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Public health law in India: A framework for its application as a tool for social change

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ABSTRACT

Public health law focuses on the nexus between law, public health and the legal tools applicable to public health issues. Though there have been consistent interventions to address public health concerns in the past, there exists a need for a contemporary framework to appropriately use modern legal tools for complex health challenges. We identify a checklist of imperative indicators to assess whether public health legislations would be an effective form of intervention to bring about the desired social change.

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INTRODUCTION

Law has had important contributions to several public health achievements but, despite this, the conceptual framework for its effective application has not been fully explicated.[1] Medicine has moved beyond treating disease to promoting health, which entails policy interventions and regulations at different levels to bring about behavioural changes in individuals. This was identified by the nineteenth century German physician Rudolph Virchow who said: 'Medicine is a social science, and politics nothing but medicine on a grand scale.' In the present-day changing scenario, physicians need to understand the social implications and the over-arching role of law. We highlight how a framework of law can be developed for promoting public health goals.

THE SCOPE OF PUBLIC HEALTH LAW

The reach of public health law is as broad as public health itself and both have expanded to meet the needs of society. The scope of the right to health and its correlation with the right to healthcare was first outlined in the Universal Declaration of Human Rights in 1948, wherein while the right to health was conceived as an individual's civil right, states were bound to provide minimum conditions to enable individuals to enjoy this right and provide primary health services in an equal and fair manner. It is important to note that while the right to health is considered an inherent human right, the right to healthcare is its progressive realization through declared constitutional and legal rights, in particular, through public health law.

The Constitution of India has provided guarantees and policy directives in Part III (Fundamental Rights) and Part IV (Directive Principles of State Policy) for the right to health and healthcare. The Supreme Court of India has articulated in several landmark judgments (Consumer Education and Resource Centre *v.* Union of India AIR 1995 SC 636; State of Punjab and Others *v.* Mohinder Singh AIR 1997 SC 1225) that the right to health is integral to the right to life under Article 21 of the Constitution of India. While on the one hand, the right to health is guaranteed as a fundamental right, the Constitution also imposes a positive duty on the State under Article 47 to raise the level of nutrition and the standard of living, and to improve public health to ensure the right to healthcare. Thus, as endorsed in the Declaration of Alma Ata in 1978, the attainment of the highest possible level of health becomes the key worldwide social goal. The Constitution of South Africa too, in its Bill of Rights, expressly declared access to healthcare, food, water and social security, besides emergency medical treatment, as the fundamental rights of individuals (Article 27 of the Constitution of South Africa).

Public health law could be defined as the study of the legal powers and duties of the State, to ensure conditions for people to be healthy with collaboration from multiple stakeholders (e.g. healthcare professionals, business, community, media and academe).[2] Unlike at the turn of the century, today the field of public health has expanded from areas of communicable diseases and environmental sanitation to address enlarged health concerns, for instance, chronic diseases and mental health as well as provide services to create a healthy environment.[3]

Eminent scholar Frank Grad observed that public health law does not come in a neat legislative package, but consists of many types of legislations which have little in common except for the benign purpose of advancing public health.[4] The preservation of public health is among the most important goals of governments and law can serve as an effective tool not only at the individual level but also at a larger community level.[5] Some international public health instruments are listed in Table I, which rely on a voluntary approach based on consent and cooperation, and have a binding effect on ratifying bodies.

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TABLE I. International public health instruments and key recommendations

Name of instrument	Key recommendation
Universal Declaration of Human Rights (1948)	Guarantees respect for economic, social and cultural rights since they are indispensable for human dignity
International Covenant on Economic, Social and Cultural Rights (1966)	Recognition of relevant rights to be exercised without discrimination in the context of a universal right to health
Declaration of Alma Ata (1978)	Primary healthcare approach to be developed as an integral whole, including promotive, preventive, curative and rehabilitative components
The Convention on the Elimination of All Forms of Discrimination against Women (CEDAW, 1979)	Requires state parties to eliminate discrimination against women in all aspects of their healthcare, including drug addiction and related problems
The Convention on the Rights of the Child (CRC, 1989)	Emphasizes the right of the child to enjoy 'the highest attainable standard of health'
International Health Regulations (IHR, 2005)	Specific undertakings for international assistance in health
UN Convention on Rights of Persons with Disabilities (UNCRPD, 2008)	States parties to take all appropriate measures to ensure access for persons with disabilities to health services that are gender-sensitive, including health-related rehabilitation
The Declaration of Istanbul on Organ Trafficking and Transplant Tourism, 2008	All forms of transplant commercialism, which targets the vulnerable; transplant tourism and organ trafficking to be prohibited

Within the framework of the Constitution of India, public health is a subject for the states to legislate. However, very few states in India have crafted public health legislations. At the national level, the archaic 112-year-old Epidemic Diseases Act, 1897 is an example of the nature of laws dealing with public health emergencies. There are also some 'policing' provisions in legislations such as the Indian Penal Code that date back to 1860, which seek to protect the public's health in the face of an epidemic. The post-Independence laws were more progressive and addressed various issues concerning public health, albeit in a piecemeal manner, for which the Constitution laid a strong foundation under Part III (Articles 14, 15, 17, 21, 23, 24), which are mandatory and Part IV (Articles 38, 39, 41, 42, 47, 48A, 51(c), 51A), which are directives. However, the need for a comprehensive public health law has always been felt. The Ministry of Health and Family Welfare, Government of India has proposed drafting this much needed law (The National Health Bill, 2009) for consideration by Parliament.

Preservation of public health through enforcement and enactment of appropriate laws is one of the most important goals of governments. The public health law approach posits that the government has both the power and the duty to regulate private behaviour in order to promote public health.[6] Law, therefore, emerges as a tool in public health to be used, where appropriate and after due process, in promoting and protecting public health goals. However, achieving a just balance between the powers and duties of the State to defend and advance the public's health while ensuring protection of the constitutional rights of individuals poses an inevitable challenge for public health law.

The basic issue in delineation and realization of health rights is the existence of conflicting constitutional and legal rights. In the Indian context, health rights emanate from the fundamental protection envisioned under Article 14 (equality before law and equal protection of all laws) and Article 21 (right to life) of the Constitution of India, in essence obligating the State with a positive duty to eliminate any adverse conditions in the enjoyment of a dignified life and ensuring complete protection of the laws. However, the most common challenge to health rights ride on the claims of fundamental freedoms granted to every citizen under Article 19. Though this may be overcome by a common legal principle of *Sic utere tuo ut alienum non ledas* that would support restrictions *vis-à-vis* enjoyment of the fundamental freedom to the extent it impacts on another's enjoyment of life, property and well-being.

FRAMEWORK FOR PUBLIC HEALTH LAW: THE ESSENTIAL INDICATORS

We aim to structure a list of imperative indicators to assess the appropriateness and effectiveness of a law when it is proposed in response to a given public health issue. These indicators have been built upon the principles laid out by Mann in his 'Four-step impact assessment'.[7] The assessment takes into account the negotiation of objectives between human rights and public health. Such an approach takes into account a measure of each discipline's overlap to expose infringement of goals. Such infringement or confluence has been mapped by Mann[7] proposed in a 2×2 table (Fig. 1). Each indicator (briefly explained below) is not mutually exclusive of the other and presents in itself a sound case for legal intervention through a public health law.

Public health risk

'Public health risk' means the likelihood of an event that may affect adversely the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct danger.[8] To begin with, it is the sheer size of a public health risk or concern that might require initiation of a law. The number of deaths, extent and nature of disabilities and diseases caused by morbid events; their incidence and prevalence and the likelihood of contiguity to human populations—these factors might pose a threat which the existing health systems may not be able to effectively deal with. Also, the costs to efficaciously deal with a public health concern would not only require its identification at every level of administration but also cooperation among the key stakeholders. It would require specific plans, mechanisms and institutions with given powers, functions and responsibilities to address the concern. This may only be mandated by law and not otherwise. Thus, public health law approaches law in a new light where it complements and facilitates but does not supplant, existing strategies, based on well-established principles of public health practice.[1]

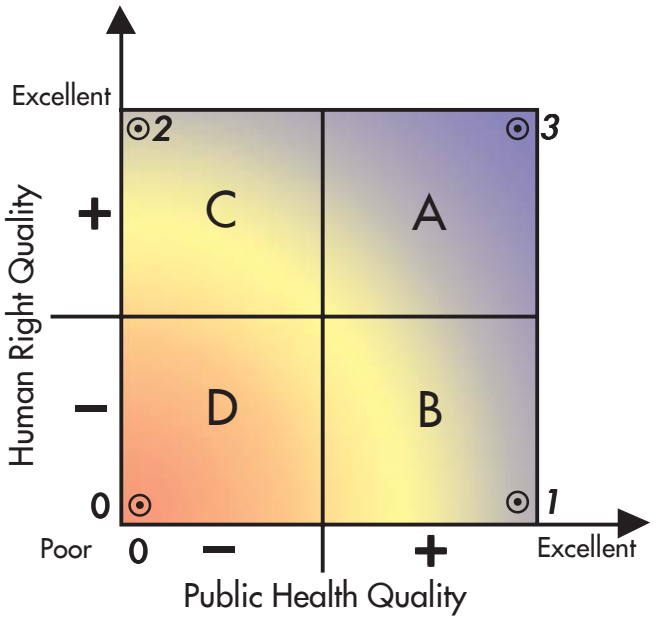

FIG 1. Four-step impact assessment: 2×2 grid of health and human rights (available at *http://en.wikipedia.org/wiki/Four-Step_Impact_Assessment*; accessed on 13 July 2008).

Magnitude of risk factors

The magnitude of risk factor(s) for which a legislative intervention is considered is one of the primary criteria which has to be investigated. Assessment is required to answer whether the risk is confined to some individuals or a section of society or affects the human population at large. Its impact also needs to be carefully assessed, i.e. the absolute risk of the event, its relative risk and the prevalence of its exposure. If an event is apprehended to generate risks attributable to a large section of society, legal interventions may become a high priority. For example, tobacco use may be responsible for over a million deaths every year in India.[9] Tobacco is today the world's biggest preventable cause of death and results in a range of diseases including cardiovascular diseases, cancers and pulmonary diseases. It is argued that a strict implementation of the Framework Convention of Tobacco Control (FCTC) and Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 can result in a decrease in the number of deaths caused every year.

Effectiveness of proposed legislations under the precautionary principle

The primary goals of public health are to prevent disease and promote health in populations. The concepts of precaution and prevention have, therefore, always been at the heart of public health practice. The precautionary principle states that action should be taken to prevent harm even if some cause-and-effect relationships have not been fully established scientifically—this concept plays a key role in the arena of public health.[10] The precautionary principle is a tool for policy- and decision-making designed to ensure that people or entities bear political responsibility to prevent damage to health and ecosystems in the face of uncertain scientific information. Often, in rigid evidence-based policy structures, social attitudes and interference by vested interests result in policy-makers having to wait unreasonable lengths of time before committing to preventive action. In these changing times, the precautionary principle shows an effective way to propose and introduce legislation for the protection of health and environment in the face of uncertain risks, while stimulating innovation in science, technology and policy. The precautionary principle was formally adopted as a guiding principle of the European Union's environmental policy in the Maastricht Treaty of 1993. The Treaty set the objective for the European Union to promote sustainable growth while respecting the environment. The policy has essentially consisted in the elaboration of a legislative framework aimed at combating pollution and protecting the environment.

Cost-effectiveness of proposed legislation

It is essential to look at the cost-effectiveness of proposed legislations, both from the perspective of socioeconomic costs arising from its health effects and the costs of implementing and monitoring these regulatory measures. Cost can be defined as the value of resources used to develop and implement a good health or healthcare service and effectiveness is the degree to which the programme interventions have succeeded in meeting the desired goals or outcomes in the usual health settings. In tobacco control, the total social costs of tobacco products exceed the direct outlay on them, owing to morbidity, mortality and negative externalities associated with the consumption of tobacco products. These factors impact the fiscal measures and policy interventions adopted by the government and provide clear indicators for measurement during monitoring and evaluation of such health measures.[11] Cost-effectiveness is a technique which assists in decision-making and helps identify areas of health programmes that require more efficiency. Such data generate an assessment of gains and resource input requirement of alternatives, and the same is given to governments to counter 'information asymmetry' projected by the industry.

Externalities that justify the use of legislations

Public health law includes analysing the externalities that affect the magnitude of a public health risk. Externality refers to an impact on a third party that was uninvolved and might be positive or negative in nature. In Fig. 2, we have tried to analyse this correlation in a theoretical sense.

Public health measures also include efforts towards reduction of negative externalities of human behaviour. For instance, one of

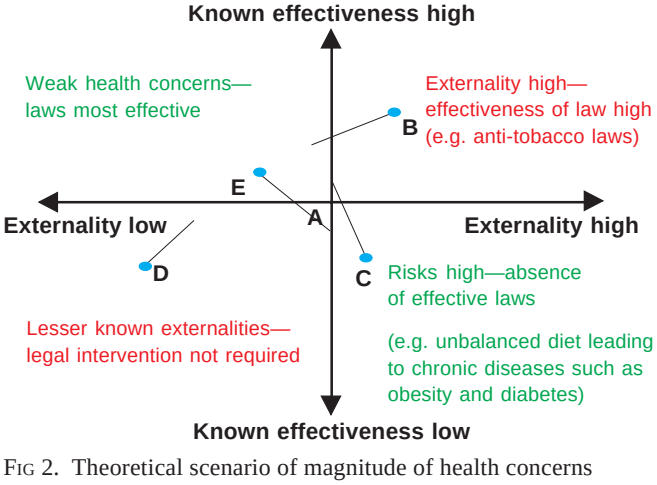

FIG 2. Theoretical scenario of magnitude of health concerns compared with effectiveness of laws

the major public health concerns is involuntary exposure to second-hand tobacco smoke. In 2001, the National Human Rights Commission of India took up the cause of violations of rights of born and unborn children who are a vulnerable group and often exposed to tobacco smoke (active and passive) in home or public areas.[12] Thus, many externalities may affect and justify the emergence and implementation of legislations.

Involuntary exposure of vulnerable groups to the risk factor

For a cost–benefit analysis of a law, efficiency measures are required at the programmatic level. However, it is not advisable to exclusively focus on the efficiency of the law through the use of cost-effectiveness that is clustered under the rubric of 'economic evaluation'.[13] It is equally imperative to know the extent to which the proposed law is beneficial to those who are not willing to be exposed to or affected by the event in question. Many individuals are often involuntarily exposed to a totally avoidable risk which calls for specific regulations to regulate external factors affecting its incidence. There is a delicate balance which needs to be struck between the powers of the State to regulate conditions for ensuring the health of populations versus constitutionally guaranteed rights of individuals. While arguments rage on whether restrictions could be allowed on individual's rights for the larger public interest, the factors that contribute to the structuring of a public health legislation would be the entire gamut of effects on the vulnerable groups who are voluntarily or involuntarily exposed to health risks.

On the other hand, regulation of public and individual behaviour, by law, might become necessary if there is an imminent danger to public health. For instance, notification of a public health emergency in the international travel advisory and the quarantine law are examples of such regulations, which in effect means stricter restraints on the local public or individuals, as the case may be.

The craftsmanship of the law assumes importance in justifying the circumstances when the freedom of an individual may be subordinated to collective well-being, i.e. the 'manifold restraints to which every person is necessarily subject for the common good'.[14]

Indirect adverse consequences

It is important to do an appraisal of the potential adverse consequences of such legislations on other multiple sectors, e.g. the economic feasibility of the proposed legislation for the exchequer remains the fuel for the law to come into force. It is argued by the tobacco lobby in India that tobacco control can negatively impact the economy by creating massive loss of employment. Simulation of the net impact of tobacco control on the Indian economy has not been adequately investigated, making it difficult to assess accurately the effect of control measures or to ponder over alternative means of employment. Studies from other countries demonstrate that losses in employment occur in the sectors that are immediately associated with cigarette production; however, these losses can be outweighed by increases in employment in all other industries, particularly in labour-intensive service industries.[15]

Factors affecting enactment of legislation

A sound public health law infrastructure establishes the powers and duties of government to prevent disease and injury, and to promote the health of the people.[16] It is important to assess the probability of the proposed legislation being a successful intervention in addressing population risks. Given the paradox of purposes and perspectives, the feasibility of the proposed law can be analysed from the support of policy-makers, enforcement officials, civil society and the public at large, besides the opposition from quarters that have vested interests in its non-implementation.

Feasibility of implementation of legislation

Apart from support for the law, the cost of implementing the law should also to be considered. Implementation may require strong political commitment, requisite infrastructure, capacity, technical and professional competencies as well as ancillary support structures, besides an overall conducive environment to obtain the desired results.

Monitoring and evaluation

Last but not the least, it is essential to build broad guidelines for monitoring implementation of legislations since evaluation becomes a tool for future decision-making. It must be taken into account as to how reliably one can monitor the impact and unforeseen negative consequences of the proposed legislation. In this regard, besides the institutional mechanisms and capabilities of the State, the role of civil society as the fourth pillar of democracy is central.[17] The ability of civil society organizations to gauge and their capacity to monitor is critical to the successful implementation of any law. Apart from them, the media and various other forums also help to create awareness of various public health risks, both among the general public and policy-makers.

However, the process of monitoring and evaluation might be hampered due to insufficient data collection. One of the glaring examples is the increasing need to monitor accurately the imbalance in India's child sex ratio. Although The Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act was introduced in 1994 with an aim to disrupt the supply side of India's discriminatory regime, the effectiveness of the legislation in terms of implementation has faced serious questioning. Difficulties arise in monitoring its effectiveness due to imperfect databases. Many local statistics originate from authorities who are eager to advertise progress in sex-ratio levels. These data are often ambiguous or incomplete, as they are based on unreliable sources, with samples that are often too small to allow for significant interpretation.[18]

The indicators that we have provided, structured into a framework, seek to illustrate the dynamic nature of the relation-ship between public health law and the broader cultural and societal factors. Table II summarizes some case studies to illustrate the indicators we have discussed. While law can drive social change, progressive laws are unlikely to be implemented until the dominant cultural mores are sufficiently favourable. While a checklist of criteria is required to evaluate whether a particular law is effective as a tool for intervention, it is also dependent on and has to respond to shifts in ideological, political, health and economic conditions.

CONCLUSION

There is need for public health law to realize the urgency of regulating the modifiable patterns of behaviour among people to strengthen the capacity of the community against public health risks involving, in particular, use of tobacco, diet and exercise. However, it is important to highlight that such legislations might have limitations and the level of effectiveness and enforcement can affect a law's effectiveness in achieving the intended public health goals.[1] Laws should, therefore, not be used in isolation but as one of several tools for the attainment of public health goals.

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TABLE II. Case studies of selected public health indicators

Indicator	Case example
Size of public health risk	In India the HIV/AIDS bill[19] 2006 was drafted to provide for prevention and control of the HIV epidemic after it was identified as a risk for more than a decade. This bill addresses issues relating to prohibition of discrimination, access to testing, treatment and counselling, social security and duties of the State. The HIV prevalence estimates in 1990 showed that there were approximately 200 000 individuals infected with HIV in India. By 2003, the number had increased to 5.1 million. The 2006 estimates released by National AIDS Control Organization (NACO) indicated that 2.5 million people are living with HIV in the country.[20] This illustration highlights the importance of the 'size' of a health risk and its contribution towards promulgation of a law.
Magnitude of risk factors	Section 6 of COPTA (Cigarettes and Other Tobacco Products Act), 2003 imposed a prohibition on the sale of any tobacco products to persons <18 years of age to restrict access and early initiation to tobacco products by children and youth, keeping in mind the magnitude of the risk involved and the number of preventable premature deaths caused by tobacco use.[21]
Involuntary exposure of vulnerable groups (individuals)	The Bhopal Gas Tragedy was an industrial disaster that took place at a Union Carbide subsidiary pesticide plant in the city of Bhopal, Madhya Pradesh, India and exposed 500 000 people to toxic gases (methyl isocyanate). It took a heavy toll on human lives and the newspapers reported that >2000 lives were lost in the first few days. Within months of the disaster, the Government of India issued an ordinance and later an Act called the Bhopal Gas Leak (Processing of Claims) Act, 1985 to ensure that claims relating to the Bhopal gas leak disaster are dealt with speedily and to the advantage of the vulnerable groups. In 1989, the Supreme Court of India directed the Union Carbide Corporation to pay US$ 470 million in 'full and final settlement' of all claims, rights and liabilities arising out of the disaster. This is a landmark case where both legislative and legal action protected the vulnerable groups.
Factors affecting enactment of legislation	The 'Pre-Natal Diagnostic Techniques (Regulation and Prohibition of Misuse) Act' of 1994 was passed after a sustained campaign spearheaded by the women's movement and concerned public health experts. Even after its enactment, little was done in terms of implementation. The continuing decline in sex ratios led to a Public Interest Litigation being filed in the Supreme Court of India in 2000, seeking directions for implementation of the Act. In May 2000, the Supreme Court issued directives for the proper implementation of the law and, over time, the Central and State governments reported regularly to the Court on the steps taken to implement the law.[22] This highlights various factors that come into play for effective enactment and implementation.
Monitoring and evaluation	An international alliance of non-governmental organizations from around the world (Framework Convention Alliance) was formed to support development of the WHO Framework Convention on Tobacco Control (FCTC) and combat tobacco industry disinformation. It was observed that civil society groups have a greater capacity to undertake operational research to strengthen implementation of policy.[17] In India, many local, national and international networks of civil societies are working towards comprehensive tobacco control either in collaboration with the national government or independently in the areas of health education, promotion, community outreach services, advocacy, litigation, legislative enforcement, tobacco cessation, etc.

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