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Arogya Legal is a firm of specialists who advise on laws that apply to health-focused businesses such as pharma, medical device, food and cosmetics which operate in a highly regulated environment.

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Medical Students Association of India

The Medical Students Association of India (MSAI) is a non-government organization of, for and by medical students of India, founded in October 2011. MSAI was adopted as the 100th National Member Organization (NMO) of the International Federation of Medical Students Association (IFMSA) on 6th March, 2012 at Accra, Ghana. It is India's first and largest nationally and internationally represented federation, comprising over 20,000 medical students across the country. They span over 22 states and 4 Union Territories in India (as of this writing).

As an organization, MSAI strives to provide its members with numerous opportunities to develop themselves as global health leaders of today and tomorrow. They follow the principle of 'Think Globally, Act Locally'.

MSAI works with issues that matter the most to the nation's youth by empowering the medical students and improving the health of the country with meaningful youth participation

AIM OF THE JOURNAL

An established healthcare system is akin to an oiled machine driving the wheels of growth. It is not only necessary for the expansion of the economy but also for its sustenance and survival. In the absence of accessible healthcare, the entire workforce of a nation can be rendered handicapped.

In India primarily through centrally-sponsored schemes the Centre has played a crucial role in providing healthcare along with the support from private parties, inspite of health being a State subject. Modern healthcare started in the post-independent era, with the establishment of the Ministry of Health. Since then, the government has invested lakhs of crores of rupees, majority of which came through the five-year plans, wherein public health has constantly been one of the most important focuses.

Notwithstanding the above-mentioned investment, there is a huge disparity between healthcare accessibility in rural and urban areas. However, it is expected that the existing paradigm is set to change. The rise of the Indian middle class saw healthcare become one of India's largest sectors, not only in terms of turnover but also in terms of the employment opportunities it generates. With the government's push for foreign investment, healthcare market in India is expected to reach US$ 372 billion by 2022, driven by rising incomes, greater health awareness, lifestyle diseases and increasing access to insurance.[1] Apart from that, the medical devices market is also simultaneously expected to reach US$ 11 billion.[2]

Although healthcare services offered by the private sector have largely eluded majority of the population, it has been successful in attracting patients from beyond the borders. While the discourse is upon the changing dynamics of the healthcare system, it is imperative to highlight the recent actions taken by the government, both at the state and central level. Launched in 2018, the 'Pradhan Mantri Jan Arogya Yojana', a nationwide insurance scheme, nears completion of its first year with treatments worth Rs. 7500 Crores carried out in 47 lakh hospital treatments.[3]

Manifold reforms in the medical education and institution sector are set to begin with the passing of National Medical Commission Act, 2019 and

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[1] *Healthcare Industry in India,* IBEF, at https://www.ibef.org/industry/healthcare-india.aspx, last accessed 30 /9/2019).

[2] Ibid.

[3] *Ayushman Bharat Scheme Commended By UN, World Bank: Harsh Vardhan,* NDTV (13/9/2019), at https://www.ndtv.com/india-news/union-health-minister-harsh-vardhan-ayushman-bharat-scheme-commendedby-united-nations-world-health-2105906, last seen on 12/10/2019.

awaited status of National Commission for Indian System of Medicine Bill, 2019, the National Commission for Homoeopathy Bill, 2019 and the Allied and Healthcare Professions Bill, 2018. More recently, the Rajasthan government awaits the "Right to Health" Act to be tabled.

World Health Organization ("WHO") recognizes access to essential medicines as part of the 'Right to Health'.[4] Access to government approved medicines for a comprehensive recovery is the right of every citizen of this country. Issues surrounding manufacture, sale & distribution of medicines/drugs transcend well beyond constitutional rights, into the dominion of intellectual property in the form of patents balancing IPR rights with regard to accessibility.

Healthcare system is incomplete without the mention of mental healthcare. The Mental Healthcare Act of 2017 is an example of this concept gaining recognition in India. The misconceptions surrounding mental health and terming issues related to it as disorders has led to it still being considered a taboo in India, resulting in those revealing their conditions to be ostracized or discriminated against. A brewing issue at both, national and international level, arena of mental healthcare remains unexplored. In the present scenario, it becomes pertinent to understand its basic concept and work on making necessary changes in the system catering to their specific needs.

While coursing through a plethora of incumbent issues in healthcare, few perennial questions along with contemporary ones arise for deliberation. In spite of considerable investments and funding over the years, India lags behind in healthcare accessibility, benefits remain unreachable and funds go unutilized. For charting the route for an accessible and efficient healthcare system it is utmost necessary to analyse and comprehend the gaping holes that exist in the various policies affecting our healthcare system. The instant issue is a small step at providing the health law practitioners, policy makers and the general public with a comprehensive tool for understanding and reading about novel themes pertaining to healthcare in India.

Aryan Babele

Editor-in-Chief

(On behalf of the RSRR Editorial Board)

[4] World Health Organization, *Access to essential medicines as part of the right to health*, available at https://www.who.int/medicines/areas/human_rights/en/, (last accessed 14 October, 2019).

FOREWORD

Dear discerning reader,

The Constitution of India puts an obligation on the government to promote and protect the health and well-being of Indians. We are aware that every incoming government puts tremendous emphasis on the health of its citizens in terms of policy and planning. After all, "health is wealth", isn't it?

But how would you feel if I told you that "health" is one of the most neglected areas of law and policy? I will explain.

We have heard stories of lack of facilities in hospitals and want of better (basic) standard of services. Do you know that we don't have a law that guarantees a common minimum standard of healthcare services? Yes, we have laws which state that a hospital should have a minimum number of beds or equipment, but we don't have a pan-India law that stipulates how frequently every hospital bed should be cleaned and how often certain equipment should be serviced so that it can provide consistent results. Imagine one of your loved ones on a hospital bed with a life support system, and you will understand why such a law is important.

Let me give you a recent example to which all of you may co-relate instantly. Personal Protective Equipment (basically body clothing, face masks, eye cover, gloves) are the single most crucial article of defence against COVID-19 virus. At the time of writing this (May 2020), no vaccine is available in the market to protect us from the virus. If I ask you to guess which government department is regulating the quality of PPEs, you may say some department in the health ministry, right? You are wrong. If I ask you, whether there are enforceable quality standards in place for manufacturing PPE for everyone, not just the government, I would perhaps get an answer which sounds something like: "Yes, obviously." Well, you will be wrong again. It is the Ministry of Textiles that is currently regulating (very topically) the quality of PPEs sold in India, and that too only those PPEs that are procured by the government. "But why?" you may ask, after all it defies common sense only to regulate PPEs that are purchased by the government especially since COVID-19 will not differentiate between who is with the government and who is not. What about the safety of the doctors in private hospitals? I don't intend to stir a controversy, but please know this: Because there was no law to regulate PPEs when COVID-19 virus hit us, our health ministry was helpless. The Ministry of Textiles had to intervene and fall back on an emergency legislation (the Essential Commodities Act, 1955) to regulate the quality of PPEs and this limited how much control it could exercise on PPEs. Our government is only as powerful (or limited) as the laws it makes.

Let me baffle you with some more examples. Indian government regulates the cost of drugs and some medical devices on the ground that they are 'essential' for our patients. But the same government does not regulate the cost of healthcare for life saving medical procedures and essential diagnostic tests; even though several independent surveys have shown that the cost of drugs and medical devices is actually a very small component of total cost of hospitalization. We all know that minor diseases such a cataract of the eye, and even serious diseases such as cancer, can be cured through medicines and devices, but hospitals and companies cannot talk about products that actually help and are effective directly with you, thanks to an anachronistic law (Drugs and Magic Remedies Act, 1954) which explicitly stops them from doing so. A businessman needs a license to sell paracetamol, but he/she does not need a license to sell ayurvedic medicines made out of poisonous substances. Our drug laws regulate quality of medicines given to animals, but our food laws do not regulate quality of food given to animals, including animals some of us consume as food. The list can go on ad-nauseam.

However, there has never been more need, or a better time, than today to deep-dive into laws that are concerned with our health & well-being, which I (fondly) refer to as health laws. The COVID-19 crisis has brought discussion on alcohol hand rubs, vaccines, infra-red thermometers, ventilators, immunity-boosting juices, alternative medicines (ayurveda and homeopathy), hospitals and just basically anything that gives us a hope of a safer tomorrow, into our drawing rooms.

What's more? A new product liability regime is round the corner, our medical device law was overhauled very recently, and telemedicine as a medium of healthcare delivery has now been permitted officially. These developments, to name a few, will bring their own unique challenges and present never-before opportunities for development of new jurisprudence. So now is the time to act, as lawyers or policy and regulatory professionals, and help draft better health laws that protect our today and guarantee our tomorrow. Now is the time to re-look at our policies and challenge the assumption on which they were made, because it directly affects all of our health and well-being.

And it is in this context that I am very pleased to present the sixth volume of this venerable journal to you. This volume has a razor-sharp focus on health laws, and the topics authored by contributors are extremely relevant. I hope that you find them to be as compelling a read as I did.

I have had the pleasure of writing this foreword, and of supporting the publication of this volume, for which I remain grateful to the publishers.

I sincerely hope that this volume, with its carefully curated and excellent content, is able to light a spark that leads to something even greater and more permanent in you, the reader.

My regards and thanks to the hard-working group of editors and researchers!

Anay Shukla

Founder and Managing Partner,

Arogya Legal (Health Laws Specialist Law Firm)

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DIGITAL HEALTH IN INDIA – KEY TRENDS AND IMPACT OF REGULATION

**Dr. Milind Antani*
***Shreya Shenolikar*
****Darren Punnen*

ABSTRACT

Technology has the potential to transform the healthcare sector in India. This revolutionary effect can be seen at all levels of service delivery, including telemedicine apps that allow patients in remote areas to consult with senior specialists in urban areas, the use of AI in treatment and diagnosis of diseases, and the prevalence of e-pharmacies that allow patients to purchase medicines from the comfort of their own homes. Proper regulation of these emerging technologies is essential to ensure that the patients are able to fully capitalize on these technological developments, without any danger to their health or safety.

This article explores the impact of existing and proposed legislation on key trends emerging in the digital health sector. Firstly, the article outlines how digital health can help boost healthcare service delivery and examines the prevalent business models and trends in the digital health sector. Secondly, the article provides a background on existing and proposed legislation which may have an impact on the digital health sector. Thirdly, the article examines the impact of existing and proposed regulation in the digital health sector. The article concludes by providing recommendations on how regulation should be framed to ensure sustainable growth of the digital health sector.

I. INTRODUCTION

The World Health Organisation defines digital health as *"a broad umbrella term encompassing eHealth, as well as emerging areas, such as the use of advanced computing sciences in 'big data', genomics and artificial intelligence"*.[1] Therefore, the expression Digital Health may be said to include the tools and services that use Information and Communication Technologies (ICT) for purposes connected to health. These purposes may include improving accuracy of diagnosis, monitoring chronic diseases more closely and improving treatment outcomes for patients.

* Dr. Milind Antani, Lead Pharma, Healthcare, Medical Device and Digital Health Practice; Lead, Social Sector Practice, Nishith Desai Associates.
** Shreya Shenolikar, Member, Pharma And Life Sciences Practice, Nishith Desai Associates
*** Darren Punnen, Member, Pharma & Life Sciences Practice, Nishith Desai Associates
[1] *WHO Guideline on Recommendations on Digital Interventions for Health System Strengthening*, World Health Organization, 9, available at https://apps.who.int/iris/bitstream/handle/10665/311941/9789241550505-eng.pdf?ua=1, last seen on 14/01/2020.

Often, ICT tools that form part of digital health are considered to be futuristic technology which will come into existence years, maybe even decades from now. However, digital health technologies are no longer a thing of the future. In fact, the world's first world's first 'tele-surgery' took place in 2001, where Dr. Jacques Marescaux (located in New York) surgically removed the gall bladder of a 68-year-old woman (located in France) using dedicated Asynchronous Transfer Mode telecommunication technology, which provided minimum response time between the surgeon and the robot.[2]

Closer to home, the Manipal Group of Hospitals have tied up with IBM's Watson for Oncology, a data-driven artificial intelligence ("**AI**"), to assist the doctors to diagnose and treat seven types of cancer.[3] Watson reportedly applies natural language processing and machine learning to assist oncologists and their care team to analyse a patient's medical record, to help identify personalized treatment options using clinical evidence.[4] Though Watson has had its fair share of controversies ranging from whether Watson is merely a 'mechanical turk' i.e. a human driven engine masquerading as AI to whether treatment plans recommended by Watson are effective[5], the potential of AI in medicine is undeniable.

A more accessible and visible digital health tool is the e-pharmacy. E-pharmacies/online pharmacies are crucial in improving accessibility of medicines (especially medicines for uncommon or rare diseases) across India as currently, healthcare resources are heavily concentrated in urban areas.

Tele-surgeries, AI and e-pharmacies are only the tip of the digital health iceberg. ICT tools in the health sector have myriad applications ranging from the use of blockchain technology to digitize health records to collating data from these health records to chart out disease prevalence and frame policy to tackle public health issues. Separately, tools for

[2] J. Marescaux, J. Leroy, F. Rubino, M. Smith, M. Vix, M. Simone, and D. Mutter, *Transcontinental Robot-Assisted Remote Telesurgery: Feasibility and Potential Applications*, 235(4) Annals of Surgery 487, 487 (2002), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1422462/, last seen on 14/01/2020.

[3] *Artificial Intelligence in the Healthcare Industry in India*, Centre for Internet and Society, available at https://cis-india.org/internet-governance/files/ai-and-healtchare-report, last seen on 14/01/2020.

[4] *Manipal Hospitals is the First Healthcare Provider in India to Adopt Watson for Oncology for Upgradation of Cancer Care*, Manipal Hospitals, available at https://www.manipalhospitals.com/blog/manipal-hospitals-is-the-first-healthcare-provider-in-india-to-adopt-watson-for-oncology-for-upgradation-of-cancer-care, last seen on 14/01/2020.

[5] C. Doctorow, *Watson for Oncology isn't an AI that fights cancer, it's an unproven mechanical turk that represents the guesses of a small group of doctors*, Boing Boing, available at https://boingboing.net/2017/11/13/little-man-behind-the-curtain.html, last seen on 14/01/2020.

augmented and virtual reality, big data, drones and 3D printing also have applications in the digital health space. Correctly leveraging digital health tools can be the key component for both developing and developed nations, to maximize efficiency in providing healthcare services to their citizens as well as to significantly improve the quality of those services.

The purpose of this article is to understand how digital health in India is currently regulated and, in cases of business models which are currently not specifically regulated, to take positions which are yet to be tested, with the hope that it would set the tone for legal discussions in larger platforms. To this end, the article begins by analysing prevailing business models from a legal and regulatory compliance perspective. Subsequently, this article contextualizes these business models within the applicable regulation, to understand whether these business models are being regulated in the best way possible. Finally, the article concludes by suggesting changes to existing regulations, identifying gaps in regulation and providing recommendations for new regulation.

II. PREVAILING BUSINESS MODELS AND TRENDS

1. Telemedicine

Telemedicine is the use of telecommunications technology to provide healthcare. Currently, 75% of the country's healthcare infrastructure is concentrated in urban areas while more than 75% of the population lives in rural areas.[6] Telemedicine could be used to effectively bridge the gap between the patient and the doctor.

While telemedicine is not a separate specialty in itself, its standout is the use of various technologies in providing traditional healthcare services. It is a broad concept that covers various aspects such as tele-radiology, tele-consultation, tele-nursing, tele-ICU and tele-surgery. Each brings its own advantages and challenges and as a result, is regulated separately under law.

2. e-Pharmacies

An e-pharmacy or online pharmacy is a pharmacy that operates over the internet and sends the orders to customers through mail, courier or delivery persons. There are various models that have been adopted where some pharmacies operate as online-only pharmacies and some as physical pharmacies with an online presence. Online pharmacies allow

[6] A.V. Patil, K. V. Somasundaram and R. C. Goyal, *Current Health Scenario in Rural India*, 10 Aust. J. Rural Health 129, 134 (2002), available at http://www.sas.upenn.edu/~dludden/WaterborneDisease3.pdf, last seen on 15/01/2020.

pharmacists to cater to a larger group of patients as the geographical restrictions inherent in physical pharmacies are removed in the online model.

3. Self-Monitoring Healthcare Devices

Monitors and sensors are now being integrated into wearables, which allow it to detect various physiological changes in the body. These smart devices are capable of tracking weight, sleep patterns, posture, diet and exercise[7]. The raw data that is collected can be used to self-monitor by detecting various health symptoms and alert the user in case of potential issues.

4. Robot-Assisted Surgery

Robotic surgery, or robot-assisted surgery, allows doctors to perform many types of complex procedures with more precision, flexibility and control than is possible with conventional techniques.[8] Using the assistance of robots, doctors are able to perform surgical procedures more efficiently. Even in minimally invasive surgeries the assistance of robotics allows surgeons to maneuver more precisely and with smaller incisions[9]. This ultimately leads to reduced loss of blood, better pain management and quicker recovery for the patient.

With advancements in deep learning, robots would be able to observe and replicate procedures that are simple and repetitive, while the surgeon concentrates on more complex tasks.[10]

5. Electronic Health Records ("EHR")

An EHR is a digital version of a patient's health records. EHRs help eliminate the problems associated with physical records such as loss and lack of accessibility. EHRs can be stored centrally and accessed at any time, irrespective of where or when the information was collected[11]. With

[7] G. Appelboom, E. Camacho and M.E. Abraham, *Smart wearable body sensors for patient self-assessment and monitoring*, 72(1) Archives of Public Health, (2014), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4166023/, last seen on 15/01/2020.

[8] *Robotic Surgery*, Mayo Clinic, available at https://www.mayoclinic.org/tests-procedures/robotic-surgery/about/pac-20394974, last seen on 15/01/2020.

[9] *Minimally Invasive Surgery*, Johns Hopkins Medicine, available at http://www.hopkinsmedicine.org/minimally_invasive_robotic_surgery/types.html, last seen on 15/01/2020.

[10] K. Claek and E. Strickland, *Robot Surgeons are Taking over the Operating Room*, IEEE Spectrum, available at http://spectrum.ieee.org/video/robotics/medical-robots/robot-surgeons-are-taking-over-the-operating-room, last seen on 15/01/2020.

[11] L. Poissant, J. Pereira and R. Tamblyn, *The Impact of Electronic Health Records on Time Efficiency of Physicians and Nurses: A Systematic Review*, 12(5) Journal of the American

EHRs, doctors are able to view their patients' complete medical history even if they are treating the patient for the first time. This helps reduce duplication of tests and facilitates the secure exchange of information, which in turn helps the patient and the healthcare facilities manage costs.

The data collected from EHRs and wearables can be put to use in different ways. This data set has multiple big data applications ranging from understanding the general state of public health to targeted advertising. Due to the potential for help and harm arising from big data, the regulation of EHRs (specifically privacy and data protection concerns) takes on even more importance.

6. Health Service Aggregation

Information asymmetry is one of the biggest challenges in healthcare. Patients are not privy to essential information which can help them pick the right doctor for their needs. Conversely, sometimes doctors are not able to reach out to a large number of patients due to a lack of visibility. A number of online platforms are springing up which attempt to solve this problem. These platforms list the names of doctors with their specialties, and allow for patients to search for and make an appointment with the right doctor to suit their specific needs. Patients are also able to rate and review the quality of the service provided by the doctor or institution, which serves as guidance for future patients to make an informed decision.

7. m-Health

Mobile health, or m-Health, is the provision of digital health services on a mobile platform. India is home to the 3rd largest smartphone market in the world, which makes m-Health a very lucrative option. The growth potential for m-Health in rural areas looks particularly promising due to the lack of access to traditional clinics coupled with the rapid increase in internet penetration in these areas.[12]

8. Artificial Intelligence

Artificial Intelligence ("AI") is the use of complex algorithms and software to emulate human cognition in the analysis of data. In the health sector, AI can be used to analyse patient records and identify a

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Medical Informatics Association 505, 505 (2005), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1205599/, last seen on 15/01/2020.

[12] N. Mathur, *India's internet base crosses 500 million mark, driven by Rural India*, Livemint (11/03/2019), available at https://www.livemint.com/industry/telecom/internet-users-exceed-500-million-rural-india-driving-growth-report-1552300847307.html, last seen on 15/01/2020.

personalized course of treatment. For instance, since many types of cancer have a genetic basis, human clinicians have found it increasingly complex to understand all genetic variants of cancer and their response to new drugs and protocols.[13] AI can help clinicians process this data to design effective treatment plans. An AI based medical device has already been approved by the drug regulator in Singapore.[14] See-Mode's Augmented Vascular Analysis (AVA) is intended to assist clinicians in interpreting and reporting vascular ultrasound studies which would otherwise require the clinician to review and analyse 50-150 individual images (including ultrasound images and doppler waveforms).[15]

III. IMPORTANT LAWS, REGULATIONS AND POLICIES GOVERNING DIGITAL HEALTH IN INDIA

Digital health in India is regulated under various laws, rules, and guidelines. While every digital health tool/business model is regulated separately, some regulations are applicable to digital health tools generally. We have provided an outline for some of these regulations below. Information Technology Act, 2000 ("IT Act"), The Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011 ("SPDI Rules"), and the Information Technology (Intermediaries Guidelines) Rules, 2011 ("Intermediary Guidelines")

The IT Act, SPDI Rules and the Intermediary Guidelines constitute the general data protection framework in India. The IT Act was enacted to provide legal recognition to online transactions and the exchange of electronic data generally. Broadly, the IT Act governs all forms of online activity including methods of authenticating digital signatures[16] and granting legal recognition to electronic records.[17] The IT Act also specifies penalties for damaging a computer system (hacking or denial of service attacks etc.) and lists out acts which amount to cybercrimes.

1. SPDI Rules

[13] T. Davenport and R. Kalakota, *The potential for artificial intelligence in healthcare*, 6(2) Future Healthcare Journal 94, (2019), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6616181/, last seen on 24/01/2020.
[14] Digital News Asia, Singapore *Approves Medical AI Software for Automated Analysis of Vascular Ultrasound*, Digital News Asia (12/12/2019), available at https://www.digitalnewsasia.com/digital-economy/singapore-approves-medical-ai-software-automated-analysis-vascular-ultrasound, last seen on 24/01/2020.
[15] Ibid.
[16] Chapter II, Information Technology Act, 2000.
[17] S. 4, Information Technology Act, 2000.

The SPDI Rules require all body corporates who collect, receive, possess, store, deal, or handle information of a provider of information to undertake measures to ensure that the provider of the data is informed about the manner in which the data would be used. These measures include publishing a privacy policy specifying, *inter alia,* the purpose of collection and usage of information and names of entities to which such information may be disclosed.[18] Additionally, it also mandates that the information collected be processed only in accordance with the terms of the consent provided by the provider of information[19] and places certain restrictions on the disclosure[20] and transfer[21] of sensitive personal information. Body corporates are also required to put in place reasonable security practices (prescribed under the SPDI Rules) to keep sensitive personal information secure.[22]

Most entities in the digital health space are required to comply with the SPDI rules as they would deal with physical, psychological or mental health conditions of persons and their medical records which are considered to be sensitive personal information under the SPDI Rules.[23]

2. Intermediary Guidelines

The Intermediary Guidelines specify the due diligence to be undertaken by an intermediary (persons processing information on behalf of other persons, such as telecom service providers, internet service providers and web-hosting service providers) so that they may avail the safe harbour provision under Section 79 of the IT Act. Section 79 of the IT Act states that intermediaries would not be held liable for third party information, data, or communication link made available or hosted by the intermediary provided the (i) function of the intermediary is limited to providing access to a communication system over which information made available by third parties is transmitted or temporarily stored or hosted, or (ii) intermediary does not initiate the transmission, select the receiver of the transmission, and select or modify the information contained in the transmission.

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[18] Rule 4, Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.
[19] Rule5, Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.
[20] Rule 6, Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.
[21] Rule 7, Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.
[22] Rule 8, Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.
[23] Rule 3, Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.

Broadly, the Intermediary Guidelines require the intermediary to publish rules and regulations, a privacy policy and a user agreement (which should contain information prescribed under the Intermediary Guidelines) as a pre-condition to access or use the intermediary's computer resource.[24] Additionally, in the event the intermediary is hosting content that is found to be in contravention of the IT Act and rules, the intermediary would be required to take down such infringing content on the receipt of a notice from a government authority to this effect.[25]

The safe harbour provision under the IT Act and Intermediary Guidelines is particularly useful for digital health services that merely facilitate the interaction between the patient and the service provider and are not directly involved in the provision of the services.

The IT Act along with the SPDI Rules and Intermediary Guidelines forms the bedrock over which any digital health business model is built.

3. Drugs and Cosmetics Act, 1940 ("D&C Act") and Drugs and Cosmetics Rules, 1945 ("D&C Rules")

The D&C Act along with the D&C Rules constitute the primary framework governing drugs in India. D&C Rules regulate the clinical trial, import, manufacture, and sale of drugs and biologics. The D&C Rules specify that certain drugs should be sold only on the basis of a prescription issued by a doctor licensed to practice in India and dispensed directly to the patient or their caretaker under the supervision of a registered pharmacist.[26] Drugs which can be sold only on prescription are stated in Schedules H, H1, and X of the D&C Rules. More generally, the D&C Act states that no person can sell any drug without a license issued by the licensing authority. The only exception in this respect are drugs specified in Schedule K of the D&C Rules which may be sold without obtaining a valid sale license from the drug regulator. These broadly include drugs not intended for medical use, quinine and other antimalarial drugs, magnesium sulphate, substances intended to be used for destruction of vermin or insects that cause disease in humans or animals and household remedies, among others.

The D&C Rules in their current form were not intended to govern e-pharmacy business models. Under the D&C Rules, a valid prescription is required to be in writing and bear the doctor's signature. However, scanned copies of signatures made by hand are not considered to be valid within the meaning of the IT Act. The Government is currently

[24] Rule 3, Information Technology (Intermediaries guidelines) Rules, 2011.
[25] Rule 3, Information Technology (Intermediaries guidelines) Rules, 2011.
[26] Rule 65, Drugs and Cosmetics Rules, 1945.

considering options on how e-pharmacies should be regulated and would hopefully take into account this difficulty faced by most e-pharmacies.

4. The Indian Medical Council Act, 1956 ("MCI Act") and The Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 ("MCI Code")

The MCI Act along with the MCI Code constitutes the regulatory framework regulating medical education and the practice of medicine in India. The MCI Act provides that only those persons who have a recognized degree in medicine and are registered with a state medical council have the right to practice medicine in India. The MCI Code lays down professional and ethical standards of interaction of doctors with patients, pharmaceutical companies and other doctors.

It is pertinent to note, however, that the MCI Act will soon be repealed by the National Medical Commission Act, 2019 ("**NMC Act**") and a new body i.e. the National Medical Commission will be constituted to replace the Medical Council of India as the apex body to regulate the practice of medicine in India.

5. Draft E-pharmacy Rules

The Ministry of Health and Family Welfare ("**Health Ministry**") released a set of draft rules to govern e-pharmacies ("**Draft E-pharmacy Rules**").[27] The Draft E-Pharmacy Rules will introduce a registration system[28] for e-pharmacies and permit them to function on par with traditional pharmacies by granting them legal recognition. It also imposes conditions on e-pharmacies, such as requiring them to maintain a confidential record of prescriptions as well as details of the drugs sold to patients.[29] E-pharmacies are also required to establish a 24/7 customer support and grievance redressal mechanism, in order to address consumer complaints.[30] Consumers are empowered to submit complaints with the drug regulator for violation of the D&C Rules (including with respect to the quality of drugs dispensed).[31] If the e-pharmacy is found to be in violation of the law, the regulator can cancel the license of the e-pharmacy in addition to other penalties prescribed.[32]

The Draft E-pharmacy Rules were released to specifically govern online pharmacies as the current regulatory framework does not account for the

[27] Draft E-Pharmacy Rules, 2018.
[28] Rule 67J, Draft E-Pharmacy Rules, 2018.
[29] Rule 67M, Draft E-Pharmacy Rules, 2018.
[30] Rule 67J, Draft E-Pharmacy Rules, 2018.
[31] Rule 67U, Draft E-Pharmacy Rules, 2018.
[32] Rule 67U, Draft E-Pharmacy Rules, 2018.

online sale of medicines. The D&C Rules require the pharmacist to dispense drugs directly to the patient or caretaker which is not convenient in the case of e-pharmacies.

The regularization of e-pharmacies has been a highly controversial subject for a few years now. After the Draft E-pharmacy Rules were published, the All India Organisation of Chemists and Druggists ("**AIOCD**") went on multiple strikes to protest against the government's decision to regularise e-pharmacies.[33] Subsequently, petitions were filed in the Madras High Court[34] and Delhi High Court.[35] Initially, both the Madras and Delhi High Court had passed orders banning online sale of medicines. However, the Madras High Court subsequently lifted the ban and directed the Government to notify the draft rules by January 31, 2019.[36] As of this writing, the Draft E-pharmacy Rules has still not been notified by the Central Government.

Subsequently, on November 28, 2019, the Drugs Controller General of India – India's apex drug regulator – issued an office letter requiring all drug controllers to enforce an order passed by the Delhi High Court in December 2018, which prohibited the online sales of medicines without a valid license.[37]

Currently, the online sale of medicines seems to be legal provided the online pharmacies are operating under a valid license that permits them to stock and sell medicines.

6. Draft Personal Data Protection Bill, 2019 ("PDP Bill")

The PDP Bill has been introduced in the Lok Sabha and is intended to replace the IT Act as the primary data protection legislation in India. The PDP Bill is currently being examined by a Joint Parliamentary Committee. The PDP Bill, if enacted will apply to[38]:

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[33] *Chemists declare strike against Centre's move to regularize e-pharmacies*, ET Retail (28/09/2019), available at https://retail.economictimes.indiatimes.com/news/health-and-beauty/pharmacy/chemists-declare-strike-against-centres-move-to-regularise-e-pharmacies/65994969, last seen on 15/01/2020.

[34] Tamil Nadu Chemists and Druggists Association v. The Union of India, W.P. No. 28716 of 2018 (Madras High Court, 17/12/2018).

[35] Zaheer Ahmed v. Union of India W.P.(C) 11711/2018 (Delhi High Court).

[36] S.R. Singh, *Two High Courts, two different views on online drugs sale,* The Hindu (21/01/2019), available at https://www.thehindu.com/news/cities/Delhi/two-high-courts-two-different-views-on-online-drugs-sale/article26045505.ece, last seen on 15/01/2020.

[37] S. Dey, *Online drugs sales may come to halt as licence made must*, Times of India (04/12/2019), available at https://timesofindia.indiatimes.com/business/india-business/e-pharmas-come-to-a-halt-as-regulator-makes-licence-must/articleshow/72357270.cms, last seen on 15/01/2020.

[38] S. 2, Personal Data Protection Bill, 2019 (passed by Lok Sabha, 11/12/2019).

i. The processing of all personal data which has been collected, disclosed, shared, or otherwise processed within the territory of India;

ii. The processing of personal data by the State (Central or State Government, public authority, government institution or any organisation performing a public function), any Indian company, any citizen of India or any person or body of persons incorporated or created under Indian law;

iii. The processing of personal data by data fiduciaries or data processors outside the Indian territory, provided such processing is in connection with any business carried on in India or any systematic activity of offering goods or services to data principals within India or in connection with any activity which involves profiling of data principals within the territory of India.

However, the PDP Bill would not apply to processing of anonymized data unless such data is being provided to the Central Government to better enable targeting of delivery of services or formulation of policies.[39] The PDP Bill, though sector agnostic, is more comprehensive compared to the IT Act when dealing with health data. Under the PDP Bill, the terms health data[40], biometric data[41] and genetic data[42] are defined clearly and have been categorized as sensitive personal information.

Additionally, the PDP Bill ensures that the data principal (natural person to whom the data relates) remains informed about the data that has been collected and the manner in which it would be processed. Most of the compliances under the PDP Bill are required to be undertaken by the data fiduciary (entities who determine the purpose and means of processing data). The data fiduciary may engage a data processor to process the data on behalf of the fiduciary by way of a written agreement.

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[39] Ibid.

[40] Section 3(21) of Personal Data Protection Bill, 2019 defines Health Data as the data related to the state of physical or mental health of the data principal and includes records regarding the past, present or future state of the health of such data principal, data collected in course of registration for, or provision of health services, data associating the data principal to the provision of specific health services.

[41] Section 3(7) of Personal Data Protection Bill, 2019 defines Biometric Data as facial images, fingerprints, iris scans, or any other similar personal data resulting from measurements or technical processing operations carried out on physical, physiological, or behavioural characteristics of a data principal, which allow or confirm the unique identification of that natural person.

[42] Section 3(19) of Personal Data Protection Bill, 2019 defines Genetic Data as personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the behavioural characteristics, physiology or health of that natural person and which result, in particular, from an analysis of a biological sample from that natural person in question.

The PDP Bill places obligations on data fiduciaries to undertake certain compliances to process personal data as follows:

i. The data fiduciary is required to provide the data principal with a notice, inter alia, regarding the nature and categories of personal data collected, purposes for which it will be utilized, who it may be shared with[43];

ii. The data collected should be processed only for the purpose specified to the data principal and for an incidental purpose for which the data principal would reasonably expect the personal data to be used for;[44]

iii. The data should be retained only until the purpose for which the data was collected is completed; and;[45]

iv. Data fiduciaries are required to implement measures to provide information to data principals in the manner in which their data is being processed and provide notification on data breaches.[46]

In each case, the consent of the data principal should be obtained for processing personal data.[47] For processing sensitive personal data (such as health information), the following additional requirements should be fulfilled:[48]

i. Consent should be obtained after informing data principal the purpose of processing the sensitive personal information which is likely to cause significant harm to the data principal;

ii. Consent should be obtained in clear terms without recourse to inference from conduct in a context: and

iii. Consent should be obtained after giving the data principal the choice of separately consenting to the purposes of processing, or the use of different categories of sensitive personal data relevant to the processing.

Separately, the PDP Bill also specifies an exhaustive list of situations in which the personal data/sensitive personal data may be processed

[43] S. 7, Personal Data Protection Bill, 2019 (passed by Lok Sabha, 11/12/2019).
[44] S. 5, Personal Data Protection Bill, 2019 (passed by Lok Sabha, 11/12/2019).
[45] S. 9, Personal Data Protection Bill, 2019 (passed by Lok Sabha, 11/12/2019).
[46] S. 25, Personal Data Protection Bill, 2019 (passed by Lok Sabha, 11/12/2019).
[47] S. 11, Personal Data Protection Bill, 2019 (passed by Lok Sabha, 11/12/2019).
[48] S. 11(3), Personal Data Protection Bill, 2019 (passed by Lok Sabha, 11/12/2019).

without the consent of the data principal. Sensitive personal data may be processed without the consent of the data principal:[49]

i. to respond to any medical emergency involving a threat to the life or a severe threat to the health of the data principal or any other individual;

ii. to undertake any measure to provide medical treatment or health services to any individual during an epidemic, outbreak of disease or any other threat to public health; or

iii. to undertake any measure to ensure safety of, or provide assistance or services to, any individual during any disaster or any breakdown of public order.

The PDP Bill also requires data fiduciaries identified to be significant data fiduciaries by the Data Protection Authority of India (no data fiduciaries have been identified yet) to appoint a data protection officer.[50]

The PDP Bill also establishes the Data Protection Authority of India to administer and enforce the PDP Bill, respond to data or security breaches and protect the rights of data principals (natural persons to whom the data relates).[51]

7. Digital Information Security in Healthcare Act ("DISHA")

DISHA, currently in the draft stage, is sought to be enacted to standardise and regulate the process related to the collection, storage, transmission and use of digital health data. DISHA, if enacted, would increase interoperability of patient data across healthcare service providers (including hospitals, clinics, primary healthcare centres and emergency response services) by instituting a health information exchange.[52] This health information exchange would be facilitated by the National Electronic Health Authority of India[53] and the State Electronic Health Authority of India[54] (to be established under DISHA) who will be responsible for coordinating data transfers between HCPs.

DISHA defines digital health data as *"an electronic record of health-related information about an individual…"*[55] Crucially, DISHA clearly identifies the

[49] Chapter III, Personal Data Protection Bill, 2019 (passed by Lok Sabha, 11/12/2019).
[50] S. 30, Personal Data Protection Bill, 2019 (passed by Lok Sabha, 11/12/2019).
[51] Chapter IX, Personal Data Protection Bill, 2019 (passed by Lok Sabha, 11/12/2019).
[52] S. 19, Digital Information Security in Healthcare Bill, 2018 (pending).
[53] S. 4, Digital Information Security in Healthcare Bill, 2018 (pending).
[54] S. 7, Digital Information Security in Healthcare Bill, 2018 (pending).
[55] S. 3(e), Digital Information Security in Healthcare Bill, 2018 (pending).

patient as the owner of the digital health data[56] and outlines a comprehensive set of rights of the patient in respect of such data.[57] These rights include the right to privacy, confidentiality and security of their digital health data,[58] the right to refuse or withdraw consent,[59] the right to know the clinical establishments and entities that may access this data,[60] the right to be notified in the event their health data is accessed by a clinical establishment,[61] and the right to seek compensation for damages caused in case of breach of digital health data.[62]

DISHA also lays down the process of storage and transmission of digital health data and the circumstances in which the digital health data may be accessed. Notably, DISHA places restrictions on the commercial use of digital health including prohibiting pharmaceutical and insurance companies from accessing digital health data stored in the health information exchange in any circumstances.[63]

IV. EVALUATION OF RULES AND REGULATIONS AND IMPACT ON DIGITAL HEALTH SPACE

The digital health space is constantly evolving as new and existing technologies are used in the health sector. Below we have analysed some of the emerging trends in the digital health sector to see how they would be regulated under existing and proposed legislation and examined the policy challenges faced by stakeholders towards fully capitalizing on these technologies.

1. Tele-medicine and E-pharmacies

Apps and websites offering online or phone consultations with doctors as well as e-commerce websites engaged in the online sale of medicines are already operational in many parts of India. Currently, telemedicine and online pharmacies are not regulated under any specific law. However, the rules generally applicable to the practice of medicine (MCI Act and MCI Code) and pharmacies (D&C Act and D&C Rules) would apply to telemedicine and e-pharmacies as well.

2. Telemedicine

[56] S. 3(j), Digital Information Security in Healthcare Bill, 2018 (pending).
[57] S. 28, Digital Information Security in Healthcare Bill, 2018 (pending).
[58] S. 28(1), Digital Information Security in Healthcare Bill, 2018 (pending).
[59] S. 28(3), Digital Information Security in Healthcare Bill, 2018 (pending).
[60] S. 28(6), Digital Information Security in Healthcare Bill, 2018 (pending).
[61] S. 28(6), Digital Information Security in Healthcare Bill, 2018 (pending).
[62] S. 28(8)(g), Digital Information Security in Healthcare Bill, 2018 (pending).
[63] S. 29(5), Digital Information Security in Healthcare Bill, 2018 (pending).

There seems to be some legal ambiguity in how telemedicine is regulated in India. The major gaps in regulation have been specified below.

Practice across State Boundaries

As discussed above, doctors are required to be registered with a state medical council (which operates under the overall supervision of the Medical Council of India) as a prerequisite to practicing medicine in India. The names registered with the state medical council also form part of a central register maintained by the Medical Council of India. An unresolved concern in this respect is whether a doctor registered with the state medical council of one state can practice medicine outside of that state. The MCI Act states that a person whose name is a part of the Indian Medical Register, which is a central register maintained by the MCI, is entitled to practice as a medical practitioner in any part of India, subject to any other conditions laid down under the MCI Act.[64] However, certain state medical council legislations expressly prohibit the practice of medicine within the state unless the medical practitioner is registered with the relevant state medical council.

One concern with cross-state practice would be to determine which state medical council would have jurisdiction to try a violation of the MCI Code in cases the violation occurs outside of the state in which the medical practitioner is registered.

The Supreme Court in the case of *Malay Ganguly v. Medical Council of India and Ors.*[65], had considered the question of liability when a medical practitioner commits an offence while practicing in an area that is outside of the jurisdiction of the relevant state from which he/she received registration. The question was sent to the MCI for deliberation, and in the meeting of the ethics committee held from 26th to 28th August, 2004, the matter was taken up for consideration. The ethics committee observed "*as such there is no necessity of registration in more than one State Medical Council because any doctor who is registered with any State Medical Council is automatically borne on the strength of the Indian Medical Register and also by virtue of Section 27 of the MCI Act, a person who is borne in the Indian Medical Register can practice anywhere in India*". The committee also laid down how complaints against a medical practitioner were to be dealt with when the medical practitioner was registered with more than one state. Unfortunately, the ambiguity regarding registration was not conclusively put to rest.

Since the ambit of a telemedicine practice would be to provide medical services that are not restricted to the location of the patient, it is unclear

[64] S.27, Indian Medical Council Act, 1956.
[65] Malay Ganguly v. Medical Council of India and Ors., (2002) 10 SCC 93.

whether a doctor registered with a state medical council would be permitted to provide medical services to patients residing in another state, and whether such doctors would be required to obtain multiple state registrations in order to be entitled to practice.

A solution may be to consider adopting some of the practices being followed by the USA in terms of special licensing for the purpose of telemedicine, which would bring some clarity and aid medical practitioners and healthcare institutions in being compliant with regulatory requirements.

Prescribing Medicines Online

Though not expressly forbidden, the Supreme Court has observed that prescriptions for drugs should not be given over the telephone, except in cases of emergencies.[66] Additionally, prescriptions given in apps providing telemedicine services (which tend to be scanned copies of prescriptions written and signed by hand) are usually not valid under law. The D&C Rules state that for a prescription to be valid, it must be in writing, signed and dated by the doctor issuing the prescription.[67] The prescription must also state the name and address of the person for whom it is given and the quantity to be supplied. Under the IT Act, a document in electronic format is considered validly signed if the information in the document is capable of being authenticated by means of electronic signature in a manner prescribed under the IT Act. Scanned copies of documents where a signature is made by hand are not considered a valid signature under the IT Act. Therefore, it is possible for pharmacists to deny supplying medicines on the basis of such prescription as a consequence for which ill patients may be left without the medicines they need.

Data Protection Requirements

Apps and websites offering telemedicine services process what is considered to be sensitive health information under the SPDI Rules. Therefore, the requirements of obtaining informed consent, publishing a privacy policy and putting in place adequate security measures are all compliances the telemedicine service providers are required to undertake. It is pertinent to note that the SPDI Rules provide only a basic level of protection to patient data by ensuring that the person providing the data is informed about the manner in which the data will be used. However, a common problem with obtaining user consent for processing their digital data is the difficulty in explaining to the user in simple terms what data is

[66] Martin F. D'Souza v. Mohd. Ishfaq, (2009) 3 SCC 1.
[67] Rule 65, Drugs and Cosmetics Rules, 1945.

being collected, how it is being processed and who it may be shared with. This problem is compounded in India due to low levels of digital literacy.

To resolve this, in addition to obtaining user consent for collecting and processing data, a robust regulatory framework on how health data can be used should be put in place.

3. E-pharmacies

The regulation of e-pharmacies has been hotly debated for a few years now, primarily because e-pharmacy business models can be manipulated by users to obtain drugs illegally. Under the current regulatory framework, there are multiple challenges to dispensing drugs online under the current framework.

Validity of Prescription

The converse of the issue faced by doctors when prescribing medicines online is applicable in the context of e-pharmacies. Generally, patients upload a scanned copy of a physical prescription provided to them by their doctor on the website or app of the e-pharmacy and the e-pharmacy supplies drugs to the patient on the basis of this prescription.

As discussed above, a valid prescription should be in writing and should be signed by the medical practitioner providing the prescription. Under the IT Act, a document that is required by law to be in writing would be deemed to be in compliance of such law if the same is made available in an electronic form and accessible in a way that it can be used for future references[68]. Hence a prescription uploaded online would fulfill the first requirement of a valid prescription under the D&C Rules. However, the IT Act further states that where a law requires for a document to be signed, it would be deemed to be in compliance only if such information or matter is authenticated by means of an electronic signature[69]. Affixing an electronic signature to any document thus becomes essential for it to fulfil a legal obligation mandating a regular signature. This would imply that uploading a scanned copy of a prescription may not be recognized as valid under law. The Draft E-pharmacy Rules also do not account for this difficulty. Prescription, under the Draft E-pharmacy Rules is defined as *"an instruction from a Registered Medical Practitioner to a patient, written by hand or in any electronic mode duly signed, to dispense a drug and quantity of drug to a patient"*.[70] As the term 'duly signed' is used, the requirements under the IT Act with respect to an electronically signed document would continue to be applicable.

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[68] S. 4, Information Technology Act, 2000.
[69] S. 5, Information Technology Act, 2000.
[70] Rule 67-I(d), Draft E-Pharmacy Rules, 2018.

Separately, it would also be challenging to ensure that the drugs are not dispensed by two different pharmacies based on the same prescription. Currently, once a prescription has been fulfilled, the pharmacists will typically stamp the prescription and put their signature on it. However, there is no way to replicate this process online. Therefore, measures must also be put in place whereby a prescription drug is not dispensed more than once against the same prescription, something that has not been accounted for in the E-Pharmacy Rules.

Validity of License for E-pharmacies

In most e-pharmacy models, the e-pharmacy supplies drugs to the patients either from an inventory maintained by the e-pharmacy in a warehouse or by providing aggregator and logistics services where the order is fulfilled by a third party seller, but delivered to the customer by way of courier or a delivery boy (engaged by the e-pharmacy). The former is similar to an inventory-based e-commerce model (e.g. the H&M online clothing store) while the latter follows the market place model where sellers list their products on an e-pharmacy portal (e.g. Amazon website).

In its current form, the D&C Act requires that all drugs must be sold under a license.[71] Thus, general retailers in India cannot sell drugs, except for a limited class of medicines such as gripe water, which can be sold without a license.[72] Moreover, a drug can only be dispensed by a registered pharmacist to either the patient or his/her caretaker. Therefore, even though most e-pharmacies have obtained a valid license under the D&C Rules, special provisions are required to be put in place for e-pharmacies where it is not mandatory for a drug to be delivered to the patient/caretaker directly by the pharmacist. It should be noted that the Draft E-Pharmacy Rules currently do not account for this requirement.

4. Digitization of Health Records

Digitization of health records is possibly the biggest challenge faced both in India and in developing countries towards making digital health a reality. Having a comprehensive and reliable set of health data for each patient is the basis to providing many other digital health services including AI (that can process data to identify patterns and trends), telemedicine (where doctors from different specialties can access the same patient data) and improving delivery of welfare schemes (by keeping a track of what services have been availed by whom). However, creating a single repository of all health records is a mammoth task from a policy

[71] Part VI, Drugs and Cosmetics Rules, 1945.
[72] Rule 123, Drugs and Cosmetics Rules, 1945.

perspective. This is because the path to digitizing health records is predicated on the following.

First, each healthcare provider including clinics of individual doctors in both urban and rural areas, primary healthcare centres, mobile healthcare providers and emergency response services would be required to have internet connectivity. *Secondly,* each of these healthcare providers would be required to follow a standardized format for capturing and storing data to ensure that the data format is compatible across different systems. *Thirdly,* it would require patients to be able to use smartphones to effectively access these services digitally. The Indian Government has already considered some legislative and policy initiative to gradually digitize health records and eventually move towards universal healthcare.

We have examined some of these policy initiatives below to understand the work that has already been done towards making EHRs a reality and the steps required to be taken moving forward.

National Health Policy, 2017 ("NHP")

The NHP serves as a guide on how to approach healthcare regulation in India by laying down long-term goals for policymakers to keep in mind.[73] The NHP has identified the attainment of universal healthcare and aims to gradually move towards it. The NHP states that:

> *"The policy envisages as its goal the attainment of the highest possible level of health and well-being for all at all ages, through a preventive and promotive health care orientation in all developmental policies, and universal access to good quality health care services without anyone having to face financial hardship as a consequence. This would be achieved through increasing access, improving quality and lowering the cost of healthcare delivery."*

The NHP also specifies the use of digital health to improve healthcare service delivery by setting up a federated National Health Information Architecture ("**NHIA**") and the establishment of a National Digital Health Authority to regulate, develop and deploy digital health across the continuum of care.

National Health Stack: Strategy and Approach released by the NITI Aayog ("NHS")

[73] *National Health Policy, 2017*, Ministry of Health and Family Welfare, Government of India, 2017, available at https://mohfw.gov.in/sites/default/files/9147562941489753121.pdf, last seen on 14/01/2020.

The NHS is a policy document laying down the framework for a nationally shared digital infrastructure usable by both the Central and State authorities across public and private sectors.[74] The NHS is designed to provide foundational components that will be required across Pradhan Mantri Jan Arogya Yojana (Aayushman Bharat Yojana) (**"**AB-PMJAY**"**) (India's centrally funded healthcare scheme provides healthcare coverage to over 100 million families) and other health programs in India. The key components of the NHS are:

i. National Health Electronic Registries to create a single source of truth to manage the master health data of the nation;

ii. Coverage and Claims Platform as building blocks to support large health protection schemes;

iii. A federated personal health records system accessible by patients as well as for medical research;

iv. A national health analytics platform to combine data from multiple health initiatives for making policy decisions; and

v. Horizontal components as required e.g. Digital Health ID, Health Data Dictionaries and Supply Chain Management for Drugs shared across all health platforms.

*National Digital Health Blueprint Report (**"**NDHB Report**"**)*

The NDHB Report aims to create a framework for the evolution of a National Digital Health Eco-System and establish a specialized organization called National Digital Health Mission to implement the National Digital Health Blueprint (**"**NDHB**"**).[75]

At its core, the NDHB contains a set of principles for digital health systems to provide guidance to the architecture of any proposed system dealing with health information. The NDHB also specifies key principles of privacy by design, confidentiality and the right to be forgotten that health systems should incorporate into their architecture. The NDHB, properly executed, should allow for interoperability of health systems at the patient, hospital and ancillary healthcare provider level (such as ambulance and emergency response services). Effectively, this would lead

[74] *National Health Stack: Strategy and Approach*, NITI Aayog, 2018, available at https://niti.gov.in/writereaddata/files/document_publication/NHS-Strategy-and-Approach-Document-for-consultation.pdf, last seen on 14/01/2020.

[75] *National Digital Health Blueprint*, Ministry of Health and Family Welfare, Government of India, 2019, available at https://mohfw.gov.in/sites/default/files/National_Digital_Health_Blueprint_Report_comments_invited.pdf, last seen on 14/01/2020.

to a creation of a health system with an electronic health record of every Indian citizen.

The NDHB broadly envisions a health system composed of over 35 building blocks which are part of a federated architecture. The health system will store data at the national, state and local (facility) level. More detailed records such as the Electronic Medical Record will be stored at a local level while a repository of standards and data dictionaries will be maintained at a national level. Each level is composed of building blocks appropriate at that level. For instance, the building block of 'Common Application' would be at the national level to publish the code of a few most commonly used applications. On the other hand, the building blocks of 'Anonymization' and 'Consent Manager' should be at the point of care while the building blocks of 'anonymizer-as-a-service' and 'consent-management-as-a-service' would be at the state level to facilitate inter-facility transfers. The entire system would be supported by call centres, a health portal, social media (for emergency management, health awareness and community-based services) and a range of apps.

The NHP, NHS and NDHB combined form the current understanding of our approach to electronic records. Currently, India is still in the nascent stage of putting in place a digital health framework and has only signalled its intent to do so. However, what are conspicuously missing from the above-mentioned policy framework are the instances in which patient data may be used for purposes other than providing healthcare services to patients. Given the resistance to the AADHAR initiative (which aimed to give unique identification numbers to every citizen), it remains to be seen whether Indians are forthcoming in providing the government with their sensitive personal data.

5. Role of Digital Health in Welfare Schemes

Digital health tools can streamline service delivery in healthcare schemes and increase efficiency by preventing duplication of work. It is difficult to ensure proper service delivery of healthcare schemes in a large country like India where the population is highly fragmented, and many reside in heavily forested or hilly areas. Digital health in these situations can greatly improve the accuracy and quality of service delivery to ensure the good health of every Indian.

Some of these digital health interventions include linking digital health records with census data to measure the degree of penetration of health schemes, providing medical services over the telephone or online, disseminating health information online for common questions such as vaccinations, pre-natal and post-natal care (as preventive care to reduce

the need for medical intervention) as well as using self-monitoring devices to gather information and provide medical care at the right times.

The poster-child of the benefits of deploying digital health tools in welfare schemes is the AB-PMJAY. AB-PMJAY is a comprehensive healthcare scheme to provide health insurance to over 500 million citizens.[76] The AB-PMJAY was structured to implement the recommendations of the NHP and aims to provide cashless and paperless access to medical services for the beneficiary right at the point of service. The scheme aims to assist in reduction of hospitalization expenditures for citizens, specifically those who are below the poverty line. The scheme issues an insurance cover of up to INR 5, 00,000 per family each year, for secondary and tertiary care hospitalization.[77] AB-PMJAY also intends to set up 1, 50,000 health and wellness centres as part of the scheme, in order to increase healthcare access for the population. Over 9,000 private hospitals have already been empanelled as part of the scheme.[78] It is expected that the provision of services through the public and private sector under Ayushman Bharat will generate enormous amounts of health data, mostly in the digital space.[79]

The AB-PMJAY has an app that enables patients to access their medical records online, view a list of empanelled hospitals, and understand whether they are eligible for the scheme. The National Health Authority (**"**NHA**"**) set up under the AB-PMJAY has also tied up with Google to strengthen the digital presence of AB-PMJAY. As part of this partnership, Google will help train NHA staff and help to improve the efficiency of NHA's everyday applications.[80]

Fully implemented, the AB-PMJAY will lead to the vast majority of Indians having an EHR which can be accessed by any empaneled healthcare facility.

6. 3D Printing ("3DP")

[76] *About Pradhan Mantri Jan Arogya Yojana (PM-JAY)*, Ayushman Bharat Pradhan Mantri Jan Arogya Yojana, available at https://pmjay.gov.in/about-pmjay, last seen on 15/01/2020.
[77] Ibid.
[78] *1 lakh benefitted under PMJAY in one month of its launch: Nadda*, ET Healthworld (22/10/2018), available at https://health.economictimes.indiatimes.com/news/policy/1-lakh-benefitted-under-pmjay-in-one-month-of-its-launch-nadda/66309902, last seen on 15/01/2020.
[79] Ministry of Health and Family Welfare, Government of India, *National Digital Health Blueprint Report*, available at https://mohfw.gov.in/newshighlights/final-report-national-digital-health-blueprint-ndhb, last seen on 15/01/2020.
[80] R. Kumar, *Google power to Ayushman Bharat-PMJAY! NHA, tech giant joint hands to strengthen Modicare,* Financial Express (04/10/2019), available at https://www.financialexpress.com/lifestyle/health/google-ayushman-bharat-pmjay-nha-collaboration-details/1726888/, last seen on 15/01/2020.

'Three-dimensional printing', or 'additive manufacturing', refers to the process by which Computer Aided Design (**"**CAD**"**) files are transformed into physical articles. There are many different types of 3DP, each using slightly different materials. However, the overall procedure applies generally to all 3DP versions. The CAD file, an all-encompassing three-dimensional electronic 'blueprint' with the schematics of the article to be printed, is created manually using dedicated software or through three-dimensional scanning devices. The file is then uploaded to a 3DP which creates the physical object through a layering process, where layers of the relevant material are continually deposited and built up in the printer, slowly building the structure, until the final product emerges.[81]

The applications of 3D printing in the pharmaceutical and healthcare sector are limited only by one's imagination. 3D printing has the potential to revolutionize the rapidly growing Indian pharmaceutical industry. 3D printing drugs can resolve supply chain inefficiencies, allow healthcare practitioners to make drugs customized to their patients' needs and reduce waste by allowing pharmaceutical companies to manufacture exactly to demand.

3D printing could be the key catalyst to push further growth of the pharmaceutical industry in India, by localizing manufacture and distribution of drugs and medical devices thereby resolving the supply chain inefficiencies that currently plague the market. 3D printing can also make clinical testing of drugs and medical devices simpler and cheaper by allowing companies to make changes to drug composition or the specifications of medical devices just by changing the CAD file.

7. Regulation of 3D Printed Drugs and Devices

Under India's existing legal framework, 3D printing of drugs and medical devices is not prohibited, provided the manufacturer obtains the requisite approvals from the regulator for manufacture of the drug or medical device. Additionally, a manufacturer of drugs and medical devices is also required to comply with strict standards in respect of plant and machinery when manufacturing a drug.

With respect to drug manufacturing, 3D printing has the potential to decentralize manufacturing as sophisticated equipment is no longer necessary. However, the main reason that drug manufacturing cannot be localized for a 3D printed drug is that the key component of the drug is its Active Pharmaceutical Ingredient (**"**API**"**), also known as bulk drug in

[81] E. Malaty and G. Rostama, *3D Printing and IP Law*, WIPO Magazine (February 2017), available at http://www.wipo.int/wipo_magazine/en/2017/01/article_0006.html, last seen on 15/01/2020.

India, is produced only by the manufacturer. Therefore, the supply of "ink" for the printer is controlled by the manufacturer of the drug.

Commercially, it could be possible to sell the API as opposed to the finished drug and allowing the patient or their caretaker to manufacture the drug in their homes. Alternate distribution models involving licensed pharmacies and hospitals can also be considered. While this would drastically reduce the cost and consequently the price of the drug, the current regulatory framework in India does not permit manufacture of drugs without a license or in facilities that are not compliant with the Good Manufacturing Practices (**"**GMP**"**).[82] The definition of "manufacturing" under the D&C Act *"includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale or distribution."*[83]

Patients, hospitals and pharmacies 3D printing the drug clearly fall under the first part of the definition as 3D printing the drugs is part of making the finished drug. However, as patients are manufacturing the drug for consumption and not for sale, the definition of manufacturing should not strictly apply to them. Regardless, pharmacies or hospitals which 3D print drugs and sell them to patients would be required to obtain permission in this regard from the drug controller and abide by the GMP. When 3D printed drugs are more common, special provisions can be introduced in the drug regulatory framework to ensure patients are able to fully benefit from this revolutionary technology.

8. Regulation of 3D Printed Organs

3D printed organs can ensure that no person loses their life due to organ shortages. Over half a million people die in India every year due to paucity of a replacement organ.[84] 3D printed organs can possibly eliminate the need to source organs from live and deceased donors. In the present system, it is difficult for doctors to find a match and then to harvest, store and transport organs so that they remain viable throughout the transplantation process. Referred to as bio-printing, customized 3D printed organs can be created for patients; saving thousands of lives every year. In India, the Transplantation of Human Organs Act 1994 (**"**THOA**"**) governs the retrieval, storage and transplantation process for organs. Organ trade in India is heavily regulated and seeks to ensure that

[82] Schedule M, Drugs and Cosmetics Rules, 1945.
[83] S.3(f), Drugs and Cosmetics Act 1940.
[84] A. Ahuja, *Lack of Organ Donation in India: Here Is Why Half A Million People Die Annually in India Due to Unavailability of Organs*, NDTV (26/11/2017), available at https://sites.ndtv.com/moretogive/lack-organ-donation-india-half-million-people-die-annually-india-due-unavailability-organs-2107/, last seen on 15/01/2020.

donors make fully informed decisions about donating organs as well as to prevent commercial trade in organs. Many other countries also have provisions in place that prevent organ trading. Sale of 3D printed organs could be considered as trade in human organs. Regardless, the ethical reasons that countries rely on to prohibit organ trade in status quo do not apply to 3D printed organs. Therefore, it may be likely that in future 3D printed organs will be regulated much like blood and plasma is regulated currently.

V. CONCLUSION

Digital Health is clearly the next milestone in healthcare. In the past, technology has helped advance medical science mainly through improving accuracy of diagnosis and assisting doctors with treatment procedures. However, the digital health revolution happening now is different than other technological advances that took place before. Rather than just advances in medical technology, digital health has the potential to change the healthcare sector as a whole, specifically with respect to service delivery. Digitization of health records increases interoperability between healthcare providers helping patients to find the best care for them. EHRs also save costs for patients as they need not duplicate tests already done. Telemedicine makes specialized and high-quality medical care available even in remote areas, thereby removing geographical barriers. Ultimately, digital health gives patients control of their health and makes for a healthier world.

India is adopting digital health tools to improve the quality of and access to healthcare in India at a rapid pace. However, the rapid growth of digital health is outpacing the regulation. Hence, the need of the hour is to have specific regulation for these tools and technologies to provide a level-playing ground for all stakeholders to provide services for the well-being of the Indian citizens.

ELECTRONIC HEALTH RECORDS IN INDIA: LEGAL FRAMEWORK AND REGULATORY ISSUES

*Harleen Kaur

ABSTRACT

The demand for healthcare is increasing globally. In India, a dual burden of communicable and non-communicable diseases along with an ageing population is affecting the demand for healthcare. Concerns for providing efficient and effective healthcare to the vulnerable population have led to the adoption of digital health records by countries. Different regulatory structures have been designed globally in order to use these health records while maintaining privacy and security of the data so generated. India is currently debating on the framework to be followed by it for the adoption and regulation of digital health records. The present article studies the evolution and structure of global models on regulation of digital health records. The proposed interventions in India are analysed based on the global study. Proposals for the way forward are made. It is suggested that India adopts a legal framework for digital health independent of the data protection laws. Clarity of objective and appropriate provisioning of incentives are critical elements of such a framework.

I. INTRODUCTION

Healthcare delivery institutions across the globe are evolving digitally in record-keeping and decision-making. This is being achieved through digital health records. These records can be designed for various purposes.

In this article, the adoption of digital health records regulatory framework is discussed with a focus on the status in India. In recent time, the policymakers in India have been debating on the type of health record system to be adopted, the regulatory framework for digital health and data protection framework surrounding it. These proposed regulatory frameworks of India are studied with respect to the experience of the US, UK, and Australia. These countries have used different approaches for digital health systems.

The US framework establishes a system of digital health records through legislation as primary mode of regulation. Australia provides a rights-based health records system to its citizens. The UK follows a hybrid model but does not have a dedicated digital health legislative framework.

* Harleen Kaur, Research Fellow, National Institute of Public Finance and Policy (NIPFP).

All three countries also have overarching data protection frameworks supplementing the digital health systems.[1]

India is at the crossroads in adoption of its digital health framework. While the Draft Digital Information Security in Healthcare Act, 2018 (**"**DISHA**"**) suggests adoption of an Electronic Health Records(**"**EHR**"**) system with patient rights at its core, National Digital Health Blueprint (**"**NDHP**"**) document envisages a mission-mode framework. The Personal Data Protection Bill, 2019 (**"**PDP Bill**"**) has conflicting provisions with respect to DISHA on components related to healthcare.

This article identifies three challenges in the way ahead for India in the digital health records domain. The *first* is the challenge of choosing a type of digital health record amongst the available models. The *second* challenge is of incentivising adoption of such digital health records. The *third* challenge is of contemplating a legal framework for digital health records that also addresses the first two challenges.

The rest of the article is structured as follows. Section 2 contains background for adoption of digital health records in the context of India. Section 3 describes the global challenges in adoption and implementation of digital health records. Section 4 discusses the current Indian scenario and section 5 concludes.

II. BACKGROUND

Healthcare establishments are now increasingly dealing with complex diseases and conditions. Developing countries like India face a double burden of communicable and non-communicable diseases.[2] This, in combination with changing demography, would increase the demand for healthcare of vulnerable persons across age-groups with time. To assuage the healthcare demands of the population, there has been a proliferation of Government funded Health Insurance Schemes (**"**GFHISs**"**) in India.[3] GFHISs like the Rashtriya Swasthya Bima Yojana (**"**RSBY**"**) and the Pradahan Mantri Jan Aarogya Yojana (**"**PMJAY**"**) are designed to provide healthcare services to persons through public & private healthcare

[1] See Health Information Technology for Economic and Clinical Health Act, 2009 (United States); My Health Records Act, 2012 (Australia); Privacy Act, 1988 (Australia); National Programmes and Plans and Data Privacy Act, 2018 (United Kingdom).

[2] See Ministry of Health and Family Welfare, Government of India, *India: Health of the Nation's States -The India State-Level Disease Burden Initiative*, available at https://www.healthdata.org/sites/default/files/files/policy_report/2017/India_Health_of_the_Nation%27s_States_Report_2017.pdf, last seen on 1/12/2019.

[3] I. Patnaik, S. Roy & A. Shah, *The rise of government-funded health insurance in India*, NIPFP Working Paper Series, 27, Working Paper Number NIPFP/WP/2018/231, National Institute of Public Finance and Policy, New Delhi (2018), available at https://www.nipfp.org.in/media/medialibrary/2018/05/WP_231.pdf, last seen on 10/02/2020.

providers. Identified members of the population, based on their income, are assured free hospital services for specific conditions within network hospitals.[4] The premiums for these schemes are paid by the government.[5] These schemes provide greater access to hospital related services to the poorer sections of the society. A digital implementation framework for the PMJAY scheme is under consideration wherein electronic health records will be generated and used.[6] On the private healthcare front, the healthcare institutions are showing trends towards consolidation, i.e., bringing together multi-specialty fields of healthcare under one roof rather than single specialty hospitals.[7] With increasing patient-generated demand for healthcare in the private sector, incorporating IT mechanisms for better coordination of patient care in the growing network of healthcare establishments is seen to be required.

India introduced its voluntary Electronic Health Records standards in 2013.[8] A survey by Indian School of Business shows that some forms of electronic medical records are being used in private or corporate hospitals in cities.[9] However, most of these systems are self-sufficient within institutions and do not allow sharing of information due to lack of interoperability.[10] The government hospitals are sought to be brought under the digital health network through *eHospital,* a Hospital Management Information System (**"**HMIS**"**) by the government.[11]

The primary intent to digitize health records is to achieve better quality of patient care while reducing costs. The data generated by these systems can also be used for population-based healthcare services and public health interventions as well as for research. The present section discusses

[4] See *About Pradhan Mantri Jan Arogya Yojana (PM-JAY)*, National Health Authority, available at https://pmjay.gov.in/about-pmjay, last seen on 10/02/2020.
[5] Ibid.
[6] See *National Health Stack: Strategy and Approach,* NITI Aayog, Government of India, available at https://niti.gov.in/writereaddata/files/document_publication/NHS-Strategy-and-Approach-Document-for-consultation.pdf, last seen on 11/02/2020.
[7] T. Thacker*, M&A deal value in hospital sector jumped by 155% in FY19*, Livemint (06/05/2019), available at https://www.livemint.com/companies/news/m-a-deal-value-in-hospital-sector-jumped-by-155-in-fy19-1557144845883.html, last seen on 15/01/2020.
[8] See *Notification of Electronic Health Records (EHR) Standards 2016 for India*, MoHFW Circular No. Q-11011/3/2015-eGov (30/12/2016), available at https://mohfw.gov.in/sites/default/files/17739294021483341357.pdf, last seen on 10/02/2020.
[9] A.C. Powell, H. Tyagi& J.K. Ludhar*, Digitising Indian Healthcare Records*, ISB Insight (28/08/2018), available at https://isbinsight.isb.edu/digitising-indian-healthcare-records/, last seen on 12/01/2020.
[10] S. Balsari et al, *Reimagining Health Data Exchange: An Application Programming Interface–Enabled Roadmap for India*, 20(7) Journal of Medical Internet Research (2018), available at https://pdfs.semanticscholar.org/3c4d/667298df5ec61f4ccb908729e8f0345aba8a.pdf, last seen on 12/01/2020.
[11] *EHR-National Standardization Initiative,* Centre for Development of Advanced Computing, available at https://www.nrces.in/download/files/pdf/nrces_ehr_nsi.pdf, last seen on 13/01/2020.

the healthcare landscape in India. This is done with intent to contextualize the policies for adoption of digital health records as studied in later stages. It also describes the various types of digital health records available globally and their uses. Understanding the distinction between these records is important to identify the intent of digitization of health records by a nation.

1. The Healthcare landscape of India

In order to understand the adoption and usage of digital health records in India, it is essential to study the healthcare landscape in India in which the system is set to operate. The healthcare landscape in India is best described as fragmented. A patient has recourse to public and private healthcare providers which use various systems of medicine for treatment. A healthcare provider can be a single doctor, a nursing home or a large hospital. Types of treatment provided in these institutes can vary considerably too. Therefore, the healthcare landscape in India can be understood on the basis of funding/ownership, type of services provided as well as the type of medicine system followed. These are described below:

- ***Based on funding and ownership:*** Healthcare is provided through public and private hospitals in the country. These hospitals may constitute of a single doctor clinic or a super-specialty care centre. The public healthcare providers are modelled on the three-tier healthcare system set-up by the Bhore Committee in 1946.[12] Private single doctor clinics and nursing homes have been parallelly providing healthcare services, especially in urban areas. After liberalization of the Indian economy, the private providers have increased in number and scale throughout the country.[13] The private healthcare providers now operate through individual, corporate or non-profit models. India also has a large number of non-registered medical practitioners.[14]

[12] Ministry of Health, Government of India, *JW Bhore Report of the national health survey and development committee (Bhore Committee Report) 1946,* available at https://www.nhp.gov.in/bhore-committee-1946_pg, last seen on 12/12/2019.
[13] See S. Kumar, *Private Sector in Healthcare Delivery Market in India: Structure, Growth and Implications*, ISID Working Paper, Working Paper Number ISID/WP/2015/185, Institute for Studies in Industrial Development, New Delhi (2015), available at http://isid.org.in/pdf/WP185.pdf, last seen on 10/02/2020.
[14] See S. Chandra, *Unqualified Medical Practitioners In India- The Legal, Medical and Social Dimensions Of Their Practice,* Centre for Public Affairs and Critical Theory-C-Pact, Shiv Nadar University, available at https://snu.edu.in/sites/default/files/UMP-BOOK.pdf, last seen on 04/01/2020.

- ***Based on the type of system of medicine:*** Healthcare providers in the country follow allopathic, ayurvedic, homeopathic and many other systems of medicine. While the central ministry for health, the Ministry of Health and Family Welfare (**"**MoHFW**"**) usually works for the modern medicine system, the Government of India established a Ministry of AYUSH in 2014 to ensure the optimal development and propagation of AYUSH systems of healthcare which include Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy.[15]

- ***Based on the type of services:*** Depending on the type of care given to the patients, healthcare services can be classified into primary, secondary, tertiary and quaternary. Primary and preventative services are the first point of care services provided to patients. Primary healthcare providers are also the source of referral to higher specializations. Secondary, tertiary and quaternary services are increasing levels of specialized care provided to the patients.

Digital health records adoption in this fragmented healthcare system is a challenge. One of the foremost tasks at this stage is to identify the type of healthcare records which should be available to the patients, healthcare providers and the State.

2. Types of digital health records

There are three broad types of digital records for patient care. These are Electronic Medical Records (**"**EMRs**"**), Electronic Health Records ("EHRs") and Personal Health Records (**"**PHRs**"**).[16]

EMRs are localized, partial health records within a single healthcare provider.[17] These records are maintained to aid in patient care and improve management and administration of their services. They are confined to the institutes which are maintaining them and are not accessible to patients or other healthcare providers.

EHR is the most common of all the digital records. They contain patient data collected from many healthcare institutes. The information is made

[15] *About us,* Ministry of AYUSH, available athttps://main.ayush.gov.in/about-us/about-the-ministry, last seen on 01/01/2020.
[16] See *What are the differences between electronic medical records, electronic health records, and personal health records?*, HealthIT.gov, available at https://www.healthit.gov/faq/what-are-differences-between-electronic-medical-records-electronic-health-records-and-personal, last seen on 26/12/2019.
[17] Ibid.

shareable by following standards of interoperability laid down at the national/international level.

PHRs are records generated by various stakeholders including providers (doctors, hospitals, laboratory, patient) across various institutes. The information in a PHR is patient-centric as it is aimed to provide information to the patient about their healthcare status directly.[18] As PHRs also collate information from various stakeholders and is not limited to healthcare providers, it requires meeting interoperability standards laid down at the national/international level. The key features of EMR, EHR and PHR are discussed in table 1.

Table 1: Types of digital patient data formats[19]

Electronic Medical Records (EMR)	**Electronic Health Records (EHR)**	**Personal Health Records (PHR)**
Electronic version of standard clinical data *with a single healthcare provider*	Electronic version of data *with multiple healthcare providers* including clinicians, diagnosticians, across institutes	Electronic version of data with multiple healthcare providers including clinicians, diagnosticians, across institutes *designed to be accessible to the patients*
Linear records within one healthcare institute	Longitudinal records aimed to follow the patient across different healthcare institutes	Longitudinal records aimed to follow the patient across different healthcare institutes and beyond

[18] Ibid.

[19] Supra 16; *Differences Between EMR, EHR AND PHR*, Health Information Management, available at http://www.himconnect.ca/meet-him/faqs/differences-between-emr-ehr-and-phr, last seen on 11/02/2020; *Understanding EHRs, EMRs and PHRs*, Canada Health Infoway, available at https://www.infoway-inforoute.ca/en/solutions/digital-health-foundation/understanding-ehrs-emrs-and-phrs last seen on 11/02/2020.

Controlled by a single doctors/hospital	Controlled by a network of doctors/hospitals	Controlled by patients
Does not require following interoperability standards	Requires following interoperability standards	Requires following interoperability standards

The primary aim for introducing digital health records is to provide efficient and effective healthcare to the patient. They also help in improving administration and management of healthcare providers, reduce wasteful spending and are a source of epidemiological data for the State.

Currently, India seems to be working towards developing an EHR framework. This framework would allow collation of health data of an individual from their birth to death across various healthcare providers. This would be helpful to the patient given the fragmented healthcare landscape and the current status of health data generated and used in the country. Under the Indian federal system of government, hospitals and public health are regulated primarily by the States and not the Union Government.[20] This leads to variable quality of health data across states and regions. One of the foremost challenges of the fragmented healthcare landscape in India has been the challenge of measurement. The health data in India is informed through census and surveys by the Government of India. These include, the civil registration of births and deaths in India, National Sample Survey Organization (NSSO) reports etc.[21] This is supplemented by the data generated from the public healthcare providers and regulators. The Health Management Information System (**"**HMIS**"**) is a database for information available in the public healthcare sector. HMIS has been marred by challenges of quality assurance.[22] Because the

[20] Art. 246, the Constitution of India; Schedule 7 (Entry 6, List II), the Constitution of India.

[21] See *Statistics*, Ministry of Health and Family Welfare, available at https://main.mohfw.gov.in/documents/staistics,last seen on 12/02/2020.

[22] S. Sharma, *Problems of the Health Management Information System (HMIS): the experience of Haryana*, The Leap Blog, available at https://blog.theleapjournal.org/2016/06/problems-of-health-management.html, last seen on 13/02/2020.

private healthcare providers are largely unregulated, the information generated by them is not available to the government or the public. Due to this, the availability of timely and accurate data is still a challenge. For instance, the information available about the number of doctors and healthcare providers in the country is incomplete till now.[23]

Within these challenges, the advocacy for EHR adoption in India is underway.[24] Consequently, the government has introduced standards for EHR in India.[25] Presently, adoption of EHR in any healthcare institute is voluntary and the standards set by the government do not have coercive value. However, the adoption of EHR is seen to be an essential component of the long-term healthcare delivery. A systemic shift in the healthcare delivery through adoption of EHR is underway. In this context, the experience of developed countries in providing digital health services is studied in the next section. This comparative analysis would be useful in navigating barriers for adoption and implementation of EHR in India.

3. The Challenge of Digital Health Records Adoption: Global Perspective

While the usage of health IT had started by the 90s, the adoption of EHR became a global interest at the turn of the new millennium. A study by the RAND Corporation in 2005 estimated that adoption of EHR in the USA could potentially save $81 billion (**"**bn**"**) annually while improving the quality of care.[26] This quantification of benefits through this estimation gave a huge push to EHR systems in the US and the rest of the world. It is claimed that EHRs are useful for patients, healthcare providers as well as the State.[27] While the veracity of the claims about savings through adoption of EHR were questioned then and were reassessed by RAND itself in 2013, the 2005 report has played an

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[23] H. Kaur, *Do Indian Patients Even Know Their Rights?*, The Wire, available at https://thewire.in/health/do-indian-patients-even-know-their-rights/amp/, last seen on 02/01/2020.

[24] See S.K. Srivastava, *Adoption of Electronic Health Records: A Roadmap for India,* 22(4) Healthcare Informatics Research (2016), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5116537/, last seen on 6/1/2020.

[25] Supra 8.

[26] R. Hillestad et al, *Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, And Costs,* 24(5) Health Affairs (2005), available at https://www.healthaffairs.org/doi/10.1377/hlthaff.24.5.1103, last seen on 01/1/2020.

[27] See *Benefits of EHRs*, HealthIT.gov, available at https://www.healthit.gov/topic/health-it-basics/benefits-ehrs, last seen on 01/1/2020; *Benefits of Electronic Health Records*, USFHealth, available at https://www.usfhealthonline.com/resources/healthcare/benefits-of-ehr/, last seen on 01/1/2020; P. Coorevits et al, *Electronic health records: new opportunities for clinical research,* 274(6) Journal of Internal Medicine (2013), available at https://onlinelibrary.wiley.com/doi/full/10.1111/joim.12119, last seen on 11/02/2020.

important role as a catalyst for adoption of EHR systems globally.[28] In the present section, the process of adoption of digital health records in the US, UK and Australia is studied. Considering these are developed countries which have been on the digitization journey for a long time, this study informs about the common challenges in their adoption and usage. After a country decides on the type of digital medical record (**"**EMR, EHR or PHR**"**) it aims to build, there are three broad challenges faced by it.

The *first challenge* observed in the adoption stage is the high cost of digital health records system that are adaptable to the interoperability standards set by the government. The need for interoperability standards is to allow sharing of data across multiple institutes. All the studied countries have had an incentive program to get the healthcare institutions to adopt systems compatible with interoperability standards. These programs are discussed in detail below.

The *second challenge* is defining the ownership of the data. As health records contain sensitive personal data that can be used for multiple purposes, deciding the ownership in favour of data generator (healthcare institute) or the source of data (patient) is the next challenge. Providing ownership to patients ensures better protection to their data and increases usage of the digital health records by the patients. However, high investment required from healthcare institutes in building digital systems as well as the potential usage beyond patient care are used to favour healthcare institutes as the owner of the data.

The *third challenge* is deciding on the governance and regulatory structure for the digital health records system. The regulating structure can be defined through legislation or a plan/program. General privacy and data protection laws of the country are also applicable to these systems, whether they have an origin in legal framework or not. The regulatory framework also defines the role of standard setting and implementing authority within the system.

Health Information Technology for Economic and Clinical Health Act (**"**HITECH**"**) of 2009 introduced incentives for EHR adoption according to prescribed standards in the USA.[29] Use of Medicare and Medicaid has provided an institutional framework for execution of these incentives. An

[28] See A.L. Kellermann & S.S. Jones, *What It Will Take To Achieve The As-Yet-Unfulfilled Promises Of Health Information Technology,* 32(1) Health Affairs (2013), available at https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2012.0693, last seen on 7/1/2020.

[29] Health Information Technology for Economic and Clinical Health Act, 2009 (United States).

amount of $27bn was set aside by the government for these incentives.[30] Till May 2016, $34bn had been given to hospitals for adoption and meaningful use of EHR by the government.[31] The law defines 'meaningful use' as the use of the certified EHR technology in a manner that provides for the electronic exchange of health information to improve the quality of care.[32] Electronic prescribing, sharing patient discharge notes within institutes are examples of meaningful use. The adoption and meaningful use are being inducted in a phase wise manner using legislation. The ownership of data generated through EHRs is dependent on state legislation. New Hampshire is the only state which allows patients to own and control the EHR data.[33] For defining interoperability standards, the Office of National Coordinator for Health Information Technology (ONC) is responsible to standardize building blocks including health care vocabulary, using secure email protocols through the use of encryption standards with open and accessible APIs.

Adoption of EHR in the UK has not been through legislative intervention. Instead, National Health Service (**"**NHS**"**) programmes and plans have aimed for gradual introduction and use of EHR for patients. The National Programme for Information Technology (**"**NPfIT**"**) of 2002 by the government was aimed to make EHR usage ubiquitous in the UK.[34] An amount of £6bn was earmarked for this exercise.[35] The UK followed a top-down approach towards implementing the programme wherein a central agency, Connecting For Health (**"**CFH**"**), was the responsible implementing body. However, the NPfIT programme was criticized for being behind schedule by the Public Accounts Committee in 2009.[36] The revised estimated cost for the exercise was put to be

[30] *The Federal Government Has Put Billions into Promoting Electronic Health Record Use: How Is It Going?*, The Commonwealth Fund, available at https://www.commonwealthfund.org/publications/newsletter-article/federal-government-has-put-billions-promoting-electronic-health, last seen on 12/02/2020.

[31] *EHR Incentive Programme,* Centers for Medicare and Medicaid Services, available at https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/May2016_SummaryReport.pdf, last seen on 01/01/2020.

[32] Department of Health and Human Services, *Electronic Health Record Incentive Program; Final Rule,* 75(144) Federal Register 2010, available at https://www.govinfo.gov/content/pkg/FR-2010-07-28/pdf/2010-17207.pdf, last seen on 02/02/2020.

[33] See *Who Owns Medical Records: 50 State Comparison*, Health Information and the Law, available at http://www.healthinfolaw.org/comparative-analysis/who-owns-medical-records-50-state-comparison, last seen on 10/10/2019.

[34] See O. Campion-Awwad, A. Hayton, L. Smith & M. Vuaran, *The National Programme for ITin the NHS: A Case History,* MPhil Public Policy 2014,University of Cambridge, available at https://www.cl.cam.ac.uk/~rja14/Papers/npfit-mpp-2014-case-history.pdf, last seen on 03/12/2019.

[35] Ibid.

[36] Public Accounts Committee, House of Commons, *The National Programme for IT in the NHS: Progress since 2006*, 2009, available at https://publications.parliament.uk/pa/cm200809/cmselect/cmpubacc/153/153.pdf, last seen on 12/01/2020.

£12.7bn.[37] Due to its slow progress and ineffectiveness, the programme was dismantled by the UK government in 2011.[38] The components of the programme are still functional within separate management and accountability structures. Due to this, the pace of adoption of digital health records varies across the UK. NHS is using policy interventions for promotion of EHR standardization and usage.[39]

Australia started its adoption of digital health records journey by setting up a regulatory authority, the National Electronic Health Transition Authority (**"**NEHTA**"**), in 2005.[40] As a part of its mandate, NEHTA developed specifications, standards and infrastructure; selected a common language for health communications; and created unique health care identification numbers for all individuals, providers and organizations.[41] Personally Controlled Electronic Health Records Act (**"**PCEHR**"** Act) in 2012 brought the EHR system within a legal framework.[42] Its review in 2014 identified issues in uptake of the PCEHR system. Recommendations for a new governance structure, richer clinical content and a move to an opt out model of uptake were made. Following this, Australian Digital Health Agency was formed in 2016 which focused on meaningful use while protecting privacy. PCEHR Act was superseded by the My Health Records Act, 2012.[43] A new opt-out PHR model, by the name of 'My Health Records' was introduced across Australia and strengthening of privacy for these records was assured through legislative means.[44] A PWC study in 2015 estimated that the total costs to the Australian government for implementation of EHR is $10bn.[45] Australian Privacy Foundation states that the conservative estimates for the cost of My Health Records is $2bn with an annual recurring cost of $500mn.[46]

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[37] Ibid.

[38] Public Accounts Committee, House of Commons, *The dismantled National Programme for IT in the NHS,* 2013, available at https://publications.parliament.uk/pa/cm201314/cmselect/cmpubacc/294/294.pdf, last seen on 01/01/2020.

[39] See *NHS Digital, Interoperability Toolkit*, NHS Digital, available at https://digital.nhs.uk/services/interoperability-toolkit, last seen on 13/02/2020.

[40] See S.J. Hambleton & J. Aloizos AM, *Australia's digital health journey*, 210(6) The Medical Journal of Australia (2019), available at https://www.mja.com.au/journal/2019/210/6/australias-digital-health-journey#12, last seen on 02/01/2020.

[41] Ibid.

[42] Personally Controlled Electronic Health Records Act, 2012 (Australia).

[43] My Health Records Act, 2012 (Australia).

[44] My Health Records Amendment (Strengthening Privacy) Act, 2018 (Australia).

[45] See J. Forsythe et al, *Australia can see further by standing on the shoulders of giants*, PricewaterhouseCoopers, available at https://www.pwc.com.au/publications/pdf/digital-hospital-2016.pdf, last seen on 13/12/2019.

[46] *Value of My Health Record,* Australian Privacy Foundation, available at https://privacy.org.au/campaigns/myhr/value-of-myhr/, last seen on 12/12/2019.

Government interventions are necessary for incentivizing and regulating the digital health records system adopted by a nation. Intense debates around what the country expects from its systems before the design and roll out at a national level are critical. For example, when Australia tried the opt-in PCEHR system, the uptake was less due to concerns about data security and privacy.[47] This led to strengthening of privacy systems and the PHR design as well as use of opt-out system to increase the uptake by the people. Similarly, it is claimed that in the US, initial technical claims have now been replaced by procedural, professional, social, political, and ethical issues.[48]

Issues with standardization of health records are widespread. Despite being in force for more than a decade, these global systems are still in progress for both adoption and implementation. For instance, the NHS was unable to get a top-down EHR system implemented in the UK and is now working at a smaller scale to nudge the use of EHR and PHR.[49] Table 2 summarizes the system of EHR adoption in the US, UK, and Australia as described in the present study. In the next section, EHR adoption in India is studied with reference to the present global analysis.

Table 2: EHR systems: Global comparison

Criteria	**US**	**Australia**	**UK**
Type of record	HER	PHR	EHR & PHR hybrid model
Data Owner	Decided by State law	Patients	-
Legal	HITECH Act	My Health	National

[47] T. Patten, *A Healthy Dose of Caution: An Analysis of Australia's My Health Record*, Baker McKenzie, available at https://www.bakermckenzie.com/en/insight/publications/2019/04/a-healthy-dose-of-caution, last seen on 12/02/2020.
[48] R.S. Evans, *Electronic Health Records: Then, Now, and in the Future,* 25(l) 1IMIA Yearbook of Medical Informatics (2016), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5171496/pdf/ymi-11-0s48.pdf, last seen on 02/12/2019.
[49] Supra 38.

framework	2009 and HIPAA Act 1996	Records Act 2012 and Privacy Act 1988	Programmes and Plans and Data Privacy Act 2018
Interoperability	Interoperability Standards Advisory * Since 2017, updated by the Office of National Coordinator for Health Information Technology (ONC)	Interoperable standards by 2022	NHS Policy
Financial incentives	Built in law	Budgeted by the union govt	NHS funded policies

4. EHR Adoption in India: Status and Concerns

Unlike its global counterparts, India does not have a single regulatory framework for digital health records yet. Presently, limited regulation is available under the IT Rules, 2011.[50] Under these rules, health data is considered sensitive personal data for which a notice and consent framework for the collection, use, disclosure, transfer and deletion is described. This is applicable only to a part of healthcare providers, i.e. those that have a body corporate structure. It also does not deal with the interoperability component required for an EHR system. The Clinical Establishment rules mandate all healthcare providers in the country to

[50] IT (Reasonable Security Practices and Sensitive Personal Data or Information) Rules, 2011.

use EHR/EMR system as prescribed by the government.[51] However, these are not being implemented in practice due to inaction by the State. Separately, the MoHFW has notified EHR Standards.[52] These are voluntary standards for identification and demographics, patient identifiers, architectural and functional requirements, terminology and coding system, imaging and data exchange. These standards are supplemented by the endorsement of accreditation bodies like the National Accreditation Board for Hospitals (**"**NABH**"**) in India.

The current EHR standards and rules are inadequate to nudge adoption by healthcare providers. Given their shortcomings, a draft right-based law for digital healthcare, DISHA, was introduced in 2018. Another policy document, the NDHB was also put out for public comments in 2019. In this section, a study of both of the proposed frameworks and their implications for the future is performed.

A Framework for EHR Regulation in India

A regulatory framework for EHR adoption and implementation is a relatively new exercise in India. So far, two frameworks for regulations have been proposed. These are the DISHA and the NDHB. Apart from these regulatory structures, the umbrella law for data protection, which would be applicable to the health IT records domain is also under consideration in the Parliament by January 2020.[53] The two proposed frameworks for EHR in India are diametrically opposite in their structure. While one is a draft law, another is a policy blueprint. The structure under the two proposed frameworks is discussed here:

I. Draft Digital Information Security in Healthcare Act, 2018 ("DISHA") seeks to set up a nodal body for adoption of e-health standards, protect privacy & confidentiality while ensuring security and standardisation.[54] A federal system of nodal agencies with National Electronic Health Authority (**"**NeHA**"**) at the union level and State Electronic Health Authorities (**"**SeHAs**"**) at the state level are envisaged. The role of NeHA would be to formulate standards and guidelines for the generation, collection, storage, and transfer of digital health data.[55] Setting interoperability standards and ensuring their compliance would also be a function of NeHA. Government would develop Health Information Exchanges (**"**HIE**"**) that will aid in sharing data within healthcare establishments. Under clause 3(j) of the Act, patients are the owners of their medical data while the healthcare establishments of the

[51] Rule 9(iv), The Clinical Establishments (Central Government) Rules, 2012.
[52] Supra 8.
[53] Personal Data Protection Bill, 2019 (pending).
[54] The Digital Information Security in Healthcare Act, 2018.
[55] Ibid.

HIEs act as trustees of the data so generated. The use of data generated by the EHR is specified and any commercial use is prohibited.

II. National Digital Health Blueprint, 2019 ("NDHB") is aimed to identify building blocks, standards, regulations and institutional framework required to adopt EHR in India.[56] One of the tasks of the committee was to study the proposed National Health Stack document which aimed to serve digitization for Ayushman Bharat, a large government funded health insurance scheme.[57] However, the scope of NDHB is not limited to commentary on the National Health Stack. The committee recommendations have four sub-themes. These are, *i) defining scope of NDHB, overarching principles and target digital services, ii) identify, define and recommend ways to use building blocks of NDHB, including Universal Health Id, iii) identify standards and regulations, iv) and identify reforms required in institutional framework to achieve EHR adoption at scale.*[58] One of the significant developments under the NDHB is the advocacy for establishing a National Digital Health Mission (NDHM) as a regulatory body. The NDHM is envisaged as a government owned body which is aimed *to be the best healthcare network globally* and this would be achieved by providing every Indian with access to digital health services.[59] This is proposed to be done by prescribing interventions like, creating National Health Electronic Registries as a single source of information and manage master health data of the nation; a federated PHR framework; a National Health Analytics Platform; unique digital health ID; health data dictionaries; and supply chain management for drugs, payment gateways shared across all health programs.

The DISHA and NDHB aim at developing a framework for EHR in India using two different approaches. The DISHA seeks to set standards through a central nodal body. The NDHB envisages a NDHM to be introduced. This mission, may or may not be formed under a law and is proposed to be structured upon existing government agencies like the UIDAI and GSTN.

In December 2019, the PDP Bill was introduced in the Parliament in India. It is currently under review within a Joint Select Committee. The PDP Bill, 2019, once passed as a law would serve to provide an overarching legal framework for personal data protection in India. Table

[56] *Placing the report on National Digital Health Blueprint (NDHB) in public domain for comments/views regarding*, MoHFW Notice No. T-21016/78/2018-eHealth (15/07/2019), available at https://www.nhp.gov.in/NHPfiles/National_Digital_Health_Blueprint_Report_comments_invited.pdf, last seen on 02/01/2020.
[57] Supra 6.
[58] Ibid.
[59] Ibid.

3 compares the basic features of the PDP Bill with DISHA. There are significant differences between the two laws. While DISHA envisages the patient to be the owner of the data generated and restricts the use of data so generated, the PDP Bill does not define data owner. The PDP Bill also allows any legal activity to be performed by the data fiduciary within restrictions provided under the law. The DISHA does not allow sharing of data by regulated entities for commercial use, specifically to insurance companies and human resource companies. There is no such barrier to commercial use in the PDP Bill. This comparison shows that in the current form, it is difficult to harmoniously interpret the two, if enacted.

Provision	**DISHA**	**PDP Bill**
Ownership	Patient (Clause3(j))	-
Definition of health data	Includes information about the health status, health services, donation or examination of a body part and details of clinical establishment accessed by the individual (Clause 3(e))	Includes data about physical or mental health, includes records regarding the past, present or future state of the health, data collected/associated in the course of registration for, or provision of health services (Clause 3(21))
Regulatory body	National electronic Health Authority (NeHA) (Clause 4)	Data Protection Authority of India (Clause 41)
Regulated entities	Clinical establishments (Clause 21 2(b)), Health Information Exchanges (Clause 19, 20), any entity with custody of health data (Clause 22)	Data fiduciaries (Clauses 2 A (C), 4-11)), Data processors (Clause 2 A (C))

Commercial use	Not allowed (Clause 29 (5))	Allowed (Clause 4)
Interoperability provisions	NeHA to prescribe standards (Clause 22)	Limited to protection of privacy & right to data portability (Clause 19)
Usage of data	Concise, restrictive	Expansive
Consent requirement	Yes (Clauses 28, 29, 30, 33 & 44(2)	Yes (Clauses 7, 9, 11, 16, 20, 23, 34, 40, 50, 82, 94)

Table 3: Comparing DISHA and PDP Bill

5. The Way Ahead

The DISHA is a progressive piece of legislation. However, under the current scenario, adoption of a healthcare specific regulatory framework under the DISHA seems to be unlikely. The MoHFW in India recently stated that it had shared the DISHA to the Ministry of Electronics and Information Technology (MeitY) to be subsumed into the PDP Bill.[60] However, the recommendations of the MoHFW in the form of DISHA have not been taken into account as the provisions related to health in PDP 2018 and PDP 2019 have no considerable difference.[61]

Therefore, it seems likely that the EHR adoption in India shall be driven by the principles in NDHB document in conjunction with the provisions in the PDP Bill. However, the present study indicates that a well-defined legal framework would enable adoption and implementation of digital health records for the benefit of patients, healthcare providers, states as well as other stakeholders.

Given this understanding, the DISHA should be brought to the public domain for further consultations. The DISHA will need to overcome

[60] *Data Transfer of Digital Health Records*, Press Information Bureau, available at https://pib.gov.in/Pressreleaseshare.aspx?PRID=1578929, last seen on 13/10/2019.
[61] See Personal Data Protection Bill, 2018 (Draft Bill, 2018); Supra 53.

certain impediments to widespread adoption and usage of the technology. These are discussed below:

What kind of digital patient records should be encouraged?

The answer to choosing a type of patient health record is complex. It depends on the existing factors as well as the anticipated gains of using one type over the other.

In the US, usage of EHRs is encouraged under the HITECH Act. The use is considered meaningful when it contributes towards improving i) quality, safety, efficiency, and reducing health disparities; ii) engaging patients and families in their health; iii) improving care coordination; iv) improving population and public health; all the while ensuring adequate privacy and security protection for personal health information. After defining the outcomes, the outputs expected of the EHR usage are set by government agencies. The healthcare institutes are rewarded for compliance with the standards and meaningfully using them under the HITECH Act and rules. Despite this, the system is at a nascent stage. While there is availability of EHR systems across hospitals, its usage is still limited. Alongside the EHR development, a strong legal framework to preserve the privacy and security of persons using consent framework, and purpose limitation by the State and non-State entities is done.

In the UK, various NHS agencies are independently responsible for developing an EHR/PHR framework for themselves. Currently, various forms of EMRs, EHRs and PHRs exist within the NHS. Electronic Summary Care Record ("SCR") containing limited patient information regarding prescriptions, allergies and adverse reactions is shared between healthcare providers and can be accessed by the patient. The NHS sets standards for EHRs and uses mechanisms like accreditation of agencies to ensure their uniform adoption.

Australia provides PHR through 'My Health Records' application to its people. It uses an opt-out method of adoption. By staying opted-in this framework, consent is given to registered healthcare providers to view patient information related to allergies, medicines, medical conditions and pathology tests in case of an emergency. At the same time, healthcare providers can add information about the patient in the record. The ultimate access to manage this database rests within the patient. Insurance companies or employers are not permitted to use the data. A framework for secondary use of the patients' data guides the usage of the data for research purposes. It is impermissible to be used for commercial purposes.

In the Indian scenario, the case for adoption of EHR is not clear. The DISHA specifies the purpose which is centred on patient care and research. A consent framework is set for data usage. Commercialization of health data by private entities is restricted under the Act but there are some exceptions wherein the State can use the health data. The NDHB, on the other hand, has a much wider scope of usage of health data. This ranges from health and well-being for all at all ages to Universal Health Coverage and includes citizen-centric efficient and effective services; accountability for performance and creation of a holistic and comprehensive health ecosystem. The broad functions defined for the NDHM vests high power in the State as it is responsible for the regulation as well as appropriate use of the data so generated for any of the above mentioned purposes.[62] Therefore, there is a need to define the purpose of EHR adoption so that the standards developed under the framework are amenable to such clearly defined objectives.

Incentivizing adoption

Whatever be the type of digital health records, it is seen that globally at the adoption stage, *incentive programmes* are put to encourage private players to adopt EHR as per government standards. No such incentives are put in any of the proposed interventions in India. One of the reasons for this could be reliance on Public-Private-Partnerships or Government Funded Health Insurance Schemes to drive such adoption. Laws like the Clinical Establishment Act have been historically unable to regulate the private sector healthcare providers in India. Due to this, incorporation of some incentive technique shall be required for initiating adoption by these entities. The healthcare landscape in India is fragmented with measurement and economic challenges. To incentivize adoption, the government would need to provide funds as well as an enabling environment to the stakeholders. Regulatory framework for ensuring credible measurement would require funding to be sustainable. With the current low level of government spending in health, a judicious prioritisation of spending on building the basic blocks of data generation, through regulation as well as financing is advisable.

Legal framework for EHR use

An overarching legal framework for adoption and use of EHRs is present in the US and Australia. The HITECH Act and the My Health Records Act provide the framework wherein the statutory regulatory bodies are set/identified and outcomes and procedural checks are defined. This is supplemented by the laws for data protection. Using a legal framework is

[62] Supra 56.

advantageous as setting up and implementation of digital health records is a long-term objective of the State which requires considerable funding and regulatory governance. The current proposed legislative and policy frameworks in India are at crossroads. Designing and implementing a strong, patient-centric legislative framework is the imminent requirement for the country before incurring expenditure on conversion to digital health records.

The DISHA in India envisages such legal framework, but is not likely to be enacted in its present form. The framework under the NDHB envisages setting up of a NDHM as the focal regulatory agency implementing the blueprint. The framework also iterates a five-year level action plan to achieve the identified targets. These include*, "establishing and managing the core digital health data and the infrastructure required for its exchange… promotion of adoption of open standards…creating a system of PHR based on international standards"*. In contrast, the US HITECH Act has been inducing a phase-wise induction of EHR adoption since 2009.[63] The meaningful adoption of EHRs is still underway. On its own, the principles stated under the NDHB do not sufficiently deal with domains like telemedicine, consent withdrawal and right to be forgotten, de-identification of data etc. In absence of a legal mandate and financial support, the incentives to adopt the blueprint by the private healthcare market are inadequate. Further, the PDP Bill, 2019 puts the patient in charge of their health data through a consent framework but refrains from calling the patient the data owner. Any lawful commercial use of health data would be allowed under the PDP bill with the consent of the patient. However, broad exceptions, specifically to the State to use the data without consent have been provided in the law under clauses 12-15. These include undertaking any measure to provide assistance or services during any disaster or any breakdown of public order. Another important concern with the PDP Bill is the power of the State to define Sensitive Personal Data and make regulations thereon.

Presently, India is hoping to create a system of standards that help achieve interoperability and increase uptake of EHRs. It is important to note that the push towards EHR adoption is occurring in the absence of any data protection law or health data protection law. For instance, the MoHFW is promoting Integrated Health Information Platform ("IHIP") which aims to enable the creation of standards compliant EHR of the citizens on a pan-India basis. IHIP also aims to integrate interoperable EHRs through a State-owned platform, the HIE.

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[63] See *Public Health and Promoting Interoperability Programs (formerly, known as Electronic Health Records Meaningful Use)*, Centre for Disease Control and Prevention, available at https://www.cdc.gov/ehrmeaningfuluse/introduction.html, last seen on 05/02/2020.

In these circumstances, the DISHA can play an important role in building a legal framework of digital health data. The framework adopted under it puts the patient at the centre of the digital health system. The law is clear in its objective of patient safety. However, some provisions of the draft law, like the powers of the HIEs, NeHA and other state authorities; complete ban on commercial activities, need to be reassessed.

The challenge of diverse population served by a fragmented healthcare network will make it difficult to achieve the aim of interoperable EHR use throughout the country without a legal mandate for the regulated entities to do so. It is also important to note that mere legal mandate, without a practical roadmap for adoption and use will be challenging to implement in the country as seen in the case of provisions under the Clinical Establishment Act. A careful discussion on the objective of the exercise powered by scientific examination through regulatory impact assessments, followed by strengthening of the existing regulatory regime for healthcare are prerequisite to designing a legal framework for action. These measures will ensure that the legal framework under the DISHA protect the patient from inappropriate use of their data from the State as well as other stakeholders in the network while incentivizing adoption and use of digital health technologies.

PRIMARY HEALTH CARE IN INDIA: CHALLENGES AND THE WAY FORWARD

[*]Dorothy Lall

ABSTRACT

Primary health care is the backbone of health care delivery world over. The vision of primary health care is one of comprehensive, integrated, accessible to all, contextually relevant health care rooted in the needs of the community. There are considerable challenges to operationalizing concepts in the delivery of primary health care, especially in low and middle-income countries like India. The epidemiological shift in disease burden characterized by an increase in non-communicable diseases is one such major challenge. A deficit of trust between patients and providers, lack of financial resources and poor governance for primary health care are other challenges in the Indian context. The WHO's primary health care operational framework identifies 'levers' as key elements that need to be addressed to operationalize primary health care in countries. I use this framework to identify opportunities to overcome the challenges identified in this paper relevant to the Indian context. Reorientation of the health care delivery systems to deliver chronic care is required due to the increase in disease burden. This is also an opportunity to empower communities that are central to primary health care as patients need to self-manage their disease conditions more than ever before. Political will, governance structures for multisectoral action, community participation and implementation research will be required for primary health care in India.

I. INTRODUCTION

The first international primary health care conference was held at Alma Ata in 1978, which brought together 134 nations to pledge 'health for all', as was articulated in the Alma Ata Declaration. The Declaration set forth a vision for primary health care as the first level of healthcare, close to people's homes. It defined primary health care as, "essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and the country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination".[1] The visionary concepts of primary health care were rooted in concepts of

[*] Dorothy Lall, Health Services cluster lead, Assistant Director (Education), Institute of Public Health, Bengaluru

[1] *Declaration of Alma Ata: International Conference on Primary Health Care*, International Conference on Primary Health Care, USSR, 6-12 September, 1978, UNICEF Document E/ICEF/L.1387, available at https://www.unicef.org/about/history/files/Alma_Ata_conference_1978_report.pdf.

social justice and equity that are echoed in Article 14 of the Universal Declaration of Human Rights.[2]

While the Alma Ata Declaration was a landmark document in the history of health care, it was criticized for being too broad and unattainable. Operationalizing the broad concept of primary health care became a challenge and led to many different interpretations of primary health care world over.[3] One such popular interpretation was 'selective' primary health care that identified a package of low-cost interventions, such as oral rehydration, breastfeeding, immunization, and growth monitoring for delivery at primary care facilities close to people's homes.[4] This selective approach did lead to improvements in health indices but did not succeed in securing health for all.[5]

Over the years, there has been a realization that to achieve equitable health for all, a comprehensive, and not a selective approach, is needed.[6] In support of this consensus, world leaders met in Astana, Kazakhstan in 2018, to commemorate 40 years of primary health care that began at Alma Ata in 1978. At Astana, world leaders declared and reaffirmed the holistic vision of primary health care given at Alma Ata.

The Declaration at Astana upholds the primary role and responsibility of governments at all levels to promote and protect everyone's right to the enjoyment of the highest attainable standard of health. Governments and societies pledged to prioritize, promote and protect people's health through strong primary health care systems.[7] Primary health care is an inclusive and societal approach to well-being, centered on the needs and preferences of individuals, families, and communities. Primary health care addresses the broader determinants of health and focuses on the

[2] UN General Assembly, *Universal Declaration of Human Rights*, 10 December 1948, Res. 217A, Sess. 3, Document 217 A (III), available at https://www.refworld.org/docid/3ae6b3712c.html, last seen on 15/04/2020.

[3] L. Magnussen, J. Ehiri, P. Jolly, *Comprehensive versus selective primary health care: Lessons for global health policy - Meeting people's basic health needs requires addressing the underlying social, economic, and political causes of poor health*, 23 Health Affairs 167 (2004), available at https://doi.org/10.1377/hlthaff.23.3.167.

[4] M. Cueto, *The origins of primary health care and selective primary health care*, 94 American Journal of Public Health 1864 (2004), available at https://dx.doi.org/10.2105%2Fajph.94.11.1864.

[5] S.B. Rifkin, *Health for All and Primary Health Care*, *1978–2018: A Historical Perspective on Policies and Programs Over 40 Years,* Oxford Research Encyclopedia of Global Public Health, available at https://www.researchgate.net/deref/http%3A%2F%2Fdx.doi.org%2F10.1093%2Facrefore%2F9780190632366.013.55.

[6] J.E. Lawn, J. Rohde, S. Rifkin, M. Were, V.K. Paul, M. Chopra, *Alma-Ata 30 years on: revolutionary, relevant, and time to revitalise*, 372 Lancet 917 (2008), available at https://doi.org/10.1016/S0140-6736(08)61402-6.

[7] *Report of the Global Conference on Primary Health Care*, Global Conference on Primary Health Care, Kazakhstan, 25Oct -26Oct 2018, WHO Document WHO/HIS/SDS/2018.61, available at https://www.who.int/docs/default-source/primary-health/declaration/gcphc-declaration.pdf.

comprehensive and interrelated aspects of physical, mental and social health and well-being.[8]

India too upholds and affirms the Astana Declaration 2018 as it did the Declaration at Alma Ata. India's journey with primary health care began even before it was articulated at Alma Ata and Indian experiences of primary health care delivery contributed to the development of concepts that shaped the Alma Ata Declaration.[9]

The basic architecture for primary health care service delivery in India was first described by the Bhore Committee in 1946.[10] In recent years, the National Health Mission has significantly impacted the delivery of health care in India. The National Health Mission undertook the development of infrastructure and developed ASHA (Accredited Social Health Activist) as frontline health workers. The recently launched Ayushman Bharat program of the Government of India is also a move towards strengthening primary care through the proposed health and wellness centers. The program envisages for all citizens, access to comprehensive health care services through financial protection and care closest to people's homes at health and wellness centers.[11]

In this paper, I discuss why the approach of comprehensive, integrated primary health care is important to achieve health in India, especially with the increase in the burden of chronic diseases such as diabetes. I highlight challenges at various levels of implementation that threaten the realization of primary health care in the Indian context. Finally, I identify opportunities that could impact primary health care in India using the lens of the WHO operational framework for primary health care.[12]

II. PRIMARY CARE AND PRIMARY HEALTH CARE

Primary care and primary health care are very similar terms that are often used interchangeably. However, there is consensus that these are two distinctly different concepts and should not be interchanged. While primary care describes more the provision of medical services by a

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[8] *Primary health care*, World Health Organization, available at https://www.who.int/health-topics/primary-health-care#tab=tab_1, last seen on 2/01/2020.

[9] Supra 4.

[10] Ministry of Health, Government of India, *JW Bhore Report of the national health survey and development committee (Bhore Committee Report) 1946,* available at https://www.nhp.gov.in/sites/default/files/pdf/Bhore_Committee_Report_VOL-1.pdf.

[11] *Ayushman Bharat for a new India - 2022 announced*, Press Information Bureau, available at http://pib.nic.in/newsite/PrintRelease.aspx?relid=176049, last seen on 19/07/2018.

[12] *Primary health care: transforming vision into action - Operational Framework (Draft for consultation),* World Health Organization, available at https://www.who.int/docs/default-source/primary-health-care-conference/operational-framework.pdf?sfvrsn=6e73ae2a_2.

primary care physician or family doctor, primary health care is a much broader concept of the health system impacting population health.[13]

The distinctive features of primary health care are that it is comprehensive, promotive, protective, preventive, curative, rehabilitative, and palliative care throughout the life of an individual, designed to meet people's health needs close to their homes and at the larger population level, through public health, functions as integrated health services. Primary health care systematically addresses the broader determinants of health such as poor sanitation, poverty and takes actions across all sectors. Primary health care also works to empower individuals, families, and communities to optimize their health.

Primary health care is therefore not merely a selective package of medical services and even though it is relevant at the primary level of health care, it is not merely describing a level at which health care services are delivered. In this paper, it is the holistic concept of primary healthcare and its implementation that I have attempted to analyze in the Indian context.

III. IMPORTANCE OF PRIMARY HEALTH CARE

Primary health care forms the foundation of any health care system. It is the first point of contact of the community with health services and can meet a majority of the community's health needs.[14] The primary level of care is the first tier of service delivery in the three-tiered delivery system prevalent in India. Primary care facilities are positioned close to people with the ability to influence healthy behaviours, promote health impacting the broader social determinants of health, such as clean drinking water, sanitation, and education.[15]

There is evidence to support the critical role primary health care has played in preventing illness and death.[16] There is also evidence that it is a good value investment, as primary health care reduces total healthcare

[13] L.K. Muldoon, W.E. Hogg, M. Levitt, *Primary care (PC) and primary health care (PHC): What is the difference?* 97 Canadian Journal of Public Health 409 (2006), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6976192/.

[14] *World Health Report 2008: Primary care now more than ever*, World Health Organization, available at https://www.who.int/whr/2008/whr08_en.pdf.

[15] K. Rasanathan, E.V. Montesinos, D. Matheson, C. Etienne, T. Evans, *Primary health care and the social determinants of health: Essential and complementary approaches for reducing inequities in health*, 65 Journal of Epidemiology and Community Health 656 (2011), available at http://dx.doi.org/10.1136/jech.2009.093914.

[16] B. Starfield, L. Shi, J. Macinko, *Contribution of Primary Care to Health Systems and Health*, 83 The Milbank Quarterly, 457 (2005); J. Macinko, B. Starfield, T. Erinosho, *The impact of primary healthcare on population health in low- and middle-income countries*, 32 The Journal of Ambulatory Care Management 150 (2009), available at 10.1097/JAC.0b013e3181994221.

costs and improves efficiency by reducing hospital admissions.[17] The compelling evidence leads the WHO to conclude that, "the broad focus of primary health care, along with the social determinants of health, should be kept foremost in the policies of all countries."[18] Primary health care is important now, more than ever, as the world has set itself the Sustainable Development Goals (SDGs). Many goals, such as improving and ensuring child health, curbing communicable diseases, and safeguarding mental health can be directly addressed through primary health care and approximately 16 other SDGs are impacted by primary health care indirectly.[19]

1. An Epidemiological Shift in Disease Burden

Primary health care is also the need of the hour, given the shifting trends of disease burdens, globally and specifically in India. The global burden of disease study, a comprehensive worldwide assessment of epidemiological trends, reports a shift in the pattern of diseases from communicable towards non-communicable diseases (**"**NCDs**"**) as the leading causes of death.

NCDs include cardiovascular diseases, diabetes, respiratory illness and cancers that together account for 80% of premature mortality globally.[20] Cardiovascular diseases were the leading cause of death worldwide in 2016 and the risk factors with the highest burden were obesity and hypertension.[21] The same trends are seen in India where, in the last decade, NCDs have overtaken communicable diseases to become the leading cause of death.[22] In 2016, deaths due to communicable, maternal, neonatal, and nutritional diseases were 27.5% (95% UI 25.4–31.5), due to NCDs were 61.8% (58.2–64.0) and due to injuries was 10.7% (9.6–11.2).[23]

Providing care for persons with a chronic condition is a huge challenge for health systems worldwide, including India.[24] Chronic disease care

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[17] Supra 3.
[18] Supra 14.
[19] L.M. Pettigrew, J. De Maeseneer, M.P. Anderson, A. Essuman, M.R. Kidd, A. Haines, *Primaryhealth care and the Sustainable Development Goals*, 386 Lancet 2119 (2015), available at https://doi.org/10.1016/S0140-6736(15)00949-6.
[20] *Noncommunicable diseases*, World Health Organization, https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases, last seen on 27/04/2020.
[21] M. Naghavi, A.A. Abajobir, C. Abbafati, K.M. Abbas, F. Abd-Allah, S.F. Abera, et al., *Global, regional, and national age-sex specific mortality for 264 causes of death, 1980–2016: a systematic analysis for the Global Burden of DiseaseStudy 2016*, 390 Lancet 1151–1210(2017), available at https://doi.org/10.1016/S0140-6736(17)32152-9.
[22] L. Dandona, R. Dandona, G.A. Kumar, D.K. Shukla, V.K. Paul, K. Balakrishnan, et al. *Nations within a nation: variations in epidemiological transition across the states of India, 1990–2016 in the Global Burden of Disease Study*, 390 Lancet 2437 (2017), available at https://www.sciencedirect.com/science/article/pii/S0140673617328040.
[23] Ibid.
[24] E. Nolte, M. McKee, *Caring for people with chronic conditions: a health system perspective*, McGraw-Hill Education (2008).

requires the sustained engagement of the health system with the patient over prolonged periods, often extending to the patient's lifetime. Continuity of care, in terms of information regarding medication and investigations as well as relational concerning the service provider,[25] is essential to the management of the disease. Coordination of care between multiple providers and health system levels is also required as, in the course of most chronic diseases, specialty care is usually required. Health systems need to support lifestyle behaviours, and self-management skills of the person and the family. Primary health care is positioned well to provide all these essential elements of chronic care.[26]

IV. PRIMARY HEALTH CARE AND INDIA

Primary health care in India has traditionally been provided mainly by the government. The Primary Health Centre (**"**PHC**"**) has been the basic unit of service provision and a PHC usually caters to a population of 30,000 persons.[27] The staff at a PHC typically includes a doctor, a nurse, a lab technician, and the pharmacist. The rural infrastructure for primary care also includes sub-centres (**"**SCs**"**) that were created for every 5000 persons in the community.[28]As of 31st March 2019, there were 1,57,411 SCs and 24,855 PHCs in India. The sub-centre is staffed by an auxiliary nurse midwife and a male and female multipurpose health worker. The activities envisaged at the sub-centre level, such as awareness and vaccination, are mainly to promote health whereas at the PHC curative services are provided.[29]

PHCs also function as gatekeepers, referring to higher, secondary and tertiary levels of care only when specialized care is required. The National Health Mission launched in 2005 substantially contributed to the strengthening of health infrastructure, health personnel, equipment and essential medicines.[30] There have also been notable contributions from non-governmental, faith-based and not-for-profit health care

[25] D. Schwarz, L.R. Hirschhorn, J.H. Kim, H.L. Ratcliffe, A. Bitton, *Continuity in primary care: A critical but neglected component for achieving high-quality universal health coverage*, 4 BMJ Global Health 1 (2019), available at http://dx.doi.org/10.1136/bmjgh-2019-001435.

[26] E.H. Wagner, B.T. Austin, K.M. Von, *Organizing care for patients with chronic illness*, 74 The Milbank Quarterly 511 (1996), available at https://www.ncbi.nlm.nih.gov/pubmed/8941260.

[27] *(IPHS) Guidelines For Primary Health Centres revised 2012*, Ministry of Health and Family Welfare, available at http://health.bih.nic.in/Docs/Guidelines/Guidelines-PHC-2012.pdf.

[28] *Indian Public Health Standards (IPHS) Guidelines for Sub-Centres Revised 2012*, Ministry of Health and Family Welfare, available at https://nhm.gov.in/index1.php?lang=1&level=2&sublinkid=971&lid=154.

[29] M. Chokshi, B. Patil, R. Khanna, S.B. Neogi, J. Sharma, V. K. Paul, S. Zodpey, *Health systems in India*, 36 Journal of Perinatology S9 (2016), available at https://doi.org/10.1038/jp.2016.184.

[30] *Framework for implementation National Health Mission, 2012-2012*, www.nhm.gov.in, available at https://nhm.gov.in/WriteReadData/l892s/nrhm-framework-latest.pdf.

organizations that were at the forefront of the health-for-all movement that gained momentum after the Alma Ata Declaration.

V. CHALLENGES TO IMPLEMENTATION OF PRIMARY HEALTH CARE IN INDIA

The primary challenge in implementing primary care in India is the departure from a holistic vision of primary health care that is comprehensive, accessible to all, contextually relevant and rooted in communities.[31] Most primary health centres merely provide limited, disease-specific curative services. The current emphasis on vertical disease control programs such as tuberculosis and leprosy contribute to the lack of comprehensive, integrated service delivery.[32] The vertical disease program structure identifies a clear flow of funds and delineates activities that need to be done at various levels of health care. While vertical programs are an efficient way to manage health care delivery, they are usually driven from the 'top'. People are at the receiving end of such arrangements and not at the centre of planning or delivery as envisaged in primary health care.

The underlying distinction between vertical and horizontal approaches is the contradiction of power; where the horizontal approach responds to patients' needs and the vertical approach is more suited to the requirements of the state.[33] The vertical arrangement of services becomes a challenge because it impedes the integration of services and a person-centered approach that are the hallmarks of primary health care. Further, it also restricts participatory approaches to designing and delivering healthcare in a bottom-up approach that is central to primary health care.

1. Reorientation to Team-Based Care for Chronic Disease

Another major challenge in delivering primary health care today is the increasing burden of chronic non-communicable diseases. The burden of communicable diseases such as diarrhoea, pneumonia, and tuberculosis in India continues to be high and NCDs are an additional burden on the health care delivery system. The epidemiological shift, described earlier in this paper, has resulted in a dual burden for health care. Our health care system is traditionally designed to deal with acute disease conditions and

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[31] Y. Balarajan, S. Selvaraj, S.V. Subramanian, *Health care and equity in India*, 377 Lancet 505 (2011), available at https://dx.doi.org/10.1016%2FS0140-6736(10)61894-6.

[32] S. Ramani, M. Sivakami, L. Gilson, *How context affects implementation of the Primary Health Care approach: an analysis of what happened to primary health centres in India*, 3 BMJ Global Health (2019), available at http://dx.doi.org/10.1136/bmjgh-2018-001381.

[33] S. Cairncross, H. Periès, F. Cutts, *Vertical health programmes*, 349 Lancet S20 (1997), available at https://doi.org/10.1016/S0140-6736(97)90079-9.

now needs to be reoriented to care for persons with a chronic condition.[34]

The organization, at the level of primary care, must ensure that services are continuous, coordinated and ensure consistent access to medicines.[35] This will involve putting in place health information systems, training and skill-building of health care professionals, referral mechanisms to allow patients to move between levels of health care as well as counselling that empowers patients.

Ensuring care for chronic diseases requires that different tasks such as recording information, counselling, examining are shared and distributed between the team members at PHCs. Each member of the team needs to be empowered to deliver aspects of care such as the nurse counsels' patients, the pharmacist ensures patient information is captured, etc. Chronic disease care needs to be team-based and studies show that improved outcomes of care result from meaningful interactions between a proactive team and empowered patients.[36] However, there are challenges inherent to the Indian health system, in implementing team-based care, that are often overlooked.

The organizational culture at primary care facilities characterized by strong hierarchies[37] is known to inhibit equal participation of all team members in the enactment of team-based care. The doctor is usually at the apex of the hierarchy and team members perform tasks directed by the doctor. Typically, primary care team members, in the Indian context, do not participate equally and do not take individual responsibilities. Reorienting primary care in India will need to include these additional aspects relevant to the context.

2. Trust Between Providers and People

Trust is understood to be a fundamental underlying principle in all social interactions. In health care, trust is the basis of the relationship between providers and patients. Trust has been conceptualized as a patient's

[34] D. Lall, N. Engel, N. Devadasan, K. Horstman, B. Criel, *Challenges in primary care for diabetes and hypertension: an observational study of the Kolar district in rural India*, 19 BMC Health Services Research 44 (2019), available at https://doi.org/10.1186/s12913-019-3876-9.

[35] D. Lall, N. Engel, N. Devadasan, K. Horstman, B. Criel, *Models of care for chronic conditions in low/middle-income countries: A "best fit" framework synthesis,* 3 BMJ Global Health (2018), available at https://doi.org/10.1136/bmjgh-2018-001077.

[36] E.H. Wagner, B.T. Austin, C. Davis, M. Hindmarsh, J. Schaefer, *A Bonomi Improving chronic illness care: translating evidence into action,* 20 Health Affairs 64(2001), available at https://doi.org/10.1377/hlthaff.20.6.64.

[37] M.A. Hall, E. Dugan, B. Zheng, A.K. Mishra, *Trust in Physicians and Medical Institutions: What Is It, Can It Be Measured, and Does It Matter?,* 79 The Milbank Quarterly 613 (2001), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2751209/pdf/milq_223.pdf.

voluntary acceptance of vulnerability in the expectation that the healthcare provider will do the best for him.[38] Trusting the health care provider is determined by a patient's assessments of physician rapport, compassion, understanding, and honesty.[39] Studies indicate that trust between healthcare providers and patients impacts compliance, regular follow up and better outcomes of disease conditions.[40] Trusting relationships also enable providers to identify and address the social determinants of health at the primary level of care.

In India, there is an acknowledgement of the erosion of trust between providers and people.[41] This is reflected in the poor utilization of public health services and the preference for private providers.[42] People do not feel confident to seek care at primary health facilities and instead seek private care. Care at public facilities is associated with long waiting times among hordes of other patients.[43] Further, many medicines and tests are not available in the public sector, so patients have to go to private shops and laboratories.

The lack of attention to primary health care has contributed to the unregulated rise of the private sector, unethical practices and lack of transparency that has further eroded trust between provider and patients. A health system founded in trusting relationships contributes to generating wider social value and better health outcomes.[44] The increasing deficit of trust between healthcare providers and the community in the Indian context is, therefore, a big challenge, especially in the provision of primary health care.[45]

3. Financial Resources

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[38] V Gopichandran, *Trust in healthcare: an evolving concept*, 10 Indian Journal of Medical Ethics 79 (2013), available at https://doi.org/10.1136/bmjgh-2018-001077.

[39] S.D. Pearson, L.H. Raeke, *Patients' trust in physicians: Many theories, few measures, and little data, 15* Journal of General Internal Medicine 509 (2000), available at https://dx.doi.org/10.1046%2Fj.1525-1497.2000.11002.x.

[40] S. Chandra, M. Mohammad Nezhad, P. Ward, *Trust and Communication in a Doctor-Patient Relationship: A Literature Review*, 3 Journal of Healthcare Communications 36 (2018), available at DOI: 10.4172/2472-1654.100146.

[41] S. Kane, M. Calnan, *Erosion of trust in the medical profession in India: Time for doctors to act*, 6 International Journal of Health Policy and Management 5 (2017), available at https://dx.doi.org/10.15171/ijhpm.2016.143.

[42] Supra 29.

[43] A. Sengupta, S. Nundy, *The private health sector in India*, 331 The BMJ 1157 (2005), available at https://doi.org/10.1136/bmj.331.7526.1157.

[44] M. Calnan, R. Rowe, L. Gilson, *Trust in health care: theoretical perspectives and research needs*, 20 Journal of Health Organization and Management 359 (2006), available at https://www.researchgate.net/deref/http%3A%2F%2Fdx.doi.org%2F10.1108%2F14777726061070168.

[45] S. Kane, M. Calnan, A. Radkar, *Trust and trust relations from the providers' perspective: the case of the healthcare system in India*, 12 Indian Journal of Medical Ethics 157 (2015), available at https://doi.org/10.20529/IJME.2015.045.

The other major challenge to realizing primary health care is chronic under-funding for health in India. Competing interests and poor political will may be reasons for the poor allocation of resources to health. India is among the countries with the lowest spending on health according to the World Bank.[46] Primary care for chronic conditions requires financial resources to ensure health professionals, access to medicines and robust information systems. The Ayushman Bharat Yojana proposes to develop 1.5 lakh health and wellness centres to deliver comprehensive services, both promotive and curative.[47] However, there is no substantial increase in budgetary allocations for the same.[48]

4. Governance and Leadership for Primary Health Care

Governance and leadership in health systems involve ensuring that policy frameworks are combined with effective oversight, regulation, and accountability. Leadership and governance structures that commit to implementation of primary health care are lacking in India. For example, there is no governance structure in the ministries of health, at the state or central level, which monitors the implementation of primary health care. Another example is the disease-focused indicators currently used to measure primary health care.

There is no standard definition of leadership in health, however, it is known to be centered on the ability to identify priorities, provide strategic direction to multiple actors within the health system, and create commitment across the health sector to address those priorities for improved health services.[49] It can be argued that the challenges of financial resources, trust between providers and people and comprehensive models of care are all related to governance and leadership issues within the Indian health system. Developing leaders that have the vision and commitment to realize primary healthcare is a challenge that is not unique to the Indian setting.[50]

Leadership for primary health care providers is not taught in medical curricula nor included in the orientation of PHC doctors. Leadership

[46] *Country Profiles*, The World Bank, available at http://data.worldbank.org/data-catalog/country-profiles, last seen on 19/01/2016.
[47] *Home,* National Health Portal of India, available at https://www.nhp.gov.in/.
[48] V. Paul, A. Shukla, T. Sundararaman, *Can Ayushman Bharat make for a healthier India?*, The Hindu (13/04/2018), available at https://www.thehindu.com/opinion/op-ed/can-ayushman-bharat-make-for-a-healthier-india/article23516837.ece, last seen on 19/07/2018.
[49] S. Chunharas, D.S.C. Davies, *Leadership in health systems: A new agenda for interactive leadership*, 2 Health Systems and Reform 176 (2016), available at https://doi.org/10.1080/23288604.2016.1222794.
[50] S. Cleary, A. Du Toit , V. Scott , L. Gilson, *Enabling relational leadership in primary healthcare settings: Lessons from the DIALHS collaboration*, 33 Health Policy Plan 65 (2018), available at https://doi.org/10.1093/heapol/czx135.

development through structured training programs is used in several countries to overcome this challenge and could be included at the time of inducting medical officers at PHCs.[51] Mentorship and positive role modeling are other ways in which leadership can be built.

VI. THE WAY FORWARD - WHO OPERATIONAL FRAMEWORK

The World Health Organization (WHO) provides a comprehensive operational framework for implementing primary health care across countries.[52] This framework is useful for planning as it identifies key elements within the health system that are crucial to advancing primary health care in countries.

Key elements in the WHO operational framework are referred to as 'levers' and are broadly categorized as those that enhance governance and those that deal with operational issues. The two are interdependent and most levers have both a policy and an operational component. Table 1 summarizes the levers and relates them to the components of primary health care over which each lever has the most influence. Both governance and operational issues directly impact the enactment of the core concepts of primary care, namely comprehensive essential care, multisectoral action to address social determinants of health and the empowerment of people and communities (Table 1).

While the framework provides a list of actions, these are not to be interpreted as meaning that each country should undertake every action in every lever. Instead, the suggestions are intended to provide practical, evidence-based actions that countries that are committed to improving primary health care can use to accelerate efforts.[53] Each country would need to prioritize as well as choose actions based on contextual issues relevant to their setting for action. I suggest below a few of these priorities for India.

Table 1: WHO Operational Framework for Primary Healthcare[12]

Levers	**Primary health care elements**		
	Comprehensive essential services	**Multisectoral action to address social**	**Empowered people and communiti**

[51] T. Wanwick , R. Varnam *Leadership development and primary care*, 3 BMJ Leader 59 (2019), available at http://dx.doi.org/10.1136/leader-2019-000145.
[52] Supra 7.
[53] Supra 12.

		determinants	**es**
Governance Levers			
Political commitment and leadership	✔	✔	
Governance and policy frameworks	✔	✔	✔
Adequate funding and equitable allocation of resources	✔	✔	
Operational Levers			
Engagement of community and other stakeholders to jointly define problems and solutions to prioritize actions	✔	✔	✔
Models of care that prioritize primary care and public health functions	✔		✔
Ensuring the delivery of high- quality and safe health care services	✔		✔
Engagement with private sector providers	✔	✔	
The workforce	✔		✔

Physical infrastructure and appropriate medicines, products and technologies	✔		
Digital technologies	✔	✔	✔
Purchasing and payment systems	✔		
Primary healthcare-oriented research	✔	✔	✔
Monitoring and evaluation			

VII. Operationalizing the Elements of Primary Health Care- Opportunities and Actions for India

1. Comprehensive Essential Services

Universal health coverage and the provision of essential services at health and wellness centres proposed in the recently launched Ayushman Bharat scheme is a huge opportunity in India that should be maximally leveraged to deliver primary health care. I recommend attention to funding for health as a priority action of the governance lever in the WHO operational framework for India. There is a need for health care providers and civil society to continue to push for greater budgetary allocations by the government.

The private sector takes care of a large proportion of the primary health care needs in India and is a reality that is here to stay. The large private sector presents opportunities to increase population coverage through partnerships and strategic purchasing arrangements. These are operational actions that are recommended in the WHO operational framework and could be prioritized. Private health care providers, communities and civil society organizations should engage and participate in delivering primary health care. However, robust regulatory mechanisms to ensure quality and transparency will need to be established before entering into partnerships. Regulation regarding pricing, availability, and adherence to standards of quality of care will be required.

2. Multisectoral Action to Address Social Determinants

Political commitment to the vision of primary health care is a basic prerequisite to the delivery of primary health care and a priority action of the governance lever (WHO operational framework) for India. Ministries of health need to ensure that service delivery at primary care is not only comprehensive in providing essential medical services but also addresses social determinants of health through multisectoral action. To strengthen the governance of primary health care, a division within the Ministry of Health for primary care could coordinate multisectoral action (between sectors such as education, water, sanitation, public works). Strong leadership that can mobilize and bring together all stakeholders will be required to drive the agenda of primary health care in our context and settings. Some lessons can be learned from other countries, even though the local context is different, that have reported positive experiences in developing leadership for health systems.[54]

3. Empowered People and Communities

Reorienting service delivery to a model for chronic care that is person-centred is an opportunity to empower communities. Encouraging and equipping families and communities to self -manage chronic conditions is the need of the hour that will only increase with the rising incidence of chronic conditions. Community participation to achieve health is a key concept of primary health care articulated in the Alma Ata Declaration. The Declaration states that primary health care 'requires and promotes maximum community and individual self-reliance and participation in the planning, organization, cooperation and control of primary health care, making the fullest use of local, national and other available resources and to this end develops through appropriate education the ability of communities to participate'. I consider this a priority action, mentioned in the WHO operational framework as an operational lever to implement primary health care.

This has been achieved to varying degrees in India but needs to be applied widely. The National Rural Health Mission, in 2005, introduced the term 'Communitisation' to describe the institutionalizing and scaling up of community led action for health. The formation of village health and sanitation committees, the selection and training of social health activists, the involvement of panchayats (local self-government) to

[54] L. Gilson, I.A. Agyepong, *Strengthening health system leadership for better governance: What does it take?*, 33 Health Policy Plan 1 (2018), available at https://doi.org/10.1093/heapol/czy052; J. Daire, L. Gilson, S. Cleary, *Developing leadership and management competencies in low and middle-income country health systems: a review of the literature*, Resyst, available at http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.1024.7623&rep=rep1&type=pdf, last seen on 19/07/2018.

monitor funds at the community level at community discretion, a formalized method to give people an opportunity at periodic hearings (Jan Sunwai or Jan Samvad) are initiatives that were begun and need to be continually strengthened. Nagaland's experience in communitisation is worth mentioning as they demonstrated significant improvement in health delivery, education, water management through community participation.[55]

Primary health care-oriented research is also an activity that should be prioritized to strengthen primary health care delivery. There is a great role for research in determining the way forward. I bring to attention the need for funding this type of research as well as the need to build the capacity of researchers to employ methods suitable for this type of research. Implementation research and quality improvement research using mixed-method designs informed by the social sciences needs to be conducted to determine locally relevant solutions. Quality improvement initiatives, governance models, multi-sectoral actions, increased community participation, as I suggest, need to be backed by evidence of what works for whom in the Indian context.

VIII. CONCLUSION

Primary health care is the backbone of health systems world over. There is compelling evidence to support that investments in primary health care save lives and are cost-effective. However, the implementation of primary health care is challenging in the Indian context. Selective primary health care instead of comprehensive, acute episodic care models, an erosion of trust between providers and people and the chronic underfunding of health in India are major challenges to the implementation of primary health care in India.

The broad, system-level vision of primary health care that empowers communities and delivers health care close to people's homes in culturally relevant and appropriate ways, needs to be continually reinforced. Operationalizing the core concepts of primary health care will require political will, governance structures, strong leadership and engagement of all stakeholders including the community listed in the WHO operational framework. Lastly, implementation and quality improvement research to test local solutions and produce evidence for scale-up are opportunities to catalyse the move towards primary health care in India.

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[55] K. Singh, K.K. Jha, *The communitisation of public institutions and services in Nagaland, India*, 40 IDS Bulletin 31 (2009), available at https://doi.org/10.1111/j.1759-5436.2009.00082.x.

BAN ON ELECTRONIC NICOTINE DELIVERY SYSTEMS IN INDIA: A REVIEW

*Amit Yadav
**Nisha Yadav

ABSTRACT

Electronic Nicotine Delivery Systems ("ENDS") were introduced in India in the late 2000s and were getting popular, especially among school going youth and young adults. ENDS were widely promoted and marketed as harm reduction products or safer alternatives to cigarette smoking. Multinational tobacco giants soon gained complete control over the production and marketing of ENDS in an effort to expand the global tobacco industry. The unregulated sale of nicotine, an addictive and psychoactive carcinogen, not only posed a general threat related to the quality and safety standards for ENDS, but also undermined the progress made in tobacco control by re-normalising smoking, appealing to the youth and creating a whole new cadre of dual users (i.e. smokers who use ENDS as the gateway to smoking and vice versa). Moreover, with every passing day scientific research has further pointed to the greater public health risks of ENDS use per se including heart disease, lung diseases, cancer etc. ENDS use has become a youth epidemic in the United States of America with 60 reported deaths from ENDS related lung injury and nearly 2700 others suffering from it. With this background, the Government of India, which had been making piecemeal efforts to curb ENDS in the previous couple of years, finally imposed a comprehensive ban on the production, manufacture, import, export, transport, sale, distribution, storage and advertisement of ENDS in the country. This paper looks at the health and other risks of ENDS use and the legal and public health implications of the recent legislation on its ban in India.

I. INTRODUCTION

Nicotine is one of the ingredients in tobacco.[1] Like cocaine and morphine, nicotine is a powerful drug that speeds up the brain's central nervous system and triggers the release of dopamine that alters one's mood, appetite and alertness. But for nicotine, there is little doubt that people would be inclined to smoke or use tobacco.[2] The industry, which denied the fact for decades that tobacco was addictive, always knew that

* Amit Yadav, PhD, MPhil, LLM. [Postdoctoral Scholar, Centre for Tobacco Control Research and Education (CTCRE), University of California, San Francisco]
** Nisha Yadav, LLM, MBA, M. Com (Assistant Professor, Harlal School of Law)

[1] See *Fact sheet on ingredients in tobacco products*, World Health Organization, WHO/NMH/PND/15.2, (2014), available at https://www.who.int/tobacco/industry/product_regulation/factsheetingredients/en/, last seen 14/02/2020.

[2] M.A.H. Russell, *The Smoking Habit and Its Classification*, 212 The Practitioner 791, 793 (1974).

it was nicotine addiction that helps sell their products. Cigarettes today deliver more nicotine and deliver it quicker than ever before.[3]

However, with the rise in global awareness together with action to reduce tobacco use and 180 countries in the world embracing the World Health Organization's Framework Convention on Tobacco Control (**"**WHO FCTC**"**), there are countries that have introduced smoking bans in public places, graphic warnings on packaging and other effective tobacco control measures.[4] More and more countries are protecting people from the dangers of tobacco smoke by enacting laws that create smoke-free workplaces and public places. The Supreme Court of India in 2001, directed the central and state governments to ensure that all public places are free from tobacco smoke.[5] The Apex Court observed,

"[F]undamental right guaranteed under Article 21 of Constitution of India, inter alia, provides that none shall be deprived of his life without due process of law. Then - why a non-smoker should be afflicted by various diseases including lung cancer or of heart, only because he is required to go to public places? Is it not indirectly depriving of his life without any process of law? The answer is obviously - 'yes'. Undisputedly, smoking is injurious to health and may affect the health of smokers but there is no reason that health of passive smokers should also be injuriously affected. In any case, there is no reason to compel non-smokers to be helpless victims of air pollution."[6]

The Parliament enacted the Cigarettes and Other Tobacco Products Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution Act, 2003 (**"**COTPA**"**) which, under Section 4, completely prohibits smoking in public places.

In 2008, the Ministry of Health and Family Welfare, Government of India (**"**MoHFW**"**) introduced stronger regulations to curb smoking in public places and imposed stricter ventilation requirements for creating smoking areas.[7] The regulations also designated enforcement officers at

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[3] *This July 4th, Gain Freedom From Tobacco Use*, The Centers for Disease Control and Prevention, available at http://www.cdc.gov/features/smokingindependence/, last accessed 06/10/2014;
D. Mosbergen,*Cigarettes Are More Addictive Than Ever Before, Suggests New Study*, Huffington Post (7/12/2014), available at http://www.huffingtonpost.com/2014/01/17/cigarettes-more-addictive-study_n_4618612.html, last seen on 06/10/2014.

[4] M. Hefler, *World: Gandhi's legacy and a Tobacco-Free World,* Tobacco Control Blog, available at https://blogs.bmj.com/tc/2019/10/01/world-gandhis-legacy-and-a-tobacco-free-world/, last seen on 04/01/2020.

[5] Murli S Deora v. Union of India, (2001) 8 SCC 765.

[6] Ibid.

[7] *National Tobacco Control Programme*, Ministry of Health and Family Welfare, Government of India, available at https://main.mohfw.gov.in/major-programmes/other-national-health-programmes/national-tobacco-control-programme-ntcp, last seen on

all public places and made the managers or owners of such public places responsible for keeping the space smoke-free or be liable to pay fine for as many instances of smoking at such public place.

Globally, such laws and regulations presented less and less possibilities for smoking, presented more and more chances for breaking the nicotine dependence and started affecting the sales of the tobacco industry. The industry that had already started testing electronic cigarettes since 1960 as 'reduced harm' or 'socially acceptable' alternatives to conventional cigarettes started its commercial production from late 2010s.[8] Although, the tobacco industry tested and patented alternative non-tobacco nicotine cigarettes British American Tobacco's (BAT) 1960s *Ariel* cigarette, RJ Reynolds' (RJR) 1980s *Premier*, RJR's 1990s *Eclipse* and Philip Morris' (PM's) 1990s/2000s *Accord*),[9] it was the introduction of modern electronic cigarettes in China as a potential cessation device or an alternative cigarette product that took the tobacco industry by surprise.[10]

To safeguard its business interests, the industry started acquiring all big and small electronic cigarettes producers globally and introducing its own electronic cigarette products. It used its size and financial firepower to take over the electronic cigarettes market and within a couple of years it was the tobacco industry that held the largest market share of the electronic cigarettes market globally.[11] Today electronic cigarettes are sold across the world in several types, names and design as seen in Figure 1 below, including e-cigarettes, "e-cigs," "cigalikes," "e-hookahs," "e-sheesha," "mods," "vape pens," "vapes," "tank systems" and the latest entrant being *"JUUL"*.[12] These are collectively known as electronic nicotine delivery devices (**"**ENDS**"**).

16/02/2020. (Smoking area may be provided only at three places i.e. a restaurant with 30 or more seating capacity, a hotel with 30 or more rooms and an airport.).

[8] L.M. Dutra, R. Grana, S.A. Glantz, *Philip Morris research on precursors to the modern e-cigarette since 1990*, 26(2) Tobacco Control 97, (2017), available at https://tobaccocontrol.bmj.com/content/26/e2/e97, last seen on 13/01/2020.

[9] Ibid.

[10] See W. Wang, Z. He, N. Feng, Y. Cai, *Electronic cigarette use in China: Awareness, prevalence and regulation*, 17 Tobacco Induced Diseases 1, (2019) available at http://www.tobaccoinduceddiseases.org/Electronic-cigarette-use-in-China-Awareness-prevalence-and-nregulation,105393,0,2.html, last seen on 16/02/2020.

[11] C. Abate, *Tobacco Companies Taking Over the E-Cigarette Industry,* Huffpost (27/01/2017), available athttps://www.huffpost.com/entry/tobacco-companies-taking-over-the-e-cigarette-industry_b_58b48e02e4b0658fc20f98d0, last seen on 22/02/2020.

[12] *Electronic Cigarettes*, Centers for Disease Control and Prevention, available at https://www.cdc.gov/tobacco/basic_information/e-cigarettes/index.htm, last seen on 14/01/2020; *What Do We Know About E-cigarettes?,* American Cancer Society, available at https://www.cancer.org/cancer/cancer-causes/tobacco-and-cancer/e-cigarettes.html, last seen on 14/01/2020.

ENDS generally look like regular cigarettes, cigars, or pipes, while some look like USB flash drives, pens, and other everyday items. ENDS are battery-powered smoking devices, which have cartridges filled with a liquid that usually contains nicotine, flavourings and chemicals.[13] The liquid is heated into a vapor, which the person inhales. Therefore, using ENDS is called "vaping."[14] Despite this common and innocuous nomenclature, some avoid using the term "ENDS", because ENDS emissions are, more accurately, aerosols which also contain "ultra-fine particles, volatile organic compounds, and other toxins."[15]

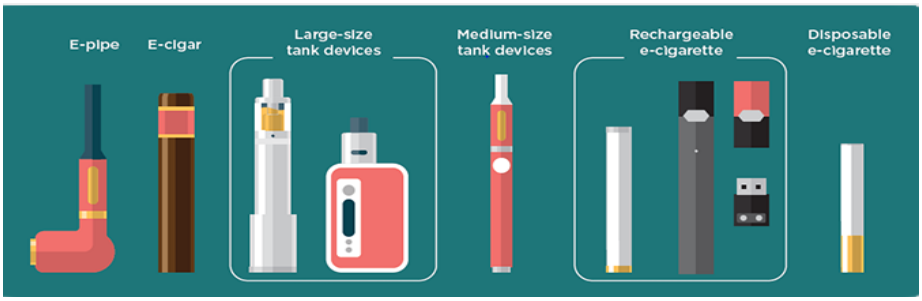

Fig-1: Different varieties of ENDS

Source: Centers for Disease Control and Prevention-USA. Electronic Cigarettes. Available at: https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html

II. EARLY MARKETING OF ENDS

Initially, the industry itself was not very sure about the strategy to market ENDS to consumers. Some of them started marketing their ENDS as a harm reduction device, some started marketing it as a cessation aid and some as an alternative to traditional cigarettes.[16] The Indian premier tobacco company started selling its own e-cigarette brand in 2014

[13] *About Electronic Cigarettes*, Centre for disease control and Prevention, available at https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html, last seen on 16/02/2020.

[14] *Electronic Cigarettes*, Centres for Disease Control and Prevention, available at https://www.cdc.gov/tobacco/basic_information/e-cigarettes/index.htm, last seen on 14/01/2020;
What Do We Know About E-cigarettes?, American Cancer Society, available at https://www.cancer.org/cancer/cancer-causes/tobacco-and-cancer/e-cigarettes.html, last seen on 14/01/2020.

[15] *Electronic Smoking Devices and Second hand Aerosol*, American Nonsmokers Rights Foundation, available at https://no-smoke.org/electronic-smoking-devices-secondhand-aerosol/ last seen on 19/01/2020.

[16] *10 Surprising Facts About E-Cigarettes*, Centre on Addiction, available at https://www.centeronaddiction.org/e-cigarettes/about-e-cigarettes/10-surprising-facts-about-e-cigarettes, last seen on 16/02/2020.

promising that it gave the 'pleasure of smoking anytime anywhere'[17] (i.e. including public places, where smoking was otherwise banned under COTPA). Warnings on several of the ENDS products suggested that they were not smoking cessation products (i.e. they only helped in maintaining the nicotine addiction and dependence while promoting dual use among tobacco users).[18]

Instead of marketing ENDS as a cessation device, as several of the initial manufacturers intended, the tobacco industry started to market ENDS as an alternative to traditional cigarettes riding on the reduced harm arguments. In doing so, the industry was also able to divide health and tobacco control professionals into two groups. One group recognized that ENDS have a reduced risk of causing disease and embraced them as a crucial element of tobacco control policy while the other focused on preventing people from beginning to use tobacco products and encouraging people to quit.

III. MYTHS RELATED TO ENDS

Although the tobacco industry presents ENDS as a part of the solution,[19] in reality it is meant not only to suppress quitting by providing an alternative device to deliver and maintain nicotine addiction among current smokers - most ENDS users are "dual users" who continue to smoke cigarettes - but, more importantly, to recruit a whole new generation that is growing under the protected environment of WHO FCTC into nicotine addiction and eventually cigarette smoking.[20]

Reviews of evidence about reducing smoking (instead of quitting) show that dual users are unlikely to see any health benefits in terms of

[17] M. Rao, *Should e-cigarettes be banned in India? Experts are divided,* Scroll.in (11/06/2020), available at https://scroll.in/pulse/810375/can-e-cigarettes-subvert-tobacco-control-measures-in-the-country, last seen on 16/02/2020.

[18] See A. Bhatnagar, L.P. Whitsel, M.J. Blaha, et al., *New and Emerging Tobacco Products and the Nicotine Endgame: The Role of Robust Regulation and Comprehensive Tobacco Control and Prevention: A Presidential Advisory From the American Heart Association*, 139(19) AHA Journals 937, (2019), available at https://www.ahajournals.org/doi/full/10.1161/CIR.0000000000000669, last seen on 16/02/2020.

[19] *Top scientists warn WHO not to stub out e-cigarettes*, Reuters (29/05/2014), available at http://www.reuters.com/article/2014/05/28/health-ecigarettes-idUSL6N0OD3ZE20140528, last seen on 24/10/2014.

[20] R. Grana, N. Benowitz, S.A. Glantz, *E-cigarettes: a Scientific Review*, 129(19) Circulation 1972, (2014), available at https://www.ahajournals.org/doi/10.1161/circulationaha.114.007667, last seen on 28/04/2020; S.A. Glantz, *129 public health and medical authorities from 31 countries write WHO DG Chan urging evidence-based approach to ecigs*, Centre for Tobacco Control Research and Education, available at https://tobacco.ucsf.edu/129-public-health-and-medical-authorities-31-countries-write-who-dg-chan-urging-evidence-based-approach-ecigs#_edn23, last seen on 28/04/2020.

cardiovascular disease.[21] Population studies of all smokers consistently show that smokers who use ENDS are *less* likely to stop smoking."[22] The fact that the tobacco industry continues to produce conventional cigarettes is evidence enough of the vicious intentions of the industry in promoting ENDS. All the claims related to ENDS made by the industry, therefore, are either contradicted by available evidence or for which no evidence is currently available.[23]

A White Paper by an expert group constituted by the Indian Council of Medical Research, New Delhi, was released on 31 May 2019.[24] The White Paper provided a telling story of how ENDS are not the products that the tobacco industry wants us to believe they are.

Prof. Simon Chapman from the Sydney University has unequivocally summarized these industry tactics and said,

"Big-Tobacco's five goals are widespread dual use; retarding smoking cessation; re-socialising public smoking back into fashion from its forlorn exile outside buildings;

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[21] Ibid; C. Pisinger, N.S. Godtfredsen, *Is there a health benefit of reduced tobacco consumption? A systematic review*, 9 Nicotine and Tobacco Research 631, (2007), available at https://www.ncbi.nlm.nih.gov/pubmed/17558820, last seen on 15/01/2020.

[22] S.E. Adkison, R.J. O'Connor, M. Bansal-Travers, et al., *Electronic Nicotine Delivery Systems: International Tobacco Control Four-Country Survey*, 44 American Journal of Preventive Medicine 207, (2013), available at https://www.ncbi.nlm.nih.gov/pubmed/23415116, last seen on 15/01/2020;
S.A. Glantz, *129 public health and medical authorities from 31 countries write WHO DG Chan urging evidence-based approach to ecigs*, Centre for Tobacco Control Research and Education, available at https://tobacco.ucsf.edu/129-public-health-and-medical-authorities-31-countries-write-who-dg-chan-urging-evidence-based-approach-ecigs#_edn23, last seen on 28/04/2020; R.A. Grana, L. Popova, P.M. Ling, *A longitudinal analysis of electronic cigarette use and smoking cessation*, 174 JAMA Internal Medicine 812, (2014), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4122246/, last seen on 28/04/2020; K.A. Vickerman, K.M. Carpenter, T. Altman T et al, *Use of electronic cigarettes among state tobacco cessation quitline callers*, 15 Nicotine and Tobacco Research 1787, (2013), available at https://www.ncbi.nlm.nih.gov/pubmed/23658395, last seen on 16/01/2020; L. Popova, P.M. Ling, *Alternative tobacco product use and smoking cessation: a national study*, 103 American Journal of Public Health 923, (2013), available at https://www.ncbi.nlm.nih.gov/pubmed/23488521, last seen on 14/01/2020; R. Grana, N. Benowitz, S.A. Glantz, *E-cigarettes: a Scientific Review*, 129(19) Circulation 1972, (2014), available at https://www.ahajournals.org/doi/10.1161/circulationaha.114.007667, last seen on 15/01/2020.

[23] S.A. Glantz, *129 public health and medical authorities from 31 countries write WHO DG Chan urging evidence-based approach to ecigs*, Centre for Tobacco Control Research and Education, available at https://tobacco.ucsf.edu/129-public-health-and-medical-authorities-31-countries-write-who-dg-chan-urging-evidence-based-approach-ecigs#_edn23, last seen on 28/04/2020.

[24] Indian Council of Medical Research, *White Paper on Electronic Nicotine Delivery System*, 149(5) Indian Journal of Medical Research 574, (2019), available at http://www.ijmr.org.in/article.asp?issn=0971-5916;year=2019;volume=149;issue=5;spage=574;epage=583;aulast=Indian, last seen on 12/01/2020.

conveying to young, apprehensive would-be smokers that nicotine is a benign drug; and welcoming back lapsed smokers."[25]

Table-1: Myths related to ENDS

	Myths related to ENDS	**Reality of ENDS**
1	Safer alternative to traditional cigarettes	Almost same risk as traditional cigarettes for causing heart attacks, lung diseases and possibly cancer as well. It has created a more vulnerable group of dual users who are unlikely to see any health benefit and are instead exposed to greatest risk of heart attacks.
2	Helps in quitting smoking	The industry itself does not promote ENDS as a cessation product. Studies indicate it might be suppressing cessation by nearly one-third.
3	Not meant for minors	Globally, wherever it was introduced, it became more popular among school going kids and young adults. In the United States, youth prevalence surpassed adult prevalence in 2014. With more than 460 brands and nearly 8000 flavours, marketing of ENDS is primarily targeted to minors. It also acts as a gateway product for minors and teenagers.
4	Not contrary to the tobacco control/smoke free regulations or the WHO FCTC mandates	It violates provisions of several domestic tobacco control statutes. It is also against the mandate of Article 16(1)(c) of the WHO FCTC which calls for "*prohibiting the manufacture and sale of sweets, snacks, toys or any other objects in the form of tobacco products which appeal to minors.*" Use of

[25] S. Chapman, *Should electronic cigarettes be as freely available as tobacco cigarettes? No*, The BMJ, available at https://www.bmj.com/content/346/bmj.f3840, last seen on 12/01/2020.

		ENDS in public places renormalizes smoking against the spirit of Article 8 of the WHO FCTC and Section 4 of COTPA.
5	Safe and standard product	Several incidents of fire and explosion of ENDS devices have resulted in loss of life and property. Accidental ingestion by kids causing their death is often reported.

The cigarette companies wanted to manufacture and market ENDS only to protect and prevent the market share of their products from the real competition from any effective cessation product in the market. The best way forward for the industry to ensure this was to takeover, design and market the potential competition product by itself. The story in India was the same as anywhere in the world. These were the same tobacco companies who were producing cigarettes, smokeless tobacco and ENDS products.

Table-2: Tobacco companies market ENDS

	Tobacco Company	**Tobacco products**	**ENDS Product**
1	ITC Pvt. Ltd.	Wills Navy Cut, Gold Flake etc.	Eon
2	Godfrey Phillips Pvt. Ltd.	Red and White, Four Square etc.	Verge
3	Trimurti Fragrances Pvt. Ltd.	Shikhar Gutkha, Shikhar Khaini etc.	Shikhar E-Cigarettes
4	Phillip Morris (ITC's partner)	Marlboro, Benson & Hedges etc.	iQOS, JUUL

5	British American Tobacco (Godfrey Phillips' partner)	Dunhill, Camel etc.	Vype, Vuse, Glo, Neo

IV. ADVERSE HEALTH EFFECTS OF ENDS

There are several apparent risks of using ENDS, including constant intake of chemicals such as propylene glycol, vegetable glycerin, polyethylene glycol and nicotine.[26] Nicotine *per se* is classified as a poison and in light of its adverse impact, its use even as an insecticide has been banned.[27] Nicotine is a highly addictive stimulant which can cause immediate cardiovascular effects such as vasoconstriction, increased heart rate, and increased blood pressure.[28] In the long term, nicotine can lead to endothelial dysfunction, platelet aggregation and other conditions which lead to cardiovascular diseases.[29] While comparing conventional cigarettes and initial verities of ENDS, it was observed that the latter required stronger vacuums (suction) to smoke than conventional cigarettes which could have adverse effect on human health.[30] The vapor from ENDS causes a pro-inflammatory response from human neutrophils which is known to contribute to lung diseases such as chronic obstructive pulmonary disease (**"**COPD**"**). It also contains several harmful chemicals, including known carcinogens.[31]

[26] A. Trtchounian, M. Williams, P. Talbot, *Conventional and electronic cigarettes (e-cigarettes) have different smoking characteristics*, 12 Nicotine & Tobacco Research 905, (2010), available at https://www.ncbi.nlm.nih.gov/pubmed/20644205, last seen on 13/01/2020.

[27] Mishra, P. Chaturvedi, S. Datta et al., *Harmful effects of nicotine*, 36 Indian Journal of Medical and Paediatric Oncology 24, (2015), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4363846/, last seen on 16/02/2020.

[28] *Nicotine*, National Center for Biotechnology Information, available at https://pubchem.ncbi.nlm.nih.gov/compound/Nicotine, last seen on 16/02/2020.

[29] A. Bhatnagar, *E-cigarettes and cardiovascular disease risk: evaluation of evidence, policy implications, and recommendations*, 10 Current Cardiovascular Risk Reports, (2016), available at https://link.springer.com/article/10.1007%2Fs12170-016-0505-6, last seen on 14/01/2020;

R.J. Schweitzer, T.A. Wills, D. Behner, *E-cigarette use and indicators of cardiovascular disease risk*, 4 Current Epidemiology Report 248, (2017), available at https://link.springer.com/article/10.1007%2Fs40471-017-0118-8, last seen on 12/01/2020.

[30] A. Trtchounian, M. Williams, P. Talbot, *Conventional and Electronic Cigarettes (E-Cigarettes) Have Different Smoking Characteristics*, 12 Nicotine & Tobacco Research 905, (2010) available at https://www.ncbi.nlm.nih.gov/pubmed/20644205, last seen on 13/01/2020.

[31] A. Higham, N.J. Rattray, J.A. Dewhurst et al.*, Electronic cigarette exposure triggers neutrophil inflammatory responses*, 17 Respiratory Research, (2016), available at https://respiratory-research.biomedcentral.com/articles/10.1186/s12931-016-0368-x, last seen on 14/01/2020; A. Scott, S.T. Lugg, K. Aldridge, et al., *Pro-inflammatory Effects of E-Cigarette*

Further, nicotine exposure during pregnancy has adverse effects on fetal growth and development, including fetal brain development.[32] Other substances in ENDS cause temporary increase in airway resistance and congestion in the lungs resulting in cough, phlegm, sinus congestion, irritation in the throat, hoarse voice, mouth ulcers, acne, hiccups, sleeplessness, bloating, dizziness, change of smell sensation and taste, headache and heartburn. The Cinnamaldehyde found in ENDS has the potential to impair respiratory immune cell function,[33] and use of ENDS alters the profile of innate defense proteins in airway secretions, inducing similar and unique changes relative to cigarette smoking.[34] Diacetyl found in e-liquids is responsible for bronchiolitis obliterans or popcorn lung and other severe respiratory diseases.[35]

In USA, several ENDS users were hospitalized with severe lung illness starting June 2019. The condition was named as 'e-cigarette, or vaping, product use-associated lung injury' or EVALI by the Centre for Disease Control (**"**CDC**"**), Atlanta, Georgia, USA.[36] CDC reported significant lung illness and death (2,668 reported cases and 60 deaths as of January 14, 2020) due to vaping in the USA.[37]

1. Harmful to others

The aerosol emitted from ENDS contains fine and ultrafine particles, nicotine and other toxic substances which are harmful for others inhaling

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Vapour Condensate on Human Alveolar Macrophages, 73(12) Thorax 1161, (2018), available at https://www.ncbi.nlm.nih.gov/pubmed/30104262, last seen on 14/01/2020.

[32] U.S. Department of Health and Human Services, Government of United States of America, *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General*, available at https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf, last seen on 16/01/2020.

[33] P.W. Clapp, E.A. Pawlak, J. Lackey et al., *Flavored e-cigarette liquids and cinnamaldehyde impair respiratory innate immune cell function*, 313 American Journal of Physiology 278, (2017), available at https://www.ncbi.nlm.nih.gov/pubmed/28495856, last seen on 15/01/2020.

[34] B. Reidel, G. Radicioni, P.W. Clapp et al., *E-Cigarette Use Causes a Unique Innate Immune Response in the Lung, Involving Increased Neutrophilic Activation and Altered Mucin Secretion*, 197 American Journal of Respiratory and Critical Care Medicine 492, (2018), available at https://www.ncbi.nlm.nih.gov/pubmed/29053025, last seen on 12/01/2020.

[35] J.G. Allen, S.S. Flanigan, M. LeBlanc et al., *Flavoring Chemicals in E-Cigarettes: Diacetyl, 2,3-Pentanedione, and Acetoin in a Sample of 51 Products, Including Fruit-, Candy-, and Cocktail-Flavored E-Cigarettes*, 124 Environmental Health Perspective 733, (2016), available at https://www.ncbi.nlm.nih.gov/pubmed/26642857, last seen on 12/01/2020.

[36] *Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping Products*, Centres for Disease Control and Prevention, available at https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html, last seen on 16/02/2020.

[37] Ibid.

these substances.[38] It is also responsible for polluting the indoor air as ENDS use leads to an increase in the concentration of carcinogenic Polycyclic Aromatic Hydrocarbons (**"**PAHs**"**) in the indoor air by 20%, and aluminium increase by 2.4-fold.[39] In addition, it increases exposure of non-smokers and bystanders to nicotine and a number of toxicants.[40] ENDS can cause toxicity among children due to accidental swallowing of e-cigarette liquids.[41] Defective e-cigarette batteries have also caused fires and explosions, some of which have resulted in serious injuries.[42]

2. Effect on youth

Studies suggest that youth in USA who had never smoked conventional cigarettes but who used ENDS were almost twice as likely to have intentions to smoke conventional cigarettes as those who had never used ENDS.[43] According to data from the USA National Youth Tobacco Survey, in 2011, the prevalence of e-cigarette use among high school students was 1.5%, which increased dramatically to 16% by 2015 and to 20.8% in 2018.[44] One of the most commonly sold versions of e-cigarettes in USA is JUUL, which now has more than a 70% share of the

[38] S.A. Glantz, D.W. Bareham , *E-Cigarettes: Use, Effects on Smoking, Risks, and Policy Implications*, 39 Annual Review of Public Health 215, (2018) available at https://www.ncbi.nlm.nih.gov/pubmed/29323609, last seen on 13/01/2020;
Electronic nicotine delivery systems Report by WHO, Conference of the Parties to the WHO Framework Convention on Tobacco Control, Russian Federation, October 13-18, FCTC/COP/6/10 (September, 2014), available at http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf?ua=1, last seen on 19/01/2020.

[39] W. Schober, K. Szendrei, W. Matzenetal. *Use of Electronic Cigarettes (E-Cigarettes) Impairs Indoor Air Quality and Increases FeNO Levels of E-Cigarette Consumers,* 217 International Journal of Hygiene and Environmental Health 62, (2014), available at https://www.ncbi.nlm.nih.gov/pubmed/24373737 last accessed 12-01-2020.

[40] *Electronic nicotine delivery systems Report by WHO*, Conference of the Parties to the WHO Framework Convention on Tobacco Control, Russian Federation, October 13-18, FCTC/COP/6/10 (September, 2014), available at http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf?ua=1, last seen on 19/01/2020.

[41] J. Mielke,*E-cigarette poisoning figures soar as vaping habit spreads across UK*, The Guardian (14/04/2014), available at http://www.theguardian.com/society/2014/apr/14/e-cigarette-poisoning-figures-soar-adults-children, last seen on 12/01/2020.

[42] *Exploding e-cigarette kills 24-year-old Texas man*, BBC (5/02/2019), available at https://www.bbc.com/news/world-us-canada-47136678, last seen on 12/01/2020.

[43] R.E. Bunnell, I.T. Agaku, R.A. Arrazola, et al., *Intentions to Smoke Cigarettes Among Never-Smoking US Middle and High School Electronic Cigarette Users: National Youth Tobacco Survey, 2011-2013,*17 Nicotine and Tobacco Research 228, (2015), available at https://www.ncbi.nlm.nih.gov/pubmed/25143298, last seen on 13/01/2020.

[44] K.A. Cullen, B.K. Ambrose, A.S. Gentzke, et al., *Notes From the Field: Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students - United States, 2011-2018,* 67 Morbidity & Mortality Weekly Report 1276, (2018), available at https://www.ncbi.nlm.nih.gov/pubmed/30439875, last seen on 15/01/2020.

cartridge-based e-cigarette market in the United States.[45] A typical JUUL cartridge, or "pod," contains about as much nicotine as a pack of 20 regular cigarettes.[46]

In Poland, e-cigarettes were the fourth most common source of nicotine among youth after cigarettes, waterpipes, and snuff.[47] Similar proportions of ENDS use was observed in a study conducted with adolescents in Finland. The study also shows that, among smokers, ENDS use was associated with lower interest in smoking cessation while never smokers were also shown to use e-cigarettes.[48] A study among adolescents in Korea revealed 8.0% of ever-dual users were currently using e-cigarettes and smoking conventional cigarettes as well. The study concluded that those who had made an attempt to quit were more likely to use ENDS but less likely to no longer use cigarettes.[49] Studies have also shown that ENDS use by youth is strongly linked to later use of regular cigarettes and other tobacco products,[50] and using ENDS may play a part in a kid or teenager wanting to experiment with other, conventional tobacco products.[51]

Studies from across the globe suggest that the factors associated with ENDS use and sources for ENDS appear similar to those for conventional cigarettes among adolescents.[52] Peers and online sales remain the key sources of acquisition of the products, while internet, social networking sites and youth magazines were reported for advertising

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[45] B.A. King, D.G. Gammon, K.L. Marynak et al., *Electronic Cigarette Sales in the United States, 2013-2017*, 320(13) JAMA 1379, (2018), available at https://jamanetwork.com/journals/jama/fullarticle/2705175, last seen on 18/01/2020.

[46] J.G. Willett, M. Bennett, E.C. Hair, et al., *Recognition, use and perceptions of JUUL among youth and young adults*, 28 Tobacco Control 115, (2019), available at https://tobaccocontrol.bmj.com/content/28/1/115, last seen on 15/01/2020.

[47] *Electronic Cigarette Use Among Teenagers and Young Adults in Poland,* 130 Pediatrics 879, (2012), available at https://www.ncbi.nlm.nih.gov/pubmed/22987874, last seen on 15/01/2020.

[48] J.M. Kinnunen, H. Ollila, El-Amin et al., *Awareness and determinants of electronic cigarette use among Finnish adolescents in 2013: a population-based study*, 24 Tobacco Control 264, (2015), available at https://tobaccocontrol.bmj.com/content/24/e4/e264, last seen on 13/01/2020.

[49] S. Lee, R.A. Grana, S.A. Glantz, *Electronic Cigarette Use Among Korean Adolescents: A Cross-Sectional Study of Market Penetration, Dual Use, and Relationship to Quit Attempts and Former Smoking*, 54(6) Journal for Adolescent Health 684, (2014), available at https://www.ncbi.nlm.nih.gov/pubmed/24274973, last seen on 14/01/2020.

[50] U.S. Department of Health and Human Services, Government of United States of America, *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General*, available at https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf, last seen on 16/01/2020.

[51] Ibid.

[52] J.M. Kinnunen, H. Ollila, El-Amin et al., *Awareness and determinants of electronic cigarette use among Finnish adolescents in 2013: a population-based study*, 24 Tobacco Control 264, (2015), available at https://tobaccocontrol.bmj.com/content/24/e4/e264, last seen on 16/02/2020.

ENDS. Despite the advertisement ban, every 10th adolescent reported having seen e-cigarette advertisements, mostly on Facebook.[53] Highlighting the rapid increase in ENDS experimentation among adolescents, Dr. Poonam Khetrapal Singh, the Regional Director of World Health Organisation, South-East Asia office, said that because there are *"almost 8,000 different flavours, including fruit and candy-like flavours, there is legitimate concern that instead of reducing the number of smokers, e-cigarettes will actually serve as a gateway to nicotine addiction, and ultimately smoking, particularly for young people."*[54]

3. ENDS use among Indian youth

A study in India with school students, teachers, parents and college students highlighted that ENDS were considered to be a non-tobacco, non-nicotine product.[55] The study also reported that there was confiscation of ENDS from all schools visited, while students reported high popularity, social acceptance, convenient availability and easy affordability of ENDS.[56]

V. THE REGIME OF REGULATING ENDS GLOBALLY

There is no uniform system when it comes to regulating ENDS globally. Different countries have taken different approach towards regulating ENDS. They are being sold in pharmacies, supermarkets, kiosks, via the Internet, retail and specialized shops, markets/market stalls, on the street, bars and pubs and leisure venues such as casinos and bingo halls.[57] The

[53] Supra 250;
M.B. Steinberg, M.H. Zimmermann, C.D. Delnevoet al., *E-Cigarette Versus Nicotine Inhaler: Comparing the Perceptions and Experiences of Inhaled Nicotine Devices*, 29 Journal of General Internal Medicine 1444, (2014), available at https://www.ncbi.nlm.nih.gov/pubmed/24830741, last seen on 12/01/2020;
M. Hua, H. Yip&P. Talbot, *Mining data on usage of electronic nicotine delivery systems (ENDS) from YouTube videos*, 22 Tobacco Control 103, (2013), available at https://tobaccocontrol.bmj.com/content/22/2/103.info, last seen on 16/01/2020.
[54] P.K. Singh, *Only a smoke screen: Electronic cigarettes are not entirely harmless and need to be regulated*, The Times of India (10/10/2014), available at https://timesofindia.indiatimes.com/blogs/toi-edit-page/only-a-smoke-screen-electronic-cigarettes-are-not-entirely-harmless-and-need-to-be-regulated/, last seen on 05/01/2020.
[55] R. Shrivastav, P. Kathuria, M. Arora et al., *(Mis)perceptions related to Electronic Nicotine Delivery Systems (ENDS) and hookah: making a case for policy strengthening through a multi-stakeholder qualitative study from New Delhi, India*, 16 Tobacco Induced Diseases 469, (2018), available at https://doi.org/10.18332/tid/84580, last seen on 12/01/2020.
[56] Ibid.
[57] *Electronic nicotine delivery systems Report by WHO*, Conference of the Parties to the WHO Framework Convention on Tobacco Control, Russian Federation, October 13-18, FCTC/COP/6/10 (September, 2014), available at http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf?ua=1, last seen on 17/01/2020.

worldwide sale and thereby regulation of ENDS has been very diverse given the diverse legal and constitutional mandates which national and municipal governments must adhere to. As per the report submitted to the Secretariat of the WHO FCTC, whether or not the Parties regulate ENDS, only a few countries are able to monitor sales levels of ENDS or their historical trends.[58]

In 2014, the sale of ENDS with nicotine was banned in 13 of the 59 countries that regulated them, including countries like, Brazil, the Seychelles, Singapore, Thailand and Uruguay that had laws banning the manufacturing, importation, distribution, and sale of ENDS.[59] Keeping with the Article 16 of the WHO FCTC, regardless of accompanying health claims and the presence or absence of tobacco or nicotine extracts in the ENDS, the Seychelles and Singapore consider ENDS as a tobacco imitation product and thus its manufacture, import, supply, distribution and sale is prohibited under their tobacco control laws. Brazil banned the sale, importation and advertisement of "any electronic device for smoking". In Canada, in the same way as manufacturers of nicotine gum and lozenges had to obtain pre-market approval, market authorization under the Food and Drugs Act, is required before importing, advertising, or selling ENDS products.[60] In the USA, ENDS and other products made or derived from tobacco can be regulated as "tobacco products" and are not drugs/devices unless they are marketed for therapeutic purposes.[61] However, in the UK, ENDS products could get marketing authorisation to be sold either as medicines or as consumer products. By 2017 the sale of ENDS was banned by 25 countries out of the 68 countries that regulated ENDS under their national laws.[62]

VI. EARLY REGULATION OF ENDS IN INDIA

[58] *The Convention Secretariat calls Parties to remain vigilant towards novel and emerging nicotine and tobacco products*, WHO FCTC, available at https://www.who.int/fctc/mediacentre/news/2019/remain-vigilant-towards-novel-new-nicotine-tobacco-products/en/, last seen on 16/02/2020.

[59] *Electronic nicotine delivery systems Report by WHO*, Conference of the Parties to the WHO Framework Convention on Tobacco Control, Russian Federation, October 13-18, FCTC/COP/6/10 (September, 2014), available at http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf?ua=1, last seen on 19/01/2020;

[60] See *Country Laws Regulation E-cigarettes: A Policy Scan*, Global Tobacco Control, available at https://www.globaltobaccocontrol.org/e-cigarette/country-laws/view last accessed 22-02-2020.

[61] Sottera, Inc. v. Food & Drug Administration, 627 F.3d 891.

[62] R.D. Kennedy, A. Awopegba, E. De León, J.E. Cohen, *Global approaches to regulating electronic cigarettes,* 26 Tobacco Control 440, (2017), available at https://tobaccocontrol.bmj.com/content/tobaccocontrol/26/4/440.full.pdf, last seen on 18/01/2020.

ENDS were introduced to Indian markets about 10 years back in 2009-2010 and soon started gaining popularity, especially among school going youth. In absence of clear regulations ENDS were sold as recreational products, substitute products, cessation aids and general consumer products in the Indian markets both at the local vendor and through online shopping portals and internet sales. Though ENDS were not regulated in India, several directives on manufacture, sale, storage, distribution and use of nicotine were available. Most of the laws and regulations dealing with nicotine classify it as a poisonous substance and prohibit its use for human consumption. These include the Drugs and Cosmetics Act, 1940; Poisons Act, 1919; Insecticides Act, 1968; Environment Protection Act, 1986; Food Safety and Standards Act, 2006; and the Manufacture, Storage and Import of Hazardous Chemical Rules, 1989.

Considering that the safety and quality of ENDS has not been established, an expert panel on ENDS was constituted by MoHFW.[63] The expert panel recommended a complete ban on ENDS in 2014.[64] It also suggested that until such time as their safety and effectiveness as cessation aids is clinically established and approved by the Drug Control Authority, sale of ENDS should be immediately prohibited under the Drugs and Cosmetics Act. The panel considered that ENDS could lead to addiction, particularly among the youth, and become a gateway to tobacco use in the country where already more than 5500 youth start tobacco use every day.[65] The Government of Punjab, in September 2013, had already issued an advisory declaring ENDS as an unapproved drug contravening the provisions of the Drugs and Cosmetics Act and directed all the drug inspectors to be vigilant about the spread of ENDS in the State.[66]

1. Hazardous and poisonous chemical

[63] Ministry of Health and Family Welfare, Government of India, *National Safety Implementation Framework (2018-2025),* available at https://main.mohfw.gov.in/sites/default/files/national%20patient%20safety%20implimentation_for%20web.pdf, last seen on 28/04/2020.

[64] ET Bureau, *India mulls total ban on e-cigarettes, as government panel says safety not established*, The Economic Times (30/08/2014), available at https://economictimes.indiatimes.com/industry/cons-products/tobacco/india-mulls-total-ban-on-e-cigarettes-as-government-panel-says-safety-not-established/articleshow/41223840.cms?from=mdr, last seen on 22/02/2020.

[65] Ibid.

[66] *Nicotine preparations coming in form of E-Cigarettes is unapproved drug and contravenes the provisions of Drugs and Cosmetics Act, 1940*, Food and Drugs Administration, Government of Punjab, Circular No. Drugs (7) Pb. 2013/16988-89, (05/09/2013), available at <http://pbhealth.gov.in/ban_e-CIgg.pdf&gt, last seen on 28/04/2020.

Nicotine is listed as a hazardous chemical under the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (in force since 24 February 2004) and the Environment (Protection) Act, 1986 (in India);[67] and as a poison under the Poisons Act, 1919 (in India).[68] Therefore, manufacture, import, storage, distribution and sale of products containing nicotine in chemical form was highly restricted in India. Further, the Punjab and Haryana High Court imposed a ban on use of Nicotine in chemical form in 2012 while hearing a petition filed by Mr. Hemant Goswami of the Burning Brain Society, Chandigarh.[69]

In April 2014, a Punjab Sessions court sentenced a shopkeeper from Mohali city to three years in jail for selling ENDS in violation of the directions issued under the Drugs and Cosmetics Act, 1940.[70] The Court observed that, *"E-cigarette contains nicotine in chemical form, which is highly addictive and potentially lethal. The youth take to such kind of addictive and potentially lethal products, and the offenders involved in promoting and selling such products should be dealt with sternly by law for the welfare of the society."*[71] The Commissioner of Food and Drug Administration, Punjab also requested the MoHFW to prevent online sale of ENDS.[72]

2. Advisory from the MoHFW

With the expert panel recommendations and requests from states still pending consideration, civil society organizations finally approached the Delhi High Court for issuing directions to the Central Government to ban ENDS. On 21 August 2018, the High Court directed MoHFW to take regulatory measures to curb ENDS within a week.[73] Based on the Court's direction, on 28th August 2018, MoHFW issued an advisory to all states and union territories to ensure that *"ENDS, e-cigarettes, heat-not-burn devices, vape, e-sheesha, e-nicotine flavoured hookah, and similar devices that enable nicotine delivery are not sold (including online sale), manufactured, distributed, traded, imported and advertised in their jurisdictions."*[74] Several states complied with

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[67] Schedule 1, The Environment (Protection) Act, 1986.
[68] The Punjab Poisons Possession and Sale Rules, 2014.
[69] Burning Brain Society v. Union of India, (2013) 1 RCR (Cri) 736.
[70] State of Punjab v. Parvesh Kumar, Sessions Case No. 03/19.05.2015.
[71] N. Jain, *E-cigarette seller gets 3-year jail in Mohali*, The Tribune (15/04/2016), available at https://www.tribuneindia.com/news/archive/e-cigarette-seller-gets-3-year-jail-in-mohali-222736, last seen on 05/01/2020.
[72] Ibid.
[73] Seema Sehgal v. Union of India and Others, W.P. (C) 10624/2017 & Criminal Appeal No. 33757/2018 (Delhi High Court, 07/09/2018).
[74] *Advisory on Electronic Nicotine Delivery Systems (ENDS) Including E-Cigarettes, Heat-Not-Burn Devices, Vape, E-Sheesha, E-Nicotine Flavoured Hookah, and the like Products*, Ministry of Health and Family Welfare, Government of India Circular No. F.No-P-16012/19/2017-TC (28/08/2018), available at

this advisory and completely banned trade, commerce and use of ENDS.'[75]

On 27 November 2018, the Central Board of Indirect Taxes and Customs (Anti-Smuggling Unit) directed all its officials to ensure implementation of this advisory and report all such consignments to the Assistant or Deputy Drugs Controller in their jurisdiction.[76] Based on the report of the Assistant or Deputy Drugs Controller, for any non-compliant consignments, action under the Drugs and Cosmetics Act, 1940 had to be initiated.[77]

Further, based on the advisory, on 22 February 2019, the Drug Controller General of India issued a directive to all state and union territory drug controllers that since no e-cigarettes or like nicotine delivery devices are approved by the authority, sale, manufacture, distribution, trade, import and advertisement of e-cigarettes and the like products is banned. The directive imposed the ban on both retail and online sales of ENDS.[78]

Further, the Ministry of Electronics and Information Technology (MEITY) proposed an amendment to the Information Technology (Intermediary Guidelines) Rules 2018 to ban the advertisement of anything that threatens public health or safety. It specifically mentioned that intermediaries should inform users to prevent transmission of information on tobacco, alcohol and ENDS.[79]

In addition, Section 2 of the Poisons Act, 1919 read with section 8 provides power to the state governments to frame rules to carry out the

https://www.tobaccocontrollaws.org/files/live/India/India%20%20MOHFW%20Advisory%20on%20ENDS.pdf, last seen on 05/01/2020.

[75] Yadav & S. Glantz, *India: government ordinance to ban ENDS with immediate effect*, 28 Tobacco Control 599, 602 (2019), available at https://tobaccocontrol.bmj.com/content/28/6/599, last seen on 18/01/2020.

[76]Yadav, *Smoking e-cigarettes is more injurious to health*, The Hindu (23/07/2019), available at https://www.thehindu.com/opinion/op-ed/smoking-e-cigarettes-is-more-injurious-to-health/article28658584.ece, last seen on 28/04/2020.

[77]*Advisory on Electronic Nicotine Delivery Systems (ENDS) including eCigarettes, Heat-Not-Burn devices, Vape, e-Sheesha, e-Nicotine Flavoured Hookah, and the like products-reg*, Ministry of Finance, Government of India Circular No. 46/2018-Custom (27/11/2018), available at https://www.tobaccocontrollaws.org/files/live/India/India%20-%20MoF%20Circular%20on%20ENDS.pdf, last seen on 28/04/2020.

[78] *ENDS and the like devices that enable nicotine delivery system reg*, Ministry of Health and Family Welfare, Government of India Circular No. Import/Misc./14/2019-DC (22/02/2019), available at https://www.tobaccocontrollaws.org/files/live/India/India%20-%20DCGI%20Letter%20on%20ENDS.pdf, last seen on 28/04/2020.

[79] Anoo Bhuyan, *Three Ministries Advance Regulations to Control E-Cigarettes*, The Wire (8/01/2019), available at https://thewire.in/health/three-ministries-advance-regulations-to-control-e-cigarettes, last seen on 05/01/2020.

purposes and objects of the Act. The states which have listed nicotine as poison under the rules can regulate or restrict the use of nicotine and therefore of ENDS as well. For instance, the State of Punjab, Haryana and Karnataka banned the manufacture, sale and distribution of ENDS as it is in contravention with the Poison Rules read with the Poisons Act within these states.[80]

3. Ordinance to ban ENDS in India

The advisory by the MoHFW was challenged in the Delhi High Court by Piush Ahluwalia, an ENDS user. He contended that the advisory violated his fundamental rights under Article 14, 19 and 21 of the Constitution of India in as much as it deprived him from using less harmful products compared to cigarettes. Hearing the petition, the Court held that it did not consider that any interference with the said advisory was warranted as the MoHFW's advisory was not binding in nature and the states were free to take an informed view on its implementation.[81] The ENDS ban decision of the state of Jammu Kashmir,[82] Karnataka[83] and Tamil Nadu[84] were also challenged in the High Courts of these respective states.[85]

The MoHFW had initially planned to implement the ban on ENDS under the Drugs and Cosmetics Act, 1940 as an unapproved drug and device. However, as a result of the litigation against its advisory and the several state orders under different laws, it finally decided to take the emergency law making route to implement the ban on ENDS by issuing an ordinance to prevent ENDS from becoming an "epidemic" among children and young adults.[86]

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[80] Indian Council of Medical Research, *White Paper on Electronic Nicotine Delivery System*, 149(5) Indian Journal of Medical Research 574, (2019), available at http://www.ijmr.org.in/article.asp?issn=0971-5916;year=2019;volume=149;issue=5;spage=574;epage=583;aulast=Indian, last seen on 22/02/2020.

[81] Piush Ahluwalia v. Union of India, W.P.(C) 12163/2018 (Delhi High Court, 2018).

[82] *AVI has legally challenged vape bans*, Vape India, available at http://vapeindia.org/india/legal/, last seen on 28/04/2020.

[83] Council for Harm Reduced Alternatives v. State of Karnataka and Others, W.P. No. 36696/2017 (Karnataka High Court, 22/08/2017).

[84] *Electronic Cigarettes: Regulatory Framework In India*, Ikigai Law, available at https://www.ikigailaw.com/electronic-cigarettes-regulatory-framework-in-india/#acceptLicense, last seen on 05/01/2020.

[85] Ibid.

[86] The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Ordinance, 2019;
Also see A. Kalra, *India proposes ban on e-cigarettes, with jail terms for offenders - government documents*, Reuters (22/08/2019), available at https://www.reuters.com/article/us-india-ecigarettes-exclusive/exclusive-india-proposes-ban-on-e-cigarettes-with-jail-terms-for-offenders-government-documents-idUSKCN1VC1RI, last seen on 05/01/2020.

The tobacco and vaping industries raised alarm that such a law will result in severe loss of revenue to those engaged in the business and especially the tobacco farmers.[87] On the other hand the civil society and health professionals refuted the industry claims and demanded an early implementation of the ban.[88] As a result, a Group of Ministers (**"**GoM**"**), led by Finance Minister, Ms. Nirmala Sitharaman, was constituted in September 2019 to review the MoHFW's proposed law.[89] The trade representatives of ENDS and vapers association approached the GoM seeking fair trial.[90] The proposal was approved by the group of ministers and accepted by the cabinet on 18 September 2019 and on the same day 'the Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Ordinance, 2019' was promulgated. Enforcement of the ordinance began in India with state governments issuing public notices to both inform the public and to ensure compliance with the law.[91]

While the government was preparing to get the ordinance passed into a legislation by the parliament, JUUL, a multinational ENDS giant, funded local ENDS importers to challenge the ordinance before the courts.[92] Two e-cigarette importers, Plume Vapour and Woke Vapours, challenged the Ordinance before the Calcutta High Court, Kolkata.[93] However, MoHFW remained committed to implementation of the ban in its present form and informed the Court of its intent to prevent the present and future generations from nicotine addiction. With the endorsement of

[87] A. Yadav & S. Glantz, *India: government ordinance to ban ENDS with immediate effect*, 28 Tobacco Control 599, 602 (2019), available athttps://tobaccocontrol.bmj.com/content/28/6/599, last seen on 18/01/2020.

[88] A. Yadav, *Smoking e-cigarettes is more injurious to health*, The Hindu 23/01/2019), available at https://www.thehindu.com/opinion/op-ed/smoking-e-cigarettes-is-more-injurious-to-health/article28658584.ece, seen on 05/01/2020.

[89] PTI, *Draft ordinance to ban e-cigarettes with jail terms for violators to be examined by GoM*, Economic Times (28/08/2019), available at https://health.economictimes.indiatimes.com/news/industry/draft-ordinance-to-ban-e-cigarettes-with-jail-terms-for-violators-to-be-examined-by-gom/70864157, last seen on 22/02/2020.

[90] *Trade representatives seek GoM hearing over bringing ordinance to ban ENDS*, Outlook India (3/09/2019), available at https://www.outlookindia.com/newsscroll/trade-representatives-seek-gom-hearing-over-bringing-ordinance-to-ban-ends/1611039, last seen on 22/02/2020.

[91] *Cabinet approves Promulgation of the Prohibition of Electronic Cigarettes Ordinance*, Press Information Bureau, Government of India, available at https://pib.gov.in/PressReleseDetail.aspx?PRID=1585437, last seen on 22/02/2020.

[92] M. Davies, J. Kasperkevic & M. Chapman, *JUUL spreads over the world as home market collapses in scandal*, The Bureau of Investigative Journalism (21/11/19), available athttps://www.thebureauinvestigates.com/stories/2019-11-21/juul-spreads-over-the-world-as-home-market-collapses-in-scandal, last seen on 20/01/2020.

[93] Plume Vapour Private Ltd. &Anr. v. Union of India, 2019 SCC OnLine Cal 7084

the Ordinance by the Parliament, the Court dismissed the two petitions.[94] While world governments have struggled in regulating and preventing the ENDS epidemic, the Prime Minister of India highlighted his Government's decisive action against ENDS to deal with the worrisome craze of ENDS among youth during his speech at the UN on September 23, 2019.[95]

4. The present legal position

The Prohibition of Electronic Cigarettes Act, 2019[96] (the Act) completely prohibits the Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement of ENDS to prevent their negative health impacts on the public, especially youth. The key features of the law include:

> **Law applicable all over India:** In the public interest the Parliament decided to take control of the ENDS industry into its control under section 2 of the Act, and therefore made the law applicable across India. Considering the varying regulations for ENDS ban by various states, this law envisioned and implemented a uniform national policy on ENDS ban.[97]

> **Definition of ENDS:** The Act defines electronic cigarettes to mean *"an electronic device that heats a substance, with or without nicotine and flavours, to create an aerosol for inhalation and includes all forms of Electronic Nicotine Delivery Systems, Heat Not Burn Products, e-Hookah and the like devices, by whatever name called and whatever shape, size or form it may have, but does not include any product licensed under the Drugs and Cosmetics Act, 1940; Explanation.—For the purposes of this clause, the expression "substance" includes any natural or artificial substance or other matter, whether it is in a solid state or in liquid form or in the form of gas or vapour;"*[98]

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[94] Ibid.

[95] *PM's remarks at the UNGA high-level meeting on universal health coverage,* PM India, available at https://www.pmindia.gov.in/en/news_updates/pms-remarks-at-the-unga-high-level-meeting-on-universal-health-coverage/, last seen on 22/02/2020.

[96] The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.

[97] M. Davies, J. Kasperkevic & M. Chapman, *JUUL spreads over the world as home market collapses in scandal*, The Bureau of Investigative Journalism (21/11/19), available athttps://www.thebureauinvestigates.com/stories/2019-11-21/juul-spreads-over-the-world-as-home-market-collapses-in-scandal, last seen on 20/01/2020.

[98] S. 3 (d), The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.

Therefore, the law not only closes the Indian market for all kinds of electronic cigarettes from different generations, but also prohibits heat not burn devises, e-hookah and any other similar devises that could be introduced in the market in future e.g ultrasonic nicotine delivery devices.[99]

Ban on ENDS: The ban on ENDS under the law is a comprehensive one and extends to production, manufacturing, import, export, transport, sale and distribution whether directly or indirectly, as a complete or in any part thereof.[100] The law also requires that no person shall directly or indirectly advertise or take part in any advertisement that directly or indirectly promotes use of ENDS.[101]

Ban on storage of ENDS: The Act also prohibits storage of any stock of ENDS and requires that all existing stocks are declared and submitted to the nearest office of the authorised officer.[102] Such authorised officer shall take necessary measures for the disposal of the stocks as per the existing law in force to that regard.[103] Such authorised officer is also vested with the power to enter, search and seize without warrant if he has reason to believe that provisions of the Act have been or are being violated.[104]

Penalties: Violation of section 4 of the law attracts up to one-year imprisonment or a fine of up to Rupee one lakh or both for first offence and up to three years imprisonment and a fine up to Rupee five lakh for a subsequent offence.[105] Whoever is guilty of storing ENDS will be liable to imprisonment of up to six months or a fine of Rupees fifty thousand or both.[106] Offences under Section 4 are cognizable[107] and the Court of Judicial Magistrate of

[99] This next generation devises work on ultrasonic high frequency vibrations to generate aerosol instead of a heating coil or other heating elements.
[100] S. 4 (i), The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.
[101] S. 4(ii), The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.
[102] S. 5(a), The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.
[103] S. 5 (b), The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.
[104] S. 6, The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.
[105] S. 7, The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.
[106] S. 8, The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.
[107] S. 13, The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.

the First Class has been designated for the trial of all offences under the Act.[108] However, a court shall only take cognizance of the violation of the provisions of this Act on the complaint of an authorised officer (i.e., any police officer not below the rank of a sub-inspector or other person so designated by the central or state government).[109]

Ban on use of ENDS: Although the Act does not directly ban the use of ENDS, the lawmakers clearly intended that no one should use them in the country by prohibiting storage of these devices. This was also expressed by the Health Ministry before the Calcutta High Court.[110]

Direction for compliance: To ensure effective implementation of the provisions of the law across the country, the Union Health Ministry issued directives to all the concerned officials in the states and union territories to take necessary measures to implement the law.[111] State authorities were asked to undertake a month-long drive with participation of police and other concerned departments. The Union health ministry also sought an action-taken report from all states and union territories with details of the case registered, stock seized, and number of traders who have deposited list of ENDS in nearest police station. Several states have further directed their state and local agencies to ensure compliance with the law.[112]

VII. GLOBAL BEST PRACTICE

By implementing a comprehensive ban on ENDS, India has not only complied with the recommendations of the Sixth Session of the Conference of Parties of WHO FCTC that invited all Parties to consider

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[108] S. 9, The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.

[109] S. 12, The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.

[110] Plume Vapour Private Ltd. &Ors. v. Union of India &Ors., 2019 SCC OnLine Cal 7084;
Also see A. Kalra, *India says e-cigarette ban implies use of devices also prohibited*, Reuters(18/11/2019), available athttps://www.reuters.com/article/us-india-ecigarettes/india-says-e-cigarette-ban-implies-use-of-devices-also-prohibited-idUSKBN1XS1DR, last seen on 17/01/2020.

[111] *Proper Implementation of the provisions laid down in the Prohibition of Electronic Cigarettes, (production, manufacture, import, transport, sale, distribution, storage and advertisement) ordinance,* 2019, Ministry of Health and Family Welfare, Government of India Notification No. D.O.No.P.16012/23/2019-TC (23/12/2019), available athttp://www.odishapolicecidcb.gov.in/sites/default/files/Ordinance.pdf, last seen on 28/04/2020.

[112] Ibid.

prohibiting or regulating the use of e-cigarettes in their countries[113], but has also followed the global best practice already implemented in over 30 countries that have banned manufacture, trade and advertisement of ENDS while countries like Singapore and Cambodia have also banned its possession.[114] It has also presented an example to emulate for other countries that are still in the process of regulating or imposing a ban on ENDS within in their jurisdiction including the USA which is trying to curb the menace of ENDS epidemic among youth.[115]

VIII. LEGAL IMPLICATIONS

The Constitution of India obligates the Government to take measures to improve public health and in doing so the Government shall endeavour to bring about prohibition of the consumption except for medicinal purposes of 'intoxicating drinks and of drugs which are injurious to health'.[116] The present Act imposing comprehensive prohibition on ENDS envisions to meet this obligation. The law is also in line with the existing provisions under the Juvenile Justice (Care and Protection of Children) Act, 2015 which prohibits access to any intoxicating liquor, any narcotic drug, tobacco product, or psychotropic substance to a person below the age of 18 years.[117] It is well known that nicotine is a unique psychotropic substance that both stimulates and depresses functions of and affects the central nervous system.[118,]However, it must be noted that the ban on ENDS is imposed on over the counter sale of ENDS as a recreational or harm reduction or alternative to tobacco consumer

[113] *Report of the sixth session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control,* Conference of the Parties to the WHO Framework Convention on Tobacco Control, Russian Federation, October 13-18, 2014, available at https://www.who.int/fctc/cop/sessions/COP6_report_FINAL_04122014.pdf?ua=1, last seen on 17/01/2020.

[114] *Advisory on Electronic Nicotine Delivery Systems (ENDS) Including E-Cigarettes, Heat-Not-Burn Devices, Vape, E-Sheesha, E-Nicotine Flavoured Hookah, and the like Products*, Ministry of Health and Family Welfare, Government of India Circular No. F.No-P-16012/19/2017-TC (28/08/2018), available at https://www.tobaccocontrollaws.org/files/live/India/India%20-%20MOHFW%20Advisory%20on%20ENDS.pdf, last seen on 05/01/2020.

[115] *The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Bill, 2019*, PRS Legislative Brief, available athttp://prsindia.org/node/843494/chapters-at-a-glance, last seen on 17/01/2020;
B. Lovelace, *The FDA bans most fruit- and mint-flavored nicotine vaping products to curb teen use*, CNBC (2/1/2020), available athttps://www.cnbc.com/2020/01/02/fda-issues-ban-on-some-flavored-vaping-products.html, last seen on 17/01/2020.

[116] Art. 47, the Constitution of India.

[117] S. 77, Juvenile Justice (Care and Protection of Children) Act, 2015.

[118] E.F. Domino, Nicotine*: A Unique Psychoactive Drug —Arousal With Skeletal Muscle Relaxation*, 22 Psychopharmacology Bulletin 870, (1986);
Effects of Nicotine on Biological Systems, 502 (Adlkofer & Thurau, 1991);
J.B. Murray, *Nicotine as a psychoactive drug*, 125 The Journal of Psychology 5, (1991), available athttps://www.ncbi.nlm.nih.gov/pubmed/2033559, last seen on 19/01/2020.

product. Law exempts from its ambit any such product that is licensed under the Drugs and Cosmetics Act, 1940.[119] This exemption provides room for manufacturers willing to sell their products as a regulated drug or device with due license from the Central Drugs Standard Control Organization of India.

The law also paves way for the Government of India to revive the amendment of COTPA for the same reasons as ENDS ban legislation.[120] Government should progressively target to make the country tobacco-free by 2030 which will prevent more than 13.5 lakh annual deaths that happen due to tobacco use[121] and annual economic loss of rupees 1,04,500 crore due to tobacco induced diseases.[122] Given that tobacco use is one of the most significant risk factors for Tuberculosis,[123]such a targeted tobacco control effort will also accelerate progress towards meeting the objectives of the National Tuberculosis Elimination Programme of ending Tuberculosis by 2025.[124]

In January this year, a challenge to the ENDS ban legislation was returned by the Supreme Court suggesting that the petitioner approach the Delhi High Court in the matter.[125] The Delhi High Court was already apprised of pre-legislation petitions both against[126] and in support[127] of the ban on ENDS. As no court has given any adverse directive against the law, its implementation continues in the country. However, given the

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[119] S. 3(d), The Drugs and Cosmetics Act, 1940.

[120] Ministry of Health and Family Welfare, Government of India, *Withdrawal of amendment to Cigarettes and Other Tobacco Products Act, 2003*, available at https://mohfw.gov.in/sites/default/files/NOTICE(1).pdf, last seen on 19/01/2020.

[121] Ministry of Health and Family Welfare, Government of India, *Global Adult Tobacco Survey 2, India 2016-17*, available at https://www.who.int/tobacco/surveillance/survey/gats/GATS_India_2016-17_FactSheet.pdf, last seen on 19/01/2020.

[122] Ministry of Health and Family Welfare, Government of India, *Report on Economic Burden of Tobacco Related Diseases in India,* available at https://ntcp.nhp.gov.in/assets/document/surveys-reports-publications/Economic-Burden-of-Tobacco-Related-Diseases-in-India-Report.pdf , last seen on 19/01/2020.

[123] P. Jha, B. Jacob, V. Gajalakshmi , et al., *A nationally representative case–control study of smoking and death in India*, 358 The New England Journal of Medicine 1137, (2008), available athttps://www.nejm.org/doi/full/10.1056/NEJMsa0707719, last seen on 22/02/2020.

[124] M. Pai, S. Bhaumik& S.S. Bhuyan, *India's plan to eliminate tuberculosis by 2025: converting rhetoric into reality*, 2 BMJ Global Health 1, (2017), available athttps://gh.bmj.com/content/2/2/e000326, last seen on 22/02/2020.

[125] *SC declines to hear plea challenging Bill banning E-Cigarettes*, Indian Legal (13/01/2020), available athttps://www.indialegallive.com/constitutional-law-news/supreme-court-news/sc-declines-hear-plea-challenging-bill-banning-e-cigarettes-82668, last seen on 19/01/2020.

[126] Piush Ahluwalia v. Union of India, W.P.(C) 12163/2018 (Delhi High Court, 2018)

[127] Seema Sehgal v. Union of India and Others, W.P. (C) 10624/2017 & Criminal Appeal No. 33757/2018 (Delhi High Court, 07/09/2018).

pending litigations the matter is far from final as we wait for the law to clear these judicial tests in due course of time.

IX. PUBLIC HEALTH IMPLICATIONS

While the government is struggling to contain substance abuse in the country, especially among youth and young adults, nicotine addiction in the form of ENDS use could present yet another challenge for the already burdened health systems. According to experts, *"India is already struggling to control several addictions such as tobacco, alcohol, areca nut and cannabis. Adding a new addiction would only worsen the situation."*[128] Globally, manufacturers of ENDS have not claimed any therapeutic value of ENDS including its use for promoting tobacco or smoking cessation. Evidence suggest that more tobacco users using ENDS end up being dual users and never able to quit the nicotine addiction.[129] On the contrary, it entices minors to take up smoking. Considering that nicotine is a psychoactive drug and is also a carcinogen, the timely action by the Government to ban ENDS will go a long way in preventing ENDS access among minors and other vulnerable populations while preventing an emerging public health threat from taking an epidemic proportion in the country.

Moreover, ENDS use is not an isolated phenomenon but affects use of combustible cigarettes, the known risks of which are extremely high.[130] Given the dual use and gateway impact of ENDS use, especially among youth and young adults, the public health effect of ENDS is severely adverse with the inherent risks of ENDS coupled with an increased risk of conventional smoking. In absence of credible evidence of ENDS being effective in smoking cessation and its impending threat of becoming a youth epidemic, the net public health impact of the present law shall be distinctly positive.

X. CONCLUSIONS

[128] P. Chaturvedi& P.C. Gupta, *Four fake narratives the tobacco lobby is floating to undermine India's e-cigarette ban*, Scroll.in (30/09/2019), available athttps://scroll.in/article/938799/four-fake-narratives-the-tobacco-lobby-is-floating-to-undermine-indias-e-cigarette-ban, last seen on 19/01/2020.

[129] S.A. Glantz & D.W. Bareham, *E-Cigarettes: Use, Effects on Smoking, Risks, and Policy Implications*, 39 Annu Rev Public Health 215 (2018), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6251310/ , last seen on 22/02/2020.

[130] D.N. Bhatta & Stanton A. Glantz, *Association of E-Cigarette Use With Respiratory Disease Among Adults: A Longitudinal Analysis*, 58 American Journal of Preventive Medicine 182, (2020), available at https://www.ajpmonline.org/article/S0749-3797(19)30391-5/fulltext, last seen on 22/02/2020.

In the last decade, various kinds of ENDS have been promoted as alternative to conventional cigarettes but none of them have been able to convincingly establish itself for smoking cessation. Globally, ENDS have raised more questions than answers to conventional smoking. The disease and deaths in several cities of the USA due to EVALI since July 2019 has been the lowest point for ENDS since its use began gaining popularity in the late 2000s and wide proliferation in the 2010s. Before it could take roots in India, the Government of India treaded a cautious path by prohibiting unrestricted production, manufacture, import, export, transport, sale, distribution, storage and advertisement of ENDS as a consumer product. In as much as nicotine is an addictive, psychotropic carcinogen, the pre-emptive action by MoHFW is in public interest and upholds the constitutional right to health of every Indian citizen.

REHOMING PUBLIC HEALTH: HAMMERING RESEARCH INTO POLICY USING COMPARATIVE MODELS OF HEALTHCARE

*Shantanu Parmar

ABSTRACT

The paper shall introduce the concept of Right to Health care and the entitlement of citizens to it by a virtue of their existence. It shall deal with the concept under variegated international treatises and obligations of party states. The research study seeks to present the existing health care mechanisms offered by different countries. A comparative analysis of these systems shall be presented which shall incorporate the advantages and lacunae thereof. The analysis shall assist the researcher to exact at a system suited to the needs of the Indian diaspora. A revamped tax structure and revenue policy shall be accorded as the goal of this research work. The author recognizes the paramount importance of such structure wherein each citizen shall have the Right to receive health aid without expending a fortune. The author seeks to present a health care system, which permeates even through the marginalized segments of the population.

The paper shall further champion such a system by resorting to human rights and constitutional philosophy. It shall analyze the role of India as a welfare state and providing affordable health care as a critical characteristic of the Indian constitution. The research paper seeks to advocate for removing the capitalist, profit-making aspect from health care and present it as a system, which is accessible, approachable, affordable and available to all.

I. INTRODUCTION

"To keep the body in good health is a duty, otherwise we shall not be able to keep our mind strong and clear" – Gautam Buddha

Health is perhaps one of the few subjects which permeates and affects us all. The following research study seeks to explore the right of citizens to healthcare. The term "right" is often used in the arguments, which focus on healthcare. It exerts authority, simplicity and emotions, which arms the potential to connect with citizens. Through the following study, we shall undertake the intricacies and implications of such a right.

A historical background and subsequent conceptualization using international instruments and treaties shall be undertaken to provide a thorough context. It is imperative to understand the healthcare policies from various systems for eliciting ground realities. Thereafter, we shall traverse and investigate the healthcare system of India. It shall be

* Shantanu Parmar, 3rd Year B.A. LL.B. (Hons.) Rajiv Gandhi National University of Law, Punjab.

analysed whether India can take steps to ameliorate the situation of medical care. Our goal is to extrapolate whether a Right to Healthcare is warranted from a constitutional standpoint and the principle of welfare state. The research design shall be regarded as an amalgamation of the explanatory and exploratory model to assist the purposes of the study.

II. INTERNATIONAL BACKDROP AND CONCEPTUALIZATION

It is stated that the contemporary idea of RHC gained public consciousness in 19th century Europe.[1] It saw the rise of public health measures owing to unhealthy working and living conditions of a nascent industrialized society.[2] Creation of various international institutions helped in the conceptualization of the idea. Article 55 of the UN Charter requires the states to seek solutions for health problems through international cooperation. Article 25 of the UDHR recognized a "standard of living adequate for the well-being" of a person.[3]Article 12 of the ICESCR recognizes the highest standard of physical and mental health as a right and also prescribes offshoots to attain the same.[4] The international consciousness and recognition of public health also led to the creation of the World Health Organization ("WHO") in 1946. The preamble of the Constitution of WHO regarded Right to Health as a "Fundamental Right" and evolved the concept into an inalienable right.[5] It stated basic principles, which required adherence from party states to attain the highest possible standard of physical and mental health. The treatises mentioned above are not exhaustive and each seems to propagate a similar idea based on extending health care to each member of society without assuming financial hardship. A majority of the nations are signatories or have ratified these international instruments. But mere acknowledgement has not garnered acceptable results. It is estimated that over half of the world's population does not have full coverage of essential health services.[6]In 2018, over 19.4 million children did not

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[1] Institute of Medicine, *The Future of Public Health*, 120 (1st ed., 1988).

[2] *The Right to Health*, Icelandic Human Rights Centre, available at http://www.humanrights.is/en/human-rights-education-project/human-rights-concepts-ideas-and-fora/substantive-human-rights/the-right-to-health, last seen on 26/12/2019.

[3] U.N. General Assembly, *Universal Declaration of Human Rights*, Res. 3/217, Sess. 3, U.N. Document A/RES/217(III), 76, (10/12/1948), available at https://undocs.org/A/RES/217(III), last seen on 26/12/2019.

[4] U.N. General Assembly, *International Covenant on Economic, Social and Cultural Rights*, Res. 21/2200A, Sess. 21, U.N. Document A/RES/21/2200A, 6, (16/12/1966), available at https://www.ohchr.org/en/professionalinterest/pages/cescr.aspx, last seen on 26/12/2019.

[5] *Constitution of the WHO,* World Health Organization, available at https://www.who.int/governance/eb/who_constitution_en.pdf, last seen on 19/3/2020.

[6] *Universal Health Coverage*, World Health Organization, available at https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-(uhc), last seen on 26/12/2019.

receive essential immunization to prevent them from life-threatening diseases.[7] 785 million people lack basic drinking water service.[8]An estimated 1 out of every 10 people contract illness from consuming contaminated food.[9] These statistics portray a grim reality, which grossly departs from the principles prescribed by the international treaties. It is stated that these jarring figures necessitate framing of a sacrosanct right, which prevents eruption of a global health crisis. It is argued that although the following research work primarily focuses on the Indian condition, it does not forbid adopting the concept as an international standard.

For the purposes of this study it is imperative to conceptualize a standard, which adheres to international norms and benchmarks. The author shall take the concept of 'right' as propounded by John Stuart Mill for formulation. Mill deliberates on the question of rights and their relationship with utility and explains that a right is violated when there is a wrong done and that wrong can be assigned to a certain person.[10] He assigns a utilitarian idea which would cast a duty upon the state to ensure that such rights are not violated.[11] If such an idea is espoused by the legislature, it would cast a duty upon the state to protect the health of its citizens. It is stated that a right based on the definition of Mill would obligate the State to protect the health of its citizens.[12]Each instrument mentioned above obligates the party states to ensure standards of health for their citizens. But contemporary times have witnessed the creation of a global order, which focuses primarily on corporate and financial interests rather than the interests of the population.[13] Herein, the idea of social protection offered by the state exhibits no relevance. It is suggested that the protective role of the state has to be revived to ensure that people do not perish under the garb of profit maximization. Governments need to adopt a 'reconstructionist' agenda to rejuvenate their role in the health sector without undermining the liberalist approach. This agenda shall theorize and include: (1) Right to Access; (2)

[7] *Immunization Coverage*, World Health Organization, available at https://www.who.int/news-room/fact-sheets/detail/immunization-coverage, last seen on 26/12/2019.
[8] *Drinking Water*, World Health Organization, available at https://www.who.int/news-room/fact-sheets/detail/drinking-water, last seen on 26/12/2019.
[9] *Food Safety*, World Health Organization, available at https://www.who.int/news-room/fact-sheets/detail/food-safety, last seen on 26/12/2019.
[10] David O. Brink, *Mill's Ambivalence about Rights*, 90 Boston University Law Review 1669, 1670 (2008).
[11] David Lyons, *Rights, Welfare and Mill's Moral Theory*, 107 (1994).
[12] T.S. Szasz, *Right to Health*, 57 Georgetown Law Journal 734, 749 (1969).
[13] Ibid, at 209.

Right to a minimum level of care; and (3) Right to participate in health decisions, which affect the individual.[14]

III. PUBLIC HEALTH INITIATIVES: A ROSE-TINTED REALITY?

"The foundation of success in life is good health"- P.T. Barnum

In the following section, the researcher seeks to analyse the different public health measures nations have adopted. It seeks to present the comparative understanding of health initiatives across states to carve out a plan tailored to the needs of the Indian diaspora. The rationale behind selecting these nations is the discernible distinction in the systems of governance and policy formulation followed by each of them.

1. USA: Does the American Dream accommodate Health Care?

The US has been particularly vocal when it comes to championing human rights around the world. It has projected itself as the white knight whose mission is to protect the sanctity of these rights. But the condition of health care as a human right in the US seems to derogate from the principles it boasts to endorse.

Prima facie, the statistics portray a favourable reality. The USA spends more money on health than any other nation.[15] These expenditures are borne by public authorities (Federal, State and Local), as well as private insurance and individual payments.[16] This fragmentation of the medical care system breeds inconvenience, unnecessary and less than complete care for the consumer.[17] It has been argued by the American Bar Association that the system adopted by the USA is not of health care but of health insurance, which does not culminate into a right[18]The following table(s) illustrates the situation of the American Health Care for the year 2018:

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[14] J. Binder, *Government and the Right to Health Care*, 10 Journal of Health and Human Resources Administration 174, 177 (1987).
[15] G.J. Scheiber, J.P. Poullier & L.M. Greenwald, *Health Care systems in twenty-four countries*, 10 Health Affiliation (Millwood) 22, 23 (1991).
[16] N.D. Lew, G. Greenberg & K. Kinchen, *A layman's guide to the U.S. health care system*, 14 Health Care Financial Review 151, 152 (1992).
[17] D.L. Madison, *The Structure of American Health Care Services*, 31 Public Administration Review 518, 520 (1971).
[18] Mary Gerisch, *Health Care As a Human Right*, American Bar Association, available at https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/the-state-of-healthcare-in-the-united-states/health-care-as-a-human-right/, last seen on 27/12/2019.

Type of Coverage	**% of Population Covered**
Any Health Plan	91.5
Uninsured	8.5

Type of Coverage		**% of Population Covered**	
Any Private Based Plan		67.3	
1.	**Employment Based**	55.1	
2.	**Direct Purchase**	10.8	
3.	**TRICARE**	2.6	

Type of Coverage		**% of Population Coverage**	
Any Public Plan		34.4	
1.	**Medicare**	17.8	
2.	**Medicaid**	17.9	
3.	**VA/CHAMPVA**	1.0	

Source: United States Census Bureau[19]

The data illustrates that most of the population is covered under some health plan. But this does not mean that the state provides for such insurance. Each of these plans requires a close scrutiny to determine whether the health care of America fulfils the promise of serving its citizens.

Private Health Plans

The data depicted above shows that the vast majority of the population relies on Private health plans. It is evident that there is a stronger tilt towards the Employer-provided health benefits. It is pertinent to mention that even though the scheme is voluntary, the predilection exists for a reason. It is because when employers pay wages in the form of health benefits, it is neither subject to personal income tax nor the Social security tax.[20] It results from decisions that were taken during World War II with no thought to how they would impact health care.[21] It leads to a disadvantage for the people purchasing health insurance on their own as it narrows the market and makes it expensive.[22] Such high expenditures have the potential to hurt the economy.[23]Even if an employee enjoys coverage under a plan, the coverage may be subject to pre-existing clauses. It may not provide for all-inclusive coverage and cost containment limits the access of care to an individual.[24] These are in the form of limitations in non-hospital services such as visits to the physician or inpatient services such as mental health care and treatment for alcohol and drug abuse.[25]

There exists a consensus among most non-economists that the major chunk of liability of health insurance is borne by the employer.[26] It projects the system as one based on the concept of welfare. But it is not representative of empirical evidence and facts. Workers bear the large proportion of healthcare costs through reduced wages.[27] But one also needs to factor in the rising costs of healthcare in America. The health

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[19] *Health Insurance Coverage in the United States: 2018*, United States Census Bureau, available at https://www.census.gov/library/publications/2019/demo/p60-267.html, last seen on 27/12/2019.
[20] Supra 13.
[21] J.V. Kennedy, *Fixing American Health Care*, The New Atlantis 47, 48 (2008).
[22] Ibid, at 49.
[23] B.M.J. *Crisis in American Health Care*, 300 British Medical Journal 765, 765 (1990).
[24] W.J. Wiatrowski, *Who really has access to employer-provided health benefits?* 118 Monthly Labor Review 36, 41-42 (1995).
[25] T.P. Burke & R.S. Jain, *Trends in employer-provided health benefits*, 114 Monthly Labor Review 24, 27-28 (1991).
[26] L.J. Blumberg, *Who pays for Employee-sponsored health insurance?*18 Health Affairs 58, 59 (1991).
[27] Ibid.

care spending increased by 4.6 percent in 2018.[28] Since the major chunk of the burden falls on the workers, it is reasonable to conclude that the workers will bear most of the burden of this rise in the form of inflation-eroded wages.[29]

The disproportionality of increase in deductibles and wages has led to unaffordability of Employee-sponsored Health Schemes in certain sectors. In the survey by Kaiser Foundation, it was found that there has been an increase in the amount of premiums without inflation.[30] It has resulted in the rise of Worker Contributions without a commensurate increase in the wages.[31] It is estimated that deductibles have risen from $826 to $1,655 on average.[32]It is leading to a steady evaporation of the disposable income of a worker thereby pulverizing the economy. The exhortation of Employee-based plans was bed-rocked on the principle of 'welfare capitalism'. But a scrutiny of the situation reveals an alternative reality. It comprises a grim actuality, which focuses on the quantity of people who are insured rather than quality of care. To further strengthen the arguments pointed by the researcher, reliance is placed upon the case of *Burnwell* v. *Hobby Lobby Stores*[33]. It allowed for an employer to deny reproductive medical coverage to workers if it did not align with the religious ideology of the employer on reproductive rights.

The statements made by the researcher have the potential to be misconstrued. The health insurance system of America is not a complete failure. It at least offers some degree of coverage to the majority of the nation. But, as pointed out, it needs to adopt a system of 'care' rather than 'insurance'. Care should not be interpreted as an empty locution. It should denote a holistic idea, which focuses on affordability and accessibility, which permeates all classes without any regard to financial standards. It should strive to create a public-private partnership with powerful built-in incentives to control costs with improving quality.[34] The

[28] *Historical|CMS*, Centers for Medicare & Medicaid Services, available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and Reports/NationalHealthExpendData/NationalHealthAccountsHistorical, last seen on 30/12/2019.
[29] B.D. Sommers, *Who really pays for health insurance? The incidence of Employer-provided health insurance with sticky nominal wages*, 5 International Journal of Health Care Finance and Economics 89, 93 (2005).
[30] *2019 Employer Health Benefits Survey*, The Henry J. Kaiser Family Foundation, available at https://www.kff.org/report-section/ehbs-2019-summary-of-findings/#figurea, last seen on 30/12/2019.
[31] Ibid.
[32] *Health Insurance premiums increased more than wages this year*, CNBC, available at https://www.cnbc.com/2019/09/26/health-insurance-premiums-increased-more-than-wages-this-year.html, last seen on 30/12/2019.
[33] Burnwell v. Hobby Lobby Stores, 573 U.S. 682 (2014, Supreme Court of the United States).
[34] J. Hacker, *The Health Care for America Plan*, 16 New Labor Forum 30, 32 (2007).

goal should be to increase drug coverage without sole reliance on private plans.[35] Moreover, it is time to obviate the administrative burden caused to the employer in providing health insurance.

Public Health Plans

Even though the vast majority of the nation does not subscribe to the Public Health Plans, it forms the fulcrum of the debate. A nation, which seeks to adopt the doctrine of 'care', has to give due recognition to these initiatives. It is no secret that America symbolizes the bellwether of capitalism but it does not dilute the importance of these plans. They cater to a part of the society which is unable to subscribe to a Private Health Plan. It can be the people who do not have the financial means or who do not form a part of the workforce to be eligible for an Employee-sponsored plan. The Public Health Plans have three distinctions in America: Medicare, Medicaid and VA.

MEDICARE: It provides health coverage for the aged and people with certain disabilities.[36] These people do not form a part of the workforce and are not subject to any employee-sponsored health plans. It is primarily funded by taxes of the workforce and transferred for the benefit of the aged beneficiaries.[37] As of 2019, employees contribute about 7.65% of their pay checks to programs relating to Social Security (6.2%) and Medicare (1.45%).[38] It offers subsidized treatment to people with certain ailments such as ALS or permanent kidney failure. It has several parts: Part A covers hospitals and nursing facilities; Part B covers preventive services such as doctor visits, diagnostic tests; Part C is known as Medicare Advantage, which offers additional benefits; and Part D covers prescription drugs.[39] Since it is funded by federal taxes, people often are under the impression that Medicare is free. But any such assertion shall be regarded as a myth.

It is true that the initial limb of Medicare (Part A) is free of cost; however, the remaining portions do not form a part of the complimentary services. It requires beneficiaries to share a portion of their costs through

[35]Ibid, at 33.
[36] Supra 13.
[37] Ibid.
[38] *Medicare Definition*, Investopedia, available at https://www.investopedia.com/terms/m/medicare.asp, last seen on 3/1/2020.
[39] *How Does Medicare work?*, The Motley Fool, available at https://www.fool.com/retirement/general/2016/05/22/how-does-medicare-work.aspx, last seen on 3/1/2020.

premiums, deductibles and coinsurance.[40] It shall be stated that Medicare only pays for slightly more than half of healthcare costs.[41]

For the purposes of the research work, analysing the tax structure is of paramount importance. Medicare is funded from three sources: 43% from General Revenue; 36% from payroll tax contributions; and beneficiary premiums contribute about 15% of the expenditure.[42] A major chunk of 15% of the total federal budget has been allotted to Medicare amounting to $605 billion.[43] The fund allocation to Medicare is certainly laudable, but it begs the question: whether it gets the job done? We shall undertake a swift analysis of the problems associated with the system to construct a better alternative for India.

It incurs large out-of-pocket expenses for services not covered by Medicare, such as prescription drugs, dental care and nursing home care.[44] The promulgation of Medicare has led to expansion of health coverage. It has been shown that an increase in insurance health coverage will lead to an increase in physicians' fees.[45] The same has been the situation in the USA. The federal government is significantly overpaying managed care companies to help Medicare to subsist.[46]The real problem in the American health care is high costs for everyone resulting in insufficient coverage for the elderly.[47] Medicare requires restructuring while retaining the risk pooling and redistributive functions.[48] Despite the several lacunae associated with the system, the researcher indubitably asserts that Medicare at least offers some sort of an alternative to Private Insurance. The system needs to lay more stress on the "care" aspect indoctrinated in its terminology.

MEDICAID: It offers health coverage for the poorer sections of the American society. As mentioned above, the financing of Medicare relied

[40] M.A. Scala-Foley, J.T. Caruso, R. Ramos & S.C. Reinhard, *Making Sense of Medicare: The Top 10 Myths about Medicare*, 104 The American Journal of Nursing 34, 34 (2004).
[41] M.A. Scala-Foley, J.T. Caruso, R. Ramos & S.C. Reinhard, *Making Sense of Medicare: Medicare's Hidden Price Tag*, 104 The American Journal of Nursing 32, 33 (2004).
[42] *The Facts on Medicare Spending and Financing*, Kaiser Family Foundation, available at https://www.kff.org/medicare/issue-brief/the-facts-on-medicare-spending-and-financing/, last seen 3/1/2020.
[43] Ibid.
[44] K. Davis & D. Rowland, *Medicare Financing Reform: A New Medicare Premium*, 62 The Milbank Memorial Fund Quarterly: Health and Society 300, 304 (1984).
[45] L. Huang, *Controlling inflation of Medicare Physcians' Fees*, 3 Policy Analysis 325, 325 (1977).
[46] J. O'Keefe & J.A. Lamphere, *Saving Medicare*, 14 Issues in Science and Technology 65, 69 (1998).
[47] T. Marmor, J. Oberlander& J. White, *Medicare and the Federal Budget: Misdiagnosed Problems, inadequate solutions*, 30 Journal of Policy and Management 928, 931 (2011).
[48] K. Swartz, *Medicare Reform Should be More Than Federal Budget Reform- And It Should be Done Soon*, 34 Inquiry 5, 7 (1997).

upon the Federal Budget; it is not the case with Medicaid. Both the Federal and State government jointly fund Medicaid.[49] The share of the Medicaid funding received by the states varies on the level of poverty in the state. It suggests that the poorer states shall receive a higher match from the Federal Government.[50] In any case federal funding for the same would not go below the floor of 50%. Hence, an aggregate of 62.5% of funding was received by the states for funding Medicaid.[51] The costs attributed to the Federal government are lessened as the two authorities share the costs. Moreover, it acts as the largest federal revenue for states.[52]

The discernible inquisition, which follows, is the liability of state funding. How can the states fund their share of the remaining Medicaid expenditure? Most states use the provider taxes and intergovernmental transfers to fund the remaining of the outlay.[53]The Provider taxes are taxes imposed on health care providers such as inpatient hospital services and nursing facilities.[54] A paragon for the same can be taken as Colorado, which used its hospital provider fees to extend services to parents and children.[55]They have instituted at least one provider tax for funding. The Affordable Care Act ("ACA")[56] also has its own positive financial benefits for the state. It stated that the states, which expand under the ACA, would receive 100% federal funding for covering the newly eligible with gradual reduction to 90% starting in 2020.[57] It has been extrapolated that expansion under the ACA leads to budget savings, revenue gains and also contributes towards overall economic growth.[58]

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[49] Laura Snyder & Robin Rudowitz, *Medicaid Financing: How Does it work and what are the implications?*, Kaiser Family Foundation, available at https://www.kff.org/medicaid/issue-brief/medicaid-financing-how-does-it-work-and-what-are-the-implications/, last seen on 23/3/2020.

[50] Supra 13.

[51] *Federal and State Share of Medicaid Spending*, The Henry J. Kaiser Family Foundation, available at https://www.kff.org/medicaid/state-indicator/federalstate-share-of-spending/, last seen on 4/1/2020.

[52] Robin Rudowitz, Kendal Orgera & Elizabeth Hinton, *Medicaid Financing: The Basics – Issue Brief*, The Henry J. Kaiser Family Foundation, https://www.kff.org/report-section/medicaid-financing-the-basics-issue-brief/, last seen on 4/1/2020.

[53] Ibid.

[54] Ibid.

[55]*States and Medicaid Provider Taxes or Fees*, The Henry J. Kaiser Family Foundation, available at https://www.kff.org/medicaid/fact-sheet/states-and-medicaid-provider-taxes-or-fees/, last seen on 4/1/2020.

[56] Patient Protection and Affordable Care Act (Act of March 23 2010), (Unites States).

[57] G.M. Kenney, V. Lynch, J. Haley & M. Huntress, *Variation in Medicaid Eligibility and Participation among Adults: Implications for the Affordable Care Act*, Inquiry 231, 231 (2012).

[58] Madeline Guth, Rachel Garfield & Robin Rudowitz, *The Effects of Medicaid Expansion under the ACA: Updated Findings from a Literature Review*, The Henry J. Kaiser Family Foundation, available at https://www.kff.org/medicaid/report/the-effects-of-medicaid-expansion-under-the-aca-updated-findings-from-a-literature-review/, last seen on 4/1/2020.

The expansion of services under the ACA coupled with Medicaid also deserves attention, as it is commendable. It is significantly important for persons with disabilities. It not only covers people with physical disabilities but also extends its umbrella to bring people diagnosed with mental illnesses and substance abuse disorders.[59] Studies have also suggested that Medicaid not only improves access to health care but also leads to measurable difference in certain health outcomes.[60] It has been found that the quality of care in Medicaid is equal to that provided in traditional fee-for-service plans and beneficiaries have also expressed satisfaction with the same.[61]

Although the public has expressed positive opinion towards Medicaid, it is also a system fraught with complications. A careful literature review is needed to shed light on these complications. These criticisms form the base of the American social welfare system, which has been described as "unusual", "wayward" or "deviant".[62] Firstly, the federal matching rate designed to equalize the ability of state to help it to provide health services to the poor has not met its objectives of redistribution. The current matching formula is based on the concept of state per capita income. The General Accounting Office has recommended shifting to a formula of the taxing capacity of the state and number of people living in poverty.[63] Dwelling on the said point, creation of right federal financial incentives for states to curtail or expand Medicaid spending is also the need of the hour.[64]

It has problems relating to coverage of the medical treatments. There are situations wherein sections, which belong to the low-income strata, have been denied coverage under the provision. To be eligible for coverage the families need to fall under a certain income standard set by different states. As a result, the program, which is meant to cater to the medical needs of the poorer groups, is not able to cover these individuals. Several cases have also been detected wherein the blanket of Medicaid has extended to people who do not fall under the criteria of low-income

[59] C.M. Grogan & S. Park, *The Politics of Medicaid: Most Americans are connected to the Program, Support Its Expansion, and Do Not View It as Stigmatizing*, 95 The Milbank Quarterly 749, 755 (2017).
[60] V. Sunkara& S. Rosenbaum, *The Constitution and Public's Health: The Consequences of the US Supreme Court's Medicaid Decision in NFIB v Sebelius*, 131 Public Health Reports 844, 846 (2016).
[61] *The Impact of Medicaid Managed Care on the Uninsured*, 110 Harvard Law Review 751, 758 (1997).
[62] S.K. Schneider, *The Impact of Welfare Reform on Medicaid*, 28 Publius 161, 165 (1998).
[63] R.J. Buchanan, J.C. Cappelleri & R.L. Ohsfeldt, *The Social Environment and Medicaid Expenditures: Factors influencing the Level of State Medicaid Spending*, 51 Public Administration Review 67, 71 (1991).
[64] T.W. Grannemann & M.V. Pauly, *Reform Medicaid First: Laying the foundation for National Health Care Reform*, 24 (1st ed., 2009).

because of the formula set by the State Government. Hence, state governments need to construct and conduct tests for income, assets and family composition similar to those of public assistance programs.[65] They have to ensure that the delivery of health welfare is not uneven and reaches the target mass i.e., the poorer sections of the society.

Since its inception, Medicaid has gone through landmark changes. The passing of any Act has its own political implications. After its promulgation, the US Supreme Court ruled that states expansion of the policy to their region is voluntary.[66] This allowed political interests to undermine and overshadow public welfare. For example, Republican governors disallowed the expansion of policy to their states and some ended up severely criticizing it. Currently, 14 states have not expanded the metamorphosed Medicaid to their state.[67] This leads to a gap wherein states where there is favourable public opinion towards the law are denied the benefit under the same. ACA set off an ideological warfare among which the people, especially the poor and the downtrodden are the sole victims. Since the advent of the Trump Presidency, the administration has tried to repeal the law and failed in its attempt. But it has been successful in bruising the key aspects of the law. An example can be seen in its elimination of the "Individual Mandate" clause. The clause imposed a penalty on the citizens of the country who had not subscribed to any health insurance. It imposed a mandate on the people to subscribe to health insurance or be subject to penalty. But the Trump administration has reduced the penalty to $0.[68] Thus, it has opened the doors for proliferation of uninsured people giving them no mandate to subscribe to a health plan.

It shall be clarified that the researcher does not promote the ACA. But it would be unwise of anyone to completely disregard the benefits it entails for the poor. It is accepted that the plan is fraught with its own complications. They require close scrutiny and discernible changes. Notwithstanding the faults, it is asserted that the promulgation of the ACA was a step in the right direction. The intent of the legislature to provide healthcare for the poor and the needy is imbibed in the text of the Act. The provisions of the ACA would make a guiding principle for any country, which wants to provide health care to its poorer classes.

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[65] K. Davis, *Achievements and Problems of Medicaid*, 91 Public Health Reports 309, 313 (1976).

[66] C. Brecher & S. Rose, *Medicaid's Next Metamorphosis*, 73 Public Administration Review 60, 62 (2013).

[67] *Affordable Care Act Medicaid Expansion*, National Conference of State Legislatures, available at https://www.ncsl.org/research/health/affordable-care-act-expansion.aspx, last seen on 5/1/2020.

[68] *Trump is trying hard to thwart Obamacare. How's that going?,* NPR, available at https://www.npr.org/sections/health-shots/2019/10/14/768731628/trump-is-trying-hard-to-thwart-obamacare-hows-that-going, last seen on 5/1/2020.

2. Canada: The Light-Bearer for Publicly Funded Health Care Systems?

In the following section, we seek to analyse the health care system of Canada. The Canadian model of health care follows a need-based ideology rather than focusing on the ability to pay. Based on the socialist notion, it lays paramount reliance on the publicly funded health care system. Firstly, we shall undertake the task to understand the financing of the system based on the principle of "layering".

Canada spends 7.7% of its GDP on Public health expenditure and 2.8% is spent on Private health expenditure.[69] This stands in stark contrast to its immediate neighbour, America where both expenditures are almost equal i.e., 8.4% (Private) and 8.5% (Public).[70] As stated above the financing is based on the concept of layering of services. For better understanding, the researcher has constructed a table using relevant literature[71]:

Layer Number	**Service(s) Provided**	**Financing**
1.	It comprises necessary hospital services such as diagnostic and physician services. [This is otherwise termed as 'Medicare']	Financing is done through general tax revenues and provided as free at the point of service as required by the Canadian Health Care Act.
2.	It contains outpatient prescription drugs, home care and institutional long-term	It is done through a mix of public and private insurance coverage and out-of-pocket payments.

[69] *Core Indicators-Visualization*, PAHO, available at https://www.paho.org/data/index.php/en/indicators/visualization.html, last accessed on 5/1/2020. ["PAHO stands for Pan-American Health Organization is an association of WHO. It extracts data from the American Continents relating to all health indicators."]
[70] Ibid.
[71] D. Martin, A.P. Miller et al, *Canada's universal healthcare system: achieving its potential*, 391 Lancet 1715, 1721 (2018).

	care. Different provinces and territories have a diverse mix of health care in this layer.	
3.	It includes dental care and outpatient physiotherapy and routine eye care for senior citizens.	Financed almost entirely using private sources using supplemental insurance such as employer sponsored insurance schemes.

The Canadian model adheres to the dictum of decentralization. It is the primary job of the provinces to provide its citizens with healthcare. The bills of providing healthcare vastly go to the provinces. The Federal government was unable to attain any sort of consensus with the provinces; hence it introduced a plan that no province could refuse. It agreed to pay half of the costs of the hospitals and doctors contingent on the fact that the provinces agree to some basic principles.[72] The Federal government used its spending capacity to accommodate the provinces, which helped Canadian healthcare usher in a uniform National Plan.

Understanding of funding and administrative methods is critical for building a model for the Indian population. The funding is generated primarily through corporate and personal income taxes. Some provinces also use other financial sources such as sales tax and lottery proceeds.[73] In order to avail health one must apply for a health card.[74] New residents to any province/territory shall apply for health coverage.[75] It is estimated that expenditure on healthcare shall amount to 11.6% of Canadian GDP in 2019.[76] 70% of this expenditure is borne by the Public sector and the rest is covered by the Private sector.[77] It also stands in stark contrast with its immediate neighbour. Canada discourages private financing

[72] P. Armstrong & H. Armstrong, *Decentralized Healthcare in Canada*, 318 British Medical Journal 1201, 1201 (1999).
[73] *Health Care Funding*, Canadian Health Care, available at http://www.canadian-healthcare.org/page8.html, last seen on 5/1/2020.
[74] *Provincial Health Insurance*, Canadian Health Care, available at http://www.canadian-healthcare.org/page3.html, last seen on 5/1/2020.
[75] Ibid.
[76] *National Health Expenditure Trends 1975-2019*, Canadian Institute for Health Information, available at https://www.cihi.ca/en/national-health-expenditure-trends-1975-to-2019, last seen 5/1/2020.
[77] *Who is paying for these services?*, Canadian Institute for Health Information, available at https://www.cihi.ca/en/who-is-paying-for-these-services, last seen on 5/1/2020.

alternatives to Medicare and the people cite justifications for the same. The primary argument asserted by them is based on the notion that privatization shall lead to creation of a 'health divide'. Primarily, this divide would exist on the basis of services provided to the beneficiary. It leads to the creation of two basic parties on the basis of their economic status i.e., Gods and Clods. The reason lies in the typical model of a private healthcare system; the distribution of services is based on the ability to pay for the services.[78] The Canadian system seeks to bridge this divide and create a system wherein benefits of healthcare are accessible to all despite their economic situation. Any differences in the timelessness and scope of access by income level would violate a strict egalitarian criterion.[79]

The Canadian system has tried to remove the profit maximization aspect from the health care sector. Most of the hospitals in Canada operate on a non-profit basis and receive payments from their respective provincial governments.[80] It is an indisputable fact that Canadians receive medical care without financial barriers and this achievement has made Canadian healthcare system a popular model for the world.[81]Although the system is publicly funded, most of the services are provided privately. Most of the hospitals are non-profit private societies or corporations. Even long-term institutional care is owned by variegated non-profit, state-owned or for-profit with different mixes in different provinces.[82] They have rid the medical industry of their voracity for profits and hammered a system, which exudes healthcare as a right for its citizens.

The Canadian system of healthcare also assumes the role of the frontrunner in maintaining healthcare on a global scale. It is one of the few states, which has shown adherence to the principles advocated by the WHO. The nation has contributed to negating the concept of self-interest. It has sought to replace it with the humanitarian grounds of moral and assistance. It emanates such adherence by ensuring that Canada and other actors under Canadian jurisdiction do not deny the fulfilment of Universal Human Rights including the Right to Health.[83] In

[78] K. Bedard, J. Dorland et al, *Needs-based Health Care Funding: Implications for Resource Distribution in Ontario*, 33 The Canadian Journal of Economics 981, 983 (2000).
[79] S. Globerman & A. Vining, *A Policy Perspective on "Mixed" Health Care Financial Systems of Business and Economics*, 65 Journal of Risk and Insurance 57, 60 (1998).
[80] E. Vayda, *The Canadian Healthcare System: An Overview*, 7 Journal of Public Health Policy 205, 206 (1986).
[81] M. Livingston, *Update on Healthcare in Canada: What's Right, What's Wrong, What's Left*, 19 Journal of Public Health Policy 267, 268 (1998).
[82] S. Lewis, C. Donaldson *et al*, *The Future of Health Care in Canada*, 323 British Medical Journal 926, 927 (2001).
[83] D. McCoy, R. Labonte & J. Orbinski, *Global Health Watch Canada? Mobilizing the Canadian Public Health Community Around a Global Health Advocacy Agenda*, 97 Canadian Journal of Public Health 142, 142 (2006).

lieu of several studies and empirical studies, this universal coverage of physician services ameliorates the socioeconomic differences in mortality.[84]

Although the Canadian system has its merits, it is short of a perfect setup. As is the case with any policy-inducted system, it has its own shortcomings. The Canadian system has the potential of leading to monopolization. The existence of public monopoly over healthcare impedes innovation in the delivery of healthcare. The Canadian system has failed to incorporate new techniques such as Managed Care, which has elicited commendable results in the USA.[85] It also affects the technological innovations in healthcare. Technology is as important to healthcare as it is to any other sector.[86] Lack of innovations in healthcare technology would stymie the growth of essential technological advancements, which prevent premature death and disability. There have been suggestions made by several research assessments to introduce agencies to identify new healthcare technologies and disseminate such information to the provincial governments and the healthcare providers.[87]A public-funded system may also suffer from financial difficulties. The Canadian Healthcare system has witnessed a bumpy history. During the evolution, which ultimately led to the Canadian Healthcare Act [**"**CHA**"**], it suffered from serious economic breakdowns. CHA also did little to resolve the underlying fiscal problems associated with the system and curtailed the tools available to the provinces for dealing with them.[88] There are no disputes to the fact that Canada spends a considerable amount of GDP on its healthcare. If one spends such an extravagant amount, it is expected that efficiency of services be guaranteed. But studies conclude that Canadian Healthcare is highly inefficient in terms of wait listing its patients.[89] There have been suggestions made in this regard to introduce new practices and increase inputs.[90] Canada manages to spend too much to gain too little. Despite spending more than most countries in the OECD, it sits at best in the middle of the pack when it comes to health outcomes and measurable

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[84] P.J. Veugelers & AM Yip, *Socioeconomic Disparities in Health Care Use: Universal Coverage Reduce Inequalities in Health?*, 57 Journal of Epidemiology and Community Health 424, 427 (2003).
[85] H.S. Webber, *The Failure of Healthcare reform: An Essay Review*, 69 Social Service Review 309, 312 (1995).
[86] D.E. Angus, *Technological Innovations in Health Care: The Need for Technological Assessment*, 79 Canadian Journal of Public Health 414, 414 (1988).
[87] D. Feeny & G. Stoddart, *Toward Improved Health Technology Policy in Canada: A Proposal for the National Health Technology Assessment Council*, 14 Canadian Public Policy 254, 262 (1988).
[88] J. Jordan, *Federalism and Health Care Cost Containment in Comparative Perspective*, 39 Publius 164, 180 (2009).
[89] A. Abeney & K. Yu, *Measuring the Efficiency of the Canadian Health Care System*, 41 Canadian Public Policy 320, 325 (2015).
[90] Ibid.

satisfaction with the system.[91] It seems as if Canada can no longer afford to pay for its healthcare and significant changes have to be made. The proposed solutions would increment American features and thus, attract American problems with healthcare. Therein lies the challenge of replacing or appending features of a foreign system while avoiding the inherent problems associated with the foreign policy.[92]

Therefore, any assertions, which champion the Canadian healthcare as a "perfect" system, would be a fallacy. But the researcher exhibits no qualms in appreciating the results it has elicited for the Canadians. The analysis of the system gives an impression of the efforts of the government to provide healthcare to its citizens despite financial considerations. The intent of the legislature is also unquestionable in this regard and we hope that the system attains the perfection it deserves.

IV. HAMMERING A HEALTHCARE POLICY FOR INDIA: CAN BHARAT FULFIL THE OBLIGATIONS TOWARDS ITS CITIZENS?

"There's nothing more important than our good health – that's our principal capital asset."- Arlen Specter

India strives to attain welfare for its citizens.[93]It aims to frame policies, which ensure the health and strength of workers, men and women and prevent the abuse of tender age of children.[94] It directs the states to regard improvement of public health of its citizens as a primary goal.[95] The Ministry of Health and Family Welfare ["MoHFW"] is accountable for the attainment of these goals. The Vision, Mission and Objective statement released by the MoHFW should draw the attention of every citizen of India. It seeks to attain the highest possible standard of well-being through preventive and promotive health care and universal access to good quality of health services.[96] But, such ambitious goals warrant a reality check to extrapolate whether these are just meaningless assertions, or efforts are being taken to fulfil them.

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[91] N. Smith, C. Mitton & P. Kershaw, *The reallocation challenge: Containing Canadian medical care spending to invest in the social determinants of health*, 107 Canadian Journal of Public Health 130, 130 (2016).
[92] R.A. Spasoff, *Health Department Administration of the Canadian Health Program*, 16 Journal of Public Health Policy 141, 149 (1995).
[93] Art. 38 (1), the Constitution of India.
[94] Art. 39 (e), the Constitution of India.
[95] Art. 47, the Constitution of India.
[96] *Vision, Mission and Objective Statement of MoHFW*, Ministry of Health & Family Welfare, available at https://main.mohfw.gov.in/sites/default/files/Vision%2C%20Mission%20and%20Objective%20Statement%20for%20MoHFW%2024092019.pdf, last seen on 11/1/2020.

The researcher does not want to stress on the health indicators of the country. It seeks to analyse the financial and coverage aspects for the citizens. India is no stranger to economic inequality. The top 1% of the Indian population controls about 73% of its wealth.[97] This would suggest that accessibility to health services is also unequal. Now, has the government restructured its finances to allay the situation? The numbers seem to portray a resounding NO.

As a percentage of GDP, public expenditure on health is 1.02%.[98] According to the report, there is only one doctor for every 11,000 people and only Rs. 3 is spent on an average Indian's healthcare.[99] The public health expenditure is below the average expenditure on health in low-income countries.[100] These numbers represent the tip of the iceberg of the health crisis in India. It sheds light on the abysmal situation of health accessibility to India. But it raises the question whether steps can be taken to ensure that people are not denied medical care despite their financial conditions. It begs the question, whether the government can fulfil their obligations towards the goal of a welfare state? It also poses an ethical question of whether the citizens deserve more in the aspect of health care. The researcher in the upcoming section undertakes the job of hammering out a plan for India to restructure its economic policies to focus on the aspect of health care. The primary goal is to create a system wherein services can be offered to the people who do not enjoy the financial capacity to afford medical care for themselves.

3. Raising the Bar of Health Care: Creating an Institutional Framework

The following study primarily focuses on creating public health outlets and a framework for attaining health care standards for its citizens. The plan is to create a holistic framework wherein all citizens can reap the benefits.

Offering Primary/Emergency Health Care

Audacious plans are seldom realistic. At the current stage, there is no tangible plan for India to achieve Universal Health Coverage. It would be

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[97] *Income inequality gets worse; India's top 1% bag 73% of the country's wealth, says Oxfam*, Business Today, (30/01/2019) available at https://www.businesstoday.in/current/economy-politics/oxfam-india-wealth-report-income-inequality-richests-poor/story/268541.html, last seen on 11/1/2020.

[98] Ministry of Health and Family Welfare, Government of India, *National Health Profile 2018*, available at www.indiaenvironemntportal.org.in/files/file/NHP 2018.pdf, last seen on 11/1/2020.

[99] *National Health Profile 2018: Here's how India is healthwise*, The Indian Express (25/06/2-18), available at https://indianexpress.com/article/india/national-health-profile-2018-heres-how-well-india-is-health-wise-5228742/, last seen on 11/1/2020.

[100] Supra 88, at 188.

highly unrealistic for the government to undertake a plan, which would offer entire health coverage for its citizens. Hence, to bring the country in the path for offering medical coverage, we submit that the initial step would be to offer primary health services [**"**PHC**"**] to its citizens.

The current primary healthcare system is extremely rigid, making it unable to respond effectively to local realities and needs.[101]Therefore, a complete overhaul of the system is warranted. Starting with the financial aspect, it is a no-brainer that the nation needs to accord more importance to its health sector. Hence, the first step would be to pump more money into the system. Every country which aims to or provides UHC spends between 5-9% of their GDP on healthcare.[102] These governments pay about 75% of their medical care and control the balance of primary care and special care.[103] Although the per capita expenditure on health has increased in India, it still remains discernibly low in comparison to other countries.[104] India's neighbours, such as Sri Lanka, Myanmar and Indonesia are spending far more on healthcare than India.[105] Funding need not be redirected from current allocations to preventive care, but India can make health spending a priority like Defence.[106] In light of the same, we recommend increasing the expenditure of GDP to a more appropriate percentage in the aspect of health care i.e., at least 5% of GDP.[107] But, a sudden proliferation in the same is unrealistic; hence a gradual increase is recommended. The goal should be to attain such expenditure and proportionate budget allocation by the year 2025.

Secondly, reforming the tax structure and expanding the tax base is also recommended. A fiscal expansion for health can utilize alternate sources of domestic revenue mobilization.[108]Currently, the lower tax rate of 25% is only applicable to companies having an annual turnover of Rs. 250 crores. The 2019 budget, titled "Budget for New India 2019" expands the

[101] H.T. Pandve & T.K. Pandve, *Primary healthcare system in India: Evolution and challenges*, 1 International Journal of Health System and Disaster Management 125, 127 (2013).
[102] R. Duggal, *Challenges in Financing Healthcare*, 47 Economic and Political Weekly 22, 23 (2012).
[103] R. Gendler, *An American Physician's foray into Scandinavian healthcare*, 44 Scandinavian Journal of Public Health 225, 226 (2016).
[104] H. Chandna, *At 1.28% of GDP, India's expenditure on health is still low although higher than before,* The Print, available at https://theprint.in/health/at-1-28-gdp-india-expenditure-on-health-still-low-although-higher-than-before/313702/, last seen on 23/3/2020.
[105] R. Kaul, India's public expenditure on healthcare continues to remain lowest globally, Hindustan Times, available at https://www.hindustantimes.com/india-news/india-s-public-health-spending-lagging-behind/story-6YPZFSfWMVlHGipDXyUEFO.html, last seen on 23/3/2020.
[106] T.S. Ravikumar& G. Abraham, *We need a leap in healthcare spending*, The Hindu (07/02/2019), available at https://www.thehindu.com/opinion/op-ed/we-need-a-leap-in-healthcare-spending/article26196313.ece, last seen on 23/3/2020.
[107] Supra 96, at 23.
[108] S. Garg, *Universal Health Coverage in India: Newer Innovations and the Role of Public Health*, 62 Indian Journal of Public Health 167, 168 (2018).

scope to include all companies of up to Rs. 400 crores.[109] This shall expand the tax receipts for the country and a part of the same could be allocated to the healthcare. Since, the Union is recipient of all corporate taxes[110], the same shall be distributed to the states to setup facilities. But Health is a state subject[111], so the Centre has to work in consonance with the State government to work for their public health. The distribution of the same has to be done by firstly adopting an architectural correction in the current system. That is, if needed, create a separate Public Health Department[112] within the system to handle and distribute revenue among states.

For financing the state aspect, we recommend reallocation of sin taxes i.e., taxes and duties levied on alcohol and tobacco. Such allocation can be done without overburdening the state exchequer. Government can play a much stronger provider role using taxation and special levies to finance such provisions.[113] An additional 2% health cess on these products can increase the costs minimally and provide an additional Rs. 7 billion annually only from tobacco.[114] The same can be done for other products such as Alcohol. It is true that a cess of 0.3% is present for National Health Mission, but the same is allocated to the General Revenue Pool.[115] Such undefined allocation would not prove to be fruitful and strict allocation lines need to be drawn. This can be done by earmarking the receivables into a non-lapsable fund for the specific purpose of health.[116] Funnelling the money obtained from them would prove to be an effective model apart from offering a metaphoric tinge. These can prove to be an ideal vehicle for revenue mobilization, as the institutional framework for collection of the same already exists.[117] These taxes have the potential to generate vast amounts of revenue, which can

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[109] *Budget for New India 2019*, Press Information Bureau, available at http://pibphoto.nic.in/documents/Others/sectorwise-Info/tax/tax1.jpg, last seen on 12/1/2020.

[110] Sch. 7, List-I, Entry 85, the Constitution of India.

[111] Sch. 7, List – II, Entry 6, the Constitution of India.

[112] M. George, *Reinstating a 'public health' system under universal health care in India*, 36 Journal of Public Health Policy 15, 19 (2015).

[113] K. Tiruvarur et al, *How to provide Healthcare*, 47 Economic & Political Weekly 4, 5 (2012).

[114] R. Duggal, *Healthcare in India: Changing the Financing Strategy*, 41 Social Policy & Administration 386, 391 (2007).

[115] J.S. Anand, *Can Sin taxes on tobacco solve funding challenges in healthcare system*, Business Standard (16/04/2019), available at https://www.business-standard.com/article/b2b-connect/can-sin-taxes-on-tobacco-solve-funding-challenges-in-healthcare-system-117011000828_1.html, last seen on 22/3/2020.

[116] A.K. Shiva Kumar, *Budgeting for Health: Some Considerations*, 40 Economic & Political Weekly 1391, 1393 (2005).

[117] Ruth Lopert, *The new Syntax for "Sin" taxes: Framing health taxes to strengthen public finances and advance population health,* Centre for Global Development, available at https://www.cgdev.org/blog/new-syntax-sin-taxes-framing-health-taxes-strengthen-public-finances-and-advance-population, last seen on 12/1/2020.

be used to build public health infrastructure, undertaking awareness programs and fund research.[118]

Building on the concept of decentralized planning[119], participation of local bodies to ensure delivery of medical services is paramount. This shall include setting up of redressal mechanisms, ensuring democratic process, defining accountability roles and regular audits to check the use of funds. In order to address the problem of paucity of practitioners, private providers can be contracted on the basis of standardized rates and norms for service delivery.[120]

It is paramount to define as to how the states shall receive the finances from the Centre. It is asserted that the creation of a methodology to determine the distribution of funds between the states is important. It is suggested that an amalgamation of Core Economic Indicators such as the number of people below poverty line (BPL), demographic indicators (Population Density) and Core Health Indicators (Mortality Rates) shall be accounted to construct a methodology. The taxation capacity of the state shall be granted its due importance in the methodology. It would create a "primacy/priority" mechanism wherein states with severe health statistics would be disbursed a larger portion of funding.

Such a system would help to create and maintain medical institutions wherein citizens are provided with primary healthcare without cost. It would be affordable, accessible and available to all despite their income standards. Further, it helps to create a taxation model, which creates additional funds, which would prove helpful in the upcoming section(s).

Affordable Insurance Schemes for Secondary/Higher Healthcare

The people also need to be provided with provisions to finance their special healthcare requirements. These would include treatments, which go beyond the purview of Primary healthcare. Considering the population of India, it is unreasonable to assume that secondary medical care can be made free of cost for everyone. But the costs of secondary healthcare are on the rise and increasingly becoming unaffordable. Therefore, to cover these bills we recommend the institution of affordable insurance schemes.

[118] M.J. Joyner & D.O. Wamer, *The Syntax of Sin Taxes: Putting it together to improve Physical, Social and Fiscal Health*, 88 Mayo Clinic Proceedings 536, 537 (2013).
[119] A. Gupta, *Universal Access to Healthcare: Threats and Opportunities*, 46 Economic and Political Weekly 27, 30 (2011).
[120] A. Phadke, *Planning Healthcare for All?*, 46 Economic and Political Weekly 15, 17 (2011).

Apart from the BPL population, it is found that even the poor can now make small, periodic contributions that can go towards meeting their healthcare needs.[121] But it does not mean that the poor are armed with the financial capacity to subscribe to a private health plan. The health insurance scheme calls for a stratification of the citizens on economic status. Thus, a plan which is based on the financial status of individuals and public sponsorship, is the need of the hour.

There is no need of over-complication of the plan. There should be only one Universal Insurance Scheme [**"**UIS**"**], with stratification of premium amounts based on the economic capabilities. It is suggested that the BPL population should be provided with BPL identity cards, which can be used at every hospital around the country. The risk-pooling and fund-pooling characteristic would be able to distribute the risk over all the people of India. Plus, the higher income classes would pay a higher number of premium amounts but would assume an equitable amount of risk. This Consolidated Health Fund [**"**CHF**"**], which denotes the amount from all the premiums collected, would be used for bill payments for the special needs of the patient(s). But it is recommended that the CHF would not be used to pay the entire amount of the bill. It is suggested that this would cover only 50 – 60 % of the bill of the patient. The table below illustrated how the balance amount of the medical bills would be paid:

Layer Name	**Annual Income (Rs.)**	**Out-of-pocket Payments (% of Remaining Amount)**	**Centre: State (% of contributions in the remaining amount)**
Below Poverty Line	>= 27,000	0	75:25
Lower Income	27,000 – 1,00,000	10	65:25
Lower Middle Income	1,00,000 – 3,00,000	15	65:20

[121] R. Ahuja & I. De, *Health Insurance for the Poor: Need to Strengthen Healthcare Provision*, 39 Economic and Political Weekly 4501, 4501 (2004).

Middle Income	3,00,000 – 6,00,000	17.5	62.5:20
Higher Middle Income	6,00,000 – 10,00,000	20	60:20
Higher Income	10,00,000 and above	22.5	57.5:20
Below Poverty Line	>= 27,000	0	75:25

A plan based on the above model uses the vast population of India towards its benefit, particularly for fund pooling. It is paramount to ensure that people subscribe to such plans. Therefore, basing itself on the "Individual Mandate" clause of the US, there needs to be a provision, which ensures creation of a mandate for the people. The people who do not subscribe to any insurance plan shall be penalized for a certain amount to ensure that citizens subscribe to a plan.

Lastly, a smart card should be issued or the insurance information can also be linked to Aadhar/UIDAI for easy access to the database. It would help to remove any procedural difficulties that usually degrade the viability of such plans. Further, a consumer grievance redressal system shall be setup to address the problems of patients. It would help in identifying problems with the system and build consumer confidence.

Concluding, a clarification is stated that the researcher does not intend to imply that the above-mentioned plan will solve the health crisis of India. But any plan based on the principles and the model would definitely go a long way to ameliorate the current situation.

Funding & Encouraging Medical Research

The importance of innovation in any field cannot be overlooked. These advancements make the system more efficient and also bridge the gaps in the existing ocean of knowledge. It contributes towards discovering uncharted territories and stipulating methods to ease the lives of the individuals. Innovation in the medical field stems from the research undertaken by individuals to venture into the unknown and come up with

pharmaceuticals, technological advancements and methods, which help to form preventive and curative techniques. It is asserted that a country, which seeks to espouse RHC as a Fundamental Right, cannot overshadow the relevance of medical research.

With research incorporated into implementation efforts, healthcare systems become laboratories, producing ecologically valid findings that are generalizable.[122] The researcher warns that a system should not limit the scope of research to just making healthcare efficient. The idea of medical research extends far beyond the scope of such averments. It should be inclusive of making the system more efficient. The problems of the users shall be ruminated over and the subsequent changes should reflect the will of the people and of welfare.

It is suggested that appropriate amounts of funds should be earmarked for research. It should be ensured that overburdening of Central funds is not done on this aspect. Suitable amount of funds should be transferred to the states, and they should be responsible for setting up respective centres for undertaking medical research. These institutions shall be subject to central rules and submit audit reports to ensure proper use of funds.

An erudite nation would also place importance on the role of NGOs and civil societies to lend help to these institutions. Coupled with these institutions, it can make significant contributions to the training of research workers by providing personal support of limited duration to younger researchers and longer-term support for research workers in maintained institutes.[123]As long as an intention of goodwill and welfare plays a pivotal role in fostering relationships, the country would go a long way to eradicate and prevent harmful diseases.

Realisation of the importance of medical research is paramount in the contemporary age. It should be regarded as an investment in the future of a nation. Stressing on the "care" aspect includes research as an integral part of the future of medicine. Thankful to the power of medical research, we are now able to live 10 years more than the average in the 1960s.[124]

Further, it is submitted that research does not only restrict itself to fulfilling the national mandate of healthcare provision. It extends its wings towards contributing to the international development of medical

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[122] B.N. Doebbeling & M.E. Flanagan, *Emerging perspectives on Transforming the Healthcare System: Redesign Strategies and Call for Needed Research*, 49 Medical Care 59, 63 (2011).
[123] D.C. Evered, *Charitable Organisations in Medical Research*, 283 British Medical Research 1348, 1349 (1981).
[124] *Participating in Health Research Studies*, Countway Library of Medicine, available at https://guides.library.harvard.edu/healthresearch, last seen on 13/1/2020.

literature.[125] It contributes towards our obligations to various international instruments and treaties. Corporate interests should not bog down the purpose of improvement of health. Any advancement in the field of medicine is the collective asset for all mankind. Therefore, it is the humble submission of the researcher that to truly constitute a holistic perspective of medical care, research cannot be de-prioritized.

V. HEALTHCARE AS A FUNDAMENTAL RIGHT: VINDICATIONS UNDER CONSTITUTIONAL JURISPRUDENCE

"Of all forms of inequality, injustice in healthcare is the most shocking and inhumane"
- Martin Luther King Jr.

As we proceed towards the end of the paper, it is important to analyse the idea from a constitutional standpoint. Before initiating, we submit that the following passages reflect the tectonic part of the study. Without recognition under Constitutional philosophy, the above paragraphs hold little relevance and can never be implemented in letter and spirit.

Healthcare should be viewed as an empowerment mechanism. People should be given a chance to be active participants in their own medical care and should not be relegated to passive recipients.[126] It acts as a positive catalyst in the field of human development. Jarring are those instances wherein people are denied healthcare on the basis of their financial conditions. The aim of a "welfare state" loses its meaning if healthcare is not an essential limb of the same.

The Constitution offers us the "Right to Life" under Article 21.[127] The Hon'ble Supreme Court has held that Right to Health Care is a Fundamental Right under Article 21 read with Articles 39(e), 41 and 43 of the Constitution of India.[128] Health forms the fulcrum of the Right to Live with Human Dignity. This Right to Live with Human Dignity forms an integral concept under Article 21 of the Constitution.[129] It resonates that arbitrary interference with the life and livelihood of a person violates the principles of the Constitution. But, in lack of statutory recognition, these directions by the Hon'ble Apex Court would be deemed as derogation of the directions of the Court and the Constitution.

[125] The Lancet Editorial, *What is the Purpose of Medical Research?* 381 The Lancet 347, 347 (2013).
[126] *Health is Fundamental Right*, World Health Organization, available at https://www.who.int/mediacentre/news/statements/fundamental-human-right/en/, last seen on 13/1/2020.
[127] Art. 21, the Constitution of India.
[128] Consumer Education & Research Centre v. Union of India, (1995) 3 SCC 42.
[129] Bandhua Mukti Morcha v. Union of India, AIR 1984 SC 802.

RHC should not be construed as the Right to remain healthy by ignoring externalities. No government has the potential to offer such a right. Health is often dependent on factors that fall outside the control of humans. Diseases can also be consequences of genetic predispositions. This research study focuses on the role of the State as the provider of healthcare facilities. State can have control over its machinery and shape the political, socio-economic and ecological conditions of health.[130] We stress on the right of every citizen to access an appropriate level of healthcare, which leads to human development. We need to ask ourselves – Does the lauded concept of welfare include healthcare? The Constitution and its subsequent interpretations can be the guiding light of the answer to this question.

The researcher urges the citizens of India to realize their rights. It is time to reflect the humanistic intention of our forefathers in our practices. The exploitation of people has to come to a halt. If we continue practicing our current trends, the Constitution would be relegated to a meaningless set of principles. A complete overhaul is the need of the hour. It is stated that these discernible changes are not going to take place overnight. It requires continuous dedication. It has to emerge from the realization of the dignity and worth of individuals.

A right, which does not enjoy recognition in positive law, would be rendered useless. The researcher submits that non-recognition of RHC is passive discrimination. Freedom of discrimination has been embraced as a right that we can expect government to enforce not only when the government itself acts but also against private actors.[131] It is a humble submission that healthcare shall not be a luxury but a right by the virtue of one's existence.

VI. CONCLUSION

"Disease, sickness, and old age touch every family. Tragedy doesn't ask who you voted for. Healthcare is a basic human right" - Elizabeth Warren

Crippling healthcare plagues contemporary societies. No system of healthcare can attain the status of being a utopian setup wherein people do not perish due to health reasons. But such realities should not act as an impediment from striving to arrive at a higher standard of healthcare. With the fear of reiteration, there should be a large focus on the "Care" aspect of the word. It should not be treated as a term without any meaning. There should be a shared set of principles between healthcare providers, organizations, government and the public to realize the aim of

130 M. Krennerich, *Healthcare as a Human Rights Issue*, 30 (1st ed., 2017).
131 A. Barnes & M. McChrystal, *The Various Human Rights in Healthcare*, 25 Human Rights 12, 13 (1998).

achieving the highest standard of healthcare. Cooperation between affected parties is indispensable to establish healthcare as a human right.

There is a need to pool the resources to ensure the delivery of the right to the society. We need to define an adequate package for healthcare, which is ethically justifiable. It is certainly a herculean task but is not impossible. Successful development of such a concept would help the society to advance the debate on how to allocate the healthcare resources.[132] We mention the principles which require ardent adherence to realize the goal of healthcare for all: (1) Healthcare is a human right; (2) It should be practiced to generate the highest standard of health; (3) Delivery systems should focus on prevention of illness and alleviation of disability (4) Cooperation between parties is imperative and; (5) Individuals involved, have the responsibility to continuously increase the standard of quality.[133]

It is perturbing to see that an issue, which affects all despite status, receives such little attention. It is urged that India needs to vacate the driver's seat and check under the hood of its governance because there are things rattling under there, that a simple tape and screw cannot fix.

[132] P.E. Kalb, *Defining an "Adequate" Package of Health Care Benefits*, 140 University of Pennsylvania Law Review 1987, 1998 (1992).
[133] Tavistock Group, *A Shared Statement of Ethical Principles for Those Who Shape and Give Health Care*, 318 British Medical Journal 249, 250 (1999).

EXAMINING THE LEGAL FRAMEWORK GOVERNING DATA PROTECTION FOR FITNESS TRACKING WEARABLE DEVICES IN INDIA

*Rahul Krishna

ABSTRACT

Health wearables have become increasingly pervasive and have access to vast amounts of private data of users. The objective of this article is to assess the state of legislation and regulation to ensure data protection in the case of health wearables in India. It attempts to highlight the existing protections afforded to citizens and the gaps that remain.

The study uses Healey's definition of "consumer products for health monitoring" as the set of devices examined.[1] These devices are collecting extensive health-related data from users using wearables. The paper subsequently contextualizes the challenges to existing concepts of privacy protection that internet-of-things devices present with health data monitored by fitness trackers. It examines the shortcomings of existing models of data protection for the scale and specificity of data captured by such devices.

The Government has proposed the Personal Data Protection Bill and the Draft Digital Information Security in Healthcare Act (DISHA) in addition to existing legislation governing health related data. The study assesses the protections extended by these regulations to health data collected by fitness trackers. It analyses the conceptual approach to data protection taken by these legislations and how it has been implemented in the document. The definitions also help identify the differences in approach and areas that need to be reconciled to ensure effective protection to data owners. The paper examines the existing set of protections afforded by law to such data as a contrast to the changes proposed, wrapping up with analysis of case law taking the judiciary's thought on the privacy requirements of health data.

I. INTRODUCTION

The recent past has seen rapid expansion in the uses and adoption of wearable technology commercially available. The technology itself has grown with advances in miniaturization to become a part of everyday life for many. These advancements have made devices like fitness trackers commercially viable. The industry for fitness trackers has witnessed unprecedented growth, reflected in Google's valuation of fitness tracker

* Rahul Krishna, Research Assistant, Observer Research Foundation

[1] Jason Healey, Neal Pollard, and Beau Woods, *The Healthcare Internet of Things: Rewards and Risks,* Atlantic Council, available at https://www.atlanticcouncil.org/wp-6content/uploads/2015/03/ACUS_Intel_MedicalDevices.pdf, last seen on 14/12/2019.

manufacturer Fitbit at $2.1 Billion.[2] India has adopted such products rapidly as well, becoming the 3rd largest market for wearable devices in the world in 2019.[3] Studies estimate that 2019 saw the sale of a 100 million units of such devices all across the world and the number is expected to grow.[4] Research also shows that adoption in countries such as the US shows that one in five adults use fitness trackers, with the number being even greater for higher income groups.[5]

However, these devices also pose significant privacy risks for individuals with the nature of data being collected by them. Data collected by such wearable devices is some of the most intimate data for humans. Such data is highly valued by several industries and it is crucial to establish a robust framework for protecting such data. The privacy risks posed by fitness trackers were on display when a university student used publicly available tools to monitor the movement of military and intelligence personnel at highly sensitive military installations and through the same determine the exact location of these installations.[6] The discovery was part of a much larger privacy breach through a software that produced a global GPS-based heat map of fitness tracker users and could also be used to identify particular individuals through their social media presence.[7]

The scandal highlighted the privacy invasions that were possible due to such devices and the requirement of extensive privacy legislation to ensure users are protected from such invasions in the future. With privacy becoming an increasingly large concern in India, it is important to analyse the privacy risks posed by these devices as well as the protections afforded to citizens. Hence, the paper analyses challenges to privacy

[2] Akanksha Rana & Noor Zainab Hussain, *Google taps fitness tracker market with $2.1 billion bid for Fitbit,* Reuters, available at https://in.reuters.com/article/6us-fitbit-m-a-alphabet/google-taps-fitness-tracker-market-with-2-1-billion-bid-for-fitbit-idINKBN1XB47G, last seen on 14/12/2019.

[3] Nidhi Singhal, *India emerges third largest wearable market in Q2, 26019,* Business Today, available at https://www.businesstoday.in/technology/news/india-em6erges-third-largest-wearable-market-in-q2-2019/story/377302.html, last seen on 14/12/20196.

[4] F. Arriba-Pérez, M. Caeiro-Rodríguez, J. Santos-Gago, *Collection and Processing of Data from Wrist Wearable Devices in Heterogeneous and Multiple-User Scenarios*, US National Library of Medicine, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5038811/, last seen on 05/01/2020.

[5] E. Vogels, *About one-in-five Americans use a smart watch or fitness tracker*, Pew Research Center, available at https://www.pewresearch.org/fact-tank/2020/01/09/about-one-in-five-americans-use-a-smart-watch-or-fitness-tracker/, last seen on 12/01/2020.

[6] L. Sly, *U.S. soldiers are revealing sensitive and dangerous information by jogging*, The Washington Post, available at https://www.washingtonpost.com/world/a-map-showing-the-users-of-fitness-devices-lets-the-world-see-where-us-soldiers-are-and-what-they-are-doing/2018/01/28/86915662-0441-11e8-aa61-f3391373867e_story.html, last seen on 05/01/2020.

[7] K. Leetaru, *Mapping Spies Through Fitness Trackers And Phones: Privacy Is Dead Even For Those In the Shadows*, Forbes, available at https://www.forbes.com/sites/kalevleetaru/2018/07/20/mapping-spies-through-fitness-trackers-and-phones-privacy-is-dead-even-for-those-in-the-shadows/#3acaadc43681, last seen on 05/01/2020.

raised by fitness trackers and the approach used by existing and proposed legal frameworks to protect citizens from these challenges.

II. DEFINING THE SCOPE

King defines wearable technology as wearables that are augmented or manufactured using technology.[8] This makes the scope of wearable technology broad; including a host of fabrics synthesized or fabricated using technology. These may or may not provide any added functions to the wearable itself. This definition can be further narrowed by requiring smart wearables to provide users with additional information or entertainment, or collecting data through various sensors. Wearable technology can have two further sub classifications namely Wearable Computers and Smart Textiles.[9] Wearable computers refer to miniaturized computers which can be worn in the form of an accessory on one's person. Smart textiles on the other hand refer to fabrics which can measure parameters in the environment around them owing to either electronics or their natural properties. This research focuses on the ability of wearables to measure parameters while not necessarily interpreting or displaying the data measured on the device itself. Smart textiles therefore form an integral part of the paper, however, the data collection elements in wearable computers are also included.

The paper further narrows its scope to focus on applications of wearable technology which collect information relevant to a patient's health and bodily functions. Healey defines four categories of networked medical devices.[10] The first are consumer products which monitor health: these may include other functionalities but must measure one or more of the wearer's bodily functions such as heart rate or steps walked. These are off-the-shelf, commercially sold products which are often linked to smartphones to display parameters measured. Earlier versions of such watches or bracelets may fall under the category of smart textiles as these merely have sensors, whereas newer versions are often wearable computers which can execute several processes. The second category is wearable medical devices. These are devices that are worn on the body with wireless connectivity that may execute a prescribed medical function to ensure the user remains healthy. These devices are usually highly

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[8] M. King, *Six Human Factors to Acceptability of Wearable Computers*, Queensland University of Technology, 2011, available at https://eprints.qut.edu.au/50948/1/Madeleine_King_Thesis.pdf, last seen on 04/01/2020.

[9] T. Page, *A Forecast of the Adoption of Wearable Technology*, 6(2) International Journal of Technology Diffusion 12, 13 (2015).

[10] J. Healey, N. Pollard, B. Woods, *The Healthcare Internet of Things*, Atlantic Council, available at https://www.atlanticcouncil.org/wp-content/uploads/2015/03/ACUS_Intel_MedicalDevices.pdf, last seen on 20/12/2019.

specialised in the function they execute and are often worn by users for whom it is medically necessary. This is unlike the first category of products which are often bought to remain health conscious even if not medically necessary. The third categories of products are internally embedded medical devices which reside inside the body of the user, are connected wirelessly and perform a specialised medical function. These include devices such as modern pacemakers. These are normally medically necessary and inserted only by doctors when essential. The fourth categories of networked medical devices are stationary medical devices such as home-care ECG machines which are connected to the internet or other communication networks.

To limit the scope of this research, the intersectionality of networked medical devices and wearable technology will be studied. Using the classifications given by Healey and Page of the two above-mentioned product categories respectively, category one of networked medical devices which have fitness tracking functions of smart textiles will be studied.[11] This constitutes consumer-oriented fitness trackers that can be connected to smartphone applications or other networks and measure one or more health parameters. These devices will be grouped under the categorization of consumer-oriented fitness trackers for the study.

These devices are usually wrist-worn, watch or bracelet like devices available commercially. There are several new devices which include vests that track bodily functions, many of which are being used by professional athletes and their teams to monitor performance. The commercial sale and affordability of such devices is still limited, yet the paper will attempt to include them in the study as well. The innovation in this field is still booming and the market for these devices is predicted to grow in the future.[12]

III. HEALTH DATA COLLECTED BY POPULAR TRACKERS AND PRIVACY POLICY

Health-related data needs to be processed to provide insights to users themselves and can also be of great aid to medical research. De-identified data from these trackers provided to medical professionals for research can be used to prompt great advancements in the field. Researchers have previously used such data to track diverse parameters such as cardiac

[11] Wearable computers which are housed in accessories such that the accessories have sensors to measure health parameters are also included in the study. The functions of the device which correspond to smart textiles, that is the functionality which allows for measurement of the parameters, are taken into consideration.

[12] J. Jose P., *Smart fabrics: The thread goes tech*, The Hindu Business Line, available at https://www.thehindubusinessline.com/specials/technophile/smart-fabrics-are-poised-to-change-the-clothing-industry/article26934897.ece, last seen on 05/01/2020.

surgery recovery practices and diabetes onset analysis.[13] However, such data is also of great value to several other companies. It is therefore important to assess the privacy concerns arising from the collection of both health and non-health data on these trackers.

Category	Xiaomi	Apple	Fitbit
Data Collected	- Activity and Sleep - Heart Rate	- Activity and Sleep - Heart Rate - Heartbeat (ECG grade) - Fall detection	- Activity and Sleep - Heart Rate - Heartbeat - Ovulation cycles
Privacy Protection	Claims that it abides by principles of necessity and explicit consent in data collection and that data is not processed for any purposes other than those declared to the user. Allows users to unsubscribe from the collection of any particular data although warns users that	Stresses on the concept of informed consent, asking for permissions with clear explanations of the sensors being used. Claims that it does not share data with any third-party services for any marketing unless the user asks it to. The data collected for the improvement of third-party	Fitbit's privacy policy allows them to sell de-identified user data to third-parties for processing. These are often sold as aggregated non-personal information for research insights.

[13] S.F. Deangelis, Patient *Monitoring, Big Data, and the Future of Healthcare*, Wired, available at https://www.wired.com/insights/2014/08/patient-monitoring-big-data-future-healthcare/, last seen on 07/01/2020.

	it may lead to certain services being discontinued.	applications is collected with consent	
Gaps in Privacy Policy	Disputes to be settled in Chinese courts which do not have high privacy protection standards. Uses data for advertising, including health related data. Does not clarify what happens with data in event of a merger.[14]	Shares data with the company's affiliates.[15]	Fitbit app does not allow users to delete individual parameters, rather one can only choose to delete or keep certain categories of data. The default setting on the device is to collect and use all possible data.

The greatest issue with wearables arises from the amount of data that is being captured on these devices. As discussed above, several these devices have access to a wealth of real-time health and other related data about users which effectively can be used to generate health profiles of each user if data is not de-identified. The revelation of personal health data could have both financial and psychosocial harms for users.[16] Financial harms include denial of insurance or higher insurance premiums, loss of job and inaccessibility to jobs in certain sectors.[17] Psychosocial harms include stigmatisation of the individual and exclusion from communities based on health data obtained, a practice prevalent in India. Data obtained through such platforms can be used to discriminate

[14] Ibid.
[15] *Privacy Policy*, Apple.com, https://www.apple.com/legal/privacy/en-ww/ last seen on 06/01/2020.
[16] J. Lane, C. *Schur, Balancing Access to Health Data and Privacy: A Review of the Issues and Approaches for the Future*, 45 Health Services Research 1456 (2010).
[17] Ibid.

in the provision of public health services to certain communities or persons.

Internet of Things (**"**IoT**"**) devices such as wearables present new challenges to traditional approaches to privacy which need to be tackled as well. It is important to understand that the nature of the device and the nature of the data collected put together demand a rethink of some principles of privacy which are uniformly applied to devices while making policy.

A concept vulnerable to ineffectiveness in the IoT domain is notice and consent. Notice and consent are an integral part of several privacy frameworks including the proposed Personal Data Protection bill. However, most fitness trackers track a variety of parameters continuously which challenges the notice and consent model. If consent is to be taken for every data set captured with notice, it would lead to a high volume of notices which would lead to consent fatigue in users. Consent fatigue refers to users being overwhelmed by the volume of consent requests and leading to users not paying attention to the notice while giving consent. The former Chairwoman of the Federal Trade Commission also questions:

> *Will consumers understand that previously inert everyday objects are now collecting and sharing data about them? How can these objects provide just-in-time notice and choice if there is no user interface at all? And will we be asking consumers to make an unreasonable number of decisions about the collection and use of their data?*[18]

A vital issue with the notice and consent model in the healthcare sector is ensuring consent is informed. Often, users do not understand the extent of information that can be gleaned about them by processing the data they have consented to give. This lack of comprehension is pronounced in the healthcare sector as subject knowledge is required to fully assess the potential of data that a user consents to give. The US President's Council of Advisors for Science and Technology also noted that the notice and consent structure fail in the face of big data, the very kind that is being collected by these devices.[19]

The notice and consent model also seek granularity of consent to be effective. If the privacy structure obtains consent for multiple functions through a singular form, the user has little control over the nature of data they permit to be collected. It turns into a situation where a user is forced

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[18] A. Thierer, *The Internet of Things and Wearable Technology: Addressing Privacy and Security Concerns without Derailing Innovation*, 21(2) Richmond Journal of Law and Technology 6 (2015).
[19] Ibid.

to choose between consenting to the collection of a large variety of data or not using the service at all. Even though some companies have implemented granularity of consent in their designs, several privacy policies still fall short in this regard. Currently, consent is obtained for a large variety of health data through a single consent form. This makes the user decide between offering up large chunks of health data or not having access to a multiplicity of services at all.

A privacy issue common to most devices is ensuring irreversible de-identification of data. De-identification of data refers to the process of decoupling data about a user from the personal identifiers that may be used to identify a user. This issue is vital in allowing user generated data to inform medical research. Even if extensive health data is being collected about a user, it is not particularly damaging if the data cannot be linked back to the individual who generated it. This will allow for the generation of trends but will prevent profiling. Most fitness band companies collect a wealth of personal data about users in addition to health data and security measures must be used not just at the company server level but also with third party processors to ensure the two data sets cannot be correlated.

Privacy in healthcare also faces the challenge of users not being able to verify enforcement of privacy policies as advertised by service providers. While governments have begun implementing regulatory measures to conduct compliance verification, users in countries where this has not occurred are left in the dark. The issue is exacerbated with medical data due to a lack of user knowledge on the backend mechanisms for storing and sharing such data and not enough information being available about third-parties processing the data.[20]

Several wearable devices in the market have voice command functions enabled on them. These allow the microphone to be on at several times through a single consent form obtained from the user at the time of configuration. Due to this, such devices pose a threat to bystander privacy.[21] While users themselves may have consented to allow their conversations to be overheard by the device, bystanders may not have entered into the same consent agreement with the company. However, by having the microphone or other such sensors functioning, the device may detect information about bystanders that may violate their privacy. This maybe the case even in private spaces where there is a reasonable expectation of privacy that the bystander has. This issue is complicated by

[20] S. Haas, S. Wohlgemuth, I. Echizen, N. Sonehara, G. Mueller, *Aspects of privacy for electronic health records*, 80 International Journal of Medical Informatics 26, 31 (2011).
[21] P. Dutta, M. Chatterjee, A.S. Namin, *A Survey of Privacy Concerns in Wearable Devices*, IEEE International Conference on Big Data (2018), available at https://ieeexplore.ieee.org/document/8622110, last seen on 07/01/2020.

the fact that companies are trying to make smart textiles and wearables indistinguishable from regular accessories. Hence, for bystanders these inadvertently become concealed recording devices which pose a significant privacy threat. Manufacturers and data processors need to take steps to ensure that bystander data is filtered out and data collected is limited to the individual who has given consent.

These issues cannot be resolved by institutional regulation alone. It requires user awareness which will prompt companies to enhance their privacy and security standards. However, bringing user awareness in specialised areas such as health data collection continues to be a challenge which needs to be overcome. Additionally, the value of such data for research cannot be ignored and overregulation could lead to companies not sharing data for crucial medical research. A nuanced approach to protecting personal data while allowing for research through de-identified data or informed and explicit consent needs to be used in regulation of the space.

IV. LEGISLATION AND REGULATION IN INDIA

In 2018, in a landmark judgement, the Supreme Court adjudicated that the Right to Privacy is a protected fundamental right of Indian citizens under Articles 14, 19, and 21 of the Indian Constitution.[22] Since the judgement, there has been a renewed focus in New Delhi on creating legislation to protect the right to privacy by regulating the digital industry in India. Digital privacy for individuals is still largely protected by the Information Technology Act, however, there has been new legislation proposed to overhaul the frameworks through which data flow is regulated to protect privacy. This section analyses the salient features of the proposed legislation and assesses the protections afforded to citizens by existing legislation. It also tries to reconcile approaches to privacy by a variety of rules that may apply to health data to ensure a uniform, coherent structure that is easy to comply with.

V. PROPOSED LEGISLATIONS

1. Personal Data Protection Bill

The Personal Data Protection (**"**PDP**"**) Bill is a proposed legislation that revamps the digital privacy protection framework in India.[23]The Bill, which has been in the pipeline for some time, was introduced in the Lok Sabha in December 2019 and has been referred to the Standing Committee on Information Technology of the Parliament. A report from

[22] K.S. Puttaswamy v. Union of India, (2017) 10 SCC 1.
[23] The Personal Data Protection Bill, 2019 (pending).

the Standing Committee is expected in the 2020 Budget Session of Parliament post which the Bill can move forward.[24] The Bill draws inspiration from the General Data Protection Regulation passed in the European Union and follows a similar approach to privacy protection in the digital sphere.

The Bill seeks to establish a regime of data protection wherein data is collected and processed in a manner which is necessary, fair, transparent and requires the consent of the user from whom the data is being collected. The Bill defines several important concepts in digital privacy protection such as de-identification and anonymisation, which gives shape to India's interpretation of these principles.[25] The Bill seeks to create a Data Protection Authority in India which will create regulations and ensure standards are maintained for the protection of data. The Bill defines the mandate of the Authority and the powers it will have when created.[26]

The Personal Data Protection Bill is an overarching piece of legislation that covers most data generated, collected and processed in India. The scope of the Bill is beyond Indian jurisdiction alone and covers data generated by Indian citizens which may be stored or processed overseas. The Bill is expected to regulate most forms of data while ensuring sectoral regulators are consulted in the implementation of codes and regulations for sector specific data.[27]

2. Digital Information Security in Healthcare Act (DISHA)

The Digital Information Security in Healthcare Act, known commonly by its abbreviation, DISHA, was released by the Ministry of Health and Family Welfare.[28] The regulation was released for public consultation in March 2018 with comments invited on the document. There has been little progress with the Bill, which could have been delayed to ensure it is in line with the Personal Data Protection Bill.[29]

The Bill governs Electronic Health Data collected in India and places data protection regulations on medical establishments and other entities collecting such data. It also seeks to create a network of Digital Health

[24] *The Personal Data Protection Bill, 2019*, Parliamentary Research Service, India, https://www.prsindia.org/billtrack/personal-data-protection-bill-2019, last seen on 05/01/2020.
[25] Supra 25.
[26] Ibid.
[27] Ibid.
[28] Digital Information Security in Healthcare, Act, 2018 (pending).
[29] S. Agarwal, P. Raghavan, *Health Ministry may await DISHA from BN Srikrishna report*, Economic Times, available at https://economictimes.indiatimes.com/tech/internet/health-ministry-may-await-disha-from-bn-srikrishna-report/articleshow/65098136.cms, last seen on 09/01/2020.

Authorities, with a nodal national authority and several state authorities.[30] The Act was one of the first proposed legislations in India to define the rights of data owners and limit the scope of collection and processing of health data. The Act also hinges on a notice and consent model, akin to the PDP Bill.[31] The Act is focused on health data collected at clinical establishments, but widens its scope to additionally cover other forms of health data generated.

3. Reconciling the Personal Data Protection Bill and the Digital Information Security in Healthcare Act with regards to regulations on consumer-oriented fitness trackers

Owing to the definitions put forth in both regulations, there appears to be an overlap in the nature of data being covered. Both regulations define a variety of data and have separate definitions of health data as well which leads to a regulatory overlap. Due to this, it is important to analyse the nature of regulations these two legislations impose on health data and if they are reconcilable. It is crucial to do so to understand the breadth of regulations that govern health data produced by consumer-oriented fitness trackers.

Both sets of regulations have definitions of health data that could be interpreted as applying to health data produced by consumer-oriented fitness trackers. The Personal Data Protection Bill includes "data related to the state of mental and physical health of the data principal" as well as data collected in the course of provision of health services in its definition of the term "health data".[32] This could be interpreted as covering the data produced by fitness trackers as most contain data that is related to the physical health of the user and is used to provide a health service as well. DISHA covers the two above-mentioned forms of data as well "information derived from the testing or examination of a body part" in its definition of Electronic Health Data.[33] Hence, it could be easily construed that DISHA covers most health data produced by fitness trackers as well. Besides, the PDP Bill also covers health data within its definition of Sensitive Personal Data, bringing fitness tracker health data under the ambit of the category as well.[34]

The PDP Bill has certain provisions which will apply to most categories of personal data collected by fitness trackers, as well as other provisions for health data and sensitive personal data which will apply to certain sub-

[30] Supra 26.
[31] Ibid.
[32] Supra 25.
[33] Supra 26.
[34] Supra 25.

categories. Unlike DISHA, which only covers the health data components of data collected by fitness trackers, the PDP Bill governs elements of non-health related personal data that these trackers collect as well. Specifically, the Bill has provisions to ensure that necessary provision of health services is not blocked and that sensitive personal data such as health data puts a higher burden on companies than personal data.[35]

The PDP Bill does not bring under its mandate the regulation of anonymised data.[36] Hence, companies are free to use anonymised data from fitness trackers for advertising, transfer to third parties and other commercial purposes. This means that any data from which the personal identifier fields are encrypted or masked, can be used to analyse trends on location, health and application usage under the Bill. The Bill operates on a notice and consent model with descriptive conditions on the nature of notice that is to be given and how consent can be obtained. The Bill however sets out several exceptions to the requirement of consent for data processing. The data collector or processor is exempted from obtaining consent to respond to a threat to life or medical emergency of any individual.[37] This exception does not cover sensitive personal data, which means fitness trackers cannot use this exception to process health data of the individual without consent but may access data such as location or home address to respond to a medical emergency. If the data collector is the employer of the data principal, they can use personal data to recruit or terminate the data principal as well.[38] The Bill also ensures that consent does not restrict governmental agencies from accessing personal data.

The first recommendatory reports for the PDP Bill suggested a requirement of data localisation on all personal data. This meant that a copy of all personal data of Indian citizens had to be stored in the physical territory of India. However, the most recent iteration of the Bill imposes this requirement only on sensitive personal data.[39] This means that fitness tracking companies will have to store copies of health data collected on fitness trackers in local data centres when the Bill comes into effect and can only transfer the data overseas for processing when explicit consent for the same is obtained from the data principal. The Central Government shall form rules on codes of processing and storage of sensitive personal data.

[35] Ibid.
[36] Ibid.
[37] Ibid.
[38] Ibid.
[39] Ibid.

While the PDP Bill has overarching regulations for a variety of data, which are also applicable to data collected on fitness trackers, DISHA expressly regulates digital health data. Large parts of the legislation govern data from clinical establishments and health information exchanges; however, by bringing "entities" which include registered companies collecting health data into the ambit of the legislation, fitness tracking companies can be interpreted to be included. DISHA outlines a digital data protection model through a rights-based approach for data owners.[40] It affords data owners several rights which give them protections against the misuse of their data and breaches of privacy. Under these rights, the owners of data have the right to refuse consent from data being generated altogether.[41] For fitness trackers, this would mean that while this data cannot be collected, it also cannot be recorded at the first instance by the sensors within the device if the relevant section is interpreted such.

A key issue with the DISHA regulations is that they prevent health data being collected on fitness trackers from being used for medical research.[42] It allows only for electronic health data captured by clinical establishments to be used for any academic research and does not allow data captured by other entities to be used for this purpose under Section 29[43]. Even for clinical establishments, it allows such research to be done only with de-identified or anonymised data with no personal identification permitted. The legislation protects data of users from being used for commercial purposes, disallowing the same even if consent is obtained.[44] The legislation expressly disallows insurance companies from insisting to access data for clients purchasing health insurance if the user does not consent to the same. DISHA imposes significant penalties on entities failing to comply with the rules and if put into effect will help strengthen the privacy protections on health data afforded to users.

VI. ASSESSING CONCEPTUAL DIFFERENCES IN THE LEGISLATIONS PROPOSED

The two bills differ in defining several other salient concepts as well, which when applied concurrently may cause compliance issues for companies. DISHA defines anonymisation as "the process of permanently deleting all personally identifiable information" from an individual's records.[45] On the other hand, the PDP Bill defines anonymisation as an "irreversible process of transforming or converting

[40] Supra 26.
[41] Ibid.
[42] Ibid.
[43] Supra 28.
[44] Ibid.
[45] Ibid.

personal data to a form in which a data principal cannot be identified".[46] While the definition of anonymisation under the PDP Bill only requires an irreversible de-linking of data sets which serve as personal identifiers from other personal data, DISHA requires companies to delete all personal data altogether when implementing anonymisation. The regulations on anonymised data in the two bills also differ. The PDP Bill excludes anonymised data from the purview of the regulations under the Bill and does not regulate such data at all. On the other hand, DISHA in Section 29(5) mandates that even anonymised digital health data cannot be accessed for commercial purposes and by insurance companies, pharmaceutical companies or employers.[47] Hence, it may be construed that while the PDP Bill allows anonymised data collected from fitness trackers to help advertisers with directed advertising, DISHA does not allow even anonymised data to be used for this purpose as it is "commercial" in nature.

The notice and consent model is distinct in these two legislations. DISHA defines consent as "expressed informed consent given by the owner after understanding the nature, purpose and consequences of the collection, use, storage or disclosure of the digital health data".[48] The PDP Bill has a more elaborate definition of consent, employing certain tests to ensure that the data principal is giving informed consent. The PDP Bill requires consent to be free,[49] informed,[50] specific,[51] clear, and capable of being withdrawn.[52] Additionally, the PDP sets a higher standard for consent for Sensitive Personal Data, which includes health data. The Bill requires data processors, before obtaining consent, to inform principals of any processing that may cause significant harm to the principal. After giving the principal the option to consent separately to sharing various kinds of sensitive personal data, it provides granularity of consent.[53] The PDP Bill also places the burden of proof for showing that the consent was obtained on the party collecting the data and not on the user.

While the PDP Bill may have a more descriptive definition of consent, DISHA gives the data owner several consent-oriented rights. DISHA

[46] Supra 25.
[47] Supra 26.
[48] Ibid.
[49] Complying with the standard of 'free' specified in Section 14 of the Indian Contract Act, 1872.
[50] Informed consent can only be given when the data principal has been provided with the requisite data under Section 7 of the same bill. This includes information about what kind of data is being collected, who is processing it, how the data is transferred, how long the data is retained and the purpose for processing the data among others.
[51] Specific consent means that the data principal should understand the scope of data he or she is giving consent for through that particular consent form.
[52] Supra 25.
[53] Ibid.

administers granularity of consent to data owners in a different manner than the PDP Bill. DISHA allows for the data owner to provide or withdraw consent at each step of the data flow, a feature missing in the PDP Bill. DISHA requires data collectors to obtain consent separately for collecting the data, storing the data, transferring the data, access of data by a third-party, and disclosure of data.[54] The legislation also ensures that if the data owner refuses to consent to one of the steps in the data flow, the services that can be provided despite that denial of consent must be provided. This means that if the data owner refuses to consent to data being transferred to a third-party, the health services that can be administered by the collector independent of the third-party must not be refused based on that denial of consent. On the other hand, the PDP Bill requires data collectors to notify the owner of most elements of the data flow, it however, does not give owners the right to refuse consent to individual steps of the data flow.[55] DISHA also mandates that separate consent be required before every individual use of the owner's data, whereas the PDP Bill allows companies to take a one-time consent for a certain kind of data from the owner. DISHA also gives users greater rights in withdrawal of consent than the PDP Bill. DISHA effectively gives users the right of erasure of data on them. This means that the user can not only withdraw consent from further collection of data but can also withdraw consent for stored data. In this circumstance, the data would need to be deleted which would mean that processing which may fall outside the consent-based model in the regulation will also not be possible. An example of processing which may fall outside the consent-based model is access to data by law-enforcement agencies. If the owner withdraws consent from the storage of data, all copies need to be deleted and hence cannot be accessed by law enforcement agencies as well. The PDP Bill does not give the same right. The PDP Bill allows only for the user to disallow disclosure of data, however, exceptions to this withdrawal of consent are also laid out under the Bill.[56] It has provisions allowing for retention of data for a certain period. Additionally, the Bill does not give granularity of consent for individual steps of the data flow, hence the data principal can withdraw consent for the collection and processing of data from that point onwards but can do very little to limit storage of data already collected in the past about them.

The two sets of regulations impose different standards for governmental access to data as well. DISHA imposes a much higher burden on government agencies for access to health-related data. Government agencies can only access data in de-identified or anonymised form and

[54] Supra 26.
[55] Supra 25.
[56] Ibid.

cannot access personal identifiers related to the health data collected.[57] The purposes for which this data can be collected is also limited under the provisions set out by Section 29 of the rules. Section 29 allows this kind of data to be used for research and policy planning, to prevent public health emergencies, to assess the quality and effectiveness of healthcare facilities, and to prevent bioterror events and infectious disease outbreaks.[58] The Government agency requesting the data has to lodge a formal request with the National Electronic Health Authority only after which they will be permitted access to data. While the provisions for preventive assessment still leave room for the government to access data on various pretexts, the fact that only anonymised data can be accessed is a significant departure from previous laws in the degree of protection afforded to data owners. However, the National Electronic Health Authority's members are appointed by the central government of which some are ex-officio civil servants in certain ministries.[59] This may lead to a dilution of the independence given to the Authority and may reduce some of the protections given to users. Despite this, the legislation sets unprecedented protections for users on governmental access to data. The only mechanism under the Rules through which personally identifiable health data may be accessed by the government or law enforcement agencies is when a court order to access such data is granted for a cognizable offence. Hence, law enforcement agencies cannot access such data without filing for a warrant with the judiciary which puts a check on abuse of power by law enforcement agencies in this regard.

The PDP Bill, on the other hand, gives the government a range of powers for processing personal data without requiring consent of the data principal. The government is allowed by the Bill to process personal data to provide any public services to individuals or for the issuance of licenses to individuals. The governments, as well as others, are permitted to process such data to provide assistance in the event of a disaster or to provide medical assistance in the event of a disease outbreak.[60] The government is also allowed to determine what data constitutes sensitive personal data. Even though the Bill lays out certain kinds of data as sensitive personal data in its definition, the government has the power to specify whether certain kinds of data fall under the category of sensitive personal data. Apart from these, provisions under Section VIII of the Bill expressly exempt the government and agencies appointed by it from the protections afforded to data principals under the PDP Bill.[61] The government is authorised to request data from any collector or processor

[57] Supra 26.
[58] Ibid.
[59] Ibid.
[60] Supra 25.
[61] Ibid.

of data if it feels that the data can help the government to prevent the incitement of a cognizable offence. For this purpose, the government does not require even a court order or warrant and merely needs to record its reasons in writing.[62] The government also has the power to authorise other companies to access and process data, including companies incorporated outside India. This permits the government to appoint intermediaries to process data on behalf of the government, with the intermediary being exempt from most protections granted under the law. All of these provisions put together, the government is virtually exempt from the regulations for most forms of data. None of the exemption provisions, however, mention sensitive personal data as being exempted from consent requirements. There is a lack of clarity on how the government will access sensitive personal data. Even though there are no exemption rules for this category, it is almost certain that some of this data will be essential for law enforcement agencies and the government can codify standards for sensitive personal data under Section 15 of the Bill. With health-related data being covered under sensitive personal data, the protections afforded to it against governmental access are not clear.

VII. EXISTING REGULATIONS APPLYING TO HEALTH-RELATED DATA ON FITNESS TRACKERS

1. Information Technology Act 2000 (amended by IT (Amendment) Act 2008)[63][64]

The IT Act is currently the legislation which forms the backbone of data protection regulations in India. It defines offences and penalties for breaches of data privacy and failure to protect data. The Act defines the "failure to protect data" and mandates compensation by companies who have been adjudicated to be negligent in handling of sensitive personal data which led to a data breach which caused harm to individuals.[65] Under the Act, the central government can decide on what data it deems must be categorised as sensitive personal data. The Act was also one of the first in India to take note of and use the notice and consent model for privacy in 2000.[66] It defined the disclosure of electronic records obtained without the consent of the owner as an offence. The Act also criminalized unauthorised access to computer systems and networks as well as unauthorized extraction of information from a computer.[67] The Act is the existing general body of rules for data protection which are

[62] Ibid.
[63] Information Technology Act, 2000.
[64] Information Technology (Amendment) Act, 2008.
[65] Supra 64.
[66] Ibid.
[67] Ibid.

augmented by sector specific regulations. The PDP Bill is set to revamp privacy protections for data under the IT Act.

Subsequently, the Government framed a set of rules under Section 87 of the IT Act. These rules, titled the "Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011"[68] lay a standard for data protection measures to be taken by data collectors and processors. The Rules brought medical records under the purview of Sensitive Personal Data as well as including physical, physiological and mental health condition.[69] This brings the health data recorded by fitness trackers under the mandate of the Rules. The Rules enforce a condition of necessity for data collection. They also elaborate on the notice and consent model mentioned in the IT Act. The Rules require notification to the data owner of information being collected, the purpose of the collection and the intermediaries that information is shared with.[70] The Rules also require the company to take explicit consent of the owner and gives the owner the right to withdraw consent at any time for the collection of data. The Rules require companies to obtain consent of the data owners for transferring their data to a third party.[71] The Rules also require the third party to have the same standards of data security as the company collecting the data. The Rules lay down other principles of data protection, such as requirements that information can only be processed for the purpose it was collected and that information should not be retained longer than required.[72] Finally, the regulation sets standards of system security to be followed by the data collector and sets out a mechanism to audit the same. As the definition of sensitive personal data under the Rules covers health-related data collected by fitness trackers, they fall under the purview of the Rules.

2. Electronic Health Record Standards (2016)[73]

The Electronic Health Record Standards are sector-specific regulations on the storage of electronic health records put forth by the Ministry of Health and Family Welfare. They specify requirements of healthcare data as a sector-specific add-on to the Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011. The Standards are recommendatory and are not legally binding.[74] The Standards acknowledge the popularity of self-care

[68] Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.
[69] Ibid.
[70] Ibid.
[71] Ibid.
[72] Ibid.
[73] Electronic Health Record Standards, 2016.
[74] Ibid.

health devices that continually produce data and note that these also constitute essential healthcare data.[75] The Standards define a category of data named electronic Protected Health Information which includes data about the past or present mental or physical health condition of an individual which is stored electronically. They confer ownership of healthcare related data which comes under sensitive personal data in the IT Rules, 2013 to the individuals from whom data is collected.[76] They also give the patients the right to restrict disclosure or access to their data and to view the data that organisations have about them. Even though anonymisation and de-identification are not defined as such, the standards recommend all healthcare data collectors to remove personal identifiers where not required.[77] The Standards also recommend granularity of consent, wherein a patient can request that specific elements of their information not be disclosed or be accessible by third parties. The recommendation also establishes data security standards that should be implemented by providers who store electronic health records.[78] They suggest healthcare providers to follow a set of global standards including various ISO standards on health informatics as well as encryption standards. The document emphasizes on the link between data security and data protection and considers data security as a necessary element of assuring data protection for companies.[79] These standards are also applicable to fitness trackers as the recommendations acknowledge self-care health devices as a part of the ambit of the recommendations. However, by virtue of them being recommendations, there is no enforceability and hence they may only shape privacy policies of companies.

VIII. CASE LAWS

It is also crucial to analyse the view that the Indian judiciary has taken in the matter. There exists case law to determine the Indian judiciary's view on the question of privacy in health-related data which has often been weighed against public interest. Through such cases, precedence has been created on issues to be considered while evaluating whether privacy of health data overrides the public interest.

1. K.S. Puttaswamy v. Union of India (2017)[80]

The judgment delivered in this case is considered a landmark as the Supreme Court manifestly declares the Right to Privacy as a fundamental

[75] Ibid.
[76] Ibid.
[77] Ibid.
[78] Ibid.
[79] Ibid.
[80] Supra 32.

right under the Indian Constitution. The Court makes several references and expresses beliefs regarding the privacy protection extended to medical information in the judgement. The Court ruled that the Right to Privacy was a natural and inalienable right of all humans. The judgement reads, *"Privacy of the body entitles an individual to the integrity of the physical aspects of personhood"*. This statement can be read to include physiological information about the body of the nature that is tracked by fitness trackers, bringing them within the ambit of the Right to Privacy. The judgement also acknowledges "Informational privacy" as a type of privacy, recognising the right of an individual to control dissemination and access to information concerning them. Under the concept of informational privacy, the Court expressly makes note of challenges arising from wearable devices. The judgement acknowledges that with such devices, users often cannot understand the vast amounts of data they have volunteered. The Court also manifestly declares that it believes that users have a reasonable expectation of privacy with data such as medical information. It also chooses to elaborate of anonymity in the sphere of health-related data. The Court expresses its belief that while personally identifiable data may not be accessed, there may be access to anonymised data for informing public health decisions. Put together, these statements exhibit the Court's belief that users have a reasonable expectation of privacy over their medical information and that the violation of privacy for such data has a relatively high burden as compared to other forms of data.

2. Mr X v. Hospital Z (1998)[81]

In this case, the Supreme Court questioned whether it was a breach of the right to privacy and confidentiality of an individual if their HIV Positive status was revealed by a hospital, tested during transfusion, to the person they were to be married to. In the 1998 judgement, the Supreme Court held that the right to privacy is not absolute and may be restricted for the prevention of crime or protection of health. It ruled that the Right to Privacy of the HIV Positive individual had not been affected in disclosing the information to the family of the spouse. The Court viewed the health of the would-be spouse in high regard and maintained that the disclosure done to protect the would-be spouse from HIV did not infringe on the Right to Privacy of the infected individual. This case promulgates a trend in several other cases where the courts have held information disclosed in public interest to not be a violation of the right to privacy. It is to be noted, however, that the Court referred to Kharak Singh v. State of U.P. and Gobind v. State of M.P. in tracing the right to privacy, which K.S. Puttaswamy v. Union of India builds on.

[81] Mr. 'X' v. Hospital 'Z', (1998) 8 SCC 296.

3. Sharda v. Dharmpal (2003)[82]

In this matter, the Supreme Court was called upon to decide, among other questions, whether the courts could subject an individual to a medical examination. The case involved a married couple of whom the respondent was filing for divorce because the appellant was not sound of mind. The lower court had asked the appellant to submit themselves to a medical examination and submit the findings as evidence in the matter. The appellant appealed to the Supreme Court claiming that the courts could not order a medical examination as it would be a violation of the appellant's privacy. The Court acknowledged that the medical information obtained from the test would be instrumental in concluding the case, but questioned whether obtaining such medical information would violate the appellant's right to privacy. In the judgement, the Court held that the Right to Privacy under Article 21 of the Constitution is not absolute. Since the Right to Privacy is not absolute, the court held that if two parties had fundamental rights in conflict with one another, the right which advances public morality would prevail. The Court held that an order for a medical examination would not be violative of the individual's right to privacy. This is because the Court believed that the case could not reach a fair conclusion without this data and added that only data necessary for delivering the judgement must be collected. The Court in its ruling also acknowledged that under certain laws the State has the right to subject an individual to a medical examination. Presumably, if the law can subject the individual to an examination, accessing data that would give the same information as the examination itself must also be permitted. The case highlighted the limitations of the Right to Privacy under Article 21 of the Constitution on medical information. However, K.S Puttaswamy v. Union of India brings the Right to Privacy within the ambit of Articles 14 and 19 of the Constitution as well. Keeping that in mind, in subsequent cases of this nature, the question of conflicting fundamental rights may need to be revisited in the case of the Right to Privacy.

IX. CONCLUSION

Current Indian legislation is found wanting in the domain of data protection for fitness trackers. The existing legislation has limited intent to protect privacy of citizens, being more focused on preventing cyber-crime and ensuring cyber security. The IT Act and rules under it do lay the groundwork for creating protections for health-related data however, defining sensitive personal data and criminalising breaches of privacy. They also impose responsibilities on companies collecting personal data

[82] Sharda v. Dharmpal, (2003) 4 SCC 493.

of citizens by penalising them for breaches where the company is found negligent in its storage of data. In recent years, following the General Data Protection Regulation in the EU and the Justice Puttaswamy judgement by the Supreme Court, the Indian government has displayed an intention to create legislation for data protection. The Electronic Health Record Standards (2016) by the Ministry of Health and Family Welfare acknowledge the necessity of creating rules for data protection and recognise the pervasiveness of self-care medical devices. In doing so, it creates the framework which is then used by proposed legislations to ensure data protection for health data.

The Personal Data Protection Bill, while covering a range of data, appears to be lenient towards data protection. Even though it is a significant improvement to India's existing data protection framework, it leaves a lot to be desired when looking particularly at health-related data. The Bill does not comprehensively cover the additional protections offered to sensitive personal data over personal data and in doing so leaves several questions over the protection of such data unanswered. The Bill uses a limited approach to notice and consent and fails to cover several aspects of the same. This leaves the protections extended by the Bill vulnerable to the nature and magnitude of data captured by internet-of-things devices, such as fitness trackers. It is unable to tackle several challenges posed by such devices to traditional notice and consent approaches as mentioned in the paper.

The proposed Digital Information Security in Healthcare Act is markedly more nuanced in the protections offered by it to health-related data than the PDP Bill. It breaks down the data flow to its fundamental processes and ensures that the notice and consent model applies to each stage, granting the data owner significantly more control than the PDP Bill. However, progress on DISHA has stalled, seemingly in anticipation of the PDP Bill. It is imperative, though, that DISHA is passed to provide directed protections to health-related data. An attempt does need to be made to reconcile the two legislations as they have differing approaches to several problems. However, DISHA must not be changed drastically from its present form to accommodate the leniency of the PDP Bill if the protections to healthcare data are to be comprehensive. Rather, DISHA must be treated as specific law and allow the legal principal of *lexspecialis derogat legigenerali,* meaning more specific rules will prevail over general rules, to apply in a conflict between the two laws. The PDP Bill is essential and useful but in bringing a variety of data under its mandate, it cannot extend comprehensive protections to any particular kind of data, which DISHA does.

SHORT ARTICLES

AYUSHMAN BHARAT PRADHAN MANTRI JAN AROGYA YOJANA: PERFORMANCE SO FAR AND CHALLENGES AHEAD

*Swagata Yadawar

ABSTRACT

Ayushman Bharat Pradhan Mantri Jan Arogya Yojana has been launched as "the world's largest government funded healthcare program" with the main aim of reducing catastrophic expenditure for hospitalisation that impoverishes people. With a larger cover, more budgetary allocation, and coverage across the country, this scheme is the most ambitious iteration of the insurance-based model that India has ever tried. However, whether it is successful in reducing catastrophic expenditure is difficult to answer since the scheme does not cover out-patients, and because of the unequal spread of health infrastructure that benefits some regions while other regions remain deprived as before.

I. BACKGROUND

The Ayushman Bharat–Pradhan Mantri Jan Arogya Yojana (**"**AB-PMJAY**"**) scheme was launched in India by Prime Minister Narendra Modi in September 2018 in Ranchi, Jharkhand.[1] It was a component of the larger Ayushman Bharat scheme that was launched as per the recommendations of National Health Policy 2017 to achieve the vision of Universal Health Coverage. AB-PMJAY provides a cashless insurance cover of Rs 5,00,000 per year for secondary and tertiary care hospitalisation. About 100 million below poverty level families, who were part of the 2011 socio-economic caste census (**"**SECC**"**) database list, are slated to be the beneficiaries of the scheme; the government has called it "the world's largest government funded healthcare program".[2] The main aim of the scheme is to reduce catastrophic expenditure for hospitalisations which impoverishes people. Another aspect of Ayushman Bharat, apart from the insurance scheme, is the creation of health and wellness centres by converting sub-centres and primary health centres. About 1,50,000 health and wellness centres are supposed to be created by 2022 to provide "comprehensive primary care" covering maternal and

* Swagata Yadavar is a health journalist based in New Delhi. She acknowledges the assistance by Ms. Sheena Verma, 2nd Year Student at the Rajiv Gandhi National University of Law, Punjab.

[1] Ministry of Health and Family Welfare, Government of India, *AB-PMJAY to be launched by Prime Minister Shri Narendra Modi in Ranchi, Jharkhand on September 23, 2018*, available at https://pib.gov.in/Pressreleaseshare.aspx?PRID=1546948, last seen on 27/01/2020.

[2] Ibid.

child health services as well as non-communicable diseases, including free essential drugs and diagnostic services.[3]

India's healthcare spending is amongst the lowest[4] in the world and lower than its own ambitions.[5] Currently, India's public healthcare spending is only 1.28% of its gross domestic product.[6] India's health-related out-of-pocket expenditure, which pushes families into indebtedness and deeper poverty, is amongst the highest in the world. In a low-middle income group of 50 nations, Indians ranked sixth among the biggest out-of-pocket health spenders in 2014.[7] Over 55 million Indians were pushed into poverty due to outpatient expenditure, 69% of them due to cost of medicines alone.[8]

The National Health Policy of 2002 and 2017 suggested health insurance as a way of ensuring universal health care. However, the reality on the ground remains different, with only 14.1% persons in rural areas and 19.1% in urban areas covered by any form of insurance cover according to health consumption data released by 75th round of National Statistical Office.[9] Further, only about 10% of the poorest Indians in rural (10.2%) and urban India (9.8%) had any form of private or government health insurance.[10] It has to be noted that since the survey was conducted before the launch of PMJAY, the latest coverage of insurance scheme is yet to be recorded.

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[3] *Ayushman Bharat Scheme: 1,20,000 Community Health Officers to be Placed at HWC's by 2022,* Outlook (10/12/2019), available at https://www.outlookindia.com/newsscroll/ayushman-bharat-scheme-120000-community-health-officers-to-be-placed-at-hwcs-by-2022/1682125, last seen on 07/02/2020.

[4] *Rs 3: Amount India Spends Every Day on Each Indian's Health*, India Spend (21/06/2018), available at https://www.indiaspend.com/rs-3-amount-india-spends-every-day-on-each-indians-health-53127/, last seen on27/01/2020.

[5] Ministry of Health and Family Welfare, Government of India, *National Health Policy 2017*, available at https://www.nhp.gov.in//NHPfiles/national_health_policy_2017.pdf, last seen on27/01/2020.

[6] Ministry of Health and Family Welfare, Government of India, *National Health Profile 2019*, available at https://www.thehinducentre.com/resources/article29841374.ece/binary/8603321691572511495.pdf, last seen on 27/01/2020.

[7] V. Vivek*, Indians Sixth Biggest Private Spenders on Health Among Low-Middle Income Nation*s, India Spend (08/05/2017), available at https://archive.indiaspend.com/cover-story/indians-sixth-biggest-private-spenders-on-health-among-low-middle-income-nations-78476, last seen on 27/01/2020.

[8] P. Salve*, Health Expenses Pushed 55 Million Indians into Poverty* (19/07/2018), India Spend (19/06/2018), available at https://www.indiaspend.com/health-expenses-pushed-55-million-indians-into-poverty-in-2017-2017/, last seen on 06/05/2020.

[9] Ministry of Statistics and Programme Implementation, Government of India, *Key Indicators of Social Consumption in India: Health*, available at http://www.mospi.gov.in/sites/default/files/publication_reports/KI_Health_75th_Final.pdf, last seen on 06/05/2020.

[10] Ibid.

Since the aim of the PMJAY scheme is to reduce catastrophic health expenditure and the focus of the scheme still remains on hospitalisation, how effective the scheme will be to achieve this end would need assessment. India already has the experience of implementing Rashtriya Swasthya Bima Yojana (**"**RSBY**"**), which provided a cover of Rs 30,000 for below poverty level families since 2008 with limited success. Till 2013, 41 million families out of a targeted 65 million families were enrolled in RSBY. However, the scheme suffered from many problems, like low enrolment, inadequate insurance cover and the lack of coverage for outpatient costs; in fact, spending on outpatient expenditure increased by 30% for the beneficiaries of RSBY.[11] While most patients showed a preference for private hospitals, some studies showed that there was not a major difference in quality between public and private hospitals. Also, since there was no specific formal regulation of the scheme, states contracted out their functions to private insurance firms often leading to frequent contractual breaches.[12]

II. HEALTH AND WELLNESS CENTRES: PERFORMANCE SO FAR

Under the Ayushman Bharat scheme, 1.5 lakh health and wellness centres are to be made operational by the end of 2022 and phased targets for each year have been set. At the end of 2020, the target is for 40,000 health and wellness centres to be operational; according to the scheme's dashboard, there are about 28,000 operational in January 2019.[13] The states with the highest score in state-wise ranking based on fulfilment of criteria and following the guidelines were Andhra Pradesh, Gujarat, Odisha, Tamil Nadu and Haryana, as per rankings in September 2019.[14]

Apart from Odisha, the other states were high income states with fairly good infrastructure. Other than the exception of Uttar Pradesh, which has the highest number of health and wellness centres according to the dashboard, most of the health and wellness centres are in other high-income states like Gujarat, Maharashtra and Tamil Nadu.[15] Also, the

[11] A. Karan, W. Yip, A. Mahal, *Extending health insurance to the poor in India: An impact evaluation of Rashtriya Swasthya Bima Yojana on out of pocket spending for healthcare*,181 Social Science & Medicine, 83-92 (2017), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5408909/, last seen on 27/01/2020.
[12] S. Khetrapal, *Assessment of the Public-Private-Partnerships Model of a National Health Insurance Scheme in India*, Volume no. 243, Journal of Social Science and Medicine, (2019), https://www.sciencedirect.com/science/article/pii/S027795361930629X, last seen on 27/01/2020.
[13] Ministry of Health and Family Welfare, Government of India, *Ayushman Bharat - Health and Wellness Centre*, available at https://ab-hwc.nhp.gov.in/#documents, last seen on 27/01/2020.
[14] Ministry of Health and Family Welfare, Government of India, available at https://ab-hwc.nhp.gov.in/download/document/Ayushman_Bharat_-HWCs.pdf, last seen on27/01/2020.
[15] Ibid.

allocation for health and wellness centres in 2019-2020 was Rs. 1600 crores, nearly a fourth of the budget allocated to PMJAY.

III. PMJAY: THE PERFORMANCE SO FAR

The National Health Authority (**"**NHA**"**), which was created by the Union Cabinet, is responsible for the design, rollout, implementation and management of PMJAY. Headed by a full-time CEO at the level of secretary, NHA is governed by a governing board chaired by the Union Health Minister with 11 other members. Its chief functions include: formulation of policies, development of operational guidelines, implementation mechanisms, and coordination with state governments, monitoring and oversight, among others.

Till December 2, 2019, PMJAY has issued over 67 million e-cards to beneficiaries, according to the PMJAY website and the NHA.[16] The scheme is operational in all states except Odisha, Telangana, West Bengal and New Delhi. Almost 53% of 18,500 hospitals empanelled are private sector hospitals.[17] It has covered over 6.8 million hospitalisations worth Rs 7,160 crore and has led to the saving of Rs 16,000 crore, as of October 2019, according to the National Health Authority. Majority of the treatments have taken place in the areas of cancer, heart ailments, bone-related problems and kidney ailments.[18] Among the top specialties under which patients have availed benefits are oncology, cardiology, orthopaedics, and urology.

At the state level, there is a State Health Authority (**"**SHA**"**), headed by a chief executive officer appointed by the state government, which is responsible for implementing the scheme in the state. The states have the flexibility to choose between a trust mode, insurance mode and mixed or hybrid mode.[19] In the trust mode, SHA makes the payment to the empanelled hospitals for the claims approved; in the insurance mode, the insurance company makes the payment; and in the hybrid mode, the insurance company makes the payment up to a coverage limit and the

[16] *Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana*, National Health Authority, available at https://www.pmjay.gov.in/, last seen on 27/01/2020.
[17] Ministry of Health and Family Welfare, Government of India, *One Year of AB-PMJAY: 50 lakh Hospital Treatments with an Eye towards Universal Health Care*, available at https://blog.mygov.in/one-year-of-ayushman-bharat-pradhan-mantri-jan-arogya-yojana-50-lakh-hospital-treatments-with-an-eye-towards-universal-health-coverage/, last seen on27/01/2020.
[18] *ASSOCHAM - India, Ayushman Bharat - A Big Leap towards Universal Health Care in India*, KPMG, available at https://assets.kpmg/content/dam/kpmg/in/pdf/2019/12/universal-health-coverage-ayushman-bharat.pdf, last seen on 27/01/2020.
[19] *Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana*, National Health Authority, available at https://pmjay.gov.in/about/pmjay, last seen on 27/01/2020.

claims higher than the limit are paid by the SHA.[20] While 17 States or union territories are implementing PM-JAY via the Trust Mode, 9 states or union territories via Insurance Mode and 6 States or union territories are using the Mixed Mode which is a combination of Trust mode and Insurance mode.

IV. FRAUDULENT TRANSACTIONS

Previous experience has shown that insurance schemes are often plagued with fraudulent activities. Apart from publishing the anti-fraud guidelines and having fixed packages, NHA has initiated mandatory pre-authorisation and use of artificial intelligence to spot suspicious trends. Moreover, two bodies, the National Anti-Fraud Unit (**"**NAFU**"**) and the State Anti-Fraud Unit (**"**SAFU**"**) were formed to monitor the system at the centre and state levels, respectively. NAFU teams often flag suspicious cases with the states for medical audits. Till now 0.25% of total admissions have been flagged by NAFU, out of which 0.07 have been confirmed as fraud.[21] In the first year, 171 hospitals were de-panelled due to fraudulent practices and Rs 4.5 crore penalty was levied on them.[22] Also, 390 hospitals were served show-cause notice in different states and six hospitals had first information reports filed against them.

Furthermore, a working paper analysing the pattern of utilisation of hysterectomy procedure in the first year showed that about three-fourths of all claims have been generated in six states, Chhattisgarh (21.2%), Uttar Pradesh (18.9%), Jharkhand (12.2%), Gujarat (10.8%), Maharashtra (9%) and Karnataka (6.6%), and more than two thirds of the claims were from the private sector.[23] Uttar Pradesh accounted for 18% of all hysterectomy claims under PMJAY, and only 5% of total claims. Also, most of the procedures involved oophorectomy – removal of ovaries – which leads to premature menopause; median age of the women undergoing hysterectomy and use of oophorectomy should be "monitored closely," said the report.

V. BIG PRIVATE PLAYERS ARE STILL ABSENT

[20] Ibid.
[21] Joe C Mathew, *Ayushman Bharat Fraud: NHA Delists 171 Hospitals over Alleged PMJAY Scam,* Business Today (06/01/2020), available at https://www.businesstoday.in/current/economy-politics/ayushman-bharat-fraud-nha-delists-171-hospitals-over-alleged-pmjay-scam/story/393248.html, last seen on 27/01/2020.
[22] Ibid.
[23] S. Kaur, Dr. N. Jain, Dr. S. Desai, *Patterns of utilization for Hysterectomy: An analysis of early trends from Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (PM-JAY)*, Working Paper 001, National Health Authority (2019).

PMJAY, in its truest sense, is a "partnership of public and private sector health systems" according to the NHA.[24] However, there has been reluctance on the part of big private sector hospitals in empanelling themselves in the scheme especially in tier-one cities. According to KPMG's analysis, the participation of private hospitals has been as follows: Gurugram (17), Mumbai (29) and Bengaluru (28).[25] Till June 2019, major corporate hospitals like Max Healthcare, Apollo Hospitals, Medanta had not joined the scheme.[26]

This is because most of the package rates in PMJAY were not viewed to be viable by the private hospitals. The reimbursement tariffs offered under the scheme do not cover more than 40-80% of the total costs, according to a 2019 report by FICCI.[27] If hospitals had to allocate 25% of their beds to PMJAY patients, they would lose up to 15-25% of revenue per bed each day, the FICCI report said.[28] The delay in settling bills could also scare off the private players. While 85% of PMJAY claims have been settled within 30-45 days cut off, cashless treatment under the Central Government Health Scheme (**"**CGHS**"**) and Ex-servicemen Contributory Health Scheme (ECHS) has often been delayed.[29] For instance, Fortis, Max and Medanta had threatened to discontinue cashless treatment under CGHS and ECHS due to non-payment of dues up to Rs. 1700 crores in December 2019.[30]

On the other hand, Indian Medical Association has said that public hospitals should be out of the ambit of PMJAY since the government can directly fund them, and has criticized the current insurance model which,

[24] One year of Ayushman Bharat Pradhan Mantri Jan Arogya Yojana: 50 lakh hospital treatments with an eye towards universal health coverage, ABPMJAY, Government of India, https://www.pmjay.gov.in/One%20year%20of%20Ayushman%20Bharat, last seen on 06/05/2020.
[25] Supra 10.
[26] P. Aggarwal, *Govt. to Revise Ayushman Bharat Rates as Several Hospitals Back Off*, The Quint (28/06/2019), available at https://www.thequint.com/news/india/ayushman-bharat-pmjay-rates-to-be-hiked-to-get-big-hospitals-on-board, last seen on 27/01/2020.
[27] *Re-engineering Indian Healthcare 2.0*, FICCI Heal, http://ficci.in/spdocument/23111/Re-engineering-Indian-healthcare-2.0_FICCI.pdf, last seen on 27/01/2020.
[28] Ibid.
[29] Ministry of Health and Family Welfare, Government of India, *Saal Ek Ayushman Anek*, available at https://www.pmjay.gov.in/sites/default/files/201910/3_Press%20release%201%20year%20completion%20of%20Ayushman%20Bharat%20PMJAY%20%2822nd%20Sep%29.pdf, last seen on27/01/2020.
[30] H. Chandna, *Fortis, Max, Medanta Want to Scrap Cashless CGHS Treatment as Govt Dues Touch Rs 1,700 Cr*, The Print (06/12/2019), available at https://theprint.in/health/fortis-max-apollo-want-to-scrap-cashless-cghs-treatment-as-govt-dues-touch-rs-1700-crore/330968/, last seen on 27/01/2020.

according to the Indian Medical Association, should be replaced by universal health coverage.[31]

VI. DOES PM-JAY PROVIDE CARE FOR THE POOREST TO TAKE CARE OF THEIR CATASTROPHIC EXPENDITURE?

1. Exclusions within the System

While the scheme has expanded widely, it still does not cover all the eligible poor households in the country. The PMJAY relies on SECC 2011 to determine eligible beneficiaries which is how the scheme was targeted to cover 100 million households. Based on the SECC 2011 data, for rural areas, households had to meet six deprivation criteria, while households in urban areas had to meet eleven occupational criteria. However, an analysis of the SECC 2011 shows that the number of poor in the list is highly underestimated; for example, while the number of homeless households according to Census 2011 are 4.7 million, SECC 2011 only counts 1.65 million as households without shelter.[32] There are as many as 20 million households which have been left out of SECC 2011 despite being poor.[33] Additionally, there are several households which are rich but have made it to the list.

This could have been solved had there been a grievance redressal mechanism to solve the inclusion errors as was suggested by the expert group constituted by the Ministry of Rural Development.[34] However, in the current form, there is no process to include households that meet the criteria but are not included in the SECC 2011 list. Notably, there were 6.5 million households out of 10.74 million poor vulnerable households which were untraceable when the NHA was preparing the list of eligible beneficiaries.[35]

2. Poor Awareness

[31] *Restrict Ayushman Bharat to the Private Sector: IMA,* Business Line (29/09/19), available at https://www.thehindubusinessline.com/economy/policy/restrict-ayushman-bharat-to-the-private-sector-ima/article29550117.ece#, last seen on 27/01/2020.
[32] NC Saxena, *Socio Economic Caste Census: Has It Ignored Too Many Poor Households,* 50(30) Economic and Political Weekly (25/07/2015), available at https://www.epw.in/journal/2015/30/commentary/socio-economic-caste-census.html, last seen on 27/01/2020.
[33] Ibid.
[34] Ministry of Rural Development, Government of India, *Report of the Expert Group on Socio and Economic Caste Census*, available at https://rural.nic.in/sites/default/files/Report_of_the_expert_group_on_SECC_2011_0.pdf, last seen on27/01/2020.
[35] R. Kaul, *6.5 Million Beneficiaries Missing from Ayushman Bharat First List,* Hindustan Times (31/07/2019), available at https://www.hindustantimes.com/india-news/6-5-million-beneficiaries-missing-from-ayushman-bharat-first-list/story-SJDi1EoiXrcuCJamYHrDeJ.html, last seen on 27/01/2020.

Even among the beneficiaries who are eligible and included in the scheme, there seems to be very low awareness regarding the scheme. A two-page letter by Prime Minister Narendra Modi was sent to 100.7 million households included under the scheme. However, a survey conducted a year later by NHA found the awareness regarding the scheme as low as 20% in Bihar and Haryana.[36] Even though they received the letters, many beneficiaries could not understand what was due to them and many had not opened the letters with their health cards. Despite the fact that Bihar had seen an Acute Encephalitis Syndrome epidemic in June-August, 2019, only 36 patients availed of the scheme during the epidemic.

3. Disease Exclusions

In its current form, the PMJAY covers 1350 medical packages, and according to the NHA, 75% of the pre-authorisation amount is towards tertiary care procedures, including medical oncology, cardiology, orthopaedics, urology and radiation oncology. On the other hand, several illnesses, like end-stage kidney disease, chronic liver disease and blood cancer, are not even covered under the scheme. Further, these patients are not able to avail the benefit of Rashtriya Arogya Nidhi (**"**RAN**"**),[37]a scheme that provides financial assistance up to Rs 15 lakh to people below the poverty line, as they are covered under PMJAY; a proposal to allow this was rejected by the Union Health Ministry.[38]

Also, since PMJAY allows coverage of medicines for just 15 days after hospitalisation, it leaves out a number of patients, like cancer patients, who may require long-term medication on an outpatient basis. "This has not only restricted the reach of the benefits to the poorest of the poor, but has also worked against the principles of the RAN umbrella scheme, which is to give financial benefit to the poor in the treatment of cancer,"

[36] N. Sharma, *Ayushman Bharat Awareness 80% in TN, barely 20% in Bihar and Haryana,* The Economic Times (03/09/2020), available at https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/ayushman-bharat-awareness-80-in-tn-barely-20-in-bihar-and-haryana/articleshow/70953467.cms?from=mdr, last seen on 27/01/2020.

[37] *Guidelines Regarding Implementation of Umbrella Scheme of RashtriyaArogyaNiti (RAN)*, Ministry of Health and Family Welfare Notification (2019), available at https://mohfw.gov.in/sites/default/files/RAN_Guideline_2019.pdf, last seen on27/01/2020.

[38] *NHRC Seeks Report OverAyushman Bharat Beneficiaries not able to avail High-cost Treatment under RAN,* The Economic Times (26/12/2019), available at https://economictimes.indiatimes.com/news/politics-and-nation/nhrc-seeks-report-over-ayushman-bharat-beneficiaries-not-able-to-avail-high-cost-treatment-under-ran/articleshow/72979534.cms, last seen on 27/01/2020.

wrote Shah Alam Khan, of Orthopaedics Department in All India Institute of Medical Sciences, Delhi in Economic and Political Weekly.[39]

4. Geographical Exclusion

The fact that there are large scale regional disparities in the health infrastructure in the country is also reflected in the empanelled hospitals under the scheme. States with low per capita incomes have lower empanelment of private hospitals by insurance companies despite having a large proportion of eligible beneficiaries under AB-PMJAY.[40] For example, West Bengal which has 10.6% of all PMJAY beneficiaries only has 588 private hospitals empanelled, while New Delhi has 0.6% of all PMJAY beneficiaries and 510 private hospitals empanelled. Further, even among states with a high number of empanelled hospitals, the distribution of private hospitals is concentrated in a few districts which accounted for the majority of claims.

Analysis of the schemes showed that 61% of all claims are from private hospitals, and the share of high value (more than Rs. 30,000) and very-high value claims (more than Rs. 100,000) is 74% and 82% respectively.[41] In fact, top 20 hospitals in a select few cities accounted for 17% of all very-high value claims. While the unique provision under PMJAY has been portability where patients can avail cashless treatment in empanelled hospitals across the country, till September 2019, 50,544 transactions or only about 0.7% of all hospitalisations had availed of the provision.[42] This means that the much lauded feature of the scheme also needs more awareness and demand generation.

VII. DISCUSSION

India has been amongst the lowest spenders on healthcare, yet there have been increased allocations on healthcare in the last couple of decades. This, along with ambitious schemes, does improve the government's ability to meet the needs of the population, but there is a debate to determine what the money should be spent on. India has adopted the insurance-based model for healthcare, as mentioned in various National

[39] S. A. Khan, *Ayushman Bharat: Hurdles to Implementation One Year On*, 54(47) Economic and Political Weekly (30/11/2019), available at https://www.epw.in/journal/2019/47/commentary/ayushman-bharat.html, last seen on 27/01/2020.
[40] M. Chaudhary and P. Datta, *Private Hospitals in Health Insurance Network in India: A Reflection for Implementation of Ayushman Bharat*, NIPFP Working paper series, Working Paper 254, National Institute of Public Finance and Policy (2019).
[41] Supra 10.
[42] S. Yadavar, *Ayushman Bharat Working to Identify those Left Out*, India Spend (08/12/2019), available at https://www.indiaspend.com/ayushman-bharat-working-to-identify-those-left-out/, last seen on 27/01/2020.

Health Policy documents. With Ayushman Bharat, the idea expanded to providing a more comprehensive cover as well as a robust healthcare infrastructure for the most vulnerable sections of the society. India has had mixed success with the model till now, and there are still fundamental problems that the scheme has been unable to tackle. Reducing catastrophic expenditure without covering outpatient expenditure seems to be a fundamental folly, especially given the fact that most Indians rely on private healthcare for their health needs. The fact that more Indians have died from poor quality medical care than due to lack of medical care should explain why there is little faith in the public system.[43] While the government aims to tackle the problem of primary healthcare through the establishment of health and wellness centres, the budget allocation shows that it has not been allocated the resources that will be needed to overhaul the primary healthcare system or maintain its quality.

Focusing only on the efforts of the government to provide tertiary care, we find that it would not succeed in giving healthcare coverage to the most deprived because the database on which the beneficiaries are determined is flawed and does not include the most vulnerable. This is because the government is using the same SECC 2011 database to even determine which households do not have latrines for the Swachh Bharat Abhiyaan; a calculation which has allowed villages and districts to be declared open defecation free even as many households do not have latrines or do not use them.[44] This is why there is an urgent need to allow provisions to include the beneficiaries that have been left out and update the database to only include the deserving.

Also, even if the base of the beneficiaries increases, much more needs to be done to increase awareness about the scheme to the public. Currently, only a small portion of the beneficiaries who have even received the card seem to be aware of the scheme. This means that the poor would continue to delay or seek care at the risk of indebtedness. Also, the issue of inequitable access to care also needs much to be desired. There is a clear concentration of empanelled hospitals in certain states and certain districts, a small proportion of them are also the ones who charged the highest number of claims for expensive specialised medical procedures. Even though the portability feature does seem to address this gap, low

[43] S. Yadavar, *More Indians Die of Poor-Quality Care Than Due to Lack of Access to Healthcare: 1.6 Million,* India Spend (06/09/2019), available at https://www.indiaspend.com/more-indians-die-of-poor-quality-care-than-due-to-lack-of-access-to-healthcare-1-6-million-64432/, last seen on 27/01/2020.

[44] S. Yadavar, *After 4 Years of Swachh Bharat, Open Defecation Down 26 Percentage Points, But Toilet Use Does Not Match Construction Spree*, India Spend (07/01/2019), available at https://www.indiaspend.com/after-4-years-of-swachh-bharat-open-defecation-down-26-percentage-points-but-toilet-use-does-not-match-construction-spree-false-claims-evident/, last seen on 27/01/2020.

utilisation of this feature points to the fact that very few beneficiaries know about it and can afford to travel for the procedure.

While PMJAY considers the private sector to be a very important part of the engagement of the scheme, to rely on private sector hospitals especially when it comes to quality and price is not advisable. Also, the NHA has not yet responded to all the concerns of the private players when it comes to the viability of the scheme. Even if all the private players are satisfied with the package rates and decide to come on board, previous experience has shown that the scheme has high chances of being exploited, despite the anti-fraud mechanism in place, because of the fundamental aim of profit generation in the private hospitals and virtually no regulatory mechanism in place. Even the presence of public-private partnerships in the public sector has shown that the private sector has not been successful in providing the kind of care stipulated in the contract. In fact, the government has had to roll back the scheme and manage the hospitals in many cases.

Despite the apparent gaps and challenges, PMJAY is the most ambitious scheme and the one that has received more political attention and finance than ever before. Also, given that it has only been a year and a half, it is expected that the scheme will both mature and grow strong in times to come. Furthermore, since the NHA has been transparent about their findings and sharing data, there is scope to analyse PMJAY's performance more critically and provide feedback.

There is already discussion to provide health insurance coverage to the middle class and move towards universal healthcare by making that a paid feature.[45] However, it is too early to expand the scheme to other groups even before understanding the impact of the scheme on the goals that it set out to achieve. We would need more time to decide if PMJAY succeeds in reducing catastrophic expenditure among the poorest of the poor, but to do so it will need to overcome its apparent challenges in terms of covering the most vulnerable and solving the problem of inequitable healthcare in the count.

[45] *NITI Aayog Mulls Healthcare System for Middle Class*, Business Today (18/11/2019), available at https://www.businesstoday.in/current/policy/niti-aayog-mulls-healthcare-system-for-middle-class/story/390562.html, last seen on 27/01/2020.

HEALTH SELLS, BUT WHO'S BUYING?

Dr. N.S. Prashanth

ABSTRACT

In a health system where - by design - people are expected to pay at the point of service delivery for their own health, it is no surprise if disease and ill-health unfairly accumulate among the poor and disadvantaged. In this commentary, drawing from a book chapter summarising research on health inequities in India,[1] I summarise evidence on how widespread socio-economic inequality in health - among other things - is selectively and unfairly worsening health of some people, more than others. Amidst this bleak scenario of widespread health inequities, the Government of India's ambitious scheme, Ayushman Bharat scheme, appears to be an important step towards addressing inequities in access to healthcare. Through its focus on primary health care on one hand and its commitment to address rising hospitalisation expenses through insurance mechanism on the other hand, the scheme is likely to be an important step towards mitigating healthcare inequities. I conclude this short note by critically examining the implications of some of the features of Ayushman Bharat in addressing unfair disadvantages faced by the poorest and most marginalised communities in accessing primary health care and hospitalisation services.

I. INTRODUCTION

Health, unfortunately, has not been explicitly held up as a right in our Constitution. However, the Constitution guarantees right to life[2] and courts have broadly interpreted right to life as being contingent upon securing appropriate healthcare.[3] Further, the Constitution's Directive Principles oblige the State to ensure social and economic justice, particularly Article 47, which obliges the State to improve nutrition, standard of living and public health.[4] Indeed, public health advocates and courts have broadly conceptualised right to health and healthcare in India

* N S Prasanth, Assistant Director Research and an India Alliance Fellow (DBT/Wellcome Trust India Alliance) at Institute of Public Health, Bangalore.

[1] *Health Inequities in India: A Synthesis of Recent Evidence*, (Ravindran, T.K. Sundari & R. Gaitonde, 1st ed., 2018).

Extract from publisher text: "This timely contribution to the global literature on health inequities approaches the subject through a synthesis and analysis of relevant published literature on India. Amongst the BRICS countries, India ranks the lowest in the gender-gap index and has the highest poverty rate, and there is clear evidence that socio-economic inequalities have increased in India in the twenty-first century. These have direct impact on the health conditions of its people; however, there has been relatively little concerted research attention on health inequities in India. This volume fills the gap by synthesizing research evidence since the year 2000 on the topic. This is perhaps the first volume on this topic of such scope and breadth."

[2] Art. 21, Constitution of India.

[3] PUCL v. Union of India, (2009) 16 SCC 149.

[4] K. Mathiharan, *The Fundamental Right to Health Care,* 11(4) Indian Journal of Medical Ethics ,123 (2016), available at https://ijme.in/articles/the-fundamental-right-to-health-care/, last seen on 12/06/2020.

as being secured indirectly through aforementioned Articles of the Constitution, various health policy documents, policy pronouncements, and India's international legal commitments and treaties.[5] For instance, the National Health Policy 2017 identifies equity as an organizing principle for our health system. One of the ways to achieve better health status for our population is timely and appropriate curative services in times of illness, in addition to health education, preventive care, health promotion and rehabilitation services. These pillars of primary health care have been upheld as the foundational building blocks of a health system.[6] Indeed, the large country-wide network of government primary health centres (**"**PHC**"**) in India are structured as per the overall principles of primary health care laid down in the WHO's Alma Ata Declaration.

Several rounds of national, demographic and health surveys[7] by the Government have shown that access and utilisation of healthcare is consistently patterned along socio-economic characteristics of households.[8] For instance, in reproductive and child health services, there has been decades of technical and financial investment for improving access and coverage. Yet, all four rounds of the National Family Health Survey (**"**NFHS**"**) show that the coverage for family planning, maternal & neonatal health, immunisation and treatment of sick children among the poorest households is half of that among the wealthiest in almost 20 states.[9] Access and coverage of various curative and preventive healthcare services has maintained a stark and stagnant difference between the rich and the poor despite these services being offered free (mostly) within a wide network of primary health centres.

For more serious healthcare requirements (which are rarer than the more often sought primary health care conditions), the rising treatment costs in the private sector render these inaccessible to a large population. In a health system where healthcare must be purchased from the open market, those who cannot afford it are most likely to be deprived of timely and appropriate healthcare. A 2011 analysis of nationwide data by William Joe and colleagues showed that the rising income levels from economic

[5] R. Duggal, *Health and development in India: moving towards the right to health* in *Advancing the Human Right to Health* (J.M**.** Zuniga, S.P. Marks, & L.O. Gostin, 1st ed., 2013).

[6] *Health for all: An alternative strategy,* available at https://hetv.org/pdf/frch-alternative.pdf, last seen on 12/06/2020.

[7] See *Home*, National Family Health Survey India (NFHS), available at http://rchiips.org/nfhs/index.shtml.

[8] M. Asaria, S. Mazumdar& S. Chowdhury et al*, Socioeconomic inequality in life expectancy in India,* 4(3) BMJ Global Health (2019), available at https://gh.bmj.com/content/4/3/e001445, last seen on 12/06/2020; Y. Balarajan, S. Selvaraj., & S.V. Subramanian, *Health care and equity in India,* 377(9764) The Lancet 505, 515 (2011), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3093249/, last seen on 12/06/2020.

[9] Dr. N. S. Prashanth, *Health Inequities in India: A Synthesis of Recent Evidence* (Ravindran, T.K. Sundari & R. Gaitonde, 1st ed., 2018).

progress was accompanied by, or even in some instances escalated, health inequalities; while higher incomes and wealth can make health and healthcare accessible for some, it also aggravates the situation of those who are unable to – for reasons often related to underlying social inequalities and access to resources – achieve economic improvements, thus entangling economic position and healthcare into a vicious feedback loop where one aggravates the other.[10]

II. RESEARCH ON SOCIO-ECONOMIC INEQUITIES

Most of our knowledge of inequities in health by socio-economic position are from NFHS surveys. Researchers have shown that there are avoidable differences in healthcare outcomes and access to health care for a variety of conditions. Indicators related to child survival, maternal mortality and morbidity, child nutrition and anaemia in women, as well as indicators related to utilisation of maternal and child health services (antenatal and postnatal care, skilled birth attendance and child immunisation) are all worse off among India's poor, although the degree to which they are worse off varies from one state to another.[11] A 2010 study on inequalities among women in Uttar Pradesh, Maharashtra and Tamil Nadu using data for three time points from 1992–93 to 2005–06 showed that increments in utilisation of antenatal care and institutional delivery were mainly noted among non-poor mothers, and the poor mothers benefited least from government sponsored maternal health care services and schemes.[12]

In addition to unequal coverage, there are also differences in the quality of services provided. Studies have looked into quality and content of advice received; they have found that healthcare advice concentrated disproportionately among the rich. In one of the few studies of its kind, a health worker examined four North Indian states (Bihar, Madhya Pradesh, Rajasthan and Uttar Pradesh) and reported higher visits to better

[10] W. Joe, U. S. Mishra, & K. Navaneetham, *Inequalities in childhood malnutrition in India: Some evidence on group disparities,* 10(3) Journal of Human Development and Capabilities (2009), available at https://www.tandfonline.com/doi/abs/10.1080/19452820903048886, last seen on 12/06/2020.

[11] Ibid; Supra 9; P. K. Pathak, A. Singh, & S. V. Subramanian, *Economic inequalities in maternal health care: Prenatal care and skilled birth attendance in India*, *1992 - 2006,* 5(10) PLoS One (2010), available at https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0013593, last seen on 12/06/2020.

[12] P. K. Pathak, A. Singh, & S. V. Subramanian, *Economic inequalities in maternal health care: Prenatal care and skilled birth attendance in India*, *1992-2006,* 5(10) PLoS One (2010), available at https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0013593, last seen on 12/06/2020.

off rather than poorer households.[13] In this study, higher social and economic status was associated with increased chances of receiving specific components including blood pressure measurement, a blood test and urine testing. In a 2012 study, which examined the rich–poor gaps in seven types of advice given to pregnant and newly delivered women, it was found that the rich–poor ratios were consistently in favour of the richer households.[14]

III. FINANCING HEALTHCARE THROUGH DEBTS

In addition to the social costs of being poor, living in a system that requires payments for healthcare at the point of service delivery, more so during periods of high vulnerability due to illness episode, impoverishes households. Poor households often cope with this by postponing care-seeking. The illness becomes unbearably severe (and hence even more expensive) or they end up debt-financing healthcare costs, further impoverishing them. Several studies show that the household effects of healthcare-related impoverishment affect the entire household and possibly has inter-generational effects.[15] One in four of the world's stunted children live in India and given the inter-generational nature of disadvantage, this can only translate into an overall poorer and a more *unfair* future, if not corrected now.[16]

IV. LIFECYCLE OF DISADVANTAGE

Hereditary transmission of various illnesses has been well documented. However, the clustering of socio-economic disadvantage within certain

[13] S. Pallikadavath, M. Foss, & R. W. Stones, *Antenatal care: Provision and inequality in rural north India,* 59(6) Social Science and Medicine 1147, 1158 (2004), available at https://www.sciencedirect.com/science/article/abs/pii/S0277953604000139?via%3Dihub, last seen on 12/06/2020.

[14] A. Singh, S.S. Padmadas, U. S. Mishra, S. Pallikadavath, F. A. Johnson, & Z. Matthews, *Socio-economic inequalities in the use of postnatal care in India,* 7(5) PLoS One, (2012), available at https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0037037, last seen on 12/06/2020.

[15] U. Bhojani, B. Thriveni, R. Devadasan *et al.*, *Out-of-pocket healthcare payments on chronic conditions impoverish urban poor in Bangalore, India*, 12(1) BMC Public Health (2012), available at https://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-12-990, last seen on 12/06/2020; T.L. Cheng, S.B. Johnson, E. Goodman, *Breaking the Intergenerational Cycle of Disadvantage: The Three Generation Approach*, 137(6) Pediatrics (2016), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4894258/, last seen on 12/06/2020; OECD and WHO Report on Poverty and Health, available at https://www.who.int/tobacco/research/economics/publications/oecd_dac_pov_health.pdf, last seen on 12/06/2020.

[16] J. Khan, S.K. Mohanty, *Spatial heterogeneity and correlates of child malnutrition in districts of India,* 18(1) BMC public health (2018), available at https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-018-5873-z, last seen on 12/06/2020.

castes, communities and population groups has its origins with social, economic and political structures. If children born into poor households are more likely to be stunted and underweight, they in turn enter adulthood carrying the burden of these disadvantages.[17] Indeed, early childhood under-nutrition translating into poor educational attainment has been well documented in public health research,[18] with various emerging evidence pointing towards both epigenetic and biomedical pathways conspiring with adverse social conditions creating intergenerational disadvantages.[19] Aside from the social justice and unfairness angle, the economic impact in terms of loss of schooling and economic productivity losses of such early childhood deprivation has been estimated to be approximately 40 billion dollars, just in India.[20]

V. PURCHASING PRIVATE CARE

Public health research on socio-economic inequities in health overwhelmingly report that healthcare financing in India is regressive. While healthcare seeking in the private sector is widespread, it is not the case for all services.[21] Wherever primary health care services have provided a high-quality service that is accessed by a wider strata of population, as is the case with immunisation for example, the potential effects of economic inequalities may have been mitigated by the universally subsidising effect of public programmes aimed at reducing

[17] A. Dharmalingam, K. Navaneetham & C.S. Krishnakumar, *Nutritional status of mothers and low birth weight in India,* 14(2) Maternal and child health journal 290, 298 (2010), available at https://link.springer.com/article/10.1007/s10995-009-0451-8, last seen on 12/06/2020.

[18] Y. Acharya, N. Luke, M.F. Haro, W. Rose, P.S. Russell, A.M. Oommen, S. Minz, *Nutritional status, cognitive achievement, and educational attainment of children aged 8-11 in rural South India,* 14(10) PLoS One, (2019), available at https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0223001, last seen on 12/06/2020; H. Alderman, J. Hoddinott, B. Kinsey, *Long term consequences of early childhood malnutrition,* 58(3) Oxford economic papers 450, 474 (2006).

[19] J. Galler, D.G. Rabinowitz, *The intergenerational effects of early adversity*, 128 Progress in molecular biology and translational science 177, (2014).

[20] *Food for thought,* Save The Children, available at https://www.savethechildren.org/content/dam/global/reports/education-and-child-protection/food-for-thought.pdf, last seen on 12/06/2020.

[21] J. W. Skordis, N. Pace, U. Bapat, S. Das, N.S. More, W. Joshi, A.M. Brannstrom & D. Osrin, *Maternal and neonatal health expenditure in Mumbai slums (India): A cross sectional study,* 11(1) BMC Public Health, 150 (2011), available at https://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-11-150, last seen on 12/06/2020;B. Kanjilal, M. Mukherjee, S. Singh, S. Mondal, D. Barman, & A. Mandal, *Health, equity and poverty exploring the links in West Bengal, India,* Future Health Systems Innovations for Equity, Research Monograph, Indian Series, (2007), available at https://www.academia.edu/25733292/Health_Equity_and_Poverty_Exploring_the_Links_in_West_Bengal_India, last seen on 12/06/2020.

mortality among children, especially the various national programmes focusing on child health.[22]

However, increased dependence on private sector for secondary and tertiary care, and increased out-of-pocket payments for care in public sector, have resulted in worse-off healthcare outcomes among the poor and socio-economically disadvantaged. The policy response in most states has been the institution of state-managed insurance schemes for the poor by purchasing secondary and tertiary care for select conditions from the private sector. Several researchers caution about the effectiveness of such schemes targeting the poor that seek to identify the *true* poor using improperly distributed identity cards (even smart cards).[23]

As expected, many research articles report on how "...non-poor, urban households have benefitted disproportionately from economic progress as well as health interventions meant for the poor and marginalised households".[24] Hence, national schemes, such as the recently announced National Health Protection Scheme *Ayushman Bharat*, which selectively cover secondary and tertiary care mostly in private hospitals, while no doubt expanding access to services, do not address the root cause of the deepening socio-economic inequity in health: the unfair distribution of good quality primary health care and the inherent rich-poor divide in the quality and quantity of healthcare being provided.

VI. TRANSLATING ECONOMIC GROWTH INTO HEALTH

Inequities in health by socio-economic position have persisted during the period of rapid economic growth (1992–93 to 2010) and despite the introduction of numerous schemes specifically to improve maternal and child survival.[25] Various research studies show that the healthcare access and health status gap between rural and urban areas and that between the

[22] S. Chalasani, *Understanding wealth-based inequalities in child health in India: A decomposition approach,* 75(12) Social Science and Medicine 2160, (2012), available at https://www.sciencedirect.com/science/article/abs/pii/S0277953612006168, last seen on 12/06/2020.

[23] H. Thakur, *Study of Awareness, Enrollment, and Utilization of Rashtriya Swasthya Bima Yojana (National Health Insurance Scheme) in Maharashtra, India,* 3(282) Frontiers in public health, (2016), available at https://www.frontiersin.org/journals/public-health/sections/public-health-education-and-promotion#editorial-board, last seen on 12/06/2020; R. Dasgupta, S. Nandi, K. Kanungo, M. Nundy, G. Murugan & R. Neog, *What the good doctor said: a critical examination of design issues of the RSBY through provider perspectives in Chhattisgarh, India,* 43(2) Social Change 227, (2013), available at https://journals.sagepub.com/doi/abs/10.1177/0049085713493043, last seen on 12/06/2020; B. Criel, et al., *Towards equitable coverage and more inclusive social protection in health,* 32 Studies in Health Services Organisation and Policies (2014).

[24] Supra 8, Y. Balarajan, S. Selvaraj, & S.V. Subramanian, *Health care and equity in India,* 377(9764) The Lancet 505, (2011), available at https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(10)61894-6/fulltext, last seen on 12/06/2020.

[25] Ibid.

poor and the non-poor have widened since 1992–93 in many states.[24] Some studies have reported that wealth inequalities in child immunisation were more pronounced in the Southern states (considered better-off in terms of health) than in the empowered action group states (considered worse-off in terms of health).[26] In fact, states with higher average survival and coverage indicators have shown a trend of widening inequalities.[27] It is very likely that schemes and services tend to be benefitting population groups in a selective manner, and hence unless there is specific push for addressing equity in design and delivery of programmes, the gaps will continue to widen. Ambitious nationwide health reforms, such as the one envisioned under *Ayushman Bharat,* will fail to address the inequitable distribution of healthcare access unless they embrace the underlying drivers, and hence, incorporate design features that do things differently for different regions, contexts, populations and other axes. Current design aims for a rather centralised health authority that oversees design for strategic purchasing of services from secondary and tertiary care, and an ambitious nationwide template for implementing reforms in primary health care through the establishment of health and wellness centres.

VII. BEYOND HEALTH SERVICES INTO SOCIAL DETERMINANTS

Healthcare access or availability is only one of the determinants of health. The Commission on Social Determinants of Health of the World Health Organisation highlighted the significant role of various social determinants of people's health.[28] The Commission's framework describes the interactions between circumstances of daily life, especially the material circumstances with various other factors including the degree of social cohesion, psychosocial factors, behaviours and biological factors together with the health system, which together shape the distribution of health and well-being. In addition to these, the framework identifies wider societal factors (structural drivers) including policies, socio-economic and political context on one hand as well as deep-rooted power

[26] P. Arokiasamy, K. Jain, S. Goli, & J. Pradhan, *Health inequalities among urban children in India: A comparative assessment of empowered action group (EAG) and south Indian states,* 45(2) Journal of Biosocial Science 167, (2013), available at https://www.cambridge.org/core/journals/journal-of-biosocial-science/article/health-inequalities-among-urban-children-in-india-a-comparative-assessment-of-empowered-action-group-eag-and-south-indian-states/FCC58276BD0A6D1BCEFECA090E13DD3D, last seen on 12/06/2020.

[27] R. P. Pande, & A. S. Yazbeck, *What's in a country average? Wealth, gender, and regional inequalities in immunisation in India*, 57(11) Social Science and Medicine 2075, (2003), available at https://www.sciencedirect.com/science/article/abs/pii/S0277953603000856?via%3Dihub, last seen on 12/06/2020.

[28] *Closing the gap in a generation: Health equity through action on the social determinants of health: Final Report of the Commission on Social Determinants of Health,* World Health Organization, (2008), available at https://www.who.int/social_determinants/final_report/csdh_finalreport_2008.pdf, last seen on 12/06/2020.

imbalances, rules and norms in society, social position, gender, ethnicity, occupation, income, etc. which interact with the circumstances of daily life in producing the (mal)distribution of health and well-being that we see today.

Increasingly, analysis of failure of specific disease control efforts in the country point out the failures in addressing social determinants. On being asked about why India still has one-third of all new cases of Tuberculosis, leading experts on disease control point out the inadequate efforts to tackle key social determinants such as poverty and malnutrition.[29] Access to quality public spaces and amenities such as clean drinking water, parks and access to transportation are already known to be unfairly distributed in cities. This difference is further aggravated by worse-off access and poor quality of services in urban poor neighbourhoods, be it for maternal and child health services, or for non-communicable diseases or infectious diseases such as Tuberculosis. Indeed, if cities aspire to be smart, the best way to get there would be by deploying fairer distribution of health, healthcare and good quality public services than through technology or industry alone.

VIII. SOCIO-ECONOMIC INEQUITIES IN HEALTH

The most obvious pathway reported in literature as driving the inequity along socio-economic lines is the over-dependence on an open and unregulated market mechanism for seeking healthcare.[30] In a health system where healthcare must be purchased from the open market, those who cannot afford it are likely to be disadvantaged with respect to health outcomes. Furthermore, healthcare by its very nature does not lend itself to being distributed equally; the fundamental organising principles of a well-functioning market for health are absent due to inherent asymmetries of information and power between the buyer and the consumer. As a result, it is not an accident that we find ourselves in a society where average income may be rising, but the degree of health inequalities is increasing as reported in studies by health economists.[31] Various psychosocial and biomedical evidence too have been presented to show how poverty and discrimination - in addition to themselves acting as barriers to healthcare - can also aggravate ill-health through independent biomedical and psychosocial mechanisms. Indeed,

[29] Supra 8; M. Pai, N. Correa, N. Mistry &, P. Jha, *Reducing global tuberculosis deaths—time for India to step up,* 389(10075) The Lancet 1174, (2017), available at https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)30790-0/fulltext, last seen on 12/06/2020.
[30] Supra 10.
[31] Supra 27.

overwhelming evidence from a wide range of studies shows us that people may tolerate inequality, but not unfairness.[32]

While the focus on widening coverage of health services and schemes to target the poor and disadvantaged is important, striving for more universal public services and systems that do not discriminate, and systems that address underlying reasons driving unfair distribution of health can only be brought about by well-funded and strong primary health care. In addition, health programmes and policies that address the drivers of unfair distributions, and shifting service and system priorities towards redressing this unfairness through better design and adaptation of programs are needed, if at all the unfairness in the distribution of health has to be corrected.

[32] C. Starmans, M. Sheskin & P. Bloom, *Why people prefer unequal societies,* 1(4) Nature Human Behaviour, (2017), available at https://www.researchgate.net/publication/315944588_Why_people_prefer_unequal_societies, last seen on 12/06/2020.

DIRECT MARKETING AND ADVERTISEMENT OF CERTAIN MEDICAL DEVICES TO PATIENTS IN INDIA – A DILEMMA

Swathi Kamath

ABSTRACT

This article attempts to highlight that while the Medical Device Rules, 2017 have been passed with an intent to provide access to patients with high quality, safe and effective medical devices, there is no law to permit and regulate dissemination of equally high quality and safe information about medical devices to the people who would potentially be using them.

Except the United States of America and New Zealand, no other country in the world allows direct to patient marketing of medical devices. Even these countries do not have separate marketing laws for pharmaceutical products and medical devices.

This article is unique because firstly, it is probably the first time that an attempt has been made to address the status quo of the Indian law on marketing of medical devices i.e. Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 that has existed with minor amendments for more than 65 years. Secondly, no other country in the world has passed a separate legislation that allows marketing of medical devices to the public at large.

This article also provides suggestions on what the new law permitting and regulating marketing/promotion of medical devices should cover to make it an effective one.

I. INTRODUCTION

Under the extant marketing law i.e. The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 (**"**DMRA**"**) that controls advertising and marketing of medical devices in India, direct to patient advertising of certain medical devices for treatment of certain conditions listed in the Schedule of the DMRA Act is not permitted. Violation of the provisions of this Act is a criminal offence that could lead to maximum one year of imprisonment.[1] The legislation was enacted in 1954, when the field of medical science had not developed and witchcraft and black magic was majorly prevalent in India. It promised "magic remedies" in the form of any talisman, amulet or any other object which possessed miraculous powers to cure, diagnose, prevent or mitigate a disease in humans or animals.

* Swathi Kamath, Legal Head & Company Secretary, Entero Healthcare Solution Pvt. Ltd.

[1] S. 7, The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.

The Indian government has finally seen the need to regulate medical devices distinctly and differently from pharmaceuticals and have introduced the Medical Device Rules 2017. These Rules are a breath of fresh air as they include the much-needed prescribed product standards for medical devices, single window clearance, perpetual licenses as opposed to time bound licenses, simpler registration for importers etc. However, the outdated DMRA Act continues to maintain its status quo without any amendments in line with the current economic situation. The Government has ignored this important piece of legislation and has left this extremely critical subject of patient education unattended for many decades.

II. ADVANTAGES OF DISALLOWING DIRECT TO PATIENT ADVERTISING OF MEDICAL DEVICES

The DMRA Act has definitely been beneficial in prohibiting advertisements relating to childbirth, women's diseases, menstrual disorders, infertility and impotency, treatment of cancer, rheumatism etc. in the early days when self-styled babas and witch doctors would deceive gullible patients owing to low literacy and inadequate health education.

In the current context, even though medical science has advanced and literacy rates have increased significantly, this prohibition restricts product specific advertisements which exaggerate the benefits of the product and downplay its risks. This leads to unrealistic expectations in the patient and could lead to distrust in their doctor who may be more informed about the product's performance in the long term. Additionally, pressure created by a patient to opt for a particular device, in response to such ads, may lead to over utilisation of medical devices, which may not be the most suitable option, thus causing doctors discomfort to satisfy inappropriate patient requests for specific treatments or devices. It is also thought that too many advertisements could confuse a patient.

III. DISADVANTAGES OF DISALLOWING DIRECT TO PATIENT ADVERTISING OF MEDICAL DEVICES

In the present context where "data is king", consumers are bombarded with advertisements on televisions, mobile phones and other products of daily use. Interestingly, patients or potential patients do not have access to similarly advertised information on disease/health awareness and the possible treatments available. It would be important for a cardiac patient to know what technologies are available for the condition that s/he is suffering from, especially in this "Right to Information" Age. Patients will be able to make more informed choices after considering their doctor's

advice and the information available to them. There will be joint decision making between the patient and the doctor with respect to the course of treatment to be adopted for the patient. Patients should be provided with evidence-based healthcare information which will help them in actively sharing the decision-making process with the doctor as it ultimately impacts their life. The doctors will also benefit from such advertisements as it will help update their knowledge with respect to newer technologies and their effects.

The primary objective[2] of the DMRA Act was to prevent people from self-medication and self-treatment and for that purpose commending certain drugs and medicines was prohibited. At the time when this law was passed in 1954, there was no scientifically proven cure for most of the diseases listed in the Schedule. However, medical science has significantly advanced over the last 65 years and a cure/remedy is available for most of the said diseases today.

IV. CURRENT LAW ON DIRECT TO PATIENT ADVERTISING IN FOREIGN JURISDICTIONS

Along with the United States of America, New Zealand allows direct to consumer advertising under their Medicines Act 1981. Direct to consumer advertising in these two countries allows (i) *product claim advertisements,* which promote a specific product and include both the product name and specific therapeutic claims and (ii) *reminder advertisements,* which provide the name of the product without containing or suggesting its use. New Zealand's rationales[3] behind permitting such advertisement are:

1. Harnesses private incentives to cover the cost of disseminating knowledge and to close the gap between what research has found and what doctors and patients know.

2. Meets increasing consumer demand for medical information, in a well-controlled and responsible way.

3. Informs consumers about new treatments.

4. Encourages people to seek medical attention for conditions or symptoms that might otherwise go untreated, including asymptomatic diseases.

[2] Hamdard Dawakhana v. Union of India, AIR 1960 SC 554.
[3] Ministry of Health, New Zealand, *Direct-to-Consumer Advertising of Prescription Medicines in New Zealand A discussion paper*, November 2000, available at http://www.moh.govt.nz/notebook/nbbooks.nsf/0/5c66d8aaa038df034c2569cb000c76b2/$FILE/dtcaDiscussionDoc.pdf.

5. Promotes patient compliance, and persistence, with recommended treatment.

6. Promotes better communication between patients and their doctors.

7. Improves the efficiency of public health care spending.

Sections 57 and 58 of The Medicines Act 1981 of New Zealand includes various provisions imposing certain restrictions on such advertisements to ensure socially responsible dissemination of information to the public. Some of the restrictions relate to not publishing any contradictory or conflicting information that is required to be on the product, the ad should not contain false or misleading information or imply that the product advertised is not harmful or habit-forming or suggest that the product is a panacea or is infallible or has been used or recommended by a registered health professional etc.

Countries like Korea, Japan, Australia, Hong Kong, China have adopted a protectionist policy of not allowing direct to patient advertising on the assumption that the public is confused when exposed to so much information and the medical information presented in such advertisements is too complex to be comprehended by laymen.

V. INDIAN SCENARIO

When the DMRA Act was passed in 1954, the objective was to prevent manufacturers from making dubious claims about certain drugs possessing magic cures and inducing patients to self-medicate. However, it is pertinent to note that the legislative intent at that time was only with reference to pharmaceutical products which can be self-administered and medical devices were not covered. Medical devices were read into the DMRA Act after the Supreme Court ruling in 1975.[4] Devices were pushed under the umbrella of "drugs" by way of an amendment to the definition of "drugs" in the Drugs and Cosmetics Act, 1940 in 1982. Hence, the DMRA Act became applicable to certain medical devices only in 1982. Thereafter, medical device manufacturers were obliged to comply with all the marketing related requirements that were applicable to pharmaceutical manufacturers. The Delhi High Court has, in one case, allowed such advertisements of devices based on the underlying principles that (i) the advertisement is only informing the public about the improved methodology and improved equipment availability of the

[4] Zaffar Mohammad @ Z.M. Sarkar v. The State Of West Bengal, 1976 SCR (2) 782.

procedure involved in the surgery; (ii) the public cannot self-medicate in this case and has to undergo surgery.[5]

The Drugs Consultative Committee has met several times to discuss the legislative need to distinguish between medical devices and pharmaceutical products owing to the increasing complexities in regulating both with the same laws and logic. The Medical Device Rules were finally rolled out in 2018 which shall separately regulate manufacture, import, distribution, clinical investigation, quality standards, labelling and the shelf life of medical devices. However, marketing of medical devices has not yet been addressed and regrettably continues to be a dilemma for the medical device industry.

The Draft DMRA Amendment Bill dated 3rd February 2020 has been circulated for comments/objections. The Ministry of Health has decided to briefly consider amending this vintage legislation. It is merely a brief consideration because the only significant amendments are the enhancement of penalty, addition of more diseases/conditions to the Schedule of the DMRA Act and constituting an Ayurvedic, Siddha and Unani Drugs Technical Advisory Board. But even the 2020 Bill, despite the passing of Medical Device Rules 2018, does not draw a distinction between the marketing of pharmaceutical products and implantable medical devices given that implantable medical devices cannot be self-administered. If this distinction is made, further steps to permit and regulate medical device marketing can be incorporated in the amended law.

The Bill is, therefore, still skewed and is missing out on an important opportunity of striking a balance between promoting patient education and ensuring that it is done in a responsible manner. The Bill continues to promote the extreme protectionist stance that was taken in 1954 instead of transforming into a consumer enabling and empowering legislation.

VI. SOLUTION PROPOSED

There is no doubt that a patient deserves to have access to quality and accurate information with respect to products that could potentially change their lives. The DMRA Act needs a complete overhaul in order to bring the legislation up to date with the present-day market reality. The law should be capable of ensuring that balanced and reliable information is disseminated to the public at large, thereby highlighting the risks alongside the benefits of the product, like in the United States of America where direct to patient marketing is permitted though regulated under the Federal Food, Drug and Cosmetic Act of 1938. The advertisements

[5] Amit Singh & Anr. v. The State, Crl. M.C. No. 648/2011, High Court of Delhi.

should not just aim at spreading product specific content, but also create disease/health awareness without creating fear in the minds of public, thereby enhancing the dialogue between the doctor and patient.

The regulator will also play an important role in monitoring/vetting these advertisements and taking strict action against the wrongdoers. It can be made mandatory that a copy of every publication or media should be uploaded on the regulator's website as well. Higher and stronger penalties can be levied on the advertising media and the medical device company.

The legislators may also impose restrictions such as permitting advertising of products only after the product claims have been approved by the relevant regulator, the product has all the relevant licenses and registrations, prohibition on comparability and superiority claims etc.

VII. KEY TAKEAWAYS

1. The name of the enactment needs to be changed. The words "Magic Remedies" in 2020 is regressive and unacceptable. Our laws need to keep pace with science and technology.

2. Given that the Indian medical device market is estimated to grow to US $8.16 billion in 2020 at a Compounded Annual Growth Rate of 16%,[6] and that it is impossible to eliminate direct to patient advertising on the internet, it is beneficial to have an appropriate regulated environment to advertise in contrast to relying on industry self-regulation.

3. Self-administration of most medical devices like stents, implants etc. is not possible, so the risk of advertising of medical devices directly to the patient is much lower compared to pharmaceutical products. Hence, the government should revamp the archaic DMRA Act on a priority basis and ensure that patients' unmet needs of quality healthcare education are being satisfied.

4. All direct to patient/public marketing material should have a brief summary about all associated risks/side effects along with the benefits of the device. Medical device companies and advertising agencies will have to find creative ways to do this given the time and space constraints involved in advertising.

[6] World Health Organisation, *Medical Device Manufacturing in India- A Sunrise*, 2017, available at https://pharmaceuticals.gov.in/sites/default/files/medicaldevicemanufacturinginindia-asunrise-170221053503%20%281%29.pdf.

5. Doctors are the last mile contact for the patients with respect to the patient's condition and available treatments, so doctors should not come under the pressure of their patients and should independently advise what is best for them.

6. Medical device manufacturers/distributors and the advertising media should be made severely liable for publishing any provocative, deceptive or misleading information in the public. The product claims should be limited to what has been approved by the regulatory authority. The current provisions should be amended with higher fines and imprisonment period to create a strong deterrent. This has also been recently discussed in a meeting of the Drugs Consultative Committee.[7]

7. Regulators also need to have a robust system in place to monitor and review marketing and promotional material targeted to patients and penalise the wrongdoers appropriately in order for the revised law to have a powerful deterrent value. This regulatory body could be something similar to Advertising Standards Council of India (**"**ASCI**"**) or the Central Consumer Protection Authority under the Consumer Protection Act, 2019. The Ministry of AYUSH has signed a MOU with ASCI to monitor misleading advertisements being published in print and TV media with respect to Ayurvedic, Unani and Siddha drugs. The option of getting these materials pre-vetted by the regulator can also be made available to the medical device industry at their cost.

[7] *Minutes of 56th Meeting of Drugs Consultative Committee*, Central Drugs Standard Control Organization, available at https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadCommitteeFiles/56thDCCmeeting.pdf, last seen on 29/04/2020.

A NOTE ON ADVANCE DIRECTIVE UNDER THE MENTAL HEALTHCARE ACT, 2017

[*]Gowthaman Ranganathan

ABSTRACT

The Mental Healthcare Act, 2017 ("Act") came into force to give effect to India's obligation under the United Nations Convention on the Rights of Persons with Disabilities ("UNCRPD"). This paper analyzes the provisions relating to advance directives in the Act. Advance directive is an essential tool to affirm personhood and autonomy for persons with psychosocial disabilities. Currently, the provisions on advance directives are contrary to the letter and spirit of the UNCRPD. The Act provides for suspension of advance directives during an emergency treatment when it should be honoured the most. It also provides for revocation of the directives by others which compromises the integrity of this instrument. The Act provides for community living, an essential shift from substituted capacity to supported capacity, to realize universal legal capacity under Article 12 of the UNCRPD. This paper argues that for an effective implementation of advance directives deinstitutionalization and a shift to community living is essential. We must look to the General Comment I (on universal legal capacity) and General Comment V (on living independently and being included in the community) of the UNCRPD to strengthen advance directives under the Act.

I. INTRODUCTION

In this note, I argue that the provisions relating to advance directive under the Mental Healthcare Act, 2017 (**"**Act**"**) must be interpreted to affirm legal capacity of persons with psycho-social disabilities.[1] Further, I suggest that it is essential to strengthen the right to community living which will provide support for persons with disabilities to affirm their legal capacity through effective use of advance directives. A prerequisite for this is to move away from institutionalization as a method of treatment. In doing this, attention must be given to the General Comment I and V adopted by the Committee on the Rights of Persons with Disabilities. These General Comments provide crucial guidelines to State Parties on realizing the rights under Article 12 and Article 19 of the United Nations Convention on the Rights of Persons with Disabilities (**"**UNCRPD**"**) on the right to legal capacity and the right to independent living and being included in the community respectively.

[*] Gowthaman Ranganathan, Fulbright-Nehru Master's Fellow, MD Anderson Research Fellow, Institute of Transnational Law, Candidate for LLM (Human Rights and Comparative Constitutional Law) University of Texas at Austin, School of Law.

[1] I use the phrase psycho-social disability to indicate that psychological disabilities also are also socially determined.

The Act came into force to align and harmonize existing laws with the UNCRPD which India has signed and ratified. At the heart of the UNCRPD is Article 12 on universal legal capacity[2] which provides that, *"States parties shall recognize that persons with disabilities enjoy legal capacity on an equal basis with others in all aspects of life"*. General Comment I defines legal capacity as *"the capacity to be both a holder of rights and an actor under the law. Legal capacity to be holder of rights entitles a person to full protection of his or her rights by the legal system. Legal capacity to act under the law recognizes the person as an agent with the power to engage in transaction and create, modify or end legal relationships*."[3] Despite the coming into force of the Act, full realization of legal capacity of persons with disabilities is yet to be achieved.[4]

Advance Directive is one tool towards realizing legal capacity of persons with psycho-social disabilities. Section 5 of the Act provides for every person who is not a minor to have a right to make an advance directive under the Act to specify the ways to be followed and not to be followed for care and treatment. The directive is executed in the manner set out in the Act. The directive is made at a prior time to ensure that when the person is not able to articulate their decisions, they can be made in accordance with the directive.

This instrument is often characterized as the Ulysses contract which draws upon the Greek text Odyssey. The story is of Ulysses who wants to listen to the sirens which is beautiful but deadly. To ensure that he does not go insane by listening to the sirens, he asks his men on the ship to tie him to the mast. Thus, he gave a command to others to bind him to the mast so he can listen to the siren without being driven by it to commit certain acts.[5]

In this oft quoted account of the Ulysses, he gets binded by asking others to bind him when he is about to hear the sirens. However, I suggest that advance directives should not be an instrument that binds oneself or asks others to bind a person. It should be seen as an injunction of others from doing or restraining from doing certain acts. In the case of medical treatment, a directive binds the caregiver, healthcare provider to the words of the person with disability from a prior time. When we understand advance directive this way, the need to provide pre-eminence

[2] G. Ranganathan, *Mental Healthcare Act: An Evaluation*, 4(2) NLUJ Law Review, (2017).
[3]*General Comment No. 1. Article 12: Equal recognition before the law,* UN Committee on the Rights of Persons with Disabilities, CRPD/C/11/4, (11/04/2014), available at https://digitallibrary.un.org/record/779679?ln=en, last seen on 31/01/2020.
[4] Laws denying legal capacity continue to be in force. This includes laws relating to contract, voting, marriage etc. For a discussion of some of these laws see Bhargavi V Davar, *Legal frameworks for and against people with psychosocial disabilities*, 47 Economic & Political Weekly 123, 125 (2012).
[5]Sarin, A., Murthy P. & Chatterjee S., *Psychiatric advance directives: potential challenges in India*, 9 Indian J Med Ethics 104, 105 (2012).

to the words of the person with disability becomes clearer. Unfortunately, the current provisions of the Act undermine the words of the person with disability during crucial times like emergency treatment. I suggest that a system of support which includes deinstitutionalization is essential to realize the full potential of advance directives.

A person with disability should have the full and unhindered right to choose the nature of their treatment in the advance directive. This may include the choice to not being institutionalized. The problems and rights violations at institutions providing mental healthcare are well documented.[6] I suggest that not only should one be able to opt out of institutionalization as a mode of treatment, but deinstitutionalization is a prerequisite to uphold legal capacity of persons with disability. Further, strengthening the right to community living as set out in Section 19 of the Act is essential towards deinstitutionalization. Community living will provide adequate support for executing advance directives that are free from duress and in turn advance directives can seek community living as a mode of care and treatment instead of institutionalization.

II. ADVANCE DIRECTIVE UNDER THE ACT

The Act provides details on advance directives in Chapter III. This includes procedure to be followed and the need to register the directives. The two primary problems with Section 5 on advance directives are with regard to Section 5(9) and Section 5(11). Section 5(9) provides that advance directive shall not apply to emergency treatment under Section 103. Section 5(9) wrongly mentions the provision relating to emergency treatment as Section 103, the correct provision is Section 94. Apart from this minor error, the matter of grave concern is that an advance directive is suspended during times of emergency treatment.

Section 94 lists out emergency treatment to include treatment to prevent death or irreversible harm to the health of a person; or the persons inflicting serious harm to himself or to others; or the person causing serious damage to property belonging to himself or to others where such behavior is believed to flow directly from the person's mental illness. It restricts emergency treatment to seventy-two hours and may extend to seven days if an emergency is declared by the appropriate government. This provision negates advance directive when it is most crucial to be honoured.[7] Non-consensual psychiatric intervention is contrary to the

[6] *Treated Worse Than Animals: Abuses Against Women and Girls with Psychosocial or Intellectual Disabilities in Institutions in India*, Human Rights Watch, available at https://www.hrw.org/report/2014/12/03/treated-worse-animals/abuses-against-women-and-girls-psychosocial-or-intellectual, last seen on 12/12/2020.

[7] For a detailed analysis of the Act in light of the UNCRPS see, *How the Celebrated Mental*

text and spirit of Article 12 of the UNCRPD.[8] Situations described as requiring emergency treatment under the Act are the ones when a person's autonomy needs to be respected the most.

The other problem is in Section 5(11) which provides for review, alteration, modification or cancelation of the advance directive. This can be done at the behest of a mental health professional or a relative or caregiver and can be granted by the Mental Health Board constituted under the Act. As discussed earlier, the advance directive is a tool to bind the action of others which will have an impact on the person with disability. Section 5(11) grants power to alter or revoke the advance directive to the very persons whose actions ought to be bound by the advance directive. Thus, the Act can be used to further forced treatment including institutionalization and obscure legal capacity of persons with psycho-social disabilities. Further, the Act does not include an explicit right to legal capacity like Article 12 of the UNCRPD. In order to uphold the letter and spirit of the UNCRPD and to truly harmonize the Act with UNCRPD, we must focus on deinstitutionalization and, independent and community living. We must look to General Comment I and V to achieve this.

III. FROM SUBSTITUTED TO SUPPORTED CAPACITY

One of the concerns regarding the effectiveness of advance directives in India is that there is not sufficient support to draft and execute them. There are also concerns around misuse of these directives by forcing people to execute it. Advance directive is a way to further the realization of legal capacity. Currently, legal capacity for persons with psycho-social disabilities is substituted by another person through systems of guardianship or such similar delegation. However, the General Comment I categorically encourages State Parties to the UNCRPD to move to a system of support based legal capacity where support is provided to persons with psycho-social disabilities to realize complete capacity.

The nature of support varies with the nature of disability and other factors. I focus on one kind of support that may be provided for persons with psycho-social disabilities which is to facilitate community living. The UNCRPD provides for the right to independent living and being included in the community. Article 19 of the Act emphasizes on community living but should be read to include independent living as

Healthcare Act Restricts Individual Liberty and Fails to Comply with International Standards, THE CARAVAN, available at https://caravanmagazine.in/vantage/mental-healthcare-act-restricts-individual-liberty-fails-international-standards, last seen on 08/03/2020.

[8] See Generally, Tina Minkowitz, *The United Nations Convention on the Rights of Persons with Disabilities and the right to be free from nonconsensual psychiatric interventions*, 34 Syracuse J. Int'l L. & Com., 405 (2006).

well. Facilitating living in a community where persons with psycho-social disability feel safe and can trust others will provide them support to make advance directives that captures their will and preference sufficiently. The General Comment I require that a person's will and preference be the guiding force behind any kind of support that is provided. Being supported by a community of their choice, persons with psycho-social disabilities can make choices regarding their treatment in the advance directive that affirms their rights and honours their legal capacity.

Currently, institutionalization is a dominant form of treatment. A shift to providing support through community living is essential to address the concerns around effectiveness of advance directives. Thus, deinstitutionalization, and shift to forms of support that are in line with the letter and spirit of the UNCRPD, is an essential prerequisite for the effective use of advance directives.

IV. CONCLUSION

Advance directive is a crucial tool to affirm the right to legal capacity for persons with psycho-social disabilities. It allows for reinforcing capacity when a person needs them the most. Unfortunately, the Act tries to undo this essential feature by making it revocable for emergency treatment and allowing other persons to revoke or alter it. These provisions are contrary to the UNCRPD. Further, for the effective use of advance directives, it is essential to move away from institutionalization and provide support through community living in addition to other kinds of supports. The guidelines to State Parties under General Comment I and V have to be taken seriously when these provisions are being used.

THE DISMAL STATE OF MEDICO-LEGAL SERVICES FOR RAPE VICTIMS IN INDIA

Dr. Indrajit Khandekar

**Khushali Mahajan*

ABSTRACT

Forensic investigation and medical examinations of rape victims in India are often riddled with loopholes and lacunae. A wide gap exists between the statutory text providing provisions for curbing rape, and their actual implementation. In this gap mushrooms a lot of medical malpractices which often interfere with the justice mechanism of the nation. In this paper, the author recognizes two such ignorant medical practices which have plagued the medical examination of rape victims for a long time. The author aims to investigate the invasive and unethical practices of the two-finger/virginity test. Further, the paper will also illuminate how maladministration of contraceptives can negatively affect the life of a rape victim.

I. INTRODUCTION

In India, victims of sexual violence have, for time immemorial, tolerated criminal justice and health care systems that pay negligible attention to their needs and rights. Because of the many deficiencies and loopholes in the system, the victims often face humiliation, shame and discrimination. These humiliations are witnessed in their own homes, police stations and also in the hospitals where they undergo inadequate and incomplete medico-legal examinations that often end up doing little beyond harming their cases in the legal processes that follow.[1]

Sexual violence is, disturbingly, a growing trend in India. According to the data compiled by National Crimes Records Bureau (NCRB), "*4,15,786 rape cases were reported across India between 2001 and 2017. On average, 67 women were raped every day across the country during these 17 years, or, in other words, about three women had been raped every hour.*"[2] A small rise in the number was noticed yet again, when in 2018 a 0.9% increase in reported

* Dr. Indrajit Khandekar, Professor & In-charge Clinical Forensic Medicine Unit, Deptt. of Forensic Medicine & Toxicology, Kasturba Hospital- MGIMS.

** Co-authored by Ms. Khushali Mahajan, 2nd Year Student at the Rajiv Gandhi National University of Law, Punjab.

[1] *Invisible Victims of Sexual Violence*, Human Rights Watch (03/04/2018), https://www.hrw.org/report/2018/04/03/invisible-victims-sexual-violence/access-justice-women-and-girls-disabilities, last seen on 20/04/2020.

[2] D. Rai, *Sexual violence pandemic in India: Rape cases doubled in last 17 years*, India Today (13/12/2019), available at https://www.indiatoday.in/diu/story/sexual-violence-pandemic-india-rape-cases-doubled-seventeen-years-1628143-2019-12-13, last seen on 29/03/2020.

rape cases was recorded.[3] Past academic work in this area provides that these figures likely underestimate the problem.[4] While the numbers are determined by the cases reported to the police, it is highly likely that a large number of rape capes go unreported.[5] Many survivors of sexual violence do not report attacks because they fear ridicule or retribution, as well as labels like "bad," "loose," or otherwise "responsible" for the attack.[6] The prevalent, and unfortunately crippling mindset of a family's honour being a woman's sole and exclusive responsibility, has prevented countless rape victims from even the hope of justice.[7] Victims and their families may also be reluctant to subject themselves to the criminal justice system. With the unfortunately low conviction rate of 27.2%, it is not uncommon for victims and their families to feel that the system does not protect them.[8]

In this paper, the terms 'victims' and 'survivors' are used interchangeably. Some women who have been raped prefer to be called victims, because the term survivor seems to them as a shallow compensation which paints a wrong picture of the power dynamics of rape; in their view, the victim is overcome by the rapist, and hence, calling them a survivor would denote an unreal amount of power which they do not have at the time of the commission of the offence.[9] On the other hand, some prefer to be called

[3] *Crime Against Women (2016-2018)*, National Crimes Record Bureau, available at, https://ncrb.gov.in/sites/default/files/crime_in_india_table_additional_table_chapter_reports/Table%203A.1_0.pdf, last seen on 20/04/2020;
V. Mishra, *A rape in India every 15 minutes: government data*, Asia Times (15/01/2020), available at https://asiatimes.com/2020/01/a-rape-in-india-every-15-minutes-government-data/, last seen on 24/04/2020.

[4] A. Pitre & M. Pandey, *Response of Health System to Sexual Violence*, Centre for Enquiry into Health and Allied Themes, 4 (2009), available at https://www.academia.edu/21088081/Response_of_Health_System_to_Sexual_Violence_An_exploratory_study_of_six_health_facilities_in_two_districts_of_Maharashtra, last seen on 23/04/2020;
P. Baxi, *The Medicalisation of Consent and Falsity: The Figure of the Habitué in Indian Rape Law*, 275 in*The Violence of Normal Times: Essays on Women's Lived Realities (*K. Kannabiran, 1st ed., 2005), available at https://www.academia.edu/1766137/The_Medicalisation_of_Consent_and_Falsity_The_Figure_of_the_Habitu%C3%A9e_in_Indian_Rape_Law, last seen on 29/03/2020.

[5] D. Pujara, G. Bhatia, K. Singh & R. Gopalakrishnan, *Statistics on rape in India and some well-known cases*, Reuters (06/12/2019), available at https://www.reuters.com/article/us-india-rape-factbox/statistics-on-rape-in-india-and-some-well-known-cases-idUSKBN1YA0UV, last seen on 23/04/2020.

[6] Ibid.

[7] S. Denyer, *In rural India, rapes are common, but justice for victims is not*, The Washington Post (08/01/2013), available at https://www.washingtonpost.com/world/asia_pacific/in-rural-india-rapes-are-common-but-justice-for-victims-is-not/2013/01/08/c13546b4-58d6-11e2-88d0-c4cf65c3ad15_story.html, last seen on 01/04/2020.

[8] PTI, *Conviction rate for rape only 27.2% even as country celebrates justice in Nirbhaya case*, The Economics Times (06/01/2020), available at https://economictimes.indiatimes.com/news/politics-and-nation/conviction-rate-for-rape-only-27-2-even-as-country-celebrates-justice-in-nirbhaya-case/articleshow/73169787.cms?from=mdr, last seen on 20/04/2020.

[9] D. Campoamor, *I'm Not a Sexual Assault "Survivor"—I'm a Victim*, Harper's Bazaar (21/05.2018), available at

survivors, because of the stigma attached to the 'victim culture' and because it resonates the qualities of strengths and endurance.[10] This interchangeable usage is not intended to be disrespectful towards any woman who has faced the horrors of rape, but instead because the victim versus survivor debate remains unresolved.

This paper draws inputs from a 2010 study by the author, but also reflects the present scenario on the forensic dimension of rape. In the 2010 study,[11] which was on the state of medico-legal services provided to rape victims in the Wardha District of Maharashtra, he found that the doctors involved in attending rape cases in hospitals treated the survivor as a police case and not as a patient in need of treatment. Their focus was on submitting a medico-legal report to the police. Due to a lack of set protocols, they even subjected survivors to the degrading two-fingers test, a test that is not based on evidence and is inhumane, which has now been declared unmeritorious.[12]

This paper seeks to explore the medico-legal help for rape victims that has been statutorily recommended, and the many shortcomings in the reception of this help in reality. One of these shortcomings is the prevalence of the two-fingers test, commonly known as the virginity test. The two-fingers test emanates from societal norms of preserving the chastity of women, which has found its way in forensic examinations, too. The paper addresses the medical, psychological and legal problems posed by the test. Another issue that shall be given attention to is the mal-administration of medical help to victims, which could possibly result in unwanted pregnancies. Further, the effect of this maladministration on the children born out of rapes shall also be investigated.

II. THE FORENSICS OF RAPE

The Delhi Gang Rape Case[13] exposed the extent to which rapists can be brutal. The nationwide outrage against it was aimed towards seeking the harshest possible punishments for the culprits. The country's outrage brought to light how the demand for justice is generally focused on the punishment the rapists receive, and little on the condition in which the survivor is left.

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https://www.harpersbazaar.com/culture/features/a20138398/stop-using-survivor-to-describe-sexual-assault-victims/, last seen on 22/03/2020.

[10] K. Harding, *I've Been Told I'm a Survivor, Not a Victim. But What's Wrong With Being a Victim?*, Time (27/02/2020), available at https://time.com/5789032/victim-survivor-sexual-assault/, last seen on 22/03/2020.

[11] Indrajit Khandekar, *Pitiable and Horrendous Quality of Medical Examination of Rape Victims in Wardha District (MH)*, 12(4) International Journal of Medical Toxicology & Legal Medicine (2010).

[12] Lillu v. State of Haryana, (2013) 14 SCC 643.

[13] Mukeshv. State (NCT of Delhi), (2017) 6 SCC 1.

The medical examination of a rape victim has been described as a "medico-legal emergency"[14] and is conducted within the limits of Section 164A of the Code of Criminal Procedure, 1973 (**"**CrPC**"**).[15] Because rape is primarily a crime against a woman's bodily autonomy, her body becomes the most important evidence for the legal processes that follow. Signs of struggle, bruises and most importantly, traces of DNA allow the police to carry investigations, which ultimately helps in identifying the rapist and delivering justice.

The forensic examination of a rape victim starts with immediate first aid. Once she files a First Information Report, it then proceeds to seek informed consent of her to initiate medical examinations.[16] A physical examination of the victim, in which injuries sustained by her and a local examination of her genitals are conducted. It is followed by documentation and sealing of any evidence which is indicative of sexual assault. The evidence is then handed to the police for investigation into the sexual assault. Additional medical help is then provided, by treating injuries, testing for sexually transmitted infections (**"**STI**"**) and pregnancy. The status of the victim's mental health is checked to identify signs of trauma. In addition to that, mental and emotional counselling is provided to help the victim get through this difficult time.[17]

The process of undergoing a forensic examination can be extremely scarring for a victim, because it can often make her revisit the crime. Therefore, it is very necessary to make her feel comfortable throughout the process. Section 53 of the CrPC calls for the medical examination of a rape victim, in the presence of a female medical practitioner.[18] Further, mental health professionals should also be present to assist the victim and make them feel safe.[19]While the medical examination is supposed to be largely procedural, it can often be tampered with because of poor evidence collection facilities.[20] Too often, survivors are shifted from one hospital or ward to another, and receive multiple examinations at each stop. Further, the lack of communication and co-ordination between the

[14] Gujua Manjhi v. State of Jharkhand, (2015) 3 AIR Jhar R 710;
N. Jagadeesh, *Legal changes towards justice for sexual assault victims*, 7(2) Indian Journal of Medical Ethics, (2016), available at https://ijme.in/articles/legal-changes-towards-justice-for-sexual-assault-victims/?galley=html, last seen on 27/04/2020.
[15] S.164 A, The Code of Criminal Procedure, 1973.
[16] S.164(7) A, The Code of Criminal Procedure, 1973.
[17] Central Forensic Science Laboratory, Ministry of Home Affairs, Government of India, *Guidelines for Forensic Medical Examination in Sexual Assault Cases (2018)*.
[18] S. 53, The Code of Criminal Procedure, 1973.
[19] *Guidelines for medico-legal care of victims of sexual violence*, World Health Organization (2003), available at https://www.who.int/violence_injury_prevention/publications/violence/med_leg_guidelines/en/.
[20] H. Pandey & P. Dhar, *Collection of rape evidence in India – an analysis*, 6(6) Forensic Research & Criminology International Journal, 460 (2018), https://medcraveonline.com/FRCIJ/FRCIJ-06-00245.pdf, last seen on 01/04/2020

hospital(s) where the examinations had taken place and the forensic labs can lead to loss of a major evidence.[21] Adding to the woes of the survivors, it may be lost or subject to processing delays, render the evidence unusable. In the important case of *State of Karnataka v. Rangaswami*,[22] the Karnataka High Court has observed that evidence of sexual assault cases is mostly tampered with, and that *"doctors have brazenly given evidence that has virtually sabotaged the prosecution"*. In the same case, the court has also observed that majority of the cases of rape end up in acquittals owing to the poor facilities in hospitals and the uninterested and unprofessional attitude of the doctors.

Our medico-legal process requires conducting of a forensic medical examination as per a 'proforma', which has to be completed by a doctor. A proforma in the question of rape, is included in the rape kit, and is like a set of instructions that a doctor has to follow in order to conduct the requisite medical check-ups. For a long time, proformas were not standardized, and hence it was at the mercy of a doctor to decide what indications fulfilled the criteria of rape.

In 2011, the State of Maharashtra released a standardized proforma and manual for medical examinations of rape victims, which streamlined the process for evidence collection and examination.[23] In 2014, national guidelines (**"**2014 Guidelines**"**) and a standardized proforma was compiled by the Ministry of Health and Family Welfare, to minimize the differences that can be brought by personalized and non-standardized medical examinations.[24]

It is critical for the victim that they receive psychological support and counselling after they report the crime, because it is this counselling that

[21] Ibid.

[22] State by Alur Police v. Rangaswamy alias Narayanagowda & Ors., 2003 Cri LJ 607.

[23] *Manual for Forensic Medical Examination of Cases of Sexual Assault*, High Court Committee, Maharashtra (2011);
Proforma: Forensic Medical Examination Report of Alleged Victim of Sexual Assault, High Court Committee Maharashtra (2011); V. Ganjapure, *In a relief to rape victims, Maharashtra government has amended the proforma for forensic medical examination for sexually assaulted victims as suggested by Dr. Indrajit Khandekar on whose report a PIL was filed. The government has prepared instruction manual, age estimation proforma, requisition letter for chemical analysis, and format for final opinion as advised by Dr. Khandekar's for proper forensic medical examination. If implemented, Maharashtra would become first state to have such proforma,* The Times of India (28/04/2011), https://timesofindia.indiatimes.com/In-a-relief-to-rape-victims-Maharashtra-government-has-amended-the-proforma-for-forensic-medical-examination-for-sexually-assaulted-victims-as-suggested-by-Dr-Indrajit-Khandekar-on-whose-report-a-PIL-was-filed-The-government-has-prepared-instruction-manual-age-estimation-proforma-requisition-letter-for-chemical-analysis-and-format-for-final-opinion-as-advised-by-Dr-Khandekars-for-proper-forensic-medical-examination-If-implemented-Maharashtra-would-become-first-state-to-have-such-proforma-/articleshow/8110558.cms, last seen on 28/04/2020.

[24] Ministry of Health and Family Welfare, Government of India, *Guidelines & Protocols: Medico-Legal Care for Survivors/Victims of Sexual Violence*, available at https://main.mohfw.gov.in/sites/default/files/953522324.pdf.

helps them in reassuring that the attack was never their fault. A victim generally faces an overlap of Rape Trauma Syndrome (**"**RTS**"**) and Post Traumatic Stress Disorder (**"**PTSD**"**).[25] It is unjust and insensitive to expect them to think rationally about the long-term impacts of rape, like probability of pregnancy and battling Sexually Transmitting Infections. It should be understood that these victims, who are at such a vulnerable stage of their lives should be given professional medical and psychological counselling at healthcare facilities by trained professionals instead of being relegated as volunteer services.

While the physical examination is standardized throughout the country, the psychological health of a victim has to be gauged without any standardized and strict rules. However, what we witness in turn is the creation of a stereotypical image of victims, which often leads to miscarriage of justice.[26] It has been noticed that if a victim gets emotional or breaks down while giving a testimony, judges find confidence in her testimony.[27] This is because of the generalization of a rape victim being emotionally battered, and hence her emotional state is accepted as a buttress to her testimony. However, on the other hand, if the victim does not portray such an emotional behaviour, but is rather calm and is able to provide a lucid testimony, her testimony could be at the risk of being deemed unreliable. For example, in the case *Raja v. State of Karanataka*, the prosecutrix went back to place where she had been raped in order to collect evidence against the accused.[28] These "confident movements" of the prosecutrix's were regarded as "out of the ordinary", hinting to a diversion what the Court would have expected a violated person to behave. The two disparate examples show that both the justice and healthcare systems seem to be less than sympathetic of women's trauma if the latter deviate from the expected behaviours of a victim. It also shows that both systems seem to rely on stereotypes and at the same time, reinforce these stereotypes of how a virtuous person should behave when they are violated. This reinforcement has emerged as a gulf in our understanding of the mental turmoil of a rape victim.

[25] A.W. Burgess & L.L. Holmström, *Rape Trauma Syndrome*, 131(9) American Journal of Psychiatry 981, (1974);
B. Kolk, S. Roth, D. Pelcovitz, S. Sunday & J. Spinazzola, *Disorders of Extreme Stress: The Empirical Foundation of a Complex Adaptation to Trauma*, 18(5) Journal of Traumatic Stress 389, (2005), available at http://www.traumacenter.org/products/pdf_files/SpecialIssueComplexTraumaOct2006JTS3.pdf, last seen on 29/03/2020.

[26] G.S. Bajpai& R. Mendiratta, *Gender Notions in Judgments of Rape Cases: Facing the Disturbing Reality*, 60 Journal of Indian Law Institute, 298 (2018), available at http://14.139.60.114:8080/jspui/bitstream/123456789/47598/1/019_Gender%20Notions%20In%20Judgments%20of%20Rape%20Cases%20Facing%20The%20Disturbing%20Reality%20%28298-311%29.pdf, last seen on 20/04/2020.

[27] Kamalanatha v. State of Tamil Nadu, (2005) 5 SCC 194.

[28] Raja v. State of Karanataka, (2016) 10 SCC 506.

While examining rape victims, it is often observed that the medical examination and forensic investigation is not limited to scientific and standardized principles. Rather, certain sociological issues taint objective procedures; one of the most harrowing of such issues is judging the character of a victim. The taboo of labelling a woman as immoral or of loose character if she is habituated to sexual activities is deep rooted in the society. This taboo was strengthened by the statutory provision of discrediting a victim's testimony, as laid in Section 154(4)[29] of the Evidence Act. Because this section was an obstruction in justice, the Act was amended in 2002,[30] with the addition of a new provision of Section 146,[31] which now disallows questioning a rape victim's character during the cross-examination. Judging a victim's character does not hold merit in law, because of the amendment in relevant statute and observation by the Supreme Court,[32] but the sociological dimension of this taboo cannot be altered simply by law.

While standardized protocols have been useful in ensuring that physical examinations and collection of evidence of the sexual assault are performed accurately and timely, this has not precluded the degrading examination procedures that are rooted in social and cultural biases which, further traumatizes the victims. One such examination procedure is the two-finger test.

III. HORRORS OF THE TWO-FINGER TEST

For centuries, sexual politics have given birth to many societal norms. At the losing end of these norms and politics were mostly women. One of the most pervasive norm is that a woman ought to be a virgin or "sexually pure" in order to be a suitable partner for marriage. A woman's virtue and her family's honour has, for centuries, been linked to her sexual history.[33] To perpetuate such norms, practices are developed around preserving women's chastity. One such practice was of the virginity/two-finger test (**"**the test**"**), in which practitioners would insert two of their fingers in inside a woman's vagina to check the laxity and presence of a hymen to determine whether she was a virgin or not. As scientifically flawed as this practice might be, it found its way to be woven in many societies over centuries, and finding resonance in forensics too.

[29] S. 154(4), The Indian Evidence Act, 1872.
[30] The Indian Evidence (Amendment) Act, 2002.
[31] S. 146, The Indian Evidence Act, 1872.
[32] State (NCT of Delhi) v. Pankaj Chaudhary, (2019) 11 SCC 575.
[33] *Collectanea Medica: Consisting of Anecdotes, Facts, Extracts, Illustrations, &C.: Relating to the History or the Art of Medicine, and the Collateral Sciences*, 51(301) The London Medical and Physical Journal 206, 211 (1824).

One of the most controversial parts of the forensic medical examination is this much debated test. Officially called Per-Vaginum Test, it is conducted to ostensibly check if penile penetration has taken place. Depending upon the laxity of the vagina, the practitioner ascertains whether the victim is 'habituated to sex'.[34] Because of the taboo of a woman who is 'habituated to sex' gives her consent to all invitations of sexual intercourse, practitioners have come to use the test as an indication of a victim's consent. Such flawed opinions raise questions like whether the forensic examination, which ought to be scientific and ethical, is for a trial of the victim's character or of non-consensual sexual intercourse.

The most important element of what draws the line between sex and rape is informed consent. The least relevant fact is victim's sexual history, as it does not stand as a yardstick to her consenting to future sexual experiences. The legal question is whether one faced a forced sexual encounter, for which the complaint has been filed. The test only seeks to establish what the doctor considers prior sexual activity, which has nothing to do with establishing the victim's consent, and hence does not help in proving rape.[35] It also does not aid forensic investigation like sophisticated methods such as DNA profiling do, but remains a sociological anomaly which has paved its way to forensic examinations.

The test is both invasive and disrespectful to a woman's body and violates her rights as a person. This test can result in a lot of mental duress and trauma because it dilutes the claims of the victim. A victim's consent is judged by the rupture of her hymen or laxity of her vagina, both of which cannot indicate either virginity or the constitution of rape.[36] This ill measure of determining her consent through her sexual history using an ethically and scientifically fraudulent technique can often make a victim feel that she is being implicated in the crime committed against her. This very system that is supposed to seek justice for victims continue to marginalise them and mark them guilty even before the perpetrator is brought to trial.

In a ground-breaking judgment of *Lillu v. State of Haryana*,[37] the Supreme Court held that *"the two-finger test and its interpretation violates the right of rape*

[34] Yogesh Kumar v. PIO, Family & Welfare Dept., 2015 SCC OnLine CIC 7912; Justice Verma Committee, *Report of the Committee on Amendments to Criminal Law,* 2013, available at https://www.prsindia.org/uploads/media/Justice%20verma%20committee/js%20verma%20committe%20report.pdf, last seen on 20/05/2020.

[35] J. Bajoria, *Doctors in India Continue to Traumatise Rape Survivors with the Two-Finger Test*, Human Rights Watch, (09/11/2017), available at https://www.hrw.org/news/2017/11/09/doctors-india-continue-traumatise-rape-survivors-two-finger-test, last seen on 23/04/2020.

[36] J.P. Modi, *A Text-Book of Medical Jurisprudence and Toxicology*, 303 (K. Kannan, 21st ed., 1979).

[37] Lillu v. State of Haryana, (2013) 14 SCC 643.

survivors to privacy, physical and mental integrity and dignity. Thus, this test, even if the report is affirmative, cannot ipso facto, be given rise to presumption of consent", hence invalidating the flawed medical practice determining whether the rape victim was indeed raped. Following this case, the 2014 Guidelines declared this test to be invalid on the ground that *"the vaginal introitus has no bearing on a case of sexual violence."*[38] The local examination of genitals has to be in accordance with these guidelines, therefore Per-Vaginum tests have to be conducted only when necessary, and for medical reasons such as checking for abrasions or bruises. A strong case must be made for all aspects of the forensic exam and the main priority of the examination has to be to assess and document the injuries that the victim had sustained in the genital region during the attack. In doing so, it would ensure that healthcare professionals are able to provide appropriate care and support to the victims of the sexual assault.

With the rise in awareness about mental health among people and surge in activism for bodily autonomy and privacy, the test has started to lose ground in India. Like in 2019, this practice was erased from the post graduate syllabus of medical students.[39]A more recent feat is the Gujarat High Court's observation of the test as 'outdated and archaic', and declaring it unconstitutional owing to the test violation of a victim's privacy, and mental and physical integrity.[40] The move against the practice of the test shows that when people speak up and question practices that have no scientific basis or benefits for the victims, there is a greater chance for change to occur, both, within and of the system.

IV. ON THE ISSUE OF CONTRACEPTION AND PREGNANCY

Rape can be a very traumatic experience for a victim, which can scar her for life. Sometimes trauma that a victim feels can even be lifelong. There are, however, other irreversible changes, too, that a woman can face because of rape. One of these is getting pregnant with her abuser's baby. The chance of this happening increases manifold when she cannot access contraceptives timely. Hence, providing contraceptives is a very important part of a survivor's forensic examination to prevent unwanted pregnancies. If the woman ends getting pregnant after the incident, she

[38] Supra 35, at 177.

[39] S. Debroy, *'2-finger virginity test' to be erased from Maharashtra syllabus,* The Times of India (08/05/2019), available at https://timesofindia.indiatimes.com/city/mumbai/2-finger-virginity-test-to-be-erased-from-maharashtra-syllabus/articleshow/69226324.cms, last seen on 24/04/2020.

[40] State of Gujarat v. Rameshchandra Ramabhai Panchal, 2020 SCC OnLineGuj 114; M. Langa, *Rape cases: Gujarat HC holds 'two-finger test' unconstitutional, violative of victim's right to privacy*, The Hindu (29/01/2020), available at https://www.thehindu.com/news/national/rape-cases-gujarat-hc-holds-two-finger-test-unconstitutional-violative-of-victims-right-to-privacy/article30682866.ece, last seen on 01/04/2020.

can be met with other major problems like no access to abortions, abandonment of children, stalling of adoption procedures, and more.

The 2014 Guidelines state that once a woman reports sexual assault, she must be given emergency contraceptive options and offered free pregnancy tests during her routine check-ups.[41] If not done so, she may be forced to make difficult decisions if she gets pregnant, which could impact her mental and physical well-being.

Ideally, the examining doctor needs to provide the rape survivor, treatment for STIs along with emergency contraception, within 72 hours of rape. If the contraception is not provided, or it fails to work, it can lead to unwanted pregnancies. Because of the legal complications, social unawareness and fear of abortion, rape victims may end up bearing children born out of the crime (**"**children**"**).[42]

The 2014 Guidelines also make it clear that if a woman becomes pregnant as a result of the sexual assault, she should have the freedom to medically terminate her pregnancy and must have access to legal abortion services.[43] All sexual assault victims must have access to health services for further follow-up at various times spanning in weeks and months post the assault, and referrals for counselling and other support services.[44] Timely access to health and legal services would ensure that women would not have to deal with unwanted pregnancies as a result of sexual assault and would not have to experience the trauma of abandoning their children if the situations provoke them to.

If the victim ends up bearing her abuser's child, the latter can be at a grave risk of being abandoned by the former due to various reasons like poverty and paucity of resources. If the victim is unmarried, the stigma of mothering an illegitimate child can often compel her to abandon her child. Moreover, the emotional trauma of having to raise a child conceived out of the fateful criminal incident influences the victim in opting for this option. These children, if abandoned, get stuck in the loop of emotional, financial and physical emancipation. Abandoned children often find their way to welfare shelters, NGOs or orphanages, often losing out on the option of having normal lives and families.

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[41] Supra 24, at 174.

[42] P. Bhate-Deosthali & S. Rege. *Denial of Safe Abortion to Survivors of Rape in India*, 21(2) Health and Human Rights 189, (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6927364/, last seen on 22/04/2020.

[43] Supra 35, at 177.

[44] *Guidelines for medico-legal care of victims of sexual violence*, World Health Organization (2003), available at https://www.who.int/violence_injury_prevention/publications/violence/med_leg_guidelines/en/.

Children also end up being given up for adoption. As compared to abandonment, giving up a child for adoption is a more sensitive solution. However, because of the legal complexities involved, this option may not be the most preferred one. Due to traditional notions of childbirth interfering with societal stigma revolving around rape, children are often considered and treated as '*muddemal*', which is the property involved in a criminal case.[45] Such children can be regarded as *muddemal* in a crime of rape because they are seen as articles or components pertinent to the crime. This could be because of various reasons like them being seen as products of the crime or being proof of the rapist's paternity.

Muddemal becomes an important component in a criminal investigation and criminal, and because of children being labeled as such, it could hinder the adoption proceedings that could run simultaneously.[46] This problem was addressed in an August 2013 landmark judgement, aimed at easing the adoption process of children born out of rape. The Aurangabad bench of the Bombay High Court ruled that the police and the Court hearing the rape case have no say in adoption matters, for which there are separate norms and procedures.[47] Adoption matters are dealt with by Central Adoption Resource Agency, which has laid elaborate rules on who is eligible to adopt and how the adoption process shall take place.[48] Therefore, the process for the adoption of the child need not be held up because of the rape trial.[49]

The maladministration of forensic examinations can have debilitating effects on a lot of lives. A slight mistake or inefficiency in conducting the medical examinations and administering proper contraception, can have a cascading effect on the life of a child born out of an unwanted pregnancy. Every step involved in a rape kit has to be followed to ensure the victim remains in good health, and is not afflicted with any ordeal that could have been easily prevented.

V. CONCLUSION

[45] D. Suryanarayan, *Conceived in rape*, Femina (13/06/2014), available at https://www.femina.in/campaigns/conceived-in-rape-2746.html, last seen on 23/04/2020.

[46] TNN, *Child born out of rape can be given in adoption*, The Times of India (22/08/2013), available at https://timesofindia.indiatimes.com/city/nagpur/Child-born-out-of-rape-can-be-given-in-adoption/articleshow/21969889.cms, last seen on 23/04/2020.

[47] Snehalaya's Snehankur Adoption Centre v. Child Welfare Committee, Ahmednagar & another, (2014) 1 Mah LJ 217.

[48] Central Adoption Resource Agency, Ministry of Women and Child Development, Government of India, *Bench Book for Adoptions*, available at http://cara.nic.in/PDF/Bench%20Book%20For%20Adoptions.pdf, last seen on 01/04/2020.

[49] Ibid.

While the legal system is constantly introduced to changes and amendments in order to actualize justice for rape victims, the forensic sector should simultaneously do its best to aid these victims in such a difficult time. The physical and psychological impacts of rape are manifold and often lifelong. From the mental distortion and agony caused, to the societal pressure she has to bear, a sensitive approach has to be implemented while dealing with rape victims. While the medical problems are largely gynaecological, the universal principles of medical ethics should be implemented while conducting examinations. Moreover, if there is an unfortunate pregnancy as a result of the crime, not only is the victim's life, but also her child's is at stake. In order to nip such unwanted problems in the bud, the requirement of administration of contraceptive shall be fulfilled in the forensic examination.

There is an urgent need for a comprehensive policy and program that directs health authorities' attention to the needs of survivors after an assault. While guidelines exist, they are not strict, and hence a lot of margin is left for forensic tests to be compromised. The 2014 Guidelines and 2013 judgement declaring invalidity of the two-finger test should be harmoniously woven into statutes and legislations for greater enforcement. The government should work in tandem with the Medical Council of India to create holistic and strict guidelines to enable women to get justice for the sexual assault they have endured. The bodily autonomy and mental health of a rape victim should not become battle grounds for the society and medical practitioners to implement acerbic weapons of sexism.

HEALTHCARE CHALLENGES: ARTIFICIAL INTELLIGENCE PROMISES QUANTUM LEAP

*Aneesha Sondhi

ABSTRACT

Since the dawn of history, humans have constantly been working towards developing ways to perform their daily tasks quickly and with ease. One such development, in the field of computer science, is Artificial Intelligence (AI). AI emphasizes on the development of intelligent machines that think and work like humans. This influx of new technologies in the information era has hit various industries, healthcare industry being one of the biggest beneficiaries. Medical literature extensively discusses the advantages of AI. Especially, as the profession requires greatest accuracy.

Before deployment, AI systems are trained via data generated from various clinical activities such as screening, diagnosis, treatments and so on, so that they can learn and process the information and then later apply the same. These systems are also equipped with self-correcting abilities so that they can improve their accuracy based on feedback received. They are increasingly being used to detect diseases, such as cancer, neurological and cardiovascular diseases, more accurately and in their early stages.

Furthermore, one can avail of certain medical services such as virtual nurses, wearable health trackers and consumer health applications within the comfort of their homes without the need of any healthcare professional. Consumer becomes in-charge of his own health and well-being. This rise of Internet of Medical Things (IoMT) gives rise to speculations that AI might eventually replace human physicians.

The intent of this paper is to survey and analyse the present status and future of AI in the healthcare industry, their regulations, and possible legal challenges.

I. INTRODUCTION

"I think AI is coming about and replacing routine jobs is pushing us to do what we should be doing anyway: the creation of more humanistic service jobs."
- Dr. Kai-Fu Lee | Chairman and CEO of Sinovation Ventures

Our ubiquitous friend, Artificial Intelligence, has played a crucial role in revolutionising healthcare. Artificial intelligence (AI) can be defined as "*the ability of a digital computer or computer-controlled robot to perform tasks commonly associated with intelligent beings*".[1] The intent of AI is to assist and sometimes even replace human beings for the purpose of effectively

* Aneesha Sondhi, 4th Year, B.A. LL. B (Hons.) University School of Law and Legal Studies, GGSIPU.

[1] *Artificial Intelligence*, Britannica, available at https://www.britannica.com/technology/artificial-intelligence, last seen on 06/12/2019.

performing simple as well as complex tasks. Human beings codify and develop the machines and the machines perform all the medical tasks. Unlike an average surgeon, these AI systems are capable of simultaneously observing and processing almost limitless number of medical inputs.[2]

Just like the inception of the internet disrupted the modern culture, AI in 2020 has the potential to change our lives completely. According to Forbes, the healthcare AI is projected to be an almost $200 billion dollar industry by 2025.[3] It is exciting for both the investors, who are seeing the sector as a lucrative option for investing, as well as consumers, who are more than eager to get their hands on the AI technology and the newest healthcare applications. The present AI trends have a patient-centred approach as they address the issues of rising medical costs and limited medical resources. The changing medical environment places patient-centric care back to the front seat. The emergence of data-driven medicine, democratization of access to Electronic Health Records (**"**HER**"**) and emergence of smartphone applications for ensuring health at home are changing the dynamics of healthcare.[4]

While the AI is growing at a rapid pace worldwide, the adoption of new technologies in India is slow, but significant. The public is super keen to participate in the healthcare cycle and Artificial Intelligence is striving to take this trend forward.

II. HEALTHCARE INDUSTRY IN INDIA: THE ABYSMAL SITUATION

For India, a country with the second highest population in the world and having demographic dividend in its favour, it is needless to say that promotion of healthcare and well-being is the need of the hour. Presently, the state of our healthcare system is abysmal. The ratio of doctors to patients is very low. We are facing an acute shortage of doctors and nurses in hospitals. The World Health Organisation recommends a ratio of 1:1,000, whereas in India, 1:1,700 is the prevailing ratio and there is only one government doctor for every 10,189 people.[5] The number of hospitals, clinics and public dispensaries is highly disproportional to our

[2] V.H. Buch, *Artificial intelligence in medicine: current trends and future possibilities*, 68(668) British Journal of General Practise, 143–144 (2018), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5819974/ last seen on 29/01/2020.
[3] T. Mills, *The top AI Healthcare trends of 2019*, Forbes (28/06/2019), available at https://www.forbes.com/sites/forbestechcouncil/2019/06/28/the-top-ai-healthcare-trends-of-2019/, last seen on 08/12/2019.
[4] Ibid.
[5] PTI, *India facing shortage of 6,00,000 doctors, 2 million nurses: Study*, The Economic Times (14/04/2019), available at https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/india-facing-shortage-of-600000-doctors-2-million-nurses-study/articleshow/68875822.cms?from=mdr, last seen on 08/12/2019.

ever-growing population. Most of the hospitals under the centre's flagship scheme are not even accredited.[6] Another cause of downfall of our healthcare system is the lack of specialist doctors such as cardiologists, pulmonologists, neurologists and others.[7] An ordinary MBBS doctor is not equipped to deal with diseases that are amongst the leading cause of deaths in India, such as brain stroke, chronic lung disease, heart disease, neo-natal pre-term birth and certain accidents.

Another pitfall, and probably the greatest one, is numerous barriers to accessing healthcare facilities, especially in the rural areas where there is shortage of medical personnel and problems of poor connectivity. There also exists a certain level of unwillingness of doctors to serve in rural areas. This creates social inequality in the healthcare arena where the rural citizens remain under-served while the health facilities are being well deployed in rich urban areas. This neglect of the rural population drives them to rely only on the traditional and cultural methods of treatment of diseases.

Furthermore, the private sector is the dominant player in the healthcare industry. The problem that lies herewith is that there is a lack of regulation in the private sector. The cost of treatment varies from one hospital to another and there is a huge difference in the quality of service. A common man cannot afford to avail of the expensive health services provided in the clinics and hospitals without burning a hole in his pocket. The alternative i.e. public hospitals may be slightly more cost effective but are generally overcrowded and have long waiting time for specialized treatment. They are never a first choice, unless one can't afford private treatment.

Finally, lack of awareness can be seen as the root cause of the problem. People do not go for regular check-ups and awareness about right to healthcare is also missing in our country. The majority of patients visit hospitals only when disease reaches an advanced stage. At this stage, the cost of treatment is high and chances of recovery become low. Consequently, *"Prevention is better than cure"* remains just an idea that does not hold weight in the Indian Healthcare scenario.

III. ARTIFICIAL INTELLIGENCE: TOOL TO ADDRESS THESE CHALLENGES

[6] V. Mani, *Two-thirds of hospitals empanelled under Ayushman Bharat not accredited,* Business Standard (27/11/18), available at https://www.business-standard.com/article/economy-policy/modicare-covers-basics-but-complex-healthcare-mostly-outside-ambit-118112601145_1.html, last seen on 08/02/20.

[7] K. Watts, *India's shortage of specialist doctors is still staggering*, Health Issues India (02/07/19) available at https://www.healthissuesindia.com/2019/07/02/indias-shortage-of-specialist-doctors-is-still-staggering/, last seen on 08/02/20.

Artificial Intelligence in healthcare can potentially be used for the purpose of early detection of diseases, diagnosis, prognosis and treatment.[8] It can also be used for the purpose of research and training. AI can be deployed, post-treatment, for the purpose of ensuring follow-up care and well-being of the patient. The basic intent is to make the computers more useful to be able to solve problematic healthcare challenges via interpreting data. AI is used for managing, compiling and analysing data such as medical records and the patient's medical history. This is the most widely used application of AI.[9] Since, the AI systems are used for analysis of data, the reports from a patient's file can be used along with external research to come out with a customized treatment design for the concerned individual.

AI certainly excels at performing well-defined tasks.[10] The help of AI can be taken for the performance of repetitive jobs such as analysing tests, X-rays and CT scans. These are certain mundane tasks that can not only be performed faster but also more accurately by AI and robots. Especially in the disciplines of cardiology and radiology, where the amount of data to be analysed is enormous and time consuming, AI can prove to be very beneficial. Drug creation is another facet of AI. Developing pharmaceuticals via clinical trials takes years and can cost millions, therefore, various companies as well as start-ups are exploiting AI to create treatment drugs. For instance, a London based company founded in 2013, BenevolentAI, that describes its mission as "*accelerating the journey from data to medicine*", recently raised 115 million dollars from investors to increase its value to more than $2 billion in 2019.[11] This company is well established in the field of drug R&D and has collaborated with Novartis, a Swiss multinational pharmaceutical company to find potential new uses for oncology drugs. AI can be used to store data of drugs that have been proven to be toxic and withdrawn from the market post approval. In the last few decades, approximately 450 medicines world over have been taken down due to the adverse reactions and side effects caused by them,

[8] S. Reddy, S. Allan, S. Coghlan & P. Cooper, *A governance model for the application of AI in health care*, 0(0) Journal of the American Medical Informatics Association (2019) available at https://www.academia.edu/40839463/A_governance_model_for_the_application_of_AI_in_health_care, last seen on 19/12/19.

[9] *10 Common Applications of Artificial Intelligence in Health Care,* Novatio, available at https://novatiosolutions.com/10-common-applications-artificial-intelligence-healthcare, last seen on 25/02/2020.

[10] Supra 2.

[11] R. Staines, *Benevolent AI and Novartis sign AI Research and Development deal*, Pharmaphorum (06/09/2019), available at https://pharmaphorum.com/news/benevolent-ai-and-novartis-sign-rd-deal/, last seen on 14/12/2019.

such as liver toxicity. [12] Companies like Cloud Pharmaceuticals make use of such data and train the machine learning algorithm to identify all the new molecules that come into being as toxic or not.[13]

Artificial Intelligence does not limit itself to the confines of hospitals and clinics where the technology is used only by health experts and practitioners. Certain AI applications are designed in such a way as to make patients and consumers the best in-charge of their own health. The best example is a health monitoring device such as wearable health trackers. With the infiltration of FitBit and Apple watches used for tracking activity levels and heart-rate and other healthcare applications used for calorie counting etc., there is a growing health consciousness amongst people all over the globe. There have been instances whereby these trackers have acted as nothing less than a miracle. A 73-year-old retired woman from Connecticut received FitBit as a gift. Upon using the tracker, she discovered that her resting heart rate was continuously increasing and therefore decided to consult the doctor, only to find out that there were two large blood clots in her lungs.[14] The FitBit was a life-saver in this case as the condition could have proven to be fatal if it were left unattended.

Due to the rampant growth of devices such as tablets and smartphones, other common usage of AI includes applications for digital consultation. These applications are generally based on personal medical history and common medical knowledge. The UK based application, Babylon, provides the patients a platform to report their symptoms, then the system gives them recommendations on the basis of their medical history.[15] They are like a personalised Google window for illnesses. SteadyMD, Sherpaa and DoctorOnDemand are some of the applications that provide for online doctor services by charging a minimum subscription fee.[16]American Well application provides for virtual waiting rooms after one chooses a doctor, and after sometime, the patient gets connected to the doctor via video call. The patient also has the option to avail the service where the doctor sends the prescriptions electronically to

[12] B. Nogrady, *Artificial Intelligence shakes up drug discovery*, The Scientist (01/05/2019), available at https://www.the-scientist.com/bio-business/artificial-intelligence-shakes-up-drug-discovery-65787, last seen on 11/12/2019.
[13]Ibid.
[14] N. Hinde, *73-Year-Old's Fitbit saved her life by alerting doctors to Lung Blood Clots*, Huffington Post (06/04/2017), available athttps://www.huffingtonpost.co.uk/entry/patricia-lauder-fitbit-saved-her-life-by-alerting-doctors-to-blood-clots_uk_58e622f4e4b0917d347760d3, last seen on 11/12/2019.
[15] Supra 9.
[16] Online Medical Care, *10 Best Online Doctor & Medical Services for 2020,* available at https://onlinemedicalcare.org/best-online-doctor-medical-services/, last seen on 13/12/2019.

the selected pharmacy.[17] It is highly advantageous as it saves a trip to the doctor for minor illnesses thereby saving time and travel expenses for other urgent needs. There are also virtual nurses to help in monitoring the patient's condition and follow up with treatment, in between doctor visits. However, these Digi-consultations cannot replace a primary care physician and order laboratory tests, therefore, are not deemed suitable for diseases and illnesses other than minor ones.

IV. AI AND THE INDIAN HEALTHCARE INDUSTRY

Government of India's Niti Aayog, came out with a discussion paper[18] that places healthcare amongst one of the focus areas for AI intervention. As compared to banking, financial, automotive and other sectors, the healthcare sector is lagging behind in the adoption and exploitation of AI techniques. Despite the fact that the statistics are not in its favour, the growth of AI in healthcare is expected to be substantial in the coming years. As regards diagnostic part of treatment, young start-ups have begun to play a very critical role in assisting doctors with early-stage diagnosis. They are doing this by creating their own diagnostic tools by way of machine learning and predictive analysis. Their endeavour is to improve upon the speed and accuracy of the diagnosis. One such start-up named 'mFine' is indeed a fine example of this trend. This Bengaluru based start-up has gone on to give 85% of correct diagnosis for about 1200 diseases stored in its data base.[19]

India's IT service provider Tata Consultancy Services (TCS), has set up a research centre in collaboration with Tata Medical Centre to develop technology for clinical trials, risk adapted treatment, predictive outcomes and biomarkers.[20] Companies such as Microsoft have also partnered with SRL diagnostics to source one million biopsy samples from those patients who have been diagnosed by doctors, so as to train their AI systems to detect cancer.[21] Microsoft has also entered into collaboration with Apollo hospitals to build a technology system that can detect heart irregularities in patients, to come out with a proper health treatment.[22]

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[17] Ibid.

[18] Niti Aayog, Government of India, *National Strategy for Artificial Intelligence*, available at https://niti.gov.in/writereaddata/files/document_publication/NationalStrategy-for-AI-Discussion-Paper.pdf, last seen 12/12/2019.

[19] K. Chadha, *Incorporating Artificial Intelligence in Indian Healthcare Sector,* Inc42 (09/10/2019), available at https://inc42.com/resources/incorporating-artificial-intelligence-in-indian-healthcare-sector/, last seen on 21/12/2019.

[20] P. Sangani, *Let AI do the Health Check*, The Economic Times (02/08/2019), available at https://economictimes.indiatimes.com/small-biz/startups/newsbuzz/let-ai-do-the-health-check/articleshow/70492061.cms?from=mdr, last seen on 17/12/2019.

[21] Ibid.

[22] Ibid.

Companies in India are largely focusing their energies on end-stage cancer treatments. One of the major reasons for that is the enormity of the problem as the incidence to mortality rate is the highest for cancer. India sees an incidence of more than 1 million new cases of cancer every year.[23] A good quality pathology service is required, which unfortunately is not present in India. If detected on time, a large number of deaths caused by cancer could have been prevented. Another reason is the high cost of treatment. Let alone a poor person, even a middle-class man can't afford the expensive end stage treatment. Other problems include low awareness amongst the citizens and the screening efforts being very poor. There is a dire need to have cost effective and less invasive screening solutions and the tech companies are continuously working towards that. These companies see a huge potential in cancer diagnosis and prediction and are trying their level best to come up with innovative solutions.

Various Indian digital healthcare start-ups have stepped into the scene to bridge the gap between health service providers and consumers. Practo, a Bengaluru based start-up is cited as one of the fastest growing healthcare platforms having a funding of $124 million.[24] Founded a decade back, it offers a platform for doctors to advertise themselves and highlight their area of practices, for the consumers to avail their services and even opt for online consultations. It has also taken various innovative steps such as introducing a 24x7 free consultation with qualified doctors for pollution-stricken Delhi post Diwali, 2019.[25] Other similar applications operating in the India include Portea Medical, Lybrate and DocEngage.[26] Whilst these applications offer doctor services, there are applications such as HealthifyMe which help in diet control by offering features such as calorie counting, activity tracker, weight loss/gain progress charts and online consultations with dieticians.

V. LEGAL AND OTHER CHALLENGES FACED BY AI IN HEALTHCARE SECTOR

1. Issue of Data Privacy – Insufficiency of existing laws

[23] Supra 18, at 28.
[24] K. Garewal, *10 Indian Digital Health Startups to Watch,* HIT Consultant, available at https://hitconsultant.net/2015/10/29/1019-10-indian-digital-health-startups-to-watch/#.XrJRgqhKg2w, last seen on 15/02/2020.
[25] *Practo introduces 24*7 free consultation with qualified doctors for pollution-stricken Delhi,* The Practo Blog, available at https://blog.practo.com/free-consult-delhi-pollution/, last seen on 12/12/2019.
[26] *Top 10 Doctor-Patient platforms in India | Most successful digital health business model in India,* Dr. Hempel Digital Health Network, available athttps://www.dr-hempel-network.com/digital-health-startups/doctor-patient-platforms-in-india-success/, last seen on 13/01/2020.

The Ministry of Health and Family Welfare has taken steps towards standardising Electronic Health Records (EHR). The EHR Standards, 2016[27] are an attempt to regulate data ownership and privacy standards around the storage of health data collected from patients.[28] The Government has laid down standards for capturing, storing, retrieving and exchanging data. These records coupled with AI can be used for analytical as well as prediction purposes. For instance, making prediction as to how a patient will react to certain medication by studying his genetic makeup. It is used to find out the most effective medication. But the issue of privacy regarding the use of such data cannot be side-stepped. Respecting a person's privacy is a vital ethical principle in the healthcare industry.[29]

Settling the uncertainties surrounding the issues of privacy, the progressive *KS Puttaswamy* case[30]recognized the Right to Privacy as a Fundamental Right. The protection of personal data is considered an essential facet of informational privacy.[31] The health record data being extremely sensitive and of personal nature, the issue of such data protection needs to be addressed on an urgent basis. The existing data protection laws are insufficient to ensure privacy and the Personal Data Protection Bill, 2018 has been under deliberations in our Parliament for quite a while. A serious attempt has been made to draft the bill in line with the General Data Protection Regulation (GDPR)[32] of the EU. It not only confers a bundle of rights on the owner of personal data but also imposes stringent fines and punishments for breach of data by other parties. Health data is part of sensitive personal data.[33] The penalty for breach of such data privacy by the fiduciary holder may extend up to five crore rupees or two per cent of its total worldwide turnover of the preceding financial year.[34]This will ensure that the fiduciary or data processor doesn't act in a negligent manner while handling such data.

The ownership of the data is retained by the patient and he is given complete control to decide who can access such data. The healthcare providers are mandatorily put under the obligation to inform patients about their rights and to ensure privacy of such data. In case the data is

[27] *Notification of Electronic Health Records (EHR) Standards 2016 for India,* MoHFW Circular No. Q-11011/3/2015-eGov (30/12/2016), available at https://mohfw.gov.in/sites/default/files/17739294021483341357.pdf, last seen on 10/02/2020.
[28] *Report on Artificial Intelligence in the Healthcare Industry in India,* The Centre for Internet and Society, available at https://cis-india.org/internet-governance/files/ai-and-healtchare-report, last seen on 20/02/2020.
[29] Supra 8, at 2.
[30] K. S. Puttaswamy and Anr. v. Union of India, (2017) 10 SCC 1.
[31] Personal Data Protection Bill, 2018 (pending).
[32] General Data Protection Regulation, 2018.
[33] Supra 31, at S. 3(25).
[34] Ibid, at S. 69.

being used for purposes other than healthcare, specific consent has to be obtained from the patient prior to such dissemination. Any unauthorised or accidental disclosure, acquisition, sharing, use, alteration, destruction, loss of access to, of personal data that compromises the confidentiality, integrity or availability of personal data would amount to breach of privacy.[35] This provision has been made not only to ensure protection of patient privacy, but also to gain the trust of clinicians and society in the use of AI in healthcare sector.

Though the Right to Privacy of the patient and the duty on part of doctor to maintain confidentiality are of utmost importance, it can only be compromised subject to protection of health of others. The information can be disclosed for the purpose of public health and safety and prevention of crime and disorder.[36] For instance, in the case of the Novel Coronavirus, it would be detrimental to public health to withhold such information. Certain situations demand placing public interest on a higher pedestal than individual rights. In such situations, the health records may be made accessible.

2. Need for a suitable intellectual property regime

A weak intellectual property regime and breakthroughs in AI can never go together. The issue of India's weak intellectual property regime should be addressed quickly to encourage local developments in AI. Here, the example of pharmaceutical industry will be pertinent. After the expiry of the patent of the original drug, the cheap generic drugs, having the same active pharmaceutical ingredients, are allowed for sale in the market. The duration of a patent being as low as 20 years, most of the pharmaceutical companies, therefore, do not prefer to engage in R&D work and rather outsource it to research organizations. Other incentives apart from the money earned on patents should be awarded to such companies. It could be in the form of a prize system,[37] or payment of grants, stipends, or regular salaries to incentivize drug creations. Now this should be done with AI too. If AI technology is to be made free after some years, it is important that AI-developers are adequately rewarded else they will not be too eager to make massive investments needed to develop AI for healthcare. So, either we need to change IPR regime, or have a new reward system for innovations.

3. AI Created Drugs – the issue of over-rewarding

[35] Ibid, at S. 3 (30).
[36] Mr. X v. Hospital Z (1998) 8 SCC 296.
[37] J.E. Stiglitz, *Economic Foundations of Intellectual Property Rights*, 57 Duke Law Journal 1697, 1719 (2008), available at https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1362&context=dlj, last seen on 13/02/20.

An emerging new problem spot for the Intellectual Property Rights (IPR) regime are the AI created drugs. Will the granting of IP rights to an AI programmer for autonomous-products generated by the AI, lead to over-rewarding of its creator? In the United States, the autonomous AI-generated products fall within the public domain i.e. they are free for use.[38] In India, a similar approach could be adopted. It would benefit the society tremendously as the right to use the medical creation would not be confined to a single group. Moreover, it would also enable the underprivileged strata to come at par as far as access to knowledge and medical developments are concerned. From legal point of view, it would also stop people from filing suits in courts upon denial of licenses or request for compulsory licensing.

So, the granting of IPRs to AI machines for products that are generated autonomously by it i.e. without human intervention, needs to be addressed quickly. Machines are believed to be capable of surpassing human intelligence in the near future. To adopt this approach and provide AI with the rights, the whole legal system that is human centric, will have to be overhauled. Whether AI will be capable of holding IPR is being deliberated by WIPO and member countries presently.[39] Hopefully, some universally-acceptable solution will soon come out of these deliberations.

4. AI - susceptible to manipulation

There are widespread concerns that while use of Artificial Intelligence in healthcare is quite benevolent, and revolutionary, it, without adequate AI security, can be disastrous at the same time. For example, a robot conducting a critical surgery, if infected with malware, can be used to botch it up to even commit a murder. It is not a far-fetched argument. Anything digitally enabled can be digitally infected and AI is not an exception. The eye-sensors of a robot can be made to determine a non-surgical area as surgical one or its hand movement sensors can be made to exert more pressure than necessary by manipulating its calibrations. Furthermore, hospitals themselves can use AI to manipulate medical and other scans in order to boost pay-outs or gain regulatory approvals.[40] So, this concern is real and will need lots of investment in AI security to

[38] K. Hristov, *Artificial Intelligence and the Copyright Dilemma*, 57 IDEA: The Journal of the Franklin Pierce Center for Intellectual Property 431, 437 (2017), available at https://ipmall.law.unh.edu/sites/default/files/hosted_resources/IDEA//hristov_formatted.pdf, last seen on 26/03/2020.

[39] *Artificial Intelligence and Intellectual Property Policy,* World Intellectual Property Rights Organization (WIPO), available at https://www.wipo.int/about-ip/en/artificial_intelligence/policy.html, last seen on 15/02/2020.

[40] C. Metz & C. S. Smith, *Warnings of a Dark Side to A.I. in Health Care*, The New York Times (03/12/19), available at https://www.nytimes.com/2019/03/21/science/health-medicine-artificial-intelligence.html, last seen on 17/02/20.

protect the patients. With this, we will have legal issues pertaining to medical negligence. Rules need to be laid down tackling issues emerging out of AI botch-ups. Whether the clinic, or the AI lab, or the outsourced AI, security firms would be held liable. Various scholars, technical and legal experts have given solutions such as conferring personhood to AI or establishing a common enterprise theory to address the AI liability.[41] There is a dire need to fix the legal responsibility by either modifying the existing laws or by enacting new legislations on the subject.

5. Regulating AI, the sooner the better

It is critical that we come up with a Regulatory Framework for the AI as soon as possible. It is imperative to impart the existing authorities like the Medical Council of India or the Drug Controller General with the ability to deal with the new developments. If needed, even a new authority can be established specifically for this area. It is crucial that an appropriate certification mechanism is provided to rule out any ambiguity and to provide for uniformity in the process of certification of AI mechanisms. Not just at National level, even State level agencies should be established to oversee and monitor the development of AI in India.

6. Need to provide boost to AI research

The development of AI needs research and research demands dedicated top-quality manpower. However, we just have an abysmal 1.67 % share of the worldwide PhDs in AI, i.e., 368 out of 22,000 worldwide. So the need to put AI research and development in the fifth gear requires the kind of urgency that we can ignore only at our own peril.[42] The situation looks even more alarming when we are confronted with the fact that not even 50 of these researchers are engaged in serious or critical research in Artificial intelligence.[43] This means, on an average, just one such serious researcher comes out of nearly 2.5 crore of our population. And even this talent is mostly limited to the IITs and IISc. These facts have been highlighted by Global AI Talent Report 2018 and Niti Aayog in a discussion paper.[44]Medical Colleges must be encouraged, and even financially and technological supported, to develop AI research hubs all over India.

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[41] H. R. Sullivan and S. J. Schweikart, *Are Current Tort Liability Doctrines Adequate for Addressing Injury Caused by AI?,* 21(2)AMA Journal of Ethics 160, 164 (2019), available at https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2019-01/joe-1902_0.pdf, last seen on 16/01/20.

[42] *Why is AI still out of reach for India?*, The Economic Times (18/06/2019), available at https://economictimes.indiatimes.com/small-biz/startups/features/why-is-ai-still-out-of-reach-for-india/factually-speaking/slideshow/69839691.cms, last seen on 12/12/2019.

[43] Ibid.

[44] Ibid.

7. Digitization, and more digitization

A major set-back to the adoption of AI techniques is the requirement of digitization. A digitized eco-system is a pre-requisite for operating AI at any level. This eco-system includes digitized medical records. However, in India, majority of the health centres still maintain their medical records on paper. Healthcare digitization to enable AI use implies the conversion of paper-based records into digitally scanned and indexed ones that are in accordance with the standards that are accepted globally. The hospitals interested in utilizing AI must be encouraged and rewarded for providing a digitized eco-system for seamless operation of AI. A digitized eco-system will also make it easier to apply laws as case information will not need to be lifted from different sources.

Finally, the biggest challenge to promote AI is lack of awareness and access to services. A large section of our population does not have access to internet connection and smartphones. Adding on to this are the vast inequalities in healthcare distribution, lack of trained healthcare professionals and infrastructural deficiencies. In such situation, it is quite likely that AI will take the backseat. However, basic healthcare and high-end AI care are not antagonistic. Even as its primary focus remains basic healthcare, the government can make efforts to promote AI-related investment by big entities and businesses. Monetary support and tax incentives should be provided by the Government to encourage the private sector to adopt AI and improve its services. It must also fund govt institutions and hospitals to invest in the future as AI is the future.

VI. GOVERNMENT INITIATIVES

The Government of India, via its recent policy initiatives, is endeavouring to address the healthcare challenges and show its commitment towards tackling the issues faced by our healthcare industry. The enactment of Electronic Health Standards, 2016 by the Ministry of Health is one such positive initiative. The National eHealth Authority (NeHA) has also been proposed by the Ministry which will develop an integrated health information system. One of the foremost objectives of NeHA is the formulation of "*National eHealth Policy and Strategy*" for coordinated eHealth adoption. It is also tasked with the responsibility of enforcement of standards and ensuring security, confidentiality, and privacy of patient's health information and records.[45]

The Union Budget of 2018 also included a commitment of Rs. 1,200 crores for Health and Wellness Centres (HWC), that aims to provide comprehensive healthcare which includes screening and management of

[45] Supra 28.

Non-Communicable Diseases (NCDs), basic dental health care; geriatric and palliative health care, and trauma care and emergency care.[46] An important component of HWC's will be universal screening for NCDs.

Other initiatives by the government includes setting up AI Task Force, formation of policy groups by Ministry of Electronics and Information Technology to explore the potential of AI and the possibility of its adoption in various industries, including healthcare. The government has also collaborated with various other countries such as the United States and has formed the United States–India Science & Technology Endowment Fund (USISTEF) for the promotion of joint activities that would lead to innovation and entrepreneurship through the application of science and technology.[47]

VII. CONCLUSION

In a world that is technologically driven and technology implies advancement, the need for resolution of issues surrounding adoption of AI in healthcare is inescapable. With new technologies coming in the market every day and various companies and start-ups diving deep in the arena of healthcare technology, the role played by the law becomes very crucial.

Even though the Government has undertaken various steps to boost the adoption of AI across healthcare agencies, there still lie a few stumbling blocks. A comprehensive legislation governing technology and healthcare and constituting a regulatory framework for the same is absolutely essential. The Medical Council of India, The Ministry of Electronics and Information Technology and the Ministry of Health and Family Welfare have a crucial role in further integrating AI and healthcare. The relevant enforcement agencies should be vested with powers to check upon potential illegal usage of AI in healthcare, rampant patent violations, theft of data privacy and other undesirable situations. Setting up of fast track tribunals for settlement of such disputes will go a long way towards protecting innovations. The growth of AI world over is a revolution in the making, and the public sector, private sector, companies, government as well as end-users should make all out efforts to reap the benefits of this revolution

[46] Supra 18, at 26.
[47] Supra 28.

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