

New Vaccines for All: Why, Which, When?

Over the last few years, to the initial six vaccines against tuberculosis, diphtheria, whooping cough, tetanus, poliomyelitis and measles; Hepatitis B vaccine has been included in the Universal Immunization Programme (UIP). A combination vaccine against diphtheria, whooping cough, tetanus, poliomyelitis and hepatitis B, the pentavalent vaccine, is being considered for inclusion in the UIP, but not without attendant doubts and questions. Further, a slew of new vaccines are competing to get into the national schedule. These include the vaccines against rotavirus, rubella and Human Papilloma Virus, and injectable inactivated polio vaccine. These developments have led to the following question - Which vaccines should be added to the national immunization schedule, so that they are offered to all children in the country? The answer to this question should be based on evidence that a particular vaccine is, compared with other interventions, not only more effective against an infectious disease of public health relevance but is also safe and cost effective on the ground and is affordable for the country. Further, the public health system should have the organizational capacity to deliver the new vaccines at appropriate times, without a negative impact on the coverage of the previously used vaccines, or on any other services offered by it and it should be able to monitor the effectiveness and safety of the vaccines. Accordingly, the National Vaccine Policy recommends a detailed evaluation of these factors before a decision to include a new vaccine is taken.

How do new vaccines find their way into the national schedule? Once a vaccine has gone through the mandatory stages of testing, professionals, public health experts and possibly vaccine manufacturers lobby and submit proposals for inclusion of a candidate vaccine into the national schedule for approval by a National Technical Advisory Group on Vaccines (NTAGI), a body that includes technical experts chosen by the Ministry of Health. This is a closed group, which deliberates and finally comes out with a recommendation based on majority voting that is then put up to the Ministry of Health for consideration of final administrative decision making and for making budgetary allocation.

Vaccines are unique given that they are the only medicines given on a mass scale to healthy people. Hence not only are they expected to adequately prevent the illnesses for which they are meant, they are not acceptable by the community in case of any major adverse events such as hospitalization, death or disability. That majority of vaccines are given to children in their first months of life, which is a vulnerable period as it is, make safety concerns doubly important. Further, there is a greater need for well-functioning health systems to run universal and effective vaccine delivery and monitoring systems for a preventive programme than is needed for, say, a malaria treatment programme.

The situation is further complicated by another set of processes that operates for some vaccines. There are a few vaccines that have variable levels of effectiveness in preventing potentially life threatening infections such as pneumococcal infections, typhoid or there are those vaccines which protect against those illnesses that may result generally in milder and sometimes troublesome illness such as chickenpox, hepatitis A and mumps. Then there are vaccines like those against Human Papilloma Virus (HPV) which variably protect against cancer of cervix and some other cancers. All these vaccines are presently far too expensive for being considered for universal use. They are being

recommended by several medical professional bodies to an 'affording population'. Some people would question: in case of some of these new vaccines the people who can afford new vaccines are least likely to acquire these infections against which these vaccines provide protection. - So why go for it. Others would argue that since vaccines are a biological drug, and is no different from any other technology that the people who can afford it should go for it, and that physicians should prescribe it. The fact that all vaccines are prescription drugs and are not consumer products open to personal choice and affordability only makes matters more complicated.

We cannot deny that vaccines also mean big business, if they are used in large populations, as would happen for a universally used vaccine and even if the unit cost is low. Pharmaceutical companies claim that they invest huge amount of money in producing new vaccines and, therefore, it is legitimate to accrue huge profit from their sale. It is another matter that they spend more on marketing than on research. Strengthened regulatory mechanisms and checks and balances must be in place towards objective recommendations and so that professional bodies like NTAGI are able to remain objective and take decisions based on scientific evidence.

Given this background, as it stands today, there is confusion and paucity of correct information, lack of trust and breakdown of dialogue among all stakeholders on the question 'whether a vaccine deserves to be included in the national Immunization schedule.' The stakeholders include- medical Scientists and vaccine experts, health administrators, doctors, parents and the lay public. Even now, NTAGI or for that matter any other technical body, has not been able to convince the people about the safety of some of the new vaccines such as pentavalent and both safety and effectiveness of rotavirus vaccine by coming out with well researched and referenced guidelines. Changing the methodology of investigating adverse events following immunization recently, and inadequately investigated AEFI without adequate transparency, furthers the sense of distrust between those vaccine enthusiasts and those who question such events and are branded as 'anti vaccine lobbyists', NTAGI should place all evidences regarding safety and efficacy of a new vaccine in the public domain so that it could be scrutinised by independent experts. For prevention of many of these infections that these vaccines prevent, there are other preventive measures such as improving water quality and sanitation practices or improving health care services or food availability, where data show that it is more cost effective to do the former.

The Centre has drastically slashed the health budget while it has decided to spend a large amount of money on inclusion of some of the new vaccines in the National Immunization Schedule. Even if we say that we should go for both vaccines and improving social determinants of these illnesses, arguing for vaccine first and these measures later tends to unburden the state of its responsibility to provide the latter.

The need of the hour is to have a dialogue on "New vaccines" in the true spirit of public health and should be of high scientific quality that moves towards building a consensus as well as a perspective on this issue.

The dialogue will be divided over two days - the first day will include three sessions with the first discussing vaccine research in India, Government policy on new vaccines. The second session is on *Prioritization of interventions for disease prevention*, followed by the third session on *Inclusion of new vaccine in the UIP: How effective are new vaccines?*

Day two will include deliberations on risk assessment and safety; cost effectiveness and financial issues; on ethics, laws and regulations, and on the health system's preparedness.

The sessions would include discussions on the questions of: At what level of cost effectiveness should one advise a vaccine as a public health tool for the governments to take cognisance of? What incidence of side effects is too much for a vaccine to be advised as a preventive health technology? What is an acceptable death rate in a vaccination programme? Would this 'acceptable level' be the same for all vaccines or would it depend upon the incidence and consequence of the infectious disease on the one hand and the incidence and severity of side-effects of the vaccine on the other? How is an investigation into an AEFI done and then documented and publicised? And then compensated for? When there is more than one tool besides a vaccine to prevent a disease, how do you weigh which one is more important? Is it really important to measure it¹?

The most transparent way to handle a new vaccine introduction should be a technical report accompanying the launch, which lays out the pros and cons and takes a clear stand on what were the reasons why the vote went in favour of a new vaccine. Is this something that NTAGI should do?

Tempered by principles of science and equity and justice concerns, the dialogue is expected to deliberate on: Which new vaccines do we think should be included in the National Immunization Programme of India?

Jan Swasthya Sahyog (JSS) Bilaspur, Sama Resource Group for Women and Health, Delhi, National Medical Journal of India (NMJI) and The Forum for Medical Ethics Society (FMES) Mumbai, would be co- organising this Seminar.

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¹Some people would argue that this relative cost argument is not very real, because there is greater possibility of a child receiving a vaccine than a sanitary latrine, given the implementation challenges for the latter.