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Research Article

Progressing towards AI based Diabetes Diagnosis services: Current status, applications, developmental barriers and prospects in Maharashtra & Karnataka, India

[1]Mr. Mrinmoy Roy, [2]Dr. Mohit Jamwal

[1]PhD Scholar, [2]Assistant professor
Mittal School of Business, Lovely Professional University, Phagwara, Punjab

Abstract

Diabetes is the major health concerns across the whole world. Increasing at a rapid rate, this global epidemic is affecting a large portion of the populace everywhere. India having the highest proportion of diabetic patients, also becoming the 'diabetes capital of the world'. Early detection of diabetes could help to prevent or postpone its onset by taking appropriate preventive measures, including the initiation of lifestyle changes. AI-based diabetes diagnostic solutions are the new trends that companies are embracing to ensure smooth diabetes care. They provide diagnostic programs to detect complex ailments from medical images. By annotating lesions and abnormalities, these programs assist medical scholars and even non-specialists to have a faster diagnosis with much more accuracy. India faces a chronic disease risk burden. Not just this, many people especially those in the age group of 25 to 40 are also being diagnosed with diabetes & cardiovascular diseases according to Journal of the American Medical Association. This research addresses the existing scenario of AI based Diabetes Diagnostic services available in Maharashtra & Karnataka states in India. Firstly, the geographic location of Maharashtra & Karnataka and its existing Healthcare & Diagnostic status are explained. Then, various policies initiated by the government and the healthcare sectors of private ventures are described. Finally, the future prospects of AI based Healthcare Diagnostics in the two states along with possible strategies to address the barriers and issues are mentioned in this paper.

Keywords: type 2 diabetes, diabetes diagnosis, AI based Diabetes Diagnosis, AI algorithms in Diagnosis

Introduction

Diabetes affects approximately 463 million adults (20-79 years) worldwide, with this figure expected to grow to 700 million by 2045. Diabetes affects 79 percent of the population in low and middle-income countries. Diabetes has resulted in the deaths of 4.2 million people. Diabetes affects approximately 69.2 million people in India, with the number estimated to rise to 123.5 million by 2040. (IDF Atlas, 2019). Diabetes chronicity is linked to long-term damage and dysfunction of multiple organ systems, including the eyes, nerves, kidneys, and heart (Diabetes care, 2016). Diabetes and pre-diabetes should be diagnosed early so that patients can begin

managing the disease and potentially avoid or postpone severe disease complications that can reduce quality of life.

In every healthcare or diagnostic environment, the topic of clinical outcome is critical. Prior to 1980, healthcare was not a top priority for India's government, which had other priorities. Healthcare has yet to reach the point where capital is invested. Since 1980, thanks to the private sector, India has been able to spend 5% of GDP in healthcare, with the government contributing 1% and the private sector providing 4%. The problem now is that the government is the sole provider of services to the rural area since the private sector is unable to do so. Even the government-run community health centre has openings for specialists such as MDs and MSs. As a result, the government must raise the number of postgraduate places, which they are currently working on. The other metric is the Human Development Index, in which we rank about 188 globally, due to the fact that HDI is focused on education, healthcare, and earning power. The third and final problem is that hospitals and roughly two-thirds of medical colleges are located in the south and west of India, where only 1/3 of the population lives. Just 1/3 of medical colleges exist in states with 2/3rds of the population, such as Uttar Pradesh, Madhya Pradesh, Orissa, West Bengal, and Kashmir. For example, there are approximately 45 medical colleges in Tamil Nadu, compared to 18-22 in Rajasthan, Uttar Pradesh, and Bihar. Here, the population is two times that of the United States, but the number of medical schools is half that of the United States, so this is a major problem that we have not been able to address. Everyone says healthcare is very expensive, and this is because none of us have set aside money for it. Patient safety and affordability are related, but patient safety necessitates good technology, good physicians, and good medical procedures, which we refer to as standard treatment guidelines, all of which are currently lacking in our healthcare system. In states like Madhya Pradesh, Bihar, Orissa, and West Bengal, primary health centers are largely inoperable. If you give them the budget, the private sector is willing to take over the primary health center on a PPP basis. Any patients from primary health centers may be sent back to their own hospitals, which is in the private sector's interest.

As a result, it's a win-win scenario, and that's the second option for addressing the rural healthcare shortage. India is gradually entering an increasing list of countries that are implementing AI in healthcare. Companies like Microsoft, IBM, Google, GE Healthcare, and a slew of health-tech startups are driving AI adoption in India. The current state of AI-based healthcare diagnostic services in Maharashtra and Karnataka is discussed in this article. To begin, the geographical position of Maharashtra and Karnataka, as well as their current healthcare and diagnostic status, are defined. Following that, the government's and PVs' healthcare sectors' various policies are listed. Finally, this paper discusses the future prospects of AI-based healthcare diagnostics in Maharashtra and Karnataka, as well as potential methods for overcoming obstacles and issues.

Overview of Maharashtra & Karnataka

Maharashtra is a state in India's western peninsula that covers a large portion of the Deccan Plateau. Maharashtra is India's second-most populous county, as well as the country's second-most populous subdivision. On May 1, 1960, Maharashtra was created by dividing the bilingual Bombay State, which had existed since 1956, into majority Marathi-speaking Maharashtra and Gujarati-speaking Gujarat. Mumbai, India's most populous city, serves as the state capital. It is India's third-largest state by area, covering 307,713 km2 (118,809 sq mi). Maharashtra is bordered on the west by the Arabian Sea, on the south by the Indian states of Karnataka and Goa, on the southeast by

Telangana, on the east by Gujarat and Madhya Pradesh, on the north by Gujarat and Madhya Pradesh, and on the northwest by the Indian union territories of Dadra and Nagar Haveli and Daman and Diu.

Maharashtra's major cities include Mumbai, Pune, Nagpur, Thane, Nasik, Solapur, Kolhapur, Sangli, Aurangabad, Amravati, and Ratnagiri. Mumbai is home to India's largest stock exchanges, capital markets, and commodity exchanges. Marathi is the most widely spoken language in the state. The other major languages are Konkani, Hindi, and English.

Parameters	Maharashtra
Capital	Mumbai
Geographical area (lakh sq. km)	3.08
Administrative districts (No)	36
Population density (persons per sq. km)	365
Total population (million)	112.4
Male population (million)	58.2
Female population (million)	54.1
Sex ratio (females per 1,000 males)	929
Literacy rate (%)	82.3

Source: *Map of India, Economic survey 2015-16, Economic Survey 2016-17, Economic Survey 2017-18, National Portal of India*

Karnataka is located on the Deccan Plateau and is bordered on the west by the Arabian Sea, on the northwest by Goa, on the north by Maharashtra, on the east by Andhra Pradesh and Telangana, on the southeast by Tamil Nadu, and on the southwest by Kerala. Karnataka is situated between 11°30' North and 18°30' North latitudes and 74° East and 78°30' East longitudes in India. It is located on a tableland in the western part of India's Deccan Peninsular region, where the Western and Eastern Ghat ranges converge to form the complex. The state is bordered on the north and northwest by Maharashtra and Goa, on the west by the Arabian Sea, on the south by Kerala and Tamil Nadu, and on the east by Andhra Pradesh and Telangana. Karnataka stretches for about 750 kilometres north to south and 400 kilometres east to west. Ankola, Bengaluru, Bagalkot, Belgaum, Bidar, Bijapur, Chikmagalur, Chitradurga, Dandeli, Hubli-Dharwad, Mangalore, Mysore, and Shimoga are some of the state's major cities. Karnataka has a tropical climate with three distinct seasons: warm and dry between February and May, monsoon between June and October, and winter between November and January. Kannada, Tulu, Kodava, Hindi, and English are the major languages spoken in Karnataka.

Parameters	Karnataka
Capital	Bengaluru
Geographical area (sq km)	192,000
Administrative districts (No)	30
Population density (persons per sq km)	319
Total population (million)	61.1
Sex ratio (females per 1,000 males)	973
Literacy rate (%)	75.6
Male literacy rate	82.5
Female literacy rate	68.1

Source: *Map of India, Economic Survey of Karnataka 2017-18, Census 2011 Office of Registrar General, India.*

Health Infrastructure of Maharashtra & Karnataka

The state government of Maharashtra has announced an outlay of Rs 15,919 crore (US$ 2.31 billion) for the Public Health Department in Budget 2019-20. The Government of India proposed Rs 767 crore (US$ 111.33 million) in 2018 to introduce the National Health Mission, which would increase the availability of good health services in Maharashtra's urban and rural areas.

Health Indicators of Maharashtra (As of Sept 2017)	
Doctor to patient ratio (as of Dec 2017)	1:27,790
Registered allopathy doctors (as of March 2019)	156,071
Registered ayurveda doctors (as of March 2019)	82,892
Registered homeopathy doctors (as of March 2019)	70,830
Birth rate (per thousand persons)	15.7
Death rate (per thousand persons)	5.7
Infant mortality rate (per thousand live births)	19

Health Infrastructure (As of May 2020)	
Type of Hospital	Number of Hospital
Sub-Centres	10,675
Primary Health Centres	2,809
Rural Hospitals (CHC)	527
Sub-District Hospital	159
District Hospitals	148

Life expectancy (2015-16)	
Male (2016-20)	69.9
Female (2016-20)	73.7

Source: *Ministry of Health and Family Welfare, Government of India, Socio Economic Survey of Maharashtra, 2018-19, BE- Budget Estimate*

In the last few decades, Karnataka has made significant progress in improving the health of its people. The state has made significant strides in developing a credible health system that includes a large institutional network that provides health care in both urban and rural areas. In the province, there are 43 district hospitals, 540 sub-district hospitals, 31 autonomous and teaching hospitals, and 146 taluk/general hospitals. The state government launched the Universal Health Coverage (UHC) scheme in February 2018, with the aim of bringing all government health schemes under one roof.

Programs under AYUSH health care services:

- AYUSH Health camp.
- District and Taluk Seminars / Workshop.
- Home remedy and Ayush awareness.
- Diabetic control program.
- School health program.
- AYUSH health expo

AI based Diabetes Diagnostic services available in Maharashtra & Karnataka

In the field of artificial intelligence, India has produced a range of brilliant minds. A large number of artificial intelligence and machine learning-based startups have emerged in recent years, and India is now one of the leading countries in the field of AI.

Many healthcare industries in India need automation for a variety of tasks, and they are using AI to assist them. In alphabetical order, here is a list of Indian startups that are leveraging the benefits of AI in the field of healthcare:

1. The Advancells This startup, founded in 2005, focuses on therapeutic applications of regenerative medicine, which is a branch of translational science in tissue engineering and molecular biology concerned with replacing and regenerating human cells, tissues, and organs to restore or establish normal function. It provides technologies to patients all over the world for safe and reliable care choices that meet the highest medical requirements.

Vipul Jain is the founder of the company.

2. Artelus: Artelus was created in 2017 and stands for "artificial learning system." The aim of this company is to use deep learning algorithms to detect diabetic retinopathy (DR). It takes a picture of the patient's retina, analyses it, and generates a study. It can detect DR in less than three minutes, which is significantly faster than humans. With the aid of its AI screening tool, it is also attempting to develop early detection tools for tuberculosis, breast cancer, and lung cancer.

Rajarajeshwari K, Lalit Pant, and Pradeep Walia are the founders.

3. ChironX: Mausumi Acharyya, the founder of ChironX, is a specialist in imaging and AI. ChironX (formerly Advenio Technosys) was established in 2017 and identifies diseases from vast populations of medical photos. It has auto diagnostic software that employs advanced image processing AI algorithms as well as traditional machine learning techniques. Deep learning algorithms are also used extensively in their modules. It is currently being used to identify retinal abnormalities and acute respiratory infections. The Biotechnology Industry Research Assistance Council (BIRAC) and the Bill and Melinda Gates Foundation are funding ChironX's research, which is being seed funded by KStart.

Mausumi Acharyya, Sombodhi Ghosh, Mausumi Acharyya, Mausumi Acharyya, Mausumi Acharyya, Mausumi Ach

4. LiveHealth is a Pune-based company that uses automation to offer diagnostics to customers. This startup from 2014 sends reports to patients or organizations as soon as they are available online. It also allows doctors to access patient data at any time, accepts online payments, and tracks all patient activities in real time. Doctors can sign patient reports with a single click as well. Their main priority in delivering medical diagnostics is full digitization and automation, which eliminates report entry errors fully

Mukund Malini and Abhimanyu Bhosale founded the company.

5. Lybrate: Lybrate is the country's first online doctor consultation site, having launched in 2014. In today's fast-paced, hectic world, we hardly have time to see a doctor for any minor health issue that arises. Because of our hectic work schedules, we often overlook symptoms that seem mild but turn out to be severe. Patients may communicate with doctors and have online consultations via Lybrate's online application. Patients can also schedule lab tests and appointments via the website.

Aside from that, Lybrate also offers weight loss, exercise, and skin and hair care services. They have doctors from all walks of life working for them around the world. It also has a Facebook Messenger bot for health advice. The aim of this startup is to create an easily accessible online consultation for all.

Saurabh Arora is the founder of the company.

6. NeuroSynaptic Communications Private Limited: Through their startup, they hope to make health care more available to the general public. It offers ReMeDi Remote Healthcare Delivery Solutions of the highest quality. It gathers data on a variety of physiological aspects of patients over the internet and provides them with a diagnosis. They make the whole diagnosis process more affordable by doing so. They currently have operations in four cities, with a primary focus on healthcare. So far, the majority of their work has taken place in classrooms, and they also have an app that allows parents to prepare healthy meals for their children. Aside from that, they have regular health screenings as well as health education. It was founded in the year 2002.

Sameer Sawarkar is the company's founder.

7. Niramai: After having cancer in their family, the two founders of this startup felt compelled to do something about it. Niramai is a Bangalore-based startup established in 2016 that offers breast cancer screening services. They created machine learning software that can detect breast cancer at an early stage, allowing for early detection.

In three modes, it offers a full hardware-software breast cancer solution:

• For specialty hospitals, a sturdy, portable screening system with cloud processing is available.

• Low-cost handheld computer for independent medical practitioners with real-time cloud-based diagnostics

• A portable screening solution for large-scale events.

Geetha Manjunatha and Nidhi Mathur are the founders.

8. OncoStem Diagnostics: This company, which was established in 2011, uses machine learning algorithms to aid in the treatment of personalized cancer. OncoStem is a tool that uses proteomics and genomics to predict cancer recurrence using a molecular fingerprint of a tumour. The ability to predict cancer recurrence would aid in the development of new medicines. It has a product called ‘CanAssist-Breast,' which aims to help minimize breast cancer by analyzing samples of the patient's tumor and predicting the risk of cancer returning. The patient is graded as ‘low' or ‘high' risk after this has been analyzed using a machine learning algorithm. Patients who are classified as "high-risk" have a higher chance of cancer recurrence than those who are classified as "low-risk." Chemotherapy is not needed for those with a low risk score.

It also aspires to create tests for a variety of cancers, including oral and colon cancers.

Manjiri Bakre is the founder of the company.

9. OnliDoc: A one-stop shop for medical diagnosis. OnliDoc makes use of AI and machine learning. It has a phone app for finding physicians, scheduling appointments, and storing medical records and medications. It has a symptom checker that uses artificial intelligence and deep learning, and reports are delivered online. It employs artificial intelligence (AI) and deep learning to assist in care selection and to suggest first steps to take. Their software is available on both the Apple App Store and the Google Play Store. It was founded in 2015

Dipendra Jain is the founder of the company.

10. Qure.ai: Established in 2016, this Mumbai-based company uses deep learning algorithms in its products. It develops deep learning algorithms using massive datasets of medical data. Three of its products are listed below:

• qXR: This product detects irregular chest X-rays and then recognizes and localizes 15 common anomalies using a million selected X-rays and radiology studies. It can also detect tuberculosis.

• qER: This product is used to aid in the diagnosis of head CT scans. It detects and localizes vital anomalies such as bleeds, fractures, and midline change, as well as their severity.

• qQuant: It has completely automated identification, quantification, and 3D visualization and is used for CT and MRI scan quantification and progression tracking products.

In the year 2016, this company was created. They claim that allowing computers to manage the less complex medical cases frees up healthcare providers to concentrate on the cases that really matter.

Prashant Warier (CEO, co-founder), Pooja Rao, Preetham Sreenivas, Sasank Chilamkurthy, Ankit Modi, Rohit Ghosh, and Tarun Raj are among the company's founders.

11. SigTuple: Founded in 2015, this Bangalore-based startup uses robotics and artificial intelligence to augment medical data in order to help the healthcare industry develop smart diagnostic solutions and make high-quality healthcare more available and affordable. The company is developing the ‘Manthana' artificial intelligence platform to aid in the efficient identification of visual data. This AI platform assists them in the healthcare industry's five screening processes:

• Examination in smears of peripheral blood
• Microscopy of urine
• Examination of sperm
• Fundus examination
• X-rays and OCT scans of the chest

The ‘Shonit' peripheral blood smear analyser solution has already been tested in a closed beta. It automates repetitive activities such as differential counts and offers malaria and anaemia screening solutions. The blood smear slides are photographed using a phone mounted on a microscope. The data is then analysed using deep learning and image recognition techniques. It produces blood reports and indicates irregularities in the blood based on this picture review. Pathologists from all over the world may review this report using any internet-connected computer. Shrava, Aadi, Dhrishti, and Vaksha are four other such solution platforms that target different areas. The first two are approaching clinical validation, though Dhrishti is still in product production and Vaksha, a chest X-ray screening solution, is still in development.

Rohit Kumar Pandey, Tathagato Rai Dastidar, and Apurv Anand are the founders.

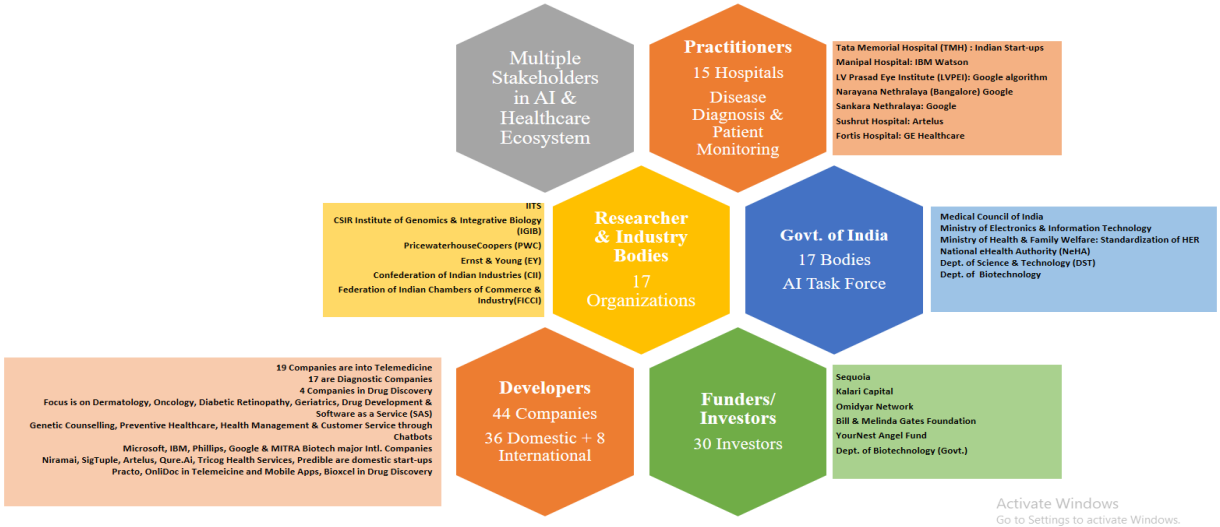
General Electric has announced a public private partnership (PPP) with the Maharashtra Government. In a consortium which includes Maharashtra’s Public Health Department, Wipro GE Healthcare Pvt Ltd and Ensocare by Enso Group, a $7-billion diversified conglomerate in sectors such as oil & gas, infrastructure & real estate, the project will set up advanced diagnostic facilities at 22 Government district and women hospitals. It will operate on a 24/7 hour basis and provide

services at Government recommended rate cards. Orange and Yellow 'Below Poverty Line' (BPL) card holders will be entitled to receive free diagnostic services under the Rajiv Gandhi Jeevandayee Arogya Yojana (RGJAY) scheme at all 22 facilities, which are expected to be operational within a year.

The PPP agreement with Maharashtra is the largest in terms of scale and includes the installation of four units of 64 slice CT scanners, 13 units of advance 16 slice CT scanners, 8 units of cutting edge 1.5T Magnetic Resonance Imaging Systems, 22 digital radiography systems, 39 colour Doppler's and 39 analog x-ray units. These advanced imaging systems will allow District Hospitals to provide early and accurate diagnosis in the clinical specialty areas of Neurology, Cardiology, Vascular Imaging, Emergency/Trauma, Oncology, Obstetrics and Gynaecology, Orthopaedics and Gastroenterology. In addition to providing general purpose radiology, women's health will be given a special boost with the inclusion of 20 screening mammography units for early breast cancer detection.

To work on healthcare diagnostics with deep learning tech, AI and digital interfaces The Indian Institute of Science (IISc) and Wipro GE Healthcare on Thursday inaugurated Wipro GE Healthcare-Computational and Data Sciences Collaborative Laboratory of Artificial Intelligence in Medical and Healthcare Imaging. The facility, located at the Department of Computational and Data Sciences (CDS) of IISc, Bangalore, is expected to work on healthcare diagnostics with deep learning technology, artificial intelligence and digital interfaces, to provide diagnostic and medical image-reconstruction techniques and protocols for faster and better imaging. To start with, the facility will work with over 50 students and three faculty members of IISc. The thrust of this collaborative laboratory will be to work closely with clinicians as well as Wipro GE Healthcare to integrate these computational models into clinical workflows to help doctors improve patient outcomes.

Various Policies initiated by Govt. & Private ventures



Government Initiatives

1. National eHealth Authority (NeHA)

The Ministry of Health and Family Welfare proposed NeHA in 2015 as an authority to be in charge of developing an integrated health information system in India. In collaboration with various stakeholders, NeHA will serve as a nodal authority in the creation of an integrated Health Information System (HIS) that includes telemedicine and mobile health (mHealth). One of the most important responsibilities is to implement laws and regulations relating to the privacy and protection of patients' health records. NeHA is envisioned as a promotional, regulatory, and standards-setting body that will lead and promote India's e-Health journey and, as a result, the orderly realization of the benefits of ICT involvement in the health sector. The primary goals of NeHA are to develop a "National eHealth Policy and Strategy" to coordinate eHealth adoption, to establish state health records repositories and health information exchanges (HIEs) to facilitate interoperability, to establish data management, privacy and security policies, guidelines, and patient health records, and to develop a certification framework for HER. It also explains NeHA's proposed roles and governance structure (National eHealth Authority, 2018).

2. **The Ministry of Health and Family Welfare** (MoHFW): This government body is working tirelessly with the National Law School of India University in Bangalore on a draught legislation on a Health Data Protection and Security Act Electronic, which addresses issues such as confidentiality, privacy, and ownership of health data, as well as the establishment of the NeHA (Raju, 2016). The researchers were unable to obtain a public copy of the draught legislation at the time of writing this paper. According to sources, the health ministry met with university legal experts in June 2016 to review the initial draught, and the draught legislation was submitted to the ministry in July 2016. According to the most recent details, the records will be used for big data analytics after they have been anonymized. This also raises concerns about the de-identification criteria being used, which are not stated in any of the mission documents made publicly available about the NeHA. There have been cases of re-identification of anonymized data sets all over the world, especially where the anonymization techniques aren't strong enough (Ohm, 2009). There are also significant problems with respect to data ownership. The NeHA's defined goals will resolve major problems in India, such as a lack of proper evidence and data in medicine. As a result, how this policy is formulated and what powers are granted to the authority will be a determining factor in the ethical use of AI and big data in healthcare.

3. Artificial Intelligence Task Force

The Ministry of Commerce and Industry established the 'Task Force on AI for India's Economic Transformation' in 2017 to investigate ways to use AI for growth in a variety of fields. Its main task is to make concrete and actionable suggestions to authorities like the government, industry, and research institutions. Experts, scholars, researchers, and industry leaders from eminent and prominent institutions across the world, as well as members from the NITI Aayog, Ministry of Electronics and Information Technology, Department of Science and Technology, UIDAI, and DRDO, make up the AI Task Force (www.aitf.org.in, 2018).

4. Policy Group on Artificial Intelligence

The Ministry of Electronics and Information Technology recently established a "policy committee" to investigate various aspects of AI technology in order to develop a policy structure

and a solid roadmap for its adoption. The policy group, which includes members from academia and the National Association of Software and Services Companies (NASSCOM), will concentrate on issues such as privacy, protection, liability, and workforce skilling (PTI, 2017).

5. National IPR Policy

In 2016, the Department of Industrial Policy and Promotion ("DIPP") published the National Industrial Policy Report ("NIPR"), titled "Creative India, Innovative India," with the aim of raising awareness about the value of intellectual property as a marketable financial asset and economic tool. NIPR defined seven broad objectives for combating infringement, ranging from raising awareness to improving compliance and adjudication mechanisms. It also discusses designing novel technology systems to ensure improved access to affordable drugs and other healthcare solutions, as well as identifying opportunities for progress in new and emerging technologies (National IPR Policy, 2016).

6. United States–India Science & Technology Endowment Fund (USISTEF)

The United States–India Science & Technology Endowment Fund (USISTEF) was founded by the US Department of State and the Indian Department of Science and Technology to encourage joint activities leading to innovation and entrepreneurship through the application of science and technology (www.usistef.org, 2018). Bi-national teams of entrepreneurs and innovators who have a creative product beyond the concept stage with a strong societal impact and the potential to commercialize within 2-3 years will apply for grants ranging from INR 25 million. The project's main goals are biomedical devices and diagnostics, as well as preventive and curative health initiatives (www.usistef.org, 2018).

7. Cognitive Science Research Initiative (CSRI), Department of Science & Technology

The Cognitive Science Research Initiative (https://dst.gov.in, 2018) was established in 2008 to provide a forum for scientists to address problems related to cognitive disorders and social concerns through the use of psychological instruments and batteries, early detection and improved treatments, intervention technologies, and recovery services. The CSRI provides funding to support cutting-edge studies in various areas of cognitive science, such as artificial intelligence. Scientists and academicians working in India can apply for funding in the form of individual research grants and Post-Doctoral Fellowships (https://dst.gov.in, 2018).

8. Biotechnology Ignition Grant Scheme (BIG), Biotechnology Industry Research Assistance Council

The Biotechnology Industry Research Assistance Council (BIRAC) is the government of India's nodal support agency for the biotech industry. BIG was founded by BIRAC in 2012 to discuss problems that startups in biotechnology and medical devices, in a nutshell, face while trying to expand due to long incubation cycles and market uncertainty. The scheme allows innovators to create and validate proof of concept (POC) for high-risk, potentially high-impact technical ideas in order to commercialize or introduce them in the future (http://birac.nic.in, 2018). The program is currently being implemented around the country by five BIG Partners that mentor and track

grantees. The scheme has been approved for a grant of INR 821.96 lakhs (USD $ 1.6 million). BIG has funded over 200 biotech and healthcare startups since 2012. (Vignesh, 2017).

9. Centre of Excellence for Data Science and Artificial Intelligence (CoE-DS&AI)

The Government of Karnataka, in collaboration with NASSCOM, is establishing a Centre of Excellence for Data Science and Artificial Intelligence (CoE-DS&AI) (NASSCOM, 2017) at a cost of INR 40 crore on a public-private partnership model to "accelerate the ecosystem in Karnataka by providing the impetus for the development of data science and artificial intelligence across the country" and to "encourage the development of data science and artificial intelligence across the country" By investing in technical infrastructure and industry-oriented research, equipping academic institutions to provide education and capability creation in DS and AI, and promoting innovation and adoption of data-driven decision making by businesses and government, the Centre will work with partners to extend AI capacity through academia, government, and businesses.

Policy and Regulatory Landscape in India

In India, a variety of policies influence the production and application of artificial intelligence in healthcare. This includes rules governing the use of health data, certification of digital medical devices, specifications for digital medical devices, and patient/relationship structures. The Indian government has also taken a range of policy measures to encourage the creation of AI and health-related solutions. A summary of applicable Indian law, policy, and standards is given below:

Information Technology Act, 2000; Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011

The application of these emerging technologies necessitates a continuous exchange of data between the patient and the service provider. Under the Data Protection Rules ("Rules"), the patient's health information, such as medical records and physiological conditions, is called Sensitive Personal Data or Information ("SPDI"), and certain laws apply when a body corporate gathers, stores, transfers, or processes such information. The Rules make it clear that consent is required. As a result, before using a patient's data, a doctor or institution must obtain written consent from them. If any data is being collected, the patient must be aware of the intent of the collection, as well as any transfers of such information to third parties and the identity of the data collection organization. The corporate body passing the SPDI must ensure that the receivers have appropriate security practices in place. The corporate body must have to publish a privacy policy on its website. The Rules also mandate the implementation of reasonable security practices and procedures in order to keep the SPDI secure - of which ISO 27001 is an accepted standard.

The Rules also contain requirements to appoint a 'Grievance Officer' whose contact details are to be published on the website, as well as the provision to allow users to opt-out or modify their SPDI if required. However, despite the existence of these rules, there has been minimal compliance in India due to lack of enforcement mechanisms. Questions have also been raised about the legislative scope of these rules which while drafted under a data security provision, may be seen as going beyond its scope. The Supreme Court in K.S Puttaswamy & Anr. v. Union of India & Ors. (Supreme Court of India, 2012). outlined the need for a comprehensive data protection framework, due to which the Ministry of Electronics and Information Technology constituted a committee of experts chaired by Justice B.N. Srikrishna to identify data protection issues and make

recommendations to address them, as well as prepare a draft legislation to be introduced in Parliament (http://meity.gov.in).

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

The MCI is in charge of establishing the basis for professional contact between doctors and patients, as well as protecting patient confidentiality and prognosis disclosure. The MCI Code states that all reasonable attempts be made to computerize all medical records so that they can be easily retrieved. Even in India, this apex body oversees doctors' practice of medicine. From July 2017, the Supreme Court of India ordered the Central Government to abolish the medical council and control the medical education system in India with the aid of five specialized doctors. The Medical Council of India (MCI) has been replaced by the National Medical Commission (NMC) following a recommendation from the NITI Aayog. Major Indian states have endorsed this decision, and India's Prime Minister has approved the NMC bill, which was also passed by parliament and signed by the President on August 8, 2019. National Medical Commission came into effect on 25 September 2020, and the Medical Council of India automatically dissolved and the nearly 63-year-old Indian Medical Council Act stood abolished.

Electronic Health Records Standards, 2016

The 2016 EHR Guidelines aim to govern data ownership and privacy standards relating to the collection of patients' health data from medical institutions, medical devices, and self-care devices and systems. The government has recognized the critical need for data standardization and has established a base of standards for data capture, storage, retrieval, sharing, and analytics, which includes images, clinical codes, and data. ISO and other national norms for EHRs are among them.

• Data Ownership: Typically, data collected by patients is held by service providers, but it will now be owned by consumers or patients, who will have unlimited access to their medical records.

• Data Access: Patients will have full control over data access, and disclosures will be based on explicit consent. There would also be a mechanism in place to correct any gaps in their medical reports.

• Data Modifications: Data entered into the system cannot be altered, and any changes that must be made should be followed by an audit trail. Any changes to medical records will be made on a new record containing the updated information, which will then be marked as "active."

• Health Information Disclosure: For use in routine and non-routine check-ups, as well as other and non-healthcare purposes, the patient's specific consent is required. Nonetheless, after deleting some personal identifiers, data can be freely disseminated without permission.

• Access to Records by Courts/Government Authorities: In the event of a court order, the above health records must be produced in their "as-is" condition. Furthermore, the legislation allows for the distribution of health information without permission to the relevant authorities in cases of national concerns such as notifiable/communicable disease.

• Healthcare Providers' Responsibilities: Healthcare providers are responsible for storing patient information and ensuring that personal identifiers are removed. They must also remind patients of their rights and take steps to protect personal information. They may also refuse to provide information to patients if a licensed doctor feels that doing so will jeopardize the patient's or others' life or safety. Even after a patient's death, electronic records must not be deleted, although they can be transferred from active to inactive status if there are no pending court proceedings that warrant this information.

• Data Encryption: Electronic health records must be encrypted with at least 256-bit encryption keys. When transmitting such data between sites, secure transmission standards must be used. All data-related actions must be recorded.

• Identification: If the patient has an Aadhaar number, it should be used as a unique identifier; if not, two government ID cards may be used instead.

Open Data Policy

The Ministry of Science and Technology formulated the National Data Sharing and Accessibility Policy (NDSAP), which was adopted by the Ministry of Electronics and Information Technology in the form of an Open Data Platform (https://data.gov.in). The NDSAP is intended to facilitate the exchange of non-sensitive data produced with public funds that is either digital or analogue (NDSAP, 2010). Depending on the level of authorization needed, access to this data is available, registered, or limited. The Health Management Information System (HMIS) provides the majority of the healthcare metrics on the Open Data Portal, but studies have cast doubt on its accuracy (Pandey et al., 2010). The information on the website is from the public sector, but nearly 70% of healthcare is provided by the private sector (https://pib.nic.in). This raises questions about the data's representativeness. Startups without access to massive databases face the problem of prototyping data scarcity (Mohandas, 2017). India needs to open up more data and incentivize private healthcare providers to provide anonymized data, as open data is a critical enabler for AI. Currently, health data is aggregated and does not have anonymized granular data. In comparison, the National Health Service in the United Kingdom (https://www.england.nhs.uk) collaborates with private organizations to provide machine-readable open data and develop organizational practices around open data and transparency agendas. Over 100,000 anonymized chest x-ray images and their related data from over 30,000 patients were recently published to the scientific community by the UK NIH Clinical Centre. Both patients are research collaborators who willingly engage in clinical trials (NIH, 2017). The government of Israel digitizes medical records and makes them available to Israeli startups (with prior government approval if the startups can provide proof of use). The American Cancer Society (a non-profit organization) in the United States, which has

access to large-scale cancer databases, makes this data available to everyone for free, along with interactive resources to work with it (American Cancer Society, 2018).

Medical Devices Rules, 2017

The Medical Device Rules of 2017 were written with the aim of making a regulatory distinction between medical devices and pharmaceuticals. The Rules determine what qualifies as a medical device, and their application is restricted to those devices that come under their purview. The Rules established a risk-based classification system for medical devices, categorizing them as Low (Class A), Low Moderate (Class B), Moderate High (Class C), and High (Class D) (Class D). Manufacturers are responsible for risk classification in accordance with the framework developed by the Drug Controller General of India. Class A medical devices do not need prior third-party audit or official inspection in order to receive a licence to produce them; Class B medical devices do require prior third-party audit but not official inspection; and Class C or Class D medical devices do require prior official inspection. Devices are required to adhere to either the central government's or the Bureau of Indian Standards' specification for the device, or to standards set by the International Organization for Standardization or the International Electro Technical Commission, among others, if no such standard exists. The product requirements for medical devices are clarified by these provisions. Other requirements include assurance of deadlines for application decisions and when an examination or inspection should be expected, the issuance of permanent licenses (that are valid until cancelled), making the licensing process smoother, and mandatory recalls in the event of awareness of a health danger. There are no special clauses in the Rules for the selling of medical devices. They do, however, resolve a practical issue faced by Indian distributors, namely stock transfers, which are simply stock transfers and not sales. The hospital is billed on a per-use basis, with the remainder of the stock being returned to the seller. A dealer normally does not keep track of stock transfers. As a result, the Rules permit the supply of implantable medical devices in exchange for a delivery notice (challan). The Rules establish a new legal structure for medical device clinical trials. The licensing authority has set a 90-day deadline for making a decision on a clinical trial application. With regard to approval of medical devices other than investigational medical devices, the Rules also adopted the principles of a "pilot trial," which is an exploratory study, and a "pivotal study," which is a confirmatory study, as well as "substantial equivalence."

ISO 13485:2016

ISO 13485 is an international standard that specifies quality control systems for medical device and equipment manufacturers, vendors, contract service providers, and distributors. Its key goal is to regulate medical devices by establishing standardized quality management system standards, which serves as the foundation for regulatory enforcement in both domestic and international markets (https://www.isoindia.org). To meet this criterion, a company must be able to demonstrate its ability to reliably provide medical devices and related services that meet consumer and regulatory requirements. Unless otherwise defined, an organization could be a part of one or more stages of the product's lifecycle, and the norm applies to all organizations regardless of their size or form. Suppliers or third parties that provide quality control services to the company in question may use the standard. This standard is being adopted as India continues to establish a system around medical devices through IS 15579:2005, which is India's attempt to move towards ISO

13485:2016. IS 15579:2005 and ISO 13485:2016 are reportedly similar, with the exception of a national foreword and slight editorial modifications, according to the Bureau of Indian Standards. IS 15579:2005, unlike its foreign equivalent, may be obligatory (Paddock, 2010).

Future prospects of AI based Healthcare Diagnostics & Possible strategies to address the barriers and issues

When the current community of hospitals, physicians, and laboratories joins forces with AI and digital healthcare networks, this is known as collaboration during healthcare disruption. The most critical factor is data flow, which is currently fragmented. The majority of the platforms listed above are provider-centric rather than patient- or consumer-centric. Although consumer-centric Apps exist, there should be a popular framework that unifies all. A sophisticated healthcare environment with a fitness tracker/wearable and a back-end treatment team that includes a personal mentor, wellness specialist, physicians, and diagnostics is critical. The ecosystem will be designed in such a way that it can carry all of the user's health data to a centralised portal where it can be processed by the care team. The consumer will obtain personalised health recommendations based on their lifestyle and activities using this device. If healthcare services are disrupted in the future, businesses must consider creating an environment that thrives on collaboration. Collaboration is the latest oil that will power healthcare in the future. Rapid advances in medical technology are being seen all over the world, and they are playing an important role in the necessary transition to sustainable care models. To get to the top, more and better cooperation between med-tech companies, doctors, the government, and other stakeholders is needed. Everywhere, strong collaborations are leading the way in defining and understanding the issues that exist, addressing them head-on, exploring new opportunities, and accelerating progress toward a better future. Looking at the big picture, a collaborative ecosystem and mechanism will lead to greater patient effect and improved outcomes, which is what the country needs right now. This will necessitate a metamorphic mentality as well as well-executed pilot projects for validation. At this stage of development, we must all evolve with various contributions from participants in order to build and manage a concrete model that will counteract organizational disruption. This includes significant stakeholders such as hospital service providers, diagnostics firms, regulators, payer groups and investors, and, most importantly, patients. We must keep in mind that the whole network of resources should be focused on the patient. It is always true that different players carry different strengths and contributions to a common forum, and the best example of this is the global genomics research that has now reached India. These types of services are co-funded by private and public agencies, and the data obtained from voluntary patient groups or recipients is used by academic organizations for further studies, as well as pharmaceutical firms for drug development. Other examples include government-sponsored programs such as C-Camp, the Biotechnology Industry Research Assistance Council (BIRAC), the National Health Authority (NHA), and the Ministry of Health (MOH), where government and private funders seed programs that use public infrastructure and resources (such as research agencies and universities) and collaborate closely with private companies to develop new products. Several data analytics firms are collaborating with private and public institutions to use their data to provide clinical intelligence platforms, which can use longitudinal data to develop AI support modules for various therapies and treatments. In the entire healthcare value chain, there are many opportunities for cooperation to face organizational disruption. Collaboration is very much in the offering, which will allow data assimilation and perform health technology assessments and use the data based on treatment results and execute a

centralized bidding process to procure medications to make them accessible and affordable through insurance schemes. India is on the verge of a huge opportunity for both economic growth and change in our people's general well-being. According to all observable indices of economic growth and human development, India's task in the current decade is to diligently build digital highways, or rather skyways, to ensure equal access to technology for all. The people of India will be able to build on top of existing infrastructure and use technology to achieve equitable social development as a result of the advent of new technologies. As a result, AI, specifically Machine Learning (ML), aims to provide a new technological capacity as well as a new exponential roadmap for the country's and society's most pressing challenges. Similarly, our core asset is a large technology-skilled workforce with a wide range of data sources and case studies. ML enables the intelligent combination of these complementary strengths to create large-scale data-driven solutions that are tailored to India's specific needs and desires. The Indian government has been working relentlessly to create a robust AI ecosystem, with the National Strategy for Artificial Intelligence (NITI Aayog) anticipating using it through three interconnected layers: Inclusive Economic Growth that positions India as a top destination for developing world-class technology solutions. India's AI moment has arrived, and a wide range of AI-based applications are now being created, moving the frontier further into uncharted business and social realms. Indian policymakers are considering and charting its potential for growth and social change.

Levels	**Advantages of Collaboration for Healthcare Organizations to impact positively in value chain**
Patients	Personal Health Data will be available with Patients also the decision making power to access healthcare or procure any services of the same and be in control of their health
Professional	There will be first-hand access of patient data and right treatment modality from authorities to Healthcare Professionals (HCPs), also they should be able to convince patients and caregivers to adhere to treatment modality to ensure better treatment outcomes
Health Authorities	Provide support in complete health technology assessment of drugs, diagnostics and treatments to make decision about the prime necessity of India and also provide access to the proper requirements with Industry partners through centralized procurement system at Govt. level and periodical review with robust and continued data.
Healthcare Organizations	Organizations can make a rightful use of the AI platforms to promote timely error free diagnostics, treatment modules and enhanced treatment outcomes of a specific therapeutic area and use of data in collaboration with partners to assess their strategy in terms of access to innovation in the country

The way forward

AI-powered healthcare applications are accompanied by certain challenges – they require a collaborative and effective framework from government and public organizations with laws to govern privacy and data integrity. Our country is currently in a unique role, establishing itself as a key player in the AI and healthcare sectors for both domestic and foreign companies. With a vast amount of health data and a burgeoning startup ecosystem, India has opened a Pandora's box for using AI to solve a variety of health-care issues. Our government has taken a range of steps to use and successfully accelerate the adoption of AI across industries in its race to become a world superpower or in its search for India to be at the forefront of the AI revolution. However, a lack of regulatory clarification on issues of data, architecture, and qualification, as well as a lack of resilient and ethical data collection and processing systems, continue to obstruct widespread adoption and implementation. Some of the measures that are needed include a robust open data policy, comprehensive privacy legislation, increased investment in AI research and development, robust national infrastructure, equipping labour forces with the necessary skills to adopt AI and be prepared for the changes that AI may bring, and a regulatory framework that ensures transparency and accountability while not hindering innovation.

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