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Identifying ethical issues in the development of vaccines and in vaccination

VEENA JOHARI

Abstract:

Vaccines are a widely accepted public health intervention. They are also a profitable tool for pharmaceutical companies manufacturing vaccines. There are many vaccines in the pipeline, for various diseases, or as combination vaccines for several diseases. However, there is also a growing concern about vaccines and the manner in which they are developed and approved by the authorities. Approvals are fast tracked and adverse events and serious adverse events following vaccination are seldom reported once the vaccine gets its marketing approval. Thus, vaccines have been clouded with many controversies and their use as a public health tool to prevent diseases is constantly under challenge.

Public health and human rights have an intrinsic link, and any public health programme can be successful if the rights of people are respected, and upheld. A routine or compulsory vaccine programme tends to ignore rights of people that augment the legal and ethical issues relating to vaccinations. This article aims to identify the legal and ethical issues in the development of vaccines and in vaccination processes.

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Introduction

About 44% of the 27 million children born in India annually receive a full schedule of immunisation, consisting of the diphtheria, tetanus, pertussis, poliomyelitis, measles, hepatitis B, rotavirus and pneumonia vaccines (1). Despite the Universal Immunisation Programme (UIP) re-launched in India in 1985, with the aim of extending the coverage of the basic vaccines to all infants and pregnant women, 9.6 million children remain unimmunised (1).

The reasons for the low immunisation levels are primarily the low spending on routine immunisation, which is only about 2.1% of the national government's health budget, a shortage of trained personnel, low levels of education with regard to vaccines and vaccination programmes, adverse events following immunisation (1), lack of transparency in decision-making on vaccines and their safety, and the inclusion of new vaccines in the UIP without proper deliberations.

Vaccines that are often accepted as safe and effective can cause serious reactions or adverse events. In such cases, some people break their silence and make their suffering public. It is only then that the process of approval, the evaluation of safety and the information given to the parents of children being immunised is questioned, debated upon and re-evaluated. It is then that the inextricable link between public health and human rights is recognised. The vulnerability of people, disability and the premature deaths of children and young adults brings societal inequalities and discrimination to the forefront, and also underscores the indifferent attitudes of the State and other stakeholders.

This paper attempts to evaluate some of the legal-ethical issues pertaining to vaccines and vaccination, a medical intervention with inherent risks and benefits (2). Some of these legal -ethical issues are raised time and again, when the vaccine conundrum is re-examined right from the development stage of the vaccine to the evaluation of its safety, till it is finally approved and administered to human beings as a tool for the prevention of disease.

Research and development in vaccines

Ever since the success of the small pox vaccine in eradicating the disease, and in later years, the success of the polio vaccine (even though it caused non-polio acute flaccid paralysis in some), vaccines are perceived to be a cost-effective method of saving the lives of children (3). Much emphasis is now given to research for vaccines that can eliminate or eradicate diseases, not necessarily only infectious or childhood diseases. A lot of money is invested in the search for new vaccines against diseases (3), as their success can influence governments to include them in the Universal Immunisation Programme (UIP) or to recommend their use in the private sector, leading to long-term, sustained profits (4). However, one vaccine may not work for all populations, and hence, it is essential to carry out clinical trials on a population before marketing or providing the vaccine. Different vaccines may be required for different virus strains to prevent the same disease (5).

Vaccines for diseases that afflict a few people are not considered a commercial proposition. Diseases that are endemic in the developing but not in the developed countries are not a priority either and are therefore, not subject to much research in terms of the development of vaccines (4). Profits, rather than health, appear to be the focus.

The legal-ethical issues connected with research in vaccines pertain to the development of the vaccine, study design, population on which the vaccine is tested, and the location of the trial.

Safety

The issues involved in assessing the safety of a vaccine centre primarily around the safety of the vaccine in terms of possible side effects, as well as for quality and freedom from contamination (6). A vaccine would be unsafe if it caused illness, disease, injury or harm to the recipient (6). Independent experts should collect and analyse the safety data and the vaccine should be tested for contaminants (6).

Before seeking approval to market the vaccine, research companies must conduct animal studies and Phase I to Phase III clinical trials to ascertain the safety and efficacy of the vaccine. Multidisciplinary experts from the scientific, medical, social, public health and allied fields, are involved in developing and testing the vaccine. Many times, there is a conflict of interest between the researchers and institutes testing the vaccine for its safety and efficacy; this can compromise the vetting system of medical research. Research involves financial intertwining between the pharmaceutical companies, medical research professionals, academic institutions conducting the research, and government agencies (7). Due to financial interests, the truth about the safety, effectiveness and efficacy of the vaccine is often compromised, misrepresented and suppressed. It was found in the USA that 3 out of 5 FDA advisory committee members who voted in favour of the rotavirus vaccine had financial ties with the pharmaceutical companies producing the vaccine (7).

Unfortunately, the data produced in clinical trials are kept confidential, and the anonymised data are not provided to independent experts for scrutiny. This creates doubts about the robustness of the approval system, as the safety data are provided by the pharmaceutical companies that produce the vaccine. In fact, the refusal to share the complete and honest data is in itself a legal and ethical issue. There are growing doubts about believing clinical research data. Close monitoring of Phase III and Phase IV clinical trials by independent bodies may bring out the truth regarding the safety and efficacy of a vaccine.

The National Technical Advisory Group on Immunisation (NTAGI), established in 2002 by the Ministry of Health, recommends that vaccination be considered in the UIP and its reach be expanded to cover all children (1). The introduction of the rotavirus vaccine by the NTAGI in 2013 was clouded by controversy due to the low efficacy (only 56%) of the vaccine and because the safety data of the clinical trials were not

revealed for expert analysis (8). Today, when the rotavirus vaccine is prescribed against diarrhoea, it is not disclosed that the child is not protected against some major strains of rotavirus (9). The trials of the vaccine revealed that vaccinated children had a three times greater risk of suffering from intestinal bleeding and many other complications (9). It is, therefore, important to make data from clinical trials available in the public domain to improve scrutiny and knowledge regarding the truth about vaccines.

Trial design

The study design, too, may raise legal-ethical issues sometimes. In randomised controlled trials, the gold standard for evaluating the safety and efficacy of new interventions is the use of a placebo control arm or a no-treatment arm, even where standard treatment is available. International ethical guidelines require that the placebo control arm or no-treatment arm should be used sparingly and only in cases in which there is a no-treatment option. Interestingly, during the Ebola epidemic, clinical trials were conducted using the stepped-wedge design, in which the clusters or individuals were randomised to receive the intervention at different points of time (10). Of course, the assumption was that the intervention was useful and likely to do more good than harm (10). Nevertheless, international guidelines do speak of providing the intervention to the other arms of the trial, if it is proven to be efficacious and better than the standard treatment or no treatment. However, the protocol of the trials rarely requires companies to provide all the participants of the trial with post-trial access to the experimental drug or vaccine.

Population

Vaccines should be tested in varied populations to understand their efficacy and safety in populations of different ethnicity. Vaccines for children must first be tested on adults, and only then on children. Ethical and legal issues are generally raised when vaccines are tested on vulnerable populations or directly on children without providing them any safety or protection, or without following the norms of informed consent. Unfortunately, the best interest of the children being vaccinated and their human rights are completely ignored. The human papilloma virus (HPV) vaccine was approved in India on the basis of bridge trials (Phase IIIB) covering a small population. The approval process of the two HPV vaccines, Cervarix and Gardasil, has generated much controversy and cases are pending in the Supreme Court of India on the issue (11).

Location

The location of the trials is of much importance as several ethical issues arise when vaccines researched in developed countries are tested in the developing countries. One needs to make sure that the ethical standards of research followed in the developed country are followed in the developing country, even if the latter has a weak regulatory system. Further, factors such as the availability of healthcare facilities at the location where the trials take place, and the availability of screening and treatment at these locations can pose a challenge in developing countries. The ethical conduct of trials can be affected if such facilities are not available and advantage is taken of the vulnerability of those participating in the trial. A Phase IV trial for the HPV vaccine was conducted by the Program for Appropriate Technologies in Health (PATH) in rural and tribal areas in India. Seven girls died after being vaccinated. The trials took place at a location with hardly any healthcare facilities. The children and their parents had no idea about the nature of the disease or the vaccine (12). This case raised a lot of legal and ethical issues, including those relating to informed consent.

Once vaccines are approved by the regulatory authorities, they are marketed the world over. They are given a push to be included in national immunisation programmes by people in influential organisations, such as the World Health Organisation, the Global Alliance for Vaccines and Immunisation and the Bill and Melinda Gates Foundation, many of whom may have conflicts of interest.

Preventive vaccination programme

Vaccination is a preventive healthcare measure that benefits individuals and public health proportionately, but the harm and risks affect individuals disproportionately. Angus Dawson states that "the key elements of the prevention problem are that: (a) preventive public health measures are performed on asymptomatic individuals; (b) every such public health intervention will carry a risk of harm; (c) the benefits of such interventions lie at the level of populations, whilst the risks of harm are borne by the individual participants in the programme. Conclusion: Such preventive programmes are unethical (given distribution of risks and benefits." (13)

There appears to be an underlying assumption that vaccines are a hundred per cent safe. However, it is known that vaccines do not suit some people, cause adverse reactions and serious adverse reactions in some people. There is, therefore, a need to make an individualised assessment before vaccinating people in general. Jonathan Mann spoke of the inextricable connection between public health and human rights, "for human rights provide public health with an explicit response to its central dilemma: how to address directly the societal forces which determine, more than anything else, vulnerability to preventable disease, disability and premature death"(14). Unfortunately, diseases caused by vaccines and the deaths of otherwise healthy people do not appear to be acknowledged as a problem. In fact, more often than not, statistics and mathematical calculations are used to justify deaths and adverse reactions, with the claim that the death is "not related" to the vaccine, or that the number of deaths is miniscule and not significant enough to ring alarm bells about the safety of the vaccine. The legal issues and need for an inquiry into the death of a person after vaccination are simply brushed aside.

Infants and adolescents are now vaccinated not only against the common childhood infections or diseases, but also against diseases that they may not be exposed to, or for

which there are other simpler methods of prevention. Nations across the world are keen to see a world with "vaccine-preventable diseases" (irrespective of whether the child will ever be exposed to the disease). The idea is to promote such vaccination not only to protect the child in the future, but also to reach an optimal level of immunisation to create "herd immunity" so as to eliminate diseases! In such a scenario, the benefit at an individual level remains unknown, as one does not know whether the individual has been protected or is lucky enough not to have come in contact with the virus (13).

Unfortunately, the NTAGI has not been transparent in its dealings and decisions regarding the inclusion of some more vaccines under the UIP. Questions have been raised and legal battles fought with regard to the inclusion of the pentavalent vaccine (a combination of diphtheria, tetanus, whooping cough, hepatitis B and haemophilus influenza B [Hib]) in the UIP primarily on account of no scientific studies conducted by the government (15). Further, the low disease burden in India of meningitis caused by haemophilus influenza B (Hib) has been a reason to question its inclusion in the UIP. Studies have also shown that there no beneficial long-term impact of the pentavalent vaccine. It was also a matter of concern in India that the pentavalent vaccine was temporarily withdrawn from the neighbouring countries of Bhutan and Sri Lanka when there were reports of adverse events following immunisation in some children (16).

Compulsory/ routine versus voluntary

Most vaccination programmes, especially those included under the UIP, are coercive and paternalistic. Any kind of mandatory testing, treatment, quarantine and isolation that restricts the rights of people can be justified only if it is aimed at preventing infectious or contagious diseases (17). The limitations on the rights of people can only be justified if it is proportional to the public interest and its objective (17). John Stuart Mill stated that "power can be rightfully exercised against somebody against her/his will if it is done to prevent harm to others" (18). In the context of vaccination, such coercion is often justified on the ground of eradicating a life-threatening disease, provided that the harm or risk of the vaccine itself is low, it is not debilitating, and it guarantees protection (18). However coercion of this type should be used with a lot of care and can have counterproductive effects (18). "Information, campaigns which appeal to the rational capacities of people and to their sense of responsibility to others" would be better options and "may prove more successful in the long term" (18).

It is interesting to note that Italy moved from compulsory to voluntary immunisation in a programme that has been successful. The Italian National Vaccine Plan (2005–7) allowed certain regions that had reached the herd immunity level to suspend compulsory vaccination and move towards voluntary vaccination, while providing for effective monitoring of the incidence of disease and outbreaks of communicable diseases (19). In countries such as Finland, Germany and the Netherlands, the State relies on disseminating information and raising awareness of the benefits of immunisation to maintain high rates of coverage (19). Voluntary immunisation perhaps also suggests trust between society and the State. The attainment of herd immunity, ie when immunisation is voluntary, indicates that the State need not make immunisation compulsory or provide incentives for immunisation (as is done in Austria and the UK) (19). It is possible to implement such a programme in India and the developing countries. In India, awareness of the prevention and treatment of HIV was raised successfully, and the rights of the most vulnerable were protected, leading to the control of the spread of HIV. Similar programmes dealing with vaccines could also be developed to move from compulsion towards voluntary vaccination.

Voluntary immunisation would necessarily entail the inclusion of aspects of complete informed consent, which are often ignored in routine or compulsory vaccination programmes.

Informed consent

Ethical and legal debates on the implementation of vaccination programmes centre around whether informed consent should be taken prior to vaccination. There is an unfounded fear that if people are given information on vaccines beforehand, it may give rise to unnecessary fears and concerns regarding the vaccination process. Generally, written informed consent is not taken for the mass-scale implementation of a preventive vaccination programme, which is almost like a compulsory programme. However, the prospective vaccinees and/or their parents must be provided with information on the vaccine, the disease(s) it proposes to prevent, the known side-effects, adverse events, and serious adverse events that have been observed not only in clinical trials, but also in places where the vaccine is approved and is given to the population.

Informed consent is required both under the law and the code of medical ethics. After all, immunisation or vaccination is a medical intervention that is not risk-free, which obligates the healthcare provider to give the vaccinee complete information on the benefits and risks of the vaccine. The person must be given information on the number of shots required for protection from the disease and booster shots and the methods of preventing disease, whether or not he/she refuses or gives consent to be vaccinated.

It is essential to respect individual rights and autonomy, and to make respect for and dignity of human rights compatible with public health strategies (17). The principle of necessity to vaccinate and participatory decision-making involving the community could make a voluntary vaccination programme more successful than a compulsory one. Berkley stated that "Ethics and implementation issues can be addressed by adherence to global standards, and truly informed consent can be acquired with careful engagement of communities in which trials are done" (20).

Vaccination implementation

The lack of the basic necessities for health, nutrition, adequate safe drinking water and medicines in developing

countries gives rise to ethical debates on what the priorities of government health programmes should be, especially where resources are scarce and health is a low priority. Should it be vaccination and prevention of disease, or should it be making provision for safe drinking water, promoting hygienic conditions, etc, so as to prevent diseases that are more often than not born out of unsafe conditions? In 1980, the then Director General of WHO, Halfdan Mahler, opined that important lessons could be learnt from the eradication of small pox, but the idea that we should single out diseases for eradication was not among them (3). He said, "The idea is tempting but illusory." (3) Mahler's concern was that targeting eradication would divert attention and resources from the structural and economic roots of ill health, and from the commitment to strengthen primary healthcare (3).

Developing countries face the twin hurdles of not only allocating scarce resources for the purchase of expensive vaccines, but also, of providing for satisfactory implementation given the lack of healthcare facilities and infrastructure and vaccine delivery mechanisms in general. The inability to make the provision required for the implementation of a preventive vaccination programme may result in further complications. For example, the product could become contaminated or be rendered unsafe if not stored and transported in the proper manner.

Ethical and legal considerations related to the prices of vaccines and access to affordable and free vaccines require some deliberation. The new vaccines are priced much higher than the old ones. The major factors that keep the prices high are patents on vaccines and the profit motive. The rotavirus vaccine is very expensive, with GlaxoSmithKline selling it at Rs 2398 and Merck selling it at Rs 2700 per course (21). Generic competition from an Indian company, Bharat Biotech, has brought the price of its Rotavac vaccine down to Rs 63 per dose (22). Even at Rs 63 per dose, the vaccine may not be affordable to large numbers of people in India, though the amount that the government would need to spend on the vaccine would fall drastically. Further, pharmaceutical companies market their vaccines in the private sector, selling the idea to doctors of selling their vaccines, but without giving full information on the side-effects. They also try to push governments to purchase their vaccines and include them in the UIP, so that they may have a permanent source of profit (4). The adverse events associated with the vaccines are borne by the vaccinated individuals, who are seldom compensated.

Conclusion

Global health disparities and inequalities bring out the ethical dilemmas involved in the prevention of diseases. In countries where healthcare is lagging behind, and children are dying due to malnourishment and other conditions related to poverty, can it be ethical to introduce expensive vaccines that do nothing to improve the people's living conditions ?

It is essential to understand public health issues in the light of a population's vulnerabilities, human behaviour, and the social, cultural, economic and political needs of each country and individual, and to connect the public health programme to the human rights of people who live in varied conditions with different and peculiar diseases, disabilities and health issues. One vaccine may not suit all, and one solution may not solve all problems either. Further, it is important to address the legal and ethical issues relating to vaccines, as well as the process of the development of vaccines and of vaccination, not only by training the persons involved, but also through regulations and open and transparent processes, including decision-making processes.

Jonathan Mann aptly said, "We are at the threshold of a rebirth – a set of new perspectives – so clearly possible because (to paraphrase Newton) we stand on the shoulders of the giants – in health and in human rights – who have preceded us. Now we have the responsibility to move forward by recognising that true interdependence and real interconnectedness require that we -- from health and from human rights -- advance together, equal partners in the belief that the world can change."(14) How we define the legal and ethical issues related to vaccines and vaccination will determine what we do about them and how we will go about implementing ethical, accessible and better healthcare services, including preventive healthcare.

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An idea whose time has come: Compensation for vaccine-related injuries and death in India

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Abstract

This paper emphasises the urgent need for a compensation policy for those affected by adverse events following immunisation in India. In the absence of such a mechanism in the country, people claim compensation by taking recourse to tort law and have to face the ensuing uncertainty and challenges with regard to the award of compensation. The paper argues that people should be provided compensation in the event of death and serious adverse events following compulsory immunisation, irrespective of whether there is a causal association between the adverse event and the vaccine, on the basis of no fault compensation.

Introduction

The Oxford English Dictionary defines "compensation" as "something, typically money, awarded to someone in recognition of loss, suffering or injury" (1). The obligation to compensate a person for injuries is grounded in human rights and the ethical principles of justice and fairness. According to WD Ross**,** reparative justice (sometimes used interchangeably with compensatory justice) requires that when we inflict an injury on others, we have a duty to apologise and repair the wrong done (2). Ross states that reparative action is morally indispensable, not only to repair the damage, but also to acknowledge the injured party as a moral agent worthy of respect and entitled to a confession of fault (2). Even when the argument in favour of reparative justice is accepted in principle, its actualisation is limited or fraught with complexities, as is evident from the existing compensation frameworks.

In the context of clinical research, for example, compensation frameworks mandate that if an untoward event occurs or a participant in a trial undergoes a serious adverse event (SAE)[1], whether during or after the trial, medical treatment must be provided and adequate compensation ensured. Vaccines, which are generally administered on a mass scale to healthy people and mainly to children, often through the Universal Immunisation Programme (UIP), like other biological products and drugs, can give rise to adverse events following immunisation (AEFIs)[2]. However, these may be considered too statistically insignificant to warrant compensation. Globally, therefore, the issue of compensating people for harm or injury following the administration of vaccines remains a matter of debate, and only about 19 countries provide such compensation. Even where frameworks for compensation exist, in the case of AEFIs, their implementation differs across countries, with historical specificities and legal traditions shaping them.

This paper provides a brief overview of the existing mechanisms for compensation following the administration of vaccines in different countries. It asserts the need for compensation and recommends possible mechanisms founded on ethics and human rights for their implementation in India.

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