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Introduction of newer vaccines in Immunization Programme of India: Challenges to be addressed

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Small Pox eradication will continue to be regarded as the humanity's greatest triumph for all times to come. Since then, several health achievements were attained that too made significant contributions towards the goals of human survival and development. Substantial reductions in deaths and disabilities have been observed in diseases like childhood Tuberculosis, Pertussis, Diphtheria, Measles and paralytic Polio. In India, considerable reduction in vaccine preventable disease (VPD) burden was observed following launch of Expanded Programme of Immunization (EPI) in 1978. Reported number of Pertussis cases came down from 320109 (1980) to 25206 (2015). Measles cases reduced from 114036 to 25488 in the same time interval. Maternal and Neonatal Tetanus has been eliminated from most part of the world including India. There

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were 18975 paralytic Polio cases reported in 1980, which came down to 'zero' in 2011, and South-East Asia region including India declared free of WPV in 2014. We are at the end game phase of another great landmark, Polio eradication. In all these successes, immunization was the core intervention.

Millennium Development Summit in 2000 focused on intensification of child health interventions for attainment of the MDG-4 of reducing under-five deaths. The benefits of traditional EPI vaccines are already evident. Worldwide, the projected number of deaths averted by Measles vaccine (including SIA rounds) during 2011-2020 will be around 14.1 million. Introduction of newer and less utilized vaccines may further boost the attainment of MDG-4. Universalizing Hepatitis-B vaccine may prevent 6 million child deaths by 2020. Newer vaccine Hib may avert 1.7 million deaths. Sustaining the current vaccines and upscaling the programme with newer vaccines is expected to prevent 25 million child deaths worldwide during 2011-2020. Also, a number of new vaccines, like malaria, dengue, new-generation tuberculosis and typhoid conjugate vaccines are in advanced stages of development and may be available in the coming years.

Upscaling the current immunization programme with introduction of newer vaccines has been mandated both at the international level [Global vaccine action plan 2011-2020. WHO; 2013] as well as at the Govt. of India level [Multi-year strategic plan 2013-17: Ministry of Health & Family Welfare, Govt. of India. 2014].

Following are some of the challenges that are to be addressed for attaining the goals.

Worldwide currently around 100 million children are vaccinated annually. But another 24 million children, mostly in the under-developed and developing countries, remain partially immunized or un-immunized. Global vaccine action plan 2011-2020 envisaged universal access to immunization, regardless of the geographic location and social or economic conditions. "Promoting equity is more than moral obligation. It is both a practical and a strategic imperative, helping to break intergenerational cycles of disadvantages and thus reducing inequalities that undermine all societies." [The state of the world's children 2016. UNICEF]

In India, with the traditional EPI vaccines, full primary immunization coverage is only around 65%. It is estimated that around 9 million children in India are not receiving all the available UIP vaccines. This is almost 40% of the global load of partially or un-immunized children. Reaching this unreached section Reaching this unreached section, and expanding the uptake of newer vaccines is a major challenge. Overcoming the barriers to access the immunization services will require addressing the supply side issues like identification of the difficult to reach areas and communities, realistic microplanning and

ensuring availability of supplies and services. The demand side issues also need to be addressed through intensified behaviour change communications and strengthened mobilization strategies.

Cost and funding mechanism is another major challenge. Per dose cost for traditional EPI vaccines like BCG, DPT, OPV are around US$ 0.05 for each vaccine. Per dose cost is many times higher for newer vaccines like Pentavalent (US$ 2.21), IPV (US$ 1.0), Rotavirus (US$ 1.0) and PCV (US$ 3.30). At the start of the EPI era in 1980s, full immunization cost per live birth in developing countries was US$ 3.50. By 2010, with phased introduction of Hepatitis-B, JE vaccine, etc., the cost escalated to US$ 18.00 per live birth. With introduction of newer vaccines like Pentavalent, Hib, Rota, Rubella and PCV, the cost will rise to US$ 30.00 per live birth by 2020. The annual cost for immunization programme of the world's 94 low and lower-middle income countries was US$ 4500 million in 2011. By 2020, the projected escalation for scaling up the programme will be US$ 9000 million per year. About 85% of this cost escalation will be for newer vaccines.

Vaccine procurement cost in India will escalate from INR 287.6 crore in 2012 to INR 3587.1 crore in 2017. More than 80% of this rise is because of roll out of new vaccines. Introduction of new vaccines will also escalate other cost components like AD syringes, cold chain equipment, capacity building, IEC and BCC. For example, projected cold chain cost will escalate from INR 39 crore in 2012 to INR 218 crore in 2017.

A strong immunization service delivery system is fundamental requirement of any health system. The system must be capable to ensure vaccine and injection safety, quality of services, equity and coverage. This requires a proactive policy support and sustainable funding mechanism. The newer vaccines will obviously utilize the already existing delivery system, but there is need for appropriate adjustments and upgradations to accommodate the newer vaccines and processes involved. Presently, the cold chain space requirement for routine immunization vaccines in India is 64 ml. per infant at district store level and 100 ml. per infant at BPHC store level. These estimates may change with phased introduction of new vaccines. Scaling up of vaccine storage and transport capacity, maintaining stringent thermoregulation, strengthening the supply chain management and capacity building in health personnel are some of the challenges that need to be addressed.

Cold chain and vaccine logistics management is a challenging issue in ensuring quality of the vaccines. National Cold Chain Vaccine Management Resource Center (NCCVMRC) and National Cold Chain Management Information System (NCCMIS) were established to develop resource materials, guidelines, operational protocols,

web-based linking of all cold chain equipment and assessment of cold chain system in the country.

The first National level Effective Vaccine Management (EVM) study conducted in 2013 assessed 4 GMSDs, 16 State & regional stores, 14 divisional vaccine stores, 28 district vaccine stores and 52 health facilities spread over 11 States of India. There were 356 indicators clubbed together in nine EVM criteria. WHO recommended performance benchmark is at least 80% score in all nine EVM criteria. The 2013 assessment results showed that 80% benchmark has not been attained in any of the EVM criteria. Consolidated criteria score for storage at recommended temperature was 54%, maintenance of cold chain equipment 57%, stock management 51% and score for distribution between each supply level was only 45%.

Quality assurance mandates addressing all these gaps effectively. In view of very high cost of the newer vaccines, this is more important to maintain stringent thermoregulation and efficient stock management systems to avoid overstock, stockouts and wastage. Rational number of cold chain points, rational microplans and number of sessions are fundamental requirements for efficient vaccine management. These, alongwith an efficient vaccine delivery system including AVD system, proper implementation of open vial policy and ensuring vaccine return from session sites will optimize the vaccine utilization and wastage.

Rational utilization of the immunization service delivery system for provision of other health interventions has several programmatic advantages. The beneficiary subgroups mostly being the same, collateral advantage of this platform must be utilized for a wide range of RCH interventions, like Vit.-A, anaemia control, deworming, growth monitoring, contraceptive distribution etc. This also provides opportunities for enhancing uptake of other public health interventions like malaria rapid testing, distribution of insecticide treated bed nets, HIV surveillance at subcenter level, and so on.

Uninterrupted availability of good quality vaccines is a prerequisite for immunization services. Since introduction of IPV, Govt. of India is facing the problems of difficulties in procurement and frequent stock-outs. Introduction of newer vaccines in newer regions and anticipated uptake in the coming years will increase the vaccine demand manifolds. There are limited number of vaccine manufacturers and production capacity cannot be scaled up overnight. Proper coordination between UN and other funding agencies, consultations between international and country level policy makers and manufacturers, demand estimates and forecasting, are essential to maintain the demand-supply balance.

Vaccine research, development and production involve different manufacturers in different countries with different manufacturing practices and regulatory mechanisms. Also a variable and complex funding mechanism is involved in immunization funding. Global standardization is crucial to ensure that all manufacturers maintain same product specifications and quality benchmarks in terms of manufacturing processes and biological characteristics of vaccines.

Intensification of VPD and AEFI surveillance is another crucial programme requirement in view of the use of newer vaccines in newer populations. VPD surveillance should be intensified to track impact and effectiveness of new vaccines. AEFI surveillance in India still has several deficiencies in terms of completeness and quality. Surveillance system must be capable to generate complete, timely and reliable data on AEFI particularly with newer vaccines. AEFI reporting, investigation and response mechanism must be strengthened. Besides programmatic decisions, evidence is also necessary to develop and sustain public confidence on the system and to address the public concerns when necessary.

In-country variation in immunization scheduling is another issue. In India, private sectors mostly follow IAP schedule that is different from the National schedule. National schedule is based on epidemiological considerations, community risk assessment and cost evaluations. The private sector schedule is based on individual risk assessment, and cost is mostly not a concern. Harmonization of different schedules needs to be considered. Coordination with private sector is also important as private sector play a major role in immunization services in India particularly in urban areas.

Following are some of the important milestones in India's immunization programme that may help us to visualize how the programme upscaling is evolving. Since launching of NRHM in 2005, besides rolling out of newer vaccines in phased manner, multiple additional technological and programmatic inputs have been provided to ensure vaccine quality and injection safety, cold chain & logistics management, and to strengthen programme management and supervision.

1997	Vaccine vial monitor introduced
2005 NRHM era: Multiple technological & programmatic inputs	Alternate vaccine delivery system operationalized
	Injection safety protocols including universal use of hub-cutters
	Incentives to ASHA for drop-out & left-out track, mobilization & full immunization
	Computer assistant in all districts for immunization data management
	VHND at outreach sites made operational
	Strengthening cold chain system and vaccine logistics management
	Fund for mobility support for supervision at all levels
2006	JE campaign followed by introduction in routine programme
2010	Measles 2nd dose introduced
2011	Open vial policy started Hepatitis-B vaccine universalized Pentavalent vaccine introduced in few States
2013	JE 2nd dose introduced
2014	India and South-East Asia region declared Polio free
2015	Maternal & Neonatal Tetanus Eliminated
	Pentavalent vaccine universalized
	Mission Indradhanush introduced in selected high priority districts
	tOPV to bOPV switch
	IPV rolled out
2016	Rotavirus vaccine introduced in four States- AP, Odisha, HP & Haryana
	Measles-Rubella vaccine pilot started
	PCV introduction in HP, Bihar, UP
	HPV pilot in Punjab (State initiative)
2017	Rotavirus vaccine to expand in five more States- Assam, Tripura, MP, Rajasthan, TN

"If the soul of a society can be judged by the way it treats the most vulnerable members, then by a similar measure, the society's future - it's long term prospects for sustainable growth, stability and shared prosperity – can be predicted by the degree to which it provides every child with a fair chance in life.'' [The State of world's children 2016. UNICEF]

In India we target 27 million children and 30 million pregnant women each year as immunization beneficiaries. The estimated number of vaccine injections that are administered each year is around 370 million! No programme anywhere in the world deals with such a huge number. Beside numbers, we are confronted with too many programmatic challenges because of extreme heterogeneity in terms of geographical

locations of our beneficiaries, climatic conditions, educational levels, and diverse socio-cultural and economic situations. All these obstacles must be optimally addressed to attain the child survival goals.

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