NATIONAL VACCINE POLICY

Ministry of Health & Family Welfare
Govt. of India
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MINISTRY OF HEALTH & FAMILY WELFARE
Government of India
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Foreword

The National Vaccine Policy document has been developed following the recommendation of National Technical Advisory Group on Immunization (NTAGI). This policy document addresses broad issues of strengthening the institutional framework, processes, evidence base and framework required for decision making for strengthening Universal Immunization Programme in India and to streamline the decision making process on new and underutilized vaccine Introduction. The document also aims to address the issues of vaccine-security, management, regulatory guidelines, vaccine research & development and product development.

I would like to thank Prof. N.K. Ganguly, Ex-DG, ICMR for drafting this Policy document which will lay down the basic guiding principles in improving the Immunization programme in the country. I also take this opportunity of thanking Secretary (DHR) & Secretary (DBT) for their critical input in drafting the National Vaccine Policy.

(K. Chandramouli)

National Rural Health Mission

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ABBREVIATIONS

ACIP	Advisory Committee on Immunization Practices
AD	Auto Disable syringes
AEFI	Adverse Event Following Immunization
ANM	Auxiliary nurse-midwife
CDC	Center for Disease Control and Prevention
CDSCO	Central Drugs and Standards Control Organization
CLAA	Central License Approving Authority
DPCO	Drug Price Control Order
DPT	Diphtheria, Pertussis and Tetanus
ECDC	European Center for Disease Prevention and Control
EPI	Expanded Program for Immunization
FSP	Financial Sustainability Plan
GAVI	Global Alliance for Vaccines and Immunization
GFR	General Financial Rules
GIS	Geographical Information System
GNI	Gross National Income
GOI	Government of India
GRADE	The Grades of Recommendation Assessment, Development and Evaluation
HMIS	Health Management Information System
ICB	International Competitive Bidding
ID	Infectious Disease
JE	Japanese Encephalitis
MoHFW	Ministry of Health and Family Welfare

NABL	National Accreditation Board for Testing and Calibration of Laboratories
NDMA	National Disaster Management Authority
NIB	National Institute of Biologicals
NIHFW	National Institute of Health and Family Welfare
NIP	National Immunization Program
NRA	National Regulatory Authority
NRHM	National Rural Health Mission
NTAGI	National Technical Advisory Group on Immunization
OPV	Oral Polio Vaccine
PAHO	Pan American Health Organization
ProMIS	Procurement Management Information System
PSU	Public Sector Unit
RCH-2	Reproductive and Child Health Phase II
SAGE	Strategic Advisory Group of Experts
SAIF	Sophisticated and Analytical Instrument Facilities
UIP	Universal Immunization Program
UNICEF	United Nations Children's Fund
VPD	Vaccine Preventable Disease
WHO	World Health Organization

NATIONAL VACCINE POLICY

EXECUTIVE SUMMARY

Vaccines are one of the most successful health interventions that bring about significant reductions in infectious diseases and adverse health consequences and improve quality of life in the population. Over the years vaccines have provided highly cost effective improvements to human health by reducing avoidable human suffering, costs of care and treatment, economic consequences of work i.e. lower productivity and loss of work. More and more diseases are becoming vaccine preventable; including those for prominent killers like pneumonia and diarrhoea, and the technology used is evolving rapidly. Since vaccines are administered to healthy people, especially children, it is pivotal to ascertain they are safe and cost effective. Consequently vaccine development has become time and resource intensive, with more stringent regulatory pathways to ensure safety and efficacy of vaccines. In a situation where there is abundance of new and expensive vaccines on one hand and limitations of resources on the other, it becomes imperative that use of vaccines through induction in the Universal Immunization Program (UIP) as well as in the free market is done through a framework of decision-making that confers positive health and economic benefits to the society.

The UIP in India targets 2.7 Crores infants and 3.0 Crores pregnant women every year and is one of the largest in the world. The country also has a strong vaccine manufacturing capacity that has recently taken on the challenge of producing more complex vaccines. Most of the new vaccines are used by one segment of the population, which can afford them, while the most vulnerable segment of the population, which is serviced through the UIP misses out on this opportunity. There is a scope for improvement in the health system and the vaccine enterprise in the country to enable its optimal functioning and bring about coordination between the various inter-dependent steps and involved stakeholders. This policy document deals with issues critical to strengthening of the vaccine enterprise to ensure long-term supply of affordable vaccines to the people who need it the most. The document is divided under the following sections:

- **Policy context and framework :** This section provides information on why this document is required, what is the scope of the document and overall framework.
- **Burden of Vaccine Preventable Diseases (VPDs) in India:** This section discusses how introduction of vaccines have impacted the burden of VPDs in India. It also outlines other diseases which can be

prevented by currently available and possibly available vaccines in future in India.

- **Vaccine research and development:** This discusses the challenges in vaccines research, mapping of capacity for vaccine research in the country, research networks and creation of bio-repositories retrospective use.
- **Introduction of new vaccines:** This section discusses processes, matrix and evidence base in decision making before the introduction of new vaccines in India.
- **Improving operational efficiency:** This section deals with Adverse Events Following Immunization (AEFI) and VPD surveillance systems, cold chain & effective vaccine management, human resources in immunization, vaccine coverage, advocacy and communication, and equity and ethics etc.
- **Program implementation and monitoring:** This section outlines how this document should be used and how the progress in the implementation of this policy can be monitored.

NATIONAL VACCINE POLICY

1. PREAMBLE

1.1. Background

The Expanded Program for Immunization (EPI) in India was launched in 1978. The ambit of EPI was increased with the inclusion of measles vaccine (and discontinuation of typhoid vaccine) in 1985 and it was renamed as the Universal Immunization Program (UIP). The aim of UIP was to cover all districts in the country by 1990, in a phased manner and target all infants with the primary immunization and all pregnant women with TT immunization. For almost 2 decades, UIP did not add any additional vaccine. However, since 2006, vaccines namely Hepatitis B, second dose of measles and Japanese Encephalitis (JE) vaccine have been introduced. During the same period, a number of other safe and efficacious vaccines have become available for major killers like pneumonia and diarrhea, which are being used in the immunization programs of many developing and developed countries.

The discussion on the formulation of National Vaccine Policy for India started in a meeting of National Technical Advisory Group of Immunization (NTAGI) in August 2010. Subsequently, in Sept 2010, Ministry of Health and Family Welfare (MoHFW) identified Dr. N.K Ganguly, Ex- DG, ICMR to draft National Vaccine Policy.

1.2. Purpose of this document

A National Vaccine Policy with specific relevance to local vaccine needs is required to guide decision-making and develop a long-term plan to strengthen the whole vaccine program and not just a component. This National Vaccine Policy does not intend to cover all aspects of immunization service delivery or is not a detailed guideline on specific vaccine. This Policy document intends to provide broader policy guidelines and framework to guide the creation of evidence base to justify need for Research and Development (R&D), production, procurement, quality assessment of vaccines for UIP in India. This document also addresses the broad issues of strengthening the institutional framework, processes, evidence base and framework required for decision making for new vaccine introduction, addresses vaccine-security & program management, regulatory issues, and product development.

1.3. Process adopted in the development of this document

The working group constituted by Dr. N.K. Ganguly in Sept. 2010 started to develop an initial draft of this policy document. The working group had a series of meetings, reviewed a number of policy, program and operational documents. The first draft was completed and shared with NTAGI members for comments in February 2011. The comments from NTAGI members and subsequent revision were done in March 2011.

2. POLICY CONTEXT AND FRAMEWORK

This document covers all categories of vaccine, vaccines being used in UIP, vaccines available but not part of UIP (both new and underutilized), and those vaccines, which are likely to become available in the future. The document also touches the aspects related to vaccine security in the country and vaccination program in broader framework of National Health Policy of India.

2.1. Current UIP vaccines

UIP in India and its core antigens have made a significant impact on the burden of diseases in the country and directly contributed to reducing child mortality. However, the regular production and supply of these vaccines, in a setting where majority of manufacturers are increasingly paying attention to the newer vaccines is a big challenge. There is limited production capacity of these vaccines in public sector units and the involvement of private sector manufacturers is required to ensure that supply of UIP vaccine is not threatened.

2.2. New and under-utilized vaccines

There are a number of new vaccines, which have become part of National Immunization Programs (NIPs) in many developing and developed countries. Many a times, the decision to introduce these vaccines is delayed due to limited production capacity, which indirectly affects the price of these vaccines too. Sometimes vaccines are not used as these are not indigenously produced or not available in sufficient quantity. On the other hands, the manufacturers don't produce vaccine because these are not used in the program. The authorities should use innovative financing, funding and assured supply mechanisms to overcome these challenges. Furthermore, there is need for the institutionalizing and strengthening of decision making process and enhancing confidence of the people in the process besides preparing in-built country mechanism for sustainable production of newer vaccines within country.

2.3. Potentially new vaccines

The diseases which are prevalent in developing countries are often different than the ones in developed countries. However, till last decade majority of the vaccine research was being done in developed countries and the focus was on the vaccines against diseases, which are prevalent in developed country setting. India has a leading vaccine industry; however, there is need for investing more on the research for the vaccines for the priority diseases in the country. Such research can be promoted only when there is conducive environment, funding and subsequent chances of vaccine being introduced in the National program.

2.4. Vaccine security and other issues

India should be able to ensure quality, safety, and efficacy of all vaccines that are either indigenously produced or imported for the use in the country. Achieving this requires a robust regulatory mechanism to be in place. Furthermore, the implementation of immunization program should be put in the perspective of broader goals of National Health Policy. The sufficient political will & support, and the necessary sufficient and sustainable financing mechanisms should also be ensured for this purpose.

3. SITUATION ANALYSIS

3.1. Burden of VPDs and their surveillance

Since the beginning of EPI in India, there has been a general decline in the reported number of cases of the main VPDs (diphtheria, tetanus, pertussis and measles).

The overarching goal of vaccine use is to reduce morbidity and mortality due to vaccine preventable diseases (VPD). While surveillance information for specific VPD is limited, trends in Infant Mortality Rate (IMR) to reflect the impact of vaccination suggest that IMR in India has fallen steadily to reach 50 deaths per 1000 live-births (SRS 2009).

For almost 2 decades since the beginning of UIP, India had same 6 antigens in the UIP and recently Hepatitis B and measles second dose has been incorporated in UIP. There are a number of diseases, for which vaccines exists for long (Typhoid, Rubella), which may further be considered for the introduction in NIP in India. Similarly, a number of new vaccines have become available in last few years. Haemophilus influenzae type b (Hib) vaccines, Pneumococcal conjugate vaccines, Rotavirus vaccines, HPV vaccines, which have estimated high burden and possible role in reducing child mortality in India.

One of the major hurdle in the decision making process for the introduction of new vaccine has been the lack of indigenous surveillance data to assess the disease burden. The country need to build upon the available investigator initiated research, modeling data, and systematic reviews to assess the disease burden. Nonetheless, the efforts should be made to strengthen VPD surveillance system. The institutional capacity building should be done for conducting demonstration projects and impact studies in the country.

3.2. Barriers to strengthen Immunization Programme

There are well recognized challenges in the implementation of immunization program in the country. These challenges are:

- Weak VPD surveillance system;
- Lack of data on disease burden in India and resulting perception that the disease is not important public health problem;
- Lack of diagnostic tools for certain vaccine preventable diseases that could be used without sophisticated instruments or specialized training;
- Lack of baseline surveillance data also is a bottleneck in monitoring the impact of vaccination;
- Limited economic evaluations to show cost effectiveness of vaccines over other interventions to support decision-making;
- Lack of a financial sustainability plan for the introduction of new vaccines in the UIP also affects decision making in this area.
- Shortage of trained manpower to manage the UIP at the Center as well as State levels, for innovations in vaccines, for disease surveillance and for procurement and effective vaccine management.

These challenges need to be addressed to improve the Immunization Programme performance in India. This policy document also aims to provide policy measures to address the above mentioned barriers.

4. VACCINE RESEARCH AND DEVELOPMENT

The research and development (R&D) and manufacturing of vaccines for locally prevalent diseases in India should be given a priority. These include vaccines for major killers like pneumonia and diarrhea, diseases with potential to cause outbreaks like JE, Dengue, Cholera, Typhoid and diseases like Leishmaniasis etc. The processes, funding, networks, repositories etc. that would make this possible are detailed in the following sections.

4.1. Institutional capacity and framework

Vaccine development is a long, multi stage process where critical actions must be decided and taken in synergy and not sequentially. The R&D of vaccines is undertaken in the academia as well as by the vaccine industry. There are a number of challenges faced by the developing countries in vaccine research.

India has a number of institutions, where vaccine related projects are implemented i.e. Indian Council of Medical Research (ICMR), Department of Science and Technology (DST), Council for Scientific and Industrial Research (CSIR), small and medium vaccine industries, medical and engineering schools, in addition to the Department of Biotechnology (DBT) supported autonomous institutions.

India's strong and growing vaccine manufacturing sector and a rapidly rising global demand in vaccine R&D is also a tremendous economic opportunity. A number of linkages need to be explored between academia, industry and international institutions such as NIH/NIAID, Gates Foundation, GAVI Alliance, PATH, WHO and the International Centre for Genetic Engineering and Biotechnology (ICGEB). Areas that require attention include the following:

- A fund for grand challenges in vaccine R&D needs to be created. This fund to be utilized for R&D of country disease burden specific vaccines,

- The vaccine grand challenge mechanism will ensure that all varied type of infrastructures and services, approved by Central Drugs Standard Control Organization (CDSCO) are available, accessible, and affordable to the investigators involved in vaccine research and development.
- Flexible governance and granting systems should be in place to ensure that additional science funding, cooperate granting system (where funding agency, project managers and investigators work as a team for collective decision making) and subcontracting mechanisms are in place.
- Enabling processes for rapid decision-making to allow building alliances and partnerships, both national and global, and for support to agencies for diffusion of the technologies into the social systems, should be in place.
- Workable mechanisms need to be developed to sustain vaccine development teams, for a decade or more, for a continuity and focus, and new skills incorporated to fulfill evolving requirements.

4.1.1. Mapping of research capacity and network

The mapping of vaccine R&D activities in the country is important to assess the strengths and gaps, and to avoid duplication of efforts. This exercise also helps identify candidates that have potential and should be taken forward and quickly abort/correct those activities that have lacunae. Mapping exercises are very important in case of vaccines, where the pipeline of candidates has to be large and the development resource-intensive.

The participation of national government institutions, private institutions and industries that have resources and manpower in the area of health research should be given a platform to share ideas and intellectual property and encouraged to collaborate. These groups when identified to have common goals should be encouraged to write joint grants and thus utilize the infrastructure and manpower to the optimum capacity. The results of mapping exercise should be made available to researchers in the country and to other funding agencies investing in similar activities.

The mapping exercise could result in disease or intervention (drug/ vaccine/ delivery systems/adjuvants) specific networks that could synergize the efforts and enable concentration of resources, both

monetary and human, towards fight against a specific disease or a group of diseases (for example a network of neglected tropical diseases).

- These networks could then collaborate within themselves, share intellectual property, expertise, biological material and also collaborate with international groups working on similar projects.
- Creation of Sophisticated and Analytical Instrument Facilities (SAIF) within a region/state will encourage sharing of expensive instruments and enable participation of investigators from various universities and institutions. This will also enable periodic upgradation of the facilities.

4.1.2. Creation of Bio-repositories

Banking of biological samples both sera and organisms that are collected during diseases surveillance, epidemics or clinical trials can be a tremendous source of materials for retrospective use in identifying biomarkers, genetic make-up or studying changes in pathogenic organisms in India in case of re-emergence of a disease. Administration, management, custodianship, and security of bio-banks can be major issues. Without proper guidelines and policies about benefit-sharing, data-sharing, privacy, access (both for depositing of samples and retrieval), policies to handle bio-piracy etc., a well intended effort can not function optimally.

- The existing guidelines that govern the functioning of a National Biorepository in India and the best practices followed in other countries should be examined and an India specific Standard Operating Procedure and Guidelines needs to be drafted with appropriate linkages with different programs,
- The bio-repositories need to be equipped with fingerprinting, sequencing for analysis of the genetic makeup of the organism, and freeze-drying facility for long-term storage,
- The repositories should be accredited and linked with International Repository System and to other discovery research units in the country,
- There is an urgent need to establish a repository for pathogenic organisms. All the data sets generated should be strongly linked with other national programs.

4.1.3. Public Private Partnerships

The concept of public private partnership (PPP) has helped in bridging the gaps between academia, industry, and funding agencies effectively. It unifies the commitment of public sector to develop products to improve health of the population with the private sectors discipline and culture in business development and marketing. The non-profit enterprise has effectively led to development of several products in the past decade. The PPPs have also evolved innovative methods for intellectual property and portfolio management, and has unique structures and methods for governance.

There are a few approaches to strengthen PPP mechanisms in vaccine research:

- Flexible governing and funding mechanisms should be evolved to support product development in the PPP mode,
- Flexibility of contracting experts, both from national and global pool for a defined period should be built-in in these partnerships.

During setting up of the policy framework, the industry may be provided a channel to voice their opinion and experiences and their concerns could be utilized in framing the policy. If industry has genuine concern about tardy regulatory mechanisms or a decision has been made to their detriment, an independent and speedy redressal mechanism should be in place. A need based realistic procurement policy should help.

There are several examples where product development have taken the public private partnership route and have resulted in shortening of the time frame for vaccine development, such as the Meningococcal Meningitis Vaccine Initiative (MMVI), where the product was produced in India with multiple partners, met international standards in quality, was exported to and used in Africa. The model has been instrumental in indigenously 116 E rotavirus vaccine being developed with effective collaboration between Indian & US academia, and Indian vaccine industry in partnership with PATH.

Another example is the development of influenza H1N1 vaccine with support of 3 Indian vaccine manufacturers under the BIPP (Biotechnology Industry Partnership). An indigenous new generation Oral Cholera Vaccine has also been brought to the market under such model with the partners being International Vaccine Institute, Korea, National Institute of Cholera and other Enteric Diseases (NICED), Kolkata, and Shantha Biotechnics Ltd, Hyderabad.

The vaccine industry suffers from the lack of support for risky vaccines. The continuous inputs needed to and from the repositories, largely set up in public sector institutes and platforms available with Indian Institutes of Technology (IITs), research institutes and universities, is largely missing. There should be robust mechanisms in place to integrate these partnerships in PPP mode.

In order to fund the long and multistage pathway of vaccine development, where the various components have to work in synergy rather than sequentially, novel funding mechanisms for various stages need to be in place with the flexibility required to fund various partners in an enterprise model. Some of these are already available like the BIPP and Small Business Innovation Research Initiative (SBIRI) mechanisms of DBT, and New Millennium Indian Technology Leadership Initiative (NMITLI) program of CSIR are available for industrial development of lead candidates.

More flexible granting mechanisms, unlike the milestone based, short-term, project-specific funding currently followed, are needed for vaccine R&D. The innovative funding mechanisms lasting for 5-8 yrs should be instituted for young investigators interested in vaccine development including flexible mechanisms for training in related areas like Good Laboratory/Clinical/Manufacturing practices ethics (Including IPR) and hands on skill development in certain technology platforms.

4.1.4. Product development for public health emergency

There is a need to develop mechanisms, where speedy regulatory clearances are possible including flexibilities in the import of biological materials needed for such development. The mechanisms need to be evolved where the risk of the manufacturers is cushioned by appropriate assistance from the Government. It should be mandatory for the Government to support such developments with Advance Market Commitments and honour the commitments.

4.2. Vaccine quality regulatory system

4.2.1. Existing vaccine regulatory system

The Central Drugs and Standards Control Organization (CDSCO) is the National Regulatory Authority (NRA) in India. CDSCO is headed

by the Drugs Controller General (India) [DCG(I)]. It approves vaccines that are introduced in the country, grant permission to conduct clinical trials, registers and controls the quality of imported vaccines, as well as lays down standards for updating India Pharmacopoeia. It also approves licenses as the Central License Approving Authority (CLAA) for the manufacture of vaccines, coordinates the activities of the States and advises them on matters relating to uniform administration of the Act and Rules. The Central Drugs Laboratory (CDL), Kasauli performs lot release for all imported vaccines as well as locally produced vaccines.

4.2.2. Scope for Improvements in the quality assessments

Indian vaccine industry has occupied an important niche in the manufacturing of EPI vaccines in the last decade. However, with the exception of measles vaccine, which is from a domestic WHO pre-qualified producer, all other NIP vaccines supplied are from WHO non pre-qualified manufacturers. This is in spite of the fact that India is one of the major suppliers to UN agencies of pre-qualified vaccines.

The Indian vaccine industry has taken up new challenges of manufacturing more complex vaccines like the meningococcal conjugate vaccine, pneumococcal conjugate vaccine, and other combination vaccines. Recognizing this emerging strength of Indian manufacturers, the NRA should be appropriately strengthened with trained manpower, and an accredited laboratory which can serve as the National Control Laboratory. There are other areas, which need to be strengthened:

- The current regulatory guidelines followed by the NRA for vaccines are dated and essentially designed for the drugs. There is an urgent need to develop vaccine specific guidelines.
- Laboratory testing for vaccine consistency is a critical component of vaccine quality. A system of accreditation of laboratories through a set of internationally accepted parameters should be in place. The institutions like the National Institute of Biologicals (NIB) need to be adequately strengthened to take on the laboratory testing of new generation of vaccines.
- India should develop prequalification standards that are in alignment with WHO-UNICEF standards. Single window system should be in place to prevent any unnecessary delays in regulatory clearances.
- Most of the EPI vaccines procured for use in India comes from manufacturers that are not WHO pre-qualified and have different risk taking ability. Adhering to the WHO-UNICEF prequalification standards will enable more domestic manufacturers to cater to international markets. Coupled with a more efficient procurement system that factors the timelines of the vaccine manufacturing process, the risk of the vaccine manufacturers will be significantly reduced.
- There is a need to set up systems for fast-track clearance of vaccines needed for emergencies. One of the ways to achieve this is that Indian NRA recognizes the NRAs of other countries as is done by countries procuring vaccines through UNICEF. In situations where time is essence, having this types of provisions will go in a long way to save several lives during public health emergencies.

4.2.3. Clinical trials

Clinical trials are very crucial for decisions making about vaccine development. These should be planned and executed according to the Good Clinical Practices (GCP) guidelines and maintain highest standards possible. GCP training courses should be mandatory for all PIs leading clinical trials.

- There is a need to create a pool of trained investigators to design and oversee clinical trials for vaccines. The Clinical Development and Services Agency, within the Department of Biotechnology and its partners, which have this mandate, should be supported appropriately.
- Capacity building for data management and biostatistics to analyze and interpret the results of a clinical trial is essential. A training program for the support staff participating in each trial may be different and therefore be budgeted in the trial.
- There should also be provision to engage trained auditors from time to time for independent assessment of vaccine trials conducted in the country.

4.2.4. Intellectual Property Rights (IPR) and technology transfer

The Indian Patent Act was amended in 2005 and the product patents have been allowed in the country, which has significant impact on the

cost of health care products in India. Improving the institutional capacity for intellectual property (IP) management and technology transfer will help investigators involved in the research to understand the patent claims and will enable them to make sound judgments, during the product development. There are a few steps needed in this arena:

- Strengthening Indian patent office, reducing the time to examine and grant a patent, and creation of more comprehensive IP databases in India
- Encouraging technology transfer from multinational companies to develop products and gaining access to technologies and know-how
- Indian patent law may have provisions to permit compulsory licensing in special situations like the H1N1 pandemic or in situations, where a technology/intermediate is needed for vaccine development.
- The country should develop/use expertise to study the flexibilities enshrined in the Trade Related Aspects of Intellectual Property rights (TRIPS) agreement to reduce the negative impact of the patents. The arrangements like 'Bolar provision' which permits the manufacturers of generic pharmaceuticals to begin product development, while the patent is still in force. This could be particularly helpful in reducing the lead-time to obtain regulatory clearances during vaccine development.
- Collective management of IPR and open access agreements should be resorted to improve innovation and access. Innovations in ways to deal with IPR of new vaccines need to emerge through innovative funding of R&D.
- It is suggested that a body is created to acquire and hold IPR for technologies beneficial for use in public health. This body could then license the technology to emerging manufacturers on acceptable terms for development of vaccines and related products.

Mechanisms needs to be set up for a robust technology transfer units, positioned to transfer technologies to companies for public good. Setting up of special infrastructure for new vaccines should be incentivised through tax relief for imports. In case of requirement of a

new vaccine, the mechanisms like SBIRI and NMITLI should provide part support as loan on soft interest rate and part as grant just as was done in case of development of H1N1 vaccines and similar funding mechanism should be available for other new vaccine development as well.

4.3. Vaccine production and supply

India is a major producer and exporter of vaccines: approximately 43% of global vaccine supply is provided by Indian manufacturers, primarily from the private sector. Till recently, both public and private sector vaccine producers were supplying vaccines to UIP.

- An effective, functional and inclusive platform needs to be created so that all the stakeholders have the same understanding of the issues and work towards a common goal to ensure sustainable and uninterrupted production and supply of good quality, safe and effective vaccines at the most competitive price.
- Local manufacturers must be encouraged to comply with WHO GMP standards. They may be assured with accurate demand estimates, followed by purchases of all ordered vaccines.
- Public sector units should be updated with long-term goals in mind. The public sector units should be lead by a person with strong scientific background and should have a forward-looking corporate like governing system.

The Indian domestic market for UIP alone is 100 million doses, and therefore has considerable bearing on global vaccine pricing. The R&D costs of UIP vaccines is minimal, however, the non-UIP vaccines involve technology licensing, R&D, infrastructure, and operational costs. In addition, the stringent regulatory requirements, for the licensing of newer vaccines, add up to the cost. The pricing policy on vaccines should be based on a realistic assessment to retain the interest of the vaccine industry in research on the new vaccines. The Public sector industry should be revived to provide vaccines that have very low profit margins and to make these units competitive, they should be able to hire global consultants through appropriate mechanisms and be allowed to hire key personnel through market competitive rates. A professional and technical management system should be in place to help identify the infrastructure gaps.

4.3.1. *Vaccine financing and sustainability*

The ideal situation for any national government is to assume ownership of NIP to the fullest extent possible and accordingly create fiscal and legislative space. Meeting benchmarks and enacting protective legislation are the essential conditions for the financial sustainability.

- A financial sustainability plan (FSP) for immunization should be created. The FSP should include the breakdown of vaccine and non-vaccine expenditures (system costs) and plan for scale up in the coming years. It should also factor in the changes to be brought about by the introduction of new vaccines, expansion in cold chain capacities and management.
- The non-vaccine expenditure should also include expansion and sustenance of trained human resource. This should clearly describe the expenditures to be met by the central and state government.
- Possibility of creation of expanded Vaccine fund through innovative financing mechanism should be considered. An inter-agency task force should be created and should assess the legal and administrative barriers to make such a fund operational. This fund could also be used for introduction of new vaccines and for development of vaccine for emergency.

5. INTRODUCTION OF NEW VACCINES IN UIP

5.1. Vaccine selection

5.1.1. *Identifying vaccines of local relevance*

The decision to include a new vaccine should be guided by the disease burden in the country. This information, ideally, be derived through strong surveillance system within country. Furthermore, the data from the investigator initiated researches, from modeling studies and the data from countries with either geographical proximity or similar demography may also be used for these decision makings.

A mid term (5-7 year) strategy on the required evidence with regard to the burden of diseases should also be in place, with scope for periodic monitoring and review. A multi-agency policy unit should be created to conduct meetings of various stakeholders to evaluate and monitor these studies periodically. It could also review status of vaccine development and manufacturing activities in the country and arrange technical assistance in various aspects of vaccine development.

5.1.2. *Criteria for selection of vaccines for introduction*

The selection of vaccine for possible introduction in NIP is a complex process. There are a few laid down guidelines. The below given criteria may be considered for an informed decision making about the introduction of new vaccine in UIP.

- Disease burden (incidence/prevalence, absolute number of morbidity/mortality, epidemic/pandemic potential);
- Safety and efficacy of the vaccine under consideration;
- Affordability and financial sustainability of the vaccination program, even if the initial introduction is supported by the external funding agency;
- Program capacity to introduce a new antigen, including cold chain capacity;
- Availability of a domestic or external vaccine production capacity;
- The cost effectiveness of the vaccination program and also of the alternatives other than vaccination.

The Grades of Recommendation Assessment, Development and Evaluation (GRADE) system is one such system followed, which allows a systematic and transparent grading of evidence with deliberate separation of quality of evidence and strength of recommendation.

5.2. Vaccine formulations and immunization schedules

There are a number of new vaccines, which may be considered for the possible introduction in UIP in India. The modifications in the existing immunization schedule may be required for accommodating these new vaccines, for a broader utilization of some vaccines or for changing the number of doses based on experience elsewhere.

- Technical consultations should be carried out to examine the possibility of any alteration in vaccine formulation (e.g. vaccines with or without preservative, with or without adjuvant, liquid or lyophilized etc.) that could enable the use of a vaccine in the

existing schedule. Such a consultative process should include scientists, program managers, cold chain managers and representatives of the manufacturers.

- The combinations vaccines have shown to improve coverage, and reduce non-program costs, especially in countries with similar issues. These factors should be considered before making a decision on the use of combination vaccines in UIP.

5.3. National Technical Advisory Group on Immunization (NTAGI)

NTAGI is a group of experts from vaccination and immunization related fields in India. NTAGI advises the national government regarding the technical issues related to the vaccination and immunization. This group meets on a regular basis and considers various technical and policy decision related to immunization program in India.

There is a general perception in India that the time lag from the availability of a vaccine to its use in the NIP should be reduced. There are a few steps which should be followed to ensure the effective and efficient functioning of NTAGI:

- The guidelines of international bodies like World Health Organization Strategic Advisory Group of Experts (WHO-SAGE) should be assessed in context of the capacity of India's National Immunization program to absorb a particular vaccine.
- The country specific 'situational analysis' for each vaccine should be done by this expert group.
- The inputs from translational research in the country to support such introduction should be improved. Capacity and infrastructure in this field should be created/revamped. The interdisciplinary collaborations within the nation and at global level need to be initiated and established. The members of NTAGI should have sufficient interaction with each other and other global advisory bodies.
- The NTAGI should be supported by subgroups that look into specific areas such as vaccine security, vaccine ethics, equity, financial sustainability, and improvements in health system.
- The NTAGI should have wider representation to include experts from the areas of Public health, Paediatrics, Epidemiology, Infectious Disease (ID), Clinicians other than ID, Immunologists, Medical Microbiologists, Cold chain experts/ logisticians, Statistic modelers, Social scientists, and Drug regulators. It is also important to have experts in ethics, health economics, and nursing/pharmacy from the field, immunization program managers, and representatives of the civil society etc. Other members should be ex-officio members from the Ministry of Health and Family Welfare. There may be also be representation from the State Ministry of Health.
- It must be mandatory for the members to declare conflicts of interest to ensure an unbiased decision making process. The members should be allowed a term of a minimum of 2 years term (which could be extended).

5.4. Decision making process

The potential inclusion of any new vaccine in UIP should initially be discussed by NTAGI. The NTAGI may consider various factors before giving technical recommendation for introducing any new vaccine in the program. The technical decision of NTAGI should be considered by immunization division for implementation. The program division may further consider the operational aspects of the decision implementation.

Moreover, the vaccine specific work plans need to be prepared, which includes review of existing evidence on burden and efficacy, identify data gaps and outline plan of work to collect any additional data needed for decision making. These work plans can be strictly adhered to streamline and support the decision making efforts in the country. The efforts should be made to address the identified gaps in these areas and the needful activities may be done in this direction in collaboration with various stakeholders.

A proportion of country's population accesses vaccines from the private market, where new vaccine entry follows the marketing strategy of the manufacturers based on their experience from introduction in developed countries. This segment of the population should be studied as it can provide valuable post marketing surveillance (Phase -IV analysis) data. The profile of the people accessing these vaccines as well as the mapping of service providers could be useful for future planning and decision making.

6. OPERATIONAL EFFICIENCY OF UIP

6.1. Improving vaccine coverage

The coverage of UIP vaccines in this country is >70% only in 11 states, 50-70% in 13 and below 50 % in the rest of the 8 states. The last group also happens to include the most populous states, which brings down the national average below 50%. This is an area of concern and issues need to be addressed to improve UIP program performance.

- An assessment of existing bottlenecks that impede success in UIP should be carried out by an independent agency.
- An in-depth assessment of the immunization systems in the states should be carried out to understand the better outcomes in a few versus the abysmal performance in others. Similarly, the neighboring country structures (e.g., Sri Lanka and Bangladesh etc.) should also be studied to learn from them.
- A systematic registration and identification of pregnancies and births along with computerization of data for data-management will be useful to facilitate reaching the every new cohort of children.
- Linking of the Geographical Information System (GIS) with UIP network can also be used to track delivery of vaccines.
- The strengths and gains from National Rural Health Mission (NHRM) in improving coverage of vaccination in certain states should be consolidated. The ANMs should be adequately incentivized to contribute to increasing coverage

6.2. AEFI surveillance system

The vaccines are administered as preventive measures to healthy individuals particularly children. The adverse events following immunization (AEFI) should be handled effectively in order to maintain/restore public faith in immunization program. The national operational guidelines on AEFI surveillance has been updated in 2010 and widely disseminated. All states and districts are now required to constitute AEFI committees, which assist in streamlining the reporting mechanism, investigate the reported serious AEFI and are involved in the causality assessment.

- The capacity building in AEFI surveillance and case investigation should be done in the entire country. The national and state level should have sufficient capacity to conduct causality assessment for AEFI. A mid term plan for capacity building should be prepared.
- There is need for establishing a strong mechanism for AEFI surveillance between immunization division and DCGI. The Post Marketing Surveillance (PMS) network being set in Maharashtra state should be used for strengthening AEFI surveillance in the entire country. Post marketing surveillance (PMS) of AEFI is also important to generate new hypotheses about vaccine reactions that are specific to the population. The experiences from Global PMS network in Maharashtra state could help in developing model practices at the state level.
- Effective collaboration and effective communication between National Control Laboratory, the National Immunization Program (NIP), and DCGI office should be established and quick identification and resolution of a vaccine batch related problem. Clarity of responsibilities and good liaison system between NRA and NIP is required and revised TOR of the immunization staff at all levels to delegate their role in the AEFI reporting has to be prepared.
- The Central Drug Laboratory at Kasauli, which is currently used for testing for vaccine samples in AEFI, should be upgraded and efforts should be made to get NABL certification.
- National Immunization Program (NIP) and National Regulatory Authority (NRA) should be provided with adequately trained human resource to manage and coordinate immunization safety initiatives.
- The national AEFI secretariat needs to be set in India. This may be established at National Centre for Diseases Control or similar identified institution. This secretariat would establish the links with the Brighton Collaboration and Global Advisory Committee on Vaccine Safety (GACVS) to further strengthen AEFI surveillance in India.

6.3. VPD surveillance

Vaccine Preventable Diseases (VPD) surveillance system in India is weak and needs to be strengthened to create an evidence base to

enable planning and deployment of effective interventions. Presently, the efforts to collect data on childhood infectious diseases of public health importance are fragmented and there is a need for reliable and comparable data to establish baseline information, monitor trends of infectious diseases, and monitoring the impact of existing interventions.

India has different surveillance models. Integrated Disease Surveillance Project (IDSP) is one of those surveillance systems. IDSP is a case-based surveillance system for detection of early warning signals of outbreaks. There are other sentinel surveillance systems which falls under different vertical national health programs for diseases targeted for control, elimination or eradication. The following steps need to be taken to further strengthen the VPD surveillance system in India:

- VPD surveillance has to be a long-term program in order to assess the impact of vaccination and therefore has to have a component for capacity building of the people involved.
- The VPD surveillance models followed in other countries like Brazil, United States of America, in Europe should be studied, with regard to integration and management of different surveillance networks in India.
- Assistance may be sought from international agencies, which already have the resource and expertise in this area, especially for training, monitoring and independent evaluation of the system.
- The country needs to establish a VPD surveillance networks with multi level system with first node being at district level. The next level can be at region; (one for each region of North, West, East South and Central India) and finally should be monitored by a Central body. These networks should work with defined and unified protocol, common SOPs, and also have a stringent and rigorous system of monitoring/auditing. These networks should also be equipped with the latest available systems for communication for timely dissemination of data to higher levels for action.
- Environmental surveillance using technology like Geographical Imaging System (GIS) and Remote Sensing (RS) should also be used to support sentinel surveillance. This could provide important details about disease hotspots and help in the prediction of epidemics and outbreaks.
- Innovations in diagnostics and tools for surveillance should be encouraged and facilitated. Tools for surveillance should be such that even the laboratories that are in the periphery at the primary health center can use it without much training of staff.
- Surveys like the National Family Health Survey (NHFS) should be further strengthened with trained manpower to create data sets on baseline demography. Such baseline demographic data is of utmost importance in interpreting disease burden data, results of clinical trials or when an adverse events following any intervention has to be investigated and causal linkages established.

The National Polio Surveillance Project (NPSP) has done extremely well in acute flaccid paralysis (AFP) surveillance in India. WHO/NPSP provides needed technical and training support for AFP and measles. This project could be used as a model for deriving lessons for VPD surveillance in the country. IDSP needs considerable strengthening in terms of laboratory and technical capacity in order to take on VPD surveillance and the efforts in this direction are already being done for inclusion of Hib and pneumococcal pneumonia and meningitis surveillance under IDSP. Since the organisms causing these two diseases are fastidious growers and are affected by prior treatment with antibiotics, inclusion of antigen based and DNA based tests will allow detection of organisms, which would otherwise be missed.

6.4. Vaccine forecasting, procurement and management

All UIP vaccines are purchased at the central level for distribution to the states. The procurement of vaccines in GoI is done under the broad overarching General Financing Rules (GFR). The vaccines are purchased using Annual Rate Contracts (as per GFR) against which Supply Orders are issued. Parallel contracts are awarded for most vaccines, because no single domestic manufacturer has enough available production capacity to cover the entire annual requirement. While the UIP vaccines are purchased by the central government from indigenous sources, OPV for mass immunization campaigns as well as Japanese Encephalitis (JE) vaccine is procured through other mechanisms.

The current dependence on a limited number of domestic vaccine producers leaves the UIP vulnerable to price increases and supply shortages. There is need for a few steps to be taken to address this issue:

- Transparent evaluation criteria and effective contract monitoring systems need to be instituted along with establishment of an independent evaluation committee with binding outcomes to oversee all vaccine procurement.
- Procurement timing has been out of step with the realities of vaccine supply. UIP vaccines have a long production time, short shelf life, and a supply that must respond to the continuous birth of babies with a specific schedule of needs. A multi year cycle of procurement should be tried and contractual lead time increased to better match vaccine production cycles.
- The current number of personnel attending to UIP procurement and distribution is not adequate for the magnitude of the task. Mechanisms to improve the efficiency of procurement and distribution must be identified.
- Quantities and delivery schedules for procurement of AD syringes must match vaccine quantity and delivery schedules.
- Closer management of delivery schedules to ensure that over-stocking and under-stocking in different states needs to be instituted.
- An in-depth study of the distribution system – including lower levels, should be undertaken to evaluate factors considered for forecasting and determining supply requirements. This will be helpful in addressing the vaccine supplies and shortages at various levels in the country.

6.4.1. Vaccine wastage

An assessment of vaccine wastage in India, conducted in 2009 revealed that wastage rates depended on formulation, presentation and was inversely proportional to session size. Both cold chain requirement and vaccine wastage is expected to increase several fold with the introduction of newer vaccines compared to the UIP vaccines. Smaller dose vial is recommended for vaccines that have only one dose in the UIP schedule (e.g. Single dose for birth dose of HepB), and 2- 5 dose vials for the newer & more expensive vaccines). A huge amount of vaccine is damaged in the primary stores, which is beyond the scope of vaccine wastage study, needs to be factored in to. Adopting WHO multi-dose vial policy at session sites may be considered.

6.4.2. Cold chain management

Cold chain storage capacity in India has improved in recent years. A nationwide cold chain assessment in 2008 revealed the shortage of cold chain equipment, of space allocation, and lack of preventive /corrective measures for breakdown of installed cold chain equipment facilities in immunization centers and storage facilities. The shortage of appropriately trained manpower to manage the cold chain logistics and equipment is another challenge.

These cold chain management challenges can be addressed by:

- Regional cold chain training cum support units should be established by GOI to provide appropriate support to the states.
- Mechanisms and systems in place for independent auditing of cold chain capacity,
- Developing some basic standards of storage and vaccine stores as per the global standard and need to be circulated to the states
- Regular self assessment of cold chain and vaccine management using standard global Effective Vaccine Management tool.

6.4.3. Vaccine stockpile in disaster and outbreak situation

The growing need is being felt to stockpile of vaccines against certain diseases with potential to cause outbreaks such as Cholera, JE and H1N1 and other seasonal influenza. These vaccines are required for an affected target population and the quantity needed for stockpile should be assessed together with the National Disaster Management Agency (NDMA). This may be achieved by taking following step:

- The manufacturers of these vaccines have to be communicated of the decision ahead of time for planning production and when the stock expires or is utilized.
- Adequate budgetary provision for such stockpiles should be created and adequate cold chain equipment earmarked for storage.

- The NDMA also needs to be intimated about the locations of these stockpiles and effective communication maintained with the agency for delivery of these vaccines during an emergency situation.

6.5. Human resource

The UIP in India is among the largest immunization program in the world, targeting 2.7 Crore infants and 3.0 Crore pregnant women. The program is administered by the Immunization Division of the MoHFW, GoI. Several assessments have revealed the shortage of appropriately trained human resource for immunization services at all levels in the country.

The present size of immunization division is extremely small, given the size of the country and number of beneficiaries to be serviced. Capacity building needs to be supported on a sustainable basis and should be adequately stressed in the national budget.

- The institutional framework for immunization and capacity for program managers with a public health background and good leadership skills to drive immunization program needs to be established.
- Immunization is a centrally driven vertical program, with limited ownership at the facility level. The knowledge, skills and attitude needed for the various functions should be reviewed, gaps identified and long-term projection for human resource need to be developed.
- The existing system should be equipped to handle the new vaccine introductions. The gap between policy and scale-up of human resource needs to be addressed.
- The central immunization division needs to be much larger and expansion needs to be looked into in terms of functional categories: Data analysis and policy, management for vertical programs, cold chain, research and communication etc. Expansion of public health cadre at the central level to enable induction of more officers from the cadre as immunizations managers both at the immunization Division at the Centre and at the State level is much needed.
- A cadre also needs to be built for monitoring and supervision of immunization program, which is currently lacking.

- The Tamil Nadu example, where an Independent Public Health Department with clear lines of supervision, needs to be studied for scale-up.
- In order to improve vaccine coverage and service delivery, all human resource initiatives should be in the framework of NHRM. Various interventions under NRHM, like provision of second ANMs, support for alternate vaccine delivery etc. should be taken into consideration for planning for HR activities. Alternate vaccine delivery needs to be strengthened to reduce vaccine wastage and improved quality of vaccination.
- Available technical resources at the national level i.e. NIHFW and other national institutes etc. can be utilized for public health training /orientation for immunization managers.
- Capacity for data management in order to improve the Health Management Information System (HMIS) and the mother and child tracking system is needed. In order to reduce the gap between reported and evaluated coverage, facility based reporting should be strengthened.
- There is a need for capacity building in cold chain management in the country. The institutional framework for strengthening cold chain management need to be built.

Health is a state subject. A clear co-ordination mechanism needs to be in place in consonance with central program. A policy for better state-center co-ordination in vaccine should be adopted maintaining the state autonomy and creating a structure to coordinate. The lessons learnt from program introduction should be used to improve the system. Setting up an appropriate infrastructure for evaluation and monitoring should be a priority. Any major shift in policy at the state level should be affected through a state and center coordination committee

6.6. Advocacy and communication

Advocacy and communication efforts are as important for community acceptance of the new vaccine as also for maintaining their confidence in the existing vaccines. This is especially important for situations where a few serious adverse events following immunization are reported. In the community, there are always people who have concerns regarding vaccines- either perceived or

real. A system has to be in place to speedily deal with them in a scientific manner, so that individual concerns do not affect the vaccination program in the community.

- Operational research to gauge the perceptions of the target community about immunizations could help in developing the communication and advocacy strategy and should be encouraged. The messages and methods used for its dissemination need to be tailored to the target audience.
- The training of health care workers is needed to respond to the frequently asked questions (FAQs) by the parents and care givers so their confidence in the immunization program is maintained and if possible augmented.
- Effective communication system should be in place to convey the benefits (and expected adverse events) as well as disadvantages of not being immunized to the population to be immunized.
- There are needs for studies and operational research to understand the public and community attitude towards immunization. This information should be utilized for policy formulation and taking corrective actions.

6.7. Ethics and equity

The ethical use and equitable access to prevention and care should be the basic mantra of any program meant for ameliorating disease burden in the country. The new vaccines, which are relatively expensive than traditional vaccines, are commonly used by the upper and middle class families through personal resources from the private market. The children of poor families, which can't afford these vaccines, are at disadvantage and introduction of these new vaccines in NIP is an approach to make vaccine accessible to the poor and needy.

- Public health benefits of vaccines in the mass immunization programs should always outweigh the adverse effects. The economic burden and inconvenience to the parents/family should always be factored in when planning.
- Studies that compare the burden to benefits ratio of vaccination to other options available for prevention should be encouraged.
- There are several models for financing of vaccination for the

impoverished other than government funds e.g. Typhoid vaccines in Pakistan, where the rich kids pay a price for the vaccine that allows it to be subsidized to the poor kids. In Bangladesh, the fishery industry finances the cholera vaccine for the poor. Such models need to be studied and similar ones to be developed for India at least for some vaccines such as pneumococcal conjugate vaccine, rotavirus vaccine and HPV vaccine.

7. IMPLEMENTATION AND MONITORING

The national vaccine policy will be widely disseminated amongst policy makers and program managers. This document will be utilized for the drafting of the strategies and operational plans. This will be key document which will be utilized for harmonizing other policy and planning document.

For each area, a number of monitoring indicators will be prepared and progress on this document will be monitored accordingly. This will include a summary of progress, identified areas where progress is lagging, and propose corrective actions, where needed.

There are multiple stakeholders, including national and state governments and development partners, in immunization program in India. The Union and state governments are involved in all aspects of program while the role of development partners are most often involved in providing technical assistance and support, rather than direct implementation.

While the policy implementation will be monitored on the regular basis, this policy will be reviewed after periodic intervals, allowing changes to be made, which respond to the reality of then health policy environment in the country.

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