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Chapter: 1

An Overview of Routine Immunization

1.1 Introduction: The famous quotation "Prevention is better than cure" by *Desiderius Erasmus* is true for all situations and more so in health. .Immunization against childhood diseases such as Diphtheria, Pertussis, Tetanus, Polio and Measles is one of the most important means of preventing childhood morbidity and mortality. Despite the low cost of basic childhood immunizations, thousands of children still die each year from vaccine-preventable diseases. Immunization is a health output with a strong impact on child morbidity, mortality and permanent disability. The usefulness of immunization coverage is not simply as a measure of the implementation of one health intervention, but as a proxy for the overall performance of the health system to support priority health interventions (Eduard Bos, 2000). This chapter tries to elicit the history of immunization, global initiative on immunization, global coverage on child immunization, initiation of routine immunization in India, immunization coverage levels in India and Andhra Pradesh, Andhra Pradesh initiative on strengthening of routine immunization and rational behind the selection of the topic. It also gives the organization of the thesis at the end of this chapter.

1.2 History of Immunization: The origin of smallpox as a natural disease is lost in prehistory. It is believed to have appeared around 10,000 BC, at the time of the first agricultural settlements in Northeastern Africa. It seems plausible that it spread from there to India by means of ancient Egyptian merchants. Smallpox was reported in ancient Asian cultures - Smallpox was described as early as 1122 BC in China and was also mentioned in ancient Sanskrit texts of India (Hopkins D.R., 1983). The earliest evidence of skin lesions resembling those of smallpox was found on faces of mummies from the time of the 18th and 20th Egyptian Dynasties during 1570–1085 BC.(Lyons AS, 1987). The concept of immunization, or how to artificially induce the body to resist infection, received a big boost in 1796, when physician Edward Jenner inoculated a young boy in England and successfully prevented him from getting Smallpox. Prior to this in and around 10th century sporadic attempts were made in Central Asia Region to induce resistance against Smallpox by inhaling virus dust or

by making number of pricks through skin. The first systematic effort begun from 1798 onwards to control a disease through immunization, after the success of variolation with cowpox virus against Smallpox came in to light by Edward Jenner.

Box: 1.1 How Vaccines Protect People:

Vaccines protect people from fatal diseases, increase life expectancy and spare countless millions from pain and suffering. A vaccine is formally defined as 'a preparation of killed, weakened, or fully infectious microbes that are given to produce or increase immunity to a particular disease'.

Most people have some amount of natural immunity. The human body can take care of itself in many circumstances—cuts, colds, and minor infections disappear without major upheaval. In other cases, the body has little or no naturally occurring immunity, so if you are exposed to diseases such as polio, influenza, smallpox, hepatitis, diphtheria, measles, or whooping cough, you will probably get sick with it, unless you have been immunized. Immunization refers to the artificial creation of immunity by deliberately infecting someone so that the body learns to protect itself. An important part of the history of immunization has been determining how to get the immunizing agent into the body. The skin, which keeps germs and mischievous substances out, is also a barrier to getting medicines and vaccines into the tissue where they can work. Physicians have used varying methods to create immunity where there is none.

Latter in 1885, Louis Pasteur developed the first vaccine to protect Humans against Rabies. Pasteur's success opened the door to the field of immunobiology. Subsequently some more vaccines for diseases like Diphtheria, Typhoid, Cholera, Plague and Tuberculosis (TB), were also developed in the 19th century. The development of the Polio vaccine in 1955 and vaccines against Measles and Mumps in 1960s had a radical impact on the use of vaccines *(Appendix: XI)*. India launched a massive public health campaign called 'Operation Smallpox Zero' in the early 1970s.The last case of smallpox occurred in India in May 1975 (Basu *et al*, 1979)

Despite the success of smallpox eradication, still many vaccine preventable diseases (VPD) persist, especially in developing countries. Polio, Measles and Rubella are still threats to millions of children and adults worldwide. In addition to this many Viral Diseases - Hepatitis, Human Immune Virus (HIV) /Acquired Immune Deficiency Syndrome (AIDS), Sub Acute Respiratory Syndrome (SARS), Swine

influenza etc appeared suddenly in recent times in many parts of the world which needs effective immunization. Hence the invention of new vaccines and new technologies for vaccine delivery are so vital. Until there are effective vaccines, these unexpected diseases will continue to affect human populations around the world.

Box: 1.2 How vaccines work

Vaccines typically provide the immune system with harmless copies of an antigen: a portion of the surface of a bacterium or virus that the immune system recognizes as "foreign." (An antigen often plays a role in causing disease — for example by enabling a virus or bacterium to attach to cells.) A vaccine may also provide a non-active version of a toxin — a poison produced by a bacterium — so that the body can devise a defense against it.

Once an antigen is detected by the immune system, white blood cells called B-lymphocytes create a protein called an antibody that is precisely designed to attach to that antigen. Many copies of this antibody are produced. If a true infection of the same disease occurs, still more antibodies are created, and as they attach to their targets they may block the activity of the virus or bacterial strain directly, thus combating infection. In addition, once in place, the antibodies make it much easier for other components of the immune system (particularly phagocytes) to recognize and destroy the invading agent.

Immune systems are designed to "remember" — once exposed to a particular bacterium or virus, they retain immunity against it for years, decades, or even a lifetime — and so are prepared to defeat a later infection, and to do so quickly. This ability and the speed with which it occurs is a huge benefit: a body encountering a germ for the first time may need from seven to 12 days to mount an effective defense, and by then serious illness and even death may occur(WHO,2005[1]).

http://www.who.int/mediacentre/factsheets/fs288/en/index.html dt.7/4/08

1.3 Global Initiative on Immunization: The public health experience in organizing Smallpox Prevention gave birth to one notable programme - 'the Expanded Programme of Immunization' (EPI) in 1974. This global Expanded Programme of Immunization initiated by the World Health Organization (WHO) and United Nations International Children Emergency Fund (UNICEF) was termed by many as the silent public health revolution of twentieth century. When the EPI was launched in 1974, less than 5 per cent of children below five years of age in developing countries were

being immunized against major childhood diseases. Nearly 5 million young children used to die every year due to Measles, Tetanus, Whooping Cough, Diphtheria, Tuberculosis, and Poliomyelitis –childhood diseases that could be prevented by simple and effective immunization. With the experience following successful Smallpox eradication, the WHO/UNICEF promoted the EPI to immunize globally 80 per cent of all children of less than 2 years of age by the end of 20th century (Roger Detels *at al*, 2002). Until the early 1980s, this Universal Childhood Immunization goal seemed impossible to many countries. Nevertheless, concerted efforts were made by many developing countries in the 1980s and 1990s have resulted in remarkable success. Global Alliance for Vaccines and Immunization (GAVI) created in the year 2000 through a Public – Private Partnership (PPP) to save children's lives and to protect people's health by increasing access to immunization in poor countries.

Box: 1.3 Commonly used vaccines

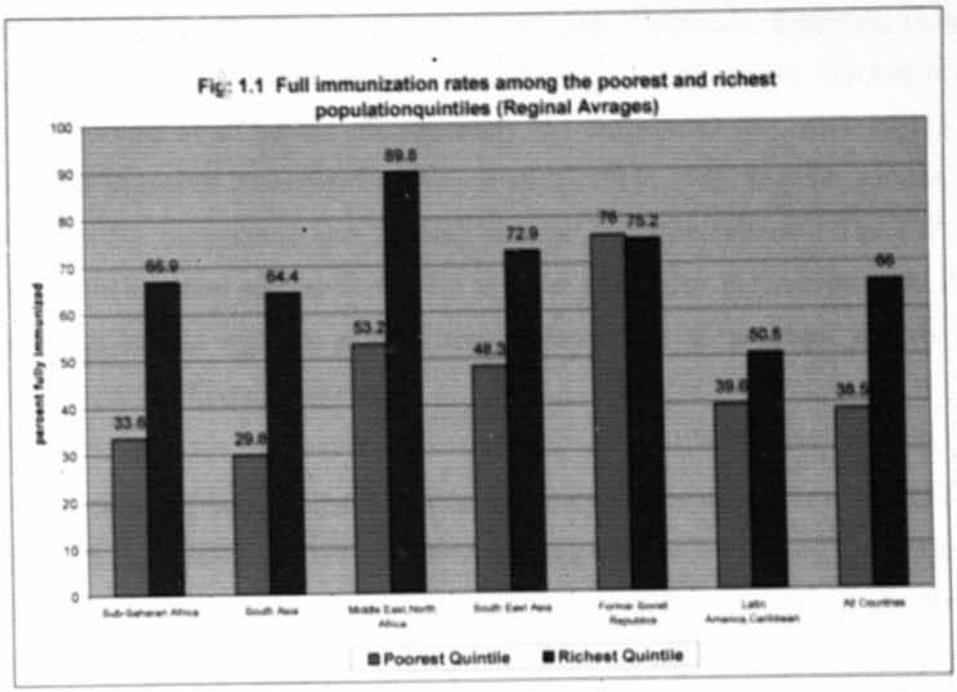
Routine vaccination is now provided in all developing countries against measles, polio, diphtheria, tetanus, pertussis, and tuberculosis. To this basic package of vaccines, that served as the standard for years, have come new additions. Immunization against hepatitis B is now recommended by WHO for all nations, and currently is offered to infants in 147 of 192 WHO Member States. Immunization against Haemophilus influenzae type b (Hib) is recommended where resources permit its use and the burden of disease is established; it is provided in 89 countries (only in selected parts of two of those countries). Yellow fever vaccine is offered in about two-thirds of the nations at risk for yellow fever outbreaks. Routine immunization against rubella is provided in 111 countries. In industrialized countries a wider span of protection is typically provided than in developing countries, often including vaccines against influenza, predominant strains of pneumococcal disease, and mumps (usually in combination with measles and rubella vaccine). Immunization programmes may be aimed at adolescents or adults — depending on the disease concerned — as well as at infants and children.

http://www.who.int/mediacentre/factsheets/fs288/en/index.html dt.7/4/08

1.4 Global Immunization Coverage: Coverage of immunization has greatly increased since WHO's Expanded Programme on Immunization began in 1974.The Immunization coverage of each antigen was around 20 per cent in the world till 1980.

Increasing immunization coverage to prevent childhood diseases is an important developmental issue (Bryce *et al.*, 2003; DISH, 2002; WHO, 1999: 2002). It also gives scope for an area of critical research (Bozette *et al.*,2003; Drain *et al.*, 2003; Edmunds *et al.*, 2002;Fairbrother *et al.*, 1999; Hethcote, 1997; Stafford and Aggarwal, 1979; Subramanyam and Sekhar, 1987). Governments, donor agencies and projects have made a lot of contributions towards the improvement of immunization rates through the improvement of health infrastructure, financing, supplies, staffing and management of national immunization programs. Preventable childhood diseases such as measles and premature deaths still occur particularly in the developing countries due to low immunization coverage (WHO, 1999). In 1990, eighty per cent of all children in the world were successfully immunized against six major vaccine preventable diseases before they reached the age of 2 years. Immunization coverage in developing countries was estimated at 85 per cent for three doses of polio vaccine, 83 per cent for Diphtheria- Pertussis -Tetanus (DPT), 90 per cent for tuberculosis (Bacillus Calmette Guerin or BCG), and 79 per cent for Measles vaccine (WHO, 1993). However some countries reported significant declines in coverage of immunization after 1990, the global coverage levels remained fairly constant and began rising slowly. In 2006, global DPT3 (three doses of the Diphtheria- Pertussis - Tetanus- combination vaccine) coverage was reported 81 per cent. Still 26 million children worldwide were not reached by DPT3 before they celebrate their first birthday. Out of them 62 per cent of children lived in China, India, and Indonesia (Anthony Burton *et al*, 2009). Those who miss out on routine vaccination programmes tend to be people living in remote locations, urban slums and border areas. They also include indigenous groups, displaced populations, those lacking access to vaccination because of various social barriers. Constraints of health delivery systems like - a lack of needed human and financial resources; rapid turnover of trained health workers, especially at district levels; weak supervision and use of data; competing health priorities; as well as the inability of some public health programmes to fully reach very poor families and minorities are some of the reasons for failure of routine immunization coverage. Further the immunization coverage is lowest in poor countries and among poorest populations in Africa and Asia. The disproportionate vaccine coverage among rich and poor societies across the continents as estimated by Gwatikin in 2001 shows mal-distribution in vaccination services (Gwatkin, 2001). There exist wide differences in full immunization rates between the rich and poor in

all the regions except in the former Soviet Republics (*Fig: 1.1*). It seems that in Soviet Republics, Governments took greater initiative to educate and convince the poorest segment of population too, on the need of immunization for the survival and well being of children.



Source: Gwatkin & Deveshwar- Bahl (2001)

Despite some of the left over pockets, the significant achievement in vaccination coverage after 1990 was witnessed not only in the WHO Southeast Asia region but also throughout the world and was made possible due to the full support of the WHO, UNICEF, bilateral and multilateral donors, national, international and non-governmental organizations.

1.5 Routine Immunization in India: Delivering effective and safe vaccines through an efficient delivery system is one of the most cost effective public health interventions in the field of preventive medicine. Immunization programme aims to reduce morbidity and mortality, causes due to vaccine preventable diseases (VPDs). Following the successful global eradication of smallpox in 1975 through effective vaccination programmes and strengthened surveillance, the Expanded Programme on

Immunization (EPI) was launched in India in 1978 to control other VPDs. Immunization against common childhood diseases had been an integral component of mother and child health services in India since adoption of the primary health care approach and was reinforced by the declaration of Health Policy in 1983 (Suresh Sharma, 2007). Initially, six diseases were included: Diphtheria, Pertussis, Tetanus, Poliomyelitis, Typhoid and childhood Tuberculosis for immunization. The aim was to cover 80 per cent of all infants. Subsequently, the programme was universalized and renamed as Universal Immunization Programme (UIP) in 1985. Measles vaccine was included in the programme and Typhoid vaccine was discontinued. The UIP was introduced in a phased manner from 1985 to cover all districts in the country by 1990, targeting all infants with the primary immunization and all pregnant women with Tetanus Toxoid (TT) immunization.

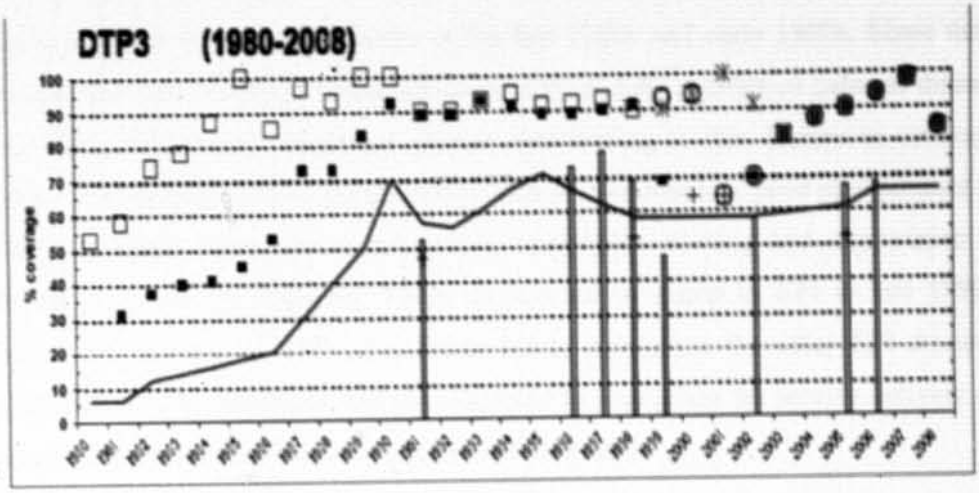
The UIP envisaged achieving and sustaining universal immunization coverage of all infants with three doses of DPT and OPV and one dose each of Measles vaccine and BCG and among pregnant women, with two doses of TT for primi and one booster dose for multi-para. The UIP also required a reliable cold chain system for storing and transporting vaccines, and attaining self-sufficiency in the production of all required vaccines. The Cold-chain system was strengthened and training programmes were launched extensively throughout the country.

In 1992, the UIP became a part of the Child Survival and Safe Motherhood Programme (CSSM) and in 1997 it became an important component of the Reproductive and Child Health Programme (RCH). Presently it is being implemented as one of the major components of National Rural Health Mission (NRHM). Intensified polio eradication activities were started in 1995-96 under the National Polio Eradication Programme beginning with National Immunization Days (NIDs) and active surveillance for Acute Flaccid Paralysis (AFP) in1997.

1.6 Immunization Coverage in India: Apart from the service statistics collected by the health department from time to time, UNICEF has also been organizing rough-and-ready rapid feedback on implementation arrangements for each round of immunization based on voluntary observer reports especially for Pulse Polio

Programme since 1995. Coverage Evaluation Surveys (CES) have been conducted by the Reproductive and Child Health (RCH) Unit of Ministry of Health and Family Welfare (MoHFW) annually as well as by All India Institute of Medical Sciences (AIIMS), International Clinical Epidemiological Network (INCLEN), Department for International Development (DFID) in 1997, the BBC Trust for WHO in 2000 and Multi Indicators Cluster Survey (MICS) by UNICEF in 2001. In addition to this National Family Health Surveys (NFHS) and District Level Household Surveys (DLHS) also provide immunization coverage statistics. There was a marginal increase in full immunization coverage between NFHS-2 and NFHS-3 from 42 per cent to 44 per cent in India. The Measles vaccine coverage had improved from 51 per cent reported in NFHS -2 to 59 per cent in NFHS-3, however no improvement in DPT3 coverage (55 per cent in both the surveys) in the above period. The percentages of full immunization differentials among the 12-23 months age group in India is ranging from 13 to 91 per cent with 46 percent of national average in DLHS -2,2004. The coverage of full immunization is less than 30 per cent in the states of Nagaland(13), Meghalaya(14), Assam(17), Bihar(23), Rajasthan(25) and Uttar Pradesh (26). It was more than 60 percent in 12 states/union territories-Tamil Nadu(91), Kerala (79), Himachal Pradesh (79), Punjab(73), Maharashtra (71), Karnataka (71) and Andhra Pradesh(63) (IIPS, 2006). The coverage of all antigens was high in DLHS-3 when compared to DLHS-2. The coverage of full immunization is also improved from 46 per cent in DLHS-2 to 54 per cent in DLHS-3. There were wide variations in coverage levels of surveyed data and reported data (WHO/UNICEF, 2008). One such example of DPT 3 coverage levels of various sources in India are shown in *Figure1.2.*

Fig: 1.2 DPT 3 Coverage in India of various sources from 1980 to 2008



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WHO/ UNICEF estimate (%)	Reported to:*		Government official estimate (%)	Reported doses administered (%)**	Survey data (%)***	
	WHO (%)	UNICEF (%)			Survey 12-23 months	Survey <12 months
——	□	■	○	✳	▯	•

*Prior to 1998 national reports to WHO/UNICEF did not specify whether information was derived from administrative records, surveys or other sources.
**Coverage based on registration of doses administered by health care providers.
***In case more than one survey was implemented in a certain year the highest value is presented. Details of all data are presented in the second section of this report.

Description of trend

Trends in officially reported data show an increase in coverage beginning in the early 1980s reflecting the phased geographic expansion of th EPI programme. In 1985 the Universal Immunization Programme, the inclusion of immunization in India's Technology Mission (one of 5 miss reporting directly to the Prime Minister) and the infusion of resources associated with the global Universal Childhood Immunization goal result rapidly increasing coverage in the late 1980s.

While official reports describe sustained high coverage following 1990, survey data suggests significantly lower coverage beginning in the lat 1980s. Coverage for 1990 & 1991 was estimated to have been 70% and 57% respectively based on an extensive sub-national Immunization Coverage Survey of 1991 and results from the 1992 National Family Health Survey (NFHS). Estimates prior to 1990 were established by calibrating the data reported to UNICEF by the 1990 estimate established by an evaluation of the 1991 & 1992 surveys.

Estimates for 1993 through 1995 are interpolated between the levels established by the 1991 and 1996 surveys. The estimates for the perio following 1995 are based on the Coverage Evaluation Surveys (CES), MICSs, and a second NFHS (1997/98) and show a marked decline in coverage during this period. The estimates for 1995-1997 are based an evaluation of the survey data. Results from previous Demographic ar Health Surveys (similar to the NFHS and MICS) suggest that coverage values based on mothers' history are affected by a recall bias for the r antigen vaccines (i.e., OPV 1,2,3 and DPT 1,2,3.) and most likely occur in longer surveys covering a variety of indicators. It does not appear a problem in surveys focused on immunization coverage such as the EPI 30 cluster surveys and the CES. To control for this bias we have adjusted the DPT3 card or history value by calculating the dropout rate from DPT1 to DPT3 based on card results and applying this multiplier the DPT1 card or history value. This adjustment may result in an overestimate since children without a card are less likely to be immunized t children with a card.

The 1996 and 1997 results of the CES seem to estimate the upper range of actual coverage. The dropout rate of 6% from DPT1 to DPT3 in t 1998/1999 CES is unusually low (dropout from the NFHS 98/99 is 13% based on card only data). The estimate of 1997 is based on an adjustment of the NFHS (1997/98) results to account for recall bias and the CES. The estimate of 62% is supported by results from the 1997 Reproductive and Child Health Survey.

The 1999 estimate is based on the MICS adjusted for recall bias. Estimates from 2000 -2002 are interpolated between the 1999 and 2002 su data. Estimates for 2000 - 2001 are interpolated between the 1999 and 2002 survey data. Review of the NFHS and CES methods suggest CI methodology may overestimate coverage. The 2003-2004 estimates are based on 2002/2004 National District Level Survey and the average between the 2005 CES and the 2006 NFHS. National data for 2004 and 2005 are for nine months only. Estimates from 2006 onward are bas the average of the 2006 Coverage Evaluation Survey results and the 2006 District Level Household Survey results.

Source: WHO /UNICEF: Review of National Immunization Coverage of India 1980 – 2008.

EPI programmes were most effective in the late 1980s and early 1990s. Since then, coverage rates have declined to around 75 per cent and the number of cases of disease is beginning to increase. Important factors contributing to this decline in coverage include weak management of programmes, lack of coordination, poor maintenance of ageing cold-chain equipment and vehicles, inadequate training and supervision of staff and poor vaccine logistics. These in turn led to slump in EPI in late 1990s. However the success of AFP surveillance led to strengthen the other EPI diseases surveillance. The Government had contemplated to strengthen the service delivery on immunization to increase the coverage as well as quality.

Service delivery systems for routine immunization need to have adequate financial, technical and managerial capabilities in order to implement the programme effectively. The impact of immunization is monitored through disease surveillance. The output of the service delivery is monitored through antigen coverage rates and drop-out rates. Complete, accurate and timely reporting of cases, antigen coverage and drop-out rates are essential for guiding disease-control activities, monitoring programme performance and directing the allocation of scarce resources.

1.7 Immunization Coverage in Andhra Pradesh: The coverage evaluation reports show better performance in Andhra Pradesh coverage levels compared to the national average in most of the immunization parameters. However the state is lagging behind in comparison with other Southern states, and a bit ahead of many of the Northern states. Full immunization of children increased from 45 per cent (NFHS-1: 1992-93) to 58.7 per cent (NFHS-2: 1998-99) and recorded a much lower performance (46 per cent) in NFHS-3: 2004-05. However the DLHS-2: 2004 conducted around the same period recorded 62 per cent of fully immunized children in 12 -23 months age group. The other antigens' coverage is more than 90 per cent except for Measles. Further research is needed to explain the lower percentage of full immunization in NFHS -3.

1.8 Strengthening of Routine Immunization in Andhra Pradesh: In recent times infection due to Hepatitis B virus became a global health problem. World Health Organization estimated, two out of every five people on earth were affected with Hepatitis B virus. Though WHO and UNICEF recommended Hepatitis B vaccination as an integral part of the National Immunization Programme, still many developing countries could not include it for various reasons. India takes initiative to strengthen routine immunization and included Hep.B vaccine in UIP in collaboration with NGOs. As such Andhra Pradesh is the first state in India that included the Hep-B vaccination in routine immunization programme under the partnership project of Govt. of Andhra Pradesh and PATH (Programme for Appropriate Technology in Health). This Project aims to introduce Hep.B vaccine in routine immunization and strengthen the routine immunization programme by introducing Auto Disabled syringes for all vaccinations and incorporating new methods, policies and procedures for a period of 5 years (2001-2006) in a phased manner.

Hep.B vaccine was introduced in routine immunization programme in Andhra Pradesh initially in 6 districts in phase I (Nov.2001), another 6 districts in Phase II (Nov.2002) and remaining 11 districts in Phase III (Nov.2003) by the Govt. of AP and PATH Partnership Project under the strengthening of routine immunization initiative. Simultaneously 'Service Delivery Support' (SDS) intervention also initiated to strengthen the Routine Immunization Programme. Service Delivery Support is a managerial programme intervention. Research on the impact of SDS on immunization is vital for continuity or for further interventions. Hence, there is a need to study the impact of Service Delivery Support on immunization.

East Godavari District was included in the last phase of SDS programme in Nov.2003. With the introduction of this interventional programme all the infants in the district started receiving Hep.B vaccination along with DPT and OPV. In addition to this Auto Disabled syringes were also introduced for vaccine administration. (East Godavari District profile was given in the chapter: 8)

Service Delivery Support intervention through the Medical College Faculty came up in the district in August 2004 based on the experiences consolidated in other partner medical colleges in the state which had already taken part in the system.

1.9 Rationale behind the Selection of Topic: The Service Delivery Support intervention is an innovative approach in the field of immunization particularly in India and the Researcher is fortunate enough being one among the team of Medical College Faculty which was involved in Service Delivery Support intervention, right from the beginning of project. The dedicated involvement in the activity motivated him to make an attempt to find out the impact of Service Delivery Support intervention in terms of improvement over the selected parameters and its sustainability in East Godavari District of Andhra Pradesh. More over a lot of inputs (technical, managerial and financial) were involved in this interventional programme. There has been no detailed study in assessing the impact of SDS on programme in a scientific manner. Hence the findings of this study would help the researchers, policy makers, administrators and service providers to make suitable plan of action to achieve the intended objectives in particular and national goals in general, in the field of immunization.

1.10 Organization of Thesis: The first chapter dealt with the history of immunization, evolution of UIP, immunization coverage at different levels and rational behind the selection of topic etc.

Chapter two describes the concept of Service Delivery Support, the need of the supportive supervision and how the intervention takes place in Andhra Pradesh.

Chapter three presents the review of literature on programme interventions and coverage of immunization.

Chapter four deals with methods and materials, which include the objectives of study, study design, sampling, instruments used in data collection, various hypotheses expected from the study, limitations of the study and some of the operational definitions used in this study.

Chapter five describes the initiation of Service Delivery Support intervention and analysis of benchmark data of East Godavari District.

Chapter six discusses the 'Service Delivery Support' interventional impact on various parameters of Routine Immunization Programme.

Chapter seven describes the sustainability of SDS impact on field practices and feedback from the service providers.

The coverage evaluation of immunization on selected background characteristics and determinants of immunization is presented in chapter eight.

Summary and Conclusions are presented in chapter nine. Some policy recommendations and areas for further research are also given..

Box: 1.4 Types of vaccines

Vaccines come in different forms. The injected polio vaccine is a killed, intact virus; the oral polio vaccine is a live, weakened virus. The vaccine for typhoid is a killed, intact bacteria. Vaccines for measles and the other standard "childhood" diseases — mumps, chickenpox, and rubella — are live, attenuated (or weakened) viruses. Vaccines for diphtheria and tetanus consist of toxins that have been "inactivated." Influenza vaccines often consist of killed, "disrupted" viruses (that is, the proteins on the coat of the virus have been released into a solution by solvents). Vaccines against Hib, pneumococcal disease, and meningococcal disease consist of highly purified complex sugars taken from bacterial coats or capsules. Vaccines are frequently administered as combinations of antigens. The most widely used combinations are diphtheria-tetanus-pertussis (DTP); diphtheria-tetanus-pertussis-hepatitis B (DTP-HepB); pentavalent vaccine: diphtheria-tetanus-pertussis-hepatitis B-Hib; and measles, mumps-and-rubella (MMR). http://www.who.int/mediacentre/factsheets/fs288/en/index.html dt.7/4/08

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