# 50 years of Immunization in India: Progress and Future

#### VM VASHISHTHA AND PKUMAR

From Mangla Hospital & Research Center, Bijnor, Uttar Pradesh; and \*Kumar Child Clinic, Dwarka, New Delhi; India. Correspondence to: Dr Vipin M Vashishtha, Director and Consultant pediatrician, Mangla Hospital and Research Center, Shakti Chowk, Bijnor, Uttar Pradesh, 246 701, India. vmv@manglahospital.org.

Immunization is one of the most cost effective public health interventions and largely responsible for reduction of under-5 mortality rate. However, vaccine preventable diseases (VPDs) are still responsible for over 5 lakh deaths annually in India. This underlines the need of further improvement. Today, India is a leading producer and exporter of vaccines, still the country is home to one-third of the world's unimmunized children. There are a number of reasons why India lags behind its many less developed neighbors in vaccination rates. They include huge population with relatively high growth rate, geographical diversity and some hard to reach populations, lack of awareness regarding vaccination, inadequate delivery of health services, inadequate supervision and monitoring, lack of microplanning and general lack of inter-sectoral coordination, and weak VPD surveillance system. In this article, we discuss some of the remedial measures to remove obstacles and improve immunization status of the country. Heightened political and bureaucratic will, increasing demand for vaccination by using effective Information, education and communication (IEC), creating more 'delivery points' for routine immunization, proper monitoring of the ryPD reduction' and 'demand creation' referred as the 'output' of entire vaccination program. Successful AFP surveillance network should serve as platform for an efficient integrated disease surveillance system. AEFI and postmarketing surveillance systems should be urgently upgraded, and there is need of strengthening the regulatory capacity of the country. Restructuring of EPI with induction of some new vaccines, clear-cut guidelines on the policy of introduction of newer vaccines, and establishing a separate, independent department of public health are few other areas that need urgent attention.

Key words: Immunization, Vaccine preventable diseases, VPD surveillance.

mmunization is one of the most cost effective public health interventions since it provides direct and effective protection against preventable morbidity and mortality. It has been a major contributor in the decline of under-5 mortality rate from ~ 233 to ~63 (per 1000) in last five decades in India [1]. However, vaccine preventable diseases (VPDs) are still responsible for over 5 lakh deaths annually in India. This underlines the need for further improvement. India, along with many developing countries, is lagging behind in sufficient coverage of Routine Immunization (RI). According to World Health Organization (WHO)/UNICEF estimates, DTP3 coverage in the South-East Asia and Africa regions of WHO for 2010 remained relatively low at 77% [2]. In India, the coverage was even lower at 61% [3]. Thus, the SEA Regional Director declared 2012 as the Year for Intensifying RI in the Region [2]. This was endorsed by Government of India (GoI) and 2012 was declared as the Year of Intensification of RI in India also [3].

This perspective summarizes the history, achievements, roadblocks and future of immunization in India.

#### THE STORY SO FAR

India and China were two countries where "some form of inoculation" was practiced even before 16<sup>th</sup> century [4].

However, modern immunization developed in India in 19<sup>th</sup> century, parallel to the Western world. Initial years saw considerable investment in research and development (R&D) in vaccines and about fifteen vaccine institutes were established beginning in the 1890s. World's first plague vaccine by Haffkine (in 1897) and Manson's development of an indigenous cholera vaccine were the most notable achievements of these institutes. However, the benefits of this early institutionalization did not last long. By the time Indians inherited the leadership of the above institutions (from Britishers), research and technological innovation was sidelined as demands for routine vaccine production took priority [5].

By early 1970s, many childhood diseases had almost disappeared from developed countries. These diseases, however, continued to take many lives in poorer countries. In fact, in 1974, fewer than 5% of children, worldwide were immunized by age 1 against diphtheria, polio, tuberculosis, pertussis, measles, and tetanus [6]. That is why WHO launched the Expanded Programme on Immunization (EPI) in 1974 to bring vaccination against these six diseases to many underserved areas.

India, on its part, launched its first vaccine exactly 50

years back: BCG in 1962 [7] as a part of National Tuberculosis Program. EPI was launched in India in 1978. Initially, it included BCG, DPT (3 doses) and typhoid vaccine; OPV was added the next year. In addition to 3 primary doses of DPT and OPV, 2 boosters at 1.5 years and 5 years were also given to cover children upto 5 years of age. Achieving self-sufficiency in production of vaccines was also a part of program. In 1985, the program was converted into Universal Immunization Program (UIP) with a lofty goal to cover 'all' eligible children in the country, immunization of 'all' pregnant women with TT and to improve quality of services. Although the first booster of DPT was retained in UIP, the second booster at 5 years was reduced to DT (pertussis component was omitted). In the same year, measles vaccine was added at 9 months of age, but typhoid vaccine was dropped from the program [8]. In next 2 decades, there were lots of administrative changes in UIP: It was given status of National Technology Mission in 1986 to give a sense of urgency and commitment in achieving the goals; then it was made part of Child Survival and State Motherhood (CSSM) programme in 1992 and Reproductive and Child Health (RCH) programme in 1997 [9]. However, the focus remained on 4 vaccines (BCG, DPT, OPV and Measles) and 6 diseases only. It was only after 2006 that new vaccines like hepatitis B, second dose of measles and Japanese Encephalitis vaccines were introduced [10]. Hepatitis B vaccine was initially introduced in 10 states and then extended to whole country [11]. The Japanese encephalitis vaccine has been introduced in 111 districts in 15 States having a high disease burden [11]. In December 2011, pentavalent vaccine (containing vaccine against diphtheria, pertussis, tetanus (DPT), Hepatitis B and Haemophilus influenzae type B (HiB)) was introduced in two states with high coverage of RI: Tamil Nadu and Kerala [12]. Recently, the Government has decided to introduce it in 6 more states: Gujarat, Karnataka, Haryana, Goa, J&K and Pondicherry [13].

In 1988, the GoI committed the nation to the goal of global polio eradication, along with all 192 member nations of the WHO (14). Pulse Polio Programme (PPP) was started initially in Delhi in 1994 and was extended to the whole country in 1995. In 1994 and 1995, children up to 3 yrs of age were covered. From 1996-97 onwards, all children up to 5 years of age are being covered under this program. House to house component was added in 2000-01 as a part of intensification of Pulse Polio Programme. The National Polio Surveillance Project (NPSP) was launched in 1997 to provide technical and logistic assistance to the GoI and work closely with state governments and a broad array of partner agencies to

50 YEARS OF IMMUNIZATION IN INDIA achieve the goal of polio eradication in India [15]. The efforts yielded good results: Number of polio cases reduced from about 35000 in 1994 to just 741 cases in 2009. Use of monovalent OPV, and later bivalent OPV (1and 3) [11] in the pulse polio rounds has paid rich dividends. The last case of polio due to wild virus was reported on 13<sup>th</sup> January, 2011 from West Bengal. India has been polio free for more than a year and was removed from the endemic countries list on February 25, 2012 by the WHO [14].

Recently, 11 centers across the country have been identified for laboratory supported surveillance for vaccine preventable diseases with special reference to potential vaccines in collaboration with the Indian Council of Medical Research (ICMR) [11]. In another recent initiative, name and telephone based tracking of pregnant mothers and children through a web enabled system has been introduced. The initiative intends to make sure that all pregnant mothers and children receive full continuum of care including complete vaccination [11]. India has also joined the global post-marketing surveillance network for reporting adverse event following immunization (AEFI) associated with new vaccines and Maharashtra is the participating state [16].

Efforts are also on to improve health infrastructure in the country: key to optimize the implementation of UIP. National Rural Health Mission (NRHM) was launched in 2005 to re-vitalize the primary health care systems for the benefit of the people living in rural areas, particularly in difficult, inaccessible and remote parts of the country. Since the launch of NRHM in 2005, more than 15 billion dollars have been provided to the States in addition to their budgets, for strengthening health systems and infrastructure with key focus on reproductive and child health, including immunization [11].

Availability of new safe and effective vaccines against major killers like diarrhea and pneumonia necessitated serious deliberations on further strengthening of National Immunization Programme. The Ministry of Health and Family Welfare formulated *National Vaccine Policy* in April 2011 to provide broad policy guidelines and framework to guide the creation of evidence base to justify need of research and development, production, procurement and quality assessment of vaccines under UIP [10].

# Current Status of RI in India

After putting up a good show in its first decade (1985-95) with coverage of RI reaching 70-85%, there has been deterioration in the performance of UIP [17]. The coverage of different vaccines has fallen by 15 to 20%.

Surveys carried out during National Family Health Survey (NFHS) I, II and III and by independent agencies such as UNICEF, have revealed that the coverage levels may be lower by as much as 15-40% compared to reported levels of coverage in the UIP [17,18]. Indeed, there are a few states in India that have efficiently running UIP and several that do not.

According to the most recent Coverage Evaluation Survey (CES), a nationwide survey covering all States and Union Territories of India, conducted during November 2009 to January 2010 by UNICEF, the national fully immunized (FI) coverage against the six vaccines included in UIP in the age-group of 12-23 month old children is 61% whereas it was 54.1% and 47.3% as reported by District Level Household and Facility Survey (DLHS-3) (2007-08) and NFHS-III (2005-06), respectively [18-20]. Regarding coverage of individual antigens in the similar age group, the CES 2009 reported BCG, OPV and DTP3 doses coverage, and measles first dose coverage as 86.9%, 70.4%, 71.5%, and 74.1%, respectively [19]. The corresponding figures cited by DLHS-3 and NFHS-3 were 86.7%, 66%, 63.5%, and 69.5%, and 78.1%, 78.2%, 55.3%, and 58.8%, respectively [18, 20]. As far as newer antigens are concerned, the 3 doses of Hepatitis B vaccine coverage among children 12-23 months in 16 States/UT where it is part of UIP evaluated to be 58.9% by CES 2009 [19]. However, birth dose administration is still a challenge in all these states. About 7.6% of children between the ages of 12-23 months have not received any vaccine [19].

There is a large inter-state variation in the coverage of RI. As per CES 2009, there are 4 states (Goa, Sikkim, Punjab and Kerala) >80% of children between 12-23 months of age are fully immunized. This percentage is < 50% for another 5 states (Bihar, Madhya Pradesh, UP, Nagaland and Arunachal Pradesh) [19]. Six states with high population contribute to 80% of 8.1 million unimmunized children in the country, 52% of the total unimmunized children reside in Uttar Pradesh and Bihar alone [21].

#### WHERE ARE WE LACKING?

#### The barriers to achieve 100% immunization coverage

There are a number of reasons why India lags behind its per capita GDP counterparts in vaccination rates (compare to Bangladesh, where 82% of children are fully vaccinated by age two). *Huge population with relatively high growth rate* is a barrier in itself. Approximately 27 million children are born in India each year – the largest birth cohort in the world – but less than 44% receive a full schedule of vaccinations [22]. To reach each and every one of such a huge cohort every year is obviously a daunting task. Geographical diversity (snow bound/ hilly areas, deserts, tropical forest areas, remote island territories), cultural diversity (with various religions, languages, traditions, beliefs and customs) and Political instability ("coalition" governments, "politically sensitive areas" like Naxal/terrorist-affected areas) are some problems that are rather unique to India and make the task more complex. Reaching out to mobile/migrant population (that is a significant proportion of population in some states) is another challenge. Special efforts are needed to identify and reach some pockets of low immunization that are still there in many states.

Coverage Evaluation Survey of UNICEF [19] found that reason for partially immunization/ non-immunization was "did not feel the need", "not knowing about the need" and "not knowing where to go for vaccination" in 28.2%, 26.3% and 10.8% cases. This means that lack of awareness is one great barrier to achieve cent percent immunization coverage. A more recent study in 225 villages of Uttar Pradesh corroborated the fact that lack of awareness is the one of the main reason for partial immunization/ non-immunization [23]. Hence, the demand for vaccines also suffers. Low levels of education negatively impact health-seeking behavior. In addition, adverse events following immunization (AEFI) even when these are shown to be unrelated to a vaccine, have been widely reported in the media and have contributed to a culture hostile to vaccination in certain communities [22].

Apart from the above mentioned barriers, there are some other issues on "supply side" that pose challenges to achieving high RI rates. They include inadequate delivery of health services (supply shortages, vacant staff positions, lack of training); lack of accountability, inadequate supervision and monitoring; lack of microplanning at district level; general lack of inter-sectoral coordination and lack of coordination between state and central governments resulting in missed opportunities to improve immunization coverage and quality. Falsification of data and over-reporting of rates are other big concerns as they give false sense of security and interfere with proper planning [8,21,24].

The above barriers are further compounded by a weak VPD surveillance system in the country. There is lack of disease burden data on many important VPDs in India that results in the perception that the disease is not important public health problem. Further, there is utter lack of diagnostic tools for certain VPDs. Lack of baseline surveillance data also is a bottleneck in monitoring the impact of vaccination.

#### VASHISHTHA AND KUMAR

Focusing on polio eradication exclusively while neglecting UIP ("de-linking" of UIP from Polio Eradication Initiative: PEI) by the policy-makers has also led to deterioration of performance of UIP [8,24,25]. It has been suggested that house-to-house rounds of PPP have also made certain sections of society "dependent" on health workers: UIP has been adversely affected by this also [8].

At Government level, resource constraints and competing priorities need careful planning and policymaking. The fund allocation for RI is still less than desirable. India had spent around \$113 million on vaccine interventions in 2011, down from \$137 million in 2009-10 [22]. There is need to step-up spending on vaccination front.

# WHAT IS NEEDED?

# The road ahead...

# Political and Bureaucratic Will

Such an elaborate program obviously can't succeed without political and bureaucratic support at all levels. The existing National level "Inter Agency Coordination Committee" (ICC) needs to increase its focus on routine immunization. A public-private partnership between GoI, NTAGI, Indian Academy of Pediatrics (IAP), Indian Medical Association (IMA), development partners, ICDS, Ministries of Railways, Education and Defence, and key NGOs involved with immunization and State representation should be strengthened [21]. The program managers need to ensure and monitor that funds are appropriately released in a timely way for operational costs. Ensure an uninterrupted supply of all antigens to state level through a vaccine stock management system that includes annual forecasting and wastage rates. Central level should provide technical support and resources for states to develop evidence based social mobilization plan. In specific low performing States, a district / block based operations research scheme could be considered and scaled up if successful. All hard-toreach and urban slum areas should be reached at least four times per year with RI or catch ups (21).

# Effective IEC Activities

Since lack of awareness has been found to be main barrier, focus should be on increasing demand for vaccination by using effective IEC and bringing immunization closer to the communities. The immunization services provided at the fixed sites should be improved. There should be better monitoring and supervision, and district authorities should be made accountable for the performance of RI in their district [24].

# 50 YEARS OF IMMUNIZATION IN INDIA Induct Innovative Methods to Improve RI

The number of immunization 'delivery points' especially in rural and remote areas having poor access to health facility, should be increased. 'Immunization booths' should be constructed at every locality in urban areas particularly in slums, and local municipality board member should be made accountable for their performances. Large and varied cadres of volunteers, including, for example, local registered medical practitioners, quacks, pharmacists, chemists and retired nurses and other health personnel can be recruited to offer immunization services. Proper training including maintenance of cold chain and basic minimum education on vaccines must be imparted to all of them. Complete immunization should be made mandatory to get admission in school by appropriate legislation. Incentives in cash and kind may be offered to those families having fully immunized kids [16].

# **Proper Monitoring of the Program**

Although vaccination is a medical intervention, the vaccination program, UIP, is not simply a medical modality – it is a management-dominant modality. The managerial, administrative and governance-related inadequacies need to be addressed on a priority basis [25]. The need to monitor the progress of control of diseases under UIP has not been realized; one element of the poor performance of UIP is precisely this lack of monitoring [16].

The fact that some states have been performing very well shows that we have the potential to achieve excellence. The success factors (in well-performing states) and failure factors (in poorly-performing states) must be identified and addressed with passion to reach our goal at the earliest [25].

Structured work allocation and accountability needs to be set and monitored: from health worker level till the highest level. For example, a health worker should be allocated 100-150 babies and he/ she should be responsible for immunization (may be along with delivery of other health services) of those children. Each rung of the health-care machinery should be answerable/ accountable to the immediate superior rung in the hierarchy [8]. Ideally immunization sessions should be supervised by a medical officer as done in Tamil Nadu, the only state of the country having this arrangement.

Running such an elaborate program without any objective record keeping and retrieval system is rather non-tenable in current era. As of now, parents have the immunization card that is filled by the health care worker. There is no record at the health center. If the card is lost, there is no way of verifying what vaccines have been taken/ not taken, if taken then from where and which batch number: there is no record!

To target only the coverage reached with different vaccines may be misleading and may fall short of achieving full objectives. The more important item to be monitored is the 'impact' or 'output' of entire vaccination program. 'Output' consists of disease reduction and demand creation. Outcome measurement by disease surveillance is essential to evaluate the success of UIP and to assess input efficiency. Every "case" detected under UIP is evidence of the success of the monitoring process as well as evidence for suboptimal output of UIP or suboptimal efficacy or schedule of a particular vaccine that call urgent remedial measures [25]. This will allow program managers to move beyond the monitoring of immunization coverage and understand the broader impact of immunization on disease reduction [16].

Thus, the UIP system must be district-based in terms of inputs, output and monitoring/evaluation. In 2002, WHO, UNICEF, and other partners introduced the concept of "Reaching Every District," which was the first step toward achieving more equitable coverage. This approach has started yielding good results whereever it was introduced [26]. To go even further, the experience of successful polio vaccination campaigns that have aimed to reach every child, even those outside of typical government outreach, can be leveraged, and the "Reach Every District" strategic approach can be recast as "Reaching Every Community" [16].

#### **Develop Effective Surveillance Systems**

UIP can seize the opportunity and establish a surveillance system for all important childhood infectious diseases. As has been demonstrated by the AFP surveillance network in India, efficient surveillance systems can be established, even in resource-poor settings, at quite low cost relative to the cost of the intervention itself. Where appropriate, this network should serve as the platform both for an integrated disease surveillance system that provides epidemiological data on other communicable diseases, and for detection and response to emerging infectious disease threats. Funding for disease surveillance is usually disease specific and time limited. In the presence of weak national systems, parallel systems tend to be established in order to generate data suited to the needs of specific programs [16]. Integrated Disease Surveillance Project (IDSP)- a state based decentralized surveillance program in the country launched by Ministry of Health and Family Welfare, GoI in November 2004, and IDsurva web-based infectious disease surveillance program developed by IAP-are laudable efforts in this regard [27, 28]. However, more comprehensive, coordinated efforts in the line of Active Bacterial Core surveillance-a population-based surveillance system run by Centers for Disease Control and Prevention (CDC), Atlanta in US would actually serve the purpose in the long run [29].

# Adverse Effects Detection, Reporting and Redressal System

There is need of having a functional real-time AEFI and post-marketing surveillance system in the country [16]. This will not only help in generating national data, but also useful to allow (and settle) compensation claims for vaccination-related injuries and serious adverse events. It will also provide sound basis for decisions to modify/ abandon certain vaccine preparation based on reactogenicity profile, should the need arise [8].

#### **Regulatory and Ethical Issues**

There is an urgent need of strengthening the regulatory capacity of the country and to have a reliable, properly functioning national regulatory authority. Currently, the Indian NRA, i.e. the Drug Controller General of India is overburdened with performing many diverse tasks including marketing authorization and licensing activities related to drugs, cosmetics, vaccines, etc. We need to have a vaccine specific NRA to oversee different issues related to vaccines such as licensing, post-marketing surveillance including AEFI surveillance, lot (batch) release process, laboratory support for vaccine testing, regulatory inspections of Good Manufacturing Practices (GMP), authorization and approval of clinical trials, etc. Hence, the NRA ought to be a more competent, effective, independent and transparent body. There should be a single window system to avoid regulatory delays, and strict guidelines for approval and cancellation of license must be formulated and practiced. We need clear national guidelines on the ethical conduct of clinical trials. Ethical concerns, skepticism, and low vaccination rates persist despite India's emergence as a global manufacturing leader in vaccines. Similar, improvement in the functioning of NTAGI is also desired.

#### Support to Indigenous Vaccine Industry

Most low-cost traditional vaccines are now produced by vaccine manufacturers in developing countries. Currently about 43% of the global UIP vaccines come from India, and the Serum Institute is the world's leading producer of measles vaccines [10]. Though, the current national vaccine policy seems supportive of Indian vaccine industry with liberal support from government-owned institutions like department of biotechnology (DBT), National Institute of Immunology (NII), department of science, etc still there is need to further empower Indian

vaccine sector to meet the indigenous demand of vaccines. The time has come to develop more effective public private partnership (PPP) and share responsibility of meeting demand of local vaccine need. Of late, there is 'orphanization of primary (EPI) vaccines' with declining interest and production of these vaccines. The private sector is more interested in developing newer expensive vaccines where all the innovation, R& D is diverted. There is need of innovation in public sector units (PSUs) producing EPI vaccines.

# Restructuring of EPI

We need to evolve with times. For the children of the country to reap benefits of advances in immunology and related sciences, new epidemiological data on major killers and emerging infections, it is essential that we relook and update our archaic UIP. Following issues need urgent attention:

*6, 10, 14 week* vs 2, *4, 6 month schedule*: The latter schedule, besides being superior immunologically also has the advantage of facilitating visits at the crucial ages of 4 and 6 months when infants are being weaned (from breast feeding) and hence vulnerable to development of malnutrition in the absence of proper nutritional advice. It will also help to reduce the large gap and hence drop-out rate (between the 3<sup>rd</sup> DPT at 14 weeks and measles vaccine at 9 months) and thereby ensure implementation of more comprehensive child health practices like growth monitoring, nutritional advice, etc. [8]. Thus, it needs serious deliberation.

Polio 'End game' and 'Post-eradication vaccine policy': India has successfully eliminated wild poliovirus and no wild case of polio is reported since January 13, 2011 [30]. Globally, there are urgent plans to withdraw tOPV and switch to bOPV under cover of IPV [31], yet no such urgency is being displayed by the GoI. There are no consultations taking place in this regard. There are many issues that need to be sorted out on future widespread use of IPV, both at strategic and technical front.

*Hib vaccine:* Following recommendations of IAP [32] and NTAGI [33], GoI has already introduced Hib vaccine in two southern states [12]. It should be extended to all over the country, as the move has the potential to save over 70,000 child deaths and significantly more cases of illness and disability every year in India [33].

*Typhoid vaccine*: Typhoid fever has possibly highest prevalence as compared to any other VPD in India. Recently, a Ty 21 polysaccharide vaccine has shown good efficacy and even effectiveness in one large scale Indian trial; its inclusion in the UIP must be actively considered.

50 YEARS OF IMMUNIZATION IN INDIA  $2^{nd}$  childhood booster of DTP: The pertussis component was dropped from the national schedule when EPI was adopted as UIP in India and it continues to be the same. This was without any sound scientific basis. It is absolutely necessary that this is restored in the schedule immediately [8]. TdaP vaccine at 10 years of age might have to be added sometime later, as "epidemiological shift" is known to occur once we reach good coverage at lower age [8].

*MMR vaccine:* Though of late, GoI has undertaken albeit quite late the initiative of providing 2<sup>nd</sup> dose of measles vaccine through RI and campaign mode, it would have been better had mumps and rubella components are also added.

Introduction of newer vaccines: There are about 23 new/ improved vaccines that are now available or would be available soon. Although inclusion of a new vaccine in national schedule adds the cost of vaccine and logistics to the health budget of a country, it also results in savings by reduction of the disease burden. Thus, the decision to include a new vaccine in national schedule needs careful scientific analysis regarding all the issues involved, ranging from policy issues (whether introduction of the new vaccine is in sync with immunization policy of the country) to technical and programmatic issues (whether implementation of the decision is technically feasible) [34]. New vaccines should not be introduced at the expense of sustaining existing immunization activities. Instead, the introduction of a new vaccine should be viewed as an opportunity to strengthen immunization systems, increase vaccine coverage and reduce inequities of access to immunization services [16]. Merely making the vaccine available in few pockets, for certain sections and for limited duration will not have any impact at national level. The 'equity' needs to be ensured so that the vaccine reaches to the section of the society who needs it the most [24].

# Integrated Delivery of Health Interventions

Strengthening of immunization systems in such a way that they support and integrate with other preventive health services like providing vitamin A supplementation, deworming, growth monitoring, distribution of insecticide-treated bed nets, etc. offer the opportunity to create synergies and facilitate the delivery of services to bolster comprehensive disease prevention and control. Incorporating immunization into integrated primary health care programs may also facilitate social mobilization efforts, help generate community demand for services and address equity issues [16]. The strategy of child health days, led by UNICEF, has also helped to promote RI [35].

# Research and Development (R&D)

Investment in research and development is bound to pay rich dividends. A large number of vaccine products are currently in the pipeline and are expected to become available in near future. According to recent unpublished data, more than 80 candidate vaccines are in the late stages of clinical testing. About 30 of these candidate vaccines aim to protect against major diseases for which no licensed vaccines exist, such as malaria and dengue. The benefits of development of better vaccines for existing VPDs like tuberculosis, typhoid and influenza, increasing the ambit of VPDs by development of vaccines against mass killers like HIV, malaria, dengue fever, RSV, enteric pathogens like E.coli, Klebsiella, etc, development of more thermostable vaccines (so that need of maintenance of cold chain is obviated) and development of alternative delivery of vaccines, like mucosal vaccines/ edible vaccines [36] cannot be overemphasized.

# Other initiatives

Apart from all the above mentioned measures, there is an urgent need of establishing a separate, independent department of Public Health. All the community health projects should be supervised and run under this department rather than in the form of different vertical programs. There must be prioritization of the need of a particular vaccine based on the disease burden data of that VPD rather than on the availability of the product in the international market. There must be clear cut transparent guidelines on the policy of introduction of newer vaccines. And in the last, efforts should be made to devise guidelines to regulate hitherto 'unregulated' private vaccine market. There must be a 'code of conduct' for marketing vaccines in private sector.

#### CONCLUSION

Immunization has delivered excellent results in reducing morbidity and mortality from childhood infections in the last 50 years. Although the success has not been as spectacular as in developed world, the fact is we have eradicated small pox, and now on the verge of eradicating polio. There has been substantial reduction in the incidence of many VPDs. It is widely believed that the progress in last two decades or so has not been as swift on this front as in other fields. Nevertheless, there has been some improvement in last few years: Introduction of newer antigens in UIP (Hepatitis B, 2<sup>nd</sup> dose of Measles, Japanese encephalitis and Hib in few states), framing of National Vaccine Policy, and acknowledging the need to intensify RI are steps in right direction. We now need to step up our efforts to strengthen all components of UIP (vaccination schedule, delivery and monitoring, and VPD/AEFI surveillance), overcome all barriers (geographical, politico-social and technical) and invest heavily in R&D to achieve immunization's full potential and a healthier Nation.

#### Funding: None; Competing interests: None stated.

#### References

- 1. Word Bank Database. Available online at: http:// databank.worldbank.org/Data/Views/VariableSelection/ SelectVariables.aspx?source=Health%20Nutrition%20and %20Population%20Statistics Accessed on September 12, 2012.
- 2. World Health Organization (Regional Office for South-East Asia). Available online: http://www.searo.who.int/ en/Section1226/Section2715.htm. Accessed on September 12, 2012.
- 3. 2012: Year of Intensification of Routine Immunization. Press Information Bureau, Government of India. Available online: http://pib.nic.in/newsite/erelease.aspx? relid=79602. Accessed on September 12, 2012.
- 4. Lombard M, Pastoret PP, Moulin AM. A brief history of vaccines and vaccination. Rev Sci Tech. 2007:;26:29-48.
- 5. Madhavi Y. Vaccine Policy in India. PLoS Med. 2005;2:e127. doi:10.1371/journal.pmed.0020127, 2005.
- 6. History of Vaccines. The College of Physicians of Philadelphia. Available online: http://www.historyof vaccines.org/content/timelines/diseases-and-vaccines. Accessed on September 13, 2012.
- 7. Bajpai V, Saraya A. Understanding the syndrome of techno-centrism through the epidemiology of vaccines as preventive tools. Indian J Public Health. 2012;56:133-9.
- 8. Mittal SK, Mathew JL. Expanded Program of Immunization in India: Time to rethink and revamp. J Ped Sci. 2010;5:e44.
- 9. Patra N. Universal Immunization Programme in India: The Determinants of Childhood Immunization. Available at SSRN: http://ssrn.com/abstract=881224. Accessed on September 13, 2012.
- Ministry of Health and Family Welfare, Government of India. National Vaccine Policy. Available online: http:// mohfw.nic.in/WriteReadData/1892s/1084811197 NATIONAL% 20VACCINE% 20POLICY% 20 BOOK.pdf. Accessed on September 13, 2012.
- 11. New initiatives help India achieve improved coverage and quality of immunization. Press Information Bureau, Government of India, Ministry of Health and Family Welfare. Available from: http://pib.nic.in/newsite/erelease.aspx?relid=73623. Accessed on September 12, 2012.
- Gupta SK, Sosler S, Lahariya C. Introduction of *Haemophilus Influenzae* type b (Hib) as pentavalent (DPT-HepB-Hib) vaccine in two states of India. Indian Pediatr. 2012;49: 707-9.
- 13. Pentavalent vaccine in six more states. The Times of India, April 17, 2012. Available online: http:// articles.timesofindia.indiatimes.com/2012-04-17/india/

31355153\_1\_haemophilus-influenzae-type-pentavalent-vaccine-hib. Accessed on September 12, 2012.

- 14. Introductory note on Pulse Polio Programme-2012-13 with Proposed Newer Initiatives-an appraisal. Ministry of Health and Family Welfare, Government of Delhi. Available online: http://delhi.gov.in/wps/wcm/connect/ doit\_health/Health/Home/Family+Welfare/ Pulse+Polio+Immunization+Program. Accessed on September 12, 2012.
- 15. National Polio Surveillance Project. http:// www.npspindia.org. Accessed on September 12, 2012.
- Vashishtha VM. Status of Immunization and Need for Intensification of Routine Immunization in India. Indian Pediatr 2012;49:357-61.
- Universal Immunization Programme (UIP) Review. World Health Organization. Available from: http:// www.whoindia.org/EN/Section6/Section284/Section286 \_507.htm. Accessed on December 12, 2011.
- National Family Health Survey (NFHS-3), 2005-06: Key Indicators for India from NFHS-3. Available from: http:// www.nfhsindia.org/pdf/India.pdf. Accessed on December 12, 2011.
- UNICEF Coverage Evaluation survey, 2009 National Fact Sheet. Available from: http://www.unicef.org/india/ National\_Fact\_Sheet\_CES\_2009.pdf. Accessed on September 14, 2012.
- 20. District Level Household and Facility Survey 2007-08. Available from: http://www.rchiips.org/pdf/rch3/state/ India.pdf. Accessed on September 14, 2012.
- 21. Vashishtha VM. Routine immunization in India: A reappraisal of the system and its performance. Indian Pediatr. 2009;46:991-2.
- 22. Laxminarayan R, Ganguly, NK. India's Vaccine Deficit: Why more than half of indian children are not fully immunized, and what can—and should—be done. Health Aff 2011; 30: 61096-1103. Available from: http:// content.healthaffairs.org/content/30/6/1096.full.pdf Accessed on October 12, 2012.
- 23. Ahmad J. Khan ME, Hazra A. Increasing complete immunization in rural Uttar Pradesh. J Family Welfare. 2010;56:65-72.
- 24. Agarwal RK. Routine immunization: India's achilles' heel! Indian Pediatr. 2008;45:625-8.

**50 YEARS OF IMMUNIZATION IN INDIA** 

- 25. Polio Eradication Committee, Indian Academy of Pediatrics (PEC,IAP), Vashishtha VM, John TJ, Agarwal RK, Kalra A. Universal immunization program and polio eradication in India. Indian Pediatr. 2008;45:807-13.
- 26. Vandelaer J, Bilous J, Nshimirimana D. Reaching Every District (RED) approach: a way to improve immunization performance. Bull WHO. 2008;86:A-B.
- 27. Integrated Disease Surveillance Project (IDSP). Available online: www.idsp.nic.in. Accessed on September 14, 2012.
- 28. I Dsurv. Available online: www.idsurv.org Accessed on September 14, 2012.
- 29. Active Bacterial Core surveillance (ABCs). Available online: www.cdc.gov/abcs/index.html Accessed on September 14, 2012.
- 30. John TJ, Vashishtha VM. Path to polio eradication in India: a major milestone. Indian Pediatr. 2012;49:95-8.
- 31. World Health Organization. Meeting of the Strategic advisory group of experts on immunization, April 2012 – Conclusions and Recommendations. Available from: http://www.who.int/wer/2012/wer8721.pdf Accessed on October 20, 2012.
- 32. Vashishtha VM. Introduction of Hib containing pentavalent vaccine in national immunization program of India: the concerns and the reality! Indian Pediatr. 2009;46: 781-2.
- 33. Subcommittee on Introduction of Hib Vaccine in Universal Immunization Program, National Technical Advisory Group on Immunization, India. NTAGI Subcommittee Recommendations on *Haemophilus influenzae* Type b (Hib) Vaccine Introduction in India. Indian Pediatr. 2009;46:945-54.
- 34. Kumar P, Vashishtha VM. The issues related to introduction of a new vaccine in National Immunization Program of a developing country. J Pediatric Sciences. 2010;5:e44.
- 35. Periodic Intensification of Routine Immunization. Lessons learned and implications for action. Available online: http:/ /www.immunizationbasics.jsi.com/Docs/ PIRImonograph\_Feb09.pdf Accessed on September 15, 2012.
- Kumar P. Novel Approaches to vaccine formulations and delivery systems. *In*: Vashishtha VM, Kalra A, Thacker N (*eds*). FAQs on vaccines and Immunization Practices, first edition, Jaypee Publishers, 2011. p. 345-79.