became a major reason for vaccine hesitancy.[3] Their risk assessment or uncertainty related to vaccination often emerges after discussion with other parents, family members and health professionals.[4] Despite the unprecedented protective benefits of vaccination, the vaccine-related risk is weighed more.[5,6] The two main determinants of vaccine reluctance among parents are the lack of perceived need for the vaccine for children and concerns about the vaccine's efficacy and side effects.[4] Parents who refused the vaccination demanded more information on vaccine safety and benefits, especially if they had adverse reactions from other vaccines taken earlier. Hence, the acceptability partly depends on previous vaccine

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experience. Parents whose children had a severe disease or know someone who had died due to illness or has been critically hospitalised are likely to accept the vaccine, while those with mild disease are less likely to accept it.[7] Additionally, there is widespread concern that combination vaccinations would overload the immune system.[8,9] Unresolved or neglected safety concerns may increase the number of young people in a community who do not receive vaccination doses. Concerns about vaccination safety, scepticism of published effectiveness data, injection discomfort, and low-risk perception have been reported in the case of newer vaccines.[10,11]

Vaccine reluctance, on the other hand, is not restricted to parents. Studies indicate that many healthcare professionals hesitate to vaccinate their children or prescribe vaccination to their patients.[10–12,] According to qualitative research among healthcare professionals from Croatia, France, Greece, and Romania, vaccine safety was the primary worry in all countries.[10] In a survey done in Turkey, one-third of nurses expressed reservations about infant immunisations.[13] Healthcare workers and parents are worried about immunisations causing autism and infertility.[10,13] It is further reported that alternative/complementary medicine use was significantly higher in the vaccine refusal group than in the control group.[4] A minority of practitioners, particularly those practising alternative medicine, do not advocate vaccination.[12] Additionally, there is widespread distrust of pharmaceutical corporations due to perceived financial interests.[10]

Thus, vaccine safety concerns and 'adverse effects following immunisation' (AEFI) incidents play a significant role in developing certain perceptions and attitudes toward vaccination. This study explores how vaccine safety concerns and AEFI experiences have become significant determinants of vaccine decision-making among non-vaccinating parents in the Alappuzha District of Kerala, an Indian state.

Adverse Effect Following Immunisation (AEFI)

AEFI refers to any untoward medical incidence followed by vaccination that does not necessarily have a causal relationship with the vaccine. These events range from mild to severe, including fever, pain at the injection site, swelling, convulsion, coma, and even death. An adverse event can be caused or triggered by a vaccine or the process of immunisation.[14] AEFIs are of different categories and precipitated by the vaccine due to one or more. These categories are – reactions caused by a vaccine quality flaw (one or more problems in the vaccine product, including the administration equipment), reactions caused by an immunisation mistake (due to errors in vaccine preparation, handling, storage or administration), and immunisation anxiety-related responses (caused by anticipatory worry over injections).

It is known that safety, quality, and efficacy are the three aspects of a vaccine that are considered before being introduced into national immunisation programmes. Vaccines undergo extensive testing and review for these aspects before licensure[15] Vaccines are usually given to healthy persons, so the general public has a low tolerance to adverse events following immunisation. However, many of the symptoms of an AEFI may or may not be due to immunisation. Hence, there is a need to differentiate between an AEFI and a coincidental event. According to the Joint Appraisal Report by Global Alliance for Vaccines and Immunization (GAVI), based on routine immunization data from 2018–2019 (pre-COVID-19), apprehension towards vaccine safety and side effects (26%) was the second major reason for low vaccine coverage in India, while information gaps (35%) constituted the leading barrier.[16,17] Although these data precede the COVID-19 pandemic, they provide critical insight into the underlying concerns and structural challenges that may have shaped vaccine attitudes during and after the pandemic. Post-pandemic studies indicate that vaccine hesitancy in India has remained a substantial issue. A systematic review reported a pooled hesitancy rate of 31%, with concerns over side effects, vaccine efficacy, and safety being the most cited reasons.[18] Another meta-analysis found a hesitancy rate of 28% among Indian adults, with significant regional variations—from as low as 13% in some states to nearly 49% in others.[19] While national-level surveys also show high overall confidence in vaccines, persistent concerns around safety and trust suggest that these earlier themes remain relevant.[20]

The World Health Organization (WHO) directs the systematic collection, analysis and evaluation of medically important AEFIs for all immunisation programmes worldwide.[21,22] This exercise aims at early detection and analysis of adverse events for appropriate and quick responses to emerging AEFI issues and to decrease the negative impact on the health of individuals and the immunisation programme. In addition, vaccine safety surveillance allows for the identification and rectifying of gaps in the system to strengthen the Expanded Programme on Immunization (EPI).[21,23] In India, the AEFI committee is responsible for determining the adverse impact after examining the reported instances.[24]

In order to communicate up-to-date information to the public on the benefit-risk profiles of individual vaccines, careful and continuous analysis of the post-marketing vaccine safety surveillance data should be ensured at various levels. This helps to counter the negative perceptions of vaccination and the resultant vaccine hesitancy by improving the transparency in the immunisation programmes.[25,26]

Rationale and Objectives

Vaccine hesitancy remains a major challenge to achieving full immunisation coverage in India, particularly in the context of concerns about AEFI. While quantitative data exist on AEFI incidence, there is limited understanding of how these experiences shape perceptions and lead to hesitancy in local communities. This study was conducted in a district with suboptimal immunisation coverage in South India to explore how AEFI experiences influence caregivers' decisions regarding childhood immunisation. The objective of the study was to document community-level perceptions and decision-making related to AEFI and identify factors that contribute to vaccine hesitancy.

Methodology

Study Setting

This study is a qualitative exploration study with a grounded theory approach.[27] This study was undertaken as a part of a study on acceptance and hesitancy toward Japanese Encephalitis (JE) vaccines in Alappuzha district, Kerala state, India, during 2020–2021. This study explores the underlying determinants of hesitance toward JE and other vaccines (provided through the universal immunisation programme) among the parents of "non-immunised' (NI)/"partially immunised' (PI) children below five years and seeks to understand how vaccination-related decisions are taken. This paper focussed on AEFIs and their relation to vaccination-related decisions. The study was guided by the following research questions: (1) How do AEFIs influence vaccine decision-making among parents? (2) What are the key concerns and misconceptions driving vaccine hesitancy? (3) How do healthcare providers perceive and address vaccine safety concerns in their practice?

The Institutional Ethical Committee of the first author approved the study protocol. All participants were informed of the purpose of the study, and informed consent was obtained according to the Declaration of Helsinki. The informed consent included the publication of anonymised responses/direct quotes.

India has a massive infrastructure for delivering primary health care through primary health centres (PHCs) and sub-health centres (SHCs). PHC is located in a bigger village and serves a population of 30,000 or more, as it is staffed with doctors and paramedics. SHCs function under the PHC. Each PHC serves several villages covering the above-mentioned population distributed in 8–12 SHCs. Each SHC, having at least two health workers, serve a population of 5000. The government is transforming the SHCs into health and wellness centres with expanded services. In some places, a community health centre (CHC) substitutes PHC and serves a population of 120,000. In the Indian public health system, health workers are of two categories - regular health workers (RHW) and community health workers (CHW). The RHWs include auxiliary nurse-midwives (ANMs), nurses and other trained personnel such as health assistants. The CHWs are accredited social health activists (ASHAs) from the community. The health and medical issues of the district are under the administrative control of the District Medical Officer (DMO). We approached the DMO through formal communication, outlining the purpose and scope of the study. The DMO acted as the administrative gatekeeper, facilitating access to immunisation records and supporting engagement with field-level health staff and local health facilities. The DMO of the study district gave details of NI and PI children and the contact information of the concerned CHWs involved in immunization activities.

The DMO grouped the PHCs and CHCs into health blocks based on demographic characteristics and physical location. The study area included 16 health blocks spread across rural and urban areas. The statistics of the DMO's office indicated 296 instances, including 20 NI and 276 PI children in the study area. However, the field data revealed 266 cases, including 11 NI and 255 PI children. The inclusion and exclusion criteria resulted in participants being parents or guardians of NI or PI children under the age of five residing in selected health blocks of the Alappuzha district. Households were excluded if parents declined to give consent. For the healthcare provider interviews, medical officers, ANMs, and ASHAs involved in immunisation services were purposively selected.

Primary data collection began with contacting 1862 CHWs in 72 villages/urban wards across 16 health blocks. The sample unit comprises NI and/or PI children from 266 households. We selected 110 households with NI/PI children. The final household sample size was determined after excluding refusals. In total, 23 parents declined to participate in the research. These refusals were due to the refusal to sign the consent form. In addition to households, 18 healthcare providers (HCPs) were identified as key-informants. They are PHC/CHC medical officers (MOs) (n=5), RHWs (n=7) and CHWs (n=6). As this study is qualitative and exploratory, we were not concerned about the sample size but instead were keen to attain data saturation. Data saturation (emergence of no new information) was observed around the 100th interview. However, interviews were continued until 120 households were covered to ensure representation across all 16 health blocks.

Data Collection

As we used in-depth interviews (IDIs) and key-informant interviews (KIIs), interview guides were prepared through brainstorming by the researchers. Standard methods were followed during conducting interviews (Spradley, 2016).[28] The important issues that emerged from the literature review were used to create a list of themes. These themes were subsequently transformed into various variables to develop interview guides. During the interviews, we used Malayalam (the native language of Kerala) as the communication medium. It was decided to interview the child's mother or father, depending on their availability. Both parents were also permitted to participate, depending on the situation. Although the length of the interviews varies, they range from 15 to 45 minutes. Conversation interviewing techniques were used for these interviews. The data collection team was comprised of two trained qualitative researchers with experience in public health. These interviewers were trained in qualitative interviewing techniques and had no prior personal or professional relationship with participants. Both male and female interviewers were involved, and gender-matching was ensured where culturally relevant. Reflexivity was maintained throughout the data collection process through regular discussions between the investigators to reflect on their positionality, acknowledge potential biases, and ensure alignment with the study's objectives. To ensure a consistent and standardised approach, both investigators used a pre-tested semi-structured interview guide and participated in joint planning and debriefing sessions. Participant information sheets, prepared in the local language, were carried out by the investigators and shared with each potential participant in person. Adequate time was provided to read or review the information, and participants were encouraged to ask questions before giving informed consent. All interviews were recorded with the consent of the participants. However, 21 parents did not give consent to record the interview. Thus, this study was designed and reported in accordance with the Consolidated Criteria for Reporting Qualitative Research (COREQ) guidelines to enhance transparency and methodological rigour (Tong et al, 2007).[29]

Data Analysis

The interview scripts were transcribed and translated into English using standard guidelines meant for qualitative research.[30,31] All audio recordings were transcribed verbatim in the local language by trained research staff familiar with qualitative transcription. These transcripts were then translated into English by bilingual team members with experience in qualitative research. No AI or automated transcription tools were used at any stage of the process. Each transcript was independently verified for accuracy after transcription and again after translation through review by a second team member to ensure fidelity to participants' original meaning and to preserve cultural and contextual nuances.

The data were subjected to thematic analysis using Braun and Clarke's reflective thematic method.[32] The inductive approach and the theoretical method were used to identify codes and themes. As suggested by scholars, we thought that data analysis need not be linear but a recursive process that requires the researcher to travel back and forth between phases of data analysis to accommodate newly discovered themes or data.[32,33] Transcripts were analysed by two researchers independently. Both analysts independently reviewed and coded the transcripts using a thematic analysis approach. The coding was done manually. Codes were noted as comments in each translated English script, and essential features were marked in a Microsoft Word document and later collated into a document. To manage biases and assumptions, the team held regular reflexive discussions throughout the coding and interpretation process. Initial codes were compared and refined jointly, and any differences in interpretation were

discussed until a consensus was reached. Themes were finalised through iterative review, ensuring they were grounded in the data and reflected participants' voices accurately. After initial coding, codes were compared and harmonised through iterative discussion. Thematic development involved collaborative refinement and triangulation. Selected participants were contacted for member-checking to ensure that the researchers' interpretations aligned with the participants' views.

A framework analysis approach was used to guide the thematic analysis. While initial coding was inductive, emerging themes were subsequently organised and interpreted using the WHO-SAGE Working Group's 3Cs model of vaccine hesitancy—Confidence, Complacency, and Convenience.[34] This allowed the team to systematically map community-level perceptions and experiences related to AEFI within an established conceptual framework while also allowing for the identification of context-specific themes beyond the framework.

Potential themes were found from the coded data extracts and then grouped within the themes that have been identified. Some early codes were accepted as primary themes, while others were incorporated into the final analysis as sub-themes. The presence of internal homogeneity within themes and outward heterogeneity across themes were investigated by repeated reading by the authors. In addition, the field notes, which comprise a daily record of field trips and interviews, were used as an adjunct. Verbatims from interviews (quotes) were given during the presentation of findings, and anonymous identifiers of those quotes were also given. The details of the data analysis, including the brief findings, are presented in Table 1.

Table 1 Thematic Summary of the Findings of the Study

Main Theme	Subordinate Theme	Codes	Quotations	Summary of Codes
Adverse Effects Following Immunisation (AEFI)	Perceived side effects and discomfort in children	Pain at injection site, swelling, persistent crying, difficulty in walking	Penta-I was taken from health subcentre, after that a swelling occurred which lasted for 2–3 weeks. [IDI 025]	Physical discomforts, though minor, led parents to postpone or discontinue vaccination fearing harm.
	Severe health outcomes attributed to vaccines	Paralysis, medical treatment post-vaccination, fear of recurrence	Here nearby, a small child's leg got paralysed after vaccination. [IDI 035]	Perceived severe outcomes like paralysis fuel vaccine hesitancy regardless of medical validation.
Influence of Family and Tradition	Intergenerational vaccine hesitancy and alternative medicine	Historical AEFI media reports, homoeopathy preference, family vaccination choices	At the time of my elder son's vaccination. six children paralysed. [IDI 092]	Family beliefs, past incidents, and reliance on alternative medicine contribute to vaccine hesitancy.
Perception of Vaccine Safety	Chemical content and fear of long-term harm	Preservatives, aluminum, mercury, brain damage, allergy	There are preservatives in the vaccine; an Aluminum component is added. Mercury will cause brain damage. [IDI 081]	Chemical content of vaccines raises concerns about neurological harm and long-term safety.
	Concerns about vaccine-induced infertility	Infertility, gender-specific rumours, mistrust in rubella vaccine	I have read that the rubella vaccine will cause infertility. [IDI 059]; . female children would lose their fertility. [IDI 001]	Fertility-related misconceptions linked especially to MMR vaccine reinforce gendered vaccine hesitancy.
Community Narratives and Historical Incidents	Polio-related events and long-term distrust	Polio paralysis, oral vaccine overdose, persistent community myths	Polio vaccine, my neighbour had a fever, and his leg was paralysed. [IDI 072]	Historical incidents and community-level narratives sustain mistrust across generations.

(*Continued*)

Table 1 (Continued).

Main Theme	Subordinate Theme	Codes	Quotations	Summary of Codes
Concerns About Vaccine Scheduling	Multiple vaccines and physical burden on children	JE and DPT booster together, fever, child fainting, hospitalisation	The JE vaccine was taken along with a booster. child fainted. [IDI 059]	Simultaneous administration of vaccines is perceived as excessive and harmful.
Vaccine-Autism Link	Developmental delays post-vaccination	Autism, regression in milestones, vaccine blame, MR campaign	We started noticing a difference after the vaccine. she started to lose the acquired skills. [IDI 046]	Suspected association of vaccines with autism and developmental disorders intensifies hesitancy.
Health System and Provider Interaction	Communication and follow-up by healthcare providers	Pre-vaccine counselling, AEFI instruction, follow-up, parental non-adherence	We give instructions and medicine after vaccination. We follow up with them even after two days. [KII 001 JPHN]	Despite counselling efforts by providers, inconsistent parental adherence and commu-nication gaps persist.
	Medical screening and safety measures	Contraindications, neurological screening, immunosuppression checks	We do not give the vaccine to those with neurological diseases, especially JE, MR vaccines. [KII 008 MO]	Doctors follow guidelines for screening and precautions, but community perceptions often override these assurances.

Result

Characteristics of Study Participants

The data were collected from 128 participants, including 110 participants who had either NI or PI children. These participants included 41.8% of men and 58.2% of women in the age range of 19–49 years, with most participants in the 30–35 years age group (70.9%). The majority of the participants (92.7%) are from rural areas. With regard to educational status, all are having formal education of at least 12 years of schooling. All men are engaged in service either in the government or the private sector, and others depend on agriculture. Most of the women (85.9%) are homemakers. The participants from the health system included five medical officers (three of whom are men), seven RHWs (including four women) and six CHWs, who are all women.

Community's Views

Perceived Adverse Events and Their Influence

Participants described a range of adverse events following immunisation, from minor and transient effects to more serious outcomes. The most commonly cited experiences were minor AEFI, such as swelling at the injection site, fever, or prolonged crying among children, which led some caregivers to delay subsequent doses. However, a few participants referred to more serious or long-lasting effects—such as inability to walk, seizures, or even reports of child death—that were either experienced first-hand or recounted by others in their community. These more severe events, though less frequently mentioned, appeared to have a disproportionately strong influence on parental perceptions and decisions regarding vaccination.

> Penta-I was taken from health subcentre, after that a swelling occurred, which lasted for 2–3 weeks. I was concerned and stopped vaccination. [IDI 025]

Parents are hesitant to continue vaccination in circumstances when children need medical treatment after immunisation due to ill effects that have not been proven by the doctor, regardless of whether the vaccine caused them. They are concerned that similar occurrences may recur with further immunisation.

> Here nearby, a small child's leg got paralysed after vaccination, around one year before. So, we fear that the same may happen to our child… [IDI 035]

Fear of side effects is one of the major concerns of the parents regarding vaccination. Previous experience of adverse events among family members leads to the discontinuation of further vaccination. Thus, AEFI incidents within the family can seriously hamper the trust in vaccines.

> My elder sister's child fell ill and had fever after vaccination. We thought the kid might die. May be because of all these, we lost the trust and believe what we hear in the news. A parent who lives in a joint family where none of the children is vaccinated other than BCG [IDI 002]

A mother who is a pharmacist by profession is sceptical about vaccines and hesitates to vaccinate her child due to AEFI concerns.

> Among my relatives, there are people who got fits after vaccination. Even my brother had fits after vaccination. We heard negatives about the new vaccines too. So, we decided not to vaccinate my child. [IDI 030]

Social and Family Influences on Vaccine Decisions

Similar kinds of perceptions have been reported by some parents who are practising alternative medicine. A mother of two children and her father, who are homoeopathic practitioners, have not fully immunised her children. Her father has not immunised this woman and her brother during their childhood. Back then, the woman's father read news about vaccine adverse effects, which made them vaccine-hesitant.

> At the time of my elder son's vaccination in 1984-85, I read in the newspaper that six children were paralysed after vaccination due to problems related to vaccine production. During those times, vaccination was not promoted this much. Here in our clinic, also parents ask whether to vaccinate their children. We ask them to take their own decision. [IDI 092]

Trust, Misinformation, and Perceptions of Vaccine Content

Parents have raised concerns over the vaccination at 18 months, where two vaccines are given together (DPT booster and JE vaccine). Vaccination simultaneously on the hand and leg is difficult for the child to bear. So, they stopped vaccination after 18 months. Another concern was that the children were too young to receive this many vaccines. Thus, some parents had concerns about multiple vaccinations.

> The JE vaccine was taken along with a booster. And I heard that it's very painful. He (the elder child) had fever and pain in his leg for two days. I have heard that a child fainted after the vaccination and was admitted to the hospital. The doctor confirmed that it is because of vaccination. [IDI 059]

There is a perception among parents that vaccines contain chemicals which may interfere with natural immunity and are harmful to children in the long run.

> There are preservatives in the vaccine; an Aluminum component is added as an adjuvant for activation and increasing the reaction. The preservative is Mercury. Mercury will cause brain damage, Aluminum will cause adverse reaction problems and allergy problems… Mercury and preservatives were first used around 1930. They haven't found an alternative to it. The majority of the vaccines still contain these …. [IDI 081]

A misconception that a vaccine contains ingredients that lead to infertility exists. Fertility-related controversies are often quoted along with a particular vaccine rather than vaccines in general.

> I have read that the rubella vaccine will cause infertility. And when I see such news, I feel it is true. [IDI 059]

> There Was a Talk That Female Children Would Lose Their Fertility After Vaccination…. [IDI 001]

A few parents in the study believed that vaccines cause autism and that vaccination is related to increased autism rates.

> My child is autistic and 100% disabled…. Like other children, she had normal development till one year age. We started noticing a difference after the vaccine was given in the 9th month; she started to lose the acquired skills one by one. We doubted it could be related to vaccination…. [IDI 046]

> There was a campaign for MR injection…. We suffered a lot because of that vaccine. With that incident, we hate vaccines. The child became very fearful after that, with constant mood swings… Doctor scolded us for vaccinating the child without informing him and asked us not to vaccinate her again…. [IDI 046]

Historical Memory and Alternative Beliefs

Another parent, apprehensive of the contents and preservatives used in vaccines, said that studies should be conducted in the Indian context to assess the side effects of vaccines in the long term. He related the high immunisation rate in the US to the increase in autism cases. He claimed the harmful effects of vaccines could only be known in the long term, and the amount of brain damage that occurred may not even be noticed. Incidents of adverse effects due to polio vaccination that happened 30–40 years before were mentioned by many parents as the sole reason for their hesitance towards vaccination. The affected could be their relatives, neighbours or close acquaintances. Some parents described the cause of infection as polio vaccination; others said infection occurred even after polio vaccination, and vaccination could not prevent the disease. Some people believe that the overdosage of polio vaccines causes the death of some children.

> In Malappuram, usually people don't take vaccines., Strictly we don't take vaccines. We are letting germs enter our bodies. A few days after the Polio vaccine, my neighbour had a fever, and his leg was paralysed. Due to that incident, people in our area have strongly objected to vaccination…. [IDI 072]

A parent from Alappuzha municipality, whose family has followed and practised naturopathy for the last ten years, has observed that children of neighbours and relatives become less active once vaccinated. She also quoted instances of a child in the neighbourhood who was fully immunised and then contracted mumps and measles.

> There was a case of a boy who got paralysed after vaccination. It has been said that the child was given an overdose of oral polio vaccine. And after that, they stopped vaccinating their other children. [IDI 051]

Healthcare Providers (HCPs)' Views

HCPs were asked about the AEFI incidents they have experienced. None of these informants reported severe adverse effects that needed hospitalisation. The common adverse effects observed by HCPs are fever, difficulty walking, syncope and swelling/pain at the injection site and to the most extent.

> There were incidents of mild adverse effects. Some children had syncope. Others had phobia and fear towards injection when they see the needle. There were no incidents of serious side effects which need to be referred. [KII 016 MO]

Some CHWs also confirmed that pain and difficulties experienced in vaccines given at 18 months (JE and DPT Booster) are comparatively higher than in other vaccines.

> We give instructions and medicine after vaccination. It is at age 1½ DPT booster, and JE is given, at that time we tell there will be difficulty in walking for two days. This is the first vaccine given to the child after they start walking. We tell them not to fear. We follow up with them even after two days. [KII 001 JPHN]

However, parents try to skip medicines, thinking it is unnecessary, or they will not strictly follow the instructions given by doctors. Some children need medicine after vaccination to keep the fever in check. Close attention and monitoring are done in children with a history of underlying medical conditions and seizures.

> I personally look into the general health and the weight of the child and suggest vaccines accordingly. If there are neurological issues and seizures, we will be careful about it. [KII 007 MO]

> Usually, we ask them (parents). We don't give the vaccine to those with neurological diseases, especially JE, MR vaccines. Live vaccines should not be given to immune-suppressed children with contraindications, and pregnant women too…. [KII 008 MO]

HCPs mentioned that general illnesses after vaccination are often wrongly linked with vaccines. They are often misinterpreted as adverse effects due to vaccination. HCPs confirmed that fertility-related rumours are very sensitive in nature and could hinder the vaccination rate.

> Some people say that it may cause infertility. They think vaccines prevent them from having the next generation. We will tell them about our experience. We are also vaccinated. We have children. [KII 014 MO]

HCPs further stated that polio vaccine-related paralysis is the sole reason for vaccine hesitancy in the Alappuzha district.

> Polio was prevalent before. In those times, polio cases were comparatively higher. Vaccines were given to all; even then, vaccines are not 100% effective. In that case, two or three people may be affected. We try to make parents understand this… [KII 016 MO]

Discussion

A key theme that emerged from the study was the role of trust in shaping immunisation decisions. While formal health guidance was available, many participants placed greater trust in informal sources such as relatives, neighbours, and community elders. Personal experiences and community stories—whether involving minor adverse effects or serious conditions like paralysis—often carried more weight than reassurance from healthcare providers. This reliance on trusted social networks, coupled with a degree of scepticism toward official health messaging, underscores how vaccine decisions are socially negotiated and grounded in relational trust rather than strictly clinical information.

Vaccines' adverse effects or, in some cases, the perceived adverse effects of vaccines are a barrier to vaccine acceptance in this Indian district. Minor adverse events are parents' most commonly reported adverse effects. In some cases, fits/seizures followed by fever were also observed. Healthcare providers say parents do not give medicines to control post-immunisation fever on time, causing high fever and seizures. Parents also tend to believe hearsay information about vaccine adverse effects and incidents of child deaths that may not relate to vaccine administration. Sometimes, co-incidental events are linked with vaccines and conveyed as adverse effects.

False information and rumours on social media have a significant impact on decision-making. People look for information on various subjects on the internet, which accelerates misconceptions concerning vaccination's adverse effects. Messages about vaccinations causing infertility, unsubstantiated adverse event reports, etc, were also cited for not vaccinating the children. This trend is consistent with global literature on COVID-19 and HPV vaccine hesitancy, where exposure to misinformation is closely associated with increased vaccine doubt and delay.[35,36]

Associated with vaccination-related side effects, vaccine-induced polio or polio vaccine-related paralysis (as described by parents) is a common reason for parental vaccine hesitancy. The occurrences recounted by parents happened 30–40 years ago, during the study participants' upbringing. The individuals impacted include family members, neighbours, or close friends. These occurrences have engendered a pervasive unfavourable attitude regarding immunisations in general. HCPs tried to convince the parents in response to these events. However, some HCPs accepted the potential of vaccine-induced illnesses, which are uncommon. Overall, the HCPs show positive perceptions of immunization and readiness for improving immunization services. Similar findings are reported from other countries.[37–42]

Andrew Wakefield's contentious and retracted Lancet publication of 1998 continues to affect parental vaccination decisions.[43] A meta-analysis of paediatric immunisation studies concluded no link between the MMR vaccine and autism.[44] Subsequent research also indicates the same.[45–47] Similar observations were made by parents from Italy about their experience.[48]

Vaccine-apprehensive individuals comprise a significantly bigger population than those who reject or partly immunise their children. Even after complete vaccination, people are expected to exhibit some reluctance. Their worries are primarily regarding the detrimental effects of vaccination and are often expressed in unclear terms. They do not hold firm anti-vaccination beliefs, which makes it relatively simple for HCPs to persuade them. This is consistent with recent literature on vaccine.[49]

Many times, co-incidental occurrences are misconstrued and attributed to vaccination.[50] These are often communicated verbally inside and around communities, resulting in the clustering of vaccine-hesitant persons within a locality/neighbourhood.[34,51] Thus, it is necessary to ascertain the amount of background occurrence to distinguish between a wrong response after vaccination and a co-incidental incidence.[20] In-depth interviews with HCPs revealed that none had noticed any substantial adverse effects after vaccination or witnessed severe occurrences necessitating hospitalisation.[52] However, appropriate care was taken during vaccination.[50]

India is a major vaccine maker, exporter and consumer. India's vaccination programme is the world's biggest, with an annual goal of around 27 million infants and 30 million pregnant women. The high vaccine consumption suggests

a significant chance of AEFI occurrences. The first two stages of the Mission Indradhanush immunisation programme, which began in 2015 to ensure full immunization with all available vaccines for children up to two years of age, resulted in an annual rise of 6.7% incomplete vaccination coverage. According to India's fifth National Family Health Survey, full vaccination coverage has grown from 62% to 76.4% among children aged 12–23 months.[53]

According to WHO's contemporaneous routine immunisation monitoring data, full vaccination coverage in India grew from 64% in 2013 to 82% in 2019 in targeted regions.[16] According to statistics from the AEFI secretariat, there has been a considerable rise in the number of AEFI cases reported in India throughout the years.[24] The necessity of AEFI reporting grows when new vaccines are introduced, and existing vaccines' safety and effectiveness are improved. India is anticipated to have an efficient AEFI monitoring system and a vaccine delivery mechanism to assure vaccination safety. With vaccination safety monitoring, we seek to discover and analyse adverse events early and to respond appropriately and quickly to minimise the negative effect on the immunisation programme. Countries may use AEFI surveillance indicators to assess their progress in establishing a practical and functional surveillance system.[54]

India's health ministry makes publicly accessible official statistics on AEFI in the form of AEFI causality assessment reports on a certain number of cases from current or prior years.[55] The data are categorised by the reason for reporting/outcome, the child's age, the date of vaccination, the antigen used, the AEFI categorisation, etc. Summaries of AEFI instances help develop strategies to tackle them. However, the findings of causation assessments conducted on particular instances are unavailable. To protect the confidentiality of cases, official government websites are devoid of socio-demographic and medical information about individuals. This severely restricts our ability to get an epidemiological picture of AEFI monitoring in India. Due to the lack of published studies on AEFI monitoring in India, comparing results from other countries is not possible.[56]

Due to the context-specific nature of vaccine hesitancy, researchers, policymakers, and HCPs must step up their efforts to better understand the breadth and scope of concerns to design contextually appropriate communication strategies. Official AEFI data may be used for this purpose. Scherer et al discovered that providing summary information about the Vaccine Adverse Event Reporting System (VAERS) boosted vaccine acceptability and confidence.[57] A quantitative analysis of the VAERS in the United States from 2011 to 2018 demonstrates the non-severity of the adverse events, which may be utilised as a communicable summary to boost vaccine acceptability.[57] Uncertainty about vaccinations and worries about adverse effects need a reorganisation of vaccine communication tactics. A culture of effective communication about the known hazards and benefits of vaccinations should be fostered within the health system.

Before concluding the paper, we would like to mention some limitations to consider while discussing the study's implications. The study design is qualitative, which is less likely to generate generalizable inferences to a broader population. However, this study aims not to generalize but to understand the AEFI experiences and vaccine safety concerns of parents and HCPs. Despite this inherent limitation, the study has methodological strengths, including a large sample drawn from a district and adopting a standard qualitative research methodology for data collection and analysis. Thus, this study provides an in-depth analysis of AEFI-related perceptions of parents and healthcare providers from India, which is hitherto unavailable in Indian literature.

Conclusions

Vaccine hesitancy is a worldwide concern, and the WHO has listed it as one of the top 10 global health hazards. Parents reported that vaccines' adverse effects are a barrier to vaccine acceptance. Healthcare providers acknowledged the occurrence of minor adverse events and focused on counselling parents to address their concerns and support informed decision-making. Hence, trust in vaccines and the vaccination process is to be built, and transparency and sustainable communication with the beneficiaries and clarifying their issues are crucial. Along with this, AEFI monitoring and reporting should be an essential component of efforts to minimise vaccination hesitancy and address vaccine safety concerns. It facilitates the communication of evidence-based information to the public and soothing public fears about AEFI.

Ethics Information

The study protocol was approved by the Institutional Ethical Committee of the Indian Council of Medical Research-National Institute of Virology, Pune, India.

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Disclosure

The authors declare that they have no competing interests.

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