Addressing Vaccine Concerns

Vaccine programmes have a responsibility to ensure public safety and call for improved surveillance, no-fault compensation for serious events and dialogue with stakeholders. The polarization of the debate on newer vaccines in India is distressing. Despite the success of India’s vaccine programmes, concerns about vaccine safety can undermine public trust necessary for successful public health campaigns. The situation mandates a calmer and a more open approach to resolving the issues involved.

The context
India has successful public health immunization programmes. It eradicated smallpox, eliminated poliomyelitis and considerably reduced many other infectious diseases of childhood. However, its vaccination programmes have received publicity for wrong reasons in recent years. Deaths after the human papillomavirus trial in young girls and those after the introduction of the pentavalent vaccine for infants have led to intense debates and highlighted the tensions within the health establishment and the medical fraternity in India.

The past few years have seen a virtual war between groups supporting the introduction of newer vaccines and those who staunchly oppose their use. The arguments against the introduction of new vaccines include the lack of data on the magnitude of adverse events, absence of detailed cost–benefit analysis, unrealistic projection of benefits, conflicts of interest and profit motives of the pharmaceutical industry. Those who support newer vaccines cite their beneficial impact, minimize adverse effects, allude to international experience and highlight successful pilot projects. They argue that the prevention of *Haemophilus influenzae B* (Hib) and hepatitis B, which cause meningitis, pneumonia and liver disease, will markedly reduce morbidity and mortality among children.

The battles have been fought at national policy-making fora, in academic journals, the mass media and in the courts, with each side identifying lacunae in the evidence produced by their opponents. A close reading of the arguments suggests that each side is unable to defend their weaknesses, while attacking opposing positions. In addition, both sides of the divide cast aspersions on the motives of their opponents.

International experience
Vaccines are clearly one of the most important accomplishments of healthcare. The prevention of diseases, which decimated populations in the past, through immunization is a spectacular triumph of modern medicine. Yet, concerns related to vaccines have re-emerged as important public health issues in many countries. Apprehensions related to the measles–mumps–rubella vaccine have threatened public confidence in vaccine programmes in many western nations. Several governments have re-launched campaigns to educate the public about the benefits of vaccination as well as safety issues.

Most public health professionals accept that once faith and confidence are lost, it is difficult to regain trust in the safety of vaccines and in public health programmes. Consequently, a primary goal of all public health programmes is to ensure and maintain public confidence in the safety and efficacy of vaccines.

The challenges
Establishing and maintaining public trust in the safety of vaccines is no easy task. Limitations in epidemiological designs and data make it difficult to show with absolute certainty that vaccines are completely safe. In addition, the use of vaccines in healthy
children means that the standards for safety are much higher than those for medication used to treat sick people. Even minor adverse events are viewed with suspicion when healthy individuals are vaccinated. Paradoxically, with the use of vaccines and the resultant decline in vaccine-preventable diseases in the population, the requirements for vaccine safety increase since they are used in healthy individuals with a low risk of acquiring the infection. Consequently, even if a small proportion of individuals decide against vaccination, herd immunity will reduce, escalating the risk of acquiring the disease.

The impasse within the Indian scientific community, with blanket denials of all problems related to vaccines by some in the establishment and pharmaceutical industry on the one hand and the concerns bordering on scare-mongering by some of their opponents on the other, complicates issues. The polarization of the debate has limited effective dialogue between the contrasting viewpoints. The stalemate is one of the most serious public health challenges facing India. Having established successful vaccination programmes, the country should not jeopardize their success. The government must be careful to ensure that while they reinforce the public safety of vaccines, they do not dismiss or underplay potential threats. The failure to adequately recognize and communicate even minor safety issues can have profound implications for public health and immunization campaigns.

The challenge for India is to study the issue from a neutral perspective and adopt informed immunization policies that are acceptable to its multiple and diverse stakeholders. A cursory survey of attitudes, even among those opposing the introduction of newer vaccines, indicates that they strongly believe in the concept of vaccination but need to be convinced that everything possible is being done to ensure public safety. Consequently, public health policies about vaccinations should seriously address the issues related to safety, while advocating national vaccination programmes. Such advocacy has an equally strong reciprocal responsibility to public safety.

Moving forward

Many strategies adopted by countries, which have faced similar conflicts and resolved them, are worth pursuing. These include: (i) establishing a good adverse event monitoring system, (ii) considering a no-fault compensation programme, (iii) developing strategies to deal with potential risks, and (iv) improving communication and addressing concerns about vaccines.

While vaccines are licensed for public health use when they have been shown to be safe, there are clear examples of vaccine-associated problems. Pre-licensing trials usually establish safety to an extent acceptable to the pharmaceutical industry and the regulatory authorities, often in the range of 1 in 10,000 adverse reactions. However, the low rates of adverse events, when translated to India’s large population can result in sizeable numbers. In addition, identifying idiosyncratic adverse reactions or individual susceptibility to vaccinations using standard epidemiological designs is difficult.

India needs to put in place a good monitoring and surveillance system, which needs to be computerized for active surveillance rather than using the traditional passive vaccine adverse event reporting system. Putting such an organization in place, maintaining computerized databases, linking vaccine information to other medical records, periodically analysing data to inform policies, establishing independent oversight of the system, and communicating the issues through the mass media will go a long way in maintaining public confidence in vaccination programmes. The acceptance of a certain level of adverse reactions will be necessary. Occasional major and some minor events are inevitable in mass immunization programmes. However, ignoring or under-emphasizing adverse events will damage trust and reduce public confidence.

The reciprocal responsibility of public health argues for compensation in the event of serious adverse events. The fact that vaccines not only provide benefit to individuals but also to society by reducing the risk of transmission implies that compensating those who experience serious adverse events is reasonable and appropriate. No-fault compensation systems need to be considered. While such programmes have been criticized by those in favour and against vaccination, they provide immediate relief for parents and help them avoid the complex and slow Indian legal system. Compensation is also an acknowledgement of the minimal but possibly serious risk of such public health approaches to a few subjects.

The country needs to develop pre-emptive strategies to manage risks due to vaccines. It needs to evolve models to decide the acceptable risk of adverse events. Failing to respond adequately to early but significant warnings will result in exposure of the vaccine
to a large but otherwise healthy population. Inappropriately responding to a risk and withdrawing the vaccine will result in shortages, which can also cause harm. Thus, having a real-time monitoring system in place to identify adverse events is crucial to the assessment of benefits of ongoing programmes and critical to withdrawal strategies and will help maintain public trust.

Effective communication about safety of vaccines is essential to show that public concerns are taken seriously. Disagreements between physicians and the public over risks due to vaccines are not uncommon and can not only compromise the health of children but also threaten national programmes. Standard information and resources for parents and the public, which address specific beliefs and concerns, are cardinal to success. Information on benefits and risks, informed consent before vaccination, systematic monitoring, surveillance and evaluation of actual risks and the availability of this information in the public domain will go a long way in improving trust.

The current impasse related to vaccine safety is not good for the nation and calls for investment into vaccine programmes to maintain public confidence in the system. The additional outlay is easy to justify given the massive benefits of disease prevention through immunization. The strategies suggested do not undermine the commitment of those in public health to protect the health of children nor exaggerate the concerns of the public regarding vaccines. We have to recognize that all involved in the debate have similar goals of improved health for India’s children.

REFERENCES

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