Artificial Intelligence for Healthcare in India: Policy Initiatives, Challenges, and Recommendations

Sheshadri Chatterjee, Indian Institute of Technology, Kharagpur, India

https://orcid.org/0000-0003-1075-5549

Michael S. Dohan, Lakehead University, Orillia, Canada

ABSTRACT

The purpose of the paper is to provide an overview of the issues related to artificial intelligence (AI) applications in the Indian healthcare sector and provide input to policymakers. A qualitative approach has been used in this study to identify government initiatives, opportunities, and challenges for applications of AI and suggest improvements in policy areas relevant to AI in healthcare. The study helps by providing comprehensive inputs for framing policy on AI in healthcare industry in India. The study also highlights that if the proper actions are taken to overcome the various challenges associated with applications of AI in healthcare sector in India by the government, then the healthcare sector will immensely benefit. This article has taken an attempt to provide inputs concerning to policy initiatives, challenges, and recommendations for improving the healthcare system of India using different applications of AI.

KEYWORDS

AI, Challenges, E-Health, Health Records, Healthcare, India, Information Technology Act, Policy, Recommendations

1. INTRODUCTION

These technologies are helping machines to comprehend, sense, learn and act so that they can smoothly perform clinical healthcare functions and administrative functions. AI is divided into three general categories: descriptive, predictive, and prescriptive (Hassanpour, 2016). Descriptive AI helps to gain insight into historical events. Predictive AI is associated with predicting events. Prescriptive AI has the ability to inform decisions, for instance on possible treatments, which is controversial as well as interesting (Mathur, 2017). Whereas traditional technology can complements human-centric skills, AI technology can help to effectively expand human healthcare activities. These include computer vision, natural language processing, voice-recognition and chatbots and so on (Ericson, 2017).

The number of applications of Artificial Intelligence (AI) in the Indian healthcare sector is rapidly increasing. It addresses both the lack of skilled doctors (Economic Times, 2018) among a multitude of ways within healthcare (Saha, 2018). It can be used to address data quality issues with Electronic Health Records (EHR) data, so it then may be used in applications such as predictive modelling in preventative health programs or predictive therapy (Eubanks, 2017; Khumalo et al., 2019; Alnsour et al., 2019). It is encouraging to note that the AI technology is found to have contributed effective supports to the Indian healthcare system. But as already stated, utilization of AI technology in the

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Indian healthcare system must be made in a systematic and methodical way. However, the planning for such applications of AI technology in the healthcare industry in India is found to be in a rudimentary stage. A comprehensive and implementable healthcare policy in the context of use of AI technology addressing all entangled challenges is needed to be articulated which has yet not been done (Kar et al., 2018; Chatterjee et al., 2019, 2020a). To fill this gap, this study seeks to provide inputs towards framing AI-healthcare policy for India. It has taken a holistic attempt to provide some laudable inputs to the policy makers mentioning the challenges and executable recommendations those are expected to be helpful while drafting the AI in healthcare policy in India.

2. AI AND HEALTHCARE INDUSTRY IN INDIA

The opportunities for AI in the Indian healthcare sector are encouraging, and predict that by the year 2035, AI would be able to add USD 957 billion to the economy of India (Accenture, 2017). As well, the Government of India (GOI) in incentivising for the growth of AI in the healthcare sector. State Governments are also helping the start-ups by funding, for example, government of Karnataka (a State of India) has taken an initiative to mobilise INR 2000 crore (~ 300 million USD) by the year 2020 to support healthcare industries for taking help of AI. A comprehensive start-up policy for AI has been already adopted by the government of Karnataka (Pitchiah, 2017), and the integration of AI with Healthcare Sector in India has brought in considerable improvement in this sector. It has provided effective contribution towards quality, cost, efficiency and so on. Different stakeholders of India are sincerely promoting AI-integrated healthcare initiatives, such as FICCI and even the Prime Minister's Office (Rao, 2017). It has been noted that AI-integrated healthcare initiatives in India mainly cover medical services to the rural area especially to the underserved population. This technology serves the economically weaker sections of India who are not able to afford costly medical facilities. It serves to those who are deprived of enjoying necessary medical infrastructure.

AI also benefits the healthcare industry by reducing economic disparity (Roy, 2017). A report of TCS global survey (TCS, 2017) highlights that although AI would reduce jobs, there will be possibility of creation of new jobs due to entry of new AI integrated healthcare projects in those companies. Another survey by Accenture (Accenture, 2017) highlighted that the application of AI in the healthcare system would lead to savings of USD 150 billion in US and a growth in the sector by USD 6.6 billion by 2021 in US.

It is noted that India suffers from the availability of skilled workers, including physicians and other healthcare roles. AI applied to the healthcare system would help alleviate the lack of skills, as it could be possible for less skilled workers to make more accurate decisions. This will considerably help the Indian healthcare sector. In some cases of ordinary health issues, AI will be able to diagnose. For complicated cases involving health issues where AI will feel less confidence in the decision, the help of expert doctors may be utilized. This mechanism will reduce cost in treatment in India (Vignesh, 2017). In this way, by the help of AI technology, many hospitals in India (Fortis Healthcare, Apollo Hospital, LV Prasad Eye Care, Aravind Eye Care System and so on) are engaged in diagnosis of many diseases with the help of the AI platforms of Microsoft, Google, IBM and so on. This is being done with less cost. In this way, AI technology is being used in healthcare industries not only in hospitals but also in pharmaceuticals, diagnostic centres and so on.

3. AI AND GOVERNMENT INITIATIVES IN INDIA

It has been observed that GOI has taken different effective initiatives to boost up technological innovation in different sectors. It has been translated into action by the GOI through some initiatives under different forums. These initiatives have helped to develop the applications of AI-enabled technologies in the different sectors. We are interested here to discuss Government initiatives

concerning to develop AI integrated healthcare system in India. GOI in this context has set up different authorities, task force, policy group and so on. These are being discussed here in brief.

3.1 National e-Health Authority

The National e-Health Authority (NeHA) authority has been set up by the Ministry of Health and Family Welfare, GOI in 2015. It is primarily responsible for developing integrated healthcare information system (IS) in India. NeHA will also guide all stakeholders how to efficiently apply different innovative technologies in the healthcare industry, including applications of AI. In doing so, this authority is supposed to receive the assistance of different stakeholders. This authority is also responsible to enforce and execute regulations and laws for maintenance of health records of the patients in the context of security and privacy issues (Chatterjee, 2015; Chaudhuri et al., 2020b; Sreenivasulu et al., 2019; Bhattacharya et al., 2020). This authority is scheduled to act as a promoter and developer of standards. It will work for appropriate realization of effective use of Information and Communication Technologies (ICTs) to improve the overall healthcare system in the journey of e-Heath for India. The initiative of this authority is to formulate a National e-Health Policy and Strategy, which would facilitate e-Health adoption, including AI-based applications in the Indian healthcare system in different sectors.

A draft legislation called the Health Data Privacy and Security Act of 2016 has been prepared by GOI in consultation with National Law School of India University in Bengaluru. This will guide how to maintain and preserve privacy, confidentiality, ownership of different health data. The draft legislation has been submitted to the Ministry of Health and Family Welfare, GOI in July 2016. The collected data will be anonymised and then will be used for Big Data analytics, but there is a chance of re-identification of the anonymised data particularly where the technique of anonymisation of data is not strong and robust (Paul, 2009). The responsibility of NeHA is to address this issue, especially in the context of analysis of data by AI.

3.2 Al Task Force

This task force has been established by the GOI under the Ministry of Commerce and Industry in the year 2017. This task force has the responsibility to explore the possibilities of appropriate applications of AI in different sectors for stimulating growth. This task force is reported to have submitted recommendations to the GOI for use of AI in industries, in research institutes and in different other fields. This task force has been formed with the help of experts from industries, from research institutes, from representative of GOI (NITI Aayog, Ministry of Electronics and Information Technology). GOI is expected to incorporate inputs available from this report. Niti Aayog is a think tank of GOI under the same ministry.

3.3 Policy Group on Al

A policy group has been formed under the Ministry of Electronics and Information Technology. It consists of representatives from academia as well as from NASSCOM. This policy group is responsible for providing an effective and implementable road map for AI adoption in different sectors. This committee is also to focus on the aspects of protection of security and privacy as well for skill development (PTI, 2017) in the context of applications of AI in different fields.

3.4 Centre of Excellence (CoE) for Data Science (DS) and AI (CoE-DS&AI)

With the help of NASSCOM, the Karnataka (a State of India) Government has set up a Centre of Excellence for Data Science and AI under a public private partnership (PPP) model with an investments of INR 40 crore (NASSCOM, 2017). The purpose of this centre is to take appropriate initiative to accelerate the ecosystem in the State of Karnataka to develop AI and Data Science throughout India. This centre would work for enhancing the applications of AI in different sectors. It will also help the educational institutes by providing skill development in the field of data science and AI.

Figure 1. Initiative



3.5 National Intellectual Property Right Policy (NIPR Policy)

The Department of Industrial Policy and Promotion, GOI introduced a theme for creation of awareness regarding the necessity of Intellectual Property Right (IPR) in the context of considering it as a marketable financial asset. In the perspective of AI applications, the concept of IP regime is due to have assumed a new shape, especially, in the context of borderless applications of AI inviting jurisdictional problems and in the context of seeking and remedying infringements on IP rights by AI applications. This is because that AI does not possess any personhood. In this background, the NIPR policy emphasizes on strengthening mechanism for addressing IPR infringements. It has also recognized the contribution of innovative technologies (like AI) in different sectors apart from healthcare sectors.

3.6 US-India Science & Technology Endowment Fund (USISTEF)

The Government of USA and India have established USISTEF. Its purpose is to incentivise innovative activities with the help of science and technology. A grant of up to INR 25 million will be awarded to the enterprises or innovators for an innovative product that has considerable societal impacts. Priority would be given towards the innovative products concerning to healthcare sectors. Beside all these initiatives for promotion of the technologies including AI technology, GOI has taken these initiatives to boost up such innovative applications in different sectors for overall growth. These are initiatives with CSR initiatives, Biotechnology Ignition Grant (BIG) Scheme and so on.

4. ETHICAL, LEGAL AND CULTURAL ISSUES

It is a fact that AI possesses immense potential to develop healthcare systems in India. However, it should be the duty of the policy makers, designers, developers and others to attach importance on ethical, legal, and cultural factors at the time of using, regulating or designing AI (Zamin-Malik, 2017). The ethical, legal and cultural aspects of AI concerning to healthcare system in India include many issues. Some of these issues are discussed here.

4.1 Cultural Acceptance

This issue often creates impediment in the use of AI, especially, in the issue of "Trust". Multifarious norms of culture are required to be accounted. Any task carried out by AI-integrated machines should be culture-specific to ensure acceptance (Simonite, 2017). Start-ups would feel problem to acquire funds by a negative news that AI would pose a threat to job security. Hence, there must be cultural acceptance.

4.2 Data Privacy/Safety

The AI solution for healthcare may be exploited by hackers. The healthcare system may collect highly sensitive and private information like protected health information (PHI). Machine learning algorithms may be misused, which will jeopardise security and privacy of data. This demands formulation of

robust and implementable legal structure to keep this in check (Chatterjee et al., 2019a, 2019b; Ghosh et al., 2019; Chaudhuri et al., 2020a). IEEE has globally formulated an ethically structured design initiative for protection of data. Ministry of Health and Family Welfares, GOI is trying to formulate consistent regulations to address the situation.

4.3 Acceptable Behaviour

There is a need to clearly define 'Acceptable Behaviour' in the context of AI system. This should be done in a specific application domain. There must be maintenance of normative discipline in the issues concerned with relationship among the doctors, patients, as well as AI applications so far as AI usage in healthcare industry is concerned. Medical Council of India (MCI) code has explained doctor-patient relationship towards confidentiality (Code of Ethics Regulations, 2002). Other regulations are there like Mental Healthcare Act, 2017; Medical Termination of Pregnancy Act, 1997 and EHR Standards, 2016. These regulations define the issue of "Acceptance Behaviour" in different contexts.

4.4 Scope of explanation

There might be error in the AI algorithms. This would lead to inaccurate outcomes by the AI tools. Therefore, AI systems are required to be explainable. Application of AI should be understandable. As per MCI regulations, for the patient's benefit, medical consultation takes place. Physicians are required to be frank with the patients. Regarding the ability to explain, some factors are to be considered. Range of factors based on which AI has taken the decision. What are the expected outcomes and what are the priorities? The logic taken by AI should be in keeping with the best practices.

4.5 Fixation of Liability

In case of wrong treatment by doctor with the help of AI technology, the question of liability must be answered. Since software is not technologically agnostic, some believe that the concerned developer is liable along with the doctor (Mohandas, 2017). In India, initially doctors are held liable under criminal and civil law (Murthy, 2007). Regarding fixation of liability, Indian Medical Jurisprudence is not known to be robust. GOI is known to have emphasized this issue.

4.6 Consent

Informed consent is considered as an ethical requirement towards medical treatment. It is concerned with personal privacy and professional confidentiality. As doctor-patient relationships are concerned, it is difficult for the patients to express unwillingness to give consent in terms of the doctor's will. Physicians are placed with high authority and the patient is to trust the doctor in the context of medical treatment. In India, especially, due to illiteracy and poverty, the patient is to accept any treatment having no other choice under this premise. Hence, there are number of dynamics in the context of doctor-patient relationship so far as the issue of consent is concerned. GOI is focusing on this issue to devise an acceptable and laudable solution by reconciling the medical jurisprudence.

4.7 Algorithmic Accountability

The AI algorithm needs to be accurate. It will help for highly effective applications of AI in several sectors. To address this possibility of inaccurate AI algorithms, India has suggested an accountability model. It includes that the algorithm will be audited before it is applied (Matthan, 2017). This accountability framework might address the system. Apart from those discussed above, there are other ethical, legal and cultural issues that need attention of the authority to harness maximum potentials from AI applications in different Indian Healthcare Sectors.

5. POLICY AND REGULATORY LANDSCAPE

GOI has taken a sincere attempt to frame policy in the area of use of AI by the Healthcare industries of India. To develop the policy, initially the regulatory framework is required to be improved. Some of the laws, policy issues and standards are being discussed here in brief.

5.1 IT Act 2000 and its Rules of 2011

The development of AI integrated healthcare system, especially in the context of doctor-patient relationships, demands continuous exchange of information between doctor and patient as well as between patient and service provider. Information of patient contains patient's personal information like information containing psychological condition as well as medical history. These are considered as Sensitive Personal Data or Information (SPDI). The Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011 contain some provisions which allow a body corporate to collect, store or transfer such SPDI. However in this context, consent is considered as a mandatory requirement for such use of SPDI as per the rules. In the context of doctor-patient relationship, written consent is to be obtained from the patient for using the patient's data. The patient is required to be informed the possible reasons for collection of such data. The rules envisage that appropriate security practices and procedures are to be maintained for keeping the SPDI secure. The standard procedure for security SPDI is ISO 27001. To ensure security of SPDI, congenial rules have been duly framed. However, the security of SPDI is found to be frequently not maintained for want of appropriate enforcement of the existing rules with good governance. In this context, it is to note that the Supreme Court of India emphasized the need of framing a comprehensive and meaningful technology-neutral data protection framework. The Supreme Court of India has mentioned this in a judgement (full bench) where it has been declared privacy is a fundamental right under the constitution of India (Puttaswamy, 2012). As a result, a draft Data Protection Bill, 2018 has already been placed in the Parliament of India.

5.2 MCI Act, 1956 and MCI Code, 2002

The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 is called MCI Code, 2002. This code has enjoined the ethical and professional standards concerning to interaction between doctor and patient. This contains norms for keeping patient's confidentiality and disclosure of the prognosis of the ailment. This rule also specifies that such patient's information is required to be computerised as medical record. This will help to retrieve it quickly. All these practices are now being monitored by 'Medical Council of India' (MCI). This is being replaced by 'National Medical Commission'. Some changes in the regulatory practices are expected when it will be in force.

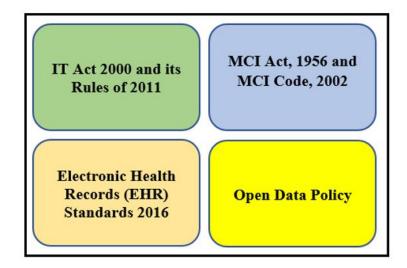
5.3 Open Data Policy

The National Data Sharing and Accessibility Policy (NDSAP) has been provided by the Ministry of Science and Technology, GOI. It is being executed by the Ministry of Electronics and Information Technology in the shape of Open Data Platform. Non sensitive data is generated with the help of government fund. This is open data. It may be shared openly. More data needed to be open to enhance AI potential in healthcare. As such, government should incentivise providers (private healthcare providers) to provide more anonymised data in the open data platform. There are other regulatory policies of the government like application of provisions of Medical Devices Rules, 2017; Standardization of International Standard like ISO 13485, 2016 and so on.

5.4 Electronic Health Records (EHR) Standards 2016

A massive amount of data is collected from the patients. These are considered as health data. EHR standard 2016 takes an attempt to regulate privacy standard and data ownership. GOI has emphasized on the need of standardization of such data. Accordingly, GOI has envisaged standards concerning

Figure 2. Policy



to information capture, retrieval, storage, analytics and exchange. It includes clinical code, images and data.

- **Data Ownership:** Patient's data is stored by the providers. Its owner is the customer without any time restriction. Patients will be able to view these records.
- **Data Access:** Patients will control as to who can access data. Patients will give consent. Patients can correct any record.
- Health-Information Disclosure: Data can easily be shared without permission after removing any personal identification.
- Access to records by Court/Government Authorities: With the order of the Court, the data
 may be accessed. Besides, for communicable diseases, health information can be disclosed with
 Government's permission.
- **Encryption of Data:** This electronic record of health must be encrypted. Transmission standard is to be strictly followed when transferring such data.
- Responsibility: Healthcare providers have the responsibility to store data ensuring its protection
 of security and privacy. It is the responsibility of the provider to keep the patient apprised about
 his/her rights. Also, the patients are to be informed what measures have been taken by the provider
 to secure the data.
- **Identification:** The identification of the patient will be accepted by the Aadhaar number. If it is not there, two other government ID Cards will suffice.

6. CHALLENGES AND RECOMMENDATIONS

6.1 Challenges

Access of data causes great challenge. This presents problems for start-ups in particular. To obtain consent, it sometimes causes problems. Quality of data is inconsistent. Want of formal regulatory region towards anonymisation of data causes another problem. India does not possess open data sets for medical data.

Want of standard guidelines towards designing of AI system causes problems. Clear design standard would address the security and privacy issues. It would also solve the question of trust and of ethics. A weak IP regime in India is another problem. The IP regime is to be revitalised in the light of AI adoption. This would ameliorate the situation. Besides, lack of robust regulatory authority, want of appropriate certification architecture, paucity of availability of robust AI infrastructure, inadequate ethical awareness of the stakeholders, inadequate investment from government side in R&D issues of AI, lack of overall awareness of the stakeholder also causes impediment. There are other causes to interrupt the growth of AI in healthcare system in India.

6.2 Recommendations

While articulating policy for India towards applications of AI in healthcare sector, human-machine interaction mechanisms are to be developed with a focus on security and privacy issues towards preservation of personal health data. Research activities are needed to be developed focusing attention on legal, ethical, cultural, and social issues so that they do not stand on the way towards execution of the concerned policy. The policy should tactfully address all the challenges to be faced while implementing it for which focus must be there to involve all the stakeholders towards AI usage in healthcare sector. PPP model must be introduced, especially, to manage the rural primary healthcare facilities with the support of AI. The quality of the training programs is to be improved towards AI usage in healthcare sector to make all the stakeholders savvy with AI technology. In brief, the following issues needs special attention while articulating the policy towards applications of AI in Indian healthcare sector. They are as follows:

- Human-machine interaction mechanism is to be developed in the healthcare sectors.
- Safety and security of AI system is to be ensured, especially, in the context of preservation of health-data of patients.
- Works of R & D in the field of AI application in healthcare sectors is to be improved.
- To realise and to combat ethical, legal, cultural and societal implications of AI in the healthcare sectors.
- Evaluating and measuring AI technologies with reference to standards. Besides, for ameliorating the application capabilities of AI in healthcare industries of India, the provisions must be there in the policy statement to nurture the challenges as already mentioned.
- In addition to all these, other issues are to be kept in mind while formulating the AI-integrated healthcare policy for India.
- Scope to be developed for participation of all the stakeholder in the field of healthcare industries of India to share inputs towards involvement of AI usage in the multifarious healthcare sectors (experience exchange program).
- By encouraging the open data system under strict regulatory restrictions in terms of privacy, safety and interoperability, scope to be developed for access to data to improve and widen the use of AI in healthcare system.
- Encouraging for development of R&D works in Medical Colleges of India by extending facilities
 to exchange of knowledge between academic establishments across India (R&D works and
 knowledge exchange program).
- PPP model is to be introduced to improve the primary health facilities, especially, in rural India with AI technology.
- Skill development activities are to be improved for making the doctors savvy with AI technology and to make them aware regarding ethical issues needed in their practices.
- Setting up dedicated legal framework for establishing balance between security and privacy issues
 of dealing with health data by AI technology and issue of development by the AI integration
 with Indian healthcare system.

• Designing appropriate standards and improving system of appropriate certification in Indian healthcare system driven by AI.

For framing AI-integrated healthcare policy in India, it is expected that these inputs will help the authority effectively to cover all the points.

6.3 Implications of the Study

This study is claimed to have effectively highlighted the prospect of AI applications in Indian healthcare industry. This study has provided different important inputs towards the different policy initiatives in the context of applications of AI in healthcare industry in India. This study has mentioned some practical entangled challenges the healthcare industry might have to face while applying AI in healthcare sector. It is expected that the policy makers or government authority or the concerned industry players might have obtained much food for reflection from the expected challenges while framing the AI related healthcare policy for India. However, this study has provided a charter of recommendations for articulating AI related healthcare policy for India focussing on the roadmap how to address those challenges. This will also provide some effective dividends to the authority for framing the concerned policy. Some of the theoretical recommendations provided in this study may not be feasible to be executed towards developing the policy. This may be construed to be a limitation of this study. This study may be considered as a baseline for the future researchers to provide inputs to them for finetuning their recommendations. This study is deemed to be helpful for framing the policy on applications of AI in healthcare sector for other emerging economies.

7. CONCLUSION

Indian healthcare industry is enjoying wide range of applications by AI technology. AI is not replacing human labour thoroughly, but it is helping to augment human capacity. Despite of several advantages enjoyed by the healthcare system with the grace of AI, it is still facing some challenges as already mentioned. For harnessing full potential of AI in the Indian healthcare system, its applications should be implemented in a planned way. Appropriate framework of law to address security and privacy issues is to be available. Besides, the present situation towards use of AI in healthcare industries is considered favourable since Indian and International companies are coming forward to utilise AI in the Indian healthcare space effectively. A proper policy for AI-integrated healthcare system in India is to be formulated by framing appropriate regulatory frameworks that would ensure accountability and transparency, but it should not hinder AI innovation. If a balance can be established between innovative abilities of AI and regulations to control misuse of AI, it is expected that India might enjoy a developed as well as flourishing healthcare ecosystem embedded with AI. In this conjecture, this study has provided a roadmap helpful for the authorities to frame a comprehensive and implementable policy towards applications of AI in healthcare sector. For this, this study has effectively provided some substantial recommendations mentioning some apprehended challenges. It is expected that these inputs will help the authorities to frame the policy on AI applications in Indian healthcare sector.

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Sheshadri Chatterjee, PhD., has completed PhD from Indian Institute of Technology Delhi, India. He is having work experience in different multinational organizations such as Microsoft Corporation, Hewlett Packard Company, IBM and so on. Sheshadri has published research articles in several reputed journals such as Government Information Quarterly, Information Technology & People, Journal of Digital Policy, Regulation and Governance and so on. Sheshadri is also a certified project management professional, PMP from Project Management Institute (PMI), USA and completed PRINCE2, OGC, UK and ITIL v3 UK.

Michael S. Dohan is an Assistant Professor in Information Systems at the Faculty of Business Administration at Lakehead University. He graduated with his PhD in Business Administration from the DeGroote School of Business at McMaster University. His academic work has been published in top-tier journals and conference proceedings, including Communications of the Association of Information Systems, America's Conference on Information Systems, the Hawaiian International Conference on Systems Sciences, and the Administrative Sciences Association of Canada conference.