Policy Document

*Based on deliberations of a workshop on vaccine policy held during 4-5 June, 2009 in New Delhi.

Evidence-based National Vaccine Policy*


Abstract

India has over a century old tradition of development and production of vaccines. The Government rightly adopted self-sufficiency in vaccine production and self-reliance in vaccine technology as its policy objectives in 1986. However, in the absence of a full-fledged vaccine policy, there have been concerns related to demand and supply, manufacture vs. import, role of public and private sectors, choice of vaccines, new and combination vaccines, universal vs. selective vaccination, routine immunization vs. special drives, cost-benefit aspects, regulatory issues, logistics etc. The need for a comprehensive and evidence based vaccine policy that enables informed decisions on all these aspects from the public health point of view brought together doctors, scientists, policy analysts, lawyers and civil society representatives to formulate this policy paper for the consideration of the Government. This paper evolved out of the first ever ICMR-NISTADS national brainstorming workshop on vaccine policy held during 4-5 June, 2009 in New Delhi, and subsequent discussions over email for several weeks, before being adopted unanimously in the present form.


National vaccine policy

Vaccines are very useful as preventive medicine in public health to reduce morbidity and mortality due to communicable diseases, though they are not a substitute to safe drinking water, sanitation, nutrition and environmental health in the long run. A national vaccine policy is needed, as a part of the broader National Health Policy, based on the principles of public health and comprehensive primary health
care. This is to enable rational and evidence-based decisions for the development, entry, production, stable supply, pricing, promotion and use of appropriate vaccines on scientific grounds. Additionally, this is also needed to protect the national vaccine programmes and national health security, as well as to leverage indigenous capabilities to cater to domestic and overseas markets.

Objectives

1. To contribute to the prevention of mortality and morbidity due to communicable diseases that afflict large populations, especially children; through the development/production and use of safe, effective and affordable vaccines, chosen rationally.

2. To ensure consistent delivery and administration of vaccines to everyone in need.

3. To achieve national self-reliance in vaccine R&D, as well as to maximize the national benefits of international sharing of indigenous biological diversity of pathogens, hosts and knowledge, to the Indian end-users of vaccines on terms that are fair and just.

4. To achieve pre-eminence in the capabilities of the indigenous public sector for self reliance and foster a leading role for them in all the aspects of vaccine development, production and immunization for national health security and biosecurity.

5. To develop and use the interdisciplinary knowledge base needed for science-based policy and evidence-based medicine in the field of vaccines.

6. To promote ethical conduct in the development, trials, adoption and administration of vaccines, especially aimed at children and pregnant women.

7. To develop a system for monitoring and compensating adverse events following vaccination where required.

8. To enable India to play a leading role in the supply of affordable vaccines to the emerging world, considering the declining interest of the multinational sector to make cost-effective vaccines for the emerging world.

9. To synergize all other relevant policies for effective implementation of the national vaccine policy to fulfill the above objectives.

Guiding principles, context and approach:

A vaccine is just one among the many inputs (food security, safe drinking water, sanitation, primary education, gender sensitivity, and health education) needed for effective public health management of communicable diseases. Even all the known vaccines put together cannot prevent all deaths due to all communicable diseases. However, amongst medicines, rationally selected vaccines are the most cost-effective in reducing morbidity and mortality and have an important role to play as a public health measure in the control of some communicable diseases.

Public Sector’s role & self-reliance: Most of the indigenous capabilities and strengths in this area were pioneered and sustained by the public sector. Strengthening the role of the public sector in the area of vaccines is crucial to ensure self-reliance and to protect national health security from the uncertainties of the local and global market forces, as well as from bio-terrorism and biological warfare.

Vaccines under UIP: Vaccination should be need-based and all vaccines are deemed non-universal, unless specified otherwise based on scientific evidence. As vaccines are given to a healthy population,
their safety and efficacy should be thoroughly assessed based on various scientific parameters, before any vaccine is introduced into the National Programme.

Vaccines outside the UIP should not be unethically promoted through direct or surrogate advertising, advocacy by individuals, groups or aid agencies, on their own or funded directly or indirectly by the vaccine industry.

**Choice of vaccine/vaccination and cost-benefit analysis:** The choice of which vaccine to give (or not to give), target population, and mode of administration, (dosage, schedule, interval between doses, intramuscular or intradermal, etc.), are important policy decisions that must be guided by a strong scientific rationale, after wider scientific debate in the country, with rigorous inputs from multicentric field epidemiology, irrespective of whether it has been proven in populations abroad.

Cost-benefit as well as risk-benefit assessment should be carried out in India taking into account local serotypes and variations in indigenous host-pathogen-environment interactions. These studies can be best done by one or more public sector institutions and the results be made available openly on the website of the concerned agency for wider peer review and public debate.

**Vaccine Procurement/production Choice:** Vaccine choice, source of procurement and the quality standards of the products and the production system should be based on sound principles to achieve maximum benefit to maximum number of people and are independent decisions of the national Government guided by this national policy (not imposed by industry and international organizations).

**Technological advances:** Technological advances in vaccines, especially for mass immunization, have to be measured in terms of their improvements in efficacy, long-term protection, safety, and cost-competitiveness, stability during storage and transport, and method of administration. Technological superiority of vaccine should not be assumed solely in terms of purity, sophisticated methods of production, combinations or other incremental innovations aimed at extension of intellectual property and commercial monopoly.

**Combination vaccines:** Combination vaccines are convenient but useful and acceptable only when universal and non-universal vaccines are not combined, whether for public or private use. In any case, the safety and efficacy of every combination vaccine has to be freshly established in the target population and cannot be extrapolated from the safety and efficacy of its individual components. In case of cocktail combinations, the price of the combination may not exceed the sum of its individual components.

**Vaccine Trials:** Unless absolutely necessary, vaccine trials in children should begin with grown up children and then move downwards. Suitable amendments may be introduced in the proposed National Biotechnology Authority Act to address Clinical trials and bio-safety regulations in vaccines targeting children and pregnant women to deal with ethical and other public health concerns. Such issues can become more critical when foreign entities conduct clinical trials on Indian children. Phase lag is necessary in such situations.

**Pricing, regulation, IPR issues and access to vaccines:** The Government shall evolve a suitable legislation enabling Adverse Vaccine Reaction Monitoring & compensation for injuries to any person(s) arising out of vaccinations in India, including for those in the trial phase. This should apply to all vaccines, whether provided by the Government, public sector or by the private manufacturers/practitioners. The legislation would be designed to fix responsibility and deliver compensation adequately and promptly in the event of injuries/adverse events due to vaccines and vaccination.

Pricing of all vaccines should be brought under the Drug Price Control Order (DPCO) and subjected to regulation in accordance with the objectives of this policy. Pricing of vaccines should be done on a
transparent basis and agreed principles of reasonable returns on investment, rates of royalty and costing of R&D efforts. There should be no overhead taxes imposed on vaccines such as excise duty, value added tax (VAT), customs duty etc. The difference between maximum retail price (MRP) and the price at which vaccines are supplied to wholesalers, retailers, hospitals or even to doctors will also be minimized to deter monetary incentives for unethical vaccine promotions.

International sharing of indigenous biological diversity of pathogens, hosts and knowledge should be governed by the legal principles of prior informed consent and benefits sharing agreements set in the National Bio-Diversity Act. The material transfer agreement should have a clause preventing the recipient from seeking or claiming intellectual property rights over any inventions derived from Indian biodiversity or indigenous knowledge. It should also have copy-left style clauses for open sharing of the research results to develop vaccines and other technologies to combat diseases. Prior informed consent to any overseas individual or entity should be subject to the condition that Indian scientists, technologists and public sector manufacturing entities will have automatic royalty-free rights to use all the further improvement in that knowledge and any technology, product or process that comes out of the shared biological resource or knowledge, or to license it further to indigenous private firms if deemed necessary. This maximizes the national benefits of international sharing to the Indian end-users of vaccines.

Publicly funded R&D on vaccine technologies should be made available widely on a non-exclusive basis to promote manufacture of quality vaccines at competitive prices. Research papers emerging out of publicly funded R&D should also be made available freely through an open access policy. In all publicly funded vaccine research and development programmes, affordable access to vaccine technologies and the crucial role of the public sector manufacture for national programmes should be given priority over all IPR issues and other technology transfer considerations. Further, knowledge commons approach to R&D and other measures that enhance access to vaccine technologies identified under the National Vaccine Policy should be promoted.

The above principles and public health concerns of the nation will have an overriding priority over any multilateral, bilateral or regional trade agreements.

**Policy measures**

**Strengthening integrated disease surveillance programme:** The success of vaccination or any other public health program, or the strategy of universal or selective vaccination depends heavily on the disease surveillance and monitoring system in the country. Ideally, such a system should contain frequently collected information on the incidence and prevalence of diseases in the population, local variations in the pathogens including serotypes, resistance to drugs/antibiotics if any, host response to vaccination, efficacy and duration of protection, etc. In order to augment the present mechanisms available for disease surveillance and monitoring as well as vaccination, the Panchayati Raj institutions should be strengthened, and training imparted to the health management information system (HMIS), integrated disease surveillance project (IDSP), Accredited social health activist (ASHA), Auxiliary Nurse Midwife (ANM) and health workers.

Critical appraisal of literature should be undertaken while considering new vaccine adoption in UI or SI decisions. Limited data on the actual prevalence of a disease may over-estimate the actual disease burden. Large multicentre and community based studies should confirm the real burden of any particular disease in the country.
Enhanced public funding and programme support for R&D into communicable diseases, especially neglected diseases and vaccine-preventable diseases. Increase in budgetary allocations for investment in proven cost-effective programmes.

Selection of appropriate vaccines in UIP: To ensure selection of appropriate vaccines on scientific grounds, for the UIP, well-defined criteria of cost-efficacy and logistical feasibility, appropriateness should form the basis. A Committee should do this selection after a broad based debate amongst the concerned Public Health experts. No new vaccine should be introduced into the UIP unless adequate and sustained resources/efforts have been devoted to achieve universal coverage of the existing vaccines. The lure of external aid/loan cannot be a sufficient ground for introduction of new vaccines under UIP.

The current National Technical Advisory Group on Immunization (NTAGI) should be restructured into a central National Vaccine Regulatory Authority (NVRA) that allows wider representation to indigenous scientists, policy experts and indigenous public sector and civil society. Apart from invited membership, provision should also be made for voluntary participation of representatives from any non-commercial organization. This authority would be empowered to take all major decisions such as monitoring disease burden, vaccine development, adoption, production, procurement, distribution, immunization and follow-up.

A critical review of the current UIP vaccines and new vaccines may be undertaken by the National Vaccine Regulatory Authority (NVRA). Any new vaccine introduction in UIP must be qualified before its introduction for Universal or Selective Immunization, based on epidemiological evidence, suitability and efficacy to the local pathogens and human populations, risk-benefit and cost-benefit analyses. Rejuvenation of the existing institutions of research, education and training of public health workers. The National Vaccine Regulatory Authority (NVRI) will identify such aspects relevant to India and coordinate with existing agencies like Indian Council of Medical Research (ICMR), DBT, Council of Scientific and Industrial Research (CSIR) etc.

Similarly, a critical review of the combination of UIP and non-UIP vaccines must be carried out in view of the stated policy objectives. Combining any UIP vaccine with any non-UIP vaccine needs rigorous scrutiny and public debate. Other combinations must be proven to be equivalent to or more effective and safer than single vaccines before adoption.

Private vaccine markets and also their use in private clinics should be regulated through a mechanism to be brought under National Vaccine Regulatory Authority (NVRA) supervision.

Ensuring stable and affordable supply of UIP vaccines: In order to ensure stable and affordable supply of vaccines to the national immunization programme and also to address national health security and biosecurity concerns, all essential vaccines covered under UIP (TT, DT, DTP, BCG, Polio, Measles) must continue to be produced by the public sector. Further, the presence of at least two functional PSUs per vaccine (as a backup for each other) must be ensured as a protection against market uncertainties, or patented vaccines and other interventions needed for public health, the Government should take all necessary law and policy measures including government use and compulsory license provisions to ensure timely availability of vaccines at an affordable cost. For off-patented vaccines, suitable law and policy measures should be taken to promote competition by providing incentives to generic manufacturers.

All the vaccine PSUs must be urgently revived and modernized to fill the demand-supply gaps in all essential vaccines and anti-sera, including the UIP vaccines. The Government purchase orders for safe & effective vaccines available from PSUs must not be diverted to the private sector under any pretext. For example, the recent introduction of a pentavalent vaccine (that combines DTP with Hepatitis B and Influenza type B) into the UIP effectively diverts all the DTP purchase order from PSUs to private
entities, as the PSUs do not manufacture them so far. Besides, the merits of universal vaccination against Hepatitis B and Influenza type B are highly debatable.

Indigenous vaccine R&D and production capacities must be strengthened to ensure a stable and affordable supply of all essential vaccines, especially the UIP vaccines. For this purpose, the core strengths of the vaccine PSUs must be preserved and nurtured with higher functional autonomy (at least at par with the Navratnas), incentives to attract interdisciplinary talent for R&D and production.

Various vaccine PSUs are currently under different managerial regimes – state and central Governments, and even within the central Government, under ministry of health and family welfare (MOHFW), department of biotechnology (DBT) and national dairy development board (NDDB). In order to enhance functional coordination between them to meet the national vaccine needs, their governing bodies should be expanded to include public health experts, epidemiologists, microbiologists, immunologists, vaccine policy experts, pharmacologists, economists, sociologists and other interdisciplinary experts and non-Governmental organizations (NGOs).

Government procurement of vaccines under UIP must be based on price and opportunity parity, and no PSU should be excluded from Government vaccine procurement, as long as the product quality and affordable price are ensured. Similarly, no PSUs should be excluded from producing any vaccine, as long as it stakes a credible claim to manufacture it in compliance with all the regulatory and quality norms at competitive prices. The Government may make advance market commitments with vaccine PSUs subject to quality parameters, but not with any other private or foreign entity to the detriment of the vaccine PSU. No private firm should be paid higher prices than their PSU counterparts supplying to UIP. The whole process should be made transparent.

Any private sector unit that wishes to produce new (non-UIP) or combination vaccines must produce some UIP vaccines (individually and not as combinations) to fill any shortfalls in PSU production and Government procurement.

**Strengthening vaccine delivery systems:** Improved logistics and supply chain system, including maintenance of cold-chain during periods of heavy load shedding, especially in rural areas. Emphasis on the outreach of vaccination programmes to remote areas and the marginalized populations, tribals etc; Promotion of awareness and trust building in communities through various measures to ensure full vaccination coverage.

Strengthening of basic infrastructure and manpower in primary health care centers (PHC) and ancillary programs such as ICDS and the ASHA network, with emphasis on name-based tracking of individual children and women, ensuring planned fixed-day immunization sessions, reporting based on correct denominators and frequent decentralized monitoring of coverage independent of service reports are keystones of successful coverage. In addition, the regular audit of vaccine utilization is essential. Currently, all these are not subject to regular and independent scrutiny, and can be brought under the ambit of NVRA. A prevailing concern has been the tendency of immunization programs to operate independently of other primary health care programs. Maintaining this balance will be critical to the success of both, the UIP and the other PHC programs.

**Regulation and Access to vaccines needed:** Regulation of advertisements and other promotional marketing activities to prevent unethical means and kickbacks to doctors. Literature should not be cited selectively to base decisions. The role of the industry as the educators of the professionals, policy makers, people and Direct-to-consumer promotional advertisements on upcoming vaccines with incomplete biased information must be discouraged/banned.

The Government of India is solely responsible for the compliance of its PSUs for good manufacturing practice (GMP) and all other regulatory norms, as well as to prevent stoppage of production on such
counts. Therefore, the Government of India must provide all the necessary administrative and financial support for PSU compliance with GMP and all other regulations. The governing bodies and other technical committees of PSUs must be expanded to enable expert monitoring/advice from vaccine policy and public health experts, apart from scientists/technologists of relevance. Representatives from private vaccine manufacturers and industry-funded medical associations/academies must be specifically prohibited to prevent conflicts of interest.

In order to make the essential vaccines more affordable to the indigenous end-consumers, measures such as tax concessions/exemptions may be considered.

A thorough and transparent review of all public private partnerships (PPP) in vaccine development, production and delivery is needed, including the upcoming vaccine park at Chengalpattu. All measures should be taken to ensure that PPPs do not amount to public spending and private profiteering. The public private partnerships for developing and manufacturing new vaccines may be beneficial only when the state of art for making vaccines remains with public sector, while private sector is made to meet vaccines that are needed.

Promotion of health systems research to formulate optimized health systems that can deliver vaccines efficiently and effectively.