

Ethical and legal challenges of vaccines and vaccination: Reflections

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Vaccines and vaccination have emerged as key medical scientific tools for prevention of certain diseases. Documentation of the history of vaccination shows that the initial popular resistance to universal vaccination was based on false assumptions and eventually gave way to acceptance of vaccines and trust in their ability to save lives. The successes of the global eradication of smallpox, and now of polio, have only strengthened the premier position occupied by vaccines in disease prevention. However, the success of vaccines and public trust in their ability to eradicate disease are now under challenge, as increasing numbers of people refuse vaccination, questioning the effectiveness of vaccines and the need to vaccinate.

A few decades ago, a theme issue on the ethical and legal challenges in vaccination, particularly in the context of a developing country like India, would almost exclusively have focused on the measures needed for universal access to vaccination. Ensuring that children do not die of vaccine-preventable diseases is one of the core elements towards achieving equity and justice in public health. So much so, that it was normally argued that no amount of public investment in making vaccines universally available to children is too high. However, public health measures are often challenged by human rights norms. Today, individual rights to bodily integrity, to make choices, to have complete information on the vaccine, and other such rights are gaining more importance and need to be an integral part of public health programmes.

In any event, for a tool to remain scientific, it must be scrutinised for its scientific merit. Vaccines will retain their premier position in public health only if there is a continuous collection of evidence supporting them. Like any other scientific tools, they have benefits but also risks. The issue of risks is particularly pronounced in the use of vaccines, because they are used on otherwise healthy children for the future prevention of disease.

Besides, vaccines cannot be regarded as the sole intervention for disease control and improving the quality of people's lives. Disease prevention demands not just medical intervention but also attention to the social determinants of health such as nutrition, safe water, sanitation and so on. The choice of public health intervention must be made in a balanced way and not allow the medical model to subsume all others.

Public trust is fundamental to the success of vaccination programmes. But such trust, even if built on a relationship of decades, cannot be taken for granted. Medical professionals, once trusted as demigods, are now facing the wrath of people's disillusionment. Not only in India but elsewhere too, the misuse of vaccines and vaccination is being questioned. Coercion, and a contemptuous attitude toward people's need for simple but scientific information, further erodes people's trust. The only way to sustain the credibility of vaccines and people's trust in them is by regular reflection on their scientific and ethical use.

This theme issue on vaccines and vaccination raises certain critical questions so as to initiate corrective measures necessary to uphold the science and utility of vaccines as an important public health measure, with their ethical use.

The theme issue has six papers which discuss four aspects of the ethical and legal challenges in vaccination as a public health measure

1. Safety of vaccines

Vaccines are used on healthy people, particularly children. The first resistance to vaccines therefore normally emerges from people's personal experience of vaccination. Such experiences are contextual; they emanate not only from the harm caused by a vaccine, but also from the management of such safety issues by the system. Those who listen to these experiences then re-examine the vaccine itself in order to understand the source of the problem. This is becoming more pronounced, not in the traditional six vaccines used in India's immunisation programme, but in the introduction of new vaccines, and of old vaccines in combination with new ones.

The paper by Hirokuni Beppu and others, "Lessons learned in Japan from adverse reactions to the HPV vaccine: a medical ethics perspective", is a case study of the introduction of the HPV vaccine in Japan. Learning from people's experiences – and

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providing data on reports of safety concerns– the authors raise scientific issues concerning the safety and effectiveness of the HPV vaccine in Japan. They attribute the widespread use of this vaccine to three major factors with both structural and ethical import, namely, “(i) Aggressive promotion by the pharmaceutical industry, (ii) Trade negotiations by economic superpowers, and (iii) Contemporary medicine, which is characterised by overconfidence in technology and the lack of the humility to listen to patient complaints.”

This paper, when read with a paper by Tom Jefferson and Lars Jorgensen published in the January 2017 issue of *IJME* (1), shows that it is essential for the companies that conducted research to make their raw data available for further scrutiny, in light of new safety concerns found for the HPV vaccine. It is astonishing that a regulatory agency like the European Medicine Agency (EMA) does not possess a copy of the raw data for reanalysis, and must revert to the companies – who have a conflict of interest–to get raw data re-examined. Invariably such exercises conclude that safety concerns were not related to the vaccine. Worryingly, the Indian drug regulator accorded marketing authorisation to this vaccine on the basis of approvals received by it from the EMA and the US FDA.

2. Human rights and law

It is very important for people to be convinced about the safety and effectiveness of vaccines. But how can this be done if the research data are protected as trade secrets of companies which carried out research on those vaccines? How would anybody believe that the companies, that privileged profit over public good over the years, are trustworthy? In such a situation, to what extent ought the state to assume a paternalistic role subsuming the individual’s human rights?

Veena Johari’s paper, “Identifying ethical issues in the development of vaccines and in vaccination”, attempts to forge a unity of public health and human rights by arguing that when a preventive health intervention is introduced for the population at large, attention must be paid to the individual’s autonomy and the risks s/he confronts. She notes that voluntariness for vaccination is not just morally correct preventive public health but also more efficacious as it makes for people’s genuine participation for the improvement of their health. Similarly, she emphasises informed consent in vaccination, requiring public health programme to share critical information with people, enhance public engagement with communities, and to be accountable to people.

The article by Sarojini N and others, “An idea whose time has come: Compensation for vaccine related injuries and deaths in India”, makes the case for instituting legal mechanisms to compensate for vaccine-related injuries and deaths in India. The authors provide information on compensation mechanisms in different parts of the world. They follow with a detailed analysis of Adverse Events Following Immunisation (AEFI) reported from various states in India to show that the AEFI reporting system is not uniformly robust and transparent. Thus, they build a solid argument for a separate compensation mechanism distinct from tort, and based on a no-fault system.

3. Trust and the prevention of distrust

As explained earlier, trust in vaccines and vaccination are important components of the success of preventive public health programmes. But there is increasing erosion of trust, not just because of people’s misconceptions about such programmes, but also because of the way the system functions. Two recent events highlight this issue:

In January 2017, in Tamil Nadu and Karnataka, a rumour circulated through the social media on safety concerns regarding the measles-rubella vaccination campaign in schools and primary health centres. Subsequently, parents refused to send their children to school or simply refused vaccination. The first knee-jerk reaction of the health authority in Tamil Nadu, as reported in the media, was to issue threats of criminal cases and arrest against rumour mongers (2). Another media report, however, analysed the problem and discovered that the vaccination was being implemented after providing minimum information to the parents and the general public. This compounded the doubts in the minds of people, including many medical practitioners, about the need for mass vaccination for these diseases, more so in schools where facilities for managing AEFI were minimal (3).

While this public resistance to the measles-rubella vaccine was playing out, in January 20, 2017 at the 54th Annual Conference of the Indian Academy of Pediatrics (IAP) in Bengaluru, IAP member Vipin Vashishtha was manhandled and evicted by fellow doctors for raising issues related to the conflict of interest in the association’s recommendation of vaccines for use in private practice (4). Dr Vashishtha had in December 2016 written a letter to members of the IAP on the subject and also written an editorial in *Pediascene.com* attacking the commercial interests of the industry and the collusion of doctors, government and funders (5).

These incidents show that people’s trust cannot be taken for granted, and that it gets further eroded by evidence of financial conflicts of interest in the healthcare system. Vijayaprasad Gopichandran in his paper titled “Public trust in vaccination: an analytical framework”, goes through the complex web of issues involved in gaining and retaining people’s trust and preventing its erosion. He argues that both transparency of policies and close engagement with communities are ethical

imperatives for maintaining trust.

The second paper on this topic by Luke Juran and others, "Considering the 'public' in public health: Popular resistance to the Smallpox Eradication Programme in India," is a field study in Bihar and traces the history of how the programme was implemented from above without showing sensitivity to people's views and culture. The authors note, "The eradication of smallpox should be viewed as a milestone for biomedicine, public health, India, and the world. We have been freed from the shackles of a fatal virus and that is a commendable achievement. However, one has a moral duty to examine historic milestones in order to understand how they were achieved. Through this critical lens, we argue that it is rare, if not impossible, for an accomplishment of such magnitude to be realised without eliciting elements of distrust or outright resistance in the target population. The global eradication of smallpox was no exception." Thus, it highlights, once more, the fundamental role of public engagement, and teaches us that instead of getting carried away by success stories, we should reflect on the way that success was achieved.

4. Vaccination is not an end in itself

The last paper in this theme issue, by T Jacob John and others, "Vaccine delivery to disease control: a paradigm shift in health policy," observes that the Universal Immunisation Programme (UIP) in India is divorced from disease control. This separation is dangerous: it limits our capacity to measure the benefits of immunisation in disease control; it precludes assessment of the other measures, particularly the social determinants in disease control; and above all, it exposes the UIP to the unhealthy manoeuvres of commercial interests in including or excluding vaccines without well considered cost effectiveness. The paper argues for the integration of both programmes.

Need for more reflection

There is a tendency on the part of public health managers and experts to view all criticism of vaccines and vaccination as being anti-vaccine, anti-science or anti-public health. Critics are often branded as "anti-vaxxers". Science does not develop by gagging critics, for critical reflection is its hallmark. Without that neither the science of vaccines nor the public health of vaccination would be able to move forward and achieve their objective of improving the health of populations. The emerging discipline of public health ethics in India has an obligation to raise uncomfortable questions and propose non-conventional alternatives.

This theme issue was not intended to cover all the ethical and legal challenges in vaccines and vaccination. Many issues of critical importance are not covered in adequate detail. We hope that there will be more discussion on the issues raised here; and contributors will come forward and write on the subjects left out in this theme issue.

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