

STUDENTS' CORNER

The legality of mandatory vaccination

KUSHAAN DOSAJH

Abstract

Vaccination in India has been carried out for the past 70 years and is seen as a major part of the public health policy of independent India. Its ability to provide for an efficient and cheap form of preventive healthcare makes it the most viable option for a developing state such as India. However, in an effort to achieve total vaccine coverage, the government ends up forcing the vaccination without taking into account the objections raised by the general populace. This leads to a reduction in the government's accountability when faced with issues of adverse events following immunisation (AEFI). Thus, while it is important that the government should provide for a better AEFI surveillance system and a vaccination data bank, stakeholder engagement has to be given due priority, in order to ensure that the programme functions with transparency and credibility.

Key words: AEFI, transparency, consent, trust, mandatory vaccination

Introduction

Vaccination¹ in public health relies on what is known as "herd immunity" ie, if the number of vaccinated people is high, the number in itself acts as a barrier and reduces the chances of those people, who are for some reason not vaccinated, getting infected. A lower force of transmission of disease, as denoted by R_0 (basic reproduction number), would be beneficial in achieving the herd immunity threshold, while a higher R_0 would indicate a higher transmission potential (1). A high rate of vaccination therefore protects the entire community, which includes the unvaccinated as well as those on whom the vaccine fails to produce the desired effect.

While the Indian immunisation system has done a commendable job by eradicating diseases such as smallpox and polio, there is a dark side to it revealed by issues concerning total vaccination coverage, lack of consent

during vaccination, lack of governmental engagement and accountability, and a severe trust deficit among the concerned stakeholders over the programme and the vaccine itself. Thus, the legality of vaccination has to be contextualised by looking into its history in India during British rule, since it was the British who introduced modern vaccination in India, during the early nineteenth century.

Vaccination in India: The colonial era

Vaccination began with the discovery of the smallpox vaccine in 1796 by Edward Jenner and was available in India within four years. However, prior to the advent of the vaccine itself, inoculation practices were widely prevalent in India as a form of defence against the dreaded disease (2). The colonial government banned the concerned practice and introduced "trained vaccinators" to tackle the disease. The vaccinators were to tour the territories and provide the vaccine for a small fee which was to be their primary source of income (2).

The British government passed the Vaccination Act in 1880 specifically to ban existing inoculation practices, while making it compulsory for children to be vaccinated (3). The British government also passed The Compulsory Vaccination Act in 1892 in order to effectively deal with a smallpox epidemic, making it the first instance of mandatory vaccination in the Indian subcontinent (4). However, the said laws were not duly implemented due to a sharp distrust of the colonial government among the population², aggravated by 19 deaths due to tetanus following vaccination against bubonic plague in Mulkowal, Punjab in 1902.

The vaccination programme was prioritised by setting up the Haffkine Institute in Bombay in 1899 for the production of the plague vaccine, after a major outbreak of bubonic plague in Bombay in 1896 (2). Plague vaccine from the Institute had been administered in Mulkowal after an outbreak there in 1902, followed by the 19 deaths. An initial inquiry indicted Dr Haffkine, as his laboratory had provided the vaccine; but a later one found unhygienic storage and handling on-site to be the cause (5). This caused a major setback to the programme, regarding which the government did not conduct any concrete trust building measures (5).

As with the First World War, the Second World War impacted healthcare drastically, and vaccine coverage plummeted. The Bore Committee Report of 1946 provided a summary of the problems plaguing the public health system of India, including

Author: **Kushaan Dosajh** (Kushaandosajh@gmail.com), Independent law researcher, and Post graduate student of Law, Tata Institute of Social Sciences, Deonar, Mumbai, INDIA.

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the high prevalence of vaccine preventable diseases such as plague and smallpox. However, what it does not mention is the importance of community participation for greater efficacy (6).

Present scenario: Contextualising the problem of trust deficit within the sphere of mandatory vaccination

At the outset it is pertinent to acknowledge the fact that, post-independence, India has eradicated diseases such as smallpox and polio, based on dedicated governmental efforts which include the provision of the Universal Immunisation Programme as well as the National Vaccine Policy (7).

A high vaccination coverage rate however, does not necessarily mean that there is acceptance of the same (8). There has been an increased resistance to vaccination both from the educated and the uneducated classes in areas where vaccination is easily available (9). To gauge the scope of the problem, one needs to take into account the healthcare providers dealing with vaccines, since it is they who are responsible for improving the programme's effectiveness.

The healthcare system in India has a vast but institutionally weak public sector and an upcoming private sector which apparently provides better healthcare facilities (10). However, issues in the two sectors compound the public health problem. While the governmental sector suffers from institutional and infrastructural weaknesses, the private health sector has in recent times been seen as existing for the sole purpose of profit (11). The exorbitant costs of private healthcare create a trust deficit in the system. Since the coverage of the Indian healthcare system is weak, a massive push towards immunisation which tries to cover remote areas, traditionally ignored by the state, makes people sceptical about the intentions of the state, thereby making them hesitant about accepting vaccination. For instance, the government-appointed Expert Committee on Tribal Health in India stated in its report that governmental measures on the health of the tribal population were highly inadequate and that the data lacked transparency. In such a scenario, mandatory implementation of vaccination is not an ideal solution, since the population does not trust the government, which has neglected it for so long (12).

A number of adverse events following immunisation (AEFI) and a substantial deficit in data collection is another problem. India has a relatively poor AEFI surveillance system (13). To put things into perspective, AEFI monitoring, together with regular check-ups, is essential to measure the effectiveness of a vaccine within the areas covered and guard against future adverse effects. With a weak AEFI system, situations arise where all sorts of diseases and adverse effects following immunisation are erroneously blamed on the vaccine. This leads to a massive trust deficit and in the present digital age, information or rather misinformation travels very quickly (14). An inadequate AEFI surveillance system makes the state unable to deal with post vaccination issues, since there is no accurate resource base to analyse the after effects of a

vaccine. The MMR vaccine has been controversial since its inception (15). It was criticised by Andrew Wakefield based on false reports and claims³, leading to a severe trust deficit in the vaccine (16). The WHO has several releases asserting the importance and safe nature of the vaccine, as a form of damage control against the erosion of public trust which despite its best efforts, did occur (17).

Furthermore, parents reject the vaccination requirement on two grounds:

- quality of the vaccine, due to which the government has to reiterate the approval of the vaccine by various national and international organisations (13);
- lack of trust in the government-run vaccination programmes. This is due to the non-existence of an accountability mechanism against the state for any possible vaccine side effects, thereby creating the impression that the state is above reproach in such matters (14).

However, on the same lines, governmental non-transparency regarding the vaccination programme is a major problem. Vaccines usually come with a good reputation based on their efficiency and approvals from the WHO and national bodies. The controversy surrounding the unethical conduct of vaccine trials (HPV) by the PATH organisation, without proper consent forms and the resultant deaths along with government inaction in making the organisation accountable creates a scenario where the government-run vaccine programmes lose their credibility (18). This incident highlights the fact that vaccine trials without proper consent are extremely problematic since the only way in which a state can justify mandatory vaccination is by demonstrating that the dose is beneficial and non-lethal (the claim itself getting nullified by such instances).

Vaccination in India: A legal perspective

While healthcare in general is dealt with under the Directive Principles of the Indian Constitution (19), public health and sanitation come directly under the state list (20). Several judgments have reiterated the responsibility of the state governments in this matter (21, 22). However, this does not mean that the Central government does not have a legislative duty to deal with such matters. Public health has always been a major concern for every government since it directly affects the people, and through them, the government. This can be showcased by a variety of Acts passed by the Government since British times to deal with the issue of vaccine-preventable diseases. Most of the following Acts are mentioned because the government relies on them when dealing with the issue of vaccination:

Central laws

- The Vaccination Act, 1880: The Act specifically deals with prohibition of the unregulated practice of inoculation/variolation prevalent at the time, with a focus on compulsory vaccination of children with the smallpox

vaccine. In areas where the Act applies, non-vaccination without sufficient cause allows for punishment under section 22 (4).

- The 1880 Act, while putting an overarching emphasis on vaccination, did not properly regulate the role of vaccinators, primarily private vaccinators. This lack of clarity and its allowing for severe draconian measures to be taken without due oversight make it problematic.
- The Epidemic Diseases Act, 1897: This British era law, despite being a century old, is relevant in the present, as can be observed by its application by several states, even as late as 2009, when there was a possibility of an outbreak of swine flu (23). It provides legal immunity to a person acting under its provisions. When it was enacted, the Act was seen as one of the most draconian laws in the health sector since it gave the government sweeping powers in the name of epidemic control. Measures included forcible segregation of affected persons, demolition of affected areas, banning of public gatherings which included festivals and much more (24). A major drawback of the Act is the fact it does not properly explain the powers provided to the authorities. The Act is seen as being of a regulatory nature dealing only with situations post the outbreak of an epidemic, with no mention of any preventive measures against such an outbreak (24).
- The Drugs and Cosmetics Act, 1940: This Act, which has been amended several times, deals primarily with quality control in the import, manufacture and distribution of drugs. The act encompasses vaccines by stating that they come under the category of “new drug” and are thus liable under the provisions of the said act. It provides for a detailed procedure for clinical testing for the drugs which are being considered for public health purposes.

State laws

- The Madras Public Health Act, 1938: The Act has recently come under the spotlight due to the Measles, Mumps and Rubella (MMR) campaign of the government in Tamil Nadu, wherein there have been instances of parents refusing to get their children vaccinated (25). The Act was enacted for making vaccination compulsory. Part II of the Act deals with the issue of how to control the spread of a disease by preventing the infected person from using public services such as a library, etc (26). Furthermore, it allows a magistrate, in case of an infected area, to prevent the assembly of more than 50 people, and gives the concerned officers special powers to deal with the same (26). Chapter 8 deals with the prevention and treatment of such diseases. This Act should be seen as a last resort since it provides sweeping powers to government authorities. (26) However, while the Act may in itself be seen as harsh, one needs to consider that it is applicable only in places where there is a high risk of an epidemic spreading and jeopardising public health

Where there is a lack of public trust in the governmental

vaccination programme (13), the spread of unfounded rumours and the possible misuse of wide ranging powers under the Act would tend to aggravate the problem, making control of an epidemic an extremely difficult task for the state.

Contextualisation of the legal perspective in the present vaccination scenario

From a legal point of view, the state has the right and duty to focus upon mandatory vaccination in the pursuit of achieving the good health of its citizens. But such an argument in itself contradicts the stand of the state as vaccination is but a part of preventive healthcare which requires the state to provide a clean environment, safe drinking water, proper sanitation and, in the near future, clean air. Various judgments in several parts of the world are testament to the fact that the courts usually follow the utilitarian argument of focusing specifically on the benefits of a vaccine for the population as the most important factor in their being literally forced upon the population.

There have been instances of the Indian state itself using obsolete British era laws in order to get legal backing for mandatory vaccination. This systemic resorting to mandatory vaccination has also gained general acceptance, especially in relation to the United States (US) which has recently been hit by an outbreak of measles (27). Since the US acknowledges various forms of exceptions to vaccines (28), the increased number has made several states mull over the possibility of re-introducing mandatory vaccination, based on the Supreme Court ruling in the landmark case of *Jacobson vs Massachusetts* (29) This is supported by the *parens patriae* doctrine provided for in the case of *Prince vs Massachusetts*; both of which explicitly support mandatory vaccination as a public good which can be enforced by the state (30). A similar problem has plagued France and Italy, both of which have the worst vaccination rates in Europe. They both face low vaccination rates and a severe trust deficit in relation to the efficacy of their vaccination programmes (31). Both countries have resorted to mandatory vaccination laws, with both of them taking an aggressive approach by barring the non-vaccinated from nurseries and schools (32).

While such a system does exist and, to a certain degree, work, there is a need to move away from it especially in India especially in the following contexts:

Conducting school-based immunisation programmes

Parental scepticism about a vaccine is a major hurdle in immunisation coverage, as reported by vaccinators (13). This is because of a lack of governmental engagement with the stakeholders ie the parents and the school authorities, especially *prior* to a vaccination drive. A lack of engagement and a consequent lack of vaccine-related information can lead to a scenario wherein the stakeholders are bound to be influenced by information on vaccine related side effects leading to a refusal to be a part of the vaccination drive, thereby destabilising the entire programme. Therefore, it is important to ensure that the relevant authorities, both at

the governmental and school level, work collaboratively to ensure that parental doubts regarding a particular vaccine, are properly addressed prior to its implementation. Such a collaborative and transparent approach will ensure a much better response than one where a government is forced to face legitimate parental and school concerns on the efficacy of a vaccine, during the implementation phase. Of late, the problem of vaccine hesitancy has been such that the WHO has acknowledged it to be one of the main threats to global health in 2019 (33).

Health facility based immunisation programmes

Most vaccination programmes in India are conducted with the help of dispensaries and primary healthcare centres which are supposed to be established in every town and village. But the process is impeded by a general lack of infrastructure, as well as a dearth of personnel, especially in rural and distant areas, which require the maximum amount of social engagement. Furthermore, the general neglect of the existing infrastructure makes people extremely hesitant about going to government run dispensaries, with a preference for the costly and less accessible private sector. However, such an option does not exist for people living in remote places as the sector does not have the outreach capabilities of the government. Such a scenario basically highlights the problems plaguing the Indian healthcare system in general.

Paternalistic enforcement of such policies by government on poor and deprived sections

The enforcement of such policies on the poor and illiterate population of India raises the legal issue of whether such compulsion is justified. As mentioned earlier, the vaccine trials conducted by the PATH foundation in India were in partnership with the government. One might argue that a deprived population may not be able to make an informed decision due to which it is for the state to go through with vaccination, by hook or by crook. But the government's stand is weakened when it is an accomplice as in the above mentioned context. This, compounded by a lack of accountability and transparency, creates an atmosphere of mistrust. It is but a consequence of this no information scenario that the people become downright critical of the vaccination programme.

The road ahead

A critical appraisal of mandatory vaccination in India is important, especially considering the current push towards tertiary healthcare rather than preventive and primary healthcare. This is exemplified by the ambitious Ayushman Bharat scheme which aims to provide coverage for tertiary health care hospitalisation. While the aim may itself be laudable, basic primary healthcare challenges remain unresolved and the scheme's Health and Wellness Centres approach to these issues has been overly simplistic, without there being any qualitative change in the approach itself. Also, it tries to divert the responsibility of healthcare on to the much-maligned private sector without any proper regulation to curb the issue of wrongful practices. Such

a policy showcases a knee jerk reaction to the issue of healthcare and does not take into account the complexities associated with it (34).

A conclusion based solely on a financial appraisal would require that governmental budgets be increased dramatically since the share of health is approximately 1.3% of its GDP (35). Still, a financial increase is only part of the solution.

An increase in budget allocation, however, has to be accompanied by the government demonstrating that it is serious about public health and is willing to act in tandem with the public. It has to hold itself open to scrutiny and be willing to be engaged with the public since the development of trust is a necessary antecedent to a successful partnership. Such a partnership would allow the government to better tackle issues in relation to hesitancy, lack of coverage etc, since it will get the support of its citizens. This engagement has to be demonstrated especially prior to a vaccination drive, and by the state medical officers in order to ensure that a person gets not only due information on the concerned vaccine, but a psychological assurance that the state positively cares for his or her child. The need for strengthening of the AEFI system cannot be over-emphasised, along with the setting up of a proper cold chain system for vaccines. While structural changes in immunisation are imperative, these changes will only work if the public is made aware of the benefits of the vaccines, so that they can make a proper and well informed decision when agreeing to the same, which is only possible when there exists a proper and well informed partnership between the people and the government (36).

Lastly the courts have to come in and immediately take cognizance of situations wherein people are used as guinea pigs for conducting vaccination trials in India, since this is a gross and severe violation of their fundamental rights, severely impacting the individuals (victims), the system and its various other participants. The court has to ensure that the governmental agencies such as the ICMR and the Drugs Controller General of India are duly held accountable and have to adhere to the highest possible standards with respect to vaccination approval. Furthermore, the question of qualified consent with respect to vaccination testing (on an illiterate population) has to be duly looked into, so that the legal lacunae with respect to consent and vaccination testing may be covered up as soon as possible. This has to be accompanied by quick judicial intervention to ensure due penalties for the wrongdoers and prompt and just redress for the victims.

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Notes

1. The WHO defines vaccine as, "a biological preparation that improves immunity to a particular disease. A vaccine typically contains an agent that resembles a disease-causing microorganism, and is often made from weakened or killed forms of the microbe, its toxins or one of its surface proteins. The agent stimulates the body's immune system to recognize the agent as foreign, destroy it, and "remember" it, so that the immune system can more easily recognize and destroy any of these microorganisms that it later encounters."

2. A major problem with the vaccinators was the charging of a fee for the vaccine. Furthermore, the distrust of the British, a belief in traditional medicinal practices, and general illiteracy and poverty made it hard for vaccination coverage to spread throughout, thereby limiting its benefits. Severe logistical problems were faced, as the vaccine was imported from England and there was a dearth of adequate storage facilities in the poorer parts of the British territory.
3. The Wakefield report was later discredited and the author punished.

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