

BALANCING VACCINATION AND LIBERTY: PROTECTING THE HUMAN HEALTH AND DIGNITY

Muhamed Fazil D*

Mukesh M**

ABSTRACT

The Right to Life amidst the pandemic warfare is one of the constitutional guarantees of life free from diseases and access to healthcare amenities and one of the fundamental rights. An interpretation to this Article provides for Right to Life with human dignity that encompasses bodily privacy and an informed consent towards mandating the vaccines. It also includes the inherent fundamental right to deny the mandatory vaccine if they wish to. Therefore, we can say that refusing vaccination is also one of the fundamental rights and state's responsibility and commitment in protecting these rights. A perusal of the situation makes it pertinent how individuals who elect not to get vaccinated are underpinned by the situational vulnerabilities through invasive measures of enforced vaccination in employment, educational, and travel contexts. Informed Consent is requisite in every medical intervention, including mandating vaccine. It is the obligation of the government agencies to ensure individuals vaccinated with apprised consent and to wipe out the apprehensions about the vaccines. This research paper analyzes the legitimacy of State's obligation to compel vaccination, violation of fundamental and human rights if any, India's international onus in the Covid-19 pandemic, necessity of a No-Fault Compensation Mechanism, with special reference to the medico legal aspects of India's mandatory vaccination and its legal, social & health repercussions.

Keywords: *Vaccination; Liberty; Health; Covid 19; Consent.*

* Student, Chennai Dr. Ambedkar Government Law College, Pudupakkam, Email: dmfazil533@gmail.com.

** Student, Chennai Dr. Ambedkar Government Law College, Pudupakkam, Email: advocatemukesh10@gmail.com.

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Introduction

The widespread of COVID-19 has caused many inevitable losses and each country strived its best to confront the pandemic and it was a mammoth task eradicating COVID-19 for several nations to ensure health, welfare and wellbeing of its citizens. While process of annihilation of the COVID-19 was in its track, managing that process and guarding the rights of the people was also a great task for the States. The invention of vaccines didn't completely annihilate the COVID-19, but it prevented the rapid spread of the disease and lowered the risk of mortality. It is the responsibility of the State to administer vaccines, preventing its hesitancy among the public and guard the entitlements guaranteed by part III of Indian Constitution. Recently, constitutionality behind mandatory vaccination was debriefed in the PIL filed in *Jacob Puliyel*¹. Hon'ble SC held that personal autonomy should be respected and if there is any mandate in contrary, then it must be proportional and reasonable. As a result of that PIL, the Central Government also stated that in accordance with "Vaccine Operational Guidelines"², a policy, tracing out State's goal for vaccine drive, the administration of vaccination was not 'compulsory' which apparently shows that vaccination is not unavoidable. The Centre also held in its affidavit that it doesn't make covid-19 vaccination compulsory³. This research paper has made an emphasis on comprehensive study of constitutionalism in jurisprudential approach, of the mandatory vaccination.

Personal Liberty & Dignity under Indian Constitution

Liberty in simple words means freedom which is not restricted where he/she can do whatever he likes but in reality, this form of liberty exists with restrictions like laws and codes of conduct in view of public interest and to safeguard the welfare of others⁴.

¹ *Jacob Puliyel v. Union of India & Ors.*, Writ Petition (Civil) No.607 of 2021.

² "COVID-19 vaccines operational guidelines", ministry of health & family welfare, government of india, <https://main.mohfw.gov.in/newshighlights-31> (last updated Dec. 28, 2020).

³ PTI, "No person can be forced to get vaccinated: Centre to SC", the economic times (Jan 17, 2022), <https://economictimes.indiatimes.com/news/india/no-person-can-be-forced-to-get-vaccinated-against-their-wishes-centre-to-sc/articleshow/88947882.cms>.

⁴ Swapnil Pattanayak, "The Aspects and Provisions of Personal Liberty under Article 21 of the Constitution of India – A Detailed Study", Volume 2 Issue 4, 1, IJLMH, 1 (2019).

The Preamble specifies liberty, one of its objectives of living document, guarantees and secures several liberties as constitutional promise. The right to life and personal liberty declares “*no person shall be deprived of his life and personal liberty except according to procedure established by law*”. The person referred to in this article includes non- citizens.

In *Maneka Gandhi*⁵ case, the Supreme Court extended “personal liberty” with broad meaning. It was held that, “personal liberty” being of wide range, covers a diverse right which make up the individual’s liberty and several rights were lifted to the position of fundamental rights and those were further shielded under Article 19. It stated that the “personal liberty” should be interpreted in a wide perspective and not in a straitened perspective. It also ruled that deprivation of this right should be the procedure established by a law which must be ensured justice, fairness and reasonableness. Right to life with dignity in simple words means enjoying his life in a dignified way. An individual’s dignity has a jurisprudential and constitutional values in the life of a human being. The term dignity is also related with the protection against the exploitation and violation of inalienable rights. The term dignity is also used by the Constitution of India in its preamble; which reads as ‘to assure individual’s dignity and the nation’s unity and integrity.’ Dignity is absorbed as identity for an individual as a person, when a human being does not enjoy the right to a person’s dignity, the person does not exist at all.

Mandatory Vaccination During Covid-19 Pandemic

India has witnessed in recent times, compulsory vaccination to the extent of limiting the access to certain permits that only vaccinated can be allowed with. The State Government of Madhya Pradesh through an order dated November 7, 2021, by the Food and Civil Supplies Department announced that the subsidized food grains will be available through rations only to those who have been completely vaccinated⁶. The State Government of Tamil Nadu has directed initiatives mandating complete vaccination for college students to attend offline classes⁷. The High Court of Judicature of Madras had refused to entertain a PIL challenging the government order insisting the

⁵ *Maneka Gandhi v. Union of India.*, AIR 1978 SC 597.

⁶ Anup Dutta, “*M.P govt. Rations: only to fully vaccinated*”, THE HINDU (Nov. 18, 2021, pg.12.), <https://www.thehindu.com/national/mp-links-ration-benefits-to-covid-19/article37549885..ece>.

⁷ IANS, “*TN makes Covid jabs mandatory for students to college*”, Business Standard (December 10, 2021 18:07 IST), <https://www.business-standard.com/article/tn-makes-covid-jabs-mandatory-for-students-above-18-yr-for-college-121121025.1.html>.

teachers of schools and colleges to get double vaccinated, whereby the Court had refused to entertain such matters⁸. The above are very few instances of administrative & executive discrepancy towards unethical mandating of vaccination. The need of discourse is the constitutional permits that elucidate the State's requirement and expediency in influencing vaccine coverage over personal liberty of public.

Jurisprudential History of Mandatory Vaccination

The smallpox vaccination was the first to enjoy the privilege of opposition among Global community both in India & Foreign nations. The history of mandatory vaccination is both jurisprudential and political in its nature, Indian and International in its territorial aspect. In India, the vaccine opposition history was political in nature characterized with public unwillingness towards the colonial imposition of vaccines to cure small pox⁹. In 1809, Massachusetts passed a law requiring the general public to get vaccinated. Then, it was found safer with good results to get vaccinated but few persons opposed it as a result of which, the vaccination law was subject to legal challenge in 1902. Henning Jackson, a claimant of lawsuit in U.S Supreme Court was first to claim adverse impacts by getting vaccinated in his childhood and protested for bodily autonomy and its ethical manifestations, which took the enforcement of his right to U.S Supreme Court, observed thus, individual liberties in regard to purpose of safety of the public can be encroached, thereby upholding the ability of State to enact such laws of compulsory vaccination (*Jacobson v. Massachusetts*¹⁰). Again in 1922, Apex Court in United States¹¹ ruled out in favor of government agencies requiring vaccination as an essential condition for admitting children in schools. Like the British invaded India, the system of mandatory vaccination & its ramification of vaccine opposition also had travelled from the west & now reached significance of discourse in the 2019 Global Pandemic.

Mandatory Vaccination and Right to Privacy & Bodily Integrity

⁸ “HC rejects plea against G.O”, THE HINDU (Nov 23, 2021, Pg. 4), <https://www.thehindu.com/news/national/tamil-nadu/hc-rejects-plea-against-govt-order-on-teachers-getting-vaccinated/article3.7236..eccc>.

⁹ Mariner WK, Annas GJ, Glantz LH, “Jacobson v Massachusetts: it’s not your great-great-grandfather’s health laws” Am J Public Health. 2005; 95:5-90.

¹⁰ *Jacobson v. Commonwealth of Massachusetts.*, 197 U.S. 11 (1905).

¹¹ *Zucht v. King.*, 260 U.S. 174 (1922).

Privacy is always a subject of controversy in recent years. Most liberal democracies in the world safeguards the individual's privacy, as this right is recognized and protected worldwide either through means of its constitution or through its Acts. UN has emphasized that it is the States obligation to foster respect to the individual's privacy, as it is an internationally recognized human right. The basis for the individual's privacy rights are integrated in the Articles 12 and 17 of UDHR, 1948 and ICCPR, 1966 respectively. So there exists a international legal foundation to protect and promote individuals privacy rights. In *Maneka Gandhi*¹² case the scope of Art 21 was extended that this Article¹³ includes all aspects of life which makes an individual's life a meaningful one. Hence Privacy is also included in those rights.

It is upon the individual's own wish to accept the vaccine or not. The State should not compel or force any individual to accept the vaccine by laying down limitations on people who are not vaccinated like refusing their approach to socialize with the society and refusing aid to them, which would infringe Article 21. Rather, it should wipe out the apprehensions about the vaccine and encourage the people to get vaccinated.

The Apex Court in *I.R. Coelho*¹⁴ held that, "Fundamental rights confers the right to life as well as right to choose". So, getting vaccinated is upon individual's own choice and compelling to take a choice of getting vaccinated is a breach of the individual's right to privacy. Mandatory vaccination causes breach of Article 21 indirectly by making the individual to accept the vaccine to get perks which might he have not got if not vaccinated. Subjecting a person to techniques impugned which is involuntary in manner violates the boundaries of privacy.

In *Puttaswamy*¹⁵ case, unanimous verdict given by the apex court pronounced privacy, an independent right under Art 21¹⁶ guaranteed by the PART III of the Indian Constitution. It also held the interpretation of this privacy rights includes decisions, freedom, liberty and choices. In this judgement, the test of proportionality was adopted and expanded by Chandrachud J. and Kaul J. respectively. It was observed by Justice Chandrachud that in this test there should exist a rational nexus between the effect and the actions. The range of interference have to be proportional to the

¹² *Maneka Gandhi v. Union of India.*, AIR 1978 SC 597.

¹³ INDIA CONST. art. 21.

¹⁴ *I. R. Coelho v. State of Tamil Nadu.*, (2007) 2 SCC 1.

¹⁵ *Justice K. S. Puttaswamy (Retd.) v. Union of India.*, (2017) 10 SCC 1.

¹⁶ INDIA CONST. art. 21.

needs to be achieved, thus observed by Justice Kaul. The test of Proportionality means the measures taken to achieve the objects should be proportional to the objects need to be achieved. This test also appraises whether the law is disproportionate to the fundamental right which tend to infringe by the measures taken in advancing the objectives. But here, vaccine mandates do not satisfy the test of proportionality, because there are no data to prove that the unvaccinated people are threat to society. Therefore, the grounds for restriction on unvaccinated people is unreasonable¹⁷.

Now coming to the occasion of apprehensions of mandatory vaccine, vaccine hesitancy is the main reason which includes apprehension about the complacency, confidence, uncertainty regarding its efficacy and side effects and common reasons like risks versus benefits, some religious beliefs, and lack of awareness and knowledge¹⁸. The factors directing this hesitancy are social factors which includes the fake messages spreading in the social media about the vaccines and health policies, agent factors like the effectiveness of the vaccine and its safety and host factors which depends on knowledge¹⁹. It was the responsibility of the State to cross those hindrances by tackling those apprehensions. As every individual has their privacy rights, refusing vaccination is also among those fundamental rights and it's the State's responsibility to protect those rights of its people. Every individual has the inherent fundamental right to deny the mandatory vaccine if they wish to.

Constitutionalism & Mandatory Vaccination

Constitutionalism is a doctrine that the State's authority on citizens is determined, regulated and limited by Constitution and it is the rule against arbitrariness by designing mechanisms and establishing limits of political domination through characterization of governing elements by a balance of power. The test of constitutionalism in enforced and mandatory vaccinations can be

¹⁷ Siddharth Chatturvedi, Priyansh Bharadwaj, "SC's Judgement on Compulsory Vaccination Addresses Executive Accountability", The Wire (June 22, 2022), <https://thewire.in/law/scs-judgment-on-compulsory-vaccination-addresses-executive-accountability>.

¹⁸ Sallam M., "COVID Vaccine Hesitancy Worldwide: A Concise Systematic Review of Vaccine Acceptance Rates" *Vaccines* 9, 2: 10, (2021), <https://doi.org/10.3390/vaccines-90260>.

¹⁹ Kumar D., Chandra R., Mathur M., "Vaccine Hesitancy: Understanding Better to Address Better", *Israel Journal of Health Policy Research* 5, 2 (2016), <https://doi.org/10.1186/s13-584-01-6-62-y>.

conducted through expertized inquiry into the constitutional application of well-established principles²⁰.

As observed by the Hon'ble High Court Judicature of Meghalaya in *Registrar General v. State of Meghalaya*²¹, adoption of any coercive methods in vaccination may vitiate the purpose of welfare attached to it. As per Article 21, the Personal Liberty of any person would only be limited by procedure established by law. A mere executive order which is not backed by a proper legislation will never satisfy the pre-requisites of procedural due process established in accordance with law²².

The Hon'ble High Court of Manipur had entertained a public interest litigation which seeks to challenge the notification issued by the Home Department, Government of Manipur, through which it considered to prioritize the opening of institutions, organizations, factories, markets and shops where the employees and workers were vaccinated, which would through an implication make vaccination an essential condition precedent to the opening of these work places.

State's Burden & Duty Not to be Ignored

The burden of the State is also to be considered while answering questions constitutional in nature if it would reflect adverse colors in practical health administration. It is very difficult for the State to sensitize the people, the pros and cons of vaccinations in order to procure the consent and the situation becomes much skeptical and complex especially when the beneficiaries belong to marginalized sections among societies including indigenous communities who are fed with deliberate misinformation in the efficacy of the vaccines which render it very complicated.

It is the duty of the State²³ under Article 38²⁴ to promote the welfare of the people by securing a social order. When fundamental rights enshrined under the Constitution prescribed limits for the government and its agency, the principles prescribed under DPSP imposes an responsibility of improving the standard of living, Public Health and safety under Art 47²⁵, through securing adequate means of livelihood under Art 39(a)²⁶.

²⁰bellamy, richard. "constitutionalism". encyclopedia britannica, (jul. 30, 2019)
<https://www.britannica.com/constitutionalism>. accessed 9 february 2022.

²¹ *Registrar General v. State of Meghalaya.*, PIL NO 6 Of 2021.

²² *Kartar Singh v. State of Punjab.*, (1994) 3 SCC 569

²³ INDIA CONST. art 12, State Definition.

²⁴ INDIA CONST. art 38

²⁵ INDIA CONST. art 47.

²⁶ INDIA CONST. art 39(a).

Several challenges may arise in mobilizing people towards administering vaccines as this new intervention must achieve greater acceptance among the community to convince them in order to effect the consent which should not be ignored before formulating any conclusion it would affect the public at large.

No Fault Compensation Mechanism-Right & the Remedy

The reason and rationality behind constitutional mandate that the enforced vaccination policies must be back by a legislation or procedure established by law is that such a law would confer the people upon a right against which, remedy shall be sought. In the case of present dispute, a law which is mandating a policy, shall confer a right upon its citizens to seek compensation as remedy, when he has encountered with any adverse impacts through abiding the policy.

The WHO and Chubb Limited (NYSE: CB), a Chubb company had underwent an accord for the purpose of administering No Fault Compensation Mechanism for the 92 economically disadvantaged countries, so that global citizen's need to seek law courts which is a costly and lengthy process is reduced²⁷. There are several problems associated with the compensation redressal mechanism, even if it is provided in law. The person who is claiming the compensation should prove that the medical error is causative factor, irrespective of who should be blamed for the same. Though proof of fault is not needed, proof of causation is necessary.

The Apex Court in India, had admitted a petition under Art 32 filed seeking ex-gratia assistance on account of deaths caused by Covid-19 pandemic under provisions of the Disaster Management Act, 2005. The Court had issued appropriate directions to the Central Government to make such payments & also had observed that delays & red tapism should be avoided.²⁸ It is also important to note that the Finance Commission in its 15th Report, had recommended the Indian Government to launch an Insurance Scheme in national level to benefit the dependents of persons died due to disaster to counter administrative burden on the Government with respect to compensation

²⁷ World Health Organization, "No-fault compensation programme for COVID-19 vaccines is world's first", Feb 22 2021, <https://www.who.int/news/item/22-02-2021-no-fault-compensation-programme-for-covid-19vaccinesisaworldfirst>.#:~:text=By%20providing%20a%20no%20lengthy%20and%20costly%20process.

²⁸ Krishnadas Rajagopal, "COVID deaths: SC to steer payments", THE HINDU (Jan 20,2022) Pg. 1., <https://www.thehindu.com/news/national/supreme-court-to-marshall-ex-gratia-payment/article39-1137..ece>.

mechanism. However, the State shall not claim financial constraints and fiscal affordability in granting those payments.

Clinical Governance to Counter Issues of Fiscal Affordability in Compensating the Claimants

Though, the State shall not make such contention as defense, it should not be ignored as the compensation for deaths of COVID-19, may be heavy, cumbersome & capricious because the deaths are due to multiple factors such as variants & co-morbidities. So, the alternate way & different methods of compensation shall be recognized as to reduce the impact of fiscal burden associated with steering the payments. For an example, fixing the compensation based on the age, causative factor of his death such as co-morbidity, constituting an alternate dispute dissolution mechanism to settle dispute pertaining to amount of payments, structured payments instead of lump-sum amounts & alternative non-cash methods such as future clinical treatment coverage, pharmaceuticals, home-nursing, employment in hospitals etc.,

Fundamental Right - A New Perspective

Fundamental right casts a duty of the State & its agency to protect & preserve the right to life and personal liberty of its citizens. The right under Art 21 includes right to means of sustenance and livelihood. The object of enforced vaccination can be best understood by proceeding beyond the rational construction associated with individual liberty. The application of fundamental rights is not very easy in unlike circumstances which are they, by nature affect only those individuals invoking such rights. Several experts have opined that getting vaccinated has driven positive & beneficial response in reduced deaths. Especially, when it is a pandemic, an individual not electing to get vaccinated if infected not only will contribute State's burden of extending advanced health access to him, but also cause the consequential increase of deaths due to his autonomous decision choosing not to get vaccinated.

The Apex Court of India has held in the case of '*Vincent v. Union Of India*²⁹ as the primary duty of the State is to improve public health as envisaged under Art 47 of the Constitution. Being free from an intrusion in private life is construed as right to privacy and bodily integrity. Whether the State has abridged the fundamental rights in case of enforced vaccination for Covid-19, has not

²⁹ '*Vincent v. UOI.*, 1987 AIR 990, 1987 SCR (2) 468

been yet decided by the Apex Court. However, Judicature of High Court of Meghalaya, in a Writ Petition challenging the order of State Authorities to ensure that the employees & workers of public institution & place of business & other public places, to place a sign “VACCINATED & NOT VACCINATED”, it was held that the authorities shall decide the actual dimension of signs in shops, institution, & other place of business and where it shall be placed. In the same case it was observed that the state agencies shall have to ensure better ways to reduce vaccine hesitancy & strictly to take action against who are spreading falsehoods on the efficacy of the vaccine³⁰.

Mandatory Vaccinations and India’s International Commitments

The COVID-19 pandemic has affected nearly 209 countries worldwide. World Health Organization officially declared the covid-19 fever as ‘Pandemic’. Art. 51(c) under Indian Constitution obligates the State with regard to its duty relating to international laws. It directs the state ‘to foster respect for international law.’ ICESCR³¹, requires necessary steps which should be taken by the states for “the prevention, treatment, and control of epidemic, occupational, endemic and other diseases.” The Strategic Advisory Group of Experts along with TAG-COV-VAC has recommended COVID-19 vaccines worldwide for protection against the death globally caused by the COVID-19 and to reduce the burden of infection³².

In case of mandate vaccines, WHO says that, mandating of vaccine should only be a last option when all other options to boost vaccination where exhausted.³³ Even though mandate vaccine policy breaches certain human rights, International laws permits derogation of the such rights that threatens nation’s life in emergency. Because, right to health also included in the fundamental human right under UDHR³⁴ and to be ensured by the State. India in its foreign policy kept health diplomacy as an emerging tool. In order to strengthen the presence, India relied on the health diplomacy through many huge donations to protect the welfare, well-being and health of India and

³⁰ *Supra note 21.*

³¹ The International Covenant on Economic, Social and Cultural Rights, 1966

³² “Interim Statement: Covid-19 vaccines: WHO technical advisory group: COVID-19 Vaccine Composition (TAG-CO-VAC), (11.01.2022), <https://www.who.int/news/11-01-2022-interim-statement-on-covid-19-vaccines-context-of-the-circulation-of-the-cov-2-variant-the-who-technical-advisory-group-on-covid-19-vaccine-composition> (last accessed on 09.12.2022)

³³ “WHO: *Mandatory Vaccinations are a last resort*”, (Dec.7, 2021), <https://unric.org/en/who-mandatory-vaccinations-are-a-last-resort/>

³⁴ “Universal Declaration of Human Rights” (December 10, 1948), <https://www.un.org/en/universal-declaration-of-human-rights>

the world. As a member of Quad vaccine partnership, India delivered around 79 million vaccines to Indo-Pacific Region, to help in its quest to end the pandemic³⁵

Informed Consent in Vaccination

Consent embodies as an ethically basic and mandatory legal standard to safeguard the right to autonomy of the individuals. The report of Nuremberg Code³⁶ addresses that the voluntary informed consent is required as it is the fundamental ethical principle. The participant has to be given their autonomy i.e., the liberty to make the decision and give consent related to their medical conditions must be given to the individual. The importance of informed consent of a patient can be traced in *Schoendorff Hospital*³⁷ case that, “Every human being above the majority age, sound mind has a right to determine what should be done with his body.” Thus, it is absolute imperative that in case of mandatory vaccination, informed consent is necessary and everyone has the right to refuse the mandatory administration of vaccination. But here, voluntariness is lacking and from a legal and ethical view, the consent becomes invalid and there is a lack of informed consent³⁸.

Without necessary consent, treatment will be considered tortious and criminal act³⁹. Section 88, Indian Penal Code says an individual of majority age can suffer harm and give valid consent to an act, which is done in good faith and for his benefit. In *Samira Kohli*⁴⁰ case, SC held that, the medical practitioner is only allowed to withhold information in genuine emergency reasons in which the patient were temporarily unconscious. In *Common Cause*⁴¹ case, Hon’ble Justice Dipak Misra expressed the view of majority acknowledging the right to make own choice of an individual and living a life without other’s interference. The NDCT Rules, 2018 states that, “In all clinical trials, informed consent must be obtained.” The medical practitioner must provide the information in the language that is understandable. But in COVID-19 vaccination, there is no proper

³⁵ Fact Sheet: *Quad Leaders’ Summit*, PIB, (Sep. 25, 2021), <https://pib.gov.in/PressReleasePage.aspx?PRID=17544>.

³⁶ “*The Nuremberg Code (1947)*: Mitscherlich A., Mielke F., “*The story of the Nazi medical crimes*”, new York: Schuman, xxiii-xxv (1949).

³⁷ *Schoendorff v. Society of New York Hospital.*, (1914) 211 NY 125.

³⁸ Zagaja A., Patryn R., Pawlikowski J, Sak., “*Informed Consent in Obligatory Vaccinations?*”, Med Sci Monit. 2018 Nov 25;24:8.5.06-89. doi: 10.1269/91393.

³⁹ Nandimath OV., “*Consent and medical treatment: The legal paradigm in India*”, Indian J Urol, 2009; 25:3-7.

⁴⁰ *Samira Kohli v. Dr. Prabha Manchanda.*,1(2008) CPJ 56 (SC).

⁴¹ *Common Cause (A Regd. Society) v. Union of India.*, AIR 2018 SC 1665.

information or consent forms and informed consent protocols was lacking.⁴² There was no consent form needed for administration of covishield, but was needed for covaxin after the guidelines were revised on the interim analysis.⁴³ Participants in some areas also said that they were not properly counselled about the risks.⁴⁴ The State in an affidavit submitted in the Hon'ble Apex Court in *Rachana Gangu & Anr v. Union of India & Ors*⁴⁵ stated that, "The Operational Guidelines issued by the Central Government clearly states that the National Covid-19 Vaccination Program is voluntary. The Government only encourages the eligible persons to be vaccinated in the public interest, there is no legal compulsion for the same. It was also stated that the government cannot be held liable for the deaths caused due to the Adverse Events Following Immunization (AEFI)"

Ethical Consideration & Informed Consent

Informed consent being a legal procedure which involves providing the patient knowledge about the risks and cost by a medical professional is reasonably prudent for him to reveal the details of foreseeable risk or harm, enabling the patient to give an opportunity to exercise his judgment over undergoing treatment or choosing an alternate treatment⁴⁶.

In 2009, Andhra Pradesh Government, Ministry of Health & Family Welfare and Gujarat Government in association with an USA based Non-Profit Organization known as PATH (Program for Appropriate Technology in Health) conducted a project for demonstration of vaccination to control cervical cancer in which school children(girls) were vaccinated against Human Papillomavirus. Those vaccines were administered to 14000 girls between ages 10 and 14, and the residential children were to get signature in the consent form from the parents in English, the language which might most of the parents not been acquainted with. Nearly, six girls from Andhra Pradesh and Gujarat were reported dead following the administration of the vaccination, which

⁴² Mathew A., "Severe lapses in Covaxin Trials in Bhopal: Consent forms not given, participants who fell ill not treated", National Herald India (Jan. 7, 2021), <https://www.nationalheraldindia.com/india/severe-lapses-covaxin-trials-bhopal-consent-forms-not-given-participant-who-fell-ill>.

⁴³ Dwivedi S., Tiwari V., "Covaxin Taken Off Clinical Trial Mode, No Consent Forms Needed Now", NDTV (Mar.11, 2021), <https://www.ndtv.com/india-news/covaxin-taken-off-clinical-trial-mode-no-consent-forms-needed-now-2388808>.

⁴⁴ Mukunth V., "Covaxin Trial's info Sheet Skips Mention of Two Rare but Known Risks", The Wire (Jan.29, 2021), <https://science.thewire.in/health/covaxin-phase-3-clinical-trials-information-sheet-ade-vaerd-informed-consent/>

⁴⁵ *Rachana Gangu & Anr v. Union of India & Ors.*, WP (C) No. 1220/2021.

⁴⁶ Meena Rajput & Luv Sharma, "Informed consent in vaccination in India", *Human Vaccines*, 7:7, 723-727.

posted a serious question of informed consent. This issue is of significant importance as the question from it arises only after Adverse Vaccine Reaction is reported⁴⁷.

There are several ethical principles which are felt to be critical, have emerged in the past experience of medico-legal regime, aiming to resolve ethical conflicts associated with vaccination with respect to autonomy of the individuals & disclosure of information, building and maintaining trust. The substitution of the Judgment that may arise out of the decision-making abilities of an individual by a health professional without ethical framework run through a risk of being viewed as paternalism⁴⁸.

Shifting to the Strategy of Non- Compulsory Alternative

To minimize the conflicts, the State shall maximize the less than compulsory strategy or increase the use of strategies where there is no compulsion experienced by the people in getting vaccinated. Repealing the law conferring conditions of compulsion may result in increased number of vaccinations. In Australia, Financial incentives were provided as stipend to families fully-vaccinated. However, any person shall not be subject to situational vulnerability of losing any access which has no rational nexus with the object of vaccine coverage. Other strategies such as recall, reminder and patient support system to secure the trust of people in favor of vaccination shall be implemented.

Special Attention Towards Vulnerable Sections

Special attention shall be paid to vulnerable sections of people such as people with co-morbidities & senior citizens who can adversely react upon vaccination administered to them. The Delta variant of COVID-19 causing the huge loss of lives in India, severely affected these sections deadly as it possessed high viral load. But, the Omicron Variant which is responsible for the third wave in India possess several mutations affording an inherent immunity escaping capabilities, especially increasing the risk among these sections.

⁴⁷ *Ibid.*

⁴⁸ Buchanan DR, “*Autonomy, paternalism, and justice : ethical priorities in public health*”, Am J Public health. 2008; 90578:15-21.

Promoting public engagement⁴⁹

Public engagement shall be promoted by maximizing transparency & responding to community concerns which can be used for assessing the public acceptability of vaccines. The assessment shall elucidate the effective inclusion of the community through human challenge studies. A dialogue & discussion of public health officials with community representatives, shall give away better results.

Drifting Social Security Benefits to Vaccinate

Social Security benefits shall be provided to those get fully vaccinated. Availing special scholarship or discounts in public offerings for fully vaccinated as a good move. Any such measure, shall only be of complementary nature and none of them shall be so essential that the public should be dispensed as it maybe prejudicial affecting those electing not to vaccinate.

Data Privacy

As the details of persons, personal & official, are collected through national database and continuously been updated in software system such as co-win application & aarogya sethu, any breach of the privacy in the information would prejudicially affect the interest of the person depending upon the object & method of such breach. The biometric data & immunization details are to be maintained best to sub-serve the need of following up in any reporting of adverse vaccine reactions from the person vaccinated.

Countering Misinformation

The ethical consideration is much concerned with obtaining the consent of the person vaccinated. However, if the object of the same is defeated through deliberate spreading of misinformation on the efficacy of vaccine without scholarly perception must be effectively countered.

Bottom-Top Approach

The Government can constitute an expert committee to address issues associated with ethical conflicts in vaccination & thereby frame ethical guidelines to healthcare professionals dealing with

⁴⁹ Gowd KK. Veerababu D., “COVID-19 and Its legislative response - India: The need for a comprehensive health laws” [published online ahead of print, 2021 Mar 21]. J Public Aff. 2021; 269.. doi:10.1002/pa.269.

COVID-19 vaccination. A bottom-top approach must be taken in implementing those guidelines as the role of field workers engaged in immunization practices are indispensable for the same. The ethical framework shall seek to include the concerns about the testing of vaccines and tensions between public and individual autonomy.

Legislative Reforms in Public Health Emergency Law to Procure Social Acceptance

A need for reforming public health emergency law to define, list, categorize, classify different types of diseases in accordance with their severity level, process of convenience on the basis of severity, emphasizing the role of local governments, regulating the import and export of various drugs and vaccines in the pandemic & data protection in the handling of digital proximity tracing technology applications, is the need of the hour.

A provision expressly conferring the right to be healthy and safe in supreme law of our land shall be inserted and healthcare infrastructure to be developed. Establishment of institutional mechanism to coordinate the government, research institution and healthcare professionals for better performance, special protection to doctors, health and para medical professionals, sanitary workers and other medical labour force shall be included in the reformed public health emergency policy⁵⁰.

Conclusion and Suggestion

The contention of the Government is that across many parts of the world, the people are requested to wear helmets, seatbelts while driving. Government require those things for the safety and welfare of the people even though they interfere with their individual's rights. Likewise, the mandatory vaccination is also ethically justified because they are crucial for safe guarding the welfare, well-being and health of the people. Even though the mandatory vaccination interferes in the rights of the individual, it doesn't make it absolutely unjustified.

It is pertinent to note that the mandatory vaccination must be viewed as gaining another important social objective, like securing the public health. Vaccinated people get the reduced risk of getting the severed illness from COVID-19 and also reduces the risk of getting re-infected.

⁵⁰*Ibid*