What should a Public Health Emergency Law for India Look Like? A White Paper

March 2021

V | D H | Centre for Legal Policy

This report is an independent, non-commissioned piece of work by the Vidhi Centre for Legal Policy, an independent think-tank doing legal research to help make better laws.

About the Authors

Akshat Agarwal, Kim D'Souza, Shreya Shrivastava and Yogini Oke are Research Fellows at the Vidhi Centre for Legal Policy.

Dhvani Mehta is Lead, Health, at the Vidhi Centre for Legal Policy.

The authors would like to thank Aakshi Chaba, Gayatri Gupta, Jai Sahni Mohanty, and Sushant Arsh Massey Khalkho, for their research assistance.

Any errors are the authors' alone.

The Report has been supported by Mahindra and Mahindra Limited.

Table of Contents

Executive Summary

Public health is a field in which the role of the law may not be immediately apparent. Nevertheless, public health administration and governance play a central role in the ability of populations and governments to prepare for, and respond to, public health emergencies ("**PHE**"). The role of government in PHE preparedness and response is derived from the moral and ethical consideration of protecting the public interest, and from the State's authority and responsibility as a sovereign entity, to enact legislation and to promote social welfare. The fundamental right to health and legislative powers (in respect of public health and PHEs) contemplated under the Indian Constitution, together with international legal obligations, create a mandate for the State to take legislative and administrative action to promote and protect public health, especially in the context of PHE preparedness and response.

Lawrence Gostin's theory of public health law outlines three key principles as the basis of any public health legislation. These are (a) 'Duty' – positive duties imposed on government and public health agencies to ensure that their mandate and responsibilities are clear, (b) 'Power' – government and public health authorities being adequately empowered to undertake appropriate regulatory measures and achieve public health objectives, and (c) 'Restraint' – safeguards and remedies in the law to prevent government overreach and protect individual rights. Thus, Gostin's Duty-Power-Restraint framework, and Robyn Martin's conception of a normative role for the law in public health, read with international standards and World Health Organisation guidelines, require a country's PHE legislation to fulfil various legal functions and normative values, such as good governance, social control, integration of human rights, accountability, transparency, inclusiveness etc. This paper's review of the legislative approaches of six sample countries (Brazil, Canada, South Africa, South Korea, the United Kingdom, and the United States of America), using the analytical framework described above, reveals that most of them: (a) identify a specific set of public actors to respond to PHEs, (b) provide for the framing of PHE-specific regulations, (c) allow for certain restrictions and mandatory measures which may suspend some rights and liberties, (d) provide for penalties for individual violators but not for failures of duty by public officials, and (e) require actions to be proportionate to the potential for harm. Further, some of these laws also provide protection to vulnerable populations, and some contemplate relaxing regulatory requirements for drugs and medical devices during PHEs.

India does not have a single, consolidated PHE preparedness and response code. Legal provisions relating to PHEs are scattered across a range of central and state laws, including laws focussed on epidemics and infectious diseases, disaster management laws, public health legislation, and criminal laws. Two central laws – the Epidemic Diseases Act and the Disaster Management Act – dominate the legal framework on PHEs. When analysed using the duty-power-restraint framework: (a) the Epidemic Diseases Act only confers powers, without creating obligations or accountability or imposing restrictions on government (these themes were largely replicated in state regulations issued under the Act during the Covid-19 pandemic), and (b) the Disaster Management Act provides for government powers and duties to manage disasters, but is not a PHE-focussed law, and therefore, does not provide for PHE preparedness and response measures. Past legislative proposals relevant to public health emergencies range from a targeted PHE law, to a general rights-based legislation, and a comprehensive state law on public health. Of these, the central PHE-specific bill is extremely limited in scope in that it only deals with the power component of the duty-power-restraint framework.

Observations from the Indian response to specific aspects of the Covid-19 pandemic further highlight the shortcomings of the existing Indian PHE laws:

- Containment – the combined framework of existing legal provisions and periodic executive orders appeared to cover the basic aspects of containment measures, but the outcomes included inconsistent implementation across states, confusion and misinformation, and frequent violations by the public;
- Quarantine and Isolation – contact tracing efforts fell short because of capacity constraints, healthcare workers went on strike to protest the lack of protective equipment, people actively avoided and absconded

from unhygienic and ill-equipped isolation and quarantine centres, and digital monitoring efforts were legally opposed for their lack of privacy safeguards;

- Testing – following a delayed start, the testing strategy eventually instituted was restrictive and likely masked the actual incidence of the disease in the population in the initial months; during this time, the exclusion of the private sector from testing exacerbated capacity constraints, and the administration see-sawed on the subject of pricing, leading to litigation;
- Authorities – ambiguity and opacity regarding the statutory authority, functioning, and respective roles of the central bodies tasked with orchestrating the pandemic response raised questions as to the legal basis and authority of their directives, and required judicial intervention;
- Treatment – inconsistent and premature advisories regarding treatments and protocols put patients and healthcare workers at risk; vagueness and opacity surrounding the regulatory procedures followed for approval of vaccines led to public concerns regarding their safety and efficacy; in the absence of appropriate protocols, attempts to arbitrarily regulate pricing, and failure to provide government funding options for treatment in private healthcare facilities resulted in public hardship when seeking treatment, and once again required the courts to intervene.

While it is impossible to draw clear causal links between the bottlenecks in response and the absence of a more comprehensive PHE law, the importance of clarity and certainty through a legal framework on PHEs cannot be overstated. The existing Indian legal framework on PHEs therefore needs to be re-evaluated to address its various shortcomings and incorporate the necessary aspects of a modern PHE legislation in a manner appropriate to the Indian context. The various issues that should be considered include:

- the scope of PHE legislation at the centre – whether it is restricted to international obligations or includes domestic administrative responsibilities;
- the need for state-specific legislation, and the principles for division of responsibilities between the different tiers of government;
- the capacity of the existing administrative infrastructure to handle PHE preparedness and response activities, demarcation of responsibilities, and institution of coordination mechanisms;
- structuring of legislation – the content and levels of specificity in primary and secondary legislation, and the status of PHE protocols vis-à-vis the law;
- the structure, functions, and purview of monitoring and accountability mechanisms;
- the nature and framing of rights under a PHE law, including the necessary level of specificity, the rationale for inclusion of corresponding duties, and the nature and accessibility of remedies for violations.

This exercise will require expertise and consultation with appropriate stakeholders from government, public health and policy experts, civil society, and vulnerable groups that have been particularly affected by the Covid-19 pandemic.

I. Why should the State act in a Public Health Emergency?

A. Introduction

The backbone of any country's response to a public health emergency ("**PHE**") like the Covid-19 pandemic is its public health administration, while the law governing and guiding such administration plays a supporting role. Any analysis of India's response to the Covid-19 pandemic must necessarily examine the manner in which public and private health systems coped with the challenges that the pandemic posed, including the actions of public officials, healthcare professionals, and expert scientific institutions. However, as the Indian experience over the last year has demonstrated, the law runs through all of this. Some of the issues that the law has been called upon to answer during the course of the pandemic are: (a) What is the nature and scope of the legal duty of the State to provide healthcare in a PHE? (b) Which level of government, central, state or district, has the legal authority to impose lockdowns? (c) Do the wide-ranging powers of the State in an epidemic allow it to control the rates of treatment at private hospitals? (d) What are the reasonable restrictions that can be imposed on individual civil liberties in the interests of public health?

As this White Paper will demonstrate, the Indian legal framework has been found wanting in its ability to answer these questions satisfactorily. In identifying how this framework needs reform, there is a fundamental question that must first be addressed—what is the role of the law in public health? While this is a question that has been explored in some detail on the international plane,[1] more work is needed to contextualise this particular role of the law in India. This is also a function that this White Paper attempts to perform.

In this first chapter, the aim is to understand the basis for State actions and the nature of legal obligations during PHEs. This analysis tells us why and on what authority the State can act in (public health) emergencies as well as the values that ought to inform its actions. The chapter analyses India's obligations to act during PHEs at three distinct levels. The first part analyses the moral and ethical basis for a sovereign State's responsibility to further the public health interests of its citizens. This part, therefore, contextualises PHEs in the broader ethical and moral justifications for State intervention in public health. It does so by relying on literature relating to both public health ethics and political obligations. The second part focusses on India and argues that India is obliged to secure the health of its citizens under the Indian Constitution which has been judicially interpreted to recognise a right to health. The final part looks at India's international obligations under the International Health Regulations issued by the World Health Organisation ("**WHO**") as well as international human rights conventions, and argues that India is obliged to enact a law tackling PHEs.

B. Of Morality, Ethics and Authority

PHEs often conjure images of a fast-spreading contagion, widespread illness and death. It is these dire circumstances and the moral imperative to prevent large-scale mortality which often prompts States into urgent action. Beyond the spread of epidemics, however, the business of public health is far more prosaic and concerns the day-to-day issues of sanitation, urban planning, a clean environment and adequate nutrition, amongst others. While the urgency of epidemics and the immediate devastation that they leave in their wake justifies visceral State responses, it becomes more difficult to understand why States owe obligations to secure the public health of their citizens in 'normal circumstances'. This is because the consequences of such public health measures are often not immediately apparent, do not seem to benefit all citizens equally, and impose restrictions on

[1] Advancing the right to health: the vital role of law. Geneva: World Health Organisation, 2017; Lawrence O Gostin, 'A Theory and Definition of Public Health Law' (2008) in Lawrence Gostin (ed), *Public Health Law: Power, Duty, Restraint* (2nd edition, 2008) <http://scholarship.law.georgetown.edu/ois_papers/8> accessed 4 January 2020.

individual liberties. However, both the mundane practice of public health and the obligation to act during emergencies are closely connected.

To understand the nature of State obligations, it is important, first, to understand the meaning of 'public health'. Public health deals with the health of populations as opposed to individuals.[2] Therefore, public health measures are essentially State laws and policies that are aimed at securing public health ends. While public health has been variously defined, most definitions share the common premise of being aimed at achieving a high level of health for society at large rather than the best possible health for a few.[3] In terms of the content of public health, academic writing focuses on both the prevention of risks and harms to health as well as the socio-economic foundations of health.[4] Strands of public health scholarship also highlight the role of equitable distribution to address existing inequalities based on sex, race etc., as well as the role that communities play in maintaining public health.[5] Therefore, the content of public health is often varied and concerns a large number of interconnected factors which influence the health outcomes of the population at large. Public health measures may thus lie across a spectrum and may range from compulsory seat-belt legislation to prevent injury in road accidents to actions that address water fluoridation, and include emergency measures to prevent the spread of large-scale infectious disease outbreaks.

In considering the role of the State in undertaking public health measures and policies, two distinct questions arise. First, what are the broad moral and ethical justifications for public health measures? Second, what is the source of the State's authority in undertaking such measures?

(a) The Moral and Ethical Question

Epidemics, including the ongoing Covid-19 pandemic, are often associated with liberty-limiting measures such as isolation and quarantine. In fact, an ill-timed quarantine even plays a significant role in the tragic ending of Shakespeare's Romeo and Juliet![6] Therefore, public health measures are often popularly understood as limiting individual liberties in the interests of health or the public good.[7] Thus, such measures are often presented as a clash between preserving the value of individual autonomy on the one hand, and achieving overall welfare and public good on the other. While liberty-limiting measures are an important aspect of public health, categorising all of public health ethics in these terms, Faden and Shebaya argue, takes away attention from various other moral dilemmas implicit in public health measures. For instance, some measures may simply be ineffective or under-serving while other measures may not account for societal issues such as structural inequalities.

Faden and Shebaya argue that public health policies can usually be justified for a number of different reasons rather than just one.[8] Apart from the general significance of public health measures for human flourishing, Faden and Shebaya identify five public health justifications which can be used in various combinations[9]:

- **Overall Benefit** implies that having public health regulation is better than its absence and that it benefits society at large regardless of whether particular interventions benefit each individual or not. This is usually the justification supplied for setting up public health regulatory agencies.

- **Collective Action and Efficiency** implies that public health is a public good. It cannot be achieved by individuals alone, but requires collective action and efficiency, suggesting the need for State intervention. This is offered as a justification for policies such as food safety standards and water fluoridation.

[2] Lawrence O Gostin (ed), *Public Health Law and Ethics: A Reader* (University of California Press 2002) 3-4.
[3] ibid. For instance, one of the most influential definitions is that of the Institute of Medicine in its 1988 report, 'The Future of Public Health', which states that "Public health is what we, as a society, do collectively to assure the conditions for people to be healthy."
[4] ibid.
[5] ibid.
[6] Stephen Greenblatt, 'What Shakespeare actually Wrote About-The Plague' (*The New Yorker* 7 May 2020) <https://www.newyorker.com/culture/cultural-comment/what-shakespeare-actually-wrote-about-the-plague> accessed 26 May 2020.
[7] An instance of this approach is a 2007 report by the Nuffield Council on Bioethics titled 'Public health: ethical issues'.
[8] Ruth Faden and Sirine Shebaya, 'Public Health Ethics' in Edward Zalta (ed), *The Stanford Encyclopedia of Philosophy* (Winter 2016 ed) <https://plato.stanford.edu/archives/win2016/entries/publichealth-ethics/> accessed 26 May 2020.
[9] ibid.

- **Fairness in the Distribution of Burdens** implies that considerations of fairness demand that unequal burdens may sometimes be imposed on different sections of the population to ensure that burdens are roughly equivalent for everyone. Compulsory immunisation programmes for illnesses that may not affect everyone equally are an instance of this.

- **The Harm Principle** which was first enunciated by John Stuart Mill in his classic essay 'On Liberty' implies that the only reason for interfering with the liberty of individuals against their will is to prevent harm to others. This is perhaps the most common justification in liberal democracies, and is advanced as the justification for infectious disease control measures such as isolation and quarantine.

- **Paternalism** implies interference with the liberty of individuals, against their will, to protect their welfare. While paternalism may rarely be practised in its pure form, various public health initiatives may have paternalistic effects. In public health, forms of paternalism such as libertarian paternalism are most prevalent. These translate to 'nudges' i.e. the creation of situations which make it easier for people to act in their best interests.

Understanding the ethical justifications for public health measures as a combination of reasons, which are inter-related, allows for greater moral scrutiny of the actual measures themselves and goes beyond the traditional understanding of such measures as being a clash between individual liberties and the public good.[10] Due to its wider amplitude in terms of both, justifications, and the capacity to interrogate specific measures, we have relied on Faden and Shebaya's framework of ethical justifications to understand the moral basis for public health measures.

These will be used later in Chapter II to develop a framework to assess the Indian legal response to the Covid-19 pandemic.

(b) The Authority Question

While the above justifications provide a fairly comprehensive overview of public health ethics, the question of why the State possesses the authority to undertake such measures remains. Nation-states are considered sovereign and therefore enjoy the sole authority to make laws and regulations regarding the health of their citizens. Gostin argues that sovereign States have the primary responsibility for public health services.[11] This is represented by the legal maxim, *salus populi est suprema lex* or 'the welfare of the people is the supreme law.' This maxim, employed in early public health law, is emblematic of the connection between the State's powers and the well-being of the public. Gostin demonstrates how the conception of the 'police power' of the State implies the authority to further all goals of government to promote the general welfare of society.[12] To promote welfare, the State may therefore regulate private interests in the exercise of its police powers. Police powers are in fact an attribute of the sovereignty of the State.

As the world reels under the Covid-19 pandemic, the argument that such epidemics change the course of history is now trite. Apart from exposing vulnerabilities of the human condition, they also expose fissures in both society and the structure and tools of governance. In the context of fissures in public health governance, understanding the role of the modern State is a necessary precursor to fixing them. The moral and ethical justifications for public health measures as well as the source of the sovereign State's authority to undertake such measures shed light on the important role of the State. These justifications and sources of authority also underscore the values that must inform public health frameworks and measures. In modern constitutional democracies, such values find expression in constitutional design and international obligations to a large extent. The next parts of this chapter will, therefore, explore the public health obligations of the State from the perspective of both constitutional as well as international obligations.

[10] ibid.
[11] Lawrence Gostin, 'Public Health Theory and Practice in Constitutional Design', (2001) 11 Health Matrix: The Journal of Law-Medicine 282.
[12] ibid, 283.

C. Of Constitutional Obligations

(a) Health as a Constitutional Right and Mandate

Like most other countries with legal systems influenced by British common law, India does not have an explicit fundamental right to health guaranteed under its Constitution.[13] The right to health and healthcare, as 'social' rights, are contemplated under the Directive Principles of State Policy contained in Part IV of the Constitution ("**Directive Principles**"). These are non-justiciable as per Article 37 but are intended to guide government policy and legislation. The Directive Principles have informed various laws in independent India, such as labour welfare and land reform laws, and the courts have repeatedly turned to them, as a component of the 'basic structure' of the Constitution, for guidance in interpreting its provisions and the corresponding obligations of the State. In particular, the courts have laid down that Article 21 of the Constitution (which guarantees the fundamental right to life and personal liberty) in conjunction with the Directive Principles, guarantees every person the fundamental right to health and healthcare, as an intrinsic component of the right to life.[14] Turning to the relevant provisions, the Directive Principles outline the State's responsibility to:

- promote the welfare of the nation and its people by securing a socially, economically, and politically just social order (Article 38),
- provide for just and humane conditions of work and for maternity relief (Article 42), and
- raise nutrition levels and the standard of living, and improve public health (Article 47).

Thus, the Constitution envisages the right to health holistically as including the right to its underlying determinants. This aligns with the prevalent international view[15] and is also reflected in the rulings of Indian courts. For instance, in *Francis Coralie Mullin v Administrator, Union Territory of Delhi and Ors*, the Supreme Court held that "…the right to life includes the right to live with human dignity and all that goes along with it, namely, the bare necessaries of life such as adequate nutrition, clothing and shelter…."[16]

Article 246 of the Constitution read with the Seventh Schedule, grants the states the exclusive power to legislate on the subjects of "Public health and sanitation; hospitals and dispensaries" (as per Item 6 of the 'State List'), empowering them to give legislative effect to the rights and principles discussed above. Apart from this power, the courts have also recognised that the State has an obligation, as a welfare state, to give effect to the ideals of social justice comprised in the Directive Principles. In *Paschim Banga Khet Mazdoor Samity v State of West Bengal and Anr*, the court observed:

> The Constitution envisages the establishment of a welfare state at the federal level as well as at the state level. In a welfare state the primary duty of the Government is to secure the welfare of the people. Providing adequate medical facilities for the people is an essential part of the obligations undertaken by the Government in a welfare state.[17]

This view is echoed in *Vincent Panikurlangara v Union of India and Ors*, where the court observed that the "maintenance and improvement of public health have to rank high as these are indispensable to the very physical existence of the community and on the betterment of these depends the building of the society…which the Constitution makers envisaged."[18]

Internationally, States have taken differing approaches to public health as well as emergency preparedness and response efforts (the latter is discussed in more detail in Chapter III). Under the 1936 Constitution of the erstwhile

[13] Hiroaki Matsuura, 'The Effect of a Constitutional Right to Health on Population Health in 157 Countries, 1970-2007: the Role of Democratic Governance' Program on the Global Demography of Aging-Working Paper No. 106 (July 2013) <https://cdn1.sph.harvard.edu/wp-content/uploads/sites/1288/2014/10/PGDA_WP_106.pdf> accessed 19 May 2020; Cole Scanlon, 'Health Consequences of Legal Origin' <https://stanfordcomparativeadvantage.files.wordpress.com/2016/12/scanlon-health-and-legal-origin.pdf> accessed 28 May 2020.
[14] *State of Kerala and Anr v NM Thoas and Ors* AIR 1976 SC 490; *Chandra Bhavan Boarding and Lodging, Bangalore v State of Mysore and Anr* AIR 1970 SC 2042; *Vincent Panikurlangara v Union of India and Ors* AIR 1987 SC 990.
[15] Article 25(1), Universal Declaration of Human Rights.
[16] AIR 1981 SC 746.
[17] AIR 1996 SC 426.
[18] AIR 1987 SC 990.

USSR, and also under Ukraine's Constitution, today, the State is required to provide free access to healthcare through public health facilities. This has proven to be a challenge to the healthcare sector, as it "constrains the effective allocation of health resources and health care delivery".[19] Similarly, "The objective of the Scandinavian health care system is considered to improve the health of the entire population rather than to consider each individual's situation…governments are obligated to provide high quality services for all, but a scarcity of resources may constrain the available health care and may not fit each individual's needs and conditions."[20] Sweden's Health and Medical Services Act of 1982 states that the goal of the Swedish health system is "good health and care on the same conditions for the entire population".[21]

This would indicate that there arise, at times, conflicts between the individual's health and the health of the population; this may be heightened in resource-poor settings, such as Ukraine's experience and India's current public health situation. It is worthwhile to note, however, that while there may arise conflicts which require resolution from the perspective of the target of the health intervention, this does not translate to a conflict in respect of the State's obligation. This is reflected in several judgments handed down by Indian courts that hold the government to account in respect of its responsibility to secure public health and its failure to implement public health schemes in a manner that fulfils the right to health of the public. Apart from the judgments already mentioned, in *Laxmi Mandal and Ors v Deen Dayal Harinagar Hospital and Ors*,[22] the court called upon the government to implement certain public health schemes properly so as to ensure that their benefits reached the intended beneficiaries. In *Devika Biswas v Union of India and Ors*, the Supreme Court held that:

> it is imperative for both the Union of India and the State Governments to implement schemes announced by the Union of India in a manner that respects the fundamental rights of the beneficiaries of the scheme. Given the structure of cooperative federalism, the Union of India cannot confine its obligation to mere enactment of a scheme without ensuring its realization and implementation.[23]

(b) Public Health Emergencies and Constitutional Mandates

The right to health includes the right to medical attention and freedom from disease,[24] and under international law, it is the Indian State's obligation to fulfil the right of the people "to the enjoyment of the highest attainable standard of physical and mental health."[25] This includes the 'prevention, treatment, and control of epidemic, endemic, occupational and other diseases',[26] as well as the obligation to 'develop, strengthen and maintain' capacities to 'detect, assess, notify and report' manifestations of disease, as well as capacities to 'respond promptly and effectively to public health risks and public health emergencies of international concern'.[27] These international obligations are in fact linked to constitutional obligations and the next part discusses the constitutional basis for giving effect to international obligations to control and prevent the spread of infectious diseases, in greater detail. The Union and the states are both empowered under Article 246, to enact legislation for the purpose of "prevention of the extension from one State to another of infectious or contagious diseases…", as per Item 29 of the 'Concurrent List' in the Seventh Schedule of the Indian Constitution.

Therefore, the constitutional mandate of the Indian State is to promote and secure public health as well as protect the right to health of the individual. This responsibility necessarily extends, and may be said to expand, in the context of a PHE, where the health and safety of the population is most at risk. In keeping with this responsibility, the State has been endowed with the necessary legislative and executive powers under the Constitution to achieve this goal. The existence of such power does not, however, mean that it can be exercised without any checks, and this is precisely where the law has an important role to play, an aspect that is discussed in greater detail in Chapter II.

[19] Matsuura (n. 13).
[20] Matsuura (n. 13).
[21] Matsuura (n. 13).
[22] 172 (2010) DLT 9.
[23] AIR 2016 SC 4405.
[24] *Vincent Panikurlangara v Union of India and Ors* AIR 1987 SC 990.
[25] Article 12(1), International Covenant on Economic, Social and Cultural Rights.
[26] Article 12(2)(c), International Covenant on Economic, Social and Cultural Rights.
[27] Articles 5 and 13, International Health Regulations, 2005.

D. Of International Obligations

India's international obligations arise by virtue of its being a signatory to various international human rights conventions and its participation in the WHO, and more specifically, being a signatory to the WHO's International Health Regulations ("**IHR**"). This part is divided into three sections. The first examines India's obligations in the context of infectious diseases under the IHR and other guidelines issued by the WHO. The second specifically looks at India's obligations towards PHE preparedness and response, keeping in mind India's commitments under various human rights conventions. The third links India's international legal obligations to its domestic legal framework under its Constitution and argues for the need to give effect to India's international obligations in the form of a PHE law, focusing on preparedness and response.

(a) International Health Regulations

History and Foundations

The IHR were first adopted by the World Health Assembly of the WHO in 1969.[28] These Regulations, which initially covered six "quarantinable diseases" were amended in 1973 and 1981, primarily to reduce the number of covered diseases from six to three (yellow fever, plague and cholera) and to mark the global eradication of smallpox. The Forty-eighth World Health Assembly in 1995 called for a substantial revision of the Regulations adopted in 1969, taking into account the increase in international travel and trade, and the emergence or re-emergence of international disease threats and other public health risks. The IHR 2005 were drafted and adopted following preliminary work and consultations in pursuance of the call for revision, and the momentum created by the emergence of the Severe Acute Respiratory Syndrome ("**SARS**").

The IHR 2005 aim to:

> prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.[29]

Are the IHR Legally Binding?

The IHR, in their current form, have been drafted, having regard to Articles 2(k), 21(a) and 22 of the Constitution of the WHO. Significantly, Article 21 (a) of the Constitution empowers the World Health Assembly to adopt regulations concerning 'sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease'. By virtue of Article 22 of the Constitution, regulations adopted pursuant to Article 21 come into force for all Member States after due notice of their adoption by the World Health Assembly. Further, the IHR contain a dispute settlement provision which allows State parties to make legal claims concerning violations of the IHR. All these factors point towards the legally binding nature of the IHR. India has been a State Party to the WHO since 1948.

IHR 2005: An Outline

The IHR 2005 are standard-setting regulations, laying down the roles and obligations of the WHO Member States when addressing public health emergencies of international concern.[30] The IHR 2005 have ten parts and nine annexures. Part I of the IHR 2005 lays down the foundations for a PHE response at an international level. It defines a 'Public Health Emergency of International Concern' to mean an extraordinary event which is determined to constitute a public health risk through the international spread of disease, and the response to which may require international coordination. Part I of the IHR 2005 also delineates the purpose of the regulations, which is to respond to the international spread of disease in a manner which is proportionate to and restricted to the public health risk, while avoiding any unnecessary interference with international trade and traffic.[31] Further, Part I of the IHR 2005 requires State parties to set up the 'National IHR Focal Point' which may be directly accessed by the

[28] Foreword, International Health Regulations, 2005.
[29] ibid.
[30] Brigit Toebes, 'International health law: an emerging field of public international law' (2015) 55 Indian Journal of International Law 299-328.
[31] Article 2, International Health Regulations, 2005.

WHO.[32] State parties, while implementing the IHR 2005 are obligated to fully respect dignity, human rights and the fundamental freedoms of persons.[33]

As already stated previously, Part II of the IHR 2005 requires State Parties to develop national capacities to respond effectively to PHEs. The WHO, in consultation with member States, is to publish guidelines to support the development of such capacities.[34]

While Part III of the IHR 2005 concerns itself with the WHO's capacities to give recommendations, Part IV requires all State parties to develop capacities at 'Points of Entry' such as 'Airports and Ports' and 'Ground Crossings'. [35] The State capacities with respect to Parts II and III of the IHR 2005 have to be developed in accordance with Annex 1 to the regulations. These include core capacity requirements for surveillance and response (at the local community, intermediate, and national levels), as well as core capacity requirements for airports, ports and ground crossings. A key component of a State's public health response includes the capacity to 'establish, operate and maintain a national public health emergency response plan.'[36]

Part V of the IHR 2005 deals with the nature and standards of public health measures which Member States may undertake in the event of a Public Health Emergency of International Concern. These require States to impose health measures only on the basis of evidence of a public health risk, to carry out medical examinations, vaccination, prophylaxis or other health measures with respect to travellers only with their prior express informed consent, and in accordance with established guidelines or standards.[37] IHR 2005 also lays down State party obligations with respect to the treatment of personal data and health information collected or received during a PHE.[38]

(b) Pandemic Preparedness and Response

Under Article 13 of the IHR 2005, the WHO has issued both general guidance on PHEs[39] as well as specific guidance on influenza pandemics.[40] The pandemic influenza-specific guidance is also accompanied by a checklist that covers the essential and desirable elements of pandemic preparedness.[41]

The checklist specifies who will do what, and when, and the kind of resources needed, all of which are critical to managing a pandemic. One component of the checklist covers legal and policy issues. Given that a pandemic response is likely to require extraordinary measures such as 'the enforcement of quarantine (overruling individual freedom of movement), use of privately owned buildings for health-care facilities, off-license use of drugs, compulsory vaccination and implementation of emergency shifts in essential services',[42] the checklist emphasises the need for a sound legal framework that can form the basis of these measures. The checklist additionally lists planning actions that are 'essential' to ensure such a framework. These are:

- a review of existing legislation relevant to pandemic influenza risk management, assessing the need for new or adapted instruments, and a review of compliance with obligations under the IHR 2005
- an assessment for the legal basis of all public health measures that are contemplated as part of a pandemic response
- an assessment of the policy on, and legal basis for, the vaccination of healthcare workers, workers in essential services or individuals at high risk
- an assessment of liability for unforeseen adverse events attributed to vaccines or off-license drugs

[32] Article 4, International Health Regulations, 2005.
[33] Article 3(1), International Health Regulations, 2005.
[34] Article 13(1), International Health Regulations, 2005.
[35] Article 12, International Health Regulations, 2005.
[36] Annex 1, International Health Regulations, 2005.
[37] Article 23, International Health Regulations, 2005.
[38] Article 45, International Health Regulations, 2005.
[39] World Health Organisation, *International Health Regulations 2005: A brief introduction to implementation in national legislation* (2009); World Health Organisation, *International Health Regulations 2005: Toolkit for implementation in national legislation* (2009).
[40] World Health Organisation, *Pandemic Influenza Risk Management: A WHO guide to inform & harmonise national and international pandemic preparedness and response* (2017).
[41] World Health Organisation, *A checklist for pandemic influenza risk and impact management: Building capacity for pandemic response* (2018).
[42] ibid.

- an establishment of regulatory pathways to expedite the importing, marketing authorisation, and licensing of pandemic influenza vaccines
- a review of the legislation, regulation and institutional arrangements governing the participation of private healthcare actors in PHEs.[43]

To the best of our knowledge, such a comprehensive review of the Indian legal framework in relation to a PHE has not been undertaken by the government. This White Paper is a step in that direction. The analysis of the legal framework in Chapter IV as well as the case studies presented in Chapter V correspond to the essential planning actions set out above.

(c) The Right to Health in International Law and PHEs

As mentioned above, in addition to the IHR 2005, India is also a signatory to the International Covenant on Social, Economic and Cultural Rights ("**ICSECR**"). General Comment No. 14 to the ICSECR highlights the minimum core state obligations towards the fulfilment of the 'Right to Health' under the ICSECR. This includes the obligation to:

> adopt and implement a national public health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the whole population; the strategy and plan of action shall be devised, and periodically reviewed, on the basis of a participatory and transparent process; they shall include methods, such as right to health indicators and benchmarks, by which progress can be closely monitored; the process by which the strategy and plan of action are devised, as well as their content, shall give particular attention to all vulnerable or marginalized groups.[44]

Comparable in importance to this minimum core obligation is the specific obligation to 'take measures to prevent, treat and control epidemic and endemic diseases.'[45] In its initial paragraphs, General Comment No. 14 specifically states the various ways through which States may fulfil their commitment to the 'Right to Health', including the core obligations set out above. The 'Framing of Legal Instruments' is one of the approaches through which States may pursue fulfilment of the 'Right to Health'.

This suggests that a rights-respecting legal framework that is able to guide the State in its performance of its public health duties, including the duty to tackle epidemic diseases, is part of the international legal obligations of the State in respect of the right to health.

(d) Linking the International Obligation regarding PHE Preparedness and Response with Indian Constitutional Law

The WHO states that the use of a national legislation/regulation/ instrument in implementing the IHR 2005 can help 'institutionalise and strengthen the role of IHR (2005) capacities and operations within the State Party' and 'facilitate necessary coordination among the different entities involved.[46]

India's approach to international law is 'dualist' in nature, such that India needs to incorporate international legal measures specifically within its municipal legal systems for such measures to be enforceable. This has been emphasized in *Jolly George Verghese v Bank of Cochin*[47] and *State of West Bengal vs Kesoram Industries Ltd ('Kesoram Industries')*.[48] In *Kesoram Industries*, the Supreme Court stated, that 'a treaty entered into by India cannot become law of the land and it cannot be implemented unless Parliament passes a law as required under Article 253.'

Although courts have cited the definition of the 'Right to Health' in the ICSECR as part of the fundamental right to life under the Indian Constitution, as well as the core obligations in General Comment No. 14,[49] there is currently no legislative recognition or protection of the right to health. India also lacks a legal framework on PHE

[43] ibid, 7.
[44] Committee on Economic, Social and Cultural Rights General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12) (Adopted on 11 August 2000, contained in Document E/C.12/2000/4), Para 43 (f).
[45] ibid, Para 44(c).
[46] World Health Organisation, *International Health Regulations 2005: A brief introduction to implementation in national legislation* (2009).
[47] AIR 1980 SC 470.
[48] AIR 2005 SC 1646.
[49] *Navtej Singh Johar v Union of India* AIR 2018 SC 4321; *Mohd Ahmed v Union of India and Ors* MANU/DE/0915/2014.

preparedness and response. In *Vishakha v State of Rajasthan*,[50] the Supreme Court read India's obligations under the Convention on Elimination of All Forms of Discrimination Against Women to address workplace sexual harassment as part of the fundamental right against discrimination on the basis of sex. The Court held that international legal obligations which were not inconsistent with fundamental rights had to be used in interpreting such rights to enlarge their meaning and scope. It therefore stressed the need for a domestic legal framework addressing sexual harassment at the workplace. This eventually led to the framing and the passage of the Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act, 2013 under Article 253 of the Constitution.

Therefore, the fundamental right to health under the Indian Constitution can be interpreted to include India's international obligations under IHR 2005 as well as its core obligations under the ICSECR. Article 253 of the Indian Constitution, which allows Parliament to enact laws in pursuance of international obligations, then, provides the basis for enacting a law on PHE preparedness and response to fulfil these obligations.

E. Conclusion

This Chapter analysed the State's obligation to act during PHEs by looking at moral and ethical justifications for State action and specific constitutional and international law obligations in the Indian context. In the process, it also engaged with the values associated with, and the content of these obligations. It located the authority to act in the interests of public health in the inherent sovereignty of the State, while it identified multiple ethical justifications for the State's public health interventions, ranging from overall benefit to Mill's harm principle. Doing so not only provided the basis for different kinds of State action, but also provided a tool to assess the value of such interventions.

The value of health under the Indian Constitution was located both in the fundamental right to health under Article 21 and in the constitutional vision of creating a welfare state. Further, India's specific international obligations with regard to PHE preparedness and responses for PHEs were traced to the IHR 2005 and the ICSECR. These international obligations provide various details regarding the exact nature and form of PHE legal and policy interventions. Finally, the Chapter linked India's international obligation to its constitutional framework by reading such obligations into the fundamental rights recognised by the Indian Constitution. Reading India's international and constitutional obligations together therefore provides a strong basis for a right to health which encompasses an adequate legal framework for PHE preparedness and response in India.

Key Takeaway

India's international legal obligations and the constitutional recognition of the fundamental right to health can be read to require the enactment of a public health emergency law that gives effect to the International Health Regulations and guides the State's response to public health emergencies.

[50] AIR 1997 SC 3011.

II. What is the Role of the Law in a Public Health Emergency?

A. Introduction

After understanding the various moral, ethical and legal bases for the State's obligations towards public health, the next step is to understand the role of the law in public health more broadly and in PHEs in particular, in order to arrive ultimately at a clear conception of a PHE law. Part I of this Chapter discusses the normative role of the law in public health, drawing largely on Lawrence Gostin's work, while Part II draws on this theoretical understanding to propose an analytical framework that can be used to evaluate and conceptualise PHE legislation.

B. The Role of Law in Public Health

(a) Gostin's Three Principles

Lawrence Gostin's influential work on the intersection of law and public health has single-handedly underscored the importance of law as an instrument to perform and further public health objectives. According to Gostin, all public health law must comprise the following three key principles:[51]

- **Duty**: Law should essentially cast a duty on the government and public health agencies to promote health and well-being within the population. These positive duties, therefore, define the mission of the agencies involved in public health and lay down minimum public health functions. According to Gostin, clearly laying down such duties ensures that there are standards to judge the public health agencies by, that society has clear expectations of public health promotion and that governments can demonstrate their commitment to public health infrastructure.[52]

- **Power**: Law should confer sufficient powers on government and public health authorities to regulate individuals and entities to achieve public health objectives such as community well-being.[53] These powers should allow authorities to set standards of health and safety which can be implemented through tools ranging from incentives, to minimally coercive interventions, to restrictive measures.

- **Restraint**: Law should impose restrictions on government to prevent it from overreaching in the name of public health and ensure that its actions respect individual autonomy, liberty and privacy to the extent possible.[54] Imposing restrictions would include laying down clear criteria for when public health actions become necessary, laying down due process requirements for the exercise of coercive powers, protecting against discrimination, and creating mechanisms which ensure that all decision-making is fair and objective.[55]

(b) The Normative Roles of the Law

Gostin's framework provides a practical way of thinking about the role of law in public health legislation. Robyn Martin, on the other hand, in their essay *The Role of Law in Public Health*, outlines a more normative understanding of the role of law. They identify that law, *first*, provides tools to public health professionals to protect populations from communicable and non-communicable diseases and *second*, that law contributes to ethics by assisting in

[51] Lawrence O Gostin, 'Public Health Law Reform' (2001) 81 American Journal of Public Health 1365-1368.
[52] ibid.
[53] ibid.
[54] ibid.
[55] ibid.

framing good public health practice.[56] Gostin's framework of duty, power and restraint neatly fits into this broader understanding, since 'duties' and 'powers' can be understood as tools of public health, while 'restraint', which refers to balancing individual rights with the exercise of state powers, gets linked to the role of law in contributing to good public health practice. Martin's formulation of the role of the law, however, adds new dimensions to our understanding by focusing on the law's use as a direct tool of social control by conferring health authorities with powers and duties and, indirectly, by influencing populations to act in health-positive ways.[57] In terms of influencing good public health practice, while Gostin's formulation of restraint captures the need to account for individual human rights, Martin additionally points to the role of tort law which allows individuals to enforce private rights against the duty to protect citizens from public health harms.[58] This is particularly visible in the form of consumer protection measures that are aimed at protecting individuals from misleading claims and advertisements and from the failure to disclose risks of products such as tobacco.[59]

In the context of thinking about legislative responses to PHEs, however, Martin's emphasis on the role of the law in setting social norms is of greater relevance. Law influences public attitudes towards the appropriateness of public health-promoting behaviour.[60] For example, Martin points out that seat-belt legislation has changed attitudes to car safety, with not wearing seat belts being considered irresponsible.[61] By regulating conduct, laws, therefore, influence, 'what is acceptable behaviour and what is not, and indeed as to what is right and what is not.'[62] Importantly, however, such positive effects may only occur when laws respond to shifts in social opinion or anticipate them, prompting the observation that 'public health statutes should embrace the reality that most interventions depend on voluntary compliance by the public.'[63] In the context of the Covid-19 pandemic, for instance, previous experiences with the spread of respiratory illnesses have meant that certain Asian countries were more amenable to mask-wearing compared to Western ones.[64] The current pandemic may create opportunities for the law to promote positive public health behaviours amongst people. Laws aimed at PHE preparedness and response must therefore keep this role in mind.

A goal-oriented and rights-based vision of the role of the law in public health is set out in a 2017 WHO report, *Advancing the Right to Health: The Vital Role of Law*.[65] The report squarely identifies the goal of universal health coverage as a means to achieving the right to health, while also emphasising the importance of the law in protecting and advancing availability, accessibility, acceptability, and quality—the four key components of the international human right to health.[66] The WHO report also identifies building blocks for effective public health laws. These are:

- legislative goals and principles
- clear responsibilities for the health ministry and other agencies and legislative tools for discharging these responsibilities
- flexibility
- the integration of human rights protections, and
- coherence between public health laws and other laws.[67]

These building blocks clearly map onto Gostin's duty-power-restraint framework, with the WHO report also providing specific guidance about the content of these legislative building blocks.

[56] Robyn Martin, 'The Role of Law in Public Health' in Angus Dawson (ed), *The Philosophy of Public Health* (Ashgate 2009), p 11.
[57] ibid.
[58] ibid, p 20.
[59] ibid.
[60] ibid, p 17.
[61] ibid.
[62] ibid.
[63] Lawrence O Gostin, Scott Burris and Zita Lazzarini, 'The Law and the Public's Health: A Study of Infectious Disease Law in the United States' (1999) 99 Columbia Law Review 59, 119.
[64] Hillary Leung, 'Why Wearing a Face Mask is Encouraged in Asia but Shunned in the US' *Time* (12 March 2020) <https://time/com/5799964/coronavirus-face-mask-asia-us/> accessed 7 August 2020.
[65] World Health Organisation (n 1).
[66] General Comment No. 14 (n 44), Para 12.
[67] World Health Organisation (n 1), Chapter 4.

Finally, in a more global governance-oriented conception of law and public health, a 2019 Lancet Commission report articulates the crucial role of law in achieving global health with justice, through legal instruments, legal capacities, and institutional reforms, as well as a firm commitment to the rule of law.'[68] Broadly, the report states that the law has an important role to play in the governance of national and global health institutions, specifically in harmonising mandates, providing mechanisms to promote cooperation, fostering State compliance through innovative legal and governance strategies, increasing transparency, openness, inclusiveness and accountability, as well as in the implementation of fair, evidence-based health interventions. While global health is the focal point of the report, the legal determinants identified by it can clearly be applied to the domestic public health context as well.

The normative visions described above, along with Gostin's tripartite framework are used in the next part to develop an analytical framework that can be used to think about what a PHE law should look like.

C. An Analytical Framework for a PHE Law

This part develops a series of questions under each of the three principles identified by Gostin for public health law-Duty, Power and Restraint. Answers to these questions will help assess the extent to which a legal framework is equipped to perform the role expected of it in a PHE. Alongside each question, the corresponding normative value is also identified, drawing on the different visions described in Part I--social control, integration of human rights, good governance, accountability, transparency, inclusiveness etc.

PRINCIPLE	LEGAL FUNCTION	NORMATIVE VALUE
DUTY	Does the law clearly define its objective and state its guiding principles and values? Does the law contain an explicit commitment to human rights?	Integration of Human Rights
	Does the law identify a specific set of public actors responsible for dealing with a PHE? Does the law identify or create a nodal authority responsible for responding to the emergency?	Accountability and Transparency
	Does the law identify specific functions for each of these actors or the nodal authority, as the case may be?	Good Governance
	What are the consequences if these actors fail to perform their functions? Does the law provide remedies for government failure to respond to emergencies? [*For example, penalties, judicial orders, takeover by another body*]	Accountability
	Does the law impose a duty to coordinate with other bodies while responding to a PHE? Does it identify these other bodies? Does it create mechanisms for coordination, for example, through a protocol or through the constitution of an ad hoc expert body?	Coherence
	Does the law impose a duty to make available in the public domain information about its actions in response to a public health emergency?	Transparency
	Does the law impose special duties for the protection of healthcare workers?	Protecting the Vulnerable
POWER	Does the law confer the power to impose a general state of emergency, where defined rights and liberties may be suspended?	Community Well-Being
	Does the law contain specific powers to: • Control the spread of information related to a PHE • Quarantine and isolate individuals and populations • Surveil individuals and populations	Flexibility

[68] Gostin et al, 'The legal determinants of health: harnessing the power of law for global health and sustainable development' (2019) 293 The Lancet 1857-1890.

	• Order compulsory medical treatment, hospitalisation and vaccination • Nationalise or requisition private property • Conscript individuals for public service • Control the price of health goods and services • Modify or suspend regulatory requirements for carrying out clinical or biomedical research, manufacturing medical drugs or devices, providing healthcare services • Ration scarce healthcare resources • Impose restrictions on the activities of individuals and companies	
	Does the law contain mechanisms to enforce its powers?	Authority
RESTRAINT	Does the law contemplate a specific procedure to determine whether a PHE exists?	Due Process, Evidence-Based Intervention
	Is there an explicit requirement to exercise the least restrictive alternative? Is there a process to balance risks and benefits? Does the law provide a graded set of mechanisms that can be used to enforce the powers and impose the restrictions mentioned above?	Proportionality
	Does the law provide mechanisms for public participation?	Transparency and Inclusiveness
	Does the law create processes to hear individuals or communities before restrictions are imposed? Does the law contain mechanisms to appeal restrictions imposed?	Fairness, Due Process
	Does the law impose a duty on public actors to mitigate the effects of restrictions, particularly in the context of access to health services?	Proportionality
	Does the law require public actors to pay special attention to, and take special measures to protect vulnerable populations?	Protecting the Vulnerable
	Does the law contain mechanisms for ongoing review of the measures taken to respond to PHEs?	Flexibility, Evidence-based Intervention
	Does the law contain a duty of non-discrimination?	Integration of Human Rights

This analytical framework is used in the next Chapter to analyse the legal responses to PHEs in other jurisdictions.

III. How do other States respond to PHEs?

A. Introduction

Regulatory and legislative inadequacies in dealing with PHEs may leave States vulnerable and unprepared to respond. Such vulnerability, and the lack of a clear regulatory road-map, may lead to an inefficient and chaotic State response to an emergency. In this Chapter, our aim is to understand how legal frameworks in countries other than India enable them to respond to the variety of challenges that are likely to arise during PHEs.

In the previous Chapter, we proposed a set of questions to analyse the State's performance of duties and exercise of powers and restraint during PHEs. In this Chapter, we will be using these questions as an analytical matrix to compare PHE-related laws across different jurisdictions as they respond to various legal, moral, ethical, and political questions that States face at such times. First, we will attempt to understand how PHE laws have evolved globally, before we examine the particulars of PHE laws from six jurisdictions using our analytical matrix.

B. General Overview of the Historical Context of PHE Laws

Laws governing public health have evolved greatly during the past century, as a result of the changing relationship between individuals and the State, changes in the understanding of 'diseases' and other scientific-military developments such as nuclear technology. Different diseases also present wholly different contexts, and thus the application of different public health measures.[69] The control, containment and treatment of PHEs often requires the widespread exercise of powers by government as well as coordination between its various levels and organs. Civil emergency laws and disaster management laws play a key role in this regard.

USA: Multiple PHE laws working in tandem

USA is an example of a legal framework where powers to respond to a PHE are not derived from a single legislation. While the key law is the Public Health Services Act, it has been amended by pandemic preparedness laws to insert specific provisions. Authorities also derive specific powers related to PHEs from the National Emergency Act, the Stafford Act, the Public Readiness and Preparedness Act etc. Moreover, in the USA, public health is the province of states and local governments and the federal government's emergency powers reflect a fundamentally bottom-up system allowing states and local authorities to retain primary responsibility even in a truly national crisis. Accordingly, states have adopted highly individualized approaches in their response to the coronavirus outbreak including varying standards in reporting and testing.

Another strategy commonly used to counter the spread of infectious diseases is 'quarantine'. Often enforced through specific quarantine regulations, 'quarantine' or obligatory control over movement of people, animals, goods etc. traces its roots back from the Black Death to cholera to the 1918 Spanish flu in the Western world.[70] Soon, these regulations came to be replicated by colonial administrations in colonised nations. Many of the quarantine regulations that exist all over the world trace their roots back to the colonial era. The United Kingdom ("**UK**") especially, has left quite a large footprint as far as quarantine regulations are concerned.[71]

Colonial era quarantine laws have continued to form the basis for public health measures in many jurisdictions such as Jamaica, Hong Kong and India. However, the use of a very old legislation in a modern context can have its challenges. Therefore, in some cases like the province of Ottawa in Canada, quarantine regulations have undergone amendments post the SARS epidemic of 2005. In the case

[69] A A Conti, 'Quarantine Through History' (2008) International Encyclopedia of Public Health 454-462.
[70] Eugenia Tognotti, 'Lessons from the History of Quarantine, from Plague to Influenza A' (2013) 19 Emerging Infectious Diseases 254-259.
[71] Justin Ling, 'How Governments Got Their Quarantine Powers' *Foreign Policy* (24 March 2020) <https://foreignpolicy.com/2020/03/24/how-governments-got-their-quarantine-powers/> accessed 16 February 2021.

of Australia, quarantine regulations were replaced by the Biosecurity Act in 2015, which continues to retain the power to quarantine.

The trajectories and stimuli for the initiation of PHE laws can be truly varied. However, at the beginning of the 21st century, a series of emergencies—many of which were health-related—exposed the high cost of not having national health laws. As a result, many countries were compelled to undergo a modernisation of public health legislation. In the United States of America ("**USA**"), the 2005 Hurricane Katrina and a new strain of the avian flu led to the passage of the Pandemic and All-Hazards Preparedness Act of 2006.[72] The 2003 SARS pandemic, as well as new strains of the H1N1 influenza in 2009, led the European Union to adopt Decision No. 1082, titled 'Serious Cross Border Threats to Health'.[73] These new regulations provide a much clearer delineation of public health functions to include 'powers', 'duties' and 'restraints', and allow for a more coordinated governmental response to pandemic-like crises.

South Korea and MERS

South Korea is known for its success story of efficiently responding to Covid-19, after learning its lessons from the Middle East Respiratory Syndrome ("**MERS**") in 2015. Post MERS, it updated its legal and policy framework, providing a legal basis for the disclosure of private information and central-local cooperation, among other things. Besides, it has a very specific law on infectious diseases which contains very detailed provisions regarding the specific kinds of restrictions that can be imposed during a PHE.

The first decade of the 20th century is also marked by the creation of softer instruments to deal with and respond to PHEs. In addition to pandemic legislation, frequent health crises in the early 2000s spurred the creation of national strategies to combat pandemics. In 2005, the WHO published a Global Influenza Preparedness Plan,[74] urging all nations to use the document as a guide to create their own national plans. The WHO routinely updates this guide, particularly in response to global developments. As mentioned in Chapter I, this guide was updated in 2017 to account for the Pandemic Influenza Preparedness Framework adopted by the World Health Assembly in 2011.[75] So far, out of 194 member countries, 99 countries have no Plan or the Plan is not publicly available, 63 countries, including India have published the Plan in or before 2009, 15 countries have published or revised their Plan between 2009-2013 and only 17 countries have published or revised their Plan in 2014 or after.

While comparing PHE laws across jurisdictions in the next section, it is important to keep in mind this historical context i.e. that different countries use a diverse range of laws, born out of various historical-political factors to enforce public health measures in relation to pandemics.

[72] Ryan Morhard and Crystal Franco, 'The Pandemic and All-Hazards Preparedness Act: Its Contributions and New Potential to Increase Public Health Preparedness' (2013) 11 Biosecurity and Bioterrorism: Biodefense Strategy, Practice and Science 145-152.
[73] A de Ruijter, 'Mixing EU Security and Public Health Expertise in the Health Threats Decision' in M Weimer and A de Ruijter (eds), *Regulating risks in the European Union: The co-production of expert and executive power* (Hart Publishing 2017), 101-120.
[74] World Health Organisation, 'WHO global influenza preparedness plan: The role of WHO and recommendations for national measures before and during pandemics' (2005).
[75] WHA64.5, 'Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits' (Sixty-Fourth World Health Assembly, 2011).

C. Countries and Laws Selected for Comparative Analysis

While choosing which countries to consider for the purpose of this analysis, we adapted a flexible, functional approach. Two of the countries we chose—the UK and the USA—are developed democracies with legislative bodies and comprehensive legislation on 'Public Health". Two others—Brazil and South Africa—are developing nations where the 'Right to Health' has been recognized as a 'Fundamental Right'. The final two—South Korea and Canada—are countries that have had prior experience fighting large epidemics and have evolved their legal systems accordingly.

Brazil: The Supreme Court and COVID-19

Brazil's Central Government has consistently downplayed the seriousness of the Covid -19 crisis. When the number of cases in Brazil was on the rise, very few measures were taken by the government to curtail the spread of the virus. However, the Supreme Court of Brazil has played an important role during this crisis. The following are some of the key decisions of the Supreme Federal Court.

- On 15 April, 2020, the Supreme Federal Court ruled that, in addition to the federal government, state and municipal governments have the power to determine rules for isolation, quarantine and restriction of transport and transit on highways due to the coronavirus epidemic [*In Referendum to injunction granted in Direct Unconstitutionality Action (ADI) 6341*].
- In early June, the Health Ministry of Brazil had suddenly removed the cumulative totals of cases and deaths from its website. In response, Supreme Justice Alexandre de Moraes said in a statement on the court's website that 'the health ministry must 'fully re-establish the daily dissemination of epidemiological data on the COVID-19 pandemic, including on the agency's website.'
- On 8 July, 2020, the Supreme Court ruled that the government must take emergency measures to protect the indigenous population of Brazil from the pandemic.

For the purpose of our analysis, we have chosen to look at two broad categories of laws for each country. In the first category, we have looked at laws dealing with public health at large, or infectious disease control. In the second category, we are looking at legislation that is specifically targeted at the Covid-19 pandemic. These include laws specially enacted to deal with the Covid-19 pandemic, disaster management laws invoked in response to the Covid-19 pandemic, pandemic-specific laws, as well as amendments to public health laws to tackle Covid-19. The table below provides an overview of the different combinations of such laws that countries have deployed during this time.

Countries	Laws dealing broadly with public health	Laws invoked or enacted specifically to deal with the Covid-19 pandemic.
UK	Public Health (Control of Disease) Act 1984	Coronavirus Act, 2020
USA	Public Health Service Act, 1944	Pandemic and All-Hazards Preparedness Act, 2006 Pandemic and All-Hazards Preparedness Reauthorization Act, 2013 Pandemic and All Hazards Preparedness and Advancing Innovation Act, 2019
Canada	Quarantine Act, 2005	Public Health Act of Quebec, 2001 (province-specific)
South Africa	National Health Act, 2003 and National Health Act (Communicable Disease) Regulations, 2008	Disaster Management Act, 2002
South Korea	Infectious Diseases Prevention and Control Act, 2009 and Quarantine Act, 2009	Framework Act on Disasters and Management of Safety Act, 2004
Brazil	Law No. 6259 of 1975, Law 8080 of 1990 (Organic Health Law), Law 9795 of 2019 and Law 9782 of 1999	Act No. 356 of 2020 Law 13979 of 2020

D. Key Observations

(a) How do PHE Laws create State obligations?

Guiding Principles and Recognition of Rights

Statutory principles and guaranteed rights can be an important way of creating corresponding State obligations under PHE laws. They might find expression in the preamble or in other provisions of the law. Of the laws compared in this Chapter, the South Korean Infectious Diseases Prevention and Control Act explicitly recognises the right to health as a fundamental right.[76] Article 6 of the same law also specifically recognises that each citizen has the right to receive a diagnosis as well as medical treatment for any infectious disease at a medical institution, with the State and local governments obligated to bear the expenses. Other laws provide guiding principles for State authorities. For instance, Chapter I of the Public Health Act of Quebec states that the public health measures taken under it should be directed as population-centric health measures, and individual-centric public health measures are to be undertaken only if the interests of the larger community are involved.

Allocation of Duties

Generally, through PHE laws, States identify a set of public actors or nodal agencies, or both, that are expected to respond to PHEs. This might be considered one of the main functions of PHE laws. In an enabling legislation such as the Public Health (Control of Disease) Act of the UK, the law specifies actors who may pass regulations, and in turn, the persons or entities who may act under these regulations. The South Korean infectious disease law, on the other hand, delegates duties to central, state and local authorities, while also allowing the possibility of creating 'Epidemic Officers'. In the two countries in this Chapter where disaster management laws have been invoked to respond to the Covid-19 pandemic, it is the inter-governmental and managerial agencies responsible for disaster management that have been made responsible.

Canada's Public Health Agency

The creation of Canada's Public Health Agency was primarily in response to the 2003 SARS pandemic, which was particularly devastating in the country. The outbreak exposed the lack of coordination between different authorities. As the cracks in the Canadian public health system became clear, the need for reform did too. Consequently, Parliament passed a new version of the Quarantine Act in 2005, as well as the Public Health Agency Act in 2006. The latter Act created the Public Health Agency, which became the new authority responsible for all public health matters in the country, and created the position of Chief Public Health Officer.

Generally speaking, the functions of public officers vary across public health laws, as well as between officers under the same law. For instance, the functions of the Justice of Peace under the UK Public Heath (Control of Disease) Act are different from those of the Minister under the same Act and are very different from those of the Secretary of State in the USA.

Coordination

As multiple actors work under the same PHE law, on multiple aspects of the PHE response, and at multiple levels, coordination between the actors becomes key to the success of their response.

The Public Health Agency of Canada, was constituted precisely for such coordination.[77] Canada, being a federal state, found it very difficult to coordinate governance and competencies across provinces during the SARS epidemic in 2006 and thus passed the Public Health Agency of Canada Act.

Another way in which States may ensure proper coordination between actors during a PHE is through the formation of 'ad-hoc bodies' as is the case in South Africa. While ordinarily the Directorate General of the National Department of Health is expected to coordinate all medical services during a disaster under the National Health Act, ad-hoc expert committees may be created for specific purposes like 'infection control'.

[76] Article 4(1), Infectious Diseases Prevention and Control Act.
[77] Andrea Riccardo Migone, 'Trust, but customize: federalism's impact on the Canadian COVID-19 response' (2020) 39 Policy and Society 382-402.

Accountability

As far as the question of requiring governments to respond appropriately to PHEs is concerned, none of the PHE laws that we studied imposed punitive measures on public officials or authorities for such failings on their part. Instead, punitive measures across all PHE laws are borne by citizens for failure to comply with their provisions.

(b) What powers are assigned to authorities under PHE laws and how are they exercised?

Powers and duties go hand in hand in enabling authorities under PHE laws to respond appropriately. PHE laws might confer broad powers to respond appropriately to PHEs or enumerate very specific powers. These powers may be both legislative and executive. The analysis below indicates some broad trends in the different kinds of powers conferred through PHE laws.

Why did the UK pass a Coronavirus Act, 2020?

The UK passed the Coronavirus Act, 2020 on March 25, 2020, soon after the pandemic hit the country. While the country did have existing public health and civil emergency regulations, Parliament passed the Coronavirus Act because of its need to act quickly with fewer restraints. Although the Public Health (Control of Disease) Act 1984 also provides a legislative framework for managing a pandemic, it greatly restricts the scope of any new regulations, requires them to meet strict criteria, and subjects them to judicial review. With coronavirus rapidly overwhelming the UK's National Health Service and overall healthcare system, the government needed to pass sweeping regulations regarding a range of topics – such as virtual legal proceedings, travel, isolation, and business closures – with fewer restraints. The result was the Coronavirus Act, a 390+ page bill described as the 'largest expansion of executive power seen in peacetime' in the UK's history.

Power to make regulations

As discussed above, most PHE laws identify nodal agencies and public actors to respond to PHEs, which are then conferred with the power to make regulations with respect to either specific aspects of infectious or communicable diseases or broad regulations to prescribe appropriate measures. For example, in South Africa, the Minister of Health has exercised their power under section 90 of the National Health Act to issue regulations regarding communicable diseases. In the UK, the Secretary of State may exercise their power under the Public Health (Control of Disease) Act to make regulations towards 'Control of Diseases'. This includes the power to make regulations ranging from the treatment of persons affected by epidemics to those relating to vessels or aircrafts that have on board cases of epidemic, endemic or infectious diseases. The Public Health Service Act in the USA authorises the Surgeon General to make and enforce such regulations with the authority of the Secretary as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases.[78]

Power to impose emergency, restrictions and suspend rights and liberties

Most PHE laws do not confer powers to impose a general state of emergency; instead, this is derived from other specific laws. For instance, in Canada, the power to declare an emergency is conferred by Article 3N of Emergencies Act of 1988 only if the situation cannot be effectively dealt with under any other law of Canada. The USA in this regard sets a unique example because section 201 of the National Emergency Act authorises the President to declare a national emergency. However, this declaration only allows for the activation of emergencies in other statutes. These are not activated automatically unless specifically identified in the President's declaration. In addition to this, the Secretary of Health and Human Services is authorised to declare a PHE under the Public Health Service Act.[79] In South Korea, the declaration of disaster under Article 36 of the Framework Act on the Management of Disaster and Safety involves the suspension of certain rights and liberties.

As far as the power to impose restrictions on individuals and companies is concerned, some countries like the UK and South Korea have specific provisions that enumerate activities that can be restricted, such as attending school, going to the workplace (if infected), large gatherings, public events, sale of certain foods etc. Additionally, in South Korea, under Article 41-2 of the Infectious Diseases Control and Prevention Act, employers are also obliged to cooperate and offer paid leave to sick employees and not treat them in an unfair manner. Laws in

[78] §264 (a), Public Health Service Act.
[79] § 247d(a), Public Health Service Act.

Canada and Brazil allow restrictions to be imposed on travel and transport in case of the spread of communicable diseases.

Disclosure, publication or restriction of information and surveillance

One of the challenges of PHEs is the lack of information amongst the general public and the spread of misinformation. With respect to providing information related to PHEs to the public, there are two major approaches that we observed across jurisdictions. In South Korea, under Article 3-2(1) of the Infectious Diseases Prevention and Control Act, citizens are guaranteed a 'right to know.' In South Africa[80] and Brazil,[81] a duty is imposed on the State to provide information to the public, although in South Africa, some of this information may be restricted, as authorised by the Minister.

As far as surveillance of citizens during PHEs is concerned, we observed that although South Korea stands out for giving its citizens the right to know information about outbreaks, prevention and control of quarantinable infectious diseases and how to deal with them, this right also forms the basis for surveilling citizens during PHEs. Articles 6 and 34-2 of the Infectious Diseases Prevention and Control Act can be invoked to allow the Minister of Health to 'promptly disclose information' about the 'movement paths, transportation means … [and] contacts of patients of the infectious disease.' As a result, private information about infectious and potential patients is disclosed to the public by the authorities. Further, listed public agencies can be mandated to provide other authorities with the personal information of citizens.[82] However, such sharing of information is restricted to 'conducting tasks related to infectious diseases under the Act, and shall be deleted when the threat has passed.'

In the UK, information may be collected from persons only by means of an order of a Justice of Peace,[83] whereas the US law emphasises strengthening bio surveillance systems for better public health preparedness.[84] Interestingly, regulations under the South African National Health Act provide the State the power to surveil communicable diseases and not people per se,[85] although if the disease is a notified disease, individual persons may also be surveilled.[86] In Canada, Chapters 4 and 5 of the Public Health Act of Quebec set an interesting example because they require proposed surveillance plans to be submitted to the ethics committee of the Institut national de santé publique du Québec for an opinion. In Brazil, under Article 13 of Law 356/2020, the Ministry of Health must 'safeguard the right to confidentiality of personal information.'

Power to order quarantine and isolation

The power to quarantine and isolate infected persons is an essential component of State responses to a pandemic. Specific quarantine and isolation powers are conferred by laws across jurisdictions except Brazil, where this can be read under the broad power given to the Department of Immunization and Communicable Diseases to take relevant action to control and prevent the spread of communicable diseases.[87] Brazil is also the only country which allows the government to quarantine and isolate individuals only 'by prescription, or at the recommendation of the epidemiological surveillance agent'.[88]

In the UK and the USA, when there is a lower level of threat, quarantine and isolation are limited only to foreigners. As the threat increases, they may be imposed on any individual reasonably believed to be infected with a communicable disease. The South Korean Quarantine Act contains very specific provisions, such as compulsory quarantine inspection for travellers who are entering or departing from the country by land[89] and the setting up of temporary quarantine and isolation facilities, etc.[90]

[80] Section 17(4)(b) of the Disaster Management Act provides for an electronic database which is to act as a repository of information with respect to all aspects of disaster and disaster management. While this database is made available to the public free of charge, certain parts of the database may be restricted to the public as authorised by the Minister.
[81] Article 11, 356/2020.
[82] Article 76-2, Infectious Diseases Control and Prevention Act.
[83] Section 45, Public Health (Control of Disease) Act, 1984.
[84] Section 205, Pandemic and All Hazards Preparedness and Advancing Innovation Act, 2019.
[85] Section 23 (ix), National Health Act, 2003.
[86] Rule 8 (1), Regulations relating to the Surveillance and the Control of Notifiable Medical Condition, National Health Act, 2003.
[87] Article 35, Law 9795 of 2019.
[88] Article 3, Law 356/2020.
[89] Article 11, Quarantine Act.
[90] Article 16, Quarantine Act.

Powers related to Counter-Measures

In relation to compulsory counter measures, Articles 46 and 49 respectively of the South Korean Infectious Diseases Control and Prevention Act allows relevant authorities to make medical examinations and vaccinations compulsory for citizens and to keep them hospitalized and/or quarantined if they believe them to be infected. While the UK[91] and Canada have provisions related to compulsory medical examination, Canada only allows it on reasonable grounds.[92] Under the Brazilian law, it has been left to the discretion of authorities to determine the need for the compulsory imposition of specific medical treatments, vaccination or other prophylactic measures.[93] South Africa stands out in this context as the law lays down certain conditions, which need to be fulfilled before taking any compulsory actions.[94]

Power to ration healthcare resources

Healthcare infrastructure might collapse during a PHE, and healthcare professionals might have to ration scarce healthcare resources. We did not observe any specific provisions in the analysed laws to deal with the scarcity of healthcare resources. However, in the UK, multiple sections of the Coronavirus Act, when read together, aim at reducing the burden on scarce healthcare infrastructure through a relaxation in regulations as well as administrative workload. Section 101(c) of the Pandemic and All-Hazards Preparedness Reauthorization Act in the US accounts for coordinated medical triage and evacuation at appropriate medical institutions based on patient medical need and taking into account regionalised systems of care.

Power to requisition private property and human resources

Public health infrastructure in many countries may not be enough to respond to a PHE exhaustively, necessitating the requisitioning of private property. However, among the laws that we surveyed, no jurisdiction except South Korea has specific provisions in this regard. Under Article 36 of the Infectious Diseases Control and Prevention Act, South Korean authorities are allowed to designate a medical institution prescribed under their Medical Service Act as an infectious disease control institution. Where patients of an infectious disease are congregated in mass, or the infectious disease control institutions designated under the law are insufficient to accommodate all patients, Article 37 of the same law allows any medical institution to be designated as an infectious disease control institution.

Sometimes, authorities also face scarcity of manpower during PHEs. Among the laws we surveyed, there were no direct provisions that empowered governments to conscript individuals for public service. However, when the existing human capacity to respond to a PHE is exhausted, while there are no direct provisions regarding the conscription of individuals, the USA[95] and the UK[96] allow emergency volunteer services by individuals. South Korea, on the other hand, has a provision for the appointment of epidemic control officers in charge of the affairs of infectious disease prevention and epidemic control, from among public officials.[97]

Power of price control

Due to the increasing demand for healthcare resources and their scarcity during a PHE, the price of health goods and services might shoot up, making them unaffordable to large sections of society. We examined whether PHE laws in the countries selected for analysis conferred the power on governments to control the price of health goods and services. While there were no direct provisions in this regard, in South Korea, the Minister of Health may prohibit the export of a drug or quasi-drug, if a classified infectious disease breaks out and public health is

[91] Schedule 21, Paras 6, 9, 10 and 11, Coronavirus Act, 2020.
[92] Article 22, Quarantine Act.
[93] Article 13, Law 13979 of 2019.
[94] Rules 14 and 15 of the Regulations relating to the Surveillance and Control of Notifiable Medical Condition, National Health Act, 2003, list the specific conditions as follows : (1) The disease or health risk must be one that has previously been determined to be hazardous to the public health (such as Ebola or drug-resistant TB) (2) The state must first attempt other measures besides forced isolation and treatment to prevent the spread of the disease (3) There must be a determination that forced isolation or treatment is the most justifiable course of action to prevent the spread of the disease (4) It must be highly likely that, without intervention, the disease will be spread to others.
[95] §217-b, Public Health Service Act.
[96] Sections 6, 7 and 8, Coronavirus Act, 2020.
[97] Article 49, Infectious Diseases Control and Prevention Act.

likely to be harmed significantly due to a sudden price increase or lack of supply of products necessary for disease prevention, quarantine, and treatment.[98]

Powers of emergency authorisation of medical interventions

When a novel influenza outbreak or similar PHE occurs, one of the top priorities is to develop a vaccine or effective treatment. This might require relaxing existing stringent requirements regarding clinical and biomedical research, and the manufacture and approval of drugs and vaccines. The USA seems to have the most progressive laws in this regard. The declaration of a PHE by the Secretary under the Public Health Service Act leads to a declaration under the Federal Food, Drug, and Cosmetic Act, 1938 that an emergency exists, which in turn justifies the expedited use of certain medical countermeasures.[99] Once this declaration has been made, the FDA commissioner may authorise the emergency use of a drug, device, or biological product during the effective period of the declaration. Additionally, under Title 4 of the Pandemic and All-Hazards Preparedness Act, 2006, the Biomedical Advanced Research and Development Authority is tasked with promoting innovation to reduce the time and cost of such countermeasures and advanced research and development. As an incentive to the persons involved in the production chain of countermeasures, a declaration can be issued under the Public Readiness and Emergency Preparedness Act to provide immunity from tort liability claims to individuals or organizations involved in the manufacture, distribution, or dispensing of medical countermeasures during a PHE.[100]

Recently, South Korea too, after its experience from the MERS outbreak, enacted an amendment to its Medical Devices Act to establish an emergency use authorisation policy, which permits the government to authorize the use of unapproved in-vitro diagnostic test kits in an emergency when no approved diagnostic tests are available.[101] Countries like South Africa go even further and subsidise (fully or partially) the costs required for research and development related to disaster management.

Power to enforce provisions

Across jurisdictions, these powers are imposed by means of penal provisions against violators. These provisions either impose fines or imprisonment or both.

(c) How do PHE laws restrain the exercise of powers?

The third of Gostin's principles—restraint—requires us to examine the in-built limits that PHE laws impose on the State's powers. As discussed in Chapter II, these restraints require proportionality, due process, public participation, and human rights integration, among others. This section analyses the extent to which these are incorporated in the PHE laws that form the subject of our study.

Evidence-based Mechanisms and Proportionality

As discussed earlier, the declaration of a PHE often allows the State to take actions which might not otherwise have been taken by it in usual circumstances. But how do States determine the occurrence of a PHE in order to exercise such extraordinary powers? Sometimes, a strict test to determine whether a situation exists that warrants the exercise of emergency powers may itself be a restraint.

In some of the countries we studied, there are absolutely no mechanisms for determination of a PHE under their PHE laws. In the USA, this determination is based on a consultative process between the Secretary of the State and public health officials under the Pandemic and All-Hazards Preparedness Act, 2006. The South African regulations rely on the definition of a PHE as laid down in the IHR, 2005.

Apart from evidence-based mechanisms to determine the existence or continuance of a PHE, none of the six jurisdictions that we studied have similar mechanisms for the exercise of their other overarching powers. A notable exception is South Africa, where a four-pronged test has been devised to permit the exercise of mandatory quarantine powers under the National Health Act.[102]

[98] Article 40-3, Infectious Diseases Control and Prevention Act.
[99] Section 564, Federal Food, Drug and Cosmetic Act.
[100] Section 2, Public Readiness and Emergency Preparedness Act.
[101] Article 46-2, Medical Devices Act.
[102] n.94.

Although evidence-based mechanisms are not a standard feature of the PHE laws that we studied, certain proportionality standards do guide the exercise of State power in most jurisdictions, although there is no clear or precise definition of what proportionality looks like. It generally requires 'the objective of the measure being imposed to be proportionate to the possible harm itself', as is the case with the UK Public Health (Control of Disease) Act.

Inclusiveness and Due Process

None of the jurisdictions that we studied impose a duty on the State to furnish information to the public with respect to the evidence on the basis of which a PHE has been declared, or on the basis of which certain countermeasures have been undertaken. Nor do any of these six jurisdictions have any provisions with respect to public participation and consultation with regard to the imposition of any measures imposed under their PHE laws.

However, some forms of redress do exist—the UK allows the judicial review of regulations,[103] while a person placed under 'involuntary quarantine' in South Korea can file a rescue claim.[104] Comparatively, the 'right to appeal' has gained more footing in the different PHE laws we studied, in contrast to restraints ensuring transparency and accountability. In the UK, any regulation made under the Public Health (Control of Disease) Act has to undergo review with respect to the necessity of its continued existence, and the Coronavirus Act, 2020 has to undergo a parliamentary review six months into its adaptation.

Human Rights Integration

The Public Health Service Act in the USA provides for the monitoring of 'emerging issues and concerns as they relate to medical and public health preparedness and response for *at-risk individuals*'.[105] The Disaster Management Act of South Africa specifically requires care to be taken at the national, provincial and municipal levels to protect vulnerable populations.[106] Further, there is a special protection under the South Korean law, for healthcare workers who are exposed and vulnerable to infectious diseases such that they can be compensated for any loss caused by the diagnosis, treatment, etc., of patients of infectious diseases.[107]

Right to Health in South Africa

In South Africa, the right to have access to healthcare is a basic human right guaranteed by section 27 of the Constitution. Section 27 also states that no person shall be denied emergency medical treatment. The government of South Africa has been in conversation with private hospitals to reach a deal to provide for the treatment of severely ill Covid-19 patients in the event that public hospitals are unable to meet the demand for critical care beds. The government has agreed to pay approximately 950 dollars per day for Covid-19 patients that get treated at critical care beds in private hospitals.

Brazil and South Africa enshrine constitutional obligations to protect the right to health, which include the obligation of non-discrimination. For instance, in Brazil, the State must uphold "equality of health care, without prejudice or privileges of any kind."

[103] Section 45(f)(6), Public Health (Control of Disease) Act, 1984.
[104] Article 42, Infectious Diseases Control and Prevention Act.
[105] Section 247(d).
[106] Sections 17, 33 and 44 of the Disaster Management Act, 2002.
[107] Article 5, Infectious Diseases Control and Prevention Act.

Key Takeaways

PHE Laws across countries vary according to their historical context. While colonial era quarantine laws form the basis of public health measures in several countries (including India), global developments, especially within the WHO, have seen many countries update their public health emergency preparedness and response legislation.

Countries have used different types of legislation to respond to the Covid-19 pandemic: Overarching public health laws, disaster management and civil emergency laws, pandemic-specific laws, and laws specifically enacted in response to the Covid-19 pandemic.

Most laws (of the six countries studied) identify a specific set of public actors or nodal agencies that are expected to respond to PHEs. While these may be listed in detail in some laws, other laws will allow identified officials to further delegate their powers.

Most laws also confer the power to frame regulations to deal with specific aspects of PHEs.

While most PHE laws do not confer powers to impose a general state of emergency, all laws allow for the restriction of certain activities, which may involve the suspension of some rights and liberties. Laws will vary regarding the degree of specificity with which activities that may be restricted are named.

There are varying levels of scrutiny regarding the collection of personal health information for public health surveillance purposes, with some laws requiring judicial sanction, while others requiring ethical review.

All PHE laws contain provisions that permit quarantine or isolation, with varying conditions regarding when such measures may be imposed. The same goes for other kinds of compulsory actions, such as medical examinations and vaccinations.

Specific powers to requisition private property or conscript individuals for public service do not exist.

Some laws have detailed provisions for relaxing regulatory requirements related to drugs and medical devices during PHEs.

All laws contain punitive provisions in the form of fines or imprisonment that operate only against individuals who violate their provisions. No specific measures are prescribed against public officials who fail to carry out their duties.

Proportionality, in most PHE legislation, requires that actions imposed are proportionate to the possible harm, with specific conditions prescribed only for the imposition of certain kinds of measures, such as quarantine.

None of the laws requires public participation or consultation with regard to specific measures taken by public officials under PHE laws.

Some laws require special attention to be paid to the health of at-risk individuals or vulnerable populations.

IV. How does the Indian legal framework respond to PHEs?

A. Introduction

In India, public health falls primarily within the legislative scope of the states, while the centre and states are both empowered to enact legislation to prevent the spread of infectious or communicable diseases between states.[108] While the specific power to legislate in respect of disaster management has not been assigned to either the centre or the states, the centre and several states have enacted disaster management laws. Consequently, there are several concurrent state and central laws dealing with the prevention and control of infectious disease outbreaks and the management of disasters, including biological disasters and PHEs. The statutory provisions in respect of the prevention and management of PHEs in India are scattered across various different central statutes, with varying levels of focus on public health, and under the superintendence of different monitoring and executive bodies, i.e. statutory authorities constituted under these laws, as well as various ministries and committees.[109] This may be partly due to the apparent lack of a conclusive and widely accepted definition of a PHE,[110] and partly on account of the varying nature of events that constitute public health risks: fast-spreading infectious diseases, 'slow onset disasters'[111] such as droughts, chemical and radiological emergencies, and those PHEs that arise in relation to other natural or human-induced disasters.

In keeping with the previously discussed role of the law in PHE management, i.e. to anchor, facilitate, and guide PHE preparedness and response measures, as well as the best practices observed from other jurisdictions, in this Chapter, we discuss the existing PHE-focused laws in force in India, and how they have been employed to tackle PHEs, and in particular, the Covid-19 pandemic.

B. Overview of central PHE laws

In India, the primary central law dealing with PHE management is The Epidemic Diseases Act, 1897 ("**EDA**"). In addition, miscellaneous provisions exist under other acts and rules relating to the licensing and patents of drugs and medical devices, quarantine and segregation powers in respect of various modes of transport—air, rail, and maritime—as well as preparedness and response provisions under laws in respect of emergencies arising from chemical, radiation, pollution, or food contamination events. This Part provides an overview of these laws, with a focus on analysing the EDA using the duty-power-restraint framework developed in Chapter II.

(a) The Epidemic Diseases Act, 1897

The EDA is the primary legislation at the central level, with the objective of preventing and controlling outbreaks of 'dangerous epidemic diseases' (a term used - but not defined, in the EDA). It was passed by the Governor General of India in Council on the 4th of February, 1897, as an urgent legislation to empower the provincial authorities to control the spread of the bubonic plague epidemic of 1896, and also in response to the fear that other countries may impose restrictions on Indian shipping for fear of exposure to the infection.[112] The EDA grants

[108] Entry 29, Concurrent List, Seventh Schedule, Constitution of India.
[109] Second Administrative Reforms Commission, 'Crisis Management - From Despair to Hope' (Third Report, September 2006) 28 <https://darpg.gov.in/arc-reports> accessed 4 August 2020; National Disaster Management Authority, Ministry of Home Affairs, Government of India, 'National Disaster Management Plan' (November 2019) 18 <https://ndma.gov.in/images/policyplan/dmplan/ndmp-2019.pdf> accessed 4 August 2020.
[110] C Nelson, N Lurie, J Wasserman and S Zakowski, 'Conceptualizing and defining public health emergency preparedness' (2007) 97 American Journal of Public Health S9-S11; Rebecca Haffajee, Wendy E. Parmet and Michelle M. Mello, 'What Is a Public Health "Emergency"?' (2014) 371 New England Journal of Medicine 986-988; R Sharma and MM Hossain MM, 'Strengthening Public Health Partnerships in India: Envisioning the Role of Law Enforcement During Public Health Emergencies' (2019) 44 Indian Journal of Community Medicine 188-192.
[111] National Disaster Management Plan (n. 110) 22.
[112] Governor General of India in Council, *Abstract of the Proceedings of the Council of the Governor General of India Assembled for the Purpose of Making Laws and Regulations* (vol XXXVI, 1897) 24-26 <https://eparlib.nic.in/bitstream/123456789/783589/1/ilcd_28-january-1897.pdf> accessed 1 June 2020.

state governments extensive powers to take steps and enact regulations to prevent and control the spread of 'dangerous epidemic diseases', including carrying out inspections of railway passengers and segregating those suspected of being infected, in hospitals or temporary accommodations.[113] Meanwhile, section 2A of the EDA empowers the central government to conduct inspections and quarantine ships and passengers at ports throughout the country.

The enactment of the EDA was promptly followed by the issuance of notifications delegating the powers of the Governor General under the Act to local authorities in respect of their respective territories.[114] Detailed regulations were also passed by the Governor of Bombay in Council, empowering the Municipal Commissioner to implement the regulations in order to manage the spread of the epidemic in the erstwhile City of Bombay, which was the epicentre of the outbreak.[115]

Over the years, the EDA has been applied from time to time, to combat epidemics in different parts of the country,[116] and states have occasionally adapted the provisions either through regulations to address specific outbreaks[117] or through amendments.[118] During the Covid-19 pandemic, some states have also issued ordinances[119] to address the need for more detailed provisions than those available under the EDA. However, the Act, overall, remains a skeletal legislation, with provisions that only confer very wide emergency powers on state and central authorities.

The table below analyses the EDA using the duty-power-restraint framework discussed in Chapter II.

Duty	Power	Restraint
No explicit duty imposed on government to take PHE preparedness or response measures.	Wide, discretionary powers conferred on authorities, including the powers to restrict the activities of private persons and entities.	No evidence-based procedure set out to determine the existence or continuance of a PHE that justifies the use of powers under the Act.
No explicit obligation of non-discrimination or protection of vulnerable populations.	No specific provision for the vaccination or treatment of infected persons (although the wide scope of powers conferred under the EDA can be interpreted to include the compulsory imposition of such interventions).	No guiding principles laid down for authorities to consider while exercising their powers.
No duty to disseminate information to the public in respect of a PHE.	No explicit powers conferred to modify regulatory requirements in relation to healthcare goods and services, such as price control or expedited drug approval.[120]	No proportionality standards, graded enforcement or provisions to hear objections from affected individuals or the public regarding the imposition of restrictions.

[113] Section 2, Epidemic Diseases Act, 1897.
[114] Government of India, Home Department, compiled by R. Nathan, *The Plague in India, 1896, 1897* vol II (Government Central Printing Office 1898).
[115] ibid.
[116] Swati Negi, Avinash Shroff, Anil Garg, Gaurav Aggarwal, Jitendra Kumar Meena and Sonu Goel, 'Implementation of epidemic disease act: An experience from a North Indian jurisdiction' (2017) 61 Indian Journal of Public Health 148-149; 'A 123-yr-old Act to combat coronavirus in India; experts say nothing wrong' *LiveMint* (14 March 2020 New Delhi) <https://www.livemint.com/news/india/a-123-yr-old-act-to-combat-coronavirus-in-india-experts-say-nothing-wrong-11584182501707.html> accessed 7 August 2020.
[117] Punjab Prevention of Out-break of Malaria Regulations, 1995; Haryana Epidemic Diseases, Malaria, Dengue, Chikungunya & Japanese Encephalitis (JE) regulations, 2016.
[118] The Epidemic Diseases (Bombay Amendment) Act, 1953 provides for delegation of the state's powers under Section 2 to the Collectors within their jurisdiction, and the Epidemic Diseases (Bihar Amendment) Act, 1960 provides for requisitioning of vehicles for the purposes of prevention or response measures in respect of a dangerous epidemic disease outbreak.
[119] Karnataka Epidemic Diseases Ordinance 2020; Epidemic Diseases (Amendment) Ordinance 2020 (Odisha); Uttar Pradesh Public Health and Epidemic Control Ordinance, 2020; The Kerala Epidemic Diseases Ordinance, 2020.
[120] It should, however, be noted that the EDA has been used to regulate treatment rates at private hospitals during the Covid-19 pandemic, and that the employment of this law for such purpose has been judicially challenged. See Akshat Agarwal and Kim D'Souza, 'Pricing and Private Hospitals: The Far-Reaching Implications of the Bombay High Court's Decision in 'Hospitals' Association, Nagpur' *Vidhi Centre for Legal Policy*

(b) Regulations under the Epidemic Diseases Act

During the Covid-19 pandemic, most States and Union Territories[121] issued regulations under the EDA to manage it ('**Covid-19 Regulations**'). These regulations fill in the detail that the parent act does not provide, and also give effect to the central directives issued under the Disaster Management Act, 2005. The key features of these regulations are as follows:

- **Governance:** The existing health administration and state, district and municipal authorities are utilised (Specific details regarding the different officials authorised to act under the regulations are provided in Annexure-I[122]). No specific functions or powers are conferred on rural local bodies. Some state regulations allow the further delegation of powers by designated authorities,[123] some regulations rely on district committees under the Disaster Management Act to strategise regarding containment measures.[124]
- **Restrictions:** Designated authorities are empowered to require the isolation of individuals who fail to cooperate with them[125] and to create containment zones to restrict the spread of the disease.[126]
- **Surveillance:** Certain information is mandatorily required to be disclosed for the purposes of disease surveillance,[127] while control is exercised over both public and private laboratories handling infected or potentially infected samples.
- **Enforcement:** Duties are prescribed for citizens, private healthcare providers as well as other private entities. A breach of the regulations attracts a penalty under section 188 of the Indian Penal Code (for disobeying an official order), with more stringent penalties prescribed for offences against healthcare workers.
- **Regulatory Pathway:** Several regulations automatically incorporate and adopt directives or guidelines issued by the central government in respect of different aspects of the pandemic.[128]

Despite this detail, there are still several areas in which the Covid-19 Regulations continue to fall short of the duty-power-restraint framework:

Duty	Power	Restraint
Do not impose any obligations on authorities to develop and disseminate pandemic-related protocols and guidelines to deal with various aspects of the disease.	Detailed procedures for the exercise of enumerated powers are missing. For instance, while the Regulations permit the requisitioning of private property, they do not set out due process requirements for such action.	No explicit limitations are imposed on the exercise of government discretion. Under most Regulations, district authorities are vested with the power to impose 'any other measure' apart from those specifically enumerated.

(11 November and 16 December 2020) <https://vidhilegalpolicy.in/blog/pricing-and-private-hospitals-the-far-reaching-implications-of-the-bombay-high-courts-decision-in-hospitals-association-nagpur/> and <https://vidhilegalpolicy.in/blog/pricing-and-private-hospitals-the-far-reaching-implications-of-the-bombay-high-courts-decision-in-hospitals-association-nagpur-2/> accessed 17 February 2021. As far as expedited drug approvals are concerned, while there are no provisions to this effect in the EDA, the New Drugs and Clinical Trials Rules, 2019, have limited provisions in this regard.

[121] No published regulations were found on government websites or other official sources, for the following states and union territories: Andaman and Nicobar Islands, Arunachal Pradesh, Chattisgarh, Dadra & Nagar Haveli & Daman & Diu, Jammu and Kashmir, Ladakh, Manipur, Puducherry, Sikkim, and Tripura.

[122] Annexure-I of the Report is available at < https://drive.google.com/file/d/1maW9y_c7l0BvI4gj4zP6YsIQQPNZxYJO/view?usp=sharing>.

[123] For instance, Regulation 16 of the Andhra Pradesh Covid-19 Regulations allows the District Collector to co-opt more officers from different departments to give effect to containment measures.

[124] Regulation 18 of the Bihar Covid-19 Regulations authorises the District Disaster Management Committee headed by the District Magistrate to prepare the planning strategy regarding containment measures for the pandemic.

[125] Regulation 11 of the Chandigarh Covid-19 Regulations state that officers authorised under the Regulations have the power to 'forcefully admit and isolate' persons suspected of Covid-19 who refuse admission or isolation. Such forcible isolation may last for a period of 14 days from the onset of symptoms or till the reports of lab tests are received or for such other period as may be necessary.

[126] Regulation 12 of the Chandigarh Covid-19 Regulations empowers the Chandigarh Administration to implement containment measures that include 'sealing of the geographical area, barring entry and exit of population from the containment area, closure of schools, offices and banning public gatherings, banning vehicular movement in the area', among others.

[127] During hospital screenings, Regulation 5 of the Delhi Covid-19 Regulations requires the travel histories, history of contact with infected persons as well as the status of infection to be recorded and communicated to the Office of the Chief Medical Officer of the district.

[128] Examples of this include the Assam, Bihar and Delhi Covid-19 Regulations.

(c) The Disaster Management Act, 2005

The other key legislation used by the central government during the Covid-19 pandemic is the Disaster Management Act, 2005 ("**DMA**"). The Act, which was enacted in the wake of the 2004 tsunami, creates an elaborate administrative structure to enable national, state, district and local authorities to prepare for, and respond to disasters.[129] Unlike the EDA, which does not create any explicit duties for government, the DMA requires the various authorities set up under it to perform specific functions. These include the preparation of policies and plans for disaster management, coordinating their enforcement and implementation, and taking other measures to prevent or mitigate disasters. The Act also confers specific powers on authorities, especially at the state level, to impose certain restrictions and to exercise control over other authorities. For instance, the State Executive Committee may control and restrict vehicular traffic as well as the entry of persons to and from vulnerable or affected areas.[130] District authorities under the Act have the power to give directions to other authorities at the district level as well as local authorities in the district to take steps for disaster preparedness and mitigation.[131] The National and State Executive Committees, as well as the District Authority specifically have the power to requisition resources, premises or vehicles for rescue operations, with the corresponding obligation to pay compensation for such requisitioning.[132] The Act takes into consideration human rights obligations by imposing a specific prohibition against discrimination on the grounds of sex, caste, community, descent or religion while providing compensation and relief to the victims of a disaster.[133] Chapter IX of the Act prescribes punishments for offences like obstruction, false claims for relief or assistance, and false alarms regarding doctors. All in all, the DMA is a more comprehensive legislation than the EDA as far as disaster preparedness and response is concerned.

Recognising this, the central government, during the Covid-19 pandemic, relied liberally on its powers under the DMA to take a wide range of measures and issue several directions in response to the crisis. The central authorities under the DMA directed[134] a nation-wide quarantine or 'lockdown' order, requiring a total cessation of all activities except for essential services and activities as stipulated in the directives. In addition to the directives under the DMA, the relevant central government departments have proceeded to issue various guidelines and advisories in respect of the different aspects of the PHE response, recommending their adoption by the states. This ranges from travel advisories to the fixation of rates for Covid-19 tests to guidelines on the practice of telemedicine.

Although the DMA is a more detailed law than the EDA, it does not specifically contemplate epidemics or PHEs in its framework. It is therefore debatable whether a pandemic may appropriately be classified as a disaster within the meaning of the DMA and whether its provisions could be used meaningfully to prepare for and respond to PHEs. With the publication of the National Disaster Management Authority's biological disaster management guidelines in July 2008, it appears that some steps have been taken to include PHEs within the ambit of the DMA.[135] However, it is debatable how effectively these guidelines have been implemented, with it being reported 'most ministries do not have a disaster management plan and each department was working in silos when it came

[129] Section 2(d) of the Act defines a disaster as 'a catastrophe, mishap, calamity or grave occurrence in any area, arising from natural or man made causes, or by accident or negligence which results in substantial loss of life or human suffering or damage to, and destruction of, property, or damage to, or degradation of, environment, and is of such a nature or magnitude as to be beyond the coping capacity of the community of the affected area'.
[130] Section 24 (a) and (b), Disaster Management Act, 2005. The District Authority can also exercise the same functions under sections 34) (b) and (c) of the Act.
[131] Section 30 (2)(v), Disaster Management Act, 2005.
[132] Sections 65 and 66, Disaster Management Act, 2005.
[133] Section 61, Disaster Management Act, 2005.
[134] By Order No. 1-29/2020-PP (Pt.II) dated 24 March 2020, issued under Section 6(2)(i) of the DMA, the NDMA directed the "Ministries / Departments of Government of India, State Governments and State Authorities" to take measures to ensure social distancing to prevent the spread of Covid19 in the country; it further stated that the National Executive Committee should issue guidelines in this regard immediately. Pursuant to the above NDMA order, the Home Secretary in his capacity as Chairperson of the NEC, issued guidelines under Section 10(2)(l) of the DMA by way of Ministry of Home Affairs Order No. 40-3/2020-DM-I(A) dated 24 March 2020.
[135] National Disaster Management Authority, Government of India, 'National Disaster Management Guidelines—Management of Biological Disasters, 2008'.

to implementing the mandate of the act.'[136] In this context, the application of the DMA to the pandemic may be viewed as a stop-gap measure to address the immediate need to authorize certain government actions required to control a PHE after it already has a foothold in the population.

A brief analysis of the DMA using the duty-power-restraint framework is provided below:

Duty	Power	Restraint
Extensive duties set out for different levels of government authorities in relation to disaster preparedness and response. However, the applicability of these duties to pandemics or other PHEs is in question.	Similarly, extensive powers that can impose obligations both on individual citizens as well as public authorities.	Procedure for compensation for requisitioning is set out. Additionally, there is an obligation of non-discrimination regarding the provision of compensation and relief under the Act. Similarly, the District Authority must ensure that non-governmental organisations carry out their activities in an equitable and non-discriminatory manner.

(d) Miscellaneous Provisions

As mentioned above, several central laws contain provisions which may be employed in the context of a PHE. Some of these are distinct from and others overlap with the EDA and the Regulations that may be issued under it. Relevant provisions are set out in the table below, although it should be noted that these are not exhaustive of the different legal provisions that may be relied on during a PHE. They are set out here to serve as illustrative examples of the fragmented legal framework on PHE preparedness and response in India.

Aspect of PHE	Legislation	Provision
Quarantine, Inspection and Restrictions on Travel	Indian Ports Act, 1908 Aircraft Act, 1934 Railways Act, 1989	Empower authorities to inspect and quarantine passengers, crew, and cargo, and prevent infected persons and ships from travelling.[137]
Modification of Standards and Control of Supply of Essentials	Drugs and Cosmetics Act, 1940 Patents Act, 1970 Essential Commodities Act, 1955	The New Drugs and Clinical Trials Rules, 2019[138] and the Medical Devices Rules, 2017[139] allow relaxations on the conduct of clinical trials and the submission of clinical data requirements that would ordinarily be required for the development of drugs, devices and vaccines. These relaxations are permitted in the context of life-threatening diseases, disasters, and unmet medical need (where the treatment of a disease is not

[136] Namrata Biji Ahuja, 'Why health ministry alone can't prevent the spread of COVID-19' *The Week* (17 March 2020) <shttps://www.theweek.in/news/india/2020/03/17/why-health-ministry-alone-cant-prevent-the-spread-of-covid-19.html> accessed 9 August 2020.
[137] The Indian Port Health Rules, 1955, enacted under clause (p) of sub-section (i) of section 6 of the Indian Ports Act, 1908; The Indian Aircraft (Public Health) Rules, 2015, enacted under section 8A of the Aircraft Act, 1934; The Carriage of Passengers Suffering from Infectious or Contagious Diseases Rules, 1990, enacted under section 60 of the Railways Act, 1989.
[138] Second Schedule, New Drugs and Clinical Trials Rules, 2019.
[139] Rules 63 and 64, Medical Devices Rules, 2017.

		addressed adequately by available therapy). The Patents Act, 1970[140] contains provisions for the expedited grant of compulsory licences in cases of national emergency, extreme urgency or public non-commercial use including public health crises relating to epidemics. The Essential Commodities Act, 1955 empowers the government to regulate the manufacture, supply, and distribution of notified commodities in the public interest.
PHEs other than infectious diseases	Rules for the Manufacture, Use, Import, Export and Storage of Hazardous micro-organisms/Genetically engineered organisms or cells, 1989 Chemical Accidents (Emergency Planning, Preparedness and Response) Rules, 1996 [Both sets of rules have been issued under The Environment (Protection) Act, 1986.]	Require emergency plans to be created for deployment in the event of an accident, and mandate the reporting of incidents that pose a risk to health.
Enforcement	The Indian Penal Code, 1860 The Code of Criminal Procedure, 1973	The Indian Penal Code imposes penalties on a person who "unlawfully", "negligently", or "malignantly" and knowingly does any act likely to spread a dangerous disease,[141] or disobeys quarantine and movement restrictions in respect of maritime vessels. It also contains provisions penalising the contamination of public water springs or reservoirs,[142] sale of food or drink unfit for consumption,[143] and rash or negligent conduct with regard to a poisonous or explosive substance such that human life is endangered.[144]

[140] Section 84, Patents Act, 1970.
[141] Sections 269 and 270, Indian Penal Code, 1860.
[142] Section 277, Indian Penal Code, 1860.
[143] Section 273, Indian Penal Code, 1860.
[144] Section 286, Indian Penal Code, 1860.

		The Code of Criminal Procedure 1973 empowers a District, Sub-Divisional, or Executive Magistrate to issue urgent orders prohibiting certain activities in the event of anticipated 'danger to human life, health or safety.'[145]

C. Overview of state PHE laws

Like the centre, the states also have various different legal provisions that may be employed for the purposes of PHE prevention and management. This section examines state laws primarily addressing PHEs. State-level legislation in respect of PHEs varies, with some states having enacted legislation to deal specifically with infectious disease outbreaks, some having enacted disaster management laws along the lines of the model law drafted by the High Powered Committee on Disaster Management in 2001,[146] and other states having public health acts[147] that contain specific provisions relating to the prevention and control of infectious disease outbreaks. The states of Telangana and Rajasthan have infectious disease acts dating back about seventy years,[148] while the states of Gujarat, Uttaranchal, Uttar Pradesh, and Sikkim have disaster management acts of more recent vintage. [149]

(a) State Health Laws

The Rajasthan Epidemic Diseases Act is effectively a reproduction of the EDA, while the Telangana Act contains more detailed provisions empowering the authorities to manage an outbreak and prohibiting the public from engaging in activities that are likely to spread the infection, as well as providing penalties for offences under the Act.

The provisions of the more general state public health acts tend to focus on ensuring clean water supply, sanitation, and pest control as preventive measures. However, the Assam Act differs significantly from the others – in addition to the provisions relating to the prevention and control of infectious disease outbreaks, it also sets out the rights and duties of patients and healthcare providers in the modern context of health and healthcare, and creates a public health board to monitor the implementation of the Act.

(b) State Disaster Management Acts

The state disaster management acts were all passed between 2003 and 2006 and have many similar provisions to the DMA. Key features are:

- **Governance:** State acts broadly utilise the existing administrative machinery, empowering Collectors, Magistrates, and Relief Commissioners, as well as setting up state disaster management authorities, and in some cases (Gujarat and Uttar Pradesh), setting up crisis management groups.[150]
- **Duties:** The roles of relevant state, district and local authorities include capacity-building, training of the community, issuing guidelines, preparing disaster management plans, maintaining disaster management funds, and carrying out disaster relief and rehabilitation efforts.
- **Non-Government Participation:** They also contemplate a role for the public and voluntary organisations in assisting the administration in the disaster response.

[145] Section 144, Code of Criminal Procedure.
[146] Ministry of Home Affairs, Government of India, 'Report of the Task Force: A Review of the Disaster Management Act, 2005' (March 2013) 5.
[147] The Andhra Pradesh (Andhra Area) Public Health Act, 1939; The Assam Public Health Act 2010; The Madhya Pradesh Public Health Act, 1949; The Goa, Daman and Diu Public Health Act, 1985; The Madras Public Health Act 1939; The Travancore Cochin Public Health Act 1955; The Puducherry Public Health Act, 1973; The Tamil Nadu Public Health Act, 1939.
[148] The Rajasthan Epidemic Diseases Act, 1957; The Telangana Infectious Diseases Act, 1950.
[149] The Gujarat State Disaster Management Act, 2003; Uttaranchal Disaster Mitigation, Management and Prevention Act, 2005; The Uttar Pradesh Disaster Management Act, 2005; Sikkim State Disaster Management Act, 2006.
[150] Ministry of Home Affairs, Report of the Taskforce (n. 143).

While the state PHE laws are far clearer and more detailed than the EDA, only a few states have these laws in place, and most are restricted to the control of infectious disease outbreaks, general preservation of public health, and prevention of public health hazards, lacking a focused approach to PHE preparedness, and failing to provide for the evolving nature of the threat posed by biological and chemical hazards and novel PHEs. Viewing state PHE laws through the lens of the duty-power-restraint framework, we find:

Duty	Power	Restraint
Significant duties are imposed on local authorities, especially as regards the provision of clean water and sanitation facilities. Health officers are required to monitor compliance and take on greater authority in the context of PHEs.	Some acts contain wide powers to segregate infected persons, direct compulsory examination and / or vaccination, conduct inspections of premises suspected to be infected, to close down public eateries and festivals, demolish infected premises, and requisition private premises in order to prevent or control an infectious disease outbreak.	Assessing the existence or threat of a PHE is left to the discretion of public authorities.
Governments may also provide for hospitals and isolation facilities to meet the needs of PHEs.	Citizens must comply with sanitary requirements and under some acts, medical practitioners as well as members of the public ought to intimate authorities regarding the occurrence of infectious diseases.	Most acts lack remedies for overreach, although due process requirements for the requisitioning of private property exist in the form of a notice period.

This overview of central and state PHE laws suggests that a broad framework is certainly in place to meet the needs of PHE preparedness and response, although it is greatly fragmented. However, as the duty-power-restraint model demonstrates, the effectiveness of a legal response requires greater specificity. This is currently missing in the Indian context. Of the two key central laws, the EDA is merely a vehicle for the exercise of wide-ranging executive powers, while the DMA, which has more detailed provisions in place, is not necessarily tailored to a PHE. As far as state laws are concerned, very few have specific PHE legislation in place. In any case, these laws mirror the EDA, do not account for categories of PHEs other than infectious disease outbreaks and do not prioritise the preparedness component of tackling PHEs. In the absence of explicit provisions that require the government to take or abstain from certain actions, that identify the rights of the various stakeholders and the core principles of a PHE response, and that provide corresponding remedies, the rights and responsibilities of the government and citizens are in limbo. As a result, courts are called upon to intervene with ad-hoc solutions (as discussed in the following chapter), at a time when streamlined protocols and clear strategies are most essential.

However, before moving on to this discussion, an overview of the Indian legal framework should also include a discussion of pending legislative proposals in relation to PHE preparedness and response. An overview and analysis of these proposals is presented in the next part.

D. Legislative Proposals on PHE Preparedness and Response

Over the last few decades, there have been a few legislative proposals for public health and PHE legislation. A 'Model Public Health Act' (for adoption by the states) was drafted by the centre in 1955 and updated in 1987,[151]

[151] Central Bureau for Health Intelligence, 'Model Public Health Act – 1987' <https://www.cbhidghs.gov.in/index4.php?lang=1&level=0&linkid=136&lid=138> accessed 10 August 2020.

containing chapters on the prevention and control of communicable diseases. In 2009, the National Health Bill[152] was drafted adopting a rights-based approach – outlining the right to health of the individual and setting out a legal framework for public health services, including powers and functions in relation to PHEs. More recently, in 2017, 'The Public Health (Prevention, Control and Management of Epidemics, Bio-Terrorism and Disasters) Bill, 2017' ('**2017 Bill**') was published by the Ministry of Health and Family Welfare, inviting comments from stakeholders.[153]

(a) The Model Public Health Act, 1987

As far as PHE preparedness and response is concerned, the Model Public Health Act is the most comprehensive of all three legislative proposals, although some of its provisions are outdated since it has been more than three decades since it was first drafted. While the Act sets out general measures for public health, Chapter X is specifically dedicated to communicable diseases. Health officers appointed under the Act as well as local authorities are contemplated as the first responders to PHEs, although the State Government and Director of Health Services have overarching powers as well. The following table sets out the key elements of the Act related to communicable diseases, using the duty-power-restraint framework.

Duty	Power	Restraint
Local authorities (when directed by Health Officers) have positive obligations to provide human resources, medical supplies, diagnostic laboratory facilities, and conveyance, and to build hospitals or other places of treatment to prevent the occurrence or spread of diseases. The quality component of the right to health is also built into this duty—local authorities are deemed not to have discharged their obligation if hospitals are not maintained in accordance with special orders issued by the Director of Health Services.	Health officers appointed under the Model Act has very general powers to recommend the adoption of measures to the local authority that they deem necessary to suppress or mitigate a disease or prevent its outbreak.	The Act incorporates due process requirements in two ways: first, relevant officials must give reasonable notice before entering and inspecting premises; second, certain kinds of actions require an application to be made to the magistrate—to close dwellings where food articles are sold, to prohibit public or private assemblages of people, to remove and dispose of a body of person who has died while suffering from a notified disease.
For specific diseases like tuberculosis, leprosy, and sexually transmitted diseases, local authorities (when directed by government) are also required to provide free case-finding and treatment facilities.	They also have a range of specific powers that place restrictions on individuals. These include the power to remove a person to hospital under certain conditions, to order the cleaning or disinfection of a house or article, to prohibit certain classes of work in affected premises, and to destroy huts or sheds.	Additionally, the Act pays some attention to vulnerable groups. Where a woman is removed to a hospital or other place of treatment, special accommodation must be provided for her. Similarly, persons suffering from sexually transmitted diseases are entitled to confidential treatment.
In the context of individual duties, enumerated persons, like medical practitioners, owners of factories,	Where the government has made a declaration that a place or area is affected by the outbreak of a	Finally, the Act allows individuals to challenge orders of compulsory vaccination or inoculation if they

[152] Ministry of Health and Family Welfare, Government of India, 'Working Draft: Version January 2009' <https://www.prsindia.org/uploads/media/Draft_National_Bill.pdf> accessed 10 August 2020.
[153] Ministry of Health & Family Welfare, Government of India – Notice No. T-180 14/3 '2004/PH dated 13 February 2017 <https://www.prsindia.org/uploads/media/draft/Draft%20PHPCM%20of%20Epidemics,%20Bio-Terrorism%20and%20Disasters%20Bill,%202017.pdf> accessed 10 August 2020.

lodging houses, or even the head of a family or owner or occupier of a house have a duty to notify authorities of the existence of notified diseases. Individuals who know that they are suffering from communicable diseases are also prohibited from exposing other persons to the risk of infection by their presence in public places. The Act imposes penalties for such violations.	notified disease, enumerated officials have the power to order evacuation, direct the examination of persons arriving from outside the area, place restrictions on their movement and close existing markets.	believe that vaccination can be injurious to their health and provided they give an undertaking to isolate themselves for a certain period.

(b) The National Health Bill, 2009

Like the Model Public Health Act, 1987, this is an overarching bill that deals with different aspects of healthcare, but differs from the earlier model legislation by incorporating explicit rights-based provisions. The bill guarantees a specific set of rights linked to the conception of the international human right to health, and creates corresponding obligations for the central and state governments. Unlike the Model Public Health Act which contains very detailed provisions on different aspects of public health, the National Health Bill creates a broad framework for the exercise of the right to health, sets up National and State Public Health Boards to carry out a range of functions (including in relation to PHEs), and accountability and monitoring mechanisms. There are few provisions explicitly related to PHEs. These are analysed in the table below.

Duty	Power	Restraint
The general obligation in the Bill to provide access to quality health care services requires governments to take effective measures in the context of PHEs. Central and state governments must review the existing legislative framework on PHEs and take steps to enact and implement laws related to PHEs.	Since the Bill is a framework legislation, it does not list specific powers related to PHEs. However, it does acknowledge that limitations may have to be imposed on the right to health of individuals in the interests of public health.	The rights-based nature of the Bill imposes inherent limitations on the exercise of State powers. The Bill also incorporates a general principle of proportionality—where limitations must be imposed on the right to health of individuals, these must be necessary in compelling public health or interest, and they must constitute the least restrictive alternative. They must additionally be of limited duration and subject to review.
State Public Health Boards constituted under the Bill must additionally implement programmes to prevent and address conditions of public health importance, including epidemics and outbreaks, through surveillance and epidemiological tracking. They must also ensure a coordinated response to PHEs by	As part of its obligation to protect the right to health, governments also have the corresponding obligation, and therefore, power, to regulate private and non-government healthcare service providers. This specifically includes the power to lay down safety and quality assurance for all aspects of healthcare. National Public Health	Chapter III sets out a comprehensive bundle of collective and individual rights in relation to health. This specifically includes the right to protection from and mitigation during PHEs. General rights include the right against discrimination, the right to dignity, the right to participation and information, and the right to

liaising with other government departments and agencies.	Boards have the power to supervise and verify compliance with rules laid down under the Act, while State Public Health Boards may establish and implement performance standards and measures for healthcare providers.	justice. Specific healthcare-related rights include the right to emergency treatment, the right to quality of care, the right to the benefits of scientific progress and technology assessment, the right to medical records and data, the right to prior voluntary informed consent, and the right to confidentiality. These rights are generally defined and have not been specifically contextualised to apply to PHEs.
		Restraint is also expressed in the form of a remedy. Designated district courts may hear complaints relating to non-compliance with or mis-performance of obligations by the government or other public authorities.

(c) The Public Health (Prevention, Control and Management of Epidemics, Bio-Terrorism and Disasters) Bill, 2017

This is the most recent legislative proposal and is specifically targeted towards PHEs unlike the other two proposals discussed in this part. It is intended to replace the EDA by incorporating an updated and expanded understanding of PHEs and conferring a more specific range of powers to respond to such emergencies than those provided under the EDA. However, the Bill only partially reflects more modern conceptions of legislative responses to PHEs. Although it confers extensive executive powers, it does not create any obligations for government, nor does it impose any reasonable limitations on the exercise of these powers. Therefore, the analysis of the provisions of the Bill using the duty-power-restraint framework is somewhat limited.

Duty	Power	Restraint
Where the state government or any district or local authority is of the opinion that a PHE is likely to arise, it may require officials to take such measures for such duration as necessary to prevent, control and manage the PHE. It may also require persons to observe such measures, thereby creating duties for individuals and officials.	The bulk of the Bill involves the enumeration of an extensive range of powers. These powers are conferred on state governments or district or local authorities. They include the power to prohibit activities likely to harm public health, to quarantine, isolate and otherwise restrict the movement of persons, and to direct compulsory medical examination of any person or class of persons.	The only restraint on the exercise of government power exists in the form of a provision for appeal under Chapter IV. Any person or body aggrieved by orders passed by the state government, district or local authority (note that overriding orders passed by the central government are excluded) may appeal against such orders before an Appellate Authority that is to be notified under the act.
	They may also inspect vehicles, vessels and ships, undertake disinfection, destruction and disposal, ban or regulate the	

	transport of hazardous or toxic material, and order the detention of persons intending to carry animals, plants or bio-hazardous material.	
	Finally, their powers extend to authorising the entry of persons, without prior notice, into premises where PHEs have occurred, disseminate information, close markets, educational and other institutions, and direct clinical establishments to admit and manage cases.	

Key Takeaways

India does not have a single, consolidated code to dictate its response to PHEs. Legal provisions on PHEs are scattered across a range of central and state laws.

Indian laws relevant to PHEs are a mixture of laws directly targeted at epidemics and infectious diseases, disaster management laws (at the centre and states), state public health legislation, and criminal laws.

Two central laws-the Epidemic Diseases Act and the Disaster Management Act-dominate the legal framework on PHEs.

A role for states is contemplated especially under the Epidemic Diseases Act, with most states issuing specific regulations to address the Covid-19 pandemic.

Only a few states have dedicated public health laws that contain provisions targeted at PHEs, and the role that these might have played in responding to the Covid-19 pandemic is unclear.

When analysed under the duty-power-restraint framework, the Epidemic Diseases Act only confers powers, without creating obligations or imposing restrictions on governments. This is largely replicated in state Covid-19 regulations issued under the Act.

The Disaster Management Act creates extensive duties for governments, but does not contain provisions targeted at PHEs.

Legislative proposals relevant to public health emergencies range from a targeted PHE law to a general rights-based legislation to a comprehensive state law on public health. Of these, the central targeted PHE bill continues to emphasise only the power component of the duty-power-restraint framework.

V. How did the Indian legal framework respond during the Covid-19 pandemic?

A. Introduction and Methodology

This Chapter uses four case studies to understand how the Indian legal framework on PHEs (described in the previous Chapter) has responded to the Covid-19 pandemic. These case studies broadly correspond to the WHO's checklist for pandemic influenza risk and impact management mentioned in Chapter I. The section on 'Legal and policy issues' in the checklist requires government to assess the legal basis for all public health measures that are likely to come into play during a pandemic response, such as isolation or quarantine, travel or movement restrictions, and the closure of educational institutions and mass gatherings. The checklist also advocates assessing the legal basis for vaccinating health care workers, assessing liability for adverse events attributable to vaccines, establishing regulatory pathways to expedite the import or manufacture of pandemic influenza vaccines, and reviewing the legal framework that governs the participation of private healthcare actors in PHEs.

On this basis, and keeping in mind that we are primarily concerned with assessing the role of public health legislation in responding to PHEs, we have chosen to study the State response in the following cases:

- Lockdown and movement restrictions
- Quarantine, contact tracing, and other preventive measures
- Testing strategy, including access to testing
- Medical treatment of Covid-19 patients

These interventions, while representing key facets of any pandemic response, are also those where the legal and governance framework has had a key role to play in guiding the response by:

- Weighing competing interests by balancing public health against individual rights to liberty and autonomy
- Guaranteeing access to quality health care, while having to ration scarce health care resources.

While analysing each of these interventions, we looked at the legal and governance framework which authorised the measures, including any litigation which arose from or impacted the measures, as a way of studying gaps in the framework, if any. Since these measures are still ongoing, the impact of these measures is contextualised through media reports on some of the consequences of these measures. Wherever necessary, comparisons are made to the international practices in responding to Covid-19 analysed in Chapter III. The objective of each case study is to highlight key tensions which have emerged in these interventions and analyse how shortcomings in the existing legal and governance framework may have contributed to these tensions.

B. Lockdown and Movement Restrictions

(a) Relevant Legal Framework

During the Covid-19 pandemic, the PHE response was built upon the existing legal framework discussed in Chapter IV, accompanied by regulations, directives, guidelines, and advisories. Many of the measures undertaken in respect of lockdown and movement restrictions were effected through central and state government directives under the various PHE laws, as well as through a co-operative effort between the central and state governments, where the centre issued guidelines and advisories in respect of various aspects of the pandemic response, and the states gave effect to these, as applicable.

The country-wide lockdown was initially effected through an order issued by the Ministry of Home Affairs in pursuance of a directive from the National Disaster Management Authority under the provisions of the DMA.[154] Prior to this, several states had taken steps to ban public gatherings, and restrict movement under Section 144 of the Code of Criminal Procedure, 1973.[155] Pursuant to the first national lockdown, some states took steps to extend these restrictions beyond the initial period, as these states were worse affected by the pandemic,[156] and several months later, some of these states had stricter regulations in place than the national norm, in light of the greater incidence of the disease in these states.[157] The centre has issued guidelines and advisories from time to time, directing or advising the states to follow the norms laid down by it,[158] including calling upon state governments to apply the provisions of the EDA in order to manage the pandemic within their respective jurisdictions.

As discussed previously, in applying the provisions of the EDA, most states and union territories issued regulations to sanction and enable the measures that were immediately necessary to contain the spread of the disease (including institutional isolation of suspected cases,[159]control of information relating to the pandemic,[160]and recording and reporting patient histories.[161]) Most of the Covid-19 Regulations issued by the states (as presented in the Annexure[162] to this paper) provide for containment orders to be issued in respect of any district or local area affected by the disease. For instance, Regulation 15 of the Andhra Pradesh Covid-19 Regulations and Regulation 12 of the Karnataka Covid-19 Regulations provide that where cases of the disease are reported from a particular area within the state, the district administration may ban public gatherings, enforce the closure of establishments, and bar entry and exit from such area.

(b) Shortcomings

The various directives and advisories issued by the centre and states from time to time operated so as to give effect to the pandemic response measures being formulated from day to day in light of increased scientific insight into the disease, epidemiological observations from the international sphere, and administrative learnings from the impact of various government measures. These directives also attempted to bridge the gaps in the legal and administrative framework relating to PHE management. While this combined framework of legal provisions and executive orders appears to cover the basic aspects of containment measures, what has been observed through news reports and the government notifications themselves, is a lack of uniformity in the implementation of various measures, between different states, and the frequent violations of regulations and orders by members of the public. This might be attributable to:

[154] By Order No. 1-29/2020-PP (Pt.II) dated 24 March 2020, issued under Section 6(2)(i) of the DMA, the NDMA directed the 'Ministries / Departments of Government of India, State Governments and State Authorities' to take measures to ensure social distancing to prevent the spread of Covid-19 in the country; it further stated that the National Executive Committee should issue guidelines in this regard immediately. Pursuant to the above NDMA order, the Home Secretary in his capacity as Chairperson of the National Executive Committee, issued guidelines under Section 10(2)(l) of the DMA by way of Ministry of Home Affairs Order No. 40-3/2020-DM-I(A) dated 24 March 2020.

[155] 'No One Allowed Within 1 km Of Rajasthan Family Tested For Coronavirus' *Press Trust of India* (19 March 2020) <https://www.ndtv.com/india-news/no-one-allowed-within-1-km-of-rajasthan-family-tested-for-coronavirus-2197075> accessed 28 September 2020; Anulekha Ray, 'Coronavirus: Section 144 in Mumbai as total cases rise over 70 in Maharashtra', (*Mint* 22 March 2020) <https://www.livemint.com/news/india/coronavirus-have-no-option-but-to-apply-section-144-in-maharashtra-says-thackeray-11584870602906.html> accessed 28 September 2020.

[156] 'Is the Centre's lockdown different from a state's lockdown', *TimesofIndia.com* (13 April 2020) <https://timesofindia.indiatimes.com/india/is-the-centres-lockdown-different-from-a-states-lockdown/articleshow/75116029.cms> accessed 21 September 2020.

[157] Pratik Mukane, 'Maharashtra extends lockdown till August 31: Here's everything that's allowed and not allowed', *Mumbai Mirror* (30 July 2020) <https://mumbaimirror.indiatimes.com/coronavirus/news/maharashtra-lockdown-guidelines-whats-allowed-not-allowed-gyms-malls-to-reopen-from-august-5/articleshow/77253130.cms> accessed 21 September 2020.

[158] Letters dated 29 June 2020 and 29 July 2020 respectively, bearing No. D.O.No.40-3/2020-DM-I(A) issued by the Home Secretary, Government of India, to the Chief Secretaries in respect of 'Unlock 2' <https://www.mha.gov.in/sites/default/files/MHADOLr_29062020.pdf> accessed 21 September 2020, and 'Unlock 3' <https://www.mha.gov.in/sites/default/files/DOLrDt_29072020.pdf> accessed 21 September 2020 respectively.

[159] For instance, Regulation 11 of The Bihar Epidemic Diseases COVID-19 Regulations 2020.

[160] For instance, Regulation 6 of the Uttar Pradesh Epidemic Disease COVID-19 Regulations 2020.

[161] For instance, Regulation 4 of The Jharkhand Epidemic Disease (COVID-19) Regulations, 2020.

[162] Annexure-I of the Report is available at < https://drive.google.com/file/d/1maW9y_c7l0Bvl4gj4zP6YsIQQPNZxYJO/view?usp=sharing>.

- **Misconception and misinformation:** This was observed in the case of religious gatherings held despite the ban on public gatherings.[163]
- **Lack of PHE Preparedness:** This was observed through the delayed institution of screening and surveillance as well as a lack of coordination from the authorities on the ground, as with the Tablighi Jamaat incident.[164]
- **Physical and economic constraints:** This was evident in the case of migrant workers. A large-scale and seemingly inevitable violation of the lockdown measures took place largely because of the implementation of a national lockdown without warning or preparation, causing the mass movement of displaced migrant workers attempting to exit cities where they had either lost employment or accommodation, or both, and make their way to their hometowns. The conditions in which this large-scale movement of workers took place did not permit them to observe the conditions of the lockdown or the distancing that it demanded.[165]
- **Effects on the vulnerable:** Apart from migrant workers, lockdown orders could not adequately take account of the needs of vulnerable and marginalised sections of the population, such as persons with disabilities, leading to acute hardship during the lockdown[166] by failing to consider the continued need to access health care services despite the restrictions on transport and movement.
- **Uncertain legal status of guidelines:** While the orders issued by the NDMA imposing the lockdown have a legal basis in the DMA, the binding force of other advisories and guidelines related to movement restrictions issued by other public authorities is not as clear. This is not helped by the fact that these advisories or guidelines do not specify the legal basis of their authority. For instance, the Ministry of Civil Aviation issued an order in May 2020 setting out detailed guidelines for passengers, airlines and airport operators, without specifying the source of its authority.[167]
- **Criminal penalties for violations:** Violations appear to have been punished by way of informal and irregular innovations by police, in the form of improvised, discretionary punishments that could be imposed immediately,[168] in contrast with the more formal and lengthy procedures for conviction for the offences that these violations constitute under the criminal law.[169]

When analysed using the duty-power-restraint framework, the following gaps in the legal framework are revealed:

Duty	Power	Restraint
No clear protocol to coordinate the imposition of restrictions between the centre, states, and other public authorities	Unclear legal basis to authorise entities and officials to issue directions or orders in furtherance of lockdown and movement restrictions Absence of flexible enforcement mechanisms	No specific duty to consider the effects of such restrictions on different groups

[163] 'Despite ban on mass gatherings, rathotsava held in Chitradurga', *The Hindu* (14 March 2020) <https://www.thehindu.com/news/national/karnataka/despite-ban-on-mass-gatherings-rathotsava-held-in-chitradurga/article31070110.ece> accessed 29 September 2020.
[164] Akash Bisht and Sadiq Naqvi, 'How Tablighi Jamaat event became India's worst coronavirus vector' (*Aljazeera* New Delhi 7 April 2020) <https://www.aljazeera.com/news/2020/04/07/how-tablighi-jamaat-event-became-indias-worst-coronavirus-vector/> accessed 29 September 2020.
[165] 'Coronavirus: Is social distancing an oxymoron in India?', Geeta Pandey *BBC News*, Delhi (23 April 2020) <https://www.bbc.com/news/world-asia-india-52393382> accessed 29 September 2020; 'State, Centre confusing people with lockdown orders', (*The Hindu*, 5 May 2020) <https://www.thehindu.com/news/national/karnataka/state-centre-confusing-people-with-lockdown-orders/article31512546.ece> accessed 21 September 2020.
[166] 'Coronavirus lockdown | In the pandemic, the disabled remain an invisible minority', Suchitra *The Hindu* (14 June 2020) <https://www.thehindu.com/news/national/coronavirus-lockdown-in-the-pandemic-the-disabled-remain-an-invisible-minority/article31828510.ece> accessed 29 September 2020.
[167] Ministry of Civil Aviation, Order No. AV. 29017/5/2020-DT, available at <https://www.civilaviation.gov.in/sites/default/files/Order_of_MoCA_dated_21st_May_2020.pdf> accessed 28 February 2021.
[168] Omkar Khandekar, '7 creative ways Indian police punish covid-19 lockdown violators', *Mint* (28 April 2020) <https://www.livemint.com/mint-lounge/features/7-creative-ways-indian-police-punish-covid-19-lockdown-violators-11588043982457.html> accessed 21 September 2020.
[169] The Covid-19 Regulations provide for penalties under Section 188 of the Indian Penal Code, 1860, and in some cases, for the initiation of proceedings under Section 133 of the Code of Criminal Procedure, 1973, in the event of a failure to comply with the orders / directions of any authorities thereunder.

C. Quarantine and Contact Tracing

Quarantine, isolation, contract tracing and other preventive measures are non-pharmaceutical interventions which are aimed at reducing transmission and preventing the spread of an infectious disease. In the context of the Covid-19 pandemic, various countries implemented quarantine, contact tracing and subsequent testing and isolation measures to check the spread of the infection. In fact, in the absence of a vaccine or a treatment, such measures are often considered the best response. The imposition of such measures, however, necessarily involves the restriction of individual liberties such as the freedom of movement and the right to privacy that are ordinarily available to citizens.

(a) Relevant Legal Framework

Due to the restrictive nature of measures related to quarantine and contact tracing, they require legal sanction in any rule of law society where individual rights are recognised. During the Covid-19 pandemic, these measures have been implemented by both, the central, and state governments. Early in March 2020, the central government advised state governments to issue regulations under the EDA to implement various non-pharmaceutical interventions to check the spread of Covid-19.[170] As discussed in Chapter IV, regulations issued under the EDA primarily provided the legal backing for such interventions.

Most of the regulations issued under the EDA and set out in detail in Annexure-I[171] had provisions that authorised the collection of information for contact tracing as well as conferring powers on authorised persons to quarantine or isolate suspected cases. For instance, Regulation 6 of The Madhya Pradesh Epidemic Diseases, Covid-19 Regulations 2020 authorised the recording of contacts of suspected or confirmed cases of Covid-19 and stipulated that the contact tracing of patients will be conducted by the Health Department and other identified staff. It also stipulated that all the collected information will be shared with the District Integrated Disease Surveillance Unit and District Magistrate immediately. Further, Regulation 7 of these regulations authorised the District Magistrate to take coercive action in proceedings under Section 133 of the Code of Criminal Procedure, 1973 if any person refused to quarantine and undertake isolation measures in accordance with the directions of the surveillance personnel. Similarly, while Regulation 5 of the Delhi Epidemic Diseases Covid-19 Regulations 2020 required the recording of contacts during screening, Regulations 9-14 authorised quarantine and isolation measures in various instances. While Regulations issued by the various states under the EDA varied in detail, broadly, they had comparable provisions for interventions such as quarantine and contact tracing (See Annexure-I[172]).

While the regulations issued by the states provided the legal backing for such measures, the central government issued broad technical guidelines regarding these measures. For instance, the Ministry of Health and Family Welfare has from time to time issued detailed technical guidelines on the screening of international travellers,[173] guidelines imposing obligations on healthcare establishments to report suspected Covid-19 cases,[174] guidelines for quarantine facilities,[175] and guidelines for home isolation[176] among others. Central Institutes such as the National Centre for Disease Control also released technical guidelines on contact tracing.[177] Since they were not

[170] Letter dated 13 March 2020 from the Secretary, Ministry of Health and Family Welfare to Chief Secretaries of all States and Union Territories, available at <https://www.mohfw.gov.in/pdf/Letterdated2032020toCSs.pdf> accessed 23 September 2020; Prashasti Awasthi, 'Centre invokes Epidemic Act and Disaster Management Act to prevent spread of Coronavrius' *The Hindu Business Line* (12 March 2020) <https://www.thehindubusinessline.com/news/national/centre-invokes-epidemic-act-and-disaster-management-act-to-prevent-spread-of-coronavirus/article31049161.ece> accessed 23 September 2020.

[171] Annexure-I of the Report is available at < https://drive.google.com/file/d/1maW9y_c7l0Bvl4gj4zP6YsIQQPNZxYJO/view?usp=sharing>.

[172] Annexure-I of the Report is available at < https://drive.google.com/file/d/1maW9y_c7l0Bvl4gj4zP6YsIQQPNZxYJO/view?usp=sharing>.

[173] Guidance Document for POEs, States and UTs for surveillance of 2019 -nCoV, Ministry of Health and Family Welfare (25 January 2020) <https://www.mohfw.gov.in/pdf/Guidance%20document%20-%202019-nCoV.pdf> accessed 23 September 2020.

[174] Guidelines for notifying Covid-19 affected persons by Private Institutions, Ministry of Health and Family Welfare (undated) <https://www.mohfw.gov.in/pdf/GuidelinesfornotifyingCOVID-19affectedpersonsbyPrivateInstitutions.pdf> accessed 23 September 2020.

[175] Guidelines for Quarantine Facilities, Ministry of Health and Family Welfare (undated) <https://www.mohfw.gov.in/pdf/9054265331158454612 0quartineguidelines.pdf> accessed 23 September 2020.

[176] Guidelines for Home Isolation of very mild/pre-symptomatic Covid-19 cases (undated) <https://www.mohfw.gov.in/pdf/GuidelinesforHomeIsolationofverymildpresymptomaticCOVID19cases.pdf; Revised guidelines are available here: <https://www.mohfw.gov.in/pdf/RevisedHomeIsolationGuidelines.pdf> accessed 23 September 2020.

[177] See <https://ncdc.gov.in/showfile.php?lid=538 > accessed 23 September 2020.

backed by any law, these guidelines were not legally binding and states could technically modify them. However, as mentioned in Chapter IV, regulations in states such as Bihar, Assam and Delhi had provisions which treated the central government guidelines as directly binding under the Regulations.

(b) Shortcomings

An analysis of news reports reveals the following bottlenecks with quarantine and contact tracing during the Covid-19 pandemic:

Avoidance of Quarantine and Stigma

Several news reports early on in the pandemic suggested extremely poor hygiene conditions in quarantine and isolation facilities which had to be set up overnight to quarantine suspected cases and incoming international travellers.[178] In fact, news reports indicated that people actively tried to avoid being isolated or quarantined and in many instances, people even fled from such facilities.[179] Some of the common problems indicated were lack of proper food, medical facilities for attending to existing conditions, and ill-treatment at the hands of staff at such facilities. This indicates the lack of proper pandemic planning and preparedness in terms of identification of potential quarantine and isolation facilities, lack of clear protocols for communication and inadequate training of staff. Further, the absence of a rights-based approach also translates into lack of adequate attention to the quality or standard of care at such facilities.

Further, the failure to clearly communicate the rationale for isolation and quarantine also led to the perpetuation of stigma. In many instances, persons who were home quarantining as a precautionary measure or were isolating after testing positive for Covid-19 had to face threats and discrimination from their neighbours and local resident welfare associations.[180]

> *The lack of protocols on public communication, clear articulation of principles behind isolation and quarantine, lack of public participation in pandemic preparedness contributed to difficulty in communicating the various precautionary measures required to check the spread of infections. A comprehensive PHE plan with clear duties in the law may have ensured that these issues were foreseen and accounted for.*

Capacity for Contract Tracing, Protection of Healthcare Workers and Privacy

Contact tracing and subsequent testing, isolation and quarantine of suspected cases has been considered a key intervention in tackling Covid-19. Experts consider this an especially useful strategy in the early stages of an epidemic and argue for its use to break the chain of transmission effectively. In India, various concerns have arisen with regard to state capacity to conduct contact tracing, privacy around such personal data collection and the protection of healthcare workers involved in grassroots contact tracing efforts.

[178] Seemi Pasha, 'Covid-19 Patients Under Government Care in Delhi Complain of Poor Conditions' *The Wire* (26 April 2020) <https://thewire.in/health/covid-19-patients-under-government-care-in-delhi-complain-of-poor-conditions> accessed 23 September 2020); Shoaib Danyal, 'Why are patient's fleeing India's Coronavirus isolation wards?' *Quartz India* (17 March 2020) <https://qz.com/india/1819659/why-are-patients-fleeing-indias-coronavirus-isolation-wards/> accessed 23 September 2020).

[179] 'Covid-19: Why people flee quarantine centers' *Times of India* (17 May 2020) <https://timesofindia.indiatimes.com/india/covid-19-why-people-flee-quarantine-centres/articleshow/75783193.cms> accessed 23 September 2020; Arvind Ojha, 'Delhi: 57 migrants jump walls, escape from quarantine centre in Tilak Nagar' *India Today* (5 May 2020) <https://www.indiatoday.in/india/story/delhi-57-migrants-jump-walls-escape-from-quarantine-centre-in-tilak-nagar-1674771-2020-05-05> accessed 23 September 2020.

[180] Betwa Sharma, Flight Attendant Quarantined By Govt, Harassed By RWA: COVID-19 Brings Out Middle-Class India's Worst Impulses' *Huffington Post* (27 March 2020) <https://www.huffingtonpost.in/entry/quarantined-govt-coronavirus-india_in_5e7da410c5b661492264fd39?guccounter=1&guce_referrer=aHR0cHM6Ly93d3cuZ29vZ2xlLmNvbS8&guce_referrer_sig=AQAAAGLIotzpbTR0fYVzZRr7ifXq5B2rAKf_1WdfSD7iH_YAtV2uSd30KQAL8suHWPGwCk7WCYmhfeBYumwx2Yu6LTTCWVp8rpSV9q-Lr6QUdUSumFYjdce1zR7l3ghEhChfM2g28F19iWxQiSWHyX6WkjEKY62Ai7ZRrUeyOEkg1M9I> accessed 23 September 2020; '32-year-old COVID patient in long line of people ostracised over disease' *Outlook* (26 June 2020) <https://www.outlookindia.com/newsscroll/32yrold-covid-patient-in-long-line-of-people-ostracized-over-disease/1878300> accessed 26 June 2020.

Many news reports have highlighted the capacity constraints faced by states in carrying out contact tracing especially at times when cases began to surge.[181] Some of the reasons assigned for the fall in contact tracing efforts which were reported in the media include lack of human resources to conduct contact tracing once cases rose beyond a point, diversion of resources to treatment efforts, and people not being forthcoming due to the stigma associated with the disease.[182] In a study conducted by the Indian Council of Medical Research ("**ICMR**"), covering the period from 22 January to 30 April, while data on contact tracing, i.e. the number of cases who had tested positive based on contact tracing, was released, state health departments and the ICMR, with the exception of Kerala, have reportedly not disclosed any contact tracing data since.[183]

> *Clear obligations in the law to conduct contact tracing and specific identification of personnel for contact tracing in pandemic preparedness plans may have addressed capacity concerns to an extent. Explicit legal obligations as well as a legal framework for data sharing may have also ensured better disease surveillance, data collection and the sharing of such data.*

Further, ASHA workers, who in many cases, were the main frontline healthcare workers carrying out contact tracing in rural areas reported the lack of protective equipment and other protections which eventually led them to go on a nationwide strike.[184] In fact, recognising the importance of ASHA workers in grassroots disease surveillance, the Brihat Bengaluru Mahanagara Palike in Bengaluru is reported to have hired an additional 1300 such workers for urban areas,[185] while the Union Health Ministry acknowledged the role of 1.6 lakh ASHA workers in tracing 30.43 lakh migrant workers who had returned to Uttar Pradesh.[186] In spite of this, ASHA workers continue to be vulnerable.

> *ASHA workers might have been better protected and their capacity used to greater potential had specific obligations for the safety of healthcare workers been articulated in PHE laws.*

Lastly, many contact tracing efforts, especially digital interventions, sparked privacy concerns. News reports indicated that states such as Karnataka raised privacy concerns by publicly declaring the names of suspected cases[187]as well as by developing intrusive applications for keeping track of isolated or quarantined citizens.[188] Moreover, the central government as well as several other states came up with their own contact tracing apps which also raised data security and privacy concerns. While concerns associated with digital contact tracing

[181] Laxman Singh *et al*, 'Contact Tracing: How Mumbai Lost the Momentum' *The Indian Express* (28 May 2020) <https://indianexpress.com/article/cities/mumbai/contact-tracing-how-mumbai-lost-the-momentum-6432020/> accessed 23 September 2020; Akshatha M, 'Surge in cases puts contact-tracing off track in Karnataka' *The Economic Times* (11 July 2020) <https://economictimes.indiatimes.com/news/politics-and-nation/surge-in-cases-puts-contact-tracing-off-track-in-karnataka/articleshow/76904989.cms> accessed 23 September 2020.

[182] Arunabh Sakia, 'Covid-19: As cases surge in India, most states abandon contact tracing', *Scroll.in* (13 July 2020) <https://scroll.in/article/967223/covid-19-as-cases-surge-in-india-most-states-abandon-contact-tracing#:~:text=India's%20Covid%2D19%20containment%20protocol,possible%20carriers%20of%20the%20disease> accessed 23 September 2020.

[183] Anuja Venkatachalam, 'Is India doing enough contact tracing in its battle against Covid-19?' *Health Analytics Asia* (18 September 2020) <https://www.ha-asia.com/is-india-doing-enough-contact-tracing-in-its-battle-against-covid-19/> accessed 23 September 2020.

[184] Shruti Srivastava, 'India's army of 600,000 Virus-Hunting Women Goes on Strike' *Bloomberg* (7 August 2020) <https://www.bloomberg.com/news/articles/2020-08-06/india-s-army-of-600-000-virus-hunting-women-goes-on-strike> accessed 23 September 2020.

[185] 'Over 1,300 new ASHA workers for Bengaluru' *The Deccan Herald* (4 September 2020) <https://www.deccanherald.com/city/bengaluru-infrastructure/over-1300-new-asha-workers-for-bengaluru-882230.html> accessed 23 September 2020.

[186] 'ASHA Workers played critical role in COVID-19 management in UP, tracked 30.43 lakh migrant returnees' *The Tribune* (30 June 2020) <https://www.tribuneindia.com/news/nation/asha-workers-played-critical-role-in-covid-19-management-in-up-tracked-30-43-lakh-migrant-returnees-106627> accessed 23 September 2020.

[187] 'Karnataka makes addresses of quarantined residents public, raises privacy concerns' *The NewsMinute* (25 March 2020) <https://www.thenewsminute.com/article/karnataka-makes-addresses-quarantined-residents-public-raises-privacy-concerns-121096> accessed 23 September 2020.

[188] 'Those in home quarantine in Karnataka directed to send selfies every hour to govt' *The Economic Times* (31 March 2020) <https://economictimes.indiatimes.com/news/politics-and-nation/those-in-home-quarantine-in-karnataka-directed-to-send-selfies-every-hour-to-govt/articleshow/74907051.cms> accessed 23 September 2020.

largely fall within the ambit of data protection law, public health law can also play an important role. Currently, while the regulations issued under the EDA envisage the collection of information during screening of patients, they do not provide details of the kind of information that can be collected nor do they provide any meaningful privacy safeguards. Good legal frameworks also contribute to better contact tracing. For instance, countries such as South Korea that had clear legal frameworks permitting personal data sharing greatly enabled contact tracing efforts.[189]

> *Incorporating principles of proportionality in designing such frameworks may have addressed privacy concerns, guided governmental action and would have provided a clear statutory basis for challenging such action when the legal standard was not observed. The law has a role to play in clearly articulating the nature of information required, incorporating principles of data minimisation, providing protocols for data sharing with designated authorities and personnel, and by providing explicit protections for information collected.*

Although Chapter IV has already assessed the regulations under the EDA using the duty-power-restraint framework, the gaps in the specific context of quarantine and contact tracing are:

Duty	Power	Restraint
While most regulations identified personnel who could be drafted to exercise various functions including disease surveillance activities, they were not allocated clear and specific responsibilities.	No prescribed procedure for the exercise of coercive measures such as quarantine and isolation.	No evidence-based standard to determine when quarantine or contact tracing are appropriate.
No specific duty to identify potential quarantine facilities or make other infrastructural arrangements for isolation facilities in advance.	Some regulations contain broad provisions that allow state governments to take over private facilities, however there are no procedures that prescribe how such requisitioning might take place.	No proportionality standard to limit restrictions on individual rights and no scope to review actions that violate such rights.
No provisions for the protection of healthcare workers involved in contact tracing and managing isolation facilities.[190]		No duty of officials to mitigate the effects of restrictions, such as loss of employment, delivery of essential food supplies during home quarantine.

[189] Emerging COVID-19 Success Story: South Korea Learned the Lessons of MERS Exemplars in Global Health <https://www.exemplars.health/emerging-topics/epidemic-preparedness-and-response/covid-19/south-korea> accessed 23 September 2020.

[190] The Central Government however issued the Epidemic Diseases (Amendment) Ordinance, 2020 that was eventually passed by Parliament as the Epidemic Diseases (Amendment) Act 2020, which prohibited violence against healthcare workers involved in contact tracing and criminalised such acts of violence.

D. Testing for Covid-19

Testing forms the basis for any containment and mitigation measures during a pandemic as it helps in assessing the spread of the disease at both the individual and population level. It is therefore a vital component of any pandemic response. In the context of COVID-19, the WHO urged countries to test as many people as possible. Research now shows that countries like Germany, South Korea and Vietnam, which adopted and enabled aggressive testing in the early days of the pandemic showed positive results in containing the disease to a great extent.[191] However, India initially initiated a restrictive testing strategy that was criticised for masking the real toll of the disease given the size of its population.[192]

This case study attempts to analyse how India responded with respect to COVID-19 testing and the framework under which testing was regulated, including the interplay between the centre and states in its execution. It also examines the role of the ICMR in managing India's testing strategy and its implications on the overall pandemic situation in the absence of a PHE law.

(a) Relevant Legal Framework

The existing legal framework in India with respect to diagnostics is scattered and unorganised. While private diagnostic laboratories are regulated under the Clinical Establishments Act, 2010, the Act is only applicable to states which have adopted it. In any case, the efficacy of regulatory structures under the Act is in question.[193] In the absence of a uniform, effective framework, private diagnostic laboratories mostly rely on accreditation by the National Accreditation Board for Testing and Calibration Laboratories ("**NAB**") or international accreditation bodies. Additionally, they have to comply with the provisions of the Drugs and Cosmetics Act, 1940 for the approval of diagnostic kits and reagents. On the other hand, public laboratories are regulated by the ICMR under a Ministry of Health and Family Welfare scheme called the Viral Research and Diagnostic Laboratories (VRDL) network.

When the question of regulation of testing came into the picture during the current pandemic, there were no set mechanisms or structures in place. While the ICMR was already in charge of VRDL network laboratories for Covid-19 testing, there were serious concerns about allowing private labs to conduct testing in the absence of an effective regulatory mechanism.

As a result, the central government, using powers under section 2(10)(l) of the DMA appointed the ICMR as the apex body for determining Covid-19 testing strategy.[194] This brought all private laboratories intending to conduct Covid-19 testing within the ICMR's purview. By virtue of this, the ICMR could not only conduct checks on the capability of private laboratories to test COVID-19 and give them approval, it could also control other aspects of testing such as reagents, commercial testing kits, etc. It should be noted, however, that this delegation of powers to the ICMR under the DMA is of doubtful legal validity, given that the Drugs and Cosmetics Act, 1940 confers the power to approve diagnostic kits on the Drugs Controller-General of India.[195]

As discussed in the case studies above, the major response mechanisms to Covid-19 were executed by means of state regulations passed under the EDA. Similarly, in the case of testing, while the strategy was centrally determined by the ICMR, it was implemented through state regulations. The sections below explain how gaps in the regulatory framework affected testing during the early stages of the pandemic.

[191] 'Finding COVID-19 Success Stories' <https://www.exemplars.health/emerging-topics/epidemic-preparedness-and-response/covid-19> accessed 12 October 2020.
[192] 'India's Restrictive Criteria for Virus Testing May Mask Toll' *U.S. News and World Report* (12 October 2020) <https://www.usnews.com/news/world/articles/2020-03-17/indias-stringent-virus-testing-criteria-may-mask-toll> accessed 12 October 2020.
[193] Sushmi Dey 'Lack of regulation haunts India's test labs' *Business Standard* (20 April 2014) <https://www.business-standard.com/article/companies/lack-of-regulation-haunts-india-s-test-labs-114041400536_1.html> accessed 15 October 2020.
[194] Order F. No. Z.28015/23/2020-EMR dated 21 March 2020, available at <https://www.mohfw.gov.in/pdf/NotificationofICMguidelinesforCOVID19testinginprivatelaboratoriesiIndia.pdf> accessed 1 March 2021.
[195] Dinesh Thakur and Prashant Reddy T, 'Which public authority should be in charge of India's policy on diagnostic kits for Covid-19?' *Scroll.in* (3 April 2020) <https://scroll.in/pulse/958059/which-public-authority-should-be-in-charge-of-indias-policy-on-diagnostic-kits-for-covid-19> accessed 1 March 2021.

Authorisation to conduct Covid-19 tests

Initially, only VRDL network laboratories under the purview of the ICMR were responsible for Covid-19 testing. Thus, the ICMR's initial testing strategy was only limited to public laboratories.[196] The existing regulatory framework for private laboratories did not prevent them from introducing a test for Covid-19. However, many states and Union Territories ("**UT**") like Andhra Pradesh, Bihar, Chandigarh, Delhi, Goa, Haryana, Jharkhand, Karnataka, Meghalaya, Mizoram, Nagaland, Punjab and Tamil Nadu, through Covid-19 regulations under the EDA, explicitly restricted private laboratories from undertaking Covid-19 testing (See Annexure-I). The regulations further specified that all collection and testing should be conducted as per Government of India guidelines, by designated facilities through the Nodal Officer. While Odisha, Madhya Pradesh and Lakshadweep did not impose any restrictions on private laboratories in their Regulations, Telangana allowed private laboratories to conduct testing on the condition that they notify the State Integrated Disease Surveillance Programme unit. State Regulations of other states like Assam, Gujarat, Kerala, Maharashtra, Meghalaya, Rajasthan, Uttarakhand, Uttar Pradesh and West Bengal allowed only authorised laboratories to take samples as per Government of India guidelines.

This not only led to confusion regarding the role of private laboratories in the response to the Covid-19 pandemic but also resulted in underutilisation of a resource pool that forms a major part of India's healthcare system. Of necessity, the government resorted to the provisions of the DMA and EDA to set up an emergency regulatory framework that gave the ICMR control over private laboratories with respect to Covid-19 testing, although neither of these laws is suited to the regulation of diagnostic facilities.

The ICMR, in the second version of its testing strategy allowed private laboratories to conduct Covid-19 testing but specified that 'private sector laboratories intending to initiate COVID-19 testing should only offer testing when prescribed by a qualified physician as per ICMR guidance for testing.'[197] Additionally, it placed several restrictions on private laboratories conducting Covid-19 tests, including requiring approvals from the ICMR for laboratory facilities, commercial testing kits, reagents used, and cost-capping for testing.

Access to testing

Since the start of the Covid-19 pandemic, the ICMR has cycled through six versions of its testing strategy, beginning by restricting testing on the ground that there was no community transmission[198] to a strategy that now allows testing on demand by opening it to all individuals who wish to be tested. It is only in this version that the ICMR states that its advisory is generic in nature and may be modified as per the discretion of state health authorities.[199]

Pricing

None of the state Covid-19 regulations that we analysed mention testing. The ICMR, in the first version of its testing strategy, which was limited to public laboratories only, specified that all individuals who were required to be tested should be offered the test at no cost.[200] When private laboratories were allowed to conduct Covid-19 testing, initially, the ICMR appealed to them to conduct testing at no cost.[201] Later, the ICMR, in addition to other restrictions, also capped the price of testing at INR 4500. However, it later removed this price cap, admitting that the price was too high and left it to individual states and UTs to 'fix up mutually agreeable prices.'[202]

[196] Testing Strategy for COVID-19 in India (9 March 2020) <https://www.mohfw.gov.in/pdf/ICMRstrategyforCOVID19testinginIndia.pdf> accessed 14 October 2020.
[197] Strategy of COVID19 testing in India (17 March 2020) <https://www.icmr.gov.in/pdf/covid/strategy/Strategy_COVID19_testing_India.pdf> accessed 14 October 2020.
[198] Testing Strategy for COVID-19 in India (9 March 2020) <https://www.mohfw.gov.in/pdf/ICMRstrategyforCOVID19testinginIndia.pdf> accessed 14 October 2020. Only two categories of persons could initially be tested: close contacts of those who tested positive and developed respiratory symptoms within 14 days of home quarantine, and those who had a history of travel to Covid-19 affected countries and developed respiratory symptoms within 14 days.
[199] Advisory on Strategy for COVID-19 Testing in India- Version VI (4 September 2020) <https://www.icmr.gov.in/pdf/covid/strategy/Testing_Strategy_v6_04092020.pdf> accessed 14 October 2020.
[200] (n. 193).
[201] Strategy of COVID19 testing in India (17 March 2020) <https://www.icmr.gov.in/pdf/covid/strategy/Strategy_COVID19_testing_India.pdf> accessed 14 October 2020.
[202] Kabir Agarwal and Pawanjot Kaur 'ICMR Removes COVID-19 Test Price Cap but Private Labs Call Government's Bluff' *The Wire* (31 May 2020) <https://thewire.in/government/icmr-covid-19-price-cap-private-labs> accessed 15 October 2020.

The issue of pricing of the Covid-19 test also attracted litigation and was examined by the Supreme Court in *Shashank Deo Sudhi v Union of India.*[203] The Supreme Court ordered free testing to be provided by all government and private laboratories to persons eligible under the Ayushman Bharat scheme or any other category of economically weaker sections of society as notified by the government as eligible for free testing. However, the Court specified that private laboratories could continue to charge money for testing from persons who were able to bear the cost of the testing fee as fixed by the ICMR.

(b) Shortcomings

India's experience with testing during the Covid-19 pandemic throws up the following stumbling blocks:

Delay in testing and surveillance strategy despite scientific warnings

While the WHO was regularly appealing to countries to test as much as possible, Indian scientists (including some scientists from the ICMR) too published research in the Indian Journal of Medical Research in late February suggesting that if one in every two who tested Covid-19 positive were to be quarantined within three days of developing symptoms, the 'cumulative incidence' could come down by 62%. However, till the end of March, India did not put in place a testing and surveillance strategy against the Covid-19 outbreak and medical experts in the National Task Force on COVID-19 expressed frustration at the inaction of the government.[204]

> *This inaction might have been addressed by a specific legal duty to create a pandemic preparedness and response plan, including a testing and surveillance strategy.*

Confusion regarding community transmission

The Ministry of Health and Family Welfare in a statement released on 5 March 2020 stated 'Since, in addition to COVID 19 cases related to travel, some cases of community transmission have also been observed, it has been decided to involve district collectors and States have been asked to form rapid response teams at the district, block and village levels.'[205] The ICMR, on the other hand, in its testing strategy dated 9 March 2020 claimed that there was no community transmission of COVID-19, as a result of which all individuals did not need to be tested. In its later testing strategies dated 17 March 2020 and 20 March 2020, the ICMR claimed that community transmission of the disease had not yet been documented. If it were to be documented, the testing strategy would undergo appropriate changes.

> *The absence of a specific obligation to disseminate information and guarantee transparency regarding various aspects of the pandemic response might have contributed to this lack of reliable scientific information.*

Inaccessible testing

The restrictive policies of the ICMR, both in terms of the entities that could conduct tests and persons who could be tested made tests inaccessible to vast segments of the population. This also hindered the assessment of the real extent of spread of the disease. While India continues to be among the countries with the lowest per million COVID-19 cases and deaths, as of October 2020, it was still amongst the countries performing the lowest number of tests per million population.[206]

Uncertain legal basis for regulating private laboratories

The lack of an effective regulatory framework for diagnostic facilities was compensated for by a strict command and control approach by the ICMR. The trust-deficit between the ICMR and private laboratories resulted in

[203] (2020) 5 SCC 132.
[204] Nitin Sethi and Kumar Sambhav Shrivastava 'Frustration In National Covid-19 Task Force' *Article 14* (24 April 2020) <https://www.article-14.com/post/no-action-taken-frustration-in-national-covid-19-task-force> accessed 15 October 2020.
[205] Update on COVID-19: cases and management (5 March 2020) <https://www.pib.gov.in/PressReleasePage.aspx?PRID=1605329> accessed 15 October 2020.
[206] See <https://www.statista.com/statistics/1104645/covid19-testing-rate-select-countries-worldwide/> accessed 14 October 2020.

micromanagement of every aspect of testing. This led to lower participation of such labs in testing for COVID-19 resulting in underutilisation of resources and unavailability of tests to the public.[207]

> *The manner in which the ICMR was plunged into an emergency regulatory role without statutory backing points towards a larger gap in PHE legislation governing different aspects of a PHE response, including a framework for testing.*

Judicial Intervention

The Gujarat High Court in a *suo motu* petition found the ICMR guidelines on testing for different categories of patients to be non-exhaustive. As a result, it modified them and also decided to review the rationale behind the ICMR's testing strategy.[208]

The Indian regulatory framework on Covid-19 testing can be analysed using the duty-power-restraint framework as follows:

Duty	Power	Restraint
No explicit duty to develop a testing protocol as part of a larger PHE preparedness and response obligation.	Lack of legal clarity regarding the role of bodies like the ICMR to: • Regulate private laboratories • Approve diagnostic kits and reagents • Control the price of testing and testing kits	No mechanisms under the law to undertake an ongoing review of measures taken by bodies like the ICMR in relation to testing strategies.

E. Medical Treatment of Covid-19 Patients

This case study discusses two aspects regarding the treatment of patients during the pandemic—the emergency use of drugs, and access to treatment. The emergency use of drugs is discussed in the context of the prophylactic use of hydroxychloroquine. Access to medical treatment is discussed in the context of the availability of beds and price caps at private hospitals for Covid-19 treatment.

In the first case, the legal and governance framework has to balance safety and speed,[209] while the second requires a robust framework for the regulation of clinical establishments.

(a) Use of New Drugs

Relevant Legal Framework

The use of pharmaceutical drugs in India is governed by the Drugs and Cosmetics Act and the New Drugs and Clinical Trials Rules, 2019 ("**NDCT Rules**"). This regulatory framework lays down the requirements that must be met before 'new drugs' are made available in the market. New drugs include drugs that have not been approved as safe and efficacious by the Central Licensing Authority, i.e. the Drugs Controller General of India ("**DCGI**"), drugs approved by this Authority for certain claims, but proposed to be marketed with modified or new claims, fixed dose combinations of two or more drugs, a modified or sustained release form of a drug or a novel drug delivery system, and vaccines.[210] Persons intending to import or manufacture new drugs for sale or distribution

[207] Harleen Kaur, Ameya Paleja, and Siddhartha Srivastava, 'Legal and regulatory framework for laboratory testing in India: A case study for Covid-19' *The Leap Blog* (3 July 2020) <https://blog.theleapjournal.org/2020/07/legal-and-regulatory-framework-for.html> accessed 15 October 2020.
[208] R/Writ Petition (PIL) 42/2020, Order dated 29 May 2020.
[209] Tanmay Singh, 'While Finding a Solution for COVID-19, Indian Drug Laws must Balance Safety and Speed' *The Caravan* (5 May 2020) <https://caravanmagazine.in/health/indian-drug-laws-must-balance-safety-and-speed-while-finding-covid-19-solution> accessed 5 October 2020.
[210] Rule 2(w), New Drugs and Clinical Trials Rules, 2019.

are to obtain permission from the DCGI. The application must typically be supported by information generated from clinical trials involving the new drug.[211]

The Second Schedule to the NDCT Rules identifies special situations when the data that is required to be submitted to obtain approval for a new drug may be relaxed, abbreviated, omitted or deferred. An accelerated approval process may be permitted for a new drug for a disease or condition, 'taking into account its severity, rarity or prevalence and the availability or lack of alternative treatments.' However, there must be a *prima facie* case that the new drug will be of 'meaningful therapeutic benefit over the existing treatment.'

Chapter XI of the NDCT Rules governs the import or manufacture of unapproved new drugs for the treatment of patients in government hospitals or government medical institutions. The latter may import a new drug provided that it is approved for marketing in its country of origin for the treatment of a patient suffering from a life-threatening disease or disease causing serious permanent disability or a disease requiring therapies for unmet medical needs.[212] Drugs imported for such purposes are not to be sold in the market and the government hospital or medical institution importing such drugs must submit a half-yearly report to the DCGI about the status and stock of the unapproved drug.[213]

The 2017 National Ethical Guidelines for Biomedical and Health Research Involving Human Participants also contain a section on the use of unapproved drugs. Monitored emergency use of unregistered and experimental interventions ("**MEURI**") may be approved during the outbreak of infectious diseases, provided that a thorough scientific and ethics review is conducted by a national level ethics committee and there is oversight by a local ethics committee. Informed consent is a vital component of such use.

During the Covid-19 pandemic, the Department of Biotechnology, Ministry of Science & Technology, Government of India released an office memorandum on 20 March 2020 that declared its decision to 'fast track' the regulatory approval process for applications for development of vaccines, diagnostics, prophylactics and therapeutics etc.[214]

Apart from these regulatory provisions under Indian pharmaceutical law, during the Covid-19 pandemic, it is the ICMR that has been spearheading the formulation of treatment protocols for Covid-19 in coordination with the Ministry of Health and Family Welfare.[215] As the previous section demonstrated, this clash in the respective roles of the DCGI and the ICMR leads to an uncertain legal basis for regulatory actions authorising the unapproved use of a drug. The manner in which this played out during the Covid-19 pandemic is demonstrated below, using the examples of the prophylactic use of hydroxychloroquine.

Shortcomings

During the Covid-19 pandemic, hydroxychloroquine ("**HCQ**") received considerable scrutiny because of its use as a prophylactic drug by at-risk frontline workers, healthcare workers, and at-risk family members of those suffering from Covid-19. The ICMR National Task Force released an advisory on 21 March, 2020, recommending the use of the anti-malarial drug HCQ as a prophylactic by asymptomatic healthcare workers involved in the care of patients suffering from Covid-19, or asymptomatic household contacts of laboratory confirmed cases.[216] A more exhaustive, and expansive advisory was released by National Task Force on 22 May, 2020, with more comprehensive information on findings and contraindications.[217] While this paper cannot comment on the scientific aspects of the advisory concerning HCQ, the following problems with its use were observed:

[211] Rules 74 and 75, New Drugs and Clinical Trials Rules, 2019.
[212] Rule 86, New Drugs and Clinical Trials Rules, 2019.
[213] Rule 88, New Drugs and Clinical Trials Rules, 2019.
[214] Department of Biotechnology (Ministry of Science & Technology-Government of India), '"Rapid Response Regulatory Framework for COVID 19" Compilation of Notifications' (*DBT*, June 2020 <http://dbtindia.gov.in/sites/default/files/new_combine_file.pdf> accessed 9 October 2020.
[215] EH News Bureau, 'ICMR Revises Treatment Protocol for COVID-19 Patients' *Express Healthcare* 1(4 June 2020) <https://www.expresshealthcare.in/covid19-updates/icmr-revises-treatment-protocol-for-covid-19-patients/421792/> accessed 6 October 2020.
[216] Ministry of Health and Family Welfare-Government of India, *Advisory on the use of Hydroxy-chloroquin as Prophylaxis for SARS-Co-V2 Infection* <https://www.mohfw.gov.in/pdf/AdvisoryontheuseofHydroxychloroquinasprophylaxisforSARSCoV2infection.pdf> accessed 5 October 2020.
[217] Indian Council of Medical Research, (Department of Health Research-Ministry of Health and Family Welfare, Government of India), *Revised Advisory on the use of Hydroxy-chloroquine (HCQ) as Prophylaxis for SARS-CoV-2 Infection (in Supersession of Previous Advisory Dated 23rd March,*

- **Use of HCQ without appropriate precautions:** The first advisory issued by the ICMR, recommending the use of HCQ as a prophylactic measure against Covid-19 did not specify contraindicated drugs or health conditions.[218] This put healthcare workers to whom the advisory was targeted at risk, especially since it was reported that a lack of attention to contraindications could, in very rare cases, lead to the death of the recipient, due to the elongation of their 'QT' interval.[219] While this omission was corrected in the later, expansive advisory, different practices were deployed to screen at-risk individuals with respect to HCQ. In some states, patients were administered the treatment only after screening for known contraindicated conditions, in others, no such practice was followed.[220] Although the initial advisory mentioned that HCQ should be used prophylactically only when prescribed by a registered medical practitioner, it was found that in some areas, the drug was being 'popped' and 'stocked' so much that the state government had to intervene.[221]
- **Bypassing regulatory provisions:** The previous section set out the different kinds of regulatory pathways through which the prophylactic use of HCQ (a new indication for an approved drug) could have been permitted. However, none of these pathways, most of which require the approval of the DCGI, appear to have been observed. The conditions for MEURI that have been incorporated into the 2017 National Ethical Guidelines for Biomedical and Health Research Involving Human Participants would have formed the most appropriate pathway, but there is no evidence of these MEURI guidelines having been observed in the context of this use of HCQ.

Confusion regarding the application of regulatory pathways for emergency use authorisation was also evident with the approvals granted to the vaccines Covishield and Covaxin.[222]

> *This confusion might have been prevented through clearer provisions regarding the criteria, trigger points and procedures for 'emergency use authorisation' in PHEs, that clearly demarcate the role of drug regulatory bodies and other scientific authorities during such times, and that integrate guidelines on clinical research and ethics.*

The following gaps in these regulatory pathways are observed when analysed using the duty-power-restraint framework:

Duty	Power	Restraint
Blurring of roles between the DCGI, which is the regulatory authority and the ICMR, which is an advisory body.	The ICMR lacks the legal authority to authorise the unapproved use of drugs except in accordance with the MEURI guidelines.	Lack of clarity regarding the precautionary conditions that should be attached to the emergency use of drugs. Lack of transparency regarding both the regulatory pathway as well as the data on the basis of which emergency use authorisations are allowed.

2020) <https://www.icmr.gov.in/pdf/covid/techdoc/V5_Revised_advisory_on_the_use_of_HCQ_SARS_CoV2_infection.pdf> accessed 4 October 2020.

[218] Priyanka Pulla, 'Set up a Code to use Experimental Drugs in an Outbreak – Then Ignored it the Wire-Science' *The Wire Science* (7 May 2020) <https://science.thewire.in/the-sciences/icmr-covid-19-hydroxychloroquine-prophylaxis-meuri-guidelines-clinical-trials/> accessed 6 October 2020.

[219] Priyanka Pulla, 'Does a Pandemic Justify Using Hydroxychloroquine to Beat the Coronavirus?' *The Wire-Science* (7 April 2020) <https://science.thewire.in/health/coronavirus-covid-19-hydroxychloroquine-icmr-guidelines-long-qt-syndrome/> accessed 5 October 2020.

[220] ibid.

[221] For example, the state government of Gujarat issued a directive to chemists not to sell the drug over the counter. See PTI, 'People pop up, Stock Hydroxychloroquine; Gujarat Govt Intervenes' *The Economic Times-Politics* (14 April 2020) <https://economictimes.indiatimes.com/news/politics-and-nation/people-pop-up-stock-hydroxychloroquine-gujarat-govt-intervenes/articleshow/75135525.cms> accessed 8 October 2020.

[222] Yogini Oke and Shreya Shrivastava, 'The Curious Case of COVISHIELD and COVAXIN Approvals' *Vidhi Centre for Legal Policy* (7 January 2021) <https://vidhilegalpolicy.in/blog/the-curious-case-of-covishield-and-covaxin-approvals/> accessed 3 March 2021.

(b) Access to Treatment

Relevant Legal Framework

While the right to health is recognised as part of the right to life under Article 21 of the Constitution of India, this has not automatically translated into the right to access medical treatment free of charge at any healthcare establishment of one's choosing.[223]

In states where the Clinical Establishments (Registration and Regulation) Act, 2010 is in force, charges for medical treatment are regulated through rules issued under the Act.[224] However, during the Covid-19 pandemic, most state governments appear to have regulated charges at private hospitals through a combination of the EDA and the DMA.[225]

The EDA and the DMA do not contain any explicit legal provisions that confer the power to impose such a price cap. However, they both provide for the requisitioning of private facilities. Section 2 of the EDA empowers the state government to *require* any person to take any measures that may be necessary to prevent the outbreak of a disease. The government may also determine how the expenses incurred, including compensation, if any, to be paid, will be defrayed. Similarly, section 65 of the DMA allows the National Executive Committee, State Executive Committee, District Authority or any officer authorised by them to requisition any resources (including men and material resources), premises, or vehicles that are needed to respond to a disaster. Such requisition should be made through an order in writing and should not extend beyond the period for which the resource is required. Under section 66 of the Act, compensation is to be paid for the requisitioning of premises or vehicles. Several states have exercised their powers under these acts to take over private hospitals for Covid-19 treatment, with some governments reimbursing them at the same rates as those prescribed under the Ayushman Bharat scheme.[226]

In addition to this, state governments have had to issue a variety of orders to private hospitals regarding different aspects of Covid-19 treatment, including directives not to refuse treatment to Covid-19 positive patients.[227] Despite these specific provisions, the absence of a robust regulatory framework for hospitals in general has seen the courts intervene in different ways in an attempt to ensure equitable access to treatment. Examples of these cases are provided in the section below.

Shortcomings

The Supreme Court and the High Courts have been very active in adjudicating matters concerning Covid-19 treatment. In *Ganta Jai Kumar versus State of Telangana*,[228] the High Court of Telangana held that patients could access treatment in private hospitals on the basis of payment. However, it ruled that for a hospital to be considered to be equipped to treat Covid-19, it had to make an application to the ICMR and get approval from the research body to that effect.

[223] Indian Courts have, however, recognised the right to access emergency medical care. See *Paschim Banga Khet Mazdoor Samity v State of West Bengal* AIR 1996 SC 426.
[224] Rule 9 (ii) of the Clinical Establishments (Central Government) Rules, 2012 states that one of the conditions for registration and continuation of clinical establishments is that they should charge rates for procedures and services within the range of rates determined and issued by the central government in consultation with state governments.
[225] See, for example, the order issued by the Maharashtra state government, which derives the power to fix treatment rates at private hospitals from the Epidemic Diseases Act, the Disaster Management Act, the Maharashtra Essential Service Maintenance (Amendment) Act, 2011, the Mumbai Nursing Homes Registration (Amendment) Act, 2006 and the Bombay Public Trusts Act, 1950.
[226] Ipsita Chakravarty, 'Coronavirus: Three States take over Private Hospitals. What does the Fine Print say?' *Scroll.In* (30 March 2020) <https://scroll.in/article/957556/coronavirus-three-states-take-over-private-hospitals-what-does-the-fine-print-say> accessed 9 October 2020.
[227] Ministry of Health and Family Welfare Department-Govt of NCT of Delhi, (6 June 2020) <http://health.delhigovt.nic.in/wps/wcm/connect/422890804e92d8c2a8d0ebd194e333e1/RVSDO.pdf?MOD=AJPERES&lmod=-1802308803&CACHEID=422890804e92d8c2a8d0ebd194e333e1> accessed 9 October 2020.
[228] MANU/TL/0048/2020.

The private health care sector has, in general, come under a significant degree of scrutiny regarding its role in the Covid-19 pandemic. In the case *Suo Motu versus State of Gujarat*[229], the Gujarat High Court, in an order on 14 May, 2020 directed the state government of Gujarat to ensure that hospitals in Ahmedabad, and even on its outskirts, 'work out modalities' with respect to fee structures. The High Court also pointed out the need to allow more hospitals to provide Covid-19 treatment, and directed the state government to ensure that private hospitals did not charge patients suffering from Covid-19, exorbitant costs. The Ahmedabad Municipal Corporation acted in pursuance of this order, and the Municipal Commissioner issued an order reserving 50 percent of hospital beds at a fixed price, and also laying down a ceiling price. When private hospitals were found to be disobeying this order, the High Court, through an order dated 22 May 2020 directed the state government to act against them.

In a similar vein, the Bombay High Court in *Abhijeet K Mangade v State of Maharashtra*[230] directed the state government to present data to the High Court as to how 'it proposes to introduce a regime where COVID patients admitted to unregulated beds may not succumb to additional pressure of excessively high expenses to be borne by him and/or his family while recuperating.'[231] In contrast, the Nagpur Bench of the Bombay High Court quashed a notification issued by the Maharashtra government imposing restrictions on private hospitals regarding pricing for non-Covid-19 treatment, on the ground that states do not have the legislative competence to regulate prices for health care treatment.[232] The constitutional validity of this reasoning is suspect.[233]

In addition to judgments and orders aimed at regulating prices charged at private hospitals treating Covid-19, other orders include setting up a coordinating body between private hospitals and governmental authorities,[234] directing hospitals to grant beds to those who need them more than those who can wait,[235] and directing governments to ensure real-time updating of data by hospitals.[236]

Again, in the absence of an effective regulatory mechanism, governments sought to implement their own directives as well as court orders through various means such as the institution of flying squads[237] and the institution of task forces.[238] The Supreme Court itself has acknowledged the lack of legal template to address issues of access to treatment. In *Sachin Jain vs. Union of India*,[239] it directed all states to come up with an executive and legislative action plan, taking a cue from the rights-based National Health Bill, 2009 discussed in Chapter IV.

These gaps in the regulatory framework for private hospitals are captured using the duty-power-restraint framework below:

Duty	Power	Restraint
No specific legislative duty to guarantee affordable access to health care during a PHE.	Weak legal basis for the regulation of private hospitals under the Epidemic Diseases Act and the Disaster Management Act.	Only command and control regulatory approach adopted towards private healthcare establishments rather than a rights-based one.

[229] MANU/GJ/0785/2020.
[230] 2020 SCC OnLine Bom 827.
[231] MANU/MH/1029/2020.
[232] *Hospitals Association, Nagpur v Government of Maharashtra* MANU/MH/1716/2020.
[233] Akshat Agarwal and Kim D'Souza, 'Pricing and Private Hospitals: The Far-Reaching Implications of the Bombay High Court's Decision in 'Hospitals' Association, Nagpur, *Vidhi Centre for Legal Policy* (11 November 2020) <https://vidhilegalpolicy.in/blog/pricing-and-private-hospitals-the-far-reaching-implications-of-the-bombay-high-courts-decision-in-hospitals-association-nagpur/> accessed 3 March 2021.
[234] *Court on its Own Motion v Union of India*, MANU/MH/1215/2020.
[235] *Jan Swasthya Abhiyan and Ors v State of Maharashtra and Ors*, MANU/MH/0784/2020.
[236] *Court on its Own Motion and Ors v State of NCT and Ors*, MANU/DE/1344/2020.
[237] PTI, 'Flying Squads will Check if Hospitals are Overcharging: Maharashtra Health Minister' *The New Indian Express* (7 August 2020).
[238] MANU/SCOR/36629/2020.
[239] Writ Petitions Civil Nos. 863/2020 with Writ Petition (Civil) No. 489/2020, Order dated 26 November 2020.

VI. What should an Indian PHE law consider?

This paper has identified an international and constitutional obligation for the Indian State to prepare and respond to a PHE through an appropriate legal framework. It has also identified the role of the law in public health, relying primarily on Gostin's duty-power-restraint framework. This framework has then been applied to critically analyse legal responses to PHEs in other jurisdictions as well as India, using case studies for the latter to highlight gaps in the legal framework. This concluding section now identifies the different issues that a more up-to-date Indian legal framework on PHEs should consider. The answers to these questions require expertise and consultation with appropriate stakeholders from government, public health and policy, civil society, and vulnerable groups that have been particularly affected by the Covid-19 pandemic.

Aspect of PHE Law	Options	Comments	Questions for Consideration
Form and subject of legislation	• Central PHE law • State PHE laws • Combination of both	The need for a central PHE legislation, at the very least, is self-evident. Some of the measures that the IHR 2005 require State Parties to undertake during a PHE can be performed only by national authorities. These include the communication of public health information to the WHO and the regulation of travellers and vessels at ports of entry into the country. A PHE may also require inter-state coordination and the regulation of the movement of people and goods between states, as was evident during the Covid-19 pandemic, calling for some degree of central intervention. However, an effective PHE response also requires building capacity at the state, district and local levels. States have the legislative competence for matters relating to public health, allowing them some flexibility in formulating legal and administrative frameworks within their jurisdiction.	Should a central PHE law be limited to giving effect to the IHR regulations, creating duties and conferring powers only on the central government? If yes, should this be supplemented by state-specific PHE legislation (like the Karnataka and Telangana Infectious Diseases Acts) or overarching state-specific public health laws with dedicated chapters on PHEs, like the Model Public Health Act, 1987? Alternatively, should there be a comprehensive central PHE law that creates duties and confers powers on all levels of government, similar to the scheme of the Disaster Management Act, but targeted towards PHEs? If yes, what should the degree of centralisation be? What principles should be applied to divide duties and powers across central, state, district and local authorities?

Governance and Responsible Authorities	• Create new authorities specifically dedicated to PHE preparedness and response • Utilise existing authorities	The Indian response to the PHE has involved a multitude of officials and authorities across different tiers of government. Several levels of delegation have taken place under both the Epidemic Diseases Act and the Disaster Management Act. While this permits flexibility in responding to different aspects of the pandemic, some of the case studies discussed in this paper demonstrated that this might also have created overlapping roles for different authorities and contributed to the uncertainty of the legal status regarding their actions. Apart from this, the absence of more modern legislation specifically targeted at PHEs has meant that capacity and expertise for PHE preparedness and response has been slow to develop. On the other hand, creating a new set of statutory authorities will necessarily involve considerable budgetary and administrative burdens.	Are existing authorities equipped to perform PHE preparedness and response functions? If yes, which of these authorities are most suited to performing these functions? Should they specifically be designated in a PHE law? If not, how can a PHE law promote the building of such capacity? Should new authorities at different levels of government be created specifically to perform PHE preparedness and response functions? If yes, what should the composition and expertise of such authorities be? Irrespective of whether new authorities are created or not, how should the law ensure the clear demarcation of functions across different authorities? What coordination mechanisms across different authorities should the law create?
Specificity of legislation	• Framework law that broadly creates and confers duties and powers respectively • Specific and comprehensive enumeration of duties and powers related to PHE preparedness and response	Of the laws and legislative proposals discussed in this paper, the Epidemic Diseases Act lies at one end of the spectrum as a framework or enabling legislation in the broadest sense. At the other end is the Model Public Health Act, 1987, which contains very detailed provisions regarding the outbreak of communicable diseases. The duty-power-restraint framework requires balancing the need for discretion and	What are the specific duties and powers that should be expressed in a primary PHE law? (For instance, the duty to draw up a PHE preparedness and response protocol, the power of compulsory vaccination etc.) To what extent should the processes by which such duties and powers are to be exercised be expressed in a primary PHE law? (For instance, should the primary law set out a detailed process

		flexibility for the authorities with accountability and guidance in the performance of their duties and exercise of their powers.	for developing a PHE preparedness and response protocol or leave it to secondary legislation?) What principles should be applied to determine which provisions are suited to primary legislation and which are suited to secondary legislation? What should the legal status of a PHE preparedness and response protocol be, given that such a protocol will not form part of the primary PHE law?
Monitoring and Accountability	• Through the Supreme Court and High Courts • Independent authority • In-built grievance redressal mechanisms	While most of the laws in the six jurisdictions surveyed in this paper created duties for public authorities regarding PHE preparedness and response, provisions for holding such authorities accountable for their performance were less clear. In the Indian context, given the constitutional recognition of the right to health, the writ jurisdiction of the higher judiciary is likely to be used to hold authorities to account for non-performance of their functions. However, there may be concerns with the accessibility and timeliness of such a remedy, as well as the competence of the courts to adjudicate such issues. Perhaps taking this into account, the draft National Health Bill 2009 created comprehensive monitoring and accountability mechanisms in the form of audits, health information systems and community-based monitoring. However, the feasibility of implementing	How important is the creation of an appropriate monitoring and accountability mechanism for an effective PHE law, outside of the writ jurisdiction of the higher judiciary? What elements of PHE preparedness and response should specifically be monitored? Which monitoring and accountability mechanisms are suitable specifically for a PHE law? Should there be a difference in the monitoring and accountability mechanisms applicable to the 'preparedness' components and 'response' components of a PHE law, given that the latter will have to operate in emergency conditions?

		these during a PHE needs consideration.	
Rights-based approach and Proportionality	• Overarching rights and principles • Specific rights and principles contextualised for a PHE	Gostin's principles emphasise the importance of integrating human rights into any public health law. The degree of specificity with which these are defined is likely to be linked to the form that the legislation takes—an overarching public health law versus specific PHE legislation. However, as important as the incorporation of rights and principles is, the challenge lies in operationalizing these to guide the actions of public officials and creating effective remedies for their violation. Exercising these remedies during a PHE poses an additional challenge.	Should the law incorporate only general rights against non-discrimination, to participation and informed consent? Or should there be specific rights not to be submitted to compulsory medical treatment? Should corresponding duties be created for every right? How can capacity for the adoption of a rights-based approach be built among public officials and authorities? What remedies should be available for rights violations during a PHE?

www.vidhilegalpolicy.in

Vidhi Centre for Legal Policy
A-232, Ratan Lal Sahdev Marg,
Block A, Defence Colony
New Delhi 110024
011-43102767/43831699

vidhi@vidhilegalpolicy.in