

Chapter -1

Introduction

Background

A child's health is of utmost importance to a family and also to a nation. As a nation's future depends on the health condition of its paediatric population similarly a child's future depends on his health and relies on proactive approach by the parents to protect the child from any kind illness. Immunization is one of it. It is an important milestone in the field of children's health and has the largest reach to children in the community areas.

India, has a total population of 139.4 Cr and its 13.59% population belongs to the age group of 0-6 years while 25.78% is aged 0-14 years. Knowledge about demographic profile of paediatric population of a country is essential. It helps us to understand the population dynamics that ultimately shapes the future of the country. The prime concern of all societies should be ensuring the healthy growth and development of children. The pace of growth and development of a child in first few years of life is fast and holds important place in a child's life. Proper development also ensures fulfilment of their social, emotional and educational needs and growth of children of all abilities, including those with special health care needs, Malnutrition and infectious diseases are preventable and yet are common among young infants.

Childhood morbidity and mortality can be effectively reduced by immunizing children against vaccine preventable diseases. A child is considered to have been vaccinated if he/she has received at least: one dose of BCG vaccine, three doses of DPT vaccine, three doses of polio and one dose of measles vaccine. NFHS-5(2019-21) reflects that 76.4% of children aged 12-23 months received all basic vaccinations according mothers recall /vaccination card. The immunization coverage was highest for the BCG vaccine (95.2%) while being lowest for the polio vaccine (third dose)

i.e.73%. second dose of measles containing vaccine had the lowest coverage (31.9%) and decreased after its first dose. ¹

Burden of VPDs (vaccine preventable diseases)

A report by World Health Organization gives a global useful overview of disease burden due to vaccine preventable diseases. According to the WHO, DPT and measles vaccination prevents upto three million deaths every year while overall 1.5 million deaths each year are claimed by vaccine preventable diseases.

DPT and MMR vaccine save millions of lives every year. Measles alone contributed to millions of deaths before introduction of its vaccine in 1963. As of today slightly more than 85% world population globally is immunized for measles today and has prevented approximately 95,000 deaths in 2017. Tetanus and pertussis were also previously big contributors of childhood morbidity and mortality. Children younger than 5 years are affected by pertussis while tetanus alone killed killing an estimated 787,000 newborns in 1988, compared to 49,000 in 2013.²

The global proportion of immunized children has remained at the same level for past few years. In India, Universal Immunization Program (UIP) targets 27 million infants and 30 million pregnant women.³ There is lack of scientific data related to deaths related to VPDs however some report 5 lakh deaths among children annually due to vaccine preventable diseases.

To prevent morbidity and mortality due to VPDs it is important that the vaccination coverage is improved. During 2018, three doses of DTP vaccine were received by 86% infants worldwide that is approximately 116.3 million infants. Also by 2018, 129 countries had 90% coverage of DTP.⁴

The immune system develops infection-fighting antibodies when the child gets vaccinated. It protects them from infectious disease if they are exposed to it in later life. When a child under six years of age gets all recommended vaccination it provide protection to the entire community as well and it is known as “herd immunity.” Herd immunity protects children cannot be vaccinated, including newborns who are too young to be vaccinated, people with a weak immune systems,

who are unable to develop antibodies to fight disease. It is therefore important that all children must undergo recommended vaccination to protect themselves and others from deadly infectious diseases.⁵

Historical aspect of vaccination

Vaccination has long been practiced in many countries, oldest being India and China where these practices were since 16th century in the form of some inoculation. Almost three centuries later India adopted modern immunization in parallel with other western countries. Our progress since then has been steady and impressive.⁶ Development of vaccination is attributed to Dr. Edward Jenner who developed vaccine for small pox which was the first widely used vaccine for humans. The deadly infection caused disfigured face and blindness. India had at that point of time reported close to 60,000 cases of small pox in few months. Later it also contributed to eradication of this disease which was achieved in 1979.^{7,8}

India has since been taking quick strides in this field be it related to manufacturing or availability to community. However the journey until this stage hasn't been easy for developing nation like ours. After eradication of small pox in 1977, a nationwide program for immunization was initiated by the name of Expanded Program for Immunization in 1978. The initial vaccines with which the program was started were oral polio vaccine , Diphtheria Pertussis Tetanus vaccine and typhoid-paratyphoid vaccine. The target in expanded programme of immunization was to have at least eighty per cent coverage in infancy, the immunization was to be by all big hospitals which are located in urban areas. Since the majority Indian population is rural, the coverage remained low. On November 19, 1985, the program was renamed as Universal Immunization Program with addition of measles vaccine. The twenty point programme launched by the Prime Minister gave immunization the status of one of the five National Technology Missions launched in 1986. Use of available resources and manpower to improve immunization coverage and focus on a few interventions such as polio eradication, and elimination of maternal and neonatal tetanus was emphasized by the Child Summit of 1990.

By the year 1990 UIP covered the entire nation and in 1992 it became a part of Child survival and safe motherhood program. In the year 2005, UIP became an integral part of umbrella health program National Rural Health Program .During the same year response guidelines and surveillance related to adverse events after immunization were released.⁹ As of now almost all vaccines provided by Government of India through UIP are being manufactured in India and some are also being exported. Quite recently Serum Institute of India, the world's largest vaccine manufacturer by volume developed a vaccine for Covid-19 in collaboration with University of Oxford's Jenner Institute.

Mission Indradhanush was launched by ministry of health and family welfare, government of India in December 2014. It was launched to ensure vaccination of all unvaccinated and partially vaccinated children under Universal Immunization Programme. Under this drive focus is given on pockets of low immunization coverage and hard to reach areas where the proportion of unvaccinated and partially vaccinated children is highest .A total of six phases of Mission Indradhanush have been completed covering 554 districts across the country. People are generally aware about vaccinations of children but are not aware of this mission. Increased participation of public can ensure increased coverage and impact the goal to achieve vaccination of above 90% children.¹⁰

Vaccination related problems and related issues

Vaccine hesitancy has been on increase in several nations especially developed nations due to side effects associated with each vaccine. Adverse events after immunization make this process troublesome and worrisome for the parents. Lack of knowledge can further aggravate this situation. Studies show that parents are sometimes hesitant and reluctant for vaccination due to communication deficits and misconceptions. Past studies have shown that parents are worried due to side effects, need for vaccination and are unaware of the mechanism how vaccines provide immunity. Vaccination coverage was also found to be affected by parent's educational status and attitude of the physician.¹¹ It has also been seen that vaccine hesitancy is linked to incomplete and delayed immunization. The researchers have

also highlighted in their study that health professionals need to explain to the parents regarding the benefits, side effects and address issue of associated pain with immunization. Different counselling strategies, discussion regarding schedule and safety of vaccines are some of the matters that should be discussed when parents visit for vaccination. It is strongly recommended that physical, pharmacological, positional methods should be used to reduce pain during vaccination.¹²

According to CDC, every time the parents visit for their children's immunization, health professional must take it as an opportunity to assess parent's level of knowledge and concerns regarding vaccination. It is also important to assess their factors affecting vaccination uptake. Parents may not always agree to health professional when it comes to children's safety and sometime hold a different opinion. Health professional must inform the parents regarding possible side effects and serious adverse event which may occur as rare as one in a million children.¹³

In a cross sectional study(2015) done in a school the investigators found out that 60% respondents did not vaccinate their children for influenza due to several concerns like vaccine safety and absence of felt need for vaccination. Other reasons stated were vaccine constituents; efficacy and waiting for natural immunity for influenza.¹⁴ WHO and UNICEF in their joint report (2015-17) have found vaccine hesitancy due to several reasons namely lack of knowledge regarding potential benefits and side effects of vaccines, traditional and cultural beliefs and socio economic issues.¹⁵

From the above mentioned studies we can observe that vaccination uptake or coverage is greatly affected by the knowledge of parents regarding vaccine side effects. These side effects or vaccine related problems have a different distribution according to age and varies according to vaccine. It is important to understand their frequency and duration, course of illness of short duration that follows immunization.

All vaccines can cause a few side effects. Most vaccines are associated with some mild reactions like pain the arm or low-grade fever and that subsides within few days. Not immunizing a child can spread the infection to other children and affect their health adversely as all VPDs are communicable. Severe effects after

vaccination are very rare. Age appropriate vaccination must be ensured by the parents as children are vulnerable to a particular infection at specific age hence a potentially life threatening infection can be averted. All vaccines undergo efficacy and safety trials before making it available to general population. This ensures vaccine safety and children's health.¹⁶

Vaccine reactions or vaccine related problems may be classified as minor and severe reactions. Ideally all vaccines cause minor reactions and are an immune response of the individual to a vaccine. These reactions usually occur within a day or two after vaccination. Measles vaccine is associated with rash six to twelve days after injection. These may persist from one to a few days. The reaction can be local (on site) and systemic response. Sometimes the components added to a vaccine to increase its efficacy and stability can also trigger reactions. Vaccine is considered to be effective and safe when it induces minimum immune reaction while providing maximum immunity.

Seizures, excessive crying, thrombocytopenia and hypotonic responsive episodes (HHE) are some of the severe side effects of vaccination. All these need to be reported to the doctor/nurse. Most severe vaccine reactions do not cause long-term problems. Severe allergic reactions (e.g. anaphylaxis) can be fatal. It can be potentially fatal but is treatable without having any long term effect on the child's health. Health professionals providing vaccinations should be aware signs and symptoms of allergic reactions and be prepared to take action in case of any eventuality. The caregiver accompanying the child must also be informed of these potential problems.¹⁷

Vaccine related problems can be *serious* or *severe* however, there is a difference between the terms "*serious*" and "*severe*" adverse events or reactions that we need to be aware of. A *serious* adverse event or reaction denotes any unexpected medical occurrence that at any dose results in death, requires immediate hospitalization or prolongs existing hospitalization. It can also lead to life-threatening situation and can cause significant persistent disability. Whereas a severe reaction includes severe reactions, but also other reactions that are severe but

do not necessarily lead to long term problems.¹⁶ According to vaccine safety and surveillance for adverse events following immunization in India The number of the reported serious AEFIs(adverse events following immunization) are still far less than the expected numbers. It also reiterated that vaccine hesitancy and confidence of parents in vaccines are some of the issues that need to be addressed.¹⁸

World Health Organization maintains that nurses and other health providers have an important role in effective communication with the parents and stakeholders regarding immunization. They also establish and maintain a practice-wide commitment to providing parents with educational materials. Nurses also ensure availability to answer their questions and making sure that families take right decision keep vaccine appointments.¹⁹

Role of health professionals and factors affecting parents' decision making.

Strengthening the parents and significant family members are the key targets for achieving important objectives of improving vaccination coverage, creating awareness, reducing hesitancy and many other issues. Their experiences of vaccination are important and to address all these problems as they also experience anxiety. In study regarding parental anxiety it was found that parents who complied with childhood vaccination schedule were found to be more anxious. A strong recommendation from a health care provider is the single most important factor in determining whether or not someone gets vaccinated. People want clear and consistent information about vaccines. As the cause of vaccine- related parental anxiety varies, targeted education is necessary to relieve common causes of vaccine anxiety, even among parents who vaccinate.²⁰

Parental perspectives of vaccine safety and experience of adverse events after immunization were studied. It was reported that 41% children had experienced an AEFI. Risks of febrile convulsion and anaphylaxis as accepted by the parents were 73% and 76% respectively. Mothers were found less accepting of the vaccine risks as compared to fathers. The study recommended that parents should be able to differentiate an expected event from an adverse event. This can improve reporting of adverse events by caregivers.²¹

Trust and experience of caregivers was further highlighted in a study related to HPV vaccination among adolescents. The investigator concluded that parents trust in health professionals and previous experience related to vaccination are related to their acceptance of a new vaccine. These results suggest that health care providers should focus on parents' concerns and who have a history of non-compliance or vaccine refusal. Information regarding vaccination should be propagated as disease prevention strategy.²²

A yet another study done used online surveys to investigate vaccine information sources of parents and to determine factors associated with their trust of information. Paediatricians were the most trusted source i.e. 76%. Other health care providers were trusted by 26% , government vaccine experts/officials by 23%, and family and friends (15%). Only 2% of the respondents trusted celebrities while 76% of the respondents did not trust them at all. Gender and race/ethnicity significantly affected the level of trust in vaccine information source.²³

Parental beliefs and attitudes toward childhood vaccination were explored through a systematic review. Several barriers related to vaccination were also identified. In more than 50% studies the respondents identified fear of pain and side effects of vaccines as the main concern. Many also believed that vaccination can be withheld in case of child's illness, lack of proper communication with the staff, and low level of awareness regarding vaccination schedule deter vaccination.²⁴

A qualitative study on maternal perception of severity, benefits and barriers to vaccination revealed subjects experience of vaccine related problems shocked them and caused them to delay further vaccination. Mothers also responded that for good decision making they needed to be well informed and have convincing information. They also expressed concern that their version of seriousness of vaccine related problems was not taken into account by health professionals and hence felt that their decision making abilities regarding vaccination of their children was not recognised.²⁵

Determinants of negative attitude towards future vaccinations among educated parents and health care workers was studied in a research. Lack of specific

knowledge was identified as a modifiable determinant. The researcher suggested targeted health education regarding vaccination of parents by health workers to overcome negative attitude.²⁶

According to Centre for Vaccine development there are barriers to vaccination from health professionals and also from the parents. Where health professionals had barriers like lack of knowledge and training, parents reported barriers like poor knowledge about vaccinations, concern about vaccine safety, or lack of transportation. Parents also had some misconceptions about vaccines. Some parents believed that giving a number of vaccines on a single event can weaken their child's immune system or may cause chronic illnesses. The author recommended that accurate information about the benefits and adverse events associated with immunization.²⁷

In an Indian study conducted among anganwadis, among the several reasons for partial immunization of children, lack of knowledge among mothers regarding vaccination schedule, vaccines preventable diseases and lack of effective communication with health personals were recognized as the main reasons.²⁸ In an another study conducted in both urban and rural areas, mothers were identified as the main decision makers regarding immunization of the child. The mothers 'source of information regarding vaccination was hospital among those from urban areas and the anganwadi worker in rural areas.²⁹

A randomized controlled trial was done in U.P state of India, the investigator summarized in his study that messages to the mothers on the benefits of vaccination can be a very cost-effective means of improving child health. This can increase immunization coverage among the unvaccinated or partially vaccinated children.³⁰

Mothers need to have information related to vaccination of their children. These needs are immediate and deferred depending on the order of birth. A study was conducted related to mothers' knowledge and information needs relating to childhood immunizations. It compared information needs of mothers who had first experience to those who already had children. The researcher concluded that mothers with one child had more information needs, while information needs were deferred

among mothers with two or more children. The main sources of vaccine information were doctors and nurses. The need for more literature was felt to determine which nursing interventions work best to satisfy a mother's information needs.³¹

Immunization prevents numerous infectious diseases in children and is an important even in the life of a child and also the mother/caregiver. It is important that in this regard the best decision is made by the caregivers regarding the need, frequency and on how to manage a child after vaccination. Knowledge regarding adverse and severe events is also important. Every international agency in the field of paediatrics has recognized and recommended empowerment and enabling of mothers and caregivers for effective management of children eligible for vaccination. It is also the duty of health professionals to make use of opportunities available to educate this population and for this we have to come out with a strategy to fulfil the existing communication gap and improve vaccination coverage also. Keeping all this mind the present study was planned to address all these issues.

Research statement

“A study to develop and evaluate the effectiveness of a need- based, interventional package on awareness and self-efficiency of primary caregivers in care of children during primary immunizations in selected health facilities.”

Research Objectives

Primary objectives

1. To explore the existing gaps between awareness and practices of primary caregivers related to vaccine related problems and their management
2. To develop and validate need based interventional package for primary caregivers in managing the children during primary immunizations.
3. To assess the effectiveness of need based interventional package in terms of awareness and self-efficiency of primary caregivers in managing the children during primary immunizations.

4. To determine the rate of occurrence of vaccine related problems.
5. To determine immunization compliance.

Secondary objectives

1. To determine the association of vaccine related problems with the selected variables of the children.
2. To determine the association of socio-demographic variables of the primary caregivers with their vaccination compliance.

Research hypothesis

All hypotheses were tested at 0.05 level of significance.

- **H₁** - There would be significant increase in the level of awareness of primary caregivers regarding management of children during primary immunizations in the interventional group compared to those in the control group after implementation of need based interventional package.
- **H₂** - There would be significant increase in the self-efficiency of primary caregivers regarding management of children during primary immunizations in the interventional group compared to those in the control group after implementation of need based interventional package.

Operational definitions

- **Need based interventional package-** is a written document consisting of information regarding immunization, schedule, indications, importance, vaccine related problems and home based methods to manage them.
- **Effectiveness-** is measured by increase in the awareness and self-efficiency scores of primary caregivers after implementation of need based interventional package in the interventional group.
- **Awareness-** is the level of knowledge the primary caregivers possess regarding the immunization as measured by a structured questionnaire.

- **Self-efficiency**- is the expressed ability/confidence of primary caregivers to manage vaccine related problems and perform care activities for the child as measured by primary caregivers self-efficiency scale.
- **Primary caregivers** - is a family member, parent or any other significant care provider of the child.
- **Primary immunization**- includes the series of vaccines that the infant receives during first year of life namely, BCG, OPV HepB, Pentavalent, Rotavac, PCV, FIPV measles and rubella.
- **Immunization compliance** – includes both uptake and timeliness of childhood immunization according to National immunization schedule.

Assumptions

- The sample is true representative of the population.
- The primary caregivers' responses to study tools are true.

Delimitations of the study

The study has the following delimitations-

- The study was conducted on literate primary caregivers who could read and write.
- Primary caregivers of children undergoing primary immunization from birth were enrolled.
- Primary caregivers visiting the selected health facility were included in the study.

Conceptual framework

The investigator's belief in this research found its base in Health belief Model (HBM). HBM was first proposed by social psychologists, Hochbaum and Rosenstock in 1950s after the U.S. government faced failure in getting peoples participation in preventive and curative programs. The model was then proposed to

explain people's behaviour to symptoms, diagnosed illness and adherence to medical regimen. HBM contains primary concepts that explain why people will take preventive action, screen themselves for diseases or seek cure. The concept of self-efficacy was added in 1988(Strecher & Rosenstock)³² These are-

- Susceptibility
- Seriousness
- Benefits and barriers to an action/behavior.
- Cues to action
- Self-efficacy

Table 1: The key concepts, their definition and application in the current study

Concept	Definition	Application
Perceived susceptibility	Belief about the chances of experiencing a risk or getting a condition or disease	Children are inherently at risk of illness due to vaccinations. The manifestations and their severity varies among children. There is no predictability about whether the child will have vaccine related problems or allergies.
Perceived severity	Belief about how serious a condition and its sequelae are	Mothers/caregivers are generally not aware of side effects and allergies and the severe reactions the child can have and need more understanding.
Perceived benefits	Belief in efficacy of the advised action to reduce risk or seriousness of impact	Enabling caregivers/mothers to differentiate a normal from an abnormal reaction reduces stress and anxiety. No cost is involved. Avoids unnecessary hospital visit and hospitalization.

Perceived barriers	Belief about the tangible and psychological costs involved to adopt the advised action	Correction of misinformation, identifying barriers via methods like focus group discussions to identify the information needs of the caregivers.
Cues to action	Strategies to activate “readiness”	Devising an interventional tool that incorporates information to help caregivers take action.
Perceived threat	Combination of perceived susceptibility and severity	Modified by individual beliefs and modifying factors
Self-efficiency	Confidence in one’s ability to take action	The caregivers can perform care functions efficiently and manage the child better during sick days. Empowering the caregivers/mothers by providing information on how to care for, when to seek help of doctor. Identifying serious signs/symptoms can help manage child’s illness and improve self-efficiency of caregiver.

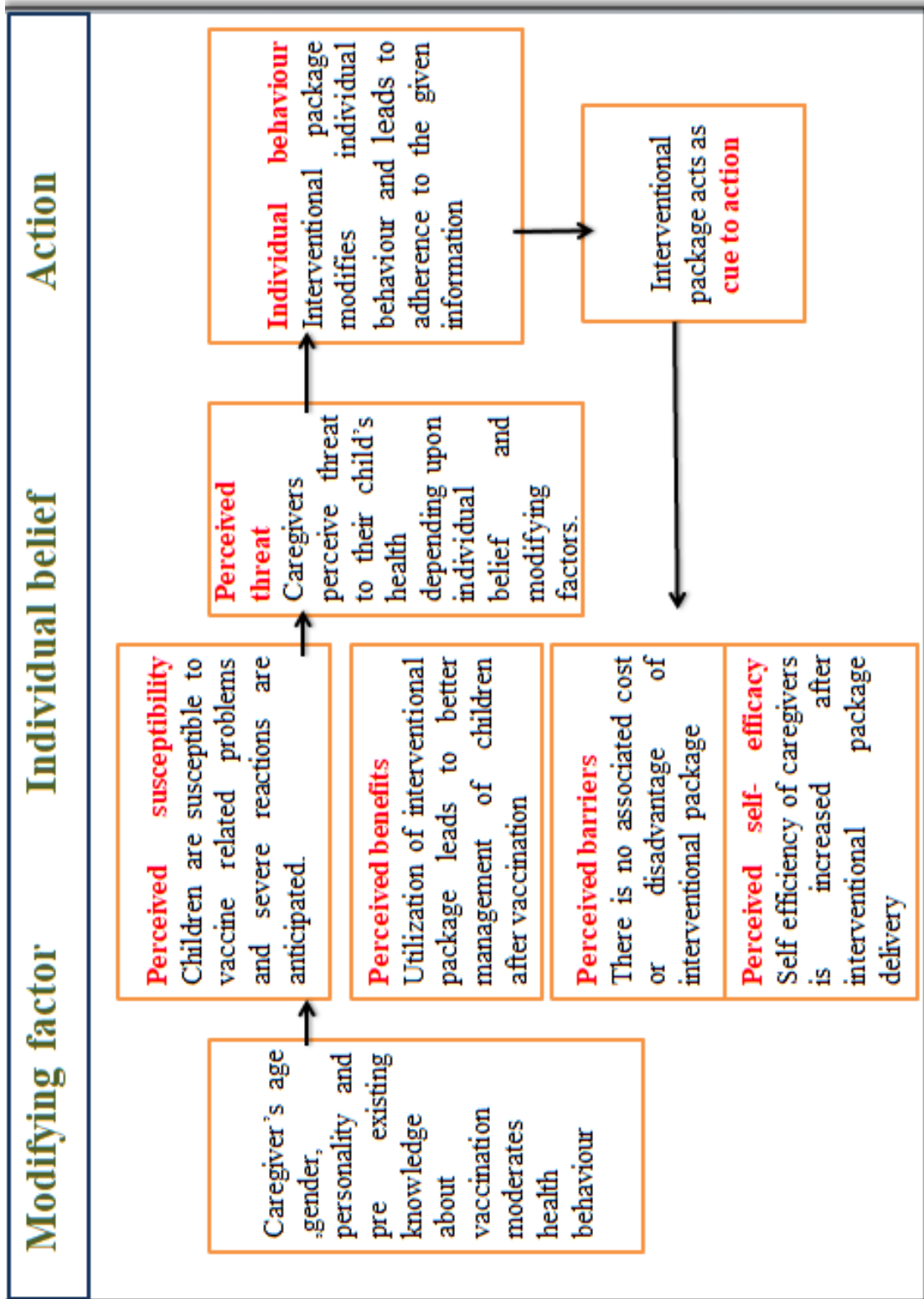


Figure1. Health Belief Model by Rosentock & Strecher (1988)

The interventional package is a multifaceted approach that works on modifiable factors like awareness of the caregivers, their beliefs that include enhancing their perceived self-efficiency and also providing cues to action. All these approaches lead to better management of the child during and after the vaccination event.