Vaccine delivery to disease control: a paradigm shift in health policy

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Abstract

India's Universal Immunisation Programme (UIP) has resulted in the creation of infrastructure, human resources and systems for the procurement and delivery of vaccines. Recently, new vaccines have been added and there are plans for the introduction of more. However, the outcomes in terms of reduction of the diseases for which the vaccines are being administered remain ambiguous. This is evident from the persistent health issues that children continue to experience, despite immunisation. This situation raises a fundamental ethical question for public health: vaccinations are one of the tools of disease control, but are they properly aligned to the control of disease so as to produce the expected public health utility or benefit?

To meet this challenge in public health ethics, and focusing on the issues raised in a recent national seminar on new vaccines, this paper argues for the need for a paradigm shift in health policy in the context of immunisation – a shift towards transforming the programme to one of disease control. It is necessary to focus on the latter to reduce the disease burden, which is not commensurate with the investments in immunisation. The paper also makes recommendations on the planning and governance of a shift towards disease control in India.

Introduction

A national seminar on "New vaccines for all: why, which, when?", jointly organised by the Jan Swasthya Sahyog (JSS), Sama Resource Group for Women and Health (SAMA), *National Medical Journal of India* (NMJI) and Forum for Medical Ethics Society (FMES), was held on October 20–21, 2016, at the National Institute of Health and Family Welfare (NIHFW), New Delhi.

The seminar sought to facilitate a dialogue on "New vaccines" in the spirit of public health and deliberations of high scientific quality towards building perspectives and consensus, where possible, on all issues. The participants included representatives from the Ministry of Health and Family Welfare (MOHFW), the Indian Council of Medical Research (ICMR) and the World Health Organisation (WHO). Many individuals from health economics and public health fields/institutions, civil society organisations, academic institutions, medical colleges/hospitals and research institutions also participated. The key points emerging from the deliberations at the seminar were expected to contribute to policy-level recommendations for the future.

The conceptualisation of the seminar was prompted by recent developments in the area of vaccines. First, a few years earlier, the hepatitis B vaccine had been included in the UIP, which initially had only six vaccines. Second, the pentavalent vaccine – a combination vaccine against diphtheria, whooping cough, tetanus, *Haemophilus influenzae* type band hepatitis B – was introduced nationally, in a phased manner. Third, the injectable inactivated polio vaccine (IPV) was included in the UIP in 2015 and a slew of new vaccines against rotavirus, rubella and pneumococci are to be rolled out in the near future. Punjab and the Union Territory of Delhi are in the process of introducing the human papillomavirus (HPV) vaccine in their immunisation programme (1, 2).

This paper is informed by the seminar's deliberations on the role and fundamental objectives of the immunisation programme; however, it does not report each of the elements that were discussed. We have used certain aspects of the framework of public health ethics to analyse the issues raised (3, 4). In particular, we focus on the utility and benefits of the immunisation programme. While the UIP is one of the tools of disease control, it needs to be a part of the overall public health measures that yields the maximum benefit in the control of diseases.

The paper is divided into three parts. The first part provides an outline of the UIP, while the second explains the deficiencies of the programme. The third part discusses issues pertaining to the relationship between the immunisation programme and disease control. The paper ends with some concluding recommendations.

The UIP: an outline

The Expanded Programme on Immunisation (EPI), launched in India in 1978, was renamed the UIP in1985, with the ambitious objective of protecting all children with vaccination against childhood diseases that were assigned priority at the time – childhood tuberculosis, diphtheria, pertussis, tetanus, polio and measles. Since the establishment of the National Technical Advisory Group on Immunisation (NTAGI) in 2001, vaccines against Japanese encephalitis (JE), hepatitis B and *H. influenzae* b have been included in the UIP. Recently, vaccines against rotavirus, pneumococcus and rubella, too, have been approved for a national roll-out.

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A robust vaccine delivery platform has been envisaged by the UIP. Procured vaccines are required to be kept in cold chain to preserve their potency, and there is a national grid of cold chain points (5). The programme requires all vaccinators to be well trained and periodically re-trained. Sterile, one-time use, auto-disable syringes and needles are to be used for all injections. The responsibility of vaccine delivery is shared between the Union and state governments. Over four years, the Union government's annual budget for the Immunisation Division doubled from the allocation in 2013 to over USD 1400 million (6).

From the beginning, the success of the EPI/UIP was monitored by surveying the numbers of eligible children reached with the scheduled doses of vaccines in the first year of life – this is the metric called "immunisation coverage". For the sake of convenience, the third dose of the diphtheria–pertussis–tetanus (DPT) vaccine and the first of the measles vaccine form the reference for coverage – a child who has taken them being defined as "fully vaccinated". Apparently, the programme is not able to reliably capture immunisation coverage data from registers documenting vaccine utilisation. Given this gap, some agencies, such as the WHO and UNICEF, use data from multiple sources that report on periodic local, regional or national coverage surveys (7).

Immunisation coverage improved during the early decades of the EPI/UIP, but going by the results of various surveys, it seems to have stagnated at around 70%–80% in the past decade (7). To improve coverage, pre-planned campaigns for immunisation were launched in low-performing districts in 2014, under the banner of "Operation *Indradhanush*"(8).

The deficiencies of the UIP

The polio, diphtheria and hepatitis B vaccines are used to illustrate some of the deficiencies in the design of the UIP. In 1980, India introduced immunisation against polio and in 1988, accepted the global polio eradication agenda. In the absence of public health surveillance of polio, the UIP was unable to properly plan disease monitoring, an essential component of eradication. Instead of bridging the gap, the government chose to establish a separate vertical National Polio Surveillance Project for polio eradication.

Although the goal of interrupting the transmission of wild polioviruses was achieved (9), the new design did not help in strengthening the UIP. Moreover, in the absence of surveillance of every case of polio to determine its aetiology, the problem of vaccine-associated paralytic polio (VAPP) remained unaddressed. Thus, one may ask what the prevalence of polio would be if there was no vaccination, and what the prevalence of paralysis is with vaccination. Has vaccine-related paralytic polio led to an increase in paralysis? Could the disease have been controlled better if adequate measures had been taken to prevent it by other means, such as basic hygiene? Thus, in the interest of disease control, it is important to ascertain whether the exclusive focus on the oral polio vaccine obfuscated the need to emphasise the social determinants of the disease. At the same time, had the magnitude of VAPP been monitored, the definition of eradication would have been zero incidence of polio caused both by wild and vaccine virus. This could have facilitated the early introduction of the safe IPV, which could have been a more appropriate public health strategy from an ethical and epidemiological perspective.

In 2015, the WHO recommended that the IPV be introduced in the UIP in preparation for the sequential withdrawal of serotypes of vaccine viruses in the oral polio vaccine. However, the closure in 1993 of the IPV-manufacturing unit established by the Government of India in 1987 hindered the introduction of the IPV. Since the IPV is not manufactured indigenously and that available in the international market is quite expensive, the UIP is facing serious shortages of the vaccine (10).

Diphtheria toxoid has a high vaccine efficacy and effectiveness when administered to children at the recommended doses. Yet, diphtheria continues to occur sporadically and in the form of localised outbreaks (11).This reflects three flaws: (i) the failure to prevent diphtheria to the maximum potential (the objective of immunisation investment); (ii) the delay in the detection of the first case in the community as a signal of an impending outbreak; and (iii) the lack of capacity to launch an immediate public health response when the disease is detected. The response ought to include an active case search, a rapid survey of the immunisation coverage and immediate "catch-up immunisation". The root cause of localised outbreaks of diphtheria is the lack of case-based surveillance, which the UIP is not empowered to carry out since it is merely a vaccine delivery platform by design.

Monitoring and implementation in the case of other vaccines currently under the UIP, such as hepatitis B, JE and *H influenzae b*, are fraught with various problems. The hepatitis B vaccine was introduced in 2003, but no convincing information on its contribution to the reduction of the frequency of infection or of the chronic carrier state is available. However, one research study has shown that vaccination has not led to any significant reduction in the incidence of acute or chronic infection (12, 13, 14). In spite of the fact that people are vaccinated against JE in all JE-prone districts, outbreaks of the disease continue to occur, resulting in many deaths (15, 16). The *Haemophilus influenza b* vaccine is also in the UIP schedule, but its impact in terms of a reduction in the incidence of either meningitis or pneumonia is not being monitored. Thus, we are not detecting and correcting various gaps in the outcome or impact of immunisation in a programme mode. We do not know if the level of reduction of the incidence of diseases is commensurate with the volume of vaccines provided. Are we reaping the full benefit of investment?

Discussion: immunisation and disease control

The discussion on this topic at the seminar focused on two aspects. The first was "disease control". Vaccines are one of many tools to achieve disease control, ie they are a means to an end and not an end in themselves. Vaccines are administered to healthy individuals and like any other medical intervention, can produce adverse effects – injuries and sometimes death,

albeit in small numbers. The alternative options, particularly interventions relating to the social determinants of the diseases against which vaccines are used, are relevant and their benefits may go beyond mere disease control by improving the quality of life. At the same time, when vaccines are used, it is necessary to ensure that vaccination and the disease control programme do not operate in silos.

The second aspect, though not discussed in this paper, is closely related to the above. It concerns the question of which new vaccines should be added to the UIP and what considerations should shape the policy decisions in this area. Any new vaccine must be introduced only after it has been critically assessed for human use in terms of the epidemiological need for it and suitability, safety, protective efficacy and affordability. Moreover, whether the government's health management system has the organisational capacity to deliver additional vaccines according to an appropriate age schedule, without affecting the coverage of the existing vaccines or other health services, should be evaluated in conformity with the National Vaccine Policy. Further, the decision to introduce some of the new vaccines must be taken after considering the other existing or essential public health measures for disease control, so as to ensure that the vaccines do not shift the focus away from the latter.

Coming back to the focus of this paper, all evidence of the deficiencies of the UIP demonstrates that the design of the programme limits it to function as a vaccine delivery platform, rather than serve as a comprehensive disease control programme. The assessment of the UIP should, therefore, include monitoring of performance measured through immunisation coverage surveys, along with monitoring of the efficiency of performance. The goal of the UIP is to maximise the prevention of disease to the point of reaching the lowest incidence that can be achieved, given the variability in the efficacy of vaccines. If the disease occurs in spite of immunisation, there should be mechanisms to identify the factors causing this. Disease reduction (for all vaccine-targeted diseases) or infection reduction (for example, hepatitis B) must be conducted in a denominator-based manner, monitored with reliable evidence.

These additional elements must be built into the UIP, but the UIP will not be able to fulfil the demands of this new design as a vertical programme. Public health surveillance should be case-based and comprehensively cover all healthcare facilities in the public and private sectors. As mentioned above, every reported case has to be responded to, with investigation and intervention.

The present situation of the UIP thus poses three key ethical challenges.

The practical separation of immunisation from disease control seriously limits the availability of a robust database to measure the positive impact of immunisation on disease control. Before making a long-term investment and sustenance of the programme, it is essential to monitor the impact of each of the vaccines under it.

Operating in isolation, the UIP precludes any discussion on the other measures, particularly those pertaining to social determinants, necessary for disease control.

The absence of a direct linkage to disease epidemiology raises the unhealthy possibility that the UIP might take arbitrary decisions on the inclusion and exclusion of vaccines. In other words, it might become more vulnerable to the marketing strategies of vaccine producers.

Conclusion

The government should adopt a paradigm shift from immunisation delivery through the UIP to disease control as a much broader strategy. When the WHO launched the EPI, India did not have a public health infrastructure to subsume it as a disease control programme. Consequently, the EPI was adopted as a vertical vaccine delivery programme. Forty years later, India still lacks a public health system that can utilise vaccine delivery as an intervention for the control of vaccine-preventable diseases.

Comprehensive disease control is virtually impossible without public health infrastructure, as illustrated by the inability to control many communicable diseases, such as tuberculosis, malaria, cholera and typhoid fever. As for the control of vaccine-preventable diseases, the essential intervention is already in place and what is of vital importance now is a paradigm shift from mere vaccine delivery to disease control. Disease control entails, among other measures, public health surveillance and a focus on the places where the target diseases are detected. Together with a paradigm shift within the UIP to work towards the control of diseases, both vaccine-preventable and others, it would be useful to create the nucleus of a public health infrastructure around the UIP. Moreover, the focus on diseases and on the most efficient and beneficial interventions for their control would necessarily lead to the examination of interventions related to the social determinants of such diseases, to supplement or use in place of vaccines, or use both in equal measure.

Once a public health platform is created, the burden of diseases which can potentially be controlled through the introduction of new vaccines can also be included in surveillance. Thus, measurement of the disease burden can be built in to obtain reliable baseline data. It will also help one follow the trajectory of disease reduction after the introduction of any new vaccine.

In summary, the UIP could serve as the nucleus for constructing a public health infrastructure within the MOHFW. Ideally, a division of public health should be established and the UIP merged with it. Eventually, all vertical programmes for the control of tuberculosis, AIDS, malaria, kala azar and other vector-borne diseases could also be merged with the division of public health, the purview of which could be expanded to cover all other communicable diseases. This division should be in a position to design, initiate and implement inter-ministerial

interventions for addressing the social determinants of the diseases, as well as be in charge of the inter-sectoral coordination between the interventions.

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