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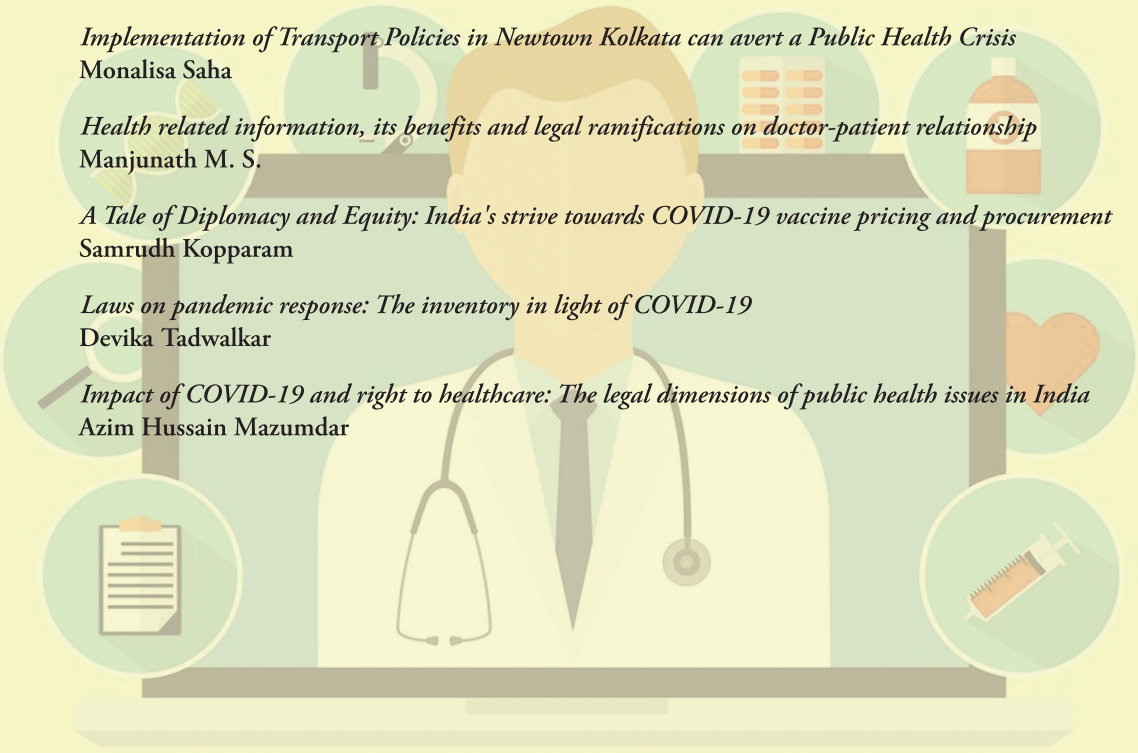

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Contents

Editorial

Humans have time and again witnessed how catastrophic global events can change the course of history. Such events have the potential to wreak havoc and cause enormous loss to human lives and livelihoods. Beyond the direct impact on health, the COVID-19 pandemic has resulted in several indirect consequences on public health systems, education, economies, and human interactions. The palpable need to prioritize relief measures for COVID-19 patients within the constrained and overburdened health infrastructure has diverted attention from patients suffering from other serious illnesses and has exposed the inadequacies of the public health infrastructure of the country.

The modern perceptions of human rights emerged as a consequence of the Second World War and the Holocaust. The Universal Declaration of Human Rights along with the other treaties and instruments concerning international Human Rights Law was framed to deal with such times of crisis. They provide mechanisms for governments to effectively respond to such situations without hampering the dignity of the individual, which is amongst the most important tenets of human rights law. The most significant challenge faced by the government was to strike an effective balance between human rights and administering relief and safeguards from the pandemic besides fulfilling other responsibilities expected of a welfare state. While certain restrictions on derogable rights necessary for responding to the needs of such emergencies are acceptable provided they are commensurate to the challenges posed by the emergency, it is important to independently assess such restrictions through the lens of law and public policy.

The need for a decentralized approach towards public health is important now more than ever. The capacities of government hospitals, public health centres and other parastatal health institutions need to be enhanced to ensure inclusive coverage of all sectors of society, including the tribal and the rural areas to ensure greater compliance with vaccination measures and health literacy that is otherwise marred by ignorance and misinformation. As opined by several

experts and researchers, the dire need of the times to come would be a move towards the adoption of universal health coverage, advocated by International Organizations like the United Nations, World Bank and World Health Organization and enunciated under Target 8 of the Sustainable Development Goals. Adoption of universal health coverage was considered by the Planning Commission of Indian in October 2010.

The High Level Expert Group constituted to firm up the policy had envisaged a healthcare system in India that ensures equitable access for all Indian citizens and residents in any part of the country, regardless of the level of income, social status, gender, caste, religion, to affordable, accountable and appropriate health services of promotive, preventive, curative and rehabilitative healthcare as well as public health services with the government being the guarantor and enabler of health and related services. Regrettably, the adoption of universal health coverage in India is still a distant dream.

The cascading effect of the pandemic has highlighted the frailties of the public health infrastructure, besides uncovering the sensitive link between the pandemic, social isolation, loss of livelihood and recreation and significant levels of mental and psychological distress. Regulatory response to such multifarious needs would need an in-depth assessment of the legal and policy strategies that are effective. The Special Edition of the Journal of Law and Public Policy: Public Policy in Public Health has feature articles that delve into different aspects of the public health law in the backdrop of the COVID-19 pandemic.

In "*Public Healthcare in post pandemic India: a policy perspective,*" Debasis Poddar puts forward the argument that with remnants of Weber's model, Indians would survive the emergency with a death toll within thousands while, the OECD states – including the United States of America with the neoliberal model would witness millions succumbing to the pandemic.

Kshitij Kumar Rai and Sakshi Agarwal, in their article "*Vaccine crisis and patent – issues and challenges: Global Perspective*", focus on the legal framework of Intellectual Property Rights and the TRIPS agreement that are creating challenges for the patent rights waiver, in addition to the issues pertaining to

vaccine shortage, patent rights regime and the consequent challenges.

In the next article "*Implementation of transport policies in Newtown Kolkata can avert public health crisis,*" Monalisa Saha attempts to assess whether transport policies adopted by the Government since 2012 to avert such public health crises and improve the transport system on various other parameters are adequate to reduce carbon emissions and reduce the burden of non-communicable diseases in the country. In furtherance of this objective, the author has specifically explored how Newtown, in Kolkata (West Bengal), has fared in trying to achieve sustainable urban mobility, especially as part of the Smart City Mission of 2015.

Manjunath M. Sin his article "*Health related information, its benefits and legal ramifications on doctor patient relationship*" explores the nuances of the doctor-patient relationship. Over time, the doctor patient relationship has changed from being paternalistic to a patient-centered one. The foundation of this kind of relationship is based on the shared decision making from both the parties (patient and the doctor). The author reviews the implications of the spread and reach of online health information that has been instrumental in achieving optimal patient-centered care. Along with this, the advantages and its associated challenges in implementation of such kind of e-health concept is also discussed in context of the changing nature of the doctor-patient relationship with respect to legal and medical aspects.

In "*A tale of diplomacy and equity: India's strive towards COVID 19 vaccine pricing and procurement*", Samrudh Kopparam addresses the relationship between diplomacy and equity vis-à-vis the COVID-19 vaccine to understand the efforts made to 'win the war' against the novel coronavirus. The author also examines the procurement and vaccine distribution policies of the Indian government in ensuring sufficient doses of vaccines are made accessible to the public at large.

In "*Laws on pandemic response: The inventory in light of COVID 19*", Devika Tadwalkar highlights that the impact of the coronavirus pandemic world-wide has been devastating. The multidimensional effect of the pandemic on every stratum of society has raised concerns about disaster management of even the most developed and advanced countries. Measures adopted by authorities

in some countries have included a wide range of restrictions: from general guidelines, curfew, lockdown to travel bans and mandatory quarantine. In this backdrop, the author directs the attention of the readers to some pertinent questions – What are the relevant obligations, powers and procedures under public international law and whether their implementation has proven effective? In order to address such questions, the article evaluates the disputed issues under other regimes of international public law, such as human rights, trade, security law and offers suggestions to restore the damage done. The last article in this volume "*Impact of COVID 19 and right to health care*" authored by Azim Hussain Mazumdar examines the need for adopting a comprehensive legal framework that provides access to health as a legislatively assured right.

Dr. Sairam Bhat
Professor of Law, NLSIU
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Public Healthcare in Post-Pandemic India: A Policy Perspective

*Debasis Poddar**

Abstract

In the wake of the public health emergency grappling India, administrative praxis with New Public Management face a setback. In recent times, administration has turned neoliberal, thereby discarding the Weberian praxis; something followed by India after its colonial legacy. The new public management has replaced the Weberian model, thereby turning public administration customized to the vested interest of corporate enterprise. The recent public health emergency, has however, highlighted lessons to minimize dependency syndrome upon the given neoliberal model. In the new model, contractual cadre is most unlikely to deliver the service in times of emergency since contractual relations are devoid of pledge to the public by default. In the Weberian model, permanent cadre is most likely to deliver the service in emergency since fiduciary relations ensure functional balance between the competing, even conflicting, interests. Finally, Weber proves pragmatic. This article puts forward the argument that with remnants of Weber's model, Indians would survive the emergency with a death toll within thousands while, the OECD states– including the United States of America– with the neoliberal model would witness millions succumbing to the pandemic.

Keywords: *fiduciary relations, public service leadership, schools of thought, best practices, etc.*

Introduction

The purpose of this article is to undertake a comparative study of administrative praxis. The classical model of bureaucracy– developed by Max Weber in the

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early twentieth century[1]-will be compared to the New Public Management (NPM), a neoliberal model– developed by the OECD literature in the late twentieth century (OECD, 2010) within the specific context of public health emergencies. Besides, the Weberian bureaucratic praxis is prescribed in the epic struggle during public health emergency across the world. By advancing adequate reasoning, the bureaucratic praxis developed by Nehruvian India is advocated as the most prudent policy with requisite modifications towards welfare governance– something that is very different from the colonial legacy that India inherited with its independence. Also, with due emphasis, the bureaucratic praxis developed by Weber over a century ago is recommended as proactive patronage by the state to tide over the challenges posed by the public health emergency; albeit, epistemic evils apart. With its default right-wing ideological proposition vis-à-vis commitment of the bureaucracy towards the welfare of the state, advantages of this are manifold: (i) Weber's model suits to the right-wing governmentality with better ease[2]; and (ii) public health emergency deserves bureaucratic cadre with passion for public welfare which deserves conviction of those in service. Since necessity knows no law, conviction of the cadre is non-negotiable during times of emergency and ideological commitment has the potential to keep them motivated, much more than standard professional ethics. Despite synergy between Weberian and Soviet praxis, Weber appears appropriate since his legacy was in vogue in Nehruvian India, and its incubation has already been put in place.

Models of Public Administration

At the outset, it is important to discuss the major policy options available so far: (i) classical model at the beginning of twentieth century; (ii) Soviet experiment of early twentieth century; (iii) liberal (public choice) model of mid-twentieth century; (iv)new public management (NPM) model of late twentieth century; (v) postmodern model at the end of twentieth century.

1 Max Weber, The Processes of Rationalization (SAGE Publications, Inc, 2014).

2 Guenther Roth, *Political Critiques of Max Weber: Some Implications for Political Sociology*, 30(2), AMERICAN SOCIOLOGICAL REVIEW 213-223 (1965).

All these models were tested across the world. The classical model was initiated by some ancient philosophers of public administration, including Fayol, Gulick, Urwick, Mooney, Reiley, Follet, Shelton, and the like at the end of nineteenth century. With varied reasonings of their own, they advance arguments towards the structural craftsmanship of public administration; something that resembles public administration for the sake of administration itself. Since then, institutionalism, among others, appears to be a core criterion, identified as an insignia of public administration. Consequently, an opposing view emerged in the public administrative discourse between individualism and institutionalism; as if, institution alone could serve purpose of public welfare; with the corollary implication that an individual was set aside as a potential player in the public administrative discourse. This prejudice appears in vogue till date with far-reaching consequences.

Thereafter, in the early twentieth century, Weber developed the scientific model named 'bureaucracy' – as a highly structured, formalized, and impersonal organization. In contrast to the classical school, Weber insisted upon the administrative personnel– more than the administrative system itself– to serve the public. Since then, the system with accountability to the public is known as public service and the cadre as public servants. To him, public servants are officials appointed by the authority to run public services as a professional career. Accordingly, elected public representatives cannot be considered public servants. While the Weberian model was in the process of development, the Soviet model emerged as a competitive alternative in the then USSR, radical enough to bring in transformation through socialist administrative governance. After the collapse of Soviet Union, however, experiment of the otherwise progressive socialist administrative discourse lost relevance due to want of practice. Even China follows *sui generis* praxis of its own. Therefore, despite its merit, Soviet model remains beyond the scope of coverage of this article.

In the post-war world, the liberal model was proposed to offer the 'public choice' doctrine. Arguments were advanced to plead the liberty of consumers to prefer public administration on one hand and private management on the other. Accordingly, more than one option was available to the commoners with the

liberty to exercise their own choice out of their common sense. The fallacy in an otherwise unproblematic liberal model lies here that common sense is more often than not uncommon amongst the public and commoners in particular, due to want of prudence and want of exposure to the given public choices. Whether and how far the so-called liberal model is liberal enough to empower the commoners with the liberty to choose is a moot point.

Late twentieth century onwards, with the slow-yet-steady rise of so-called liberalization-privatization-globalization (LPG), the Westerners initiated a 'business-like' neoliberal model in contemporary public administration through the spread of New Public Management (NPM) worldwide. This model was somewhat like the personnel management model limited to private enterprises alone so far. With the advent of the New Economic Policy in India since 1991, the neoliberal model appeared to be on the rise to preach the potential of minimal state interference. With the passage of time, after the introduction of the neoliberal model, public services were to be gradually supplemented or perhaps, finally supplanted by market-driven forces. Public health was no exception. Imposition of market-driven forces, manipulated by private operators, involved systemic power wielded by the private sector; something inimical to the practice of liberty advanced by the discourses on liberalism and neo-liberalism.

With the gradual emergence of the postmodern model, since the last quarter of the twentieth century, the original wisdom of Woodrow Wilson is back in a new form, emphasizing pragmatism vis-à-vis objective reality of the society. It has been emphasized that rather than dogmatism and the orthodox approach once advocated by Weber. Unlike the Weberian model, postmodernism is a critique of the sundry praxis experimented so far. This article advocates a policy that takes stock of all sundry models mentioned above, thereby identifying one that is backed by public reasoning feasible for practical application and acceptable to all stakeholders in the discipline of public administration.

By these standards, the Soviet model may get eliminated on two counts. First, in the global administrative landscape, socialism is reduced to naught by default. Second, totalitarian command structured upon administrative

apparatus has proven to be counterproductive to public good, regardless of the technical meaning of the term. China can be cited as a classic illustration where productivity was escalated at the cost of fundamental human rights and environmental violations; something that is contrary to international law and the Indian constitutional principles.

In this context, India has experienced transition, if not transformation. At first, Nehruvian India modified the principles of Max Weber to suit the regional reality of a developing economy to proceed with 'the tryst with destiny'; as quoted by Nehru. Accordingly, under Part XIV of the Constitution, bureaucracy has reserved a permanent seat in public administration since 1950. After India embraced the new economic policy, there has been a paradigm shift in the liberal model of 'public choice' in its administrative sphere. In recent decades, after a decisive electoral verdict in favour of the present right-wing regime since 2014, a slow-yet-steady shift appears to be on the rise to supplant the liberal model with a neoliberal one. This has already been witnessed in the sphere of public health and public education. In the wake of the pandemic, the present public health emergency, can serve as the litmus test to identify a model of public administration that seeks to best suit public welfare.

Three models of public administration– Weberian, liberal and neoliberal models have been discussed in this article. The comparative advantage of one administrative model or a combination of two or more models over the other/s is analysed to see which model meets the needs of the prevailing public health emergency in India. Besides, effort is made to demonstrate the critical crossroads of law and public policy in the context of the pandemic under the broad rubric of disaster management. In addition to the comparative study of the ideological models, spatial models in the major cities across the globe would also be compared.

Weberian bureaucracy in Postcolonial India

Contrary to popular notion, the bureaucracy in India is neither comparable to the century old model suggested by Max Weber, nor suitable for a developing economy. In the then European context, Weber emphasized upon objectivity in

bureaucracy to advocate strict professionalism in bureaucratic service; followed by functional separation between public life and private life *inter se* and the same was initiated with recruitment based on merit. The rationale behind fair and transparent procedure for recruitment was introduced with the reasonable expectation that the same would get reflected in the quality of public service. Therefore, although suitable for a different time and place, the narrative of Weber deserves academic attention in the South Asian discourse on public administration. After independence, India inherited the legacy of a coercive administrative and service cadre from the colonial rulers. Native stakeholders of the cadre thereby continued as they were. Consequently, structural features survived in public service. In its spirit, however, services underwent volte-face with the change in character of statecraft. For instance, private domain was bureaucratized even before Weber; way back in the mid-nineteenth century:

This enormously important occurrence (in India), by which former traders changed into public administrators, took place in three stages. First phase was from 1601 to 1740, when the Company, whose business in this period was primarily related to trade, carried out only minor administrative tasks. Second period incorporates years from 1741 to 1833, when its commercial tasks gradually decreased while administrative work and its importance increased. The final period, lasting from 1834 to 1858, saw the final transformation of commercial corporation to public service organisation. What was once "privatisation" of the state's mission in a distant land now encompassed the complete "publicization" of the government's commission which, by reason of state, passed into the hands of the crown.[3]

After independence, the trend of nationalizing private enterprises continued, including in the sectors of. telecommunication, bank, insurance, etc. However, the change was apparent with the involvement of the public administration in implementing the postcolonial agenda towards national reconstruction via planned economy in India:

When the career in Indian administration was created, the duties of civil servants had grown to such an extent that … hardly any matter remained outside their

3 Margaret Schroedertrans, OmarGuerrero-Oroz, *Public Administration in Great Britain: History of Institutions and Ideas*,(Institute of Public Administration, Mexico 2014), http://www.omarguerrero.org/OGO_GREATBRITAIN.pdf (last visited Sept. 10,2021).

purview except those relating to the navy, defence and health. The civil servant was administrator, tax expert, judge, secretary and diplomat. His tasks in his assigned district included construction of roads and canals, bridges and walls, administration of prisons, and health inspection. He further served as police officer, postal worker, supervisor, customs official, educator, comptroller, salt agent, lottery official, superintendent, auditor, army paymaster, and banker. … But this process did not consist only in proliferation of the tasks as in a Weberian bureaucracy; that is, the ability to take on diverse variety of tasks, but also an upward technological progression that led to the establishment of specialised departments staffed by experts.[4]

Thus, despite such a paradigm shift in the essence of public service, Nehruvian India followed the Weberian model. First, the personnel were conversant with the bureaucracy and found it easier to practise. Second, the ancient traditions of the region were destroyed by the colonial regime to such an extent that revival of its remnants in an altogether different period appeared neither possible nor prudent; more so in the context of transition that existed then:

Arabs, Turks, Tartars, Moguls, who had successively overrun India, soon became Hindooied, the barbarian conquerors being, by eternal law of history, conquered themselves by the superior civilization of their subjects. The British were the first conquerors superior, and therefore, inaccessible to Hindoo civilization. They destroyed it by breaking up the native communities, by uprooting the native industry, and by levelling all that was great and elevated in the native society. The historic pages of their rule in India report hardly anything beyond that destruction. The work of regeneration hardly transpires through a heap of ruins.[5]

Thus, in the Nehruvian India, Weber was customized to serve the felt needs of the hour. No wonder that, despite drawing learnings from him, the then administrative regime was far separated from his model. For instance, compared to his classical model of centralization, status quo, and self-regimentation, the *sui generis* model developed by Nehru transcended Weber with the agenda of decentralization, development, and public participation, among others; thereby spearheading the post-Weber praxis in India.

4 *Id.*

5 Karl Marx, *The Future Results of British Rule in India,* Daily Tribune, (Aug. 8, 1853) http://dcac.du.ac.in/documents/E-Resource/2020/Metrial/422AakanshaNatani2.pdf (last visited Sept. 15, 2021).

Post-Nehruvian paradox in globalized India

The developed nations, however, acted differently. The Weberian model was instrumental in planting the seeds of fascism in Germany, by regimentation of the cadre in public service. In one way or the other, the legacy of Bismarck continued with Weber to reach the Third Reich of Hitler. On the other hand, the Soviet model culminated into totalitarianism under the leadership of Stalin. Neither of these models was conducive for global capital. Thus, keeping liberty as the buzzword of democracy, statesmen in the West preferred to discard policy advocacy for 'public choice'; thereby reviving the invisible hand under the disguise of market force. Accordingly, private enterprises penetrated the public service sector to create a competitive market and enable consumers to choose from a wide variety of options available. A basic assumption behind public choice is that all consumers are prudent and rational enough to pick what suits them. Another assumption is the default integrity of market players. Regrettably, both assumptions are vitiated since several people fall prey to bad decision making. Likewise, most market players indulge in malpractice. Therefore, exercise of public choice, more so in the South Asian context, has often proven to be made wrongly.

Watertight compartmentalization does prove otiose as witnessed in the first quarter century of the LPG regime (1991-2014) when India experienced the (or) deal of 'public choice'. In recent times, albeit arguably, 'public choice' is being supplemented with the New Public Management; more so in the two main domains of welfare governance: education and health. Once undertaken by the welfare state to ensure education and health for all as universal socio-economic rights, read with similar rights recognized by the national legal regime,[6]the laissez-faire state of the present times is reluctant to recognize these obligations as its own. Also, to fill in the systemic vacuum (incentive was introduced by the statecraft to encourage private players. In recent times, until public health emergency, effort was initiated by the laissez-faire state to get rid of the odious onus vis-à-vis public education and public health as its

6 INDIAN CONST. Parts III and IV.

own since- after the post-Weberian polemics, these 'services' ought to be left to market players as non-sovereign services. Accordingly, the so-called minimal state ought to limit itself to sovereign services including, defence, police, justice, and the like. Education and health are thereby reduced to 'services' and are subject to private management.

The health emergency has toppled this given trend. With kneejerk reflexes, India is back to its erstwhile castle of bureaucracy; with whatever remnants that have survived this far. All emergency services are generated by the hitherto side-lined hospitals and other state-run institutions for medical treatment, research, and development. Its staff cadre are by and large engaged round-the-clock; and have even been infected by the virus. Cases of health service cadre and frontline workers getting infected, even succumbing to the virus, are no longer sporadic in India. Rare exceptions apart, private players have withdrawn from the scene. The pandemic has acted as an eye-opener. In general, private players can be compared to fair-weather friends vis-a-vis healthcare 'services'. In times of crisis, the State is left with no other option but to rush back to its public healthcare services with its own all-weather infrastructure and personnel; often ignored by the neoliberal state because of its obsession towards the market.

Here lies the paradox that this article seeks to address. During normalcy, healthcare is seen as a 'utility services' and, therefore, left to private players who profit from the plight of the public. During emergency, healthcare turns into 'essential services' and, therefore, put to personnel who are engaged in public service. Corollary to the caveat, private players disengage from the scene during emergency and public servants engage in *pro bono* service, normalcy and emergency alike; something against the settled legal maxim: *QUOD APPROBO NON REPROBO*, i.e., legal heir ought to perform the condition, or to renounce the benefit.[7] A principle of equity, the legal maxim should get extended to the public healthcare sector. While the private players make profit out of the plight of the public, they should perform their social responsibility during public emergency as well or should be ready to renounce the profit

7 Herbert Bloom, A Selection of Legal Maxims (Johnson& Co. Philadelphia,1874).

during normalcy. Had the public hospitals and similar state-run institutions received proactive patronage from the state exchequer as they did before the policy shift that favoured market driven forces, infrastructure and personnel would have been far better enabled than at present to deal with the public health emergency. After decades of departure from the classical model (1991-2020), India has had the potential to extend humanitarian aid through the donation of lifesaving drugs to the USA and European states; that have otherwise been hailed as more advanced than India for their potential in providing healthcare services. In the wake of the emergency, India has been left with no other option but to license public sector enterprises like Bengal Chemicals and Pharmaceuticals Limited, established in 1901 and nationalised in 1977, to undertake large scale production of lifesaving drugs. Notwithstanding the need to champion 'public choice', the state should boost the public healthcare sector for it to be compliant with the Disaster Management Act, 2005; and better cope with similar circumstances in the times ahead. Moreover, incentives for the private sector under the *Ayushman Bharat Pradhan Mantri Jan Arogya Yojana* (AB PPMJAY)[8] should be provided subject to reasonable conditions such as providing healthcare services on a non-profit basis in times of public health emergency. Taken together, a two-way approach ought to fortify the present healthcare policy regime better than earlier.

Treatment more detrimental than the predicament

All the aforementioned models are pregnant with prospects and consequences of their own. Besides, sundry models may be productive in appropriate time and space while non-productive or even counterproductive- otherwise. A moot point before contemporary India, therefore, lies in policy preference- during the health emergency and even afterwards- available. Therefore, deliberation will get divided in two parts: (i) emergency and (ii) post-emergency policy preference; although neither appears less relevant than other, while at the same time both are connected to one another.

8 Ministry of Health and Family Welfare, Government of India, *Broad Guidelines for Private Investments in setting up of Hospitals in Tier 2 and Tier 3 cities subsequent to PMJAY* https://pib.gov.in/newsite/printrelease.aspx?relid=187353 (last visited Jan. 8 2021).

The governance of health services during normalcy ought to influence the delivery of services during emergency. This hypothesis can be drawn from instances that have transpired in the West during the pandemic. The neoliberal model introduced by the OECD regime has hit the health governance hard; to such an extent that the number of deaths due to the pandemic in developed countries speaks for itself. Even a decade back, in the context of the economic meltdown, the flaw of the neoliberal model was prima facie apparent:

New public management (NPM) is related to the changing balance of power between economic theories since 1980s. The economic doctrines of Keynes, which ruled after the Second World War, grew outdated in the 1980s. Keynes' economic theory could not explain stagflation, a combination of inflation and long-term unemployment. Consequently, the Keynes theory was attacked by three alternatives: monetarism, supply side economics and public choice theories. The combination of these ideas is collectively known as neo-liberalism. Economic neo-liberalism is currently in deep trouble as a consequence of the worldwide financial crunch. After more than 30 years of ideological hegemony, neo-liberalism today seems powerless to explain developments in the real world.[9]

Consequently, an offshoot of neoliberalism, NPM is ridden with flaws and thereby falls short to cope with the health emergency. Since the 1980s, OECD states have encouraged NPM in public healthcare, which shifted the burden of providing health services to private players. What was intended through the introduction of NPM was better health governance. Besides, during normalcy, private players by and large performed well:

Over the past two decades, enhancing public sector performance has taken on new urgency in OECD member countries as governments face mounting demands on public expenditure, calls for higher quality services and, in some countries, a public increasingly unwilling to pay higher taxes. To address these challenges, various OECD countries have sought to enhance public sector performance by adopting a range of few levers and approaches to management budgeting, personnel and institutional

9 Jouke de Vries, *Is New Public Management Really Dead*? 1 OECD JOURNAL ON BUDGETING, 1-5(2010).

structures. Within government, these have included the introduction of performance measures … and changes in public employment typified by the adoption of contracts for public servants and the introduction of performance-related pay. Examples of institutional change include the creation of executive agencies and the privatization or outsourcing of the provision of public services.[10]

However, in the present health emergency it has backfired to put public healthcare to peril. The reason behind the success of NPM in normalcy and failure of the same in emergency lies in systemic fallacy that goes unnoticed. When healthcare was privatized, the treatment costs came down to meet demand at comparable prices in the competitive market, albeit not to the same extent as the public healthcare sector. But the market-driven private healthcare industry does not owe any duty to the public; something that has been instrumental in keeping state-sponsored healthcare services afloat. The private healthcare industry has withdrawn from the business during the pandemic since it serves the client. On the contrary, under the patronage of the state, the public healthcare service is back since it serves the patient. In the Weberian model, social security benefits were given to those in public healthcare. Therefore, even in times of emergency, cadre prefer public service owing to socio-economic reasons and they cared for patients for the fear of loss of service. In the neoliberal model, service providers are contractually bound by the management. Consequently, they suffer from want of commitment towards patients. Thus, recruitment and retention engage regular business for the OECD states:

Different underserved regions have different characteristics that affect recruitment and retention. Some are remote, others isolated or simply poor areas, some have specific cultural or ethnic characteristics. Their populations may have different social, economic, demographic and epidemiological profiles. Decentralizing education and training programmes and recruiting from local communities helps adapt health professionals to the needs of the population they are expected to serve. Incentives, such as access to housing, may have more impact in certain regions. Financial incentives

10 OECD, Modernising Government: The Way Forward.56, (OECD Publishing, 2005).

may need to be calibrated according to the features of the place, the motivations and aspirations of practitioners or the nature of the work.[11]

Besides, recent experience proves beyond doubt, that health governance during normalcy and during emergency needs approaches that are poles apart. India is a classic example to this end. While India practiced with 'public choice' in the recent times and experimented with NPM, in the wake of the public health emergency, however, India is back to the Weberian model once again. Had public healthcare received proactive patronage from the state exchequer, the public health emergency would have been handled with better ease. Therefore, all stakeholders in the federal administrative structure resorted to the Weberian model.

Although the Weberian model is ridden with drawbacks of its own import the NPM model to supplant the Weberian model poses certain challenges. Prudence, therefore, lies in bringing in reform to the Weberian model; thereby customizing it to meet the need of the hour. The Indian bureaucracy ought to prove no less than other models on several counts. Therefore, rather than replacing the existing model, prudence lies in improving it. Moreover, the other models should supplement bureaucracy; with specific reference to the 'public choice' doctrine. With greater emphasis on professional ethics, continuous learning and with the assistance of updated health technology and infrastructure etc, the healthcare service cadre could be oriented towards efficiently discharging their responsibilities. Here lies the relevance of the postmodern praxis which makes room for combining the positives of sensitivity and subjectivity. In the words of Woodrow Wilson:

The bureaucrat is everywhere busy. His efficiency springs … out of care to make ingratiating obeisance to the authority of a superior. … He serves, not the public, but an irresponsible minister. The question for us is, how shall our series of governments within governments be so administered that it shall always be to the interest of the public officer to serve, not his superior alone but the community also, with the best

11 Bremner Bariball et al, *Recruitment and Retention of the healthcare workforce in Britain* (European Commission, 2015) https://ec.europa.eu/health//sites/health/files/workforce/docs/2015_healthworkforce_recruitment_retention_frep_en.pdf (last visited Sept 25, 2021).

efforts of his talents and the soberest service of his conscience? How shall such service be made to his commonest interest by contributing abundantly to his sustenance, to his dearest interest by furthering his ambition, and to his highest interest by advancing his honor and establishing his character? And how shall this be done alike for the local part and for the national whole?[12]

In recent history, a similar conundrum about '*nokarshahi*' (administrative service) was voiced with cynicism by Atal Bihari Vajpayee - another postmodern statesman. Vajpayee too intended to supplement bureaucracy with other models, modelled along the lines of 'public choice'; but not to supplant Weber with other models.

Implementation: Top-Down versus Bottom-Up

Implementation of a public healthcare regime is also subject to the preference of one policy over the other. Two options are available (i) top-down, (ii) bottom-up, both of which have advantages and consequences of their own. Arguments against both the top-down model of classical bureaucracy and the bottom-up model of classical self-governance can be advanced. However, these polemics otherwise poles apart can be synergized to arrive at a praxis that is suitable for times of crisis. So far as the World Health Organization's report is concerned, with less than 10 doctors per 10000 people, public healthcare services in India are yet to meet global standards.[13] Whatever public healthcare services exist are limited to urban and peri-urban India. It is somewhat non-existent in rural India. In the absence of top-down services, bottom-up services, like grass root level practitioners- engaged in public healthcare in remote rural and tribal hamlets with traditional healing knowledge- deserve gradual empowerment with state-sponsored capacity-building events since they reach-out to the poorest people of India. In the absence of qualified medical practitioners, traditional medical practitioners ought to be certified while they engage in

12 Woodrow Wilson, *The Study of Administration*, 2(2)POLITICAL SCIENCE QUARTERLY 197-222(1887).

13 After the comparative statistics of the World Health Organization, number of WHO-recommended doctors per 10,000 population in India is 9.28 (2019); one among the lowest after global standards. https://www.who.int/data/gho/data/indicators/indicator-details/GHO/medical-doctors-(per-10-000-population) (last visited Sept. 30, 2021).

sui generis healing practice within rural regions after they have been imparted basic medical training through capsule courses in medical studies by the state-sponsored public health departments.

While top-downers or top bureaucrats exercise control on the structure of implementation in order to achieve the purpose of the legislation, grass root level workers are directly involved with implementation where services are to be delivered to the citizens.[14] In the healthcare regime, policy often appears to be vague and ambiguous; something that is inimical to good governance in healthcare. On the other hand, workers engaged with grass-root level implementation may not necessarily face the brunt of erratic policy formulations:

Traditional top-down models based on the public administration tradition, present an accurate description of the implementation process when policy is clear and conflict is low. … Bottom-up models provide an accurate description of the implementation process when policy is ambiguous and conflict is low. … Under conditions identified as political implementation, where conflict is high and ambiguity is low, the newer top-down models- to emphasize the importance of structuring access and providing resources with a conscious concern for the heavily politicized atmosphere that attends such policies-provide an important starting point. When there is substantial conflict and an ambiguous policy, both models have some relevancy. Microlevel actors dominate the process, but actions are highly political as emphasized by top-down models. One implicit concern underlying this model is that ambiguity should not be seen as a flaw in a policy. … Ambiguity can ease agreement both at the legitimation and the formulation stage. It provides an opportunity to learn new methods, technologies, and goals. … Ambiguity should be viewed neither as evil nor as good. It should be seen as a characteristic of a policy, without imbuing it with any normative value.[15]

Moreover, the possessive zeal of bureaucrats for formulating policies may hit the healthcare regime hard. Accordingly, it is axiomatic, that top political representatives conceive and formulate policy; and leave the administration

14 Guy Peters, Jon Pierre (Eds.), Handbook of Public Policy, (Sage 2006).

15 Richard E. Matland, *Synthesizing the Implementation Literature: The Ambiguity-Conflict Model of Policy Implementation* 5(2)JOURNAL OF PUBLIC ADMINISTRATION RESEARCH AND THEORY 145-174(1995).

and implementation to those in the administrative cadre who drive the policy and deliver services to the people. Consequently, within the administrative hierarchy, mutual disconnect between personnel responsible for formulation and implementation cause damage- to the implementation of the policy. The first disconnect lies in the conceptualization of the policy; which is primarily done by elected representatives who aim to align it with their political manifesto with little or no consultation- with those in the bureaucracy, who are later made responsible for formulating these policies. The second disconnect lies in the formulation of the policy by those in the bureaucracy, who have little understanding of the realities at the grassroots. Therefore, differing attitudes and views of elected representatives, bureaucrats and those engaged in the public healthcare service cadre has posed challenges in the seamless delivery of health service Prudence lies in the participation of all players in all spheres with functional divides in the matter of policy implementation. Although 'separation of policy-making, implementation and decentralization of/in the implementation authority' has been advocated this article pleads for its reversal;[16]and the consolidation of policy-making: taking the political, administrative and service cadres together. Last but not the least, consolidation of the efforts and experiences of personnel at different stages of the bureaucratic and service hierarchy can help bridge the gap in information required for the implementation of the policy regime; more so in healthcare governance where the service cadres engage themselves in life saving service.

Best Practices in Foreign Healthcare Regimes

While India preaches the UN agenda towards Universal Health Coverage (UHC)[17]in pursuance of its express commitment to achieve the objectives on or before 2025,[18]the state of affairs reflect otherwise even during the pandemic.[19] A

16 Sushma Yadav, *Public Policy and Governance in India: The Politics of Implementation*, 71(2) THE INDIAN JOURNAL OF POLITICAL SCIENCE 439-457(2010).

17 The (UN) General Assembly Resolution: *Transforming our world: the 2030 agenda for sustainable development*, A/RES/70/1, (21 October 2015), paragraph 26. https://undocs.org/en/A/RES/70/1 (last visited Oct.4, 2021).

18 National Health Policy (2017),paragraph 2.3.1(B) (The Ministry of Health and Family Welfare, Government of India, New Delhi), https://www.nhp.gov.in/nhpfiles/national_health_policy_2017.pdf(last visited Oct.4, 2021).

19 The availability of health care services provided by the public and private sectors taken together is inadequate; the quality of healthcare services varies considerably in both the public and private

comparative study is hereby drawn to reflect upon the status of public healthcare regimes across the world.

In the United Kingdom, universal public healthcare programme in the form of the National Health Services is run by the state out of the state exchequer.[20] Similar to the United Kingdom, France extends *pro bono* state sponsored health coverage to its people.[21] In Germany, USA, and in the other states of the Organization for Economic Cooperation and Development (OECD), public healthcare regimes nowadays are by and large administered through a combination of public and private enterprise; with each sector's involvement to differing degrees.[22] Among the BRICS states, India falls behind vis-à-vis public healthcare due to its practices; rather than its policy. The Achilles' heel lies in non-implementation of its otherwise worthy regime. For instance, private insurance coverage delivers result in China.[23] The reasoning lies here: (i) people pay premiums on time, (ii) private players pay back medical claims in appropriate cases. In India both parties often fail to fulfil their roles until compelled by the court. A more fundamental challenge lies in the extreme poverty faced by some of the citizens and their consequent inability to get medical insurance coverage. While state-sponsored schemes make an attempt to fulfil the agenda of Universal Health Coverage, want of adequate awareness among the target population deprives them of the benefits.

sector as regulatory standards for public and private hospitals are not adequately defined and, are ineffectively enforced; and the affordability of health care is a serious problem for the vast majority of the population, especially at the tertiary level. Universal Health Coverage https://in.one.un.org/task-teams/universal-health-coverage/(last visited Oct 7, 2021).

20 The United Kingdom provides public healthcare to all permanent residents, about 58 million people. Healthcare coverage is free at the point of need, and is paid for by general taxation. Josh Chang *et al*, The UK Health Care System http://assets.ce.columbia.edu/pdf/actu/actu-uk.pdf (last visited Oct 10,2021).

21 The French health care system was initially organized according to a Bismarckian model of provision and payment for health care. However, it has developed into a mixed Beveridge and Bismarck model, characterized by an almost single public payer, the increasing importance of tax-based revenue for financing health care and strong state intervention. Official document of the French Republic, 2017 https://www.who.int/health-laws/countries/fra-en.pdf(last visited Oct 10, 2021).

22 OECD Indicators, *Health at a Glance* (OECD Publishing, 2019)https://www.oecd-ilibrary.org/docserver/4dd50c09-en.pdf?expires=1628780690&id=id&accname=guest&checksum=0680F1FCC27EC46E244B8FD45F7E57F8 (last visited Oct 10,2021).

23 LAWTON ROBERT BURNS, GORDON G. LIU (ED.), China's Healthcare system and Reform, (Cambridge University Press, 2017).

Conclusion

Out of the five major policy alternatives available for India, the Soviet model is clearly unsuitable. Among the other four, the Weberian model is acceptable; albeit, with the reforms suggested in the article: (i) Nehruvian engineering upon the Weberian model aligned by the Nehruvian ideology of public administration; and (ii) improvement of public infrastructure and personnel to meet the needs of the time. The liberal model of 'public choice' is welcome since the bureaucracy ought to stay alert in a competitive healthcare market. To isolate public enterprise from the healthcare market would render the neoliberal model problematic for the healthcare regime in India. Lastly, the postmodern model has potential of its own for practical implementation considering the objective reality of the circumstances. So far as formulation of policy vis-à-vis implementation of policy is concerned, functional balance between elected representatives and bureaucrats and the grass root level service cadres is suggested for concerted efforts of all stakeholders engaged in healthcare governance.

In populated countries like India, community healthcare deserves priority. However, India's performance has been poor, in community health services as reflected by the official data released;[24] Therefore, in light of the recent pandemic which leaves no sector of the state unscathed, inclusion of basic lessons on public health in primary education, appears to be a non-negotiable need to empower individuals keep good health and recuperate from ill health. Other concomitant factors that affect health such as hunger, malnutrition, and the like- remain outside the purview of this article. However, in the larger context of public healthcare, the public health care regime should incorporate the requirement of maintaining health logistics on priority basis under Article 47 of the Constitution.

24 *National Health Profile* (Central Bureau of Health Intelligence, Ministry of Health and Family Welfare, Government of India 2019),https://www.thehinducentre.com/resources/article29841374.ece/binary/8603321691572511495.pdf (last visited Oct 20,2021).

2

Vaccine Crisis and Patent Rights - Issues and Challenges: A Global Perspective

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Abstract

The recent tussle between the developing and the developed nations has been a focal point of discussion regarding the waiver of patent rights of the COVID19 vaccine. In October 2020, a joint statement was submitted by India and South Africa to the World Trade Organization (WTO). The said statement exempted its member nations from enforcing some patents, trade secrets or any sort of pharmaceutical monopolies on the COVID vaccine under the Trade Related Intellectual Property Rights (TRIPS) Agreement, in order to make vaccines affordable and accessible to the least developing nations and to remove unnecessary regulations. The said joint statement was objected to by several nations like the United Kingdom, Brazil, Germany etc. on grounds of innovation, Intellectual Property Rights, technology and competition. The legal framework of Intellectual Property Rights and TRIPS agreement that are creating challenges for the patent rights waiver are the focus of this article in addition to the issues pertaining to vaccine shortage, patent rights regime and the consequent challenges. The possible impact of patent waiver, if permitted and its implications on the availability of the affordable COVID19 vaccine are also explored.

Keywords: *COVID-19, Vaccine, Patent, TRIPS, Generic Medicine*

Introduction

Due to the outbreak of the Corona Virus pandemic across the globe, not only have human lives been affected, but the world economy has also been disrupted.

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In 2020, when this pandemic spread across the world, it was perceived to be one amongst the deadliest health emergencies ever, forcing several nations including India to impose complete lockdown on the movement of people and restrictions on the functioning of industries and factories, resulting in loss of income and detriment to the economy. The need of the hour was to develop the COVID vaccine as soon as possible to curtail the spread of the pandemic and to protect the health of the people and impact on economy.[1] Although it takes between several months to years to develop an effective vaccine that normally involves a long drawn out manufacturing and control processes, in the wake of the coronavirus pandemic, a few pharmaceutical companies initiated the process of manufacturing of COVID-19 vaccines in a limited span of time.[2] As people were getting infected at an alarmingly high rate and the economy was also badly hit, the availability and use of vaccine became crucial, especially for the least developing nations.[3]

Since its outbreak in December 2019 in Wuhan, China, COVID-19 worsened in May-June 2020, especially in nations like Italy, France, UK etc. which, despite being amongst the most developed nations, were the worst affected.[4]To battle this new crisis and to control its global impact, collaborative efforts among several nations, research institutions, international organizations, private sector units and philanthropic institutions[5]was imperative to develop the COVID 19 vaccine.

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1 Rebecca Weintrau, Prashant Yadav and Seth Berkley, *A COVID-19 Vaccine Will Need Equitable, Global Distribution*, Harvard Business Review, (Apr. 2, 2020) https://hbr.org/2020/04/a-COVID-19-vaccine-will-need-equitable-global-distribution.

2 *Seven Indian Pharmaceutical Companies Race to Develop Vaccine for Deadly Coronavirus*, Healthwoeld.com, The Economic Times, (July 19, 2020) https://health.economictimes.indiatimes.com/news/pharma/seven-indian-pharmaceutical-companies-race-to-develop-vaccine-for-deadly-coronavirus/77051473.

3 *Coronavirus (COVID-19) Vaccines for Developing Countries: An Equal Shot at Recovery, Policy Responses to Coronavirus (COVID-19)*, The Organisation For Economic Co-Operation And Development(Feb. 4, 2021)https://www.oecd.org/coronavirus/policy-responses/coronavirus-COVID-19-vaccines-for-developing-countries-an-equal-shot-at-recovery-6b0771e6/.

4 *Global Economic Effects of COVID-19*, (Congressional Research Service, June 17, 2021) https://fas.org/sgp/crs/row/R46270.pdf.

5 *COVAX Announces Additional Deals to Access Promising COVID-19 Vaccine Candidates; Plans Global Rollout Starting Q1 202*1, (World Health Organization, Dec. 18, 2020) https://www.who.int/news/item/18-12-2020-covax-announces-additional-deals-to-access-promising-COVID-19-vaccine-candidates-plans-global-rollout-starting-q1-2021.

Several pharmaceutical companies have manufactured and rolled out vaccines to fight the novel coronavirus. At the time when vaccines were being rolled out, it was reported[6] that vaccines would not be sufficient for the treatment of all nations across the globe and there arose a need to remove the patent rights on those vaccines. The reports suggested that vaccines are not sufficient even for the richest nations across the globe let alone the poor nations.[7] It is to be noted that in such a scenario the availability of vaccines does not guarantee a beginning of the end of the pandemic. Rather, it signifies a beginning of the wait for the availability of sufficient number of vaccine doses due to shortage of vaccines. Hence, some countries took an initiative to make an application to the World Trade Organization (WTO) for the removal of patent from the COVID-19 vaccine. Subsequently, in October 2020, a joint statement[8] was submitted by India and South Africa to the WTO for exempting the WTO member nations from enforcing such patents, trade secrets or any sort of pharmaceutical monopolies on the COVID-19 vaccine under the agreement on Trade Related Intellectual Property Rights (TRIPS). This exemption was intended to make the vaccine affordable and accessible to the least developing nations and to remove unnecessary regulations once it comes into the open market. Additionally, such a move would help in sharing the formula with the other pharmaceutical companies as well.

But the said joint statement regarding the waiver of patent rights on the COVID-19 vaccine faced opposition from developed nations including the United States (US), European Union (EU), Britain, Norway, Switzerland, Japan, Canada, Australia, and even the developing nation of Brazil.[9] They

6 Karen Walsh, Andrea Wallace, Mathide Pavis, Natalie Olszowy, James Griffin and Naomi Hawkins, *Intellectual Property Rights and Access in Crisis*, 52, THE INTERNATIONAL REVIEW OF INTELLECTUAL PROPERTY AND COMPETITION LAW 379–416 (2021).

7 Oliver J Wouters, Kenneth C Shadlen, Maximilian Salcher, Andrew J Pollard, Heidi J Larsen and YotTeerawattananon, *Challenges in Ensuring Global Access to COVID-19 Vaccines: Production, Affordability, and Deployment*, The Lancet, (Feb. 12, 2021)https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00306-8/fulltext.

8 *Intellectual Property: Protection and Enforcement*, (World Trade Organization),https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Oct. 28, 2021).

9 Asit Ranjan Mishra, *Co-sponsors of Vaccine Patent Waiver to Soon Issue Amended Version of their Proposal*, The Mint, (May 18, 2021) https://www.livemint.com/news/world/cosponsors-of-vaccine-patent-waiver-to-issue-amended-version-of-their-proposal-11621348440555.html.

argued that if WTO granted the waiver, it would allow the member nations to amend their laws enabling their pharmaceutical companies to produce generic versions of COVID-19 vaccines. Although the US gave its approval in May 2021, several developed nations and some developing nations objected to the waiver of patent right.[10] One of the major apprehensions of these developed nations regarding the grant of patent right for COVID-19 vaccine is that due to such an arrangement, their revenue would be adversely affected. In this regard, it is important to note that although every patent holder has a right to protect their patent as its innovative work, when it comes to protection of humanity and well-being of people all over the world some relaxations should be inevitable. Needless to say, that in a pandemic, revenue and profit should not be the primary goals. It is to be noted that the black marketing of medicines and medical equipment, including ventilators, injections, oxygen cylinders and off late even vaccines is rampant.[11]In May 2021, India and South Africa once again made a fresh push[12] to get the vaccine patent free and to make it easily available for several nations.

IP Regime and access to Medicines

The intertwining of corporate capture of global Intellectual Property (IP) regime, state complicity and vaccine imperialism has shaped public health responses to the pandemic. The WTO's agreement on TRIPS is based on the Euro-American model[13] of property and an international legal regime made

10 KirtikaSumeja, US to support India-SA Patent Protection Waiver Proposal for Easy Vax Access, The Economic Times, (May 06, 2021). https://economictimes.indiatimes.com/news/international/world-news/us-announces-support-for-COVID-19-vaccine-patent-waiver-as-proposed-by-india-south-africa/articleshow/82422977.cms?from=mdr.

11 *COVID-19:Law Students write over Key Drugs, Oxygen Black Marketing*, Business Standard, (Apr. 29, 2021) https://www.business-standard.com/article/current-affairs/COVID-19-law-students-write-to-cji-over-key-drugs-oxygen-black-marketing-121042900125_1.html.

12 Rezaul H Laskar, *India, South Africa to Make Fresh Push for Waiver of Vaccine Patents at WTO*, The Hindustan Times, (May 01, 2021) https://www.hindustantimes.com/india-news/india-south-africa-to-make-fresh-push-for-waiver-of-vaccine-patents-at-wto-101619886294125.html.

13 During the negotiation on TRIPS in the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1986-1994, there were intense lobbying from the United States, European Union and other developed countries. Also campaigns of unilateral economic encouragement played a significant role in defeating competing policy positions favoured by developed countries like Brazil, Thailand, India and Caribbean states. Thus, US and other

for the interest of particular classes, nations and regions to underwrite, export and resolve the domestic IP claims. IP rights such as copyrights, trademarks, patents, trade secrets and geographical indications are granted to inventors and creators, thereby protecting brands, inventions, designs, and biological materials. With reference to pharmaceuticals, patents are widely used as a form of IPR for protecting the innovation of medicine. In general, the patents grant a limited right to inventors for their inventions with an exception that the inventor must disclose sufficient information enabling the competitors in making preparation to enter the market. Such legal right protects the patent holder, mostly big multinational corporations, by preventing others from making, using or selling the patent invention.

The TRIPS Agreement has been in force since 1995, through which the Uruguay Round of multilateral trade negotiation provided a minimum of 20 years of patent right with an objective to recover the cost of developing, testing and up-scaling such innovative pharmaceutical material.[14]It is worth noting that certain imbalanced legal rights embodied in the TRIPS agreement have created numerous challenges.

First, the exclusive rights guaranteed to the patent holder[15]results in the creation of a market monopoly wherein the pharmaceutical corporations divide the market as per their standards, between the lifesaving medicines and freely available medicine, thereby resulting in technological barriers. For instance, during 1990 and early 2000, when the HIV/Aids crisis was at its peak, the developing nations were more affected as compared to the developed nations.[16]This was because the patients in developed nations were able to afford Antiretroviral (ARVs) treatment but patients of developing nations especially the Africans struggled for such treatment.[17] Due to such medical crisis, around 2.4

European Countries were the major players in the creating of TRIPS.

14 WORLD TRADE ORGANIZATION, *Overview: The TRIPS Agreement*,https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm(last visited Oct. 28, 2021).

15 Trade Related Aspects of Intellectual Property Rights, 1995, Art. 28.

16 The Joint United Nations Programme on HIV/AIDS, *Report on the Global HIV/AIDS epidemic*(2000), p. 8,https://data.unaids.org/pub/report/2000/2000_gr_en.pdf (last visited Oct. 28, 2021).

17 William W Fisher III and Cyrill P Rigamonti, *The South Africa AIDS Controversy A Case*

million people died of AIDS.[18] Accordingly, the African Government amended its Patent laws by allowing the collateral imports of patented pharmaceuticals and encouraged the use of generic medicines. The US Pharmaceuticals Research and Manufacturers of America (PhRMA) sued the aforesaid amendment as it highlighted the willingness of such pharmaceutical companies to protect their profits even at the cost of human lives but withdrew it later on.[19] It is remarkable to note that in the US, the healthcare sector incurs highest expenditure because of which medicines are sold at an excessive price.[20] The US also has the highest number of drug patents among all nations.[21]

Second, it may be argued that due to the provision of compulsory licensing, competition is further restricted.[22] Keeping in mind the local conditions of several WTO member nations, the compulsory licensing when applied to areas like medicines, diagnostics, health development; results in denial of the early entry of generic products in the market. For instance, in 2013, US granted the use of a drug invented by Gilead Sciences - 'sofosbuvir', for the treatment of hepatitis C, and patent was granted to the company till 2024 for its use in many countries including US and it created a monopoly market which cost $84,000 in the US but in Egypt the same medicine cost $1900 only.[23]

Third, the provision of time-bound protection against the generic use of data by

Study in Patent Law and Policy, Harvard Law School, (Feb. 10, 2005), https://core.ac.uk/download/pdf/33087557.pdf.

18 Rachel L. Swarns, *Drug Makers Drop South Africa Suit Over AIDS Medicine*, The New York Times, (Apr. 20, 2001) https://www.nytimes.com/2001/04/20/world/drug-makers-drop-south-africa-suit-over-aids-medicine.html.

19 Charles L Hooper, *Pharmaceuticals: Economics and Regulation*, (The Library of Economics and Liberty), https://www.econlib.org/library/Enc/PharmaceuticalsEconomicsandRegulation.html(last visited Oct. 28, 2021).

20 Irene Papanicolas, Liana R Woskie and Ashish K Jha, *Health Care Spending in the United States and Other High-Income Countries*, 319(10) JAMA 1024–1039 (2018).

21 Pallavi Arora and Sukanya Thapliyal, *Digital Colonialism and the World Trade Organization*, WORLD APPROACHES TO INTERNATIONAL LAW REVIEW November 2019, https://twailr.com/digital-colonialism-and-the-world-trade-organization (last visited Oct. 28, 2021).

22 Trade Related Aspects of Intellectual Property Rights, 1995,Art. 31.

23 Prasanna S Saligram and Priyam Lizmary Cherian, *COVID -19, The World needs to back India and South Africa's call to remove TRIPS hurdles*, The Caravan, Nov. 16, 2020) https://caravanmagazine.in/health/the-world-needs-to-back-india-and-south-africas-call-to-remove-trips-hurdles-to-COVID-technology.

pharmaceutical companies has further added to the woes.[24]It is to be noted that in order to avail such protection, the regulations mandate undergoing safety and efficacy tests before approval to ensure that they are not harmful. The procedure prescribed for availing the aforesaid protection is long drawn and lengthy which further delays the medicine to reach the common person. Further, such time bound protection once obtained, is misused by the pharmaceutical companies. This is evident from the fact that by making minor changes to the drug, the companies are granted further protection of 20 years. It is obvious that such changes are of no significant advantage to patients and involve minor modification such as change in administration mode, new dosages, extended release or change in colour. Such additional patents on minor changes to existing drugs restrict the entry of competitors. In the cases of US-Jordan Free Trade Agreements (FTA) (2000)[25], US-Australia FTA (2004)[26] and US-Korea FTA (2007)[27], the patent for new forms, uses or methods for the use of existing product was allowed.

In India, the *Novartis*[28]case is the leading case on the matter. In this case, the petitioner applied to secure patent on new and more convenient versions with marginal changes to Gleevec (Cancer drug) to block the entry of generic medicines. The Novartis patent application for Gleevec (Cancer drug) was rejected by the Supreme Court of India due to lack of its novelty. However, it is lamentable that the petitioner had secured its patent on the basis of such marginal changes in other countries such as US and Australia.

In 2015, Martin Shkreli obtained the patent right of an anti-malarial drug and raised the price of the drug by 5000%.[29]Recently, Pfizer did the same to secure an additional patent for the Pristiq drug with identical chemical

24 Trade Related Aspects of Intellectual Property Rights, 1995, Art. 31.

25 United States – Jordan, Free Trade Agreement, 2000, https://ustr.gov/trade-agreements/free-trade-agreements/jordan-fta (last visited Oct. 28, 2021).

26 United States – Australia, Free Trade Agreement, 2004, https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/archives/2004/february/summary-us-australia-free-trade-agreement (last visited Oct. 28, 2021).

27 Unites States – Korea, Free Trade Agreement, 2007, https://ustr.gov/trade-agreements/free-trade-agreements/korus-fta (last visited Oct. 28, 2021).

28 Novartis AG v. Union of India, (2013) 6 SCC 1.

29 Bianca Seidman, *Drug Price increases 5000 percent overnight*, CBS NEWS, (Sept. 22, 2015) https://www.cbsnews.com/news/generic-drug-price-increases-5000-percent-overnight/.

compounds that had no added benefit to the patient.[30] Such cases demonstrate how pharmaceutical companies aim to obtain profits by the use of excessive patenting strategies to force patients to overspend on lifesaving drugs. Such provisions need to be reconsidered by the WTO and approval of a patent waiver is important in this critical situation where every country is fighting to preserve public health and economy.

IP and COVID-19 Vaccine Diplomacy

The role of Intellectual Property (IP) is significant in delivering goods and services when needed in health emergencies. In 2020, during the pandemic outbreak, the shortage of Test Kits, PPE Kits and ventilators was witnessed. Once again, this was because they were distributed based on the principles of 'pay more' instead of who 'needed them the most'.[31] The adopted practice of developed nations of 'beggar-thy-neighbour' also contributed to the failure in curbing the spread of virus globally with more mutations, which made the existing vaccines less effective.[32]

In some reports,[33] it has been observed that the COVID-19 pandemic has a greater impact on nations where people of darker skin tones are residing. For instance, in US, the COVID-19 mortality rate among Americans is highest while in African-American communities it has been found to be 2.3 times higher than the Asians and Latin Americans, and 2.6 higher than the Caucasians. This is also the case in the UK where black and minority ethnic groups are at a higher risk of loss of life and livelihood. In Latin America and the Caribbean, around 70 % of the population has been affected due to the pandemic and shortage of

30 Chidanand Rajghatta, *Pfizer Pledges Drugs and seeks Expedited pathway to make vaccine in India, but silent on Patent waiver*, The Times Of India, (May 4, 2021) https://timesofindia.indiatimes.com/india/pfizer-pledges-drugs-and-seeks-expedited-pathway-to-make-vaccine-in-india-but-silent-on-patent-waiver/articleshow/82373885.cms.

31 Haward Baucher, Phil B. Fontanarosa and Edward H. Livingston, *Conserving Supply of Personal Protective Equipment – A Call for Ideas*, 323(19) JAMA1911(2020).

32 Trade and Development – From Global Pandemic to Prosperity For All (United Nations Conference of Trade and Development, Rep. No. 20, 2020), https://unctad.org/system/files/official-document/tdr2020_en.pdf (last visited Oct. 28, 2021).

33 Maritza Vasquez Reyes, *The Disproportional Impact of COVID-19 on African Americans*, 22(2) HEALTH AND HUMAN RIGHTS 299–307(2020).

income. Also, in India, the poor people who have less income or limited access to healthcare have been affected a lot. Hence, this crisis has further perpetrated racism and structural inequality.

As has been illustrated in the previous section, the exploitation of patent rights has been widespread during the COVID-19 pandemic as well. For instance, a US pharmaceutical manufacturing company, Moderna,[34]that has mass produced a COVID vaccine by a same name, has filed more than 100 patents using the mRNA (Messenger Ribonucleuc Acid) technology. The company has received funds from the US Government (IP partly owned by US National Institutes of Health). Similarly, both Pfizer[35] (US Company) and BioNTech (German Company who has received 450 million dollars from the German Government to speed up IP vaccine and expansion in the country) have filed multiple patents not only for COVID-19 vaccine product but also for the manufacturing process, method of use and related technologies. Even Johnson and Johnson, Regeneron, Novavax, Sanofi and GlaxoSmithKline, AstraZeneca and others have been funded by the US Government.[36] Due to such boost by way of government funding, these pharmaceutical companies fully own the patent and accordingly decide the place of manufacturing and its final price. Here, as is evident, the taxpayers are burdened to pay twice i.e. for the vaccine's development and for the final product. Such instances clearly illustrate that private rights in reality outweigh the public interest by catering to the interest of the corporate giants only.

If this is related to price disparity, it has been observed that less developed nations

34 *FDA To Add Warning About Rare Heart Inflammation to Pfizer, Moderna Vaccines*, The Economic Times, (June 24, 2021). https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/fda-to-add-warning-about-rare-heart-inflammation-to-pfizer-moderna-vaccines/articleshow/83797810.cms.

35 Riley Griffin, Drew Armstrong, Bloomberg, *Germany Funded the Development of Pfizer's COVID Vaccine-Not US's Operation Warp Speed*, Fortune, (Nov. 10, 2020). https://fortune.com/2020/11/09/pfizer-vaccine-funding-warp-speed-germany/.

36 Naoh Higgins-Dunn, Kevin Dunieavy and FraiserKansteiner, *COVID-19 Tracker: Vaccine Latecomer Clover inks COVAX Supply Deal; Sinovac Shot Shows Promise in Kid*s, Fierce Pharma, (November 20, 2021). https://www.fiercepharma.com/pharma/COVID-19-tracker-pfizer-vaccine-data-babies-could-come-by-september-spain-s-reig-jofre-to.

are required to pay more for purchase of the vaccine. For instance, Uganda, is paying USD 8.50 per dose for AstraZeneca whereas EU pays USD 3.50 per dose.[37] Hence, prioritizing monopoly rights in certain western Corporations, due to misuse of IPR norms creates inequities and inequality in the health sector.

The IP law regime also discourages state complicity and vaccine imperialism, which is evident via certain provisions. For example, Article 7 of TRIPS[38] provides the objective of the Agreement as 'protection and enforcement of intellectual property rights, to contribute to the promotion of technological innovation and to the transfer and dissemination of technology'. Even Article 66(2) of TRIPS[39] provides for the responsibility of developed countries to 'provide incentives to enterprises and institutions within their territories to promote and encourage technology transfer to least developed country.'

Possible Impact: Waiver of Vaccine Patent

As has been sufficiently substantiated in the previous section of the study, even in the face of the COVID-19 crisis, the Western pharmaceutical companies have not only declined to share technology with the generic manufacturers but have also obstructed production at large scale through the generic manufacturers by misusing their patent rights. It is disheartening to observe that even in such a global health crisis, the developed countries are blocking the TRIPS waiver proposal put forward before the WTO which has been supported by more than 62 developing countries[40] and many more support it.[41] It is notable that the waiver proposal jointly filed by India and South Africa, proposes only temporary

37 Esther Nakkazi, *Uganda Defends Price Paid for AstraZeneca COVID19 Vaccine; New Study Suggests Vaccine Could Cut Transmission by Two-Thirds*, Health Policy Watch, (Feb. 03, 2021) https://healthpolicy-watch.news/uganda-defends-astrazeneca-price-says-its-not-higher-than-other-countries/.

38 Trade-Related Aspects of Intellectual Property Rights, 1995, Art. 7.

39 *Id. at* Art. 66 (2).

40 Press Trust of India *India, South Africa's patent waiver proposal in WTO achieved tremendous mileage, progression: Commerce Secretary*, The Hindu, (June 10, 2021) https://www.thehindu.com/news/national/india-south-africas-patent-waiver-proposal-in-wto-achieved-tremendous-mileage-progression-commerce-secretary/article34778668.ece.

41 *Members Discuss TRIPS Waiver, LDC Transition Period and Green Tech Role For Small Business*,(World Trade Organization Mar., 11, 2021) https://www.wto.org/english/news_e/news21_e/trip_11mar21_e.htm.

relaxation in provisions of the TRIPS agreement for the purpose of treating, containing and preventing COVID-19 till vaccination is completed all around the world. If such patent right is waived, it will surely upgrade and quicken production and supply of the vaccine across the globe. So, acceptance of the aforesaid proposal will ensure production and supply of vaccines for COVID-19 treatment including therapeutics, diagnostics, and other technologies.[42]

Such kind of waiver is not new. It has been proposed in the past too, by nations like Columbia, India, Thailand and Malaysia, who have revoked the provisions of compulsory licensing for increasing access to cancer medicines.[43] Hence, by opposing the patent waiver for the sake of huge financial profits, such developed nations and their pharmaceutical companies are actually contributing to the aggravation of the situation in the long run by hindering access to a vital tool to combat COVID-19 i.e. the vaccine.

The world is facing another issue of vaccine nationalism, by which rich and developed nations like US, UK etc. are purchasing the global supply of vaccines by way of advance purchase agreement (APA) with pharmaceutical companies for their own citizens at the expense of other countries.[44] But in such a global health crisis, the aforesaid practice of vaccine imperialism needs to be stopped. According to a report by the WHO,[45] high income countries have purchased around 3.8 billion COVID-19 vaccine doses including the US which has kept a significant stock(400 million) of COVID-19 vaccine doses of Pfizer, BioNTech and Moderna vaccines.US has also entered into APAs for around 1 billion vaccine doses with four other pharmaceutical companies. Similarly, the

42 Vikas Dhoot, *What the Easing of IP Norms on COVID Vaccines Means for India*, The Hindu, (May 7, 2021) https://www.thehindu.com/news/national/explained-what-the-easing-of-ip-norms-on-COVID-vaccines-means-for-india/article34499807.ece.

43 Pier DeRoo, *Public Non-Commercial Use' Compulsory Licensing for Pharmaceutical Drugs in Government Health Care Programs*, 32 MICHIGAN JOURNAL OF INTERNATIONAL LAW 348 (2011), https://repository.law.umich.edu/cgi/viewcontent.cgi?article=1054&context=mjil.

44 Abhishek De, *Vaccine Nationalism, and How it Impacts the COVID-19 Fight,* The Indian Express, (Aug., 23, 2020) https://indianexpress.com/article/explained/what-is-vaccine-nationalism-how-does-it-impact-the-fight-against-COVID-19-6561236.

45 Covax Reaches Over 100 Economies, 42 Days After First International Delivery (World Health Organization Apr.,8, 2021), https://www.who.int/news/item/08-04-2021-covax-reaches-over-100-economies-42-days-after-first-international-delivery.

European Union ordered[46]around 2.3 billion and 300 million doses during the negotiation. While the world is grappling due to the shortage of vaccines, such purchases will enable developed countries to vaccinate their own citizens twice while developing regions like Africa and India will suffer. In addition to this, the aforementioned deals are negatively affecting initiatives like COVID-19 Vaccine Global Access Facility[47] which aimed at global distribution of the vaccine.

In the Indian context, it is pertinent to note that the approval of vaccines like Pfizer and Johnson & Johnson is the need of the hour. Although the Indian government had given approval to Moderna[48] vaccine on 29th June 2021 but Pfizer and Johnson & Johnson etc. are still in the waiting list and need to be approved at the earliest. Presently, India has three vaccines Covaxin, Covishield (AstraZeneca) and Sputnik V but due to the shortage in their supply, people are not getting vaccinated at the required pace. In addition to this if the patent waiver is approved by the WTO, it will allow the other pharmaceutical companies to escalate their supply especially in India wherein more than 5000 pharmaceutical companies[49] are present and ready for its generic use.

Concluding Remarks

The COVID-19 pandemic has given a glimpse of the projected intentions and actual actions of the developed countries when they make assertions of extending a helping hand to the developing nations not in the context of the existing health crisis but also in general. It is highly deplorable on the part of developed nations to attempt to not only deny but also capitalise on essential medicines that are needed to protect public health and the economy. As has been elucidated in the previous section of the article, the developed nations

46 *COVID-19 Vaccination in the EU*, (European Commission Jan., 8,2021),https://ec.europa.eu/commission/presscorner/detail/en/qanda_20_2467.

47 *Covax: With a Fast Moving Pandemic, No One is Safe, Unless Everyone is Safe*, World Health Organization https://www.who.int/initiatives/act-accelerator/covax(last visited Nov. 04, 2021).

48 Aparna Banerjee, *Moderna's COVID vaccine becomes 4th jab to get emergency use approval in India: Govt*, LIVE MINT, (June 29, 2021) https://www.livemint.com/news/india/moderna-becomes-4th-COVID-vaccine-to-get-emergency-use-approval-in-india-govt-11624964397005.html.

49 Melissa Cyril, *India's Pharmaceutical Industry – Foreign Investment Opportunities, Incentives*, INDIA BRIEFING, (Apr. 13, 2021) https://www.india-briefing.com/news/indias-pharmaceutical-industry-investment-trends-opportunities-incentives-18300.html/.

especially the US and the EU through their pharmaceutical companies have focused on generating their own revenue/profit even in the face of such grave health crisis that the world is trying to cope with.

In this article, it has been clearly established that a number of nations, and even the world at large is suffering from a shortage of vaccines. The same is attributable to various factors viz, hoarding of vaccines by some developed nations, the existing imbalances in the legal rights regarding patents that are embodied in TRIPS such as monopoly rights and compulsory licensing, and the nonchalant attitude of the nations in supporting the waiver of patent rights over the vaccines and the non-approval of the said waiver by the WTO.

As is evident, the developed nations through their pharmaceutical companies have tried to capitalise on the vaccines in a bid to ensure maximum profits by making the vaccines available at a premium price, by giving preference to developed nations, contributing to the shortage of supply of the vaccine and giving unreasonable objections regarding the patent waiver. Even though the TRIPS agreement provides protection to the patent holder from third party infringement, relaxation in such norms is indispensable to ensure wide reach of the vaccine. It is not just about the basic right to life but also about the need to understand that the COVID-19 pandemic is a rare health emergency where human life and the economy of several nations are at risk. If a country like US (earlier objecting) is now favouring the patent waiver (due to factors like the death of its own population and the blow to its economy), it is only prudent for other countries like UK, Australia, Brazil etc. to follow suit.

Hence, there is a need to relax certain legal provisions in the TRIPS agreement for temporarily for dealing with the COVID-19 pandemic, including relaxation in the norms of compulsory licensing, restriction of monopolistic policies in IP laws and removal of other diagnostic and technological barriers in the production and supply of vaccines. A consensual and unified approach of the WTO member nations is indispensable to tackle the issues at hand. The flawed IPR regime along with the profit-driven approach adopted by developed countries needs to be refurbished and the present pandemic provides a suitable

opportunity to do so. The denial and incentivisation of the vaccine for private profits of the corporate giants highlights contemporary capitalism at its peak and substantiates the assertion that preservation of human life is outweighed by maximisation of profits and expansion of developed economies.

It must be asserted that sharing of knowledge and technology is the way forward for escalating the production and supply of vaccines. Measures such as harmonisation of regulatory processes, relaxation in the IPR regime, establishing a proper supply chain infomediary and ensuring expansion of vaccine manufacturing; can prove to be significant in dealing effectively with the existing crisis. It should be remembered that extraordinary circumstances require extraordinary measures.

3

Implementation of Transport Policies in Newtown Kolkata can Avert A Public Health Crisis

Monalisa Saha[*]

Abstract

A public health crisis can emerge slowly over a long period and is not always a consequence of a sudden disaster or the outbreak of a virus. The burden of diseases due to non-communicable diseases has been on the rise over the last few decades. Amongst many other factors, vehicular-induced air pollution has been of particular concern to India. Reliance on internal combustion engine vehicles (ICEV) has meant that nearly 30 percent of lives that India annually loses are due to the breathing in of toxic air. The government has brought about many transport policies since 2012 to avert such public health crises and improve the transport system on various other parameters. The author in this article has attempted to assess whether these policies are adequate to reduce carbon emissions and reduce the burden of such non-communicable diseases in the country. In furtherance of this objective, the author has specifically explored how Newtown, in Kolkata (West Bengal) has fared in trying to achieve sustainable urban mobility, especially as part of the Smart City Mission of 2015.

Keywords: *internal combustion engine vehicles, toxic air, Newtown, Kolkata, health crisis, burden of diseases*

Introduction

Before delving into the nuances of "public health emergency," it is important to understand the meaning of public health. The definition of health has undergone a paradigm shift over the last few decades. Previously, public health concerns were limited to curing populations of various diseases like

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tuberculosis and malaria. But today the discourse on public health has widened in scope to include not only this but also in promoting health. The impact that demographical transition to environment changes can have on the health of humans is being recognised and scientists, policy manners, planners, and academicians are all trying to devise ways in which we can recognise, and tackle various kinds of communicable and non-communicable health ailments caused by such factors[1]. But it is not easy to understand what good public health entails either. The Indian Academy of Public Health defines "Public Health" as the science of "promoting health, preventing diseases, prolonging the life of the mass qualitatively."[2]

Emergency implies a situation that requires immediate attention which if not handled would in all probability lead to irreversible and grave consequences. But society in general tends to associate health emergencies with only those that are caused by sudden disasters or those that are caused due to highly virulent microorganisms. It appears that conditions which emerge over time and do not have immediate impact are not prioritised by the government and other relevant stakeholders. For instance, even though it is well known that older commercial vehicles like buses and yellow taxis plying on Kolkata roads emit toxic fumes, they have not been successfully phased out even as of 2021.[3]

Various factors contribute to the presence of toxic gases in the air that is known to cause a variety of respiratory (e.g., asthma[4]) and cardiovascular diseases amongst humans. Apart from the generation of electricity, the other most prominent contributor to air pollution is the tailpipe emissions from fossil fuel-based transport modes.[5] The operation of fossil fuel-based transport

1 Subitha Lakshminarayan, *Role of Government in Public Health: Current Scenario in India and future scope*, 18 JOURNAL OF FAMILY & COMMUNITY MEDICINE 26 (2011).

2 FU Ahmed, *Defining Public Health*, 55 INDIAN JOURNAL OF PUBLIC HEALTH 241 (2011).

3 Krishnendu Bandhyopadhyay, *2 Lakh banned old vehicles still ply in Kolkata, turning air quality toxic*, The Times Of India (July, 17, 2019) https://timesofindia.indiatimes.com/city/kolkata/2l-banned-old-vehicles-still-ply-in-city-turning-air-quality-toxic/articleshow/70252759.cms.

4 Greenpeace India, *Air Pollution from fossil fuels costs India Rs. 10.7 lakh crore annually,reveals a new report,* greenpeace, (Feb, 12, 2020) https://www.greenpeace.org/india/en/press/4683/air-pollution-from-fossil-fuels-costs-india-us150-billion-annually-reveals-a-new-report/.

5 The National Electric Mobility Mission Plan 2020 (Ministry of Heavy Industries &Public

releases a variety of toxic gases into the atmosphere. The most worrisome of these include carbon dioxide, sulphur dioxide, nitrous oxides and particulate matters of various sizes (primarily $PM_{2.5}$ and PM_{10}).[6] The Air Quality Index (AQI) in many prominent Indian cities[7] (Delhi, Mumbai, Kolkata) and towns has been beyond the safe threshold for a prolonged period of time. In fact, the World Health Organisation (WHO) Report states that 14 Indian cities feature in the list of the most congested cities of the world.[8] Apart from reduced quality of life due to various diseases, air pollution-induced deaths claim nearly 30 percent of lives annually in India.[9]

The effect of such fossil fuel vehicular based emission is a grave concern in today's ever urbanising India because the population is also increasing significantly each year. By 2030, around 40 per cent of India's population is predicted to reside in cities.[10] Further, the vehicular population has also been on a consistent rise. The number of registered vehicles in the fiscal year 2019 was pegged at 295.8 million.[11] All these vehicles contribute approximately 142 million tonnes of CO_2 annually into the atmosphere. Of the various modes of transportation, it appears that CO_2 emissions from road-based transportation are the highest, with emission of 123 million tonnes of CO_2.[12] Therefore, rethinking the fossil fuel-based transport sector has been on the priority list of Indian policy makers over the years.

Enterprises, Government of India), 23.

6 Emissions of air pollutants from transport, (European Environment Agency) https://www.eea.europa.eu/data-and-maps/indicators/transport-emissions-of-air-pollutants-8/transport-emissions-of-air-pollutants-8 (last visited Nov. 7, 2021).

7 Krishnendu Bandhopadhyay, *Bengal after UP, Bihar in fossil fuel linked deaths*, Times Of India, (Feb.11, 2021) https://timesofindia.indiatimes.com/city/kolkata/bengal-after-up-bihar-in-fossil-fuel-linked-deaths/articleshow/80797967.cms.

8 *Transforming India's Mobility. A Perspective*, (NITI Aayog, Sep., 7 2018),http://niti.gov.in/writereaddata/files/document_publication/BCG.pdf.

9 Mohana Basu, *Air Pollution from fossil fuels causes over 30% deaths in India every year: Harvard Study*, The Print, (Feb10, 2021), https://theprint.in/science/air-pollution-from-fossil-fuels-causes-over-30-deaths-in-india-every-year-harvard-study/601757/.

10 The Smart Cities Mission Guidelines; Mission Statement and Guidelines (Ministry of Urban Development Government of India, 2015), p. 5.

11 *Number of vehicles in Operation across India from financial year 1951 to 2019*, Statista, (Jul, 29, 2021) https://www.statista.com/statistics/664729/total-number-of-vehicles-india/.

12 Ramanath Jha, *Preparing Indian Cities for a Shift to E-Mobility*, Observer Research Foundation, (Apr., 12, 2021) https://www.orfonline.org/research/preparing-indian-cities-shift-emobility/.

Transport Policies to tackle vehicular based air pollution

Previously, the government paid attention to the transport sector purely from an economic viewpoint. The transport sector in India contributes significantly to the Gross Domestic Product and in 2017 it had contributed around 7.1% to the GDP.[13] So, when the First Automotive Mission Plan for the period 2006-2016 was launched[14] in 2005, it did not in any way tackle vehicular induced air pollution. The focus on the 2006-2016 Plan was exclusively on developing India as the most desirable destination in the world for the design and manufacture of automobiles and automotive components.[15] The focus of this plan was to increase the transport sector's contribution to the GDP and infuse employment opportunities for 25 million people in the entire value chain.[16]

It was not until 2012 when, the harmful effects of air pollution resulting from fossil fuel-based vehicles were recognized by the Indian government and concrete initiatives started being introduced. In 2012, the National Electric Mobility Mission Plan (NEMMP) was introduced.[17] This plan as formulated by the Department of Heavy Industry (Ministry of Heavy Industries & Public Enterprises, Government of India)[18] focused on creating India as a manufacturing hub for all types of electric or xEV[19] vehicles (two-wheeler and four-wheeler). It was also hoped that India would adopt such electric vehicles for its own use and cut down on its reliance on fossil fuel-based vehicles.[20] However, penetration of electric vehicles in India still remained low because of the high rate of Good and Service Tax (GST) imposed on all EVs. Though the

13 *India's EV Story, Emerging Opportunities*, (Innovation Norway Report, 2017) https://www.innovasjonnorge.no/contentassets/815ebd0568d4490aa91d0b2d5505abe4/india-ev-story.pdf, (last visitedNov. 07, 2021).

14 *Id.*

15 *Supra* note 5.

16 *Id*.

17 Jha, *supra* note 12.

18 S*upra* note 5.

19 Includes the range of electric vehicles available (BEVs, P-HEVs, Full/Mild Hybrid vehicles etc)

20 *Supra* note 6, at 2.

GST imposed on EV at 12% was still lower than the 28% that was imposed on fossil fuel-based vehicle, the problem was that the tax (GST) imposed on the batteries (both lead-acid batteries and lithium-ion batteries) continued to be as high as 18%.[21] Along with this the lack of infrastructure in terms of insufficient charging stations[22] and the long period of time required[23]to recharge an electric vehicle proved to be additional hindrances towards adoption of electric vehicles as against its fuel-based counterpart.

In 2015, two relevant schemes were introduced: Smart Cities Mission and Faster Adoption of Electric Vehicles in India (FAME-1). The focus of the Smart Cities Mission was on identifying and providing opportunities to 100 cities to become infrastructurally sound and environmentally sustainable on various aspects, including but not limited to waste management, water supply, electricity, safety and education and urban mobility.[24] This is a centrally sponsored scheme which requires equal participation of States and various urban local bodies. The financial support extended per city was Rs. 100 crores per year, and the total amount allocated for the entire mission was Rs. 48,000 crores for a 5-year period.[25]While the focus of FAME-1 was exclusively on promoting electric vehicles, the government sought to incentivize production and use of electric vehicles. There were four sub-parts under which FAME-1 was operationalized included: (i) Demand Creation, (ii) Technology Platform, (iii) Pilot Project and (iv) Charging Infrastructure which was allocated a total fund of Rs 795 crore.[26] FAME-1 continued to be extended till 2019.[27] But when an evaluation of the implementation of FAME-1 was done, it was found to be unsatisfactory.

21 Kritti Bhalla, *Electric Vehicles at Union Budget, 2021: EV Makers Seek lower GST, Import Duty Cut & More*, INC42, January, 28, 2021 https://inc42.com/infocus/electric-vehicles-this-week/electric-vehicles-at-union-budget-2021-ev-makers-seek-lower-gst-import-duty-cut-more/

22 *Id.*

23 *Id.*

24 Govt. of India*, supra* note 10, at 5.

25 *Id.*

26 Notification, S.O. 830 (E) dated 13th March 2015.

27 Ministry of Heavy Industries and Public Enterprises (Department of Heavy Industry) Notification, 08.03. 2019, S.O 1300 (E).

Although FAME-1 had achieved a reduction in fuel consumption and the various harmful vehicular emission, it had failed to achieve the set targets.[28] When FAME-II was notified in 2019, the intention was to catch up on all that was missed in FAME-1 and introduce other changes. A total of Rs. 10,000 crores were allocated to ensure: a) demand incentives; b) establishment of charging stations and; c) administration of scheme including Publicity, IEC (Information, Education & Communication) activities.[29] In June 2021, a few modifications were further made to FAME II in terms of the subsidy allocated for electric two wheelers, electric three wheelers and electric buses. Increasing the aggregate demand has been the focus of this modification.[30]

In 2018, NITI Aayog had undertaken a study of the transport policies in various countries and subsequently came up with a recommendation to transform India's mobility.[31] This was probably the first time that the transport policy looked beyond GDP and sustainability and focused on inclusiveness and the need to also decongest our roads. This report focussed on three objectives labelled as "the 3Cs": Clean, Convenient and Congestion-free. The report highlighted the need to create mobility that includes the elderly and disabled. It emphasised the need to build safe infrastructure for non-motorized transport and the need to use renewable energy to fuel our motorized transport modes.

Newtown Kolkata and Urban Mobility

Kolkata is unique in terms of transportation. It gradually transitioned from being one of the first cities to run the tram, electricity driven mode of public transport to becoming a city that suddenly became dependent on fossil fuel-based mode of public transport like buses, auto rickshaws and cars. Tramlines exist in only a few parts of the city and trams ply at the speed of 35km/hr,

28 Press Information Bureau, *FAME India Scheme*", PIB, Jul., 09 2019, https://pib.gov.in/PressReleasePage.aspx?PRID=1577880.

29 *Supra* note 27.

30 *FAME-II scheme revised to deliver new boost for electric two wheelers, buses and more*, Times Now, (Jun, 12, 2021) https://www.timesnownews.com/auto/features/article/fame-ii-scheme-revised-to-deliver-new-boost-for-electric-two-wheelers-buses-and-more/769681.

31 *Supra* note 8.

significantly slower than the motorized modes of transport.[32] Therefore, its use waned in comparison to other motorized forms of transportation that quickly overtook the public transport system of the city. As on date, Kolkata is the 20th most polluted city in the world.[33]Further, the particulate emission from transportation in Kolkata, takes it to the seventh rank among the top ten megacities in the world, and to the third position among the Indian urban cities.[34]

Since 25%[35] of all vehicles in operation in West Bengal are in Kolkata, studying the transport changes in and around the city was considered desirable to understand the implementation of various transport schemes. Further since, Newtown Kolkata secured a much-coveted position in the list of 100 cities that have received funds and other technical and advisory support under the Smart Cities Mission, the author decided to delve deeper into understanding how the efforts towards urban mobility also integrated with the objectives of the other transport schemes in operation in the entire country. Although most of the schemes in operation in India have seemingly focused on shifting the focus away from fossil fuels, it appears that some elements of the NITI Aayog's 2018 recommendations is on track to being implemented by Newtown Kolkata, through its concentrated efforts at building infrastructure to support non-motorized transport and motorized electric transport.

Non-Motorized Transport

Transportation can be sub-categorised based on many parameters. One such criterion is whether the mode of transportation is mechanized or not. In this

32 *Kolkata's famous tram gets a makeover*, The Economic Times, (May 29, 2019) https://economictimes.indiatimes.com/industry/transportation/railways/kolkatas-famous-tram-gets-a-makeover/on-the-right-track/slideshow/69560011.cms (check link).

33 *India- Transition to Electric Vehicles Puts Kolkata on the Road to clean Transport*, (The World Bank, Brief, Report No. 155533,2021) https://documents.worldbank.org/en/publication/documents-reports/documentdetail/479341609914443074/india-transition-to-electric-vehicles-puts-kolkata-on-the-road-to-clean-transport(last visited Nov. 08,2021).

34 *Implementation Plan for Electrification of Public Transportation in Kolkata*, India Smart Grid Forum, (Oct., 11 2017), https://indiasmartgrid.org/reports/Report_Implementation_Plan_for_Electrification_of_Public_Transport_in_Kolkata_1_November_2017.pdf.

35 Ankush Sharma et al, *Impact of Plug-in Electric Vehicles on Power Distribution System of Major Cities of India: A Case Study*, (IIT Kanpur, 2019), https://home.iitk.ac.in/~ansharma/EV_Report_V1.pdf (last visited Nov. 08, 2021).

section, emphasis will be laid on understanding non-motorized modes of transport in operation in Newtown Kolkata. Rental cycle (E.g. PBS Cycles[36]) have been made available by the Newtown Kolkata Development Authority and efforts are underway to build cycle lanes, cycle sheds, dedicated cycle signage/signals and pedestrian walkways that integrate with various public transportation modes. Most people do not choose cycle as a means of transportation, primarily because it is unsafe to ride in the same lane as fast-moving motorized vehicles and because there is no safe space to dock the cycle when one has reached one's destination. To address this problem,the Urban Development and Municipal Affairs Department of West Bengal has developed many cycle-stands. In fact, a fund of Rs. 5 crores has been allocated towards building cycle stands.[37] Smart cycle stands having amenities such as 24*7 CCTV surveillance, LED displays for public messaging and mobile charging points etc.,[38]are to be set up at the Action Areas that fall within the jurisdiction of the Newtown Kolkata Development Authority.[39] Rs. 3.15 crore has been allocated to design, procure, install, operate and maintain public bicycle sharing system and Rs. 0.62 crores has been allocated for the construction of graded cycle tracks, cycle sheds, signal and signage.[40] Rs. 0.16 crores has also been earmarked to install solar stud light and road stud for safe cycling.[41] Regular cycling events are held to increase awareness[42] about the benefits of using cycles for one's health and the environment. Most of the pedestrian walkways in Kolkata are either non-existent or encroached, such that it almost acts as a disincentive to walk. Newtown Kolkata has however spent a substantial amount of money to create unencumbered[43]pathways. Over Rs. 61 crores have been allocated to

36 Newtown Green City, *Cycle 4 Change*, (Handlebar Survey carried out by NKGSCCL, 2020), https://www.newtowngreencity.in/wp-content/uploads/2021/03/Documentation-on-New-Towns-Cycle-4-Change_October-2020.pdf (last visited Nov. 08 , 2021).

37 *Pan City Projects*, (Green Smart City Corporation Ltd, Pan City Projects) https://www.newtowngreencity.in/pan-projects/ (last visitedNov. 08 , 2021)

38 *Supra* note 36.

39 *Construction of Smart Cycle Stand adjacent to DLF subway, AA-IA, New Town, Kolkata*, (Newtown Green City initiatives), https://www.newtowngreencity.in/wp-content/uploads/2020/02/Smart-Cycle-Stand_31012020.pdf (last visited Nov. 09, 2021)

40 *Supra* note 37.

41 *Id.*

42 *Supra* note 36.

43 *Success Story: Construction of 14.5 km of smart barrier-free pedestrian walkway and cycling track*

the development of pedestrian pathways.[44] The work involves construction of a 14.5-kilometre barrier-free pedestrian way, on the Major Arterial Road in New Town's Action Area 1.[45]

Motorized Transport

Electrification of vehicles has been a major concern and efforts have been taken towards building a supportive infrastructure to increase the purchase and use of both commercial and personal electric vehicles. Newtown has electric vehicle charging points at 11 locations. There are three types of charging stations in operation: 1-hr charging points; 5- hr charging points and a heavy-duty charging station for electric vehicles. There are 10 other 5-hr charging stations where four and two wheeled e-vehicles can be charged at Rs. 20 and Rs.10 respectively. These charging stations[46]are placed at strategic locations so that people can wait in a comfortable place, while waiting for their vehicles to get recharged. Furthermore, there are 3 heavy-duty charging stations for charging electric buses which are located at bus terminals.[47] In 2020, Lithium Urban Technologies started a collaboration with West Bengal Housing Infrastructure Development Corporation to set up 25 charging stations in Newtown. The intention is to convert corporate diesel-based transport to electric vehicles and to try and abate annual carbon emissions to the tune of 10,000 MT.[48]

Since the cost of electric vehicles due to the imposition of various taxes continues to be high, the purchase of electric vehicles remains low even till today. To address this, State-owned Energy Efficiency Services Ltd (EESL) has given a proposal to the government of West Bengal as of 2019 to supply electric sedans

in New Town Kolkata, (Newtown Green City initiatives), https://www.newtowngreencity.in/wp-content/uploads/2020/01/PEDESTRIAN.pdf (last visited: Nov. 09, 2021).

44 *Supra* note 36.

45 *Supra* note 43.

46 Soumitra Nandi, *New Town gets the fastest e-vehicle charging station in Bengal*, Millenium Post, (March, 18, 2019), *Charging stations are available at (Rabindra Tirtha, Tata Medical Centre, Nazrul Tirtha, Gates 1/4/6 of Eco Park, Café Ekante, Axis Mall, Eco Urban Village and Central Mall,*http://www.millenniumpost.in/kolkata/new-town-gets-the-fastest-e-vehicle-charging-station-in-bengal-345312?infinitescroll=1.

47 *Id.*

48 Krishnendu Bandyopadhyay & Suman Chakraborti ,*25 EV Charging Stations launched*, Times Of India, (Sep, 17, 2020), https://timesofindia.indiatimes.com/city/kolkata/25-ev-charging-stations-launched/articleshow/78154974.cms.

on lease. There are two models that have been proposed: Rs. 22,500 a month (for 6 years) for "dry lease"; and "driver's lease" for Rs. 37,000 a month[49] to ensure that electric vehicles are purchased and used. There are over 1000 toto e-vehicles operating in Newtown,[50] and over 100 electric buses put in operation by the West Bengal Transport Corporation (WBTC)[51]. The government has expressed its intention to take this number up to 5,000 by the year 2030.[52]

These new versions of electric modes of transport have been well received by the people perhaps not because it helps in reducing carbon emissions or steers us clear of our over-dependence on imported crude oil, but because Newtown, Kolkata has tried to make public electric vehicle transport system more attractive to the public. When public motorized transport is scarce or of poor quality, people are forced to choose private motorized transport for their various commuting needs. Towards this objective the electric buses that have been introduced are fitted with a host of amenities like Intelligent Transport System (ITS), Air Conditioning and Wi-Fi entertainment in order to make the passenger's travel worth their while with the hope that this enhanced experience will steer them away from private motorized transportation.

The other major problem with the use of public transportation is the huge amount of time one spends at bus stands with the uncertainty of the availability of the next bus towards a certain destination. The Real Time Passenger Information Display System to be introduced in Newtown is intended to reduce wait time for passengers, so that passengers feel more confident, independent and in control of their movement and time.[53]There are other amenities that Newtown, Kolkata has adopted to transform urban mobility. It has allocated Rs. 0.2 crore towards Intelligent traffic and parking management system. The

49 Press Trust of India, *EESL plans to set up EV charging stations in Kolkata*, *New Town*, Business Standard, (Sep. 3, 2019), https://www.business-standard.com/article/pti-stories/eesl-plans-to-set-up-ev-charging-stations-in-kolkata-new-town-119090301193_1.html.

50 *Case Study: E-Mobility including Last Mile Connectivity in New Town*, (New Town Green City case studies), https://www.newtowngreencity.in/wp-content/uploads/2019/09/CASESTUDY5.pdf (last visited Nov. 10, 2021).

51 *Kolkata Beats London with its Electric Vehicle Adoption*, Outlook India, (Mar., 9, 2021) https://www.outlookindia.com/outlooktraveller/travelnews/story/71275/kolkata-wins-the-electric-vehicle-race-against-london.

52 *Id.*

53 *Supra* note 37.

intention is to create a system of fastag-based vehicle parking solution to save time. Smart Bus shelters have been already created and many more would be created with the Rs. 0.24 crore fund that has been allocated for the same.[54]

Conclusion

The situation in Kolkata's transportation seemingly appears to be paradoxical. Even with 80-85% of access and use of shared public transportation, it has recorded the highest amount of particulate matter and nitrous oxide emissions per 0.1 million of vehicular population.[55] In fact, Kolkata has the widest variety of public transport modes, comprising ferries, trains, trams, sub-urban metro rails and various other road transport modes like auto-rickshaws, buses etc. But the problem is that even though Kolkata in comparison to other cities has fewer vehicles plying on its roadways, most of the buses in operation continue to belong to the old fleet of diesel-based vehicles. Around 1500 of the buses in operation in Kolkata comply with Euro-III & IV emission standards, while a meagre 38 comply with Euro- II emission standard. With the recent introduction of 100 electric buses plying across the city and the 1000 electric totos operating in Newtown, Kolkata there appears to be a very real possibility of reduction in PM and NOx emissions and in cutting down annual CO_2 emissions by at least 3,094 tonnes.[56]

However, the long-term solution towards carbon emission cannot be achieved solely by reliance on electrification of vehicles. Most efforts of the government in terms of the 2012 National Electric Mobility Mission Plan, FAME-I and FAME-II scheme were to provide incentives to electric vehicle manufacturers. Until the Smart Cities Mission in 2015 and the recommendation on transportation put forward by NITI Aayog in 2018, the focus on encouraging use of non-motorized transport modes like cycling and walking was limited. Though Newtown was selected in the Smart City Mission Programme in 2016, it was not until 2018 when the Special Purpose Vehicle (SPV) called the New

54 *Id.*

55 Alekhya Datta et al, *Integrating electric buses in public transport: Kolkata's success story*, TERI, (Jun 16, 2020) https://www.teriin.org/casestudies/integrating-electric-buses-public-transport-kolkatas-success-story.

56 *Id.*

Town Kolkata Green Smart City Corporation Limited[57] was established to implement the objectives of the Mission. In the last few years, it is true that Newtown, Kolkata has already built certain supportive infrastructure for cyclists and walkers, but a lot remains to be implemented even today. Large parts of fund allocation towards resources is yet to be utilized and even though many parts of the city have built cycling tracks and pedestrian walkways, there is a lack of a seamless network of the same. Additionally, the lack of safe cycle docking space and presence of truncated roads makes cycling or walking undesirable. Building exclusive signage for cyclists, presence of washrooms, and demarcated lanes for cyclists at major crossings would further incentivize the use of non-motorized transportation.

Even with the electrification endeavour, it appears that Newtown has to set up more charging stations and try to find a solution to curtail the long waiting period that is presently proving to be a disincentive to a driver. A wait between one to five hours to recharge one's vehicle would continue to make the 5 minutes wait at the fossil-fuel refilling stations seem more attractive. Other concerns that also require attention are ensuring uninterrupted power supply and exploring ways in which such power itself can draw from green energy sources like solar panels.

Therefore, to conclude, it appears that India and especially Newtown, Kolkata has been taking significant interest in revamping its transport system to curb vehicular pollution, which is a major factor for various health conditions and deaths in the country. The various transport policies however focus on goals apart from decarbonization. It is geared towards electrification of all motorized modes of transportation by which it hopes to reduce our dependence on crude oil imports and achieve fuel security/independence. However, a public health crisis cannot be averted if we do not make modifications as a priority and also simultaneously focus on creating supportive infrastructure for various kinds of non-motorized transportation. We need to devise mechanisms to encourage the populace to embrace non-motorized transport modes and forsake the private motorized transport modes for shared/mass motorized transport alternatives.

57 New Town Green City, *Newtown Kolkata Green Smart City Corporation Limited*, https://www.newtowngreencity.in/about-nkgsccl-2/ (last visited Nov. 10,2021).

4

Health Related Information, its Benefits and Legal Ramifications on Doctor-Patient Relationship

*Manjunath M. S.**

Abstract

Over a period of time, doctor-patient relationship has changed from being paternalistic to a patient-centered one. The foundation of this kind of relationship is based on shared decision making from both the parties (patient and the doctor). Nowadays, the main source of shared information lies in the aspect of online health information. This has been possible primarily due to the progression of digitalization and the introduction of internet at a global level. This article reviews the implications of the spread and reach of online health information that has been instrumental in achieving optimal patient-centered care. Along with this, the advantages, and its associated challenges in implementation of such kind of e-health concept is also discussed in context of the changing nature of the doctor-patient relationship with respect to legal and medical aspects. It was realized that even though the amount of information pertaining to health is a choice of source for the information seekers, however, the accuracy of the data is not validated. This is the major challenge involved in online information especially in the domain of health. Among the various solutions lies the need of strengthening the existing legal framework. This may lead to increased patient satisfaction, which can revamp the doctor-patient relationship, open treatment options due to the universality of online health information and reduce the chances of medical errors and litigations.

Keywords: *doctor-patient relationship, e-health, online health information, internet, patient empowerment, patient-centered care, Information Technology Act (2000), Telemedicine Practice Guidelines (2020).*

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Introduction

It is a well-established fact that the doctor-patient relationship forms the foundation stone for any successful medical practice.[1]It has been pointed out that the success of this relationship primarily relies on the quality of interaction between the patient and the doctor along with the knowledge or skills of the consulting doctors as a certain set of expectations get formed from the moment the patient meets their doctors. Over the years, the doctor-patient relationship has undergone an evolutionary change.[2]There has been a wholesome transition in the core concepts of this relationship, which has changed from a dominating (paternalistic) attitude of the doctors to an egalitarian behaviour, where equal power is distributed between the patients and the doctors.[3] In recent times, this has further changed towards patient centeredness. These changes have occurred as a result of increased cases of mismatch in the expectations of the patients. This can possibly occur due to multiple reasons, which include decrease in the availability of doctors for a higher number of patients, expectation of a complete cure once the condition has been diagnosed by the patients, etc. Moreover, doctors tend to examine patients rather quickly due to time constraints and work pressure, causing increased patient dissatisfaction. Discontent in patients also occurs when doctors do not disclose full information about the patients. This can be avoided by providing adequate and compulsory information to the patients. Earlier, it was a common practice to withhold any information regarding the illness and treatment so as to maintain the peace of mind of patients ahead of the treatment. However, it has been observed that this lack of information from the doctor may cause the patients to doubt the capabilities of the doctor in current times. Moreover, this information also makes the patients more knowledgeable and aware of their rights, which is useful to avoid the harms of commercialization in the medical field.[4]

1 Ganesh, K, *Patient-doctor Relationship: Changing Perspectives and Medical Litigation,* 25(3) INDIAN JOURNAL OF UROLOGY 356 (2009).

2 R. Kaba, P.Sooriakumaran, *The Evolution of the Doctor-Patient Relationship,* 5 INTERNATIONAL JOURNAL OF SURGERY 57 (2007).

3 Vijaykumar Harbishettar et al., *The Enigma of Doctor-Patient Relationship,* 61 INDIAN JOURNAL OF PSYCHIATRY 776 (2019).

4 Sourabh Paul & Vikas Bhatia, *Doctor Patient Relationship: Changing Scenario in India,* 7 ASIAN

Although adequate communication with patients seems to decrease the fear of malpractice, however, in case of uncertainty with regard to any medical condition, this acts as an exception and jeopardizes the position of the doctor. This indicates deterioration of the patient-doctor relationship.[5] Thus, it can be observed that there has been a drastic shift in the decision-making process with respect to the medical aspects. Any level of decision making was previously a core responsibility of the doctor, but is now dependent upon the shared 'information' framework available to the patients and doctors, also making the patients active participants in the medical decision making process.[6] On the contrary, doctors are considered to be the most 'reliable source' of health related information.[7] However, there has been a drastic shift in this area over the last few years and health information has now become more readily available due to the advent of digitalization and the 'rapid diffusion of internet' in the recent years.[8] This digitally acquired information related to health has been labelled as 'e-health'.[9] Nowadays, it is mostly referred to as online health and covers the application of 'digital technologies for health care'. This augments the effectiveness of the medical treatment and helps in more accurate and personalized medical actions. Additionally, this type of information has become increasingly easier to access with time and has revolutionized the understanding of medical issues among patients as well as doctors.

However, this free flow of information has its own 'flip side' and therefore its reliability has become a matter of serious concern.[10] Thus, a careful evaluation of this information seems to be the need of the hour. This has been highly

JOURNAL OF MEDICAL SCIENCES 1 (2019).

5 Shin-Yun Wang & Wing P Chan, *Uncertainty and Its Consequences in Clinical Practice,* 30 JOURNAL OF KOREAN MEDICAL SCIENCE 1710 (2015).

6 Doval, D. C et al., *Shared Decision-Making and Medicolegal Aspects: Delivering High-Quality Cancer Care,*26 INDIA INDIAN JOURNAL OF PALLIATIVE CARE, 405 (2020).

7 De Rosis, S., & Barsanti, S, *Patient Satisfaction, E-Health and The Evolution of The Patient–General Practitioner Relationship: Evidence From an Italian Survey*, 120(11) HEALTH POLICY 1279 (2016).

8 Ma, T. J., & Atkin, D, *User Generated Content and Credibility Evaluation of Online Health Information: A Meta Analytic Study*, 34(5) TELEMATICS AND INFORMATICS 472 (2017).

9 Kaba, Sooriakumaran *supra* note 2.

10 Carolyn Lagoe& David Atkin, *Health Anxiety in the Digital Age: An Exploration of Psychological Determinants of Online Health Information Seeking,* 52 COMPUTERS IN HUMAN BEHAVIOR 484 (2015).

researched in the last few years, however, most of the studies are restricted towards medical aspects, that too proposing only research directions.[11] There has been hardly any reported legal literature on this topic. There are restricted levels of health knowledge, which are validated by the limited number of studies on the evaluation of internet literacy with respect to health and medical data.[12] Realizing this huge research gap in this area of study, this article seeks to bridge these gaps. The objective of the present article is to discuss the legal implications of Online Health Information (OHI) and to understand whether such access to information has changed the fundamental nature of the doctor-patient relationship. This discussion has been based on the review of both medical and legal literature with regards to the concept of patient-centered care (PCC).

The concept of Patient-Centered Care (PCC) and legal aspects associated with it

Patient-centric relationships can be described as those "therapeutic" associations whose central characteristics in therapy include unrestricted positive support along with agreement towards shared compassion between the doctor and patient.[13] Along with this, it involves comprehensive, time-coordinated and convenient care, providing access to patient records, exchanging clear and reliable patient information, respecting patients and their caregivers, showing empathy towards their issues, and being fair towards providing any form of services.[14] Thus, attaining PCC is a matter of 'cultural adjustment' and primarily involves considering the personality and character traits of the patients along with their illness. These relationships force the doctors to get involved in experience process faced by the patients and their families apart from providing

11 Fariha Afsana, Muhammad Ashad Kabir, Naeemul Hassan and Manoranjan Paul, *Towards Domain-Specific Characterization of Misinformation, arXiv:14806.*, httpa://2007.14806.pdf (arxiv.org) (last visited Nov. 12, 2021).

12 Gopi Battineni et al, *Factors Affecting the Quality and Reliability of Online Health Information,* 6 DIGITAL HEALTH 1 (2020).

13 Rogers, E. S., Chamberlin, J., Ellison, M. L, *Measure Empowerment Among Users of Mental Health Services*, 48 PSYCHIATRIC SERVICES, 1042 (1997).

14 Steven Lewis, *Patient-Centered Care: An Introduction to What It Is and How to Achieve It,* 112 SASKATCHEWAN MINISTRY OF HEALTH, (2009).

the best medical advice to the patient.[15]

The concept of PCC has been reported to be new in India.[16] Some aspects relevant to PCC in the Indian context includes the care, follow up care, 'guidance and supervision' from the healthcare professionals and their support staff along with the nature of communication.[17]In addition to the behaviour of the doctor, PCC can be evaluated in terms of medicine availability, medical information, staff behaviour and clinical infrastructure.[18] In short, it can be considered as the combination of 'professional knowledge' of doctors and experiential knowledge of the patients.[19] A conceptual framework for the practice of PCC comprising of three levels, namely, (a) the health care system at the organizational level,(b) the patient-healthcare provider level and,(c) the patient-health care provider-healthcare systems level was described by Santana et al.[20] In this study, access to care and patient report outcomes in those levels were evaluated.[21] There are five main factors of PCC, including the presence of effective communication with the nurse as well as the doctor, their service performance, reliability and the physical surroundings that induce satisfaction among patients.

It was argued that PCC has often been confused with patient empowerment and patient participation.[22] In a research study, snowballing search strategy was

15 Judy Brown et al, '*The Patient-Centred Clinical Method, Definition and Application*, 3 FAMILY PRACTICE 75 (1986).

16 *Id.*

17 Mayuri Duggirala, Chandrasekharan Rajendran &Anantharaman R. N, *Patient-Perceived Dimensions of Total Quality Service in Healthcare*, 15 BENCHMARKING: AN INTERNATIONAL JOURNAL 560 (2008).

18 Krishna Dipankar Rao, David H. Peters & Kare Bandeen-Roche, *Towards Patient-Centered Health Services in India—a Scale to measure patient perceptions of quality.,*18 INTERNATIONAL JOURNAL FOR QUALITY IN HEALTH CARE, 414 (2006).

19 Eva Marie Castro & others, *Patient Empowerment, Patient Participation and Patient-Centeredness in Hospital Care: A Concept Analysis Based on a Literature Review*, 99 PATIENT EDUCATION AND COUNSELING 1923 (2016).

20 Maria J. Santana, Kimberly Manalili, Rachel J. Jolley, Sandra Zelinsky, Hude Quan and Mingshan Lu *How to Practice Person-centred Care: A Conceptual Framework*, 21 HEALTH EXPECTATIONS 429 (2018).

21 Shahidul Islam, Nazlida Muhamad, *Patient-Centered Communication: An Extension of the HCAHPS Survey,* 28(6) BENCHMARKING: AN INTERNATIONAL JOURNAL 2047 (2021).

22 Oliver Groene, Niek Klazinga, Cordula Wagner, Onyebuchi A Arah, Andrew Thompson, Charles Bruneau, Rosa Suñol,*Research Project:Investigating Organizational Quality Improvement*

used to build a conceptual process model where all these three concepts were integrated to achieve an improvement in the quality of care at the hospitals that would eventually be helpful for the society. These variables were differentiated according to their characteristics, evaluation scale, antecedents, and outcomes. Patient empowerment was described as the process that enables personal alterations to enhance self-determination, whereas patient-centredness revolved around shared decision making and partnerships and patient empowerment was found to be a consequence of patient centredness.[23]

The notion of PCC has been put to practice as a part of health care since 2001 in many countries such as the USA, the UK, Israel, etc. promoted by the local governments.[24] The Patient Protection and Affordable Care Act in the USA, National Health Services in the UK and Patient Rights Act in Germany have prioritized shared decision making and PCC.[25]In India too, there are certain legal rights protecting patient interest that have been enlisted and codified in various laws and guidelines to ensure self-determination and autonomy, empowering patients to be involved in the decision-making process. The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 specifies the responsibilities and duties of the doctor along with the disciplinary actions for their wrongful conduct. In addition to this, Consumer Protection Act (both old and new) came to the rescue of patients to safeguard their rights as consumers of medical service and to remediate their grievances and provide solutions for any deficiency in medical services.[26] Thus, it can be debated whether the health laws in India are truly patient-centered.[27]

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*Systems, Patient Empowerment, Organizational Culture, Professional Involvement and the Quality of Care in European Hospitals: The "Deepening Our Understanding of Quality Improvement in Europe (DUQuE)" Project*10 BMC HEALTH SERVICES RESEARCH 281(2010).

23 *Id.*

24 Wolfe, A, *Institute of Medicine Report: Crossing The Quality Chasm: A New Health Care System for the 21st Century,* 2 POLICY, POLITICS, & NURSING PRACTICE 233 (2001).

25 Kaba, Sooriakumaran *supra* note 2.

26 Ashish Vashist, Swati Parhar, Ramandeep Singh Gambhir, Ramandeep Kaur Sohi, Puneet PuneetTalwar, *Legal Modalities in Dental Patient Management and Professional Misconduct,* SRM J RES DENT SCI. 91 (2014).

27 Joan H Krause, *Can Health Law Truly Become Patient Centered,* 45 WAKE FOREST LAW REVIEW 1489 (2010).

A recent judgement by the Kerala High Court in *Faheema Shirin v. State of Kerala*[28] held that the right to access the internet is a fundamental right under the Constitution of India, which further protects patient autonomy and the right to self-determination in healthcare to realize the goal of patient-oriented care. One of the steps towards achieving this objective is to make available healthcare-related information and education to patients. Also, it is pertinent to note the landmark decision in *Justice K. S. Puttaswamy (Retd.) and Anr. v. Union of India and Ors.,*[29] where the Supreme Court held that the right to live with human dignity incorporates "right to autonomy" and free choice about one's life decisions. Justice Chandrachud stated that "*The best decisions on how life should be lived are entrusted to the individual... The duty of the state is to safeguard the ability to take decisions – the autonomy of the individual – and not to dictate those decisions*." In the medical context, the right to autonomy implies the right to make one's decision about their treatment choices.

In order to introduce comprehensive legislation in this regard, some of the states in India have passed Acts, with the medical sector in mind. One such state is Karnataka, where the Karnataka Private Medical Establishment (KPME) Act was passed in the year 2007 and amended in 2018.[30] This Act intends to regulate the private medical establishments such as clinics, polyclinics, health check-up centres, integrated counselling centres, hospitals, dental labs, Ayush therapy centres, medical laboratories and blood banks that are used for consultation, diagnostic support, dispensary and observation purposes, which are located in Karnataka. This enactment also incorporates complaint redressal mechanisms for grievance redressal. Similarly, the Government of Kerala has enacted the Kerala Clinical Establishments [Registration and Regulation] Act, 2018 where all public and private clinical establishments practicing the recognised medicine systems such as allopathy, ayurveda, homeopathy, naturopathy, siddha and

28 Faheema Shirin R. K. v State of Kerala and others WP (C) No. 19716 of 2019 (L).

29 K. S. Puttaswamy v. Union of India, Writ Petition (Civil) No. 494 of 2012 (Sup. Ct. India Aug. 24, 2017).

30 Krishna, *A Perspective of Private Health Care Providers in the State of Madhya Pradesh on Adopting Key Strategies of the India Hypertension Control Initiative,* THE JOURNAL OF CLINICAL HYPERTENSION (2020).

unani need to be registered. [31] The objective of the Act is to regulate all clinical establishments in the State towards achieving minimum standards of services and further improve public health. [32]

Even though the legal system has been linked to the health care system for proper regulation, in most countries, litigation becomes a default mode of grievance redressal since the legal mandate of securing informed consent from patients is not fully accomplished. Moreover, the compensation ordered to be given does not rectify the fault of the doctor and does not help the patient to overcome the grievance suffered. This clearly shows that there are many weak points in the legal protection system in areas where patient-centredness is involved. Even though PCC was considered 'essential', a study pointed out that its implementation in practice remains a big challenge.[33] In a recent qualitative study, it was observed that despite PCC forming a critical part of the United Nations Sustainable Development Goals, administrative concerns were found to be the main cause for the non-implementation of PCC. Other challenges faced in India include shortage of labour, supply of free drugs and apprehensions towards the quality of medications that are supported by the authorities.[34]Some of the gaps in implementation found to be commonly noticed across the world have been identified, which reveals the absence of communication, poor decision support system, dearth of policies and guidelines in this regard and lack of training.[35] Overcoming these issues requires a lot of behavioural adjustment along with building up trust and providing training to the healthcare professionals.[36]

31 Government of Kerala http://portal.clinicalestablishments.kerala.gov.in/userLogin (last visited Nov. 12, 2021).

32 *Id.*

33 Ben Natan, *Patient-Centered Care in Healthcare and its Implementation in Nursing* 1 INTERNATIONAL JOURNAL OF CARING SCIENCES (2017)... *See* also DC Doval et al,, *Shared Decision-Making and Medicolegal Aspects: Delivering High-Quality Cancer Care in India,* 26(4) Indian Journal of Palliative Care 405-410(2020).

34 Krishna, *supra* note 18.

35 Doval, *supra* note 33.

36 Harbishettar, *supra* note 3.

Sources of Shared Health Information

Since the foundation of PCC is based on the health information that is shared between the patients and healthcare professionals, it becomes critical to evaluate the authenticity of these available sources of health information. Ideally, any medical professional, specifically the attending doctor acts as the primary source of health information.[37] However, in today's world, internet has become the most common and easy source of information exchange for almost everything including health.[38] Apart from the internet, the other popular sources include mobile applications, newspapers and television followed by radio.[39] In some developed countries such as the USA and Australia, the extent of internet usage for acquiring health information was almost 80%.[40] However, in developing countries such as India, the mobile phone plays very little role other than being the mode of communication between the patient and their families with the healthcare professionals, particularly in the rural areas.[41] However, in the urban parts of India, the usage of the internet was central to understanding health information and was used by 82.7% of the common people.[42]

In a study undertaken to understand the perceptions and behaviour of persons seeking health information, the results showed that apart from respondents belonging to the older generation and those with lower educational qualifications, others were quite accustomed to the use of the internet for acquiring all kinds of information, especially health related.[43] It also depends upon the severity of the disease and the quality of treatment received.

37 Rosis, Barsanti, *supra* note 7.

38 Miriam McMullan, *Patients Using the Internet to Obtain Health Information: How this Affects the Patient–Health Professional Relationship,* 63 PATIENT EDUCATION AND COUNSELING 24 (2006).

39 Deepa Makesh & Sandhya Rajasekhar, *A Study of Health Information Search Behaviour and Its Application among Young Adults,* 7 INDIAN JOURNAL OF YOUTH AND ADOLESCENT HEALTH 2349 (2020).

40 Kenneth Lee and others, *Consumer Use of "Dr Google": A Survey on Health Information-Seeking Behaviors and Navigational Need*, 17 JOURNAL OF MEDICAL INTERNET RESEARCH 4345 (2015).

41 Sherwin I DeSouza et al. *Mobile Phones: The Next Step towards Healthcare Delivery in Rural India,* 9 PLOS ONE 104895 (2014).

42 Makesh, Rajasekhar, *supra* note 39.

43 T. W. Joanna, Chu et al., *How, When and Why People Seek Health Information Online: Qualitative Study in Hong Kong,* 6 INTERACTIVE JOURNAL OF MEDICAL RESEARCH 7000 (2017).

There are two main ways in which health information is accessed: active and passive modes.[44] Within active modes, the internet is applied for the participation in support groups; for self-managing patient portals and for accessing online medical health records, personal health records and interactions with the healthcare personnel besides conducting health related search options.[45] Some of the popular platforms used for accessing information regarding health include Google and other search engines, social media platforms such as Facebook, Instagram or Twitter, websites and blogs.[46] The passive way involves receiving information indirectly through promotions.[47]

Online Heath Information: Challenges

The online health information (OHI) system comes with all the benefits that can be associated with the internet[48] and has been held as one of the most promising sources for dissemination of medical and health information.[49] Some of the benefits revolve around instant and round the clock availability of huge quantity of data, easy accessibility and interaction facilities, higher reach to end users, exposure to a higher number of expert opinions and empowerment of the person seeking the information, which can lead to a higher level of patient satisfaction.[50] In addition, it was suggested that the spread of public education becomes easier. There is a higher possibility of building connections with people facing similar issues, the possibility of remote access, avoidance of any stigma associated with consultations, reduction in travel, thereby saving time and the environment in the process.[51] Moreover, it provides a whole set

44 Minsun Shim & Heui Sug Jo, *What Quality Factors Matter in Enhancing the Perceived Benefits of Online Health Information Sites? Application of the Updated DeLone and McLean Information Systems Success Model,* 137 INTERNATIONAL JOURNAL OF MEDICAL INFORMATICS 104093 (2020).

45 Mike Benigeri& Pierre Pluye, *Shortcomings of Health Information on the Interne,* 18 HEALTH PROMOTION INTERNATIONAL 381 (2003).

46 Afsana, *supra* note 11.

47 Shim, Jo *supra* note 44.

48 Makesh, Rajasekhar *supra* note 39.

49 Makesh, Rajasekhar *supra* note 39.

50 Pippa Powell, Dan Smyth, Isabel Saraiva, Karin Lisspers, Georgia Hardavella, Juan Fuertes, Kate Hill, *What do patients know? Education from the European Lung Foundation perspective,* 14 BREATHE 30 (2018).

51 *Id*. at 51.

of opportunities for patients with physical disabilities as online information may aid in getting rid of their dependence on others to seek medical aid.[52] The main advantages of using the internet lies in easy access to the healthcare professional within a specific time frame, increasing self-awareness and in overcoming the tedious method of getting a specialist consultation.[53] A conceptual model explaining the perception of positive health was reported where the information seeking behaviour of the patients and the perceived communicational competence together led to a sense of empowerment and positive health perception.[54]Another study[55] extended this convenience to young school students as there is an increased level of privacy while using the internet. This could cause an increase in the trust levels between patients and healthcare professionals.[56] Online information has not only been beneficial to patients and their families, but it has also been found to be useful for health care professionals.[57] High quality medical knowledge can be accessed in a far easier manner than before, and timely medical interventions can be initiated along with the validation of treatments within a short span of time. Support groups discussing common medical issues open up new avenues of treatment and thereby instil a sense of confidence. Due to its fast dissemination power, OHI is becoming the fastest growing platform for prevention of diseases and spread of overall well-being.[58]

However, with all these advantages, various disadvantages have also been associated with the OHI. These include inconsistency in the quality of

52 Huigang Liang et al., *Understanding Online Health Information Use: The Case of People with Physical Disabilities,* 18(6) JOURNAL OF THE ASSOCIATION FOR INFORMATION SYSTEMS (2017).

53 Chu, *supra* note 43.

54 Gul Seçkin et al., *Digital Pathways to Positive Health Perceptions: Does Age Moderate the Relationship Between Medical Satisfaction and Positive Health Perceptions Among Middle-Aged and Older Internet Users*? 3 INNOVATION IN AGING 1 (2019).

55 Tatjana Gazibara et al, *Searching for Online Health Information Instead of Seeing a Physician: A Cross-Sectional Study among High School Students in Belgrade, Serbia,* 65 INTERNATIONAL JOURNAL OF PUBLIC HEALTH 1269 (2020).

56 *Id.*

57 Hannah C Cai, Leanne E King & Johanna T Dwyer, *Using the Google™ Search Engine for Health Information: Is There a Problem? Case Study: Supplements for Cancer,* 5 CURRENT DEVELOPMENTS IN NUTRITION (2021).

58 Kye S. Y. & others, *Sharing Health Information Online in South Korea: Motives, Topics, and Antecedents,* 34 HEALTH PROMOTION INTERNATIONAL 182 (2019).

medical information, incongruity in the access to information among a variety of socioeconomic users and the risk of over-consumption of data due to information overload.[59]The biggest challenge in OHI has been the question over its own authenticity as most of the information is directly aimed at the public. In fact, present times can be identified as the 'era of the fake news'.[60] Due to this reason, it was observed in a study that only half of the respondents were persuaded to follow it.[61] However, a few scholars suggest[62] that this number of believers may be even more, as up to 80% of the people are self-diagnosing their treatments using Google as the base of their understanding. This number will continue to increase due to the enhanced exposure of the population to the digital world. Some of the other challenges include the questionable authenticity of information, non-reliability of the said information, negligent misstatement, liability in tort and misuse of online medium for publicity. However, the biggest challenge lies in prescribing medication without any physical examination by the doctor. Moreover, this 'spread of misinformation' can become highly misleading if not verified accurately. Dishonest attitudes of the individuals who are posting information online primarily for financial, personal or political gains can be the major reasons responsible for the spread.[63]

This threatens the whole concept of acquiring and disseminating medical information and may cause adverse effects on public health, particularly in case of aspects related to treatments and vaccination programs. This spread of misinformation is common as people tend to independently search for medications and cure on the internet instead of consulting with the medical professionals. The consequences of such behaviour can be detrimental for the entire health sector.[64] The challenges faced in developing nations like India

59 Benigeri, Pluye *supra* note 45.

60 Wang, *supra* note 5.

61 Makesh,Rajasekhar. *supra* note 39.

62 Anna Kłak, Emilia Gawinska, BolesławSamolinski and Filip Raciborski, *Dr Google as the source of health information – the results of pilot qualitative study,* 24 POLISH ANNALS OF MEDICINE 188 (2017).

63 Afsana *supra* note 11.

64 Sameer Dhoju et al., *Differences in Health News from Reliable and Unreliable Media* COMPANION PROCEEDINGS OF THE 2019 WORLD WIDE WEB CONFERENCE 981-987 (2019). (Association for Computing Machinery 2019).

include the lack of manpower and the impediments that the government goes through during the data sharing process of patients as it is considered to be an invasion of a person's privacy.[65] Similarly, even developed countries such as Saudi Arabia face similar issues, which involves the presence of inexperienced health care workers, lack of funds and facilities, absence of coordination among the service providers, technical issues and the enhanced need for services that can be received free of cost.[66] In case of rural areas, these obstacles get amplified as the population living in those areas are unaware of the concept of e-healthcare. In addition, online consultations conducted from the rural areas areonly a form of secondary source. Scholars have reported that health care professionals have failed as 'filters for the public' and so have systematic reviewers as they are not equipped to detect and rectify any misinformation[67]. Nowadays, as a protective measure, the search engines are taking extra precautions to ensure quality information using algorithms to test the 'expertise, authoritativeness and trustworthiness (EAT)' of the published document.[68]

Some solutions to overcome such issues have been proposed. These include the use of technological remedies where researchers, doctors and health record maintenance managers are all in sync to review the process in a correct manner. This also includes the application of accurate content filters, which can validate the contents that have been or are going to be published. This may increase health literacy among populations through the intermediary role of the practitioner. Some scholars have also suggested that there should be a national data sharing policy that includes the private health sector and the introduction of digital record keeping for patient's health history[69]. However, these systems have a long way to go to fully control the complete accuracy of the information at all times. In order to overcome the issues faced during the adoption of e-health

65 Krishna, *supra* note 30.

66 Hassan Taibah, Sudha Arlikatti& Bill Delgrosso, *Advancing e-Health in Saudi Arabia: Calling for Smart Village Initiatives,* XIV THE SUSTAINABLE CITY 261 (2020).

67 Irma Klerings, Alexandra S. Weinhandl and Kylie J. Thaler, *Information overload in healthcare: too much of a good thing?*109 Z. EVID. FORTBILD. QUAL. GESUNDH. WESEN (ZEFQ) 285 (2015).

68 Cai, King, Dwyer *supra* note 57.

69 Krishna, *supra* note 30.

strategies, a study reported that the Saudi Arabian government is focusing on the following eight areas conceptualized by World Health Organization (WHO): a) foundation of e-health through policies, strategies and capacity building; b) developing legal e-health frameworks; c) country wide overview of electronic health records (EHR) through tele-health aspects;d) Introduction and use of EHR; e) e-learning among students and healthcare personnel; f) promotion of mobile for access of health care information and services; g) use of social media by health care organizations and even professionals; and h) the use of big data as policy and strategies.[70]In a recent study, it was concluded that obtaining accurate results is still a big issue as the amount of information is increasing exponentially day by day.[71]

Legal Aspects of Online Health Information

Due to this spread of misinformation, it becomes extremely significant to determine the legitimacy of the information obtained.[72] This is typically covered in the legal aspects of health information that is obtained through the internet and forms one of the components of e-health strategies and is a factor for evaluating the success of e-health.[73]W.M. Sage has defined legal framework as the 'set of rules' imposed by the government to guide, regulate and instruct the attitude of individuals, systems and organizations[74].Thus, the protection of privacy of health records and allowing population to have access to their own data are also considered under legal aspects.[75] The role of institutional trust plays a critical part of the present legal framework providing structural assurance in the disclosure of personal information on websites in relation to health. Accordingly, the presence of a privacy statement on the website adds to the trust of the patients and their family members on the visited websites and forms a part of the legal framework. Several countries follow a dissemination

70 Taibah, Arlikatti, *supra* note 66.

71 Cai, King , Dwyer. *supra* note 57.(supra note to be rechecked)

72 Afsana *supra* note 11.

73 Taibah, Arlikatti, *supra* 66.

74 Sage, W. M, *Regulating Through Information: Disclosure Laws and American Health Care,* 99 COLUM. L. Rev 1701 (1999).

75 Shim, Jo, *supra* note 44.

protocol for health-related information through official websites released by their government and managed by their health agencies only.[76] Some of the examples of these important agencies with their web addresses have been listed in Table 1. However, in some countries such as Saudi Arabia, the legal framework is highly restrictive to individual privacy and accessibility to information.[77] In order to gain full advantage of the information obtained, it is suggested that the nations need to design their legal frameworks depending upon the behaviour of the population and their propensity to seek health information online, their requirements for healthcare and their economic status.

Table 1: Official health agencies specifically used for the exchange of health information

Name of the agency	Country name	Website address
Center for Disease Control and Prevention	USA	https://www.cdc.gov
Korean Center for Disease Control and Prevention (KCDC)	South Korea	http://health.cdc.go.kr
National Health Services	UK	https://www.nhs.uk/
National Health Protal	India	https://www.nhp.gov.in/
Health *Direct*	Australia	https://www.healthdirect.gov.au/

Coverage and application of the Information Technology (IT) Act, 2000 in terms of liability for publication of medical information

Due to the rapid advancement in digital technologies, India has been recognized as 'the most cyber-branded' nation in the world.[78] As a part of providing legal protection against the dissipation of any type of misinformation with respect to biometric, medical, finance related and personal data or unique identifiers, the Government of India (GoI) has introduced the Information Technology

76 *Id.*

77 Taibah, Arlikatti, *supra* note 66.

78 Dr. Chandrika Subramaniyan, *Why India must amend its Information Technology Act in the age of Artificial Intelligence,* 14 IEEE INDIA INFO 116 (2019).

Act, 2000, with an amendment in 2008 as a 'legal framework for governance of information and data shared through electronic communication.[79] This covers not only the protection of data, but also entails security, lawful or unlawful interceptions and protection against cybercrimes. Even though there is no mention of specific provisions covering the application of the IT Act on medical data, liability for its publication is protected under it, as a part of e-governance.[80] Both civil and criminal liability exists in case of 'wrongful disclosure or violation of' personal data either in terms of compensation or punishment, respectively.[81] In the 2008 amendment, it was construed that any 'body corporate' can be held liable for negligence during implementing or maintaining the procedures and practices pertaining to the safety of information. In a notification released by the Ministry of Communications and Information Technology (2011), 'medical records and history' falls under the consideration of sensitive personal data or Information (SPDI). Under the IT (Reasonable Security Practices and Procedures and SPDI) Rules, 2011, the SPDI can be shared only with the individual's written consent, with the exception of government agencies who do not require any prior consent.

The 'data protection regimes' of the European Union, UK and USA were compared to the Indian norms.[82,83]An analysis of the applicability of privacy laws reflects that under the Electronic Health Record Standards (2016), based on the Clinical Establishments (Registration and Regulation) Act, 2010 and Clinical Establishment Rules, 2012, practicing physicians, hospitals, diagnostic institutions, etc, are bound to maintain the secrecy of health records. However, in reality, there seems to be hardly any liability incurred under these acts for the disclosure of medical information. This is because unfortunately, medical data of millions of Indians are found to be easily accessible through the internet.

79 Nandiga Rubavarshini R. R., *Privacy and the Information Technology Act,* 5 INTERNATIONAL JOURNAL IN MANAGEMENT AND SOCIAL SCIENCE2 46 (2000).

80 Nidhi GhanshyambhaiJoshi, *Application of e-Governance in Medical and Crime Factor In India.* 2(3), INTERNATIONAL JOURNAL OF ADVANCED RESEARCH IN SCIENCE, COMMUNICATION AND TECHNOLOGY, 145 (2021).

81 Taibah, Arlikatti, *supra* note 66.

82 Namita Srinivas & Arpita Biswas, *Protecting Patient Information in India: Data Privacy Law and its Challenges,* 5 NUJS LAW REVIEW 411 (2012).

83 Taibah, Arlikatti, *supra* note 66.

Moreover, the SPDI Rules are not applicable to patient records, who get treated through telemedicine, which is now one of the most prevalent forms of treatment, especially in the times of the pandemic.

Telemedicine Practice Guidelines 2020 [84]

Telemedicine has been described as the means of diagnosing and treating a patients remotely using technological interventions.[85] This form of consultation can be extremely useful in a highly populous country like ours, especially where the doctor-patient ratio is also extremely low. The treatment gap has been estimated to be in the range of 75-93% [86], which can be improved through telemedicine.[87] A National telemedicine task force was set up in 2005 by the Health Ministry of India along with the National Telemedicine Portal. In order to regularise the telemedicine practices which, deliver healthcare services using any form of technology as a means of communication in the form of voice, audio, video, text and digital media, Telemedicine Practice Guidelines (2020) have been introduced keeping in mind the inclusions, exclusions, restrictions, scope and type of communication.[88] The registered medical practitioner (RMP) has to follow these under the Code of Ethics Regulations, 2002. This Guideline defines telemedicine, tele-health as well as RMP and describes its importance, purpose, applications, and exclusions. The categories of telemedicine are dependent upon the timing of the transmitted information (real time or asynchronous), purpose of consultation (emergency and non-emergency), the types of individuals involved along with the mode of communication used. There are four categories of individuals who can avail of telemedicine. These include patient or caregiver or another doctor or a health worker to the consulting physician. Moreover, the strengths and weaknesses of each mode of communication are compared.

84 Telemedicine practice Guidelines 2.

85 Taibah, Arlikatti, *supra* note 66.

86 Melur Sukumar Gautham, et al, *National Mental Health Survey of India, 2016: Prevalence, Socio-demographic correlates and treatment gap of mental morbidity.* 66 JOURNAL OF SOCIAL PSYCHIATRY 361 (2020).

87 Damodharan Dinakaran, Narayana Manjunatha, Channaveerachari Naveen Kumar& Suresh Bada Math, *Telemedicine practice guidelines of India, 2020: Implications and challenges*, 63 INDIAN JOURNAL PSYCHIATRY 97 (2021).

88 *Id.*

The Guidelines outline seven aspects for consideration prior to any form of telemedicine consultation. These include: a) suitable context and complexity of the health condition of the patient; b) knowledge of identity of doctor and patient; c) form of communication to be used during consultation; d) consent and information exchange; e) type of consultation (first or a follow up consult); f) assessment of the patient and g) treatment management through counselling, prescribing medications and awareness towards health condition. Moreover, the doctor needs to display their State Medical Council registration number while discussing the treatment plan and issue e-prescription that advises medicines from specified lists. The general duties and responsibilities of the consulting physicians were outlined with an emphasis on medical ethics, information privacy, confidentiality, misconduct, and maintenance of digital documentation. Frameworks depending upon the individual consulting physician and emergent conditions were suggested that can be followed. Additional information on the technology platforms and special advisory of the Board of Governors with the Medical Council of India have also been deliberated upon. HIPAA (Health Insurance Portability and Accountability Act) is the United States enactment that provides protection and privacy of healthcare information. Violations of the provisions of HIPAA are stringently dealt with and entail liability for the transgressor.[89]India does not have a specific legislation equivalent to HIPAA.

Conclusion

From this review, it can be concluded that the doctor-patient relationship has evolved towards a patient-centered care over the years. Therefore, it is also critical to understand the various challenges of sharing health related information so that both patients and the healthcare professionals are party to the medical decision taken in the best interest of the patient and the patient is provided with maximum level of treatment benefits. The sources of shared health information are many, the primary being the online mode, which has evolved as the primary source due to the advent of the internet and the subsequent progression in

89 Peter F. Edemekong; Pavan Annamaraju; Micelle J. Haydel, Health Insurance Portability and Accountability Act. (StatPearls Publishing; 2021).

digital technologies over the years. It must also be realized that both the active and passive modes of access to health information are significant for an overall improvement in healthcare services. This article also highlighted that there are various benefits and challenges of online health information, which is mostly dependent on the population and their tendency to seek health-information. Some solutions have been considered for overcoming the challenges faced during the use of online information. However, it mostly involves development of a strong legal framework, which is predominantly lacking in developed as well as developing countries.

The onus of sharing authentic health related information still seems to be ascribed to the patient or their families, who are seeking health care information and any legal responsibility for health-related information found online is still found to be lacking. This can lead to spread of lot of misinformation, especially in times of the COVID-19 pandemic. The study of existing literature on the subject indicates that there is a lot of scope in this regard as there are hardly any laws regulating such kind of information. In order to improve the health care scenario, all the stakeholders, namely, patients, their families, healthcare professionals, healthcare organizations, policy makers and local governments must join hands to understand the power of online health information, and utilize it to its utmost extent by overcoming the challenges associated with it. Moreover, the focus should be on increasing the e-health literacy of the citizens and also make them aware about the ways through which accurate information can be filtered and received.

5

A Tale of Diplomacy and Equity: India's Strive towards COVID-19 Vaccine Pricing and Procurement

Samrudh Kopparam*

Abstract

India being the world's second-most populous country with one of the largest pharmaceutical manufacturing capacities, occupies a central role in the novel coronavirus (COVID-19) immunization initiative. Yet, in the aftermath of the 'second wave,' India faces severe vaccine shortages, a crippled economy, and rising inequality amongst the populace. Between the crossfire of adequate procurement and equitable dissemination, India has been riddled with numerous challenges like rushed approval, profiteering, bureaucratic hurdles, 'vaccine nationalism,' etc. By weighing these hurdles, this article aims to highlight the closely interwoven relationship between diplomacy and equity vis-à-vis the COVID-19 vaccine to understand the efforts made to 'win the war' against the novel coronavirus. The article also closely examines the procurement and vaccine distribution policies of the Indian government in ensuring sufficient doses of vaccines are made accessible to the public at large.

Keywords: *Coronavirus (COVID-19), Government, Infrastructure, Vaccine, Equity*

Introduction

The world's largest immunization drive was rolledout on 16th January 2021 by the Ministry of Health and Family Welfare, Government of India, vaccinating 15 lakh people within a span of 4 days[1]. A systematic rollout of vaccines to

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1 Kamala Thiagarajan,*COVID-19: India is at centre of global vaccine manufacturing, but opacity threatens public trust,*(The BMJ), https://doi.org/10.1136/bmj.n196.(last visited Nov.13,2021).

four broad priority groups facilitated the mass vaccination program. These groups were the frontline workers, COVID 'warriors' or healthcare personnel, individuals over the age of 50 years, and individuals suffering from pulmonary or chronic co-morbidities that make them prone to milder symptoms. In the initial stages of distribution, vaccines were provided for free to healthcare personnel at highly subsidized rates. The Covishield vaccine developed by AstraZeneca of Serum Institute of India was priced as low as Rs. 200 per dose, whilst the Bharat Biotech's Covaxin vaccine cost Rs. 295 per dose[2]. In this manner, the initial distribution policy invoked and satisfied the strict principle of 'equity.' By prioritizing individuals prone to attracting the coronavirus or those who face a higher mortality rate as against individuals who possess a comparatively stronger immunity against the virus, a balance was created, by placing parties are on an equal footing[3]. Furthermore, the subsidized price of vaccines in a country already riddled with poverty and widespread unemployment guarantees accessibility and adherence to 'the right to health' envisaged under Article 21[4] of the Indian Constitution. However, trouble arose after the Indian government continually changed its strategy and adopted a more 'liberal' and 'inclusive' policy due to the high volatility in testing rates. The last of these changes came suddenly in April 2021, when the Indian government announced that everyone above the age of 18 years would be eligible for vaccination and removed any distribution or price controls for manufacturers.[5] This led to a two-fold problem: first, there arose a massive shortage in vaccines and second, under the disguiseof inclusivity, there appeared greater inequality in accessibility due to the monopolistic and predatory pricing of Covishield and Covaxin.

This policy reform led to a string of voids in vaccine procurement and equitable

2 *COVID-19 vaccine rollout: Adar Poonawalla says vaccine will be sold to private players at Rs 1,000 per dose*, Business Today India (Jan.12, 2021) https://www.businesstoday.in/current/economy-politics/COVID-19-vaccine-rollout-adar-poonawallasays-vaccine-will-be-sold-to-private-players-at-rs-1000-per-dose/story/427727.html.

3 Dr. Soumyadeep Bhaumik, *COVID-19 vaccination in India: we need equity*, The BMJ GH Blogs, (May 18, 2021) https://blogs.bmj.com/bmjgh/2021/05/18/COVID-19-vaccination-in-india-we-need-equity/.

4 INDIA CONST. art. 21.

5 Prasantha Sahu, *New 'liberal' policy: States to spend a tidy sum for vaccination drive*, The Financial Express, ,(Apr. 22, 2021) https://www.financialexpress.com/economy/new-liberal-policy-states-to-spend-a-tidy-sum-for-vaccination-drive/2237743/.

distribution. Through the lens of basic economics, with the massive increase in demand for these vaccines, low supply, privatization, and lack of regulation on vaccine pricing cumulatively perpetuated differential distribution. In the following sections, the implications of these policy reforms, challenges faced during procurement and distribution shall be discussed, and lastly, recommendations to ensure that the principle of 'equity' is assuaged shall be put forward.

Analyzing the Opportunity Cost of COVID-19 Vaccination

After first emerging in Wuhan, China in late 2019, the novel coronavirus or severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has disrupted global economies, and caused a worldwide 'pandemic.'[6] The proportions of the imminent threat to 1.4 billion people that lay ahead were largely unknown to India when the first case of COVID-19 was reported on 27th January 2020 in Kerala. Within a year of the 'expose', India faces a massive 3.25 crore cases of COVID-19, second only to the United States of America with 3.8 crores. With the numerical 4.35 lakh reported deaths to COVID-19, it has become evident that mass vaccination is the only effective means of protection from the virus[7]. Alternatives like the slew of lockdowns, tattled social-distancing norms, etc., have been largely ineffective in stemming the spread of the disease. The option of creating a 'herd immunity,' i.e., the natural spread of illness to develop antibodies against the virus, proves to be infeasible in the Indian context, as about 70% of India's population would have to be naturally infected by COVID-19 and with an assumption of 1.5% mortality rate; the death toll to reach such herd immunity would be an unacceptable loss of 15 million lives[8]. Furthermore, with new 'variants' of COVID-19 emerging, like the infamous 'delta variant' and

6 Brody H. Foy. Et. al, *Comparing COVID-19 vaccine allocation strategies in India: A mathematical modelling study*,103.International Journal of Infectious Diseases431, 432 (2021).

7 M.A. Andrews et. al,*First confirmed case of COVID-19 infection in India: A case report*, 151 Indian J Med Res. 5 490, 492 (2020).

8 Shambhavi Naik. Et al, *A COVID-19 Vaccine Deployment Strategy for India*, 1 Indian Public Policy Rev. 2 42, 44 (2020).

'alpha variant', a true herd immunity against the virus would cause more harm than good. Therefore, adequate planning needs to be carried out for equitable distribution and mitigation of widespread COVID-19 clusters.[9]

In pursuance of the mass production of vaccines, countries around the globe initiated various programs to support the health and clinical sector. For instance, the USA commenced operation warp speed[10], a public-private partnership with 'promising' countermeasure candidates to facilitate and accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics. It also committed $10 billion in funds for investments in manufacturing and distribution, of which the 'vaccine leaders' AstraZeneca-Oxford received $1.2 billion, Novavax reported $1.6 billion, and Moderna received $1.53 billion. On the contrary, India had not initiated any program to accelerate vaccine production or logistics in its distribution until recently. On 3rd June 2021, the Union Health Ministry announced its collaboration with Biological E (Bio-E), a Hyderabad-based company, to procure 300 million doses of COVID-19 vaccine 'Corbevax' for Rs. 1500 crore[11]. Even though Corbevax is under stage 3 of the clinical trial, this incentive was rendered after due diligence by the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC), as Corbevax has the potential to protect individuals from future variants. While the shift in policy to encourage Research and Development (R&D), advancing infrastructure, and manufacturing comes a little late, it proves to be essential for adequate vaccine procurement and safe deployment for a mammoth 1.3 billion population. In the context of supply chains, the need for 2 billion doses is unlikely to be effectively met; however, such initiatives that expedite and accelerate the manufacturing process can aid the goal of 80% immunization of the population by December 2021.

9 *Id. at* 46.

10 Vasudevan Mukunth, *Vaccines at 'Warp Speed': The Difference Between the US and India*, The Wire, (June 5, 2021), https://thewire.in/government/vaccines-at-warp-speed-the-difference-between-the-us-and-india).

11 *Centre bets big on Biological E's COVID-19 vaccine candidate: What we know so far about Corbevax,* TimesNow News, (June 4, 2021) https://www.timesnownews.com/india/article/centre-bets-big-on-biological-es-COVID-19-vaccine-candidate-what-we-know-so-far-about-corbevax/766163).

Preliminary response by the Indian Government

Before the vaccine rollout, the Indian government took drastic preventive and mitigative steps to control COVID-19 clusters and spread. It is essential to understand these responses as they go hand-in-hand with immunization, culminating in winning the 'war' against the virus. Some of the stringent public health measures taken to avert internal spread were lockdowns and movement restrictions, gnomic and epistemological surveillance, and a curb on mass gatherings[12]. India was amongst the first countries to announce a nationwide 'lockdown' dubbed 'Janta curfew' lasting 21 days from 25th March 2020[13]. While the lockdown temporarily reduced the spread of the virus, it led to a more significant 'harm' due to the unpreparedness of the administration. There was a massive state of panic due to the sudden decision, a migrant crisis due to the closure of daily-wage and unorganized employment, and a dent in the economy resulting froma shutdown of commercial and private establishments. Additionally, throughout the year, states like Kerala, Telangana, Karnataka, etc., had individual state-wide lockdowns to reduce the rising cases. However, these were riddled with issues of public leniency, a gross violation of standard operating procedure (SOP) of COVID-19 protocols, and the populace's reluctance to follow the COVID appropriate behaviour (CAB).

With the increase in cases and 'evolution' of the virus, the Indian government faced potential threats from new virus variants. Early identification of such variants by genome sequencing and epistemological surveillance is necessary for nationwide control. Another significant mitigative action to be taken was the restriction in cross-border movement or international travel. As of August 2021, India has travel restrictions only with countries known to be ridden by the Delta variant, i.e., Canada, United Arab Emirates (UAE), France, etc[14]. Lastly,

12 Om Prakash Choudhary. et al, *Third wave of COVID-19 in India: Prediction and preparedness*, 1 J Formos Med Assoc. (2021).

13 NistulaHebbar, *PM Modi announces 21-day lockdown as COVID-19 toll touches 12,* The Hindu, (Mar. 25, 2020) https://www.thehindu.com/news/national/pm-announces-21-day-lockdown-as-COVID-19-toll-touches-10/article31156691.ece.

14 Priyanka Kumari, *COVID-19: Canada extends ban on flights from India till Sept.21*, The Hindu, (Aug 11, 2021) https://www.thehindu.com/news/international/COVID-19-canada-extends-ban-on-flights-from-india-till-sept21/article35849362.ece

one of the most punitive measures taken was the curb on mass gatherings. Yet, mass election rallies and religious gatherings were carried out like the ordinary during the peak of the COVID-19 second wave. One such instance is of the 2021 West Bengal elections, wherein daily COVID-19 cases exacerbated by 75 times since the Election Commission of India (ECI) announced assembly elections. The rise in cases from day 0 increased from 216 to 16,403 with a massive 30% increase in positivity rate, i.e., the proportion of people testing positive to those tested[15]. The gross negligence was also identified by the Judiciary of India, with the Madras High Court holding the ECI accountable and responsible for the second wave of COVID-19. Furthermore, the Chief Justice of Madras High Court, Justice Sanjib Banerjee, remarked that it would have been justified to charge EC officers with murder[16]. Additionally, the Calcutta High Court also expressed dissatisfaction over measures taken by the poll panel to enforce COVID-19 safety norms in campaigning.

The Need for Equity in Health Care

The Union Government in 2017 formulated the National Health Policy (NHP) after recognizing the need for an effective and efficient public health administration[17]. Through the NHP, there is a 'universalization' of health care facilities. However, its primary objective was to provide health care for all. The COVID-19 pandemic has left a deep impact on India's health, healthcare system, human security and has truly tested the NHP 2017[18]. The policy's principle of reinforcing people's trust in the public healthcare system, aligning the private healthcare sector's growth with public health goals, and the quantitative goals were definitely deferred. This can be observed from the widespread supply

15 Joydeep Thakur, *Bengal: 75 times spike in daily cases after poll announcement*, The Hindustan Times, (Apr. 28, 2021), https://www.hindustantimes.com/elections/west-bengal-assembly-election/bengal-75-times-spike-in-daily-cases-after-poll-announcement-101619555128270.html.

16 TNM, Election Commission officers should be booked for murder: Madras HC slams ECI, The News Minute, (Apr. 26, 2021), https://www.thenewsminute.com/article/election-commission-officers-should-be-booked-murder-madras-hc-slams-eci-147844.

17 Priya Gauttam. et al, *Public Health Policy of India and COVID-19: Diagnosis and Prognosis of the Combating Response,* 13 Sustainability 6 3415, 3419 (2021).

18 *Id. at* 3420.

crunch during the second wave of COVID-19. Based on a study by the Central Bureau of Health Intelligence and the Centre for Disease Dynamics, Economics and Policy (CDDEP), the lack of equity in healthcare can be established by considering the case of Maharashtra. In May 2021, Maharashtra reported on average 9300 confirmed cases every day and cumulative 11,58,543 cases with a 23% positivity rate. There was a cumulative of 27,359 reported deaths due to COVID-19, and it has been speculated that more than 74% of these deaths were due to a lack of public health infrastructure.[19]To put this into context, Maharashtra has 5793 Ventilators, 11,587 ICU Beds, and 2,31,739 hospital beds. It is also to be noted that more than 77.8% of these resources are of the private sector that is out of the purview of pricing regulations. This establishes that the vast proportion of the population has difficulties in accessing healthcare. Additionally, Pew Research Center, using World Bank data, estimated that the number of poor in India (with income of $2 per day or less in purchasing power parity) has more than doubled to 134 million from 60 million in just a year due to the pandemic-induced recession[20].

India primarily follows a public-private partnership model in the health care sector. It has nearly twice the number of private hospitals compared to government hospitals (43,487 to 25,778), despite 85% of the rural population and 80.9% urban population having no adequate health insurance. Furthermore, the lack of adequate regulation and 'check' in these dire circumstances, private health care facilities are charging exorbitant fees to treat COVID-19 patients. Various personal anecdotes have been shared, one of which is as follows.A small cycle-store owner, who was only allowed to be admitted in a private hospital at Bengaluru after paying an advance of Rs. 38,000 recovered from COVID-19, but at the cost of Rs. 1,78,000 lakh and additional (miscellaneous) expenses[21]. He was being treated at the hospital for a mere ten days, and the

19 COVID19India, COVID Tracker Software, https://www.COVID19india.org/state/MH.

20 Rakesh Kochhar, *In the pandemic, India's middle class shrinks and poverty spreads while China sees smaller changes,*Pew Research Centre Blog,(Mar. 18, 2021) https://www.pewresearch.org/fact-tank/2021/03/18/in-the-pandemic-indias-middle-class-shrinks-and-poverty-spreads-while-china-sees-smaller-changes/.

21 RanjaniMadhavan, *Burden too high, private hospitals charging exorbitantly, claim COVID-19 patients,*The Indian Express, (July 1, 2020),https://www.newindianexpress.com/states/karnataka/2020/jul/01/burden-too-high-private-hospitals-charging-exorbitantly-claim-

pandemic struck for the second time. First, affecting and crippling his business, and second, forcing additional financial burden through extortionate hospital rates. These anecdotes bring about the need for 'equity' in healthcare since an individual who is deprived of his employment (and lacks job security) and has no health insurance cannot be put in the position of paying such high fees for treatment. As established before, vaccination remains the only viable solution in reducing the burdens of COVID-19, and a lack of equity in immunization can prove detrimental to the country.

A Tale of Two Vaccines: Covishield and Covaxin

There is a monopoly over the vaccination market in India, effectively dominated by Covishield and Covaxin, which have been approved by the Drugs Controller General of India (DCGI).[22]Covishield is better known due to its affiliation and prospect as a version of the Oxford University's AstraZeneca vaccine. It has an average efficacy of 70.4% and is based on the technology of using a weakened genetic material of the adenovirus. On the other hand, there is India's first home manufactured vaccine developed by Bharat Biotech, collaborating with the Indian Council of Medical Research and the National Institute of Virology– Covaxin. While both vaccines require two doses to attain maximum efficacy, the Covaxin vaccine has been the centre of much controversy due to its rushed approval and mixed efficacy results[23]. The controversy arose after a volunteer for the Vaccine trial, Deepak Marawi, a daily wage labourer from Bhopal, died a few days before getting his second dose administered. While the doctors who conducted the post-mortem suspected the probable cause of death to be a cardio-respiratory failure as a result of poisoning, there was no adequate 'report' even though the New Drugs and Clinical Trials Rules 2019 mandate that all adverse events must be reported, whether related to the trial medication or not.[24] Furthermore, the dubious double-blind trial process casts

COVID-19-patients-2163754.html.)

22 Reshma Ramachandran. et al, *Future of COVID-19 vaccine pricing: lessons from influenza*, The Bmj (2021), http://dx.doi.org/10.1136/bmj.n1467.

23 Kamala Thiagarajan, *COVID-19: India is at centre of global vaccine manufacturing, but opacity threatens public trust,* The BMJ,, (Jan. 28, 2021) https://doi.org/10.1136/bmj.n196.

24 Prasad Nichenametla, *Bhopal Volunteer's Death unrelated to COVAXIN,* The Deccan Herald

further apprehensions as the dose content (test vaccine or placebo) is revealed neither to the subject/volunteer nor to the administrator. These instances, coupled with the stirrups by the media, have created uneasiness and discomfort amongst the populace. However, many health experts have also come forward to dispel any conspiracy by citing the primary concern of lack of transparency and information released to the general public.

In the context of vaccine pricing, post the policy shift, due to the lack of regulation, Covishield costs Rs. 720 a dose, whilst Covaxin costs Rs. 1,410 per dose with a ceiling of a maximum of Rs. 150 as 'service charge.'[25] Furthermore, in government hospitals, the 'same' vaccines are administered at Rs 300 per dose of Covishield and Rs. 600 per dose of Covaxin. In a country where the average monthly per capita income for a household of four members is Rs. 4,979, affording such exorbitant prices for vaccines remains a significant challenge. This is unparalleled as no other federal democracy makes citizens pay for COVID-19 vaccines or have states competing to secure supplies. Serum Institute of India (SII) and Bharat Biotech fixed prices for state governments at almost twice the price paid by the Union government, four times in the case of private hospitals. An immediate consequence of this was that most state governments could not offer vaccines for high-risk groups. In contrast, richer people (who can pay Rs. 1600-2400) in non-priority groups of 18-45 years of age can access vaccines from private hospitals. The "liberal policy" also perpetuates regional inequities, wherein richer state governments will be able to buy more doses for non-priority groups whilst poorer states (with weaker health systems) will have to wait for revenue to accrue for buying vaccines for priority groups.[26] These factors can be analogized to a daylight robbery of access to health care and an outright contradiction of the National Health Policy. Thus, there must be equitable distribution of vaccines by modifying and regulating the pricing of vaccines.

(Jan. 10, 2021)https://www.deccanherald.com/national/bhopal-volunteers-death-unrelated-to-covaxin-says-bharat-biotech-937199.html.

25 V.K. Paul, *Government caps prices of COVID-19 vaccines at private hospitals,* The Hindu, (Jun. 8, 2021)https://www.thehindu.com/news/national/high-cost-of-vaccination-at-private-hospitals-unacceptable-paul/article34763106.ece.

26 Sahil Deo. et al, *COVID-19 Vaccine: Development, Access and Distribution in the Indian Context*, ORF Issue Brief 378 (2020).

Equitable Distribution of Vaccines: How should the Price be Regulated?

India has a two-dose immunization regime that would require approximately two billion doses to vaccinate 80% of its population.[27] To vaccinate such a proportion of the population, the medium to vaccinate must be affordable, accessible, and wholly equitable. First, to make the immunization program accessible and equitable, distribution needs to be carried out on the lines of equity and reciprocity.[28] On one hand, the principle of equity suggests that vaccine distribution must be based on the degree of risk, i.e., priority must be given to those who have a higher degree of being exposed to the virus. On the other hand, the principle of reciprocity dictates that individuals whose occupation exposes them to significant risk but are necessary for the welfare and benefit of society should be prioritized. While these 'essential firsts' were initially prioritized, they have been neglected in the aftermath of the second wave. This approach would be beneficial to strengthen the backbone of India's response to COVID-19.[29] It would also help sustain the economy and to a certain extent neutralize the adverse effects of the pandemic by maintaining the continuity of essential services. Another vital factor to be considered is demographic inequality. While the former approach prioritizes, it fundamentally ignores individuals above the age of 65 years and those of the unorganized sector.[30] In the degree of risks, these individuals are highly likely to contract the virus. Furthermore, with the third wave around the corner, it is vital not to neglect any part of the population. When integrating the targeted 'demographic' approach with the 'essential first' approach, the government can significantly reduce the mortality and hospitalization rate. Another important aspect regarding the accessibility of immunization is the digital health-driven inequity. In the current vaccination regime, citizens must pre-register through a centralized

27 Chiranjib Chakraborty et al, *COVID-19 vaccine: Challenges in developing countries and India's initiatives*, 29 Infez. Med. 165, 166 (2021).

28 Shambhavi Naik. et al, A COVID-19 Vaccine Deployment Strategy for India, 1 Indian Public Policy Rev. 2 42, 49 (2020).

29 *Id. at* 46.

30 *Id. at* 47.

online digital system called Co-WIN.[31]

With the prevalent supply crunch, the registrations are allowed on a firstcome-firstserve basis. Due to this method, there arises a 'digital divide' as only individuals with fast, uninterrupted access to the internet can easily register for vaccination. Furthermore, only 20% of India's population has 'adequate' bandwidth of internet to access the Co-WIN portal. Thus, the implementation strategy draws away from the ground realities. It is important to note that this divide is more noticeable in rural areas, particularly amongst the Adivasi/Tribal communities who remain clueless about the system. While the utilization of digital health is not wrong, the complete dependence on digital health defers equity. Another important aspect to consider is that there are many tech-neophytes in India, which puts them at risk of being 'duped'. This can be observed with the Delhi Cyber department making a recent arrest on two 'fraudsters' who created an app and website identical to the Co-WIN portal and collected money under the pretext of registration for COVID-19 Vaccination. The duo made around Rs. 40 Lakhs by defrauding these individuals who have limited knowledge and access to technology.[32] This further exacerbates the issue of the 'digital divide' and thus, it is recommended for the government to invest in employing more vaccinators and vaccination officers, and adopt time-tested walk-in and community outreach vaccinations.

After establishing the importance of equitable accessibility and distribution policies, vaccine affordability must be ensured to the Indian populace. In this respect, it is important for the government to intervene, as free-market pricing would lead to competitive pricing. Since households would bear the cost of vaccines, there would be inequitable distribution. Thus, government intervention becomes imperative. It is recommended that the government bears all costs of the vaccine, effectively making it zero price for Indian residents.

31 Dr Soumyadeep Bhaumik, *COVID-19 vaccination in India: we need equity*, The BMJ GH Blogs, (May 18, 2021) https://blogs.bmj.com/bmjgh/2021/05/18/COVID-19-vaccination-in-india-we-need-equity/.

32 Yasmin Ahmed, *"Government warns against downloading fake CoWIN apps on PlayStore"*, India Today, (Jan. 7, 2021) https://www.indiatoday.in/technology/news/story/government-warns-against-downloading-fake-cowin-app-on-playstore-1756758-2021-01-07.

However, this approach is quite utopian and is not foolproof as it can lead to pilferage and even corruption over time. It is important to make certain market-based assumptions, like vaccine pricing trends may not function according to standard market forces, paralleling trends of some pharmaceuticals. With more research and development (R&D) investments by multiple branded pharmaceutical companies, market competition would inevitably form over time that can impact the vaccine's prices. To overcome such hurdles and truly make an effective pricing policy, the government is recommended to initiate a 'One Nation One Price' policy.[33]To overcome the chances of pilferage or corruption, it can issue regulatory guidelines for compulsory licensing of all COVID-19 vaccines under Section 92 of the Indian Patent Act, 1970.[34] A single buyer and a fixed price for the entire nation would prevent pandemic profiteering, regional inequalities and save most lives as well as life years.

Self Sufficiency in Vaccine Manufacturing: The Role of Diplomacy

While India is considered the world's manufacturing hub, potentially contributing to 60% of the global vaccine supply, it has never attempted to inoculate millions of people. The most recent mass vaccination attempt was in 2011, wherein 172 million children were administered oral polio vaccine in a span of five days under the national polio immunization program.[35] However, this attempt cannot be juxtaposed to COVID-19 immunization due to the varying circumstances. The case of COVID-19 brings up the contested issue of healthcare rationing, as the demand for the vaccine continually increases until the pandemic is at its brink. This demand is free from the effects of other parameters like price, supply, purchasing capacity, etc. Thus, there would be government rationing of vaccines, where price caps and waivers would often be imposed to combat shortages. Currently, vaccine procurement is guided by India's National Vaccine Policy of 2011. The Central government procures

33 *Id.*

34 The Patents Act, 1970, No. 39, Acts of Parliament, 1970, § 92.

35 Chiranjib Chakraborty. et al, *India's cost-effective COVID-19 vaccine development initiatives*, 38 Vaccine. 50 7883 (2020).

vaccines under the overarching General Financing Rules (GFR) and later distributes them to the states.[36] The vaccines are either purchased under Annual Rate Contracts against which supply orders are issued or Parallel contracts are awarded for most vaccines because no single domestic manufacturer has enough available production capacity to cover the entire annual requirement. Additionally, the government and its private partners have initiated multiple diplomatic relations and foreign collaborations to enhance vaccine supply.[37] Serum Institute of India (SII) has signed bilateral deals with British Big-Pharma AstraZeneca to secure a license to mass-produce over a billion vaccine doses developed by the University of Oxford. It has also tied up with US-based biotech firm Codagenix, which will produce a live-attenuated vaccine. The company recently sold its Czech Republic-based subsidiary Praha Vaccines to Novavax, a prominent US-based vaccine developer. Bharat Biotech has also ventured into the US market after signing a letter of intent with US pharmaceutical company Ocugen to co-develop the vaccine.[38] To bring in more credible and tested vaccine candidates into the Indian market, the government recently purchased 50 million doses of the Pfizer vaccine, authorized the collaboration between Dr. Reddy's and the Russian Direct Investment Fund (RDIF) to supply the Sputnik V vaccine, signed a memorandum with the Brazilian president for manufacturing 2 million doses of Covishield and 5 million doses of Covaxin, and initiated an electronic Vaccine Intelligence Network (eVIN) to provide real-time information about the storage, logistical support, distribution and usage of vaccines on the ground.

India's diplomacy in COVID-19 vaccine production and distribution is genuinely commendable in sharp contrast to some high-income countries which stockpile vaccines and block proposals to suspend intellectual property rights in World Trade Organisation (WTO), India has been pushing for equity. Under Project Maitri,[39] India supplied over 15 million vaccines to impoverished

36 Sharun Khan, Kuldeep Dhama, *India's role in COVID-19 vaccine diplomacy*, 1 Journal of Travel Medicine (2021).

37 *Id.*

38 Niladri Chatterjee. et al, *Politics of Vaccine Nationalism in India: Global and Domestic Implications*, 48 Forum for Development Studies 2 357, 365 (2021).

39 Amiti Sen, *India's 'Vaccine Maitri' initiative earns praise at WTO,* The Hindu Business Line,

countries like Bangladesh, Mauritius, Nepal, Bhutan, Maldives, etc. India donated over 20 Lakh doses to the United Nations peacekeepers. India has also been an active participant of the COVAX or COVID-19 Vaccine Global Access, a global initiative by the World Health Organization (WHO), the Coalition for Epidemic Preparedness Innovations (CEPI), and Gavi, the Vaccine Alliance. Lastly, during the peak of the first wave of COVID-19, India mass-produced and donated two antiviral drugs, Remdesivir and Favipiravir, mitigating the global humanitarian crisis to a large extent.

Vaccine Nationalism: A Prevalent Concern and Hurdle To Equity

To understand the phenomenon of 'vaccine nationalism' and its implications, immunization must first be perceived as nationalistic. Immunization or vaccination is 'nationalistic' as it is prioritized and empirically carried out based on an individual's national identity, State machinery, and obligation towards its citizens. The COVID-19 vaccination program with an estimated 5 billion doses worldwide is the largest exercise of its kind in history. This mammoth amount of required quantities has led a few countries to stockpile vaccines for their citizens to fierce competition among states to develop vaccines and vaccine diplomacy. This 'stockpiling' is known as vaccine nationalism.[40] Such nationalism can be carried out internationally as well as domestically and can have disastrous implications if not regulated. An instance of this stockpiling can be seen with the US's attempt at procuring more than 1 billion doses through six bilateral deals. To put this into perspective, the US has a total population of ~ 331 million. Thus, a billion doses is more than enough to inoculate the total population.[41] In the international context, when wealthy countries hoard COVID-19 vaccines by advance purchase agreements, developing countries with negligible manufacturing capacity and infrastructure are stranded

(Mar. 3, 2021), https://www.thehindubusinessline.com/news/national/indias-vaccine-maitri-initiative-earns-praise-at-wto/article33979754.ece.

40 Niladri Chatterjee. et al, *Politics of Vaccine Nationalism in India: Global and Domestic Implications*, 48 Forum for Development Studies 2 357, 359 (2021).

41 *Id. at* 359.

at the end of the queue, increasing the risk of mutation of the virus. The WHO also voices its concerns, holding such counter-productive measures to prolong the pandemic and cause a moral failure. It is important to note that these economically advanced countries only constitute ~24% of global population.[42]This action of theirs thereby allows the majority of the world's population to go unvaccinated and will only perpetuate the needless virus.

In the Indian context, indigenous pharmaceutical companies are major manufacturers of vaccines distributed worldwide, particularly those for low-income countries, supplying more than 60% of vaccines to the developing world. Despite the strong manufacturing base and early access to COVID-19 vaccines, Indian companies are struggling to produce enough doses to sufficiently manage the pandemic. In contrast to 'wealthy countries', India has pursued its own forms of vaccine nationalism, i.e., to gloss over the failures of the initial pandemic management and improve its standing in the international community through vaccine diplomacy and advancing the socio-economic construct an idiom of nationalism. This shift towards global politics in India highlights how global changes affect local reconfigurations.[43] However, the maintenance of healthy international diplomatic relations has cast apprehensions within the country. Post the second wave of COVID-19, there have been political ramifications vis-à-vis adequate domestic supply of vaccines. In India, economic liberalization transformed the federal structure from cooperative to competitive federalism as states vied for private capital. This can be observed with the recent West Bengal elections, where the regional party and the Bharatiya Janta Party (BJP) have crept 'vaccination policies' within their election manifestos. Furthermore, the politics can be observed with the allocation of vaccines/funds preferential to the BJP-ruling states causing regional disparity.[44] Additionally, allegations made by oppositions in states like Uttar Pradesh (UP) calling Covaxin a 'BJP Vaccine' hampers the logistics and steady supply of the vaccine. In terms of the electoral announcement and hurried permissions, the politicization of vaccines

42 *Id. at* 363.
43 *Id. at* 362.
44 *Id. at* 365.

can dent confidence in both vaccines and one's own government. Thus, the nation's leaders must be more transparent and not stir unmerited controversy.[45] On the international front, global organizations and alliances must be stringent in regulation and control hoarding practices to benefit global public health.

Conclusion

From the aforementioned discussion, it can be concluded that equity in healthcare is the need of the hour, especially in the Indian context, which is monopolized by two vaccines- Covishield by SII and Covaxin by Bharat Biotech. It has also been established that vaccination and complete immunization is the solution to overcome the pandemic. Thus, every individual needs to be able to access, afford, and utilize the available vaccines. In the current state, where the threat of the third wave looms large, all elements mentioned earlier are lacking. To ensure equitable distribution and access, the government must intervene and ensure that predatory pricing of these vaccines is regulated. It must lean towards a One Nation One Price policy and mitigate the 'digital divide' that has arisen due to the registration process. After ensuring that the immunization program is accessible and affordable to all strata of society, the government must ensure that there is sufficient supply and availability of the vaccine. In this context, diplomacy plays a crucial role in vaccine procurement. However, along with diplomacy comes unmerited politics. Thus, it is vital for the state to not politicize vaccine procurement. As discussed, vaccine nationalism would lead to peripheral consequences of worsening the pandemic. Such nationalism can cause turmoil, even within the geographical frontiers of the country. Thus, the government must keep upholding the principle of equity to abstain from such deprecatory practices.

45 *Id. at* 364.

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Laws on Pandemic Response: The Inventory in Light of COVID-19

*Devika Tadwalkar**

Abstract

The impact of the coronavirus pandemic world-wide has been devastating. The multidimensional effect of the pandemic on every stratum of society has raised concerns about disaster management of even the most developed and advanced countries. Measures adopted by authorities in some countries have included a broad spectrum of restrictions: from general guidelines, curfew, lockdown to travel bans and mandatory quarantine. This crisis makes us ponder: What are the relevant obligations, powers and procedures under public international law and whether their implementation has proven effective? In order to address such questions, the article evaluates the disputed issues under other regimes of international public law, such as human rights, trade, security law and offers suggestions to restore the damage done.

Keywords: *coronavirus pandemic, COVID-19, World Health Organization, International Health Regulations (IHR), human rights, lockdown*

Introduction

The COVID-19 virus was first detected in 2019 in Wuhan, China, which isconsidered the epicentre of the outbreak. The virus gradually spread throughout the world and led to a dramatic increase in the loss of lives and livelihoods and caused discernible damage to the world economy. Tens of millions of people were affected, not just in terms of health but also socially and economically.

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According to the World Health Organization report published in 2020[1], there were 690 million malnourished people in the world. The number might increase to 822 million worldwide. A look at the[2]data from three countries which have been majorly impacted by the pandemic - India (most affected in Asia), Italy (most affected in Europe) and the US (an advanced health-care system and a superpower), statistically showcases the effect of the pandemic on the affected population. The article addresses the issues pertaining to implementation of various policies, laws, and rules by the aforementioned countries, the synergy between their government and executive bodies, human rights violations resulting from the pandemic, and their adverse effects on international relations and the countries' economies.

PARAMETER	INDIA	ITALY	US
POPULATION	135.26 crores	6.04 crores	32.27 crores
CONFIRMED CASES	1.07 crores	19.64 lakhs	1.8 crores
RECOVERED	96.37 lakhs	12.81 lakhs	1.08 crores
DEATHS	1.46 lakhs	69,214	3.2 lakhs
FATALITY RATE	1.5%	3.5%	1.8%
RECOVERY RATE	95.6%	65.2%	58.5%

*As per the compilation of data from the official website of *Our World in Data*[3]

Pandemic Laws: Multi-Dimensional Efforts of Countries in Response To COVID-19

This section delineates and critically analyses the primary legal and policy measures adopted by India, USA, and Italy to contain the spread of the virus.

1 World Health Organization,*Healthy diets, the double burden of malnutrition and COVID 19* (World Health Organization), https://www.who.int/docs/default-source/searo/ncd/dr-chizuru---healthy-diets-the-double-burden-of-malnutrition-and-COVID-19.pdf?sfvrsn=c9e82bc7_2 (last visited Nov. 23, 2021).

2 As referred from the table below.

3 Our World In Data, *Daily Confirmed COVID 19 cases per million people*, https://ourworldindata.org/explorers/coronavirus-data-explorer?zoomToSelection=true&time=2020-03-01..latest&pickerSort=asc&pickerMetric=location&Metric=Confirmed+cases&Interval=7-day+rolling+average&Relative+to+Population=true&Align+outbreaks=false&country=USA~GBR~CAN~DEU~ITA~IND (last visited Nov. 23, 2021).

India

In a health emergency, the duties of the state and municipal governments include the maintenance of general well-being, hygiene, and decontamination of its citizens.[4]; Maintenance of quarantine facilities and isolation centers are other statutory duties[5]. Further, the Central Government had drafted several additional guidelines that were to be executed by the state governments to curb the virus. Some measures taken by Central Government in this regard include:

- In January 2020, the Centre empowered the local and state governments to utilize available resources with the State Disaster Response Fund for COVID-19 (As per Disaster Management Act, 2005).
- In March 2020, the Ministry of Health and Family Welfare informed state governments to make arrangements according to Section 2(2b) of the Epidemic Diseases Act, 1897.
- As a signatory to the International Health Regulations, 2005 (IHR), India was under an obligationto set up a fitting response to curtail the worldwide spread of diseases. The Integrated Disease Surveillance Program (IDSP) was the key body to initiate the same. The objective of the IDSP is to maintain a decentralized laboratory-based IT-enabled disease surveillance system for epidemic prone diseases to monitor disease trends and to detect and respond to outbreaks in early phases through trained Rapid Response Teams (RRTs). During the initial phase of the nationwide lockdown, state governments urged that the federal government continue to administer it. The states submitted their decision-making power and political capital to the Central Government. Their autonomy was restored in subsequent phases of the lockdown, but Indian states today have less functional power compared to the Centre. The nation-wide lockdown practically suspended all economic activities and the state governments saw a significant drop in revenue. Considering the implementation of various legislations such as the Epidemic Diseases Act, 1897, the pandemic may have given rise to a new federal relationship between the Centre – State, one of a kind

4 Park, Textbook of Preventive and Social Medicine, (Banarsidas Bhanot Publishers, 2007).

5 *Guidelines for Quarantine Facilities* (Government of India), https://www.mohfw.gov.in/pdf/90542653311584546120quartineguidelines.pdf (last visited Nov. 23, 2021).

which generations of the past and future are yet to canvass.[6]

The Epidemic Diseases Act, 1897:

Drafted with the intention of channelizing governmental bodies and state efforts when there is a significant danger of a scourge infection, the aim of the Epidemic Diseases Act, 1897was not to be used as a code for building an overall public health framework. The arrangement of the provisions under the Act comprises of four areas which gives broad powers to the public authority. It empowers the state governments to manage the spread of dangerous 'epidemic' diseases, although the term has not been defined under the Act. Non-compliance with any rule or order made under this Act is punishable under the Indian Penal Code, while public officials performing their duties under the Act enjoy immunity from liability for performing their duties under the Act[7].

The Epidemic Diseases Act, 1897 is the guide to what is and what is not a "genuine" emergency, as it is within its ambit that the government must anticipate and prevent the spread of any epidemic disease. It is difficult to draft explicit and elaborate guidelines for a novel disease in the parent Act itself. Therefore, the law allows the state to draft guidelines and carry out its duties under the Act in accordance with the emergent needs of the times. However, it is necessary to throw light at the discrepancies of the Act, especially when the state's lack of preparedness in dealing withtheCOVID-19 pandemic is still palpable. First, the Epidemic Diseases Act, 1897 fails to define "epidemic" which leads to ambiguity about the objective and scope of application of the Act. Second, the Act provides punishment for disobedience of the rules and orders passed under it under Section 188 IPC, which leaves gaps in interpretation if one considers its wide scope[8]. Third, the Act allows the government to invoke its provisions whenever it is "satisfied."[9] Such vague and ambiguous words have resulted in misuse and ambiguity. Fourth, the Act was drafted pre-independence and fails

6 IDSP official website, https://idsp.nic.in/index4.php?lang=1&level=0&linkid=313&lid=1592 (last visited Nov. 25, 2021).

7 The Epidemic Diseases Act, 1897.

8 The Epidemic Diseases Act, 1897,§ 3.

9 The Epidemic Diseases Act, 1897,§ 2(A).

to meet the requirements of the 21st Century, since there is no mention of laws for rail and airways, but only that of road and sea ways. Besides, protection for the health care service personnel had to be incorporated in the Act by way of an amendment in September 2020,when the COVID-19 pandemic was at its peak. Therefore, it would not be wrong to contend that in a globalized world, the age-old colonial law has failed to stand the test of time.

Pandemic and the authority of the states

Most Indian states including Punjab, Haryana, Karnataka, Maharashtra, Sikkim, Odisha and Union Territories of Dadra and Nagar Haveli and Diu Daman had summoned their response teams under the Epidemic Disease Act, 1897 since they have no separate legislations for Public Health. The Act, thus, empowered them to attempt Non-Pharmaceutical Interventions (NPIs) to treat the spread of the disease in the absence of medication through the imposition of lockdowns and detentions. The Act authorizes the State to appoint public officers to keep a track of quarantines and admit an exposed or vulnerable person to institutional quarantine facilities.[10] While every statutory body and authority would act in accordance with the laws and guidelines issued by the government, it had to ensure that there is no violation of personal rights guaranteed under the Indian Constitution during emergencies.

In the Puttaswamy[11]judgment, the Court had crafted four tests to restrict the vigilance of the State governments under the blanket of national security which include any activity endorsed by law: the activity must be a genuine issue, degree of such impedance should be proportionate to the requirement for such obstruction, and there should be procedural guarantee against maltreatment of such obstruction.

In this respect, the Disaster Management Act, 2005 is an authentic example of

10 MINISTRY OF HOME AFFAIRS ,Order No. 40-3/2020-DM-I(A), March 29, 2020, https://mhArticlegov.in/sites/default/files/MHA percent20Order percent20restricting percent20movementpercent20ofpercent20 migrants percent20andpercent 20 strictpercent 20enforementpercent 20 ofpercent20lockdownpercent20measurespercent20-percent2029.03.2020.pdf. (last visited Nov. 25, 2021).

11 Justice K. S. Puttaswamy (Retd) v. Union of India and ors. SC August 24, 2017.

the above-mentioned opinion. It separates the responsibilities of the Central and the State Governments under different services. Besides, Article 253 of the Indian Constitution permits the Central Government to implement a law that reflects the intentions and ideas of the International Health Regulations (IHR) which requires the Government to set up systems to forestall, control and ensure health management of the disease on a global level. Any such law when intended to be implemented in India, must be assessed, and approved by the Supreme Court of India[12].

USA:

The Public Health Service Act, 1944:

The Public Health Service Act, 1944 (PHS Act) shapes the establishment of the US Department of Health and Human Services (HHS's) lawful expertise for acting upon public health crises by approving its key moves. The functions of the PHS include leading all government health care and clinical actions, proclaiming epidemics, helping states in executing the laws, keeping up the Strategic National Stockpile (SNS) and controlling communicable diseases. The Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006[13]replaced the earlier PHS Act and was followed by the Pandemic and All-Hazards Reauthorization Act (PAHPRA) of 2013. Issuing declarations under the Robert T. Stafford Disaster Relief and Emergency Assistance Act 1988, the President may proclaim a crisis with the concurrence of the Governor of the respective state, or a Chieftain of an affected Tribe.

The Public Health Secretary may, under Section 319 of the PHS Act confirm that an illness or epidemic presents a mass health crisis, including critical flare-ups of the disease or biological war, in any existing case. Following Section 319 affirmation, the Secretary can make numerous moves during a pandemic-including delivering orders; signing treaties and agreements; leading and supporting research concerning the reason, treatment, or anticipation of the

12 Vellore Citizens Welfare Forum v Union of India AIR 1996 SC 2115 (precautionary principle) Vishakha v State of Rajasthan AIR 1997 SC 311 (CEDAW).

13 Public Health Service Act U.S. Food and Drug Administration.

disease; adjusting certain medical care, aids, and insurances. These waivers or changes are allowed under Section 1135 of the Social Security Act, 1935 to guarantee that adequate medical care things and administrations are accessible during a general wellbeing crisis.

Under the Public Health Service Act, the Health and Human Services' Secretary is authorized to provide immunity to cases of loss emerging out of, associated with, or coming about because of countermeasures dictated by the Secretary during the pandemic, except in cases where the Secretary himself is found to be indulging in wilful wrongdoing.

The Federal Food, Drug, and Cosmetic Act, 1938 (FD&C):

The Federal Food, Drug, and Cosmetic (FD&C) Act provides for the establishment of the Food and Drug Administration (FDA). The role of the FDA includes advancing the general wellbeing of the people in addition to guaranteeing the security and viability of human and medical facilities, and ensuring the wellbeing and security of the country's food supply. Section 564 of the FD&C Act, approves the HHS Secretary to proclaim a crisis advocating the Emergency Use Approval (EUA) of Medical Counter Measures (MCMs) during epidemics.[14]Emergency Use Approval (EUA) declaration models are verified and when logical proof is accessible, they are implemented during a crisis.[15]Under Section 361 of the PHS Act, the Secretary is empowered to take measures to forestall the cross-border transmit-ability of the pandemic into the US and between States.

The U.S. federal structure is such that a major portion of the responsibilities and decision-making is left in the hands of local bodies and states. There was evident disparity amongst the authorities besides lack of a coordinated approach in implementing the public policies. This could have led to a sudden and exponential rise in the cases from May 2020. Considering the decentralized

14 Authorizations and Revocation of Emergency Use of Drugs During the COVID-19 Pandemic https://www.fdArticlegov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization(last visited Nov. 25, 2021).

15 *Id.*

nature of the US government, it can further be concluded that any form of leadership during such national emergency would find it difficult to contain the spread, which heavily depends on the cordial Centre-state relations and channelized decision-making and implementation of the same.

When the pandemic began exposing the vulnerabilities of the US, a federal country with an advanced healthcare system which should be capable of withstanding such an event, it took on a more serious tone. In the US, political commentators began to advocate for an inflexible dual federal system, in which health is solely the responsibility of states and local governments[16]. Observers compared the United States' early experience to China's quick response in Wuhan as proof of the effectiveness of a centralized response.

Italy

On March 11, 2020, the Italian Government issued the Decree of the President of the Council of Ministers[17]endorsing critical measures to contain the disease from the COVID-19 infection. The proclamation of the decree involved the prompt call to the Provincial Committees for public concerns and security for acceptance of the planning measures (Article 1). The Decree prohibited social gatherings of individuals in places open to the public all through the public region (Article 1(2)); suspension of all games in 2020 (Article 1(1)(d)); explicit travel bans to Italy for people from other nations (Article 2); self-affidavit of evidence of reasonable purpose of travel to be provided by travellers (Article 2(e)); controls on travel to pilgrimages in Venice(Article 2(f));

Further, the Decree listed the measures to contain the virus in the districts of Lombardy and the areas of Piacenza, Reggio nell 'Emilia, Alessandria, Asti, Novara, Verbano-Cusio-Ossola, Vercelli, Padova, Modena, Parma Treviso, Rimini, Pesaro and Urbino, and Venezia which included directions as follows:

16 Jennifer Selin, *How the Constitution's federalist framework is being tested by COVID-19*, Brookings, (Jun. 8, 2020),https://www.brookings.edu/blog/fixgov/2020/06/08/how-the-constitutions-federalist-framework-is-being-tested-by-COVID-19/

17 'Decree By the Presidency of The Council of Ministers' Associazione Nazionale Filiera Industria Automobilistica, March 11, 2020.

Boycotting the section of major footfall, with the exception of demonstrated reasons identified with work, wellbeing, or need (Article 1(1)(a));

Closure of school, universities and exams of any type, including advanced education establishments (Article 1(1)(h));

Granting business exercises depending on the prerequisite that the heads ensure no evasions of the safety-measures (Article 1(1)(o));

Isolating people who have come in close contact with patients who have tested positive (Article 1(2)(h)).

Despite such a stringent pandemic-control policy, Italy witnessed the loss of several lives, the economy and public trust. The measures were taken to keep the pandemic under control. However, it is contended that the timing of implementation and relaxation of the measures amidst the lockdowns did not match the severity of the waves and thus, resulted in loss of lives, lack of hospital and ICU beds, financial burden on the economy and halt in supply of resources. An empirical analysis of long-term effects of the pandemic is essential to get a better understanding of the policies and their implementation.

In Italy, the regional governments are responsible for healthcare, which has resulted in the establishment of disparate regional "welfare regimes "and fragmentation of social policies".[18] Professor Giliberto Capano noted, "in the case of the COVID-19 pandemic, the regional institutional arrangements of the Italian state emerged as a key dimension affecting the nature of the government response" with "key activities organized very differently from region to region."[19]Regional politics in Italy was less combative than in other EU countries, but it was nevertheless fractured. This, along with a regionalized health system, resulted in a variety of regional responses to the epidemic, each with its own set of effects and results.

18 Vampa Davide, The regional politics of welfare in Italy, Spain and Great Britain, (Palgrave Macmillan, 2016).

19 Capano Gilberto, *Policy design and state capacity in the COVID-19 emergency in Italy: If you are not prepared for the (un)expected, you can be only what you already ar*e, 39(3) POLICY AND SOCIETY, 326–344(2020).

COVID-19 has reinforced that pre-existing territorial fragmentation in a setting of "poor centralization" and the absence of coordinating mechanisms encourages "policy dispersion."[20]Studying the COVID-19 management of the three countries makes it evident that the directives and actions of most of the countries to tackle the alarming rise in COVID-19 cases was abrupt and fragmented, with the prolonged lockdown putting a strain on economic activities. Human rights' violations, which can lead to psychological anguish, were rampant, with the marginalized groups more susceptible to its negative effects.

Responses to COVID-19 Pandemic and Violation of Human Rights

Right to Health:

Although the Directive Principles of State Policies[21] mentions about the Right to Health and its promotion, critical responses to such emergencies should not come at the cost of loss of human rights. COVID-19, as lethal as it has proved to be, must be taken as a warning for future emergencies and therefore, India must build a robust policy to promote resilience. Right to health is not a fundamental right but serious thought must be given to include it within the ambit of fundamental rights.

Both India and Italy experienced acute shortage of medical supplies including COVID testing kits and Personal Protective Equipment (PPE), necessary to curtail the spread of the virus. A few reports attribute the unavailability of the PPEs as the major cause for the spread of the coronavirus among the health-care workers[22].Accordingly, providing fundamental safety gears and equipment to medical professionals is a commitment that state governments must fulfil.

20 Vampa Davide, *The Territorial Politics of Coronavirus: is this the hour of Central Government?*, Democratic Audit, (April 15, 2020) https://www.democraticaudit.com/2020/04/15/the-territorial-politics-of-coronavirus-is-this-the-hour-of-central-government/.

21 INDIAN CONST .a rt. e 39E, 42, 47 and 243G.

22 *Shortage of personal protective equipment endangering health workers worldwide,* World Health Organization, (Mar. 3, 2020) https://www.who.int/news/item/03-03-2020-shortage-of-personal-protective-equipment-endangering-health-workers-worldwide.

Right to Privacy

In order to control the spread of COVID-19, a few state governments divulged information pertaining to individuals who had been quarantined. This information included names, details of government IDs, locations and phone numbers. In India, the AarogyaSetu Application was projected as a critical tool by the Central Government in arresting the spread of the virus. The application records information of the user's health status and further, uses it to track their updates and movements. The application informs users about the presence of COVID positive patients in their vicinity. Questions have been raised about the threat to an individual's privacy by the use of the AarogyaSetu Application. As of now, the use of the application has been completely wilful, however, numerous institutions including means of public transport like airlines have directed the use of the application for availing their services. To forestall the abuse of private information of citizens, the Central and State Governments should take all measures to protect the privacy.[23]

In the US, the emergence of "contact-tracing" applications rose swiftly after the ever-rising cases seemed unmanageable. Several states took the assistance of tech-giants like Google and Apple to track individuals and retain their data to curb the spread of the virus. The US government ordered gathering personal data for the purpose of tracking persons who had contracted the virus.[24]The very idea of making a choice between tackling a crisis and protecting the personal and/or fundamental rights of citizens is the basic responsibility of the state. As per the GDPR laws, European Data Protection Board permits collection of data; personal or general, related to health and exposure, while ensuring that personal and fundamental rights are not violated.[25]

23 Tanisha Ranjit, *AarogyaSetu: Mandatory or not,* Internetdemocracy.in (Apr. 22, 2021) https://internetdemocracy.in/2021/04/aarogya-setu-mandatory-or-not-we-traced-it-for-ten-months-through-our-tracker.

24 Alex Hern, *Experts warn of privacy risks as US uses GPS to fight coronavirus spread,* The Guardian, (Apr. 2, 2021) https://www.theguardian.com/technology/2020/apr/02/experts-warn-of-privacy-risk-as-us-uses-gps-to-fight-coronavirus-spread.)

25 *Guidelines on the use of location data and contact tracing tools in the context of the COVID-19 outbreak* (European Data Protection Board 2020)*https://edpb.europa.eu/sites/default/files/files/file1/edpb_guidelines_20200420_contact_tracing_COVID_with_annex_en.pdf*(last visited Nov. 27, 2021).

Responses to COVID-19 Pandemic and The Economy

Effects of the Pandemic Laws of respective countries on their GDPs:

The UN had cautioned that COVID-19 would have a chronic effect on world economy. Additionally, the United Nations Economic and Social Survey of Asia and the Pacific (UNESCAP) 2020 had predicted that the COVID-19 pandemic would have financial repercussions in the areas of travel industry, migration of labourers, trade and economic relations and development. The Economic Survey 2019–2020[26]had predicted the GDP of 2019-20 in India at 5 percent, as against 6.8 percent in 2018–2019. Goldman Sachs predicted India's GDP at 1.6 percent due to the 21-day lockdown.[27] In India, hospitality, tourism, and real estate were the worst-hit sectors. However, industries like e-leaning industry, pharmaceuticals and insurance have boomed.

United States ordered relief aid to the tune of $2.2 trillion under the Coronavirus Aid, Relief, and Economic Security Act (CARES) on March 18, 2020. The Congressional Budget Office (CBO) assessed that the monetary deficit for 2020 would rise to $3.3 trillion a figure that is triple the amount in 2019,highest deficit since 1945[28]. The CBO additionally predicted that the debt owed by the people would increase to 98 percent GDP in 2020, as against 79 percent in 2019 and 35 percent in 2007 paving way for the Great Recession.

There was a tremendous fall in the population-employment ratio in mid-2020 which declined from 63 percent to 51 percent. The calculations of the population were done as per 9.9/100 individual, which distorted the employment bubble, wherein it was presumed that more people were employed,

26 INDIAN BUDGET ECONOMIC SURVEY (2020) https://www.indiabudget.gov.in/budget2020-21/economicsurvey/doc/vol1chapter/echap10_Vol1.pdf (last visited Nov. 27, 2021).

27 Goldman Sachs, *Revised global growth forecast for 2020 to -2% and that of US to -6%,* Economic Times, (Apr. 9, 2020) https://economictimes.indiatimes.com/markets/expert-view/goldman-sachs-revised-global-growth-forecast-for-2020-to-2-and-that-of-us-to-6-prachi-mishra/articleshow/75065449.cms).

28 CONGRESSIONAL BUDGET OFFICE REPORT (2020), https://www.cbo.gov/publication/57170(last visited Nov. 27, 2021).

which in fact, was not the reality.[29] It is presumed[30] that the high mortality in the US was an indirect consequence of the economic slump. The far-reaching effects of the economy on social, financial, and administrative mechanisms and their nexus must be studied and steps must be taken to ensure their balanced interdependency.

The Italian National Institute of Statistics (ISTAT) reported that in the first quarter of 2020, the GDP of Italy had dropped by 4.7 percent compared to the past quarters, and by 4.8 percent over the same quarter of the past year. The lockdown in Italy negatively affected the Italian exchange. In Italy, by far most of the organizations are small and medium enterprises (SME), that may have less versatility and adaptability in managing and sustaining the costs during emergencies. As on March 22, 2020, with the shutting down of all vital sectors, an expected 7.8 million skilled workers were temporarily unemployment or were laid-off. Italy has sustained a debt of 134 percent of its GDP even before the outbreak of the pandemic. The European Union does not entertain countries with a debt higher than 60 percent of their GDP.[31] EU would certainly be affected due to the economic slowdown in Italy and labourers are bound to be informally employed or engaged in low-paying labour contracts.

Conclusion

COVID-19 has affected countries worldwide on a massive scale. The national and international lockdowns, particularly, have impacted social life and the economy and the multi-sectoral effect of the pandemic is clearly discernible. What is surprising and significant to note is that despite apprehensions raised by the World Health Organization (WHO) in 2019 about the shortcomings of the nations in battling a worldwide pandemic, cognizance of it was taken

29 Victoria Udalova, *Pandemic impact on mortality and economy varies across age groups and geographies*, (United States Census Bureau, March 8, 2021) https://www.census.gov/library/stories/2021/03/initial-impact-COVID-19-on-united-states-economy-more-widespread-than-on-mortality.html.

30 *Id*.

31 Silvia Amaro, *Italy vows to implement 'a massive shock therapy' against the coronavirus*, CNBC, (Mar. 9, 2020) https://www.cnbc.com/2020/03/09/italy-wants-more-public-spending-to-fight-coronavirus-amid-lockdown.html.

by developed as well as developing countries. A 2019 joint report from the WHO and the World Bank assessed the effect of a powerful pandemic at 2.2 percent to 4.8 percent of worldwide GDP. In another report *COVID-19 and the world of work: Impact and policy response*[32] by the International Labour Organization, it was clarified that the emergency has now changed into an economic and employment crisis, affecting not just stockpile (creation of products and enterprises), but also the demand graph (utility, consumption and investment). India is also burdened because of the pandemic and financial experts are quantifying the expense of the COVID-19 lockdown at US$120 billion or 4 percent of the Indian GDP[33]. The pandemic has impacted the manufacturing, production as well as the service sector.

While a federalist public health system might respond appropriately to a pandemic, this would necessitate the development of a set of concrete federal pandemic response rules that avoid any conflict between state and central policies. First, 'stay-at-home' orders should be imposed, backed by data-driven research vis-a-vis number of positive cases, transmission rates and positivity rates of bordering states. These findings put together should prompt states to impose lockdown measures. Second, with precise, data-driven allocation standards, the distribution of medical supplies and equipment should be systematized. An emergency helpline channel or Ministry could create a simple application gateway for states to request supplies, allowing for more effective mapping of needs and responses. Third, data collection for epidemics should be standardized[34]. Finally, assistance is desperately needed for under-staffed and resource deficit hospitals, particularly in rural areas. While giving out direct monetary endowments might act as a quick fix, expanding the insurance coverage is essential. These proposals maintain federalist flexibility by permitting

32 *COVID-19 and the world of work: Impact and policy response*, (International Labour Organization, March 18, 2020) https://www.ilo.org/wcmsp5/groups/public/---dgreports/---dcomm/documents/briefingnote/wcms_738753.pdf.

33 *India's economy is ailing from more than COVID-19,* Economic Times (Jun.26, 2020) https://economictimes.indiatimes.com/news/economy/indicators/view-indias-economy-is-ailing-from-more-than-COVID-19/articleshow/76637162.cms.

34 Greenleaf, Abigail R et al, *Building the Evidence Base for Remote Data Collection in Low- and Middle-Income Countries: Comparing Reliability and Accuracy Across Survey Modalities*, 19 JOURNAL OF MEDICAL INTERNET RESEARCH (2017).

states to go above a federally mandated minimum standard. Furthermore, the majority of these measures do not necessitate legislative action. However, putting these changes in place will necessitate increased coordination and cooperation at all levels of government. International cooperation, as well as domestic coordination at levels of the government, are vital for addressing international, regional, and local socio-economic concerns and long-term recovery from the pandemic. A study of comparative law to decide upon an appropriate working model of how to uplift the nations with appropriate study of data available, shall definitely be an instrumental move in recovering from the great depression of the COVID-19 pandemic.

7

Impact of COVID-19 and Right to Healthcare: The Legal Dimensions of Public Health Issues in India

Azim Hussain Mazumdar[*]

Abstract

The right to healthcare is fundamental since it enables an individual to enjoy all the other rights. It focuses on the nexus between the health of people and the constitutional commitments towards health and well-being of people. The Constitution of India has made a strong appeal to the state to have a fair standard of living through the insertion of Directive Principles of State Policy. The outbreak of COVID-19 in 2020 and the second wave in 2021 revealed the true picture of India's healthcare system. This pandemic has opened the eyes of people and rekindled the debate of framing a comprehensive law ensuring the right to healthcare. It is believed that a properly structured right to health could enable the judiciary to take a closer look at policy measures and can push the policymakers towards fulfilling the commitment of universal healthcare. The issues of public health vis-a-vis the constitution and the existing laws on the subject have been discussed in this article. The need for adopting a comprehensive legal framework that provides access to health as a legislatively assured right has been emphasized upon.

Key words: *COVID-19, public health, right to health, law, the Constitution of India.*

Introduction

Good health is one of the basic human necessities globally recognized as a prerequisite for fostering socio-economic development. Health does not mean mere absence of diseases rather it is a complete mental, physical and social well-

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being of a person. The World Health Organization defines health as *"a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."*[1] The Declaration of Alma Ata identifies health as a fundamental right. The fulfilment of highest level of health is important as good health confers a person freedom from illness and thus gives the ability to realize one's potential.[2] Healthcare is an indispensable basis for defining a person's sense of well-being. The outbreak of the COVID-19 pandemic has shaken the healthcare service and public health systems in India. It is often said that this pandemic has led to the collapse of our healthcare system but looking at the healthcare scenario in India, it can be said that the pandemic has exposed our poor and inadequate healthcare system.[3] The impact of COVID-19 on people's socio-economic well-being has been considerable. This unprecedented pandemic has even taken a toll on states like Kerala and Tamil Nadu that have usually fared well in the healthcare sector in comparison to the other parts of the country.[4]

While one can argue that no country in the world was fully prepared to handle such a health crisis but death due to a lack of oxygen, lack of treatment and inadequate healthcare services is unjustifiable and unacceptable. Thousands of adults, children and senior citizens lost their lives because of poor and inadequate healthcare system. Amidst this crisis when the death toll reached 388,164 as per official data[5], concerns were raised as to the genuineness of the number of reported positive cases and deaths due to COVID-19. Experts have raised questions about data manipulation that has thwarted efforts in ascertaining the real impact of the pandemic which has negatively affected the fight against

1 WORLD HEALTH ORGANIZATION, 1948, S 3.

2 Declaration of Alma-Ata was adopted by the World Health Organization (WHO) at the International Conference on Primary Health Care, Almaty, Kazakhstan (formerly Alma Ata of KazakhSoviet Socialist Republic, 6–12 September 1978.

3 Shahid Akhter, *COVID-19 has exposed the basic problems plaguing the Indian healthcare: Dr Ramakanta Panda, Asian Heart Institute,* The Economic Times, (Oct., 24 2020) https://health.economictimes.indiatimes.com/news/industry/COVID-19-has-exposed-the-fundamental-problems-plaguing-the-indian-healthcare-systemdr-ramakanta-panda-md-vice-chairman-asian-heart-institute/78839260.

4 *Explained: The 5 states with 68% of India's active cases, and challenge they face,* The Indian Express, (Apr, 20, 2021) https://indianexpress.com/article/explained/explained-why-five-states-account-for-over-68-of-indias-active-COVID-cases-now-7271801/.

5 *See* Worldometer COVID-19Data, June,21, 2021https://www.worldometers.info/coronavirus/country/india/.

COVID-19.[6] There have been discrepancies between official state tallies of deaths due to COVID-19 and actual numbers of bodies in crematoriums and burial grounds. In last few months, the heart-wrenching images from crematoriums and burial grounds got published in many international media houses.[7]Determining the exact numbers of deaths in a pandemic often proves to be difficult owing to several people dying at home whose deaths go unregistered.[8]

India's poor performance in tackling the pandemic has largely been blamed on the low expenditure on public health. India has never spent more than 2% of its GDP on healthcare[9]. The expenditure on public health in 2019-20 was 1.29% of the GDP which is lower than most other countries.[10] The healthcare facilities across the country function at different levels of efficacy and sufficiency. Some states have done well in providing healthcare facilities whereas others have failed to provide basic amenities. One of the reasons for this weak public healthcare system in India is the absence of a statutory framework that gives guarantee of a fundamental right to health. A comprehensive healthcare law appears quite necessary for India within whose legal framework this crisis could have been addressed with human rights principles of solidarity, proportionality, and transparency. Implementing the right to healthcare within the framework of co-operative federalism would enhance India's capabilities of fighting back the COVID-19 pandemic. This article aims to give a critical appraisal of India's healthcare laws, the significance of right to healthcare in the light of the constitution and how the outbreak of COVID-19 has forced citizens to rethink our existing laws.

6 *As death toll crosses two lakh mark, data manipulation lets down India's COVID fight,* The Indian Express, (Apr, 29, 2021) https://www.newindianexpress.com/nation/2021/apr/29/as-death-toll-crosses-two-lakh-mark-data-manipulation-lets-downindias-COVID-fight-2296099.html.

7 *Deaths climb as India reels from deadly COVID wave,* The BBC News, (Apr., 25, 2021) https://www.bbc.com/news/world-asia-india-56855712.

8 Upmanyu Trivedi, Sudhi Ranjan Sen, Bloomberg, *Even record death toll may hide extent of India's COVID crisis,* The Economic Times, (Apr, 23, 2021) https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/even-record-death-toll-may-hide-extent-of-indias-COVID-crisis/articleshow/82212594.cms?from=mdr.

9 PTI, *India's overall spending on health sector 'low', says Niti Aayog member,* The Hindu, (Nov, 19 2020) https://www.thehindu.com/news/national/indias-overall-spending-on-health-sector-low-says-niti-aayog-member/article33132569.ece.

10 Puja Mehra, *India's economy needs big dose of health spending,* The Live-Mint, (Apr., 8, 2020), https://www.livemint.com/news/india/india-s-economy-needs-big-dose-of-health-spending-11586365603651.html.

Healthcare Services and International Covenants

The Universal Declaration of Human Rights (UDHR, 1948) adopted by the United Nations is regarded as the first framework that outlines the scope of right to healthcare. Article 25 of UDHR refers to a standard of living that ensures health and prosperity of people including food, apparel, lodging, clinical consideration, important social services. It also speaks of the right to security in case of joblessness, ailment, incapacity, widowhood, mature age, or other absence of occupation in conditions outside human control.

The International Covenant on Economic, Social and Cultural Rights, 1966 (ICESCR)under Article 12 provides that the states should accord the right to physical and psychological wellness to everybody, and the means to accomplish the full acknowledgement of this privilege should incorporate the steps essential. The Declaration of Alma Ata 1978 has a wide scope that recognizes health as a state of complete mental, physical, and social well-being and not merely the absence of any infirmity or disease. This approach identifies health as a fundamental right and recognized the fact that the fulfilment of the highest level of health is important from a global perspective, whose comprehension demands the action of several socio-economic sectors along with healthcare as well. The Convention on the Elimination of All Forms of Discrimination against Women (CEDAW, 1979) requires the state parties to eliminate discrimination against women in all aspects of their healthcare including drug addiction and related problems. The Convention on the Rights of the Child (CRC, 1989) emphasizes the right of the child to enjoy the highest attainable standard of health. The International Health Regulations (IHR, 2005)has been a specific undertaking for international assistance in healthcare issues. The UN Convention on Rights of Persons with Disabilities (UNCRPD, 2008) requires the state parties to take all appropriate measures to ensure access for persons with disabilities to health services that are gender-sensitive, including health-related rehabilitation. The Declaration of Istanbul on Organ Trafficking and Transplant Tourism, 2008 prohibits all forms of transplant commercialism, which targets the vulnerable mostly.

Right to Healthcare Services and the Constitution of India

Law has always been instrumental in reforming a society. Law plays a significant and structural role in public health achievements. It creates specific frameworks to address the issues. Moreover, with the adoption of human rights, the right to health has been recognized as an inherent human right. The right to healthcare has been a progressive realization of it through codified constitutional and legal rights. The right to public health has been recognized as a fundamental right in many welfare states around the world. The Universal Declaration of Human Rights (UDHR, 1948) is regarded as the first international legal framework in outlining the scope of right to healthcare.[11]

The principle of socialism in a welfare state aims at all round development of the people including improvement of public health. The Preamble to the Constitution of India strives for a welfare state with a socialistic pattern of society. The right to health is a fundamental one as it enables an individual to enjoy all the other rights. Article 21 guarantees the right to life and personal liberty. The Directive Principles of State Policy (DPSP) explicitly speak on the health and well-being of people. Article 39(e) talks about the duty of the state towards the health of men, women and children who are working as laborers. Article 42 provides for just and humane conditions of work and maternity relief. It further provides that the State shall make provisions for securing just and humane conditions of work and for maternity relief. Article 47 imposes obligations on state to raise the level of nutrition and the standard of living and to improve public health. The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health among its primary duties and, in particular, the state shall endeavour to bring about prohibition of the consumption, except for medicinal purposes, of intoxicating drinks and of drugs which are injurious to health. Article 48 and 51A refer to the preservation and improvement of healthy environment which is crucial for the improvement of health of all living beings. However, since

11 Universal Declaration of Human Rights 1948, art. 25.

DPSPs are non-enforceable as declared under Article 37 and this has narrowed the scope for enforcing the DPSPs through judicial interventions although t these principles are fundament in the governance of the country and the state is duty bound to apply these principles while formulating laws.

The pandemic in India has been dealt within the purview of the Epidemic Diseases Act 1897 which was enacted by the colonial government to tackle the outbreak of bubonic plague (also known as Bombay Plague Epidemic). The bubonic plague led to the death of many people within a short period of time. Since independence, India has witnessed many other major health crises like outbreak of Cholera, Chikungunya, H5N1 Influenza, Nipah virus, and Japanese Encephalitis. In all these cases, the Epidemic Diseases Act 1897 was used repeatedly. This Act empowers both the Central and State Governments to take special measures and prescribe relevant regulations regarding the tacking of epidemic diseases.[12]

The Indian Judiciary regularly takes an active role in the governance of different crises as and when they emerge by entertaining Public Interest Litigations (PIL) under Articles 32 and 226 that authorize the courts to assess the socio economic and environmental situations of the downtrodden, underprivileged and disadvantages group of people. The Supreme Court has ruled in several cases that the right to health and medical treatment is a basic right protected under Article 21 since good health is necessarily required for a meaningful and purposeful life. The Supreme Court of India in *Bandhua Mukti Morcha* v. *Union of India (1984)*[13]interpreted that the right to health has been covered under right to life under Article 21 as there is no specific provision which clearly acknowledges the right to healthcare as a fundamental right. The Supreme Court reaffirmed in the case of *State of Punjab* v. *Mohinder Singh Chawla*

12 Section 2 of the Epidemic Diseases Act 1897 confers a discretionary power upon the state government to adopt temporary regulations to be observed by the public or by any person/ class of persons as it shall deem necessary to prevent the outbreak of such epidemic. The central government's power was however inserted by an amendment in 1920. According to section 2A of the act, the central government, concerned that any part or the entire country is threatened with an outbreak of an epidemic, may take measures and prescribe regulations. As per section 3 of the Act, anyone who violates the act shall be deemed to have committed an offense punishable under section 188 of the Indian Penal Code.

13 Bandhua Mukti Morcha v. Union of India, (1984) AIR 802, 1984 SCR (2) 67.

(1997)[14]that right to health is central to the right to life and the government has a constitutional duty to provide health services to its citizens. The court also went on to support the principle of state's duty to establish health facilities in the case of *State of Punjab & others* v. *Ram Lubhaya Bagga (1998).*[15]Also, the Supreme Court, in its land mark judgment in *Paramanand Katara* v. *Union of India &others(1989)*[16] ruled that *"every sector whether at a government hospital or otherwise has the professional obligation to extend his services with due expertise for protection life. No law or state action can intervene to avoid or delay the discharge of the paramount obligation cast upon members of the medical profession. The obligation being total, absolute, and paramount, laws or procedure whether in statutes or otherwise which would interfere with the discharge of this obligation cannot be sustained, and must, therefore give way."*

State Responsibility and The National Health Policy 2017

The socialistic principles embodied in the Part III and Part IV of the Constitution and several legal precedents over time have established that the government is responsible for healthcare of its people. The right to healthcare was conceived as an individual's civil right and states were made bound to provide minimum conditions enabling the citizens to enjoy this right with primary healthcare services. The Constitution of India does not specifically provide for the right to health care under any specific provision. However, there are multiple references in it with respect to public health and the state's responsibility to ensure healthy condition of the people. The Supreme Court in interpreting Article 21 (right to life and personal liberty) has added the right to healthcare as a fundamental right.[17] The 7th Schedule of the Constitution of India has enlisted public health as a state subject. However, there has been debate around shifting public health to concurrent list from state list since the enlistment of public health in the state

14 State of Punjab & Others v. Mohinder Singh Chawla, (1996) 113 PLR 499.

15 State of Punjab & othersv.Ram LubhayaBagga,1998 4 SCC 117.

16 Pramand Katara v. Union of India & others,(1989) AIR 2039, 1989 SCR (3) 997.

17 *See, State of Punjab & Others* v. Mohinder Singh Chawla,(1996) 113 PLR 499, The Apex Court reaffirmed that the right to health is fundamental to the right to life and should be put on record that the government had a constitutional obligation to provide health services.

list has given a lot of discretionary power to the state governments to adopt, enact and enforce public health related laws.

To make healthcare as an "assured service" for the citizens and to address the current and emerging challenges arising from the ever-changing socio-economic, technological, and epidemiological scenarios, the Ministry of Health and Family Welfare issued the National Health Policy in 2017. Before that, the National Health Policy of 1983 and subsequently the National Health Policy of 2002 have served well in guiding the approach for the health sector in the Five-Year Plans. The Health Policy 2017 proposes free drugs, free diagnostics and free emergency and essential health care services in all public hospitals in a bid to provide access and financial protection.[18]The National Health Policy 2017 provides for a comprehensive primary healthcare system through the "Heath and Wellness Centers" and represents an important change from a very selective to comprehensive primary healthcare package which includes care for major non-communicable diseases, mental health, geriatric healthcare, palliative care and rehabilitative care services. The Policy assures two beds per 1000 population which are to be distributed in such a way that enable access to hospital beds within the golden hour that is the period after the traumatic injury when the victim is most likely to benefit it. Additionally, it also provides for increased accountability of the healthcare sector by envisaging effective grievance redressal mechanisms with the involvement of local bodies and encouraging community monitoring and evaluation of programmes. The policy proposes raising public health expenditure to 2.5 per cent of the GDP in a time-bound manner. It intends to increase life expectancy at birth from 67.5 to 70 by 2025 and reduce infant mortality rate to 28 by 2019. It also aims to reduce "under five" mortality to 23 by the year 2025.[19]

18 *What is National Health Policy 2017: Everything you need to know,* The Indian Express, (Mar., 22, 2017) https://indianexpress.com/article/what-is/what-is-national-health-policy-2017-4574585/.

19 *Id.*

Laws Related to Public Health And Epidemic Diseases in India: An Overview

Laws and policies affect almost every aspect of human life. There are several legislations in India that pertain to the sector of healthcare in India. Specific legislations help a state to address a particular issue more conveniently. Outbreak of epidemic or infectious diseases leads to large scale death of people and can also result in a pandemic. Legislative measures become necessary to tackle such crisis. Legislative framework for handling health crisis in India has its root in the colonial legislations. Regarding the vaccination policy of the country the Vaccination Act, 1880 was enacted. The Act aimed at prohibition of inoculation and to make the vaccination of children compulsory in certain municipalities and cantonments. The Epidemic Diseases Act, 1897 was enacted to formulate better framework to prevent the spread of dangerous epidemic diseases. This Act was enacted to tackle the outbreak bubonic plague (also known as Bombay Plague Epidemic) at that time. The Live-Stock Importation Act, 1898 primarily aims regulating the importation of livestock and livestock products which are likely to be affected by infectious and contagious disorders. This Act under Section 4 empowers the government to make rules for the detention, inspection, disinfection, or destruction of imported livestock. The Indian Ports Act, 1908under Section 6 empowers the government to make rules for the prevention of danger arising to the public health. It authorizes the government to prevent the introduction and the spread of any infectious or contagious disease from vessels arriving at or being in any port.

The Drugs and Cosmetics Act, 1940 under section 26B empowers the government to regulate, restrict, or manufacture drugs in public interest. The Act provides that if the government is satisfied that a drug is essential to meet the requirements of an emergency arising due to epidemic or natural calamities and that in the public interest, it is necessary or expedient so to do, then, that government may, by notification in the Official Gazette, regulate or restrict the manufacture, sale or distribution of such drug. The Integrated Disease Surveillance Project (IDSP, 2004) has been a surveillance project under the Ministry of Health and Family Welfare of the Government of India.

The prime objective of IDSP was to strengthen and maintain a decentralized laboratory-based IT enabled disease surveillance system for epidemic prone diseases to monitor disease trends and to detect and respond to outbreaks in early rising phases through a trained Rapid Response Team. Initially, the project was launched aiming 2010 as its target year. However later it was further restructured, and the time period was extended. The project mainly focuses on capacity building, data management and surveillance system with application of Information and Communication Technology.

There are number of other laws which cover areas like qualifications and conduct of medical professionals, manufacture, distribution supply and sale of drugs, chemicals, tobacco, blood and blood products and prevent misuse of all these, women empowerment and health issues, child protection, protection of old persons, protection to person with disability, welfare and rehabilitation of disadvantaged people. Moreover, there are quite a few state legislations in India addressing the issues of public health. The Madras Public Health Act, 1939 under Section 81 empowers the government to make such rules as they deem fit for the treatment of persons affected with any epidemic disease and for preventing the spread of such disease. It also has a clause on infectious diseases that are transmissible through animals under Section 61.The Cochin Public Health Act, 1955 empowers the government under Section 86 to make rules as they deem fit for the treatment of persons affected with any epidemic, endemic or any other infectious disease. The Goa, Daman and Diu Public Health Act, 1985 was also enacted to address the issues of epidemic or infectious diseases.

In 2020, with the outbreak of COVID-19 in India, a few Indian states adopted regulations in furtherance to the Epidemic Diseases Act 1897, which are quite similar to each other. The West Bengal Epidemic Disease COVID-19 Regulations, 2020 mandates all government and private hospitals for the screening of suspected COVID-19 cases in the state. The imposition of social distancing, wearing of masks in public places, declaring certain areas as containment zone, quarantining infected as well as suspected persons etc. have been done under this regulation. Similarly, the Maharashtra Regulations for Prevention and Containment of Coronavirus Disease, 2020, the State Integrated

Disease Surveillance Unit under IDSP, 2004 and the District Collectors were entrusted with certain duties and obligations to combat COVID-19 disease. The Municipal Commissioner was also made competent to implement containment measures in the state. The Delhi Corona-virus Regulations,2020 also empowers the surveillance personnel to enter any premises to trace and detect COVID-19 cases and such entry has been declared lawful under the regulation. Besides, there were other states which framed regulatory guidelines in addressing the deadly pandemic of COVID-19. The Central Government has also taken recourse to Disaster Management Act, 2005 and declared the COVID-19 as a notified disaster.

The Outbreak of COVID-19 and Healthcare Issues in India

The ongoing COVID-19 pandemic has shattered the public health infrastructure in many countries. India is one of the worst victims of this pandemic. Although there have been several initiatives taken by the Centre and the state governments who have adopted an integrated approach in fighting the pandemic, still the country has witnessed huge shortage of oxygen supply, hospital beds, intensive care unit facilities and other essential medicines. The crisis that the pandemic has created is unprecedented in India.

The state governments were authorized to appropriately deal with the second wave of COVID-19 in 2021 including issues like movement restrictions, mandatory institutional quarantine, and imposing criminal liability on those who do not follow the rules. The government also imposed fines on the people who were on the streets without masks and those who violated other COVID-19 protocols. However, it is ironical that despites these restrictions and protocols, there was no check on the government policies for the production of oxygen, availing of medicines and providing proper healthcare to the patients and frontline workers.[20]

20 Karan Tripathi, *COVID Deaths: Are Governments Criminally Liable for Mass Misery?,* The Quint, (May 10, 2021) https://www.thequint.com/news/law/holding-government-criminally-liable-for-COVID-mass-misery.

Since the beginning of this pandemic in 2020, unavailability of necessary items like PPE kits, masks, hand sanitizers etc. for the doctors and other frontline health workers has repeatedly been brought to everyone's attention. Despite the claims by the government that all the necessary requirements to the frontline workers have been provided, the reports and personal interviews of the persons engaged in the service have put forth a different story.[21]The healthcare infrastructure did not improve much in 2021 with the outbreak of 2nd phase in comparison to the situation of 1st wave. There were reports on lack of slots in crematoriums in various states leading the COVID-19 victims' relatives to take dire measures to bury or cremate their dead bodies. There were also shocking reports of dead bodies being carried to crematoriums in garbage vans and street dogs eating flesh from dead bodies in burial grounds and dead bodies of suspectedCOVID-19 patients found floating in the Ganga in different parts of Uttar Pradesh and Bihar.[22]

Judicial interventions against the mismanagement in handling the COVID-19 crisis

The Allahabad High Court while hearing a PIL observed that death of COVID-19 patients owing to the non-availability of oxygen in hospitals is a criminal act and is nothing less than a genocide and the judges directed the government to take immediate remedial measures.[23]A petition had been filed before the Supreme Court, requesting for its intervention in the case where about 100 bodies found floating in the Ganga, all of whom were suspected of having died due COVID-19. The petition requested that a Special Investigating Agency be established to investigate the death of 100 people whose bodies were found floating in the Ganga in Buxar, Bihar, and Ghazipur and Unnao, Uttar

21 Sautik Biswas, *COVID-19: How India failed to prevent a deadly second wave,* BBC News, (Apr, 19, 2021) https://www.bbc.com/news/world-asia-india-56771766.

22 Geeta Pandey, *COVID-19: India's holiest river is swollen with bodies,* BBC News, (May 19, 2021), https://www.bbc.com/news/world-asia-india-57154564.

23 *Death of COVID patients for non-supply of oxygen criminal act, not less than genocide: Allahabad High Court,* The Economic Times, (May 05, 2021),https://economictimes.indiatimes.com/news/india/death-of-COVID-patients-for-non-supply-of-oxygen-criminal-act-not-less-than-genocide-allahabad-hc/articleshow/82397585.cms?from=mdr.

Pradesh.[24] The petition requested the Supreme Court to establish a Special Investigating Agency, which would be led by a sitting or retired judge of the Hon'ble Court, to oversee the investigation. The plea read as follows - *"It is clear and apparent that the person whose dead bodies floated has not died their natural death. The Administration in order to hide /save their face from the responsibility of such inhuman act has prepared false verbatim Post-mortem without actually doing the Post Mortem of dead bodies. The petitioner makes this statement very responsibly and on personal information received to the petitioner from the reliable sources."*

The Madras High Court ordered the State Government to issue an advisory to all local bodies instructing them to sanitize and spray disinfectant in areas within their jurisdiction to the farthest extent possible, and to equip the ESI hospitals with the necessary facilities to treat COVID patients.[25] The Judiciary has also intervened in the issue of non-availability of COVID-19 vaccine and has asked the state machinery to ensure that both doses under the vaccination program are completed. The Karnataka High Court ruled that failing to administer a second dose of COVID-19 vaccine would be a breach of Article 21 of the Constitution's right to life. The Court in its order said *"Once a dose is due it is the obligation of the state government to provide the second dose. If a second dose is not provided, it will be a violation of fundamental rights of citizen under Article 21."*

An Inclusive Public Health Law - The Need of The Hour

The public health service sector in India has been largely understaffed and under-resourced. Many experts are of the opinion that the COVID-19 crisis has not brought about the collapse of our health care system; rather it has exposed how poor the system has been. Looking at the state expenditure on health

24 *Plea in Supreme Court seeks direction for removal of bodies found floating in river Ganga*, The Hindu, (Jun, 2, 2021) https://www.thehindu.com/news/national/plea-in-supreme-court-seeks-direction-for-removal-of-bodies-found-floating-in-river-ganga/article34706251.ece.

25 Sparsh Upadhyay, *COVID 19- Issue Advisory To Local Bodies To Sanitise, Spray Disinfectants; Prepare ESI Hospital To Treat COVID Patients: Madras High Court,* The Live Law, (May 14, 2021) https://www.livelaw.in/news-updates/madras-high-court-COVID19-issue-advisory-to-local-bodies-to-sanitise-spray-disinfectant-174147.

service, India has never spent more than 2% of its GDP on healthcare.[26]There are legislations and other initiatives which have their relevance to the issue of public health and state responsibility, but they seem inadequate and have largely failed to address the issue of equitable access to public healthcare service. Considering the absence of a rationally structured legislation the Central Government advised the states to invoke the Epidemic Diseases Act, 1897 to handle the COVID-19 crisis in March 2020. There is no comprehensive legal measure to tackle this deadly disease. The state machinery both in the Centre and in the states are trying to mitigate the issues with by issuing different administrative orders under the Epidemic Diseases Act, 1897 and the Disaster Management Act, 2005.

To address the issue of public healthcare and the constitutional commitments towards health and well-being of the people the Central Government attempted to bring in some comprehensive legislation at different times in the past. In 1955 and 1987 the Government developed Public Health Act but the initiatives did not get the desired support from the states.[27] In 2009, the Government took a landmark decision when it decided to introduce the National Health Bill aiming to establish a comprehensive legal structure by including essential public safety program and obligations in public health emergency through a successful collaboration between the centre and the states.[28] But even after 10 years of its introduction, it has failed to be enacted. Along with many other reasons, the absence of a political will has been cited as the prime reason behind it. This Bill recognizes health as a fundamental right and states that every citizen has a right to the highest attainable standard of health and well-being. In 2017, the Government of India put the draft of the Public Health (Prevention, Control and Management of Epidemics, Bioterrorism and Disasters) Bill in the public

26 Dibyendu Mondal, *India spends just 1.26% of GDP on public healthcare,* The Sunday Guardian, (Jan, 2, 2021) https://www.sundayguardianlive.com/news/india-spends-just-1-26-gdp-public-healthcare.

27 EH News Bureau, *Why this is the right time for a Public Health Bill-2020 in India,* The Express Healthcare, (Sep., 4 2020) https://www.expresshealthcare.in/news/why-this-is-the-right-time-for-a-public-health-bill-2020-in-india/424502/.

28 Sanjeev V. Thomas, *The National Health Bill 2009 and afterwards,* 12 (2)ANNALS OF INDIAN ACADEMY OF NEUROLOGY, 79 (2009).

domain and sought comments from various stakeholders.[29] The proposed draft authorizes the state and local authorities to take appropriate actions to tackle health emergencies. This Bill proposes for repealing the age-old colonial law of the Epidemic Diseases Act, 1897 which largely fails to cover many aspects of health emergencies that have developed after its enactment.

One of the positive impacts of this otherwise devastating pandemic has been the realization that it has brought in people of the importance of a universal and comprehensive public health law. The need for quality healthcare which is equitably accessible to everyone has become a dire need now. The effect of the pandemic was largely felt in the big cities and had affected the middle class the most. Thus, this is the right time for the government to push for a comprehensive legal framework addressing the issues of public healthcare and to set a legal road map for addressing other unforeseen pandemics like COVID-19.

Conclusion

A comprehensive central law that guarantees the right to basic public health care services and infrastructure would lay down a new route for every citizen of this country to access basic healthcare service. Public health legislation must evolve with the changing health scenario of a country like India where the health indicators are still far from the desired targets. India needs to raise the healthcare expenditure much more than the present expenditure on health. Death is the ultimate truth of life, but death due to lack of basic healthcare, lack of medical equipment and medicines is highly deplorable and reflects very poorly on the commitment of the state machinery towards its citizens. COVID-19 has also exposed the fault lines of other countries that have generally boasted of advanced healthcare infrastructure. But for a country which was already staggering under a relatively poor public healthcare infrastructure, COVID-19 has sounded the death knell. It has forced people to re-examine the existing frameworks of both healthcare systems and health laws. In this regard, it is also necessary to

29 Yogesh Bahurupi, Aprajita Mehta, Mahendra Singh, Pradeep Aggarwal, Surekha Kishore, *Epidemic Diseases Act 1897 to Public Health Bill 2017: Addressing the epidemic challenges,* 64 (6) INDIAN JOURNAL OF PUBLIC HEALTH, P-253-255 (2020).

emphasize the need for effective implementation of these legislations, which can improve the picture to a considerable extent as the success of legislations depends on their proper execution.

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