



A CASE FOR IMPLEMENTATION OF COVID-19 VACCINATION: A BRIEF OUTLINE OF THE VARIOUS ASSOCIATED LEGAL ASPECTS IN INDIA

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“But it’s not vaccines that will stop the pandemic, it’s vaccination... ensure fair and equitable access to vaccines...”¹

INTRODUCTION

In early 2020 videos of lockdown in the Chinese city of Wuhan² had surfaced and were virally circulated in the social media platforms. Meanwhile, the first Indian case of this novel virus was reported from Kerala.

¹ See “COVID-19 vaccines”, available at <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines> (last visited on 21st July 2021).

² See “Viral Video: Wuhan residents stuck at home due to coronavirus sing anthem, shout slogans”, *The Indian Express*, available at <https://indianexpress.com/article/trending/trending-globally/coronavirus-wuhan-residents-slogans-6243949/> (last visited on 21st July 2021)

³ On 30th January 2020 the WHO Director-General declared the novel coronavirus outbreak as a Public Health Emergency of International Concern (this is the highest level of alarm that can be issued with regard to health emergencies by the WHO).

⁴ On 4th April 2020 it was clear from the WHO report that there has been a tenfold increase in less than a month of the confirmed cases of COVID-19 worldwide.

However, soon the viral nature of the videos on the social media platform was aptly mirrored in the real society and the speed with which the virus started spreading from one human host to another in rapid succession was soon characterised from being an outbreak to being a pandemic³. And thus the world was caught unprepared and ill-equipped amidst one of the most severe and outrageous health crisis in recent human history⁴. As reflected in the latest international data, as of 20th July 2021⁵ there have been 190,671,330 COVID-19 confirmed cases including the unfortunate death of 4,098,758 people. Further, by 18th July 2021 the total vaccine doses that have been administered are stated to be 3,436,534,998. A plain reading of the two preceding statements may lead to the inference that vaccines were readily available and that vaccination is the most common, widespread and obvious solution to the present problem⁶. However, such a simple and plain conclusion may well lead us away from the various issues connected with *vaccination as a process*. It is this characterisation of vaccination as a process

⁵ See WHO Coronavirus (COVID-19) Dashboard available at <https://covid19.who.int/> (last visited on 21st July 2021).

⁶ The development of the various COVID-19 vaccines has been approximately a yearlong process in several countries of the world. During this one year period, countries have been applying several other forms of measures to contain the disease. On February 2020 it was stressed by the WHO-China Joint Mission on COVID-19 that in order to reduce the COVID-19 related illness (including death), there should be “*large scale implementation of high-quality, non-pharmaceutical public health measures*”. The countries were prompt to implement these measures (such as individual case detection and isolation, quarantine, contact-tracing and social distancing measures) which at that time were the only possible way to contain the virus.



(and not just as a medical intervention) that will help us in dealing with the pandemic more effectively. This is more so, because the huge implementation bottlenecks of any vaccination drive can be successfully met only when we identify this form of medical intervention as a process and not just as another form of disease prevention or as a medical cure.

In analysing and studying the various aspects of vaccination as a process, two questions need to be posed right at the outset. These are respectively what the alternatives to vaccination are? And what is the desired process of vaccination? From the first question asked, the urgency of the vaccination program can be examined, whereas from the second question asked, the various safeguards of any vaccination drive can be outlined. The purpose of the present paper is to attempt a brief answer to the above mentioned questions primarily from a legal perspective. Further, it will also be an additional (secondary) objective of the present paper to put forward brief arguments to support the claim that in the answer to the above questions, the rights-based broader questions of the citizens can be subsumed.

The present paper does not attempt to probe into the legal nature of the vaccination program in detail and comprehensively. Further, neither jurisprudential analysis of the various concepts involved nor a comprehensive analysis of the medical nature of the problem is being attempted in the present paper. The paper will be limited to provide only a brief and broad overview of the legal nature of the above mentioned two

questions. The division of this paper is made into two parts. Section-I will cover some preliminary points about the pandemic and its origin, respective measures, etc. Section-II will build on the points discussed in the previous section and will attempt an answer to the questions posed.

SECTION I

Origin and Source:

The world was re-introduced to the concept of Zoonosis⁷ when the novel COVID-19 outbreak was declared a health emergency by the WHO. The origin of this novel virus is attached to the issue of Human-Animal interaction which have thus become all the more important today as the World is facing an unprecedented challenge of the COVID-19 pandemic. Research papers have been written about the multiple evidences which support an evolutionary origin of the virus from bats where it is non-pathogenic but show a great genetic diversity. In this respect, a 2012 paper noted the following:

“Bats are known to be reservoir hosts for several human viruses, including rabies, Marburg, Nipah, Hendra, and the severe acute respiratory syndrome coronavirus (SARS-CoV) (5). In addition, virome studies have shown unprecedented numbers of viruses present in the fecal samples of this ancient mammalian species (11, 24). However, little is known about the genetic architecture of most bat species, the virus variation and gene flow that occur

⁷ Another name for a Zoonotic disease, which is defined as a type of disease which passes from an animal or insect to a human some of which don't make the animal host sick but will sicken the human and can

even cause death. Prominent examples include bird flu, dengue fever, Ebola, encephalitis, malaria, plague, rabies, swine flu, etc.



through different species, the potential of different bat species to support human virus replication, the differences between the bat and human immune systems, or the potential of bat viruses to undergo zoonotic transmission to humans and other mammals.”⁸

A 2008 study estimated that approximately one billion cases of illness and millions of deaths occur every year from zoonoses whose share in the emerging infectious diseases reported globally is 60%. Further, over 30 new human pathogens have been detected in the last three decades, 75% of which have originated in animals⁹. Yet we were caught unaware and unprepared by the new pandemic. This is a reminder about the potential threat of spill-over of pathogens and infections due to coming into close contact with wildlife and/or their body parts. On-going investigations points out that there are about 1.6 million unknown viruses in birds and mammals and 700,000 of these could pose a zoonotic risk¹⁰.

The above-mentioned risk runs in face of the uncertainty of such Human-Animal interactions and the experience that in human history a pandemic have never been predicted. Further, the above paragraphs points towards the urgency of any situation caused due to such unforeseen biological agents.

⁸ Jeremy Huynh, Shimena Li, Boyd Yount, *et. al.*, “Evidence Supporting a Zoonotic Origin of Human Coronavirus Strain NL63” , 86 (23) *Journal of Virology* 12816-12825 (2012), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3497669/> (last accessed on 29th June 2020, 02:30 AM)

⁹ Jones KE, Patel N, Levy M, *et. al.*, “Global trends in emerging infectious diseases”, 451 *Nature* 990-994 (2008), Cited in a World Health Organisation article

Tackling the virus:

Although the individual on-ground response of various countries have been diversified and varied, yet, on a conceptual scale they were all akin to each-other. Thus, they can be classified into two different kinds of measures: medical and legal.

i. Medical Measures: These are the measures that were suggested by the medical professionals and used by the industry-led mechanism. These measures can be further grouped into non-pharmaceutical (self-isolation, social-distancing, etc.), preventive care (use of face-masks, hand sanitizers, etc.) and preventive medicine (vaccines).

ii. Legal Measures: These measures included those which were suggested and implemented by the legal authorities to contain the spread of the virus. Examples of such include lockdown-imposition, regulation of essential supplies, travel-restrictions, restrictions on public assemblies, Disaster Management Rules, penalizing of offenders, etc.

Although the efficacy of such measures differed according to the various circumstances and the context in which they were applied, the primary aims of these were identical. It can be said that ultimately both the medical and the legal measures were/are being directed to bring about *behavioural and attitudinal changes in the common*

available at <http://www.emro.who.int/about-who/rc61/zoonotic-diseases.html>, (last accessed on 29th June 2020, 03:30 AM)

¹⁰ See Christian Walzer, “The COVID-19 pandemic has introduced us to a new word: Zoonosis”, Op-Ed, Live Science, April 1, 2020, available at <https://www.livescience.com/dangers-of-zoonoses-pandemics.html>



people. The wearing of face-masks and using hand sanitizers, coupled with social distancing and prevention of public gatherings and prevention of proximate interactions are the new-normal.

Concerns involved:

Although there can be a number of associated and related issues with respect to the tackling of the pandemic, yet the most common measure of evaluation for all such processes have been the rights-based approach. Rights-based approach here means any approach that has as its normative and value foundations, the theory of legal-rights. It also means an approach that is operationalized from the dual system of identifying and ensuring the implementation of rights and duties. Thus, in the present scenario, it will be the duty of the government to contain the spread of the virus, or to provide effective medical care, whereas the complimentary rights of such services will reside in the common population of the country concerned.

On 22nd July 2020¹¹, COVID-19 Law Lab initiative was launched by the WHO in association with certain other bodies in order to form a strong foundation for the collection and sharing of legal resources and to aid in the development of a strong legal framework to deal with the pandemic. This initiative is based on the principle of ensuring protection of human rights, dignity and prevention of poorly designed legal response to the pandemic. Here, it is to be noted that poor legal response would certainly involve responses which strengthen social divisions and lead to marginalisation of communities

¹¹ See “New COVID-19 Law Lab to provide vital legal information and support for the global COVID-19 response”, available at [https://www.who.int/news/item/22-07-2020-new-](https://www.who.int/news/item/22-07-2020-new-covid-19-law-lab-to-provide-vital-legal-information-and-support-for-the-global-covid-19-response)

or individuals. The importance of the design, evaluation and implementation of proper legal measures having been established, next some philosophical compulsions may be stated briefly.

First, with respect to the current situation, it can be said that the restrictions (including mandatory vaccination requirements) are imposed from the point of view of *common public benefit*. This concept has been a central idea in all the social contract theories and is used in order to justify restrictions imposed over individual rights.

Second, another concept of present interest may well be the concept of *greater individual good*. This means the higher needs of an aware individual in classical liberalism. Thus, any restrictions may be justified using the argument that the individual by themselves would have chosen the same option as being for their best interest, had they been aware and educated to choose in accordance to their higher-self.

Third, while designing the mechanism to deliver on the principles mentioned above, the institutional practice has to be grounded in *justice*. Thus, the operation of the processes must not lead to marginalisation. Certain groups which can be prone to marginalisation are the poor, semi-literates and poorly-educated (due to susceptibility to fake news); migrant and informal sector workers, etc.

The various preliminary points having been stressed in this section, the answering of the

[covid-19-law-lab-to-provide-vital-legal-information-and-support-for-the-global-covid-19-response](https://www.who.int/news/item/22-07-2020-new-covid-19-law-lab-to-provide-vital-legal-information-and-support-for-the-global-covid-19-response) (last visited on 21st July 2021).



previously mentioned questions can be attempted in the following section of the article. It is to be mentioned here that vaccination *as a process* will be evaluated on the basis of the above three concerns outlined in this section.

SECTION II

Alternatives to Vaccination: (Vaccination as a process)

This part of the paper will be dedicated to the answering of the first question posed, that is, what the alternatives to vaccination are? It is necessary to understand and answer the present question, because, it is only through this answer that we will be able to appreciate the urgency of the vaccination drive. Vaccines are developed based on the knowledge of the genome structure or the protein contents of the biological agent that causes the illness. However, it has been seen that COVID-19 is capable of mutation and thus can develop new variants of the virus. Hence, vaccination may not be completely effective, as the new variants can be immune to the previous forms of vaccines. Thus, vaccination not being a complete solution, the possibility remains that the other forms of measures to tackle the virus will be in use in addition to vaccination. Thus, vaccination will be a member of the vast group of measures utilised for the pandemic. Further, in respect to the mutation of the virus, vaccination would mean that newer vaccines are continuously being developed and probed into. This process again points out to the characterisation of vaccination *as a process*.

In India, the various alternatives¹² employed in varying measures up to now are as follows:

- i. Restricting and regulating of various activities by virtue of the powers under *The Epidemic Diseases Act, 1897*. This is the Act that empowers the passage of wide-reaching regulations to contain the spread of any epidemic and to restore public health.
- ii. Imposition of lockdown by virtue of *Disaster Management Act, 2005*. This Act was utilised to impose nation-wide lockdown and to empower the Union to take various steps to contain the pandemic.
- iii. Violation of the directions and regulations can be penalised under the *Indian Penal Code, 1860*.
- iv. Respective district authorities have powers under the *Code of Criminal Procedure, 1973* which were utilised to impose local restrictions on movements, gatherings, etc.

Several of the aforementioned laws are of colonial origin and it has been alleged that there can be executive overreach in using these laws, due to their ‘umbrella clauses’¹³. While an examination of the laws mentioned will be beyond the purview of the present paper, yet, the various social challenges thrown by such measures can be outlined here. Thus, the migrant workers, informal labourers, old age people, persons with disabilities, etc. are severely affected by such measures. Here, mention may be made of the fact that cases of domestic violence, depression and negative effect on mental

¹² The non-pharmaceutical measures like lockdowns, isolation, etc. are referred to in this part. The various preventive measures like wearing of face-masks, use of hand sanitizers, etc. are not referred here because of the limited effect of such measures on the rights of the people.

¹³ See Gautam Bhatia, “India’s Executive Response to COVID-19”, *The Regulatory Review*, available at <https://www.theregreview.org/2020/05/04/bhatia-indias-executive-response-covid-19/> (last visited on 21st July 2021).



health and suicides have also been caused by the stress and strain of such measures. When compared with vaccination, these laws cannot be said to be better. Vaccination, if implemented properly, will benefit every section of the society and probably will not have disparate effects on different social groups.

It is not being argued here that vaccination should be accompanied with removal of all such regulations and restrictions and complete disregard of other measures to deal with the pandemic. However, it is reasonable to state that an increase in vaccination will certainly aid in the gradual relaxation of some of the harshest of such provisions. Further, vaccination can also be argued for in terms of the three concerns raised in the previous section.

The desirable process of vaccination:

The urgency and immediate requirement of vaccination being emphasised, this part will be dedicated to comment on the desirable process of vaccination. This will form the answer of the second question posed. However, this desirability will be evaluated from the perspective of law and the Constitution and not in terms of technical and logistics requirement. The various technical aspects of the vaccination program¹⁴ are beyond the scope of the present paper. However, certain aspects of the technical features will be outlined because of their effect on accessibility of vaccines (assuming

that other technical factors remaining constant).

The legislative framework of vaccination programs:

- i. *International Legal Framework:* The WHO website lists certain six¹⁵ legal instruments to safeguard the vaccination program apart from the Health Regulations. These are very comprehensive and deals with aspects related to diverse areas like international borders, digital surveillance, social isolation, human rights, etc. Thus from a rights-based perspective, these are to be ensured effectively
- ii. *Fundamental Rights provisions:* Articles 14 (equality before law and equal protection of law) and 21 (protection of life and personal liberty) of Part III has to be protected in case of vaccination programs.
- iii. *Other Constitutional provisions:* Articles 39 (policy for health and strength of workers, children, etc.), 41 (right to public assistance in certain cases), 42 (humane conditions of work and maternity benefit), 47 (nutrition and public health improvement) of Part IV deals with various aspects of health. Further, Article 51A (Fundamental Duties) also has provisions related to health.
- iv. *Liability under Tort Law:* The duties of medical professionals are also covered under the common law principles of Tort, particularly that of *negligence*. As a tort this means the breach of pre-existing legal duty to take care and the eligibility of consequential damages.

¹⁴ For example, number of vaccine doses available, number of healthcare personnel, cold storage, etc.

¹⁵ These instruments are Convention on the Elimination of All Forms of Discrimination against Women, International Covenant on Economic Social and Cultural Rights (1966), International Covenant on

Civil and Political Rights (1966), International Convention on the Elimination of all Forms of Racial Discrimination, Convention on the Rights of Persons with Disabilities, and International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families.



- v. *Criminal liability*: Sections 269 and 270 (spread of infectious diseases dangerous to life), Section 271 (disobedience of quarantine rules) and Section 304A (causing death by negligence) particularly deal with the criminal liability of the personnel involved in the vaccination process.
- vi. *Liability under Consumer Protection law*: Paid Vaccination programs organised by the private concerns in the country would fall within the category of *service* under the Consumer Protection law and thus protected through the law.
- vii. *Liability under Law of Contract*: The Indian Contract Act, 1872 deals with various aspects of offer, acceptance and the law of principal and agent. Compensation and remedy may be provided under this legislation.
- Hence, in light of the above brief discussion, the following can be stated as the State responsibilities in any vaccination program:
- a. In *State of Punjab v. Ram Lubhaya Bagga*¹⁶ it was held that the State is obliged to protect the right to health of any citizen under Article 21 and also under Article 47. With respect to vaccination, this would mean appropriate measures to vaccinate the population and also services within the reach of the people.
 - b. In *Paschim Banga Khet Mazdoor Samity & ors. V. State of West Bengal & anor.*¹⁷, it was held that protection of life is of paramount importance under Article 21 and can in no manner be relaxed. Thus, vaccination as a medical service provided by a Welfare State will be well within Article 21 and thus of paramount importance.
 - c. In the landmark judgement of *Pt. Parmanand Katara v. Union of India & ors.*¹⁸, it was held that procedures cannot be made to delay the duty of preserving life that professionals owe to the people. Thus, vaccination program cannot be halted only due to the requirements of procedures if the cases are of critical nature or have a direct relation to the right to life.
 - d. In *Consumer Education and Research Centre & ors. V. Union of India*¹⁹, it was held that the right to health of the worker is protected under Articles 21, 39I, 41, 43 and 48A and compulsion to work under situations which curtail the worker's health will be a violation of Article 21. Thus, by virtue of this case it can be contended that employers are liable to provide vaccination and other safety measures to protect the workers from coronavirus.
 - e. Further, vaccination camps are also constitutionally protected and all such camps in their operation should not amount to the violation of any right or any injury to the beneficiaries²⁰.
 - f. Again, while the Government is actively probing into the possibility of enlarging the scope of government services, the mere allowing of private vaccination and COVID-19 treatment may also be a violation of tort principles certain cases. Thus, prohibitive and high costs of treatment in private concerns²¹, and faulty vaccination drives²² may amount to negligence.
 - g. Lastly, the professionals engaged in implementation of the vaccination program

¹⁶ (1998) 4 SCC 117.

¹⁷ (1996) 4 SCC 37.

¹⁸ AIR 1989 SC 2039.

¹⁹ (1995) 3 SCC 42.

²⁰ See *A.S. Mittal & ors. v. State of Uttar Pradesh & ors.*, AIR 1989 SC 1571.

²¹ See *Spring Meadows Hospital v. Harjol Ahluwalia*, (1998) 4 SCC 39.

²² See *State of Haryana v. Smt. Santra*, (2000) 5 SCC 182.



have a *duty of care* towards the beneficiary under the consumer protection law as well as law of contract. In the case of *Dr Ravinder Gupta v. Ganga Devi*²³, it was held by the Chandigarh State Commission that a deficiency in medical service under the consumer law includes the tort of negligence, but is wider than strict liability under the tort law. In *Indian Medical Association v. V.P. Santha*²⁴ it was held that a professional has a duty to reasonable care under the law of contract in addition to the law of tort and can be made liable to pay damages.

- h. Finally, the vaccination programs must not violate the international legal framework identified above.

SUMMATIONS AND SUGGESTION

Thus, from the brief discussion attempted in the previous sections of the paper, the two questions posed at the very outset seem to be answered. In Section-I of the paper, the origin and source of concern about the present pandemic and the biological agent associated with it has been stated. Further, three concerns were raised, broadly from the sphere of legal philosophy which can be used in justifying vaccination and also mandatory vaccination. Next, in Section-II, the importance of recognising vaccination not just as a medical intervention but *as a process* has been highlighted. In this section, an attempt has also been made to arrive at the conclusion that in case of absence of vaccination program, the other measures that may be resorted to will further erode away from a healthy functioning of the society. In addition, the various alternatives do have substantive social repercussions. Hence, vaccination is the safest way to approach the pandemic, both medically and legally.

The various legislations that have been earlier stated in this paper are sufficient to deal with instances of mandatory vaccination. Or else, the threat of such penal provisions may act as an incentive to consent for the vaccination process. Finally, it was established through a brief survey of the various court judgements that vaccinations (free and paid) are a matter of right, especially in the present instance of rising death rates in the country. In this respect, even the State non-interference and thus indirect approval of private vaccination drives may well come into the purview of rights-violation. Thus, in conclusion it can be stated that every human being has a right to health, and any measure to protect the same can be substantiated by the present legal structure.

It was beyond the purview of the present paper to comprehensively probe into the legal nature of the problem. However, certain aspects like the digital literacy, digital divide, access to internet, etc. may be probed into in future researches. This is because the Government have been an active champion of dealing with the pandemic with the aid of digital tools like the *Aarogya Setu* app and the CoWin portal for vaccine registration and administration. Any initiative on such a large scale must ensure that no one is left back only because of some handicaps, like digital illiteracy, non-availability of internet, economic capacity, etc.

As of now, India is slowly and gradually proceeding towards complete vaccination, and the graded approach that the Government has taken in this case is highly appreciated.

²³ (1993) 3 CPR 255.

²⁴ (1995) 6 SCC 651.