



Himachal Pradesh National Law University, Shimla (India)

Journal Articles

HPNLU Journal of IPIR

Volume: I (2024)

Digital Health Interventions In The View Of Pandemic And IP Interface In India
Ruchi Sapahia & Surbhi Mathur

This article can be downloaded from:

<https://hpnlu.ac.in/journal-level-2.aspx?ref-id=32>

ISSN: XXXX-XXXX

Recommended Citation:

Ruchi Sapahia & Surbhi Mathur, Digital Health Interventions In The View Of Pandemic And IP Interface In India, I HPNLU IPIR. 69 (2024)

Disclaimer

This Article is published and brought to you for free and open access by Himachal Pradesh National Law University, Shimla. For more information, please contact editoripir@hpnlu.ac.in

Contents

S.No.	Title	Pages
1	CHARTING A ROADMAP FOR INTEGRATION OF AI AND IPR: Analysing the Domestic and Global Regulatory Framework Posing Humanistic Challenge- <i>Shivang Tripathi & Neha Singh</i>	1-19
2	PROTECTION OF TRADITIONAL KNOWLEDGE THROUGH INTELLECTUAL PROPERTY RIGHTS- <i>Sunil Dutt Chaturvedi & Rohit P. Shabran</i>	20-38
3	ARTIFICIAL INTELLIGENCE AND INTELLECTUAL COPYRIGHT: Use of Artificial Intelligence and Intellectual Property Rights in India, <i>Swati Kaushal & Amitvikram Pandey</i>	39-52
4	GEOGRAPHICAL INDICATION IN HIMACHAL PRADESH CULTIVATING ECONOMIC GROWTH AND PRESERVING CULTURAL HERITAGE- <i>Hari Chand & Surya Dev Bhandari</i>	53-68
5	DIGITAL HEALTH INTERVENTIONS IN THE VIEW OF PANDEMIC AND IP INTERFACE IN INDIA- <i>Ruchi Sapahia & Surbhi Mathur</i>	69-80
6	BEYOND BORDERS: The Globalization of Intellectual Property Rights and Its Implications for Competition Law- <i>Parineeta Goswami</i>	81-98
7	AI-DRIVEN CREATIVITY: Legal Implications and the Future of Intellectual Property- <i>Varin Sharma</i>	99-114
8	DIGITAL LIBRARIES AND FAIR USE- <i>Kanishka Agarwal</i>	115-132
9	IPR AND GROWING PHARMACEUTICAL SECTOR: Revisiting the Development of Patent Law in India- <i>D Akshay Kumar & S. Divya</i>	133-145
10	INNOVATION AND ACCESS: Compulsory Licensing as a Catalyst for Digital and Green Technology in India: - <i>Kritin Sardana</i>	146-166
11	BOOK REVIEW Travelogue of a Treasure Trove in North East India (V.K. Ahuja)- <i>Debasis Poddar</i>	167-172

DIGITAL HEALTH INTERVENTIONS IN THE VIEW OF PANDEMIC AND IP INTERFACE IN INDIA

Ruchi Sapahia¹ & Surbhi Mathur²

Abstract

The world is witnessing a paradigm shift in digitization. Today when health care has become a center of focus for everyone, especially after Coronavirus (COVID-19) pandemic spread, countries are moving towards a systematic recording of health history of every individual which can be accessed easily. The performance reports of Electronic Health Record (EHR) or Digital Health or E-Health systems adopted by USA, China and many more countries have shown a growth in health care facilities. The paper will analyze if this system can be adopted in India as well. The paper will also investigate the intellectual property laws related challenges which EHR software may face because of different municipal laws.

Key words: Digital health, pandemic, Coronavirus, Electronic Health Record.

“Health is the greatest gift, contentment the greatest wealth, faithfulness the best relationship”- Buddha

Introduction:

We have grown up listening to a famous adage ‘an apple a day, keeps the doctor away,’ which means, to remain healthy, one should indulge in healthy habits. With the outbreak of Coronavirus disease (COVID-19/COVID) pandemic in India from March 2020, health has become worrisome for everyone. Entire world had to stay indoors with absolutely no human interaction for months, which made us introspect about our very existence, which is social being. We all know, man is a social animal. The lockdowns and curfews in all parts of the world have made us realize the insignificance of human existence. As a direct consequence of this pandemic, adversely affecting physical health, mental health is also being jeopardized.

¹ Associate Professor, Himachal Pradesh National Law University, Shimla

² Research Scholar, Himachal Pradesh National Law University, Shimla

Today, ‘health’ has become a major concern for all countries. Millions of people lost their lives during the pandemic, and we still cannot claim whether the virus has been eradicated or can be eradicated or not.³ In developing countries like India and other South Asian countries, the pandemic has hit hardest. Union government for the longest time did not know how to manage situations in hospitals. Pharmacies ran out of basic medicines, oxygen supply reserves got exhausted, people lost their jobs, markets crashed, daily wagers had to migrate to their hometowns for shelter and the damage was endless.⁴ Previous budgetary allocations for healthcare sector in India amounted to only 2.3% of the GDP and realized it the hard way during the pandemic that such low allocation will not be enough for the treatment of such a huge population.⁵The World Health Organization (WHO) has kept this standard to be of minimum 5% of a country’s GDP.⁶The unprepared attitude of governments around the world has made us think, whether we are headed in the right direction? It is high time that the government should intervene in exhaustive and meaningful research in health sector. India, being a welfare state and a strong democracy, there is a big responsibility on the shoulders of government to ensure maximum protection to citizens.

Through Intellectual Property Rights (IPR) various devices and methods can be invented in digital diagnosis, cure, and monitoring of wellbeing of people. In simple understanding, any property generated with the help of human intellect is called intellectual property and to protect it, IP rights come into play.⁷ Under patent law most of the health care protections are seen which include invention of drugs, vaccines, and other products. Recently, as the emerging technology is taking a huge space in every field of life, it has entered the realms of health care facilities to bring a phenomenal change in society.

Many countries during pandemic developed their own mobile applications to monitor the growth rate of COVID-19, as ‘Aarogya Setu’ in India. India is moving fast

³ Hannah Ritchie, Edouard Mathieu, Lucas Rodés-Guirao, Cameron Appel, Charlie Giattino, Esteban Ortiz-Ospina, Joe Hasell, Bobbie Macdonald, Saloni Dattani and Max Roser, Coronavirus (COVID-19) deaths, *Our world in data* <https://ourworldindata.org/covid-deaths>(Mar. 12th,2022 7:46 AM).

⁴ Isha Goel, Seema Sharma and Smita Kashiramka, Effects of the COVID-19 pandemic in India: An analysis of policy and technological interventions, *National Library of Medicine, National Center for Biotechnology Information*, <https://pubmed.ncbi.nlm.nih.gov/3352063> (Mar.12th, 2022, 7:50 AM).

⁵ Bharath Kancharla, Data: What is the ‘Public Health Expenditure’ in India as a share of GDP?, Faculty Website, [https://factly.in/data-what-is-the-public-health-expenditure-in-india-as-a-share-of-gdp/#:~:text=The%20spending%20increased%20to%201.4,spending%20because%20of%20the%20pandemic_\(Mar.12%20,2022,7:57%20AM\),](https://factly.in/data-what-is-the-public-health-expenditure-in-india-as-a-share-of-gdp/#:~:text=The%20spending%20increased%20to%201.4,spending%20because%20of%20the%20pandemic_(Mar.12%20,2022,7:57%20AM),).

⁶ Abhishek Naharia, National Health Policy: A step towards right to health, *CNLU LJ* (7) [2017-18] 185.

⁷ Prof. Dr. Samiya Tabasum, Intellectual Property Rights and theories, 3 *University Book House Pvt. Ltd*, 2018.

towards digitization of health records of every citizen with ‘National Digital Health Mission’ or ‘Ayushman Bharat Digital Mission’⁸ and IPR is playing an enormous role in giving protection to innovators and ensuring public welfare. In this research paper, the author will highlight the inventions and developments in patent law, copyright law, design protection and trademark law interface in the field of digital health during the pandemic. Author will also discuss instances of software which already exist and evaluate their adequacy of larger good. The paper will also propose suggestions on how IPR can be used as a tool to improve digital health records to ensure quick cure of diseases.

Analyzing existing IP international laws on digital health:

For protection of digital health records, the umbrella IP law which is Art. 10 of The Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994 (TRIPS) mentions copyrightability of computer programs. Under Art. 27(1) of TRIPS recognizes patent protection for software related inventions for the member states if the invention satisfies the requirements for patentability which are country specific. As per WHO’s report on ‘Global strategy on digital health 2020-2025’ there are 120 countries who have adopted digital health systems.⁹ As per the famous 17 Sustainable Development Goals, which have to be adopted till 2030, the 3rd goal is ‘ensuring good healthy lives and promote well-being for all’ Digital health records can prove to be a remarkable method to ensure that.¹⁰

As per the global report, WHO has defined ‘Digital Health’ as *“The field of knowledge and practice associated with the development and use of digital technologies to improve health. Digital health expands the concept of e-health to include digital consumers, with a wider range of smart-devices and connected equipment. It also encompasses other use of digital technologies for health such as the Internet of things (IoT), artificial intelligence, big data, and robotics.”*¹¹ With this idea, the nuanced concepts of computer science of dealing in data will be used to predict appropriate policy reforms and trends in health care. With perspective of IPR, there is no specific law which could regulate it. However, patent

⁸ National Health Authority, Ayushman Bharat Digital Mission, <https://abdm.gov.in/> (Jan. 28th, 2022 10:13 AM).

⁹ World Health Organization Report, *Global Strategy on digital health 2020-2025*, <https://www.who.int/docs/default-source/documents/gsdhdaa2a9f352b0445bafbc79ca799dce4d.pdf> (Mar.13, 2022, 4:08PM).

¹⁰ United Nations Department of Economic and Social Affairs, *Sustainable Development*, <https://sdgs.un.org/goals> (Mar. 13, 2022, 4:21PM).

¹¹ World Health Organization Report, *Global Strategy on digital health 2020-2025*, <https://www.who.int/docs/default-source/documents/gsdhdaa2a9f352b0445bafbc79ca799dce4d.pdf> (Mar.13, 2022, 4:08PM).

laws and copyright laws will give an umbrella protection to the software developers for their applications or Apps which are formulated under it.

1.1. Digital health and IP in The United States of America (USA):

The USA is one of the initiators of digital health regime and record keeping policies in the world. Under the USA patent law, ‘abstract idea’ is not patent eligible, only ‘inventive concepts’ are eligible for it. Digital health inventions may fall within the definition of an ‘abstract idea,’ so they are not eligible for patent.¹² IP rights for digital health technologies are enforced in the same manner as other property rights, in civil litigation in state and federal court. A recent decision by the Federal Circuit held that, although a patent claim was directed to an abstract idea, the specific configuration of hardware and software provides a plausibility inventive step to overcome a motion to dismiss.¹³

The USA is considered to have best medical and health care infrastructure in the world because of the technology advancements taking place on an everyday basis. The Office of the National Coordinator for Health Information Technology was established in 2004 with an objective to digitize the health records and adopt Electronic Health Record (EHR) system. As on 2018, USA government spends highest in health care, around \$11,172 on an average.¹⁴ From 2008 to 2017, approximately 96% of the non-federal acute care hospitals¹⁵ and 86% of office-based physicians¹⁶ had adopted EHR system. Even though a lot of physicians reported increase in administrative work because of data entries, but with constant updates in software, things became more user friendly.

Subsequently, The Health Information Technology for Economic and Clinic Health Act, 2009 (HITECH) was enacted for proper regulation of EHR system and issues relating to its

¹² Seyfarth Shaw LLP, At a glance: intellectual property for digital health in USA, https://www.lexology.com/library/detail.aspx?g=6eadd142-d685-45c3-ab1d-a4a5df6dc8d7__ (Mar. 13, 2022, 4:50 PM)

¹³ Seyfarth Shaw LLP, At a glance: intellectual property for digital health in USA, https://www.lexology.com/library/detail.aspx?g=6eadd142-d685-45c3-ab1d-a4a5df6dc8d7__ (Mar. 13, 2022, 4:50 PM)

¹⁴ M. Hartman, National Health Care Spending in 2018: Growth Driven by Accelerations in Medicare and Private Insurance Spending, *Health Affairs* 39, no.1 (Jan. 2020) 8-17.

¹⁵ Office of the National Coordinator for Health Information Technology, Non-federal Acute Care Hospital Electronic Health Record Adoption, Available on: <https://www.healthit.gov/data/quickstats/non-federal-acute-care-hospital-electronic-health-record-adoption> (June 24, 2022, 10:50 AM).

¹⁶ Office of the National Coordinator for Health Information Technology, Office-based Physician Electronic Health Record Adoption, Available on: <https://www.healthit.gov/data/quickstats/office-based-physician-electronic-health-record-adoption> (June 24, 2022, 10:55AM).

adoption. The Act also mandates physicians and hospitals to adopt EHR with penal sanctions if not done.¹⁷ The Health Insurance Portability and Accountability Act, 1996 (HIPAA) helps in maintaining the data privacy issues of EHRs. The system is now very deep rooted and because of the positive results it has shown in past decades, EHR can be considered a model structure for other countries who are still in a developing phase. Also, USA being one of the founding members of TRIPS, has good hold over IP laws requirements or data privacy issues. On an outset, it can be assumed that the approaches adopted by the USA may prove to be a model regulatory method for digital health records and technologies for developing countries.

Digital health and IP in China:

China is another country which initiated digital health record keeping over the last decade. As per studies conducted by CHIMA Annual Survey of Health Information Systems from 2007 to 2018, there is significant improvement in health care system in China after the advent of EHR.¹⁸ The number of hospitals who have adopted EHRs has exceeded 16,000. Some laws which are followed for digital health regulation are Civil Code of PRC, Data Security Law of PRC, Anti-unfair Competition Law of PRC etc.¹⁹ For software devices for medical devices, separate laws like Medical Devices Regulation, guiding principles for AI Medical software products etc. are enacted which is a good foresighted step. The design patent is one of the patent types regulated under the Patent Law of PRC, and it protects innovative designs of the whole or part of the product in terms of shape or color. China being an upcoming superpower in the world and competing with US has a lot to unfold with respect to IPR and health care sector.

The countries who have already adopted a digital health system have had an overall pleasant experience in the improvement of health care system. To accomplish seventeen sustainable goals, the UN should produce a model law for regulations and adoption of digital health in the member countries. The model will help create a blueprint for countries to have a

¹⁷ The Health Information Technology for Economic and Clinic Health Act, 2009 (42 U.S. Code Sec. 1320a–7b).

¹⁸ Jun Liang, Ying Li, Zhongan Zhang, Dongxia Shen, Jie Xu, Xu Zheng, Tong Wang, Buzhou Tang, Jianbo Lei and Jiajie Zhang, US National Library of Medicine National Institutes of Health, Adoption of Electronic Health Records (EHRs) in China during the past 10 years: Consecutive survey data analysis and comparison of Sino-American challenges and experiences, (Feb. 18th, 2021) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7932845/>.

¹⁹ Digital Health Law and Regulations China, 2022, <https://iclg.com/practice-areas/digital-health-laws-and-regulations/china> (Mar. 14, 2022, 10:00AM).

minimum standard and adjust laws according to their country's situation. Through 'compulsory licensing,' technology can be availed in any part of the world with a procedure established as per municipal laws.²⁰ Digital health needs more awareness about its advantages and disadvantages, so that its implementation becomes easy.

Analyzing existing IP laws on digital health in India:

WHO defines health as the state of complete mental, physical, and social well-being and not just merely the absence of any disease or infirmity.²¹ Digital health or E-Health is something where a health record of past diseases and health problems of an individual are maintained? This is a valuable tool for the user for tracking his health in a better way, for government to keep a record and make policies by recognizing the trends. In India, all laws originate from sacred provisions of Constitutional law only. Under the Constitution every right and duty in a person's life has been mentioned in the most practical manner. Health, education, women's & child's rights give base to all laws in India.

Under Article 21 of the constitution²², every person has right to life and personal liberty.²³ The Supreme Court while examining the issue of the Constitutional right to health care under Article 21, 41 and 47 in *State of Punjab v. Ram Lubhaya Bagga*²⁴, held that this right of one person is correlated to the duty of other individuals also. This is a good reason for government to work towards improvement in health care system in India. In another landmark case, it was held that it is obligatory on the part of doctor or other medical staff to provide immediate emergency aid to any victim who has succumbed to injuries, on the part of both public and private hospitals.²⁵ Proper recording and maintaining the history of every citizen will ensure government in making policies and training doctors and other health care professionals to provide better health infrastructure and treatments to the individual.

Under other constitutional law provisions, the Directive Principles of State Policies explain the grounds on which the state has a special duty to take care of welfare of citizens. Some of the provisions are Art. 38 (e) & (f), 42, 47 and 48A. Health care aspect is also

²⁰ The Agreement on Trade-Related aspects of Intellectual Property Rights, 1994, Art. 31, https://www.wto.org/english/docs_e/legal_e/27-trips.pdf (Mar.14th, 2022, 11:50 AM).

²¹ Abhishek Naharia, National Health Policy: A step towards right to health, *CNLU LJ* (7) [2017-18] 185.

²² *Consumer Education & Research Centre v. Union of India*, (1995) 3 SCC 42.

²³ Indian Constitution Art. 21, 'No person shall be deprived of his life or personal liberty except according to procedure established by law'.

²⁴ (1998) 4 SCC 117.

²⁵ *Pt. Parmanand Katara vs. Union of India & Ors.*, 1989 AIR 2039.

covered under parts of schedule XI and XII of the constitution. These provisions have always persuaded the state to work in the direction for maximum benefit of the citizens. Looking at the judicial pronouncements made by the Supreme Court it can be said that it is now a settled law that right to health is integral to right to life and the government has a constitutional obligation to provide health facilities.²⁶ Union and state governments, time and again formulate various health welfare policies backed through these provisions in order to ensure maximum benefit to the people. Some of the recent policies include National Policy for Rare Diseases, 2021, National Health Policy, 2017, National Mental Health Policy, 2014 etc.²⁷ In Rajasthan as well, policies like Nirogi Rajasthan Abhiyaan, 2019²⁸ and Rajasthan Udaan Yogana, 2022 policies for mensuration and hygiene awareness for girls in 2021 are some recent developments. During the pandemic, many policies, rules, and laws were enacted which helped the government in keeping records of health and tracking spread of COVID. These will be dealt separately by the author in upcoming sections.

Indian Patent Act, 1970 is used for protection of inventions of those commodities which can be used to make any task easier and beneficial. Sec. 3(k) of the Act provides patent protection to software. Patent law, Copyright Act, 1957 and Information Technology Act, 2000 are used to protect the software of digital applications or Apps which keep records. For preparing software, the coding and algorithms are subject matter of protection as every App has a separate set of codes with separate intended brain application. There have been conflicts all over the world for protection of codes as under copyright or patent, but the argument which holds strong that it is literary content and hence is subject matter of copyright law.²⁹

The section 63 of Copyright Act, 1957³⁰ stands like an umbrella provision and covers all kinds of infringements subsisting in copyrighted works. With regards to infringed copy of software, the amendment introduced as section 63B in 1994 mentions the

²⁶ Sonia Jain, Right to health: With special reference to women's right to reproductive health in India-A human rights perspective, (2012) PL July 76.

²⁷ National Health Portal, Health Policies, https://www.nhp.gov.in/health-policies_pg (Mar.13, 2022 10:00 AM).

²⁸ Department of Medical, Health & Family Welfare, *Nirogi Rajasthan Abhiyaan*, 2019, <http://rajswashya.nic.in/Nairm%20Rajasthan%202019.htm> (Mar. 13th, 2022, 10:09AM)

²⁹ *In re Bilski*, 545 F. 3d 943, 88 U.S.P.Q. 2d 1385 (Fed. Cir.2008).

³⁰ The Copyright Act, 1957 No. 14 of Acts of Parliament, 1957 Sec. 63 'Offences of infringement of copyright or other rights conferred by this Act.

punishment with imprisonment and fine.³¹This infringement of software is also termed as software piracy. Software piracy is global problem for politicians, businesses and consumers, as there are uncertainties surrounding cross-border conflicts, business losses and consumer victimization of viruses.³²For protection, the software developers use anti-circumvention measure like Digital Rights Managements (DRM), Technology Protection Measures (TPM), and Rights Management Information (RMI) or through End User Licensing Agreements (EULA). There is very few software like MOSS (Measure of Software Similarity) which can be used to check the plagiarism quotient.³³ Unfortunately, India may still not be considered as an IP friendly country because of lack of awareness of protection for software developers. There is still a long way to go. These measures are used to ensure maximum protection of intellectual property of developers. With the contemporary trends of artificial intelligence (AI), the author would like to suggest use of AI for plagiarism detection. The role in this digital world will help the readers understand the significance of protecting this software under the copyright law.³⁴

Under Indian Evidence Act, 1872, under section 65A and 65B, the electronic records can be protected for evidentiary value and admissibility in the court of law.³⁵ Electronic record keeping helps in creating a profile and locating a particular profile, rather than searching in a bunch of files.

In terms of E-health, the two components that would require design protection would be the graphical user interface (GUI) and the design representation of the application. It would be protected under Designs Act, 2000 more specifically under Designs Rules, 2001 which also covers 'screen displays and icons'.³⁶The design of various devices could also be protected under the Designs Act. The mark of an e-health application or device could be registered as a trademark under the Trademarks Act, 1999, subject to certain exclusion criteria that can be refused.

³¹ The Copyright Act, 1957 No. 38 of Acts of Parliament, 1994 Sec. 63B 'Knowing use of infringing copy of computer program to be an offence'.

³² Yang, D., Sonmez, M., Bosworth, D & Fryxell, G. Global Software Piracy: Searching for further explanations, 87 (2), *Journal of Business Ethics*, 269-283 (2008).

³³ See generally: A system for detecting software similarity, <https://theory.stanford.edu/~aiken/moss/> (Mar.13, 2022 11:25 AM).

³⁴ Priyanka Bhattacharya, Leveraging Legal Stringency on Artificial Intelligence Application-A Copyright law on Artificial Intelligence Debate, *UC Berkeley thesis* (2017).

³⁵ The Evidence Act, 1872, No. 1 of Acts of Parliament, 1872, Sec. 65A 'Special provisions as to evidence relating to electronic record' & Sec. 65B 'Admissibility of electronic records.

³⁶ Vaishali Singh, Healthcare on the Cusp of a digital revolution: Is India Ready, *2019 SCC Online Blog OpEd* 17.

During the pandemic, the union government announced few policies like ‘Ayushman Bharat Mission’ and ‘National Digital Health Mission’ to bring systematized and affordable health and well-being for people. The mission “*aims to develop the backbone necessary to support the integrated digital health infrastructure of the country. It will bridge the existing gap amongst different stakeholders of healthcare ecosystem through digital highways.*”³⁷ Aarogya Setu App was made to keep a track of spread of COVID in India by keeping a record of test reports details taken from people and indicating movements of COVID positive person from one place to another.

The intention was good, but many challenged the concept of record keeping from individuals with data privacy.³⁸ So the idea of record keeping will be beneficial but the infrastructure of protection of data of users and software may be questioned in India. With The Personal Data Protection Bill, 2019 still pending in India, a systematic and protected record keeping cannot be ensured by the government which makes digital health technologies difficult to thrive.³⁹ Hence, under Indian IPR regime there are few aspects under which protection to digital health can be encouraged, but comparatively it is a much-nuanced concept. With the help of guiding principles given by WHO from time to time, a momentous change may be expected.

Digital health existing implementations:

Under digital health, presently there are various applications to implement it. There are some highly effective ways by which digital health can be tracked and can be IP protected. Some of them are as follows:

1. *E-Pharmacies*- With their introduction buying of medicines and drugs has become convenient as well as affordable. They have their own Apps which are protected as software programs under patent law or copyright law. Some of them are Medi Buddy, Pharm Easy, Net meds, 1mg, Med life etc.

³⁷ National Health Authority, Ayushman Bharat Digital Mission, <https://abdm.gov.in/> (Jan. 28th, 2022 10:13 AM).

³⁸ Abhijit Bhaskar, Why privacy advocates have concerns over Aarogya Setu App, <https://www.livemint.com/industry/infotech/why-privacy-advocates-have-concerns-over-aarogya-setu-app-11588509094177.html> (Mar. 14th, 2022, 7:15AM).

³⁹ PRS Legislative Research, Ministry of Law and Justice, The Personal Data Protection Bill, 2019, <https://prsindia.org/billtrack/the-personal-data-protection-bill-2019> (Mar.14th, 2022, 8:00AM)

2. *M-Health/Telemedicine*- Mobile health services are digital health platforms for medical services. Just like other Apps they are also mobile based records. For instance, Practo, Apple Health etc.⁴⁰
3. *AI/ IoT/ Machine Learning methods*- In the era of computer science, digitization of every field is possible now. Through machine learning and software, data analysis and processing has become easy, which in turn makes it easy to diagnose health issues. This is a boon for medical and health care services. For instance, Digital watches or patches which monitor heart rate throughout the day, blood pressure, sleeping patterns etc. These records when linked to software Apps may help in early detection of diseases like cancer and more. Software applications like Apple Health, My Fitness Pal etc. are performing tremendously in EHR systems.

Many countries have their own ways of digital health record maintenance. Through cyber security, protection can be ensured for the users and their data protection. Right to privacy being a fundamental right under Art. 21 of the constitution recently, has given an upper hand to citizens for ensuring personal data protection through offline or online methods.⁴¹

Need of digital health records in India:

So far, we have analyzed, digital health is witnessing a shift in recording of medical history from paper to electronic form. India, country with second largest population in the world⁴², must deal with a lot of issues in handling data related to population. As announced by Hon'ble Prime Minister of India Shri Narendra Modi on 15th August 2020 during his speech from Red Fort, Delhi, National Digital Health Mission, or Pradhan Mantri Digital Health Mission was founded under which "*access and exchange of longitudinal health records of citizens with their consent*" will be made.⁴³ Pandemic has truly taught us the value of good health both physical as well as mental.

⁴⁰ AMLEGALS, Digital Health vis-à-vis Intellectual Property Rights, <https://www.mondaq.com/india/trademark/934772/digital-health-vis-vis-intellectual-property-rights> (Mar.16th, 2020)

⁴¹ *Justice K.S. Puttaswamy vs. Union of India*, (2019) 1 SCC 1.

⁴² US Census Bureau current population, World population as on 2021, <https://www.census.gov/popclock/print.php?component=counter> (Mar.14th, 2022 1:38PM).

⁴³ PM Modi launches Pradhan Mantri Digital Health Mission, here's all you need to know, (Sep.27th, 2021) <https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/pm-modi-to-launch-pradhan-mantri-digital-health-mission-monday/articleshow/86528938.cms> .

India is moving towards an era of healthcare adversities. Ranging from the survival of lower economic class to absolving mental health issues of the upper class, India is a country with extremes and achieving equality seems like a distant dream. Digital health system if adopted, will give more advancement in diagnosis and health care in India as:

- a) *Systematization* of health records of every citizen will lead to better treatment facilities.
- b) By following the trends in digital health records, *quick diagnosis* of citizens can be ensured.
- c) Today, due to lack of infrastructure in record keeping, patients must go from one doctor to another to get *diagnosed of the actual problem*. This leads to draining of patient's hard-earned money. With digital health records, a profile will reduce the pain of visiting doctors.
- d) '*One citizen, one Unique Health ID*' will bring personalized health care regime which can help in quick cure.
- e) Digital health records can help government analyze the trends of diseases, ailments and health issues people are suffering at a particular point of time. By giving special stress on that issue, *policy formation* for cure can be made straightforward.
- f) Determining health content appropriate for implementation by understanding the *requirements and expectations* of people. By using data analytics, action plans can be created and executed effectively.⁴⁴
- g) India no doubt has to upscale its game in IP regime by *strict enforcement*; digital record-keeping can be a reality. For COVID vaccination drive which started from 16th January, 2021, by compelling registration of every citizen on Co-WIN App, has helped government in keeping a record of vaccinated citizens.⁴⁵

As the government has conducted such a large-scale and most importantly a successful COVID vaccination drive all over the country by doing online registrations, then we are near to using digital health system in our daily lives. Digital health, IP interference and proper allocation of budget to health care facilities will bring a massive change in health of India.

Conclusion:

⁴⁴ Report Part Title: Linkages to broader digital health ecosystem, Report Title: Digital adaptation kit for antenatal care, *World Health Organization (2021)*.

⁴⁵ Ministry of Health and Family Welfare, Co-WIN winning over COVID-19, (Mar.15th, 2022, 7:54AM) <https://www.cowin.gov.in/>.

Digital health and IP have a good interface with each other for the benefit of the inventors or marketers who are expecting monetary benefits from their invention. It is up to countries to implement and build an infrastructure where healthcare is approachable and affordable to all. A patient expects their healthcare treatment to be nominal, and it is the duty of the state to ensure that by providing all facilities. India is still in a developing phase of digital health systems.

By thinking of the larger goals and intentions of this system, it is certain that it will bring a tremendous change in India's health care and welfare regime. The only thing to ensure is a balance between public interest and rights of inventors of digital health systems.