

Panel Discussion 2: Regulatory aspects of AI for health

Dr R.S. Sharma, ICMR

Artificial Intelligence

Artificial intelligence ("AI") is broadly defined as the use of advanced computer science to develop machines that can learn, reason, communicate, and make human-like decisions. It is the ability for computer algorithms to approximate conclusions without direct human input.

- **AI is a new market place reality.**
- **Increase in computing power, improved algorithms and the availability of massive amount of data are transforming the society.**
- **According to the International Data Corporation (IDC), the AI market is expected to hit \$ 35.8 billion in 2019, which represent an increase of 44% since 2018.**
- **IDC has also projected global spending on AI to double by 2022 reaching \$ 79.2 billion.**

Ministry of Commerce and Industry, Govt. of India



Established

A Task Force on AI to leverage AI for economic benefits, and provide policy recommendations on the deployment of AI for India.

- **Report was released on 21st March 2018**

The Reports attempt to answer following three Policy Questions

- 1. What are the area where Govt. should play a role**
- 2. How can AI improve the quality of life and solve the problem of the Indian Citizen.**
- 3. What are the sectors that can generate employment and growth by use of AI**

Sectors identified as domains of relevance to India

Task Force

1. Manufacturing
2. Fin Tech
3. Agriculture
4. Healthcare
5. Technology for the differently –
abled
6. National Security
7. Environment
8. Public Utility Services
9. Retail and Customer Relationship
10. Education

NITI Aayog

1. Healthcare
2. Agriculture
3. Education
4. Smart cities and
Infrastructure
5. Smart Mobility and
Transportation

AI In Health Care

AI has already arrived in Healthcare

1. Managing Medical Records and Other Data

Since the first step in health care is compiling and analyzing information (like medical records and other past history), data management is the most widely used application of artificial intelligence and digital automation. Robots collect, store, re-format, and trace data to provide faster, more consistent access.

2. Doing Repetitive Jobs

Analyzing tests, X-Rays, CT scans, data entry, and other mundane tasks can all be done faster and more accurately by robots. Cardiology and radiology are two disciplines where the amount of data to analyze can be overwhelming and time consuming. Cardiologists and radiologists in the future should only look at the most complicated cases where human supervision is useful.

3. Treatment Design

Artificial intelligence systems have been created to analyze data – notes and reports from a patient’s file, external research, and clinical expertise – to help select the correct, individually customized treatment path.

4. Digital Consultation

Apps like [Babylon in the UK use AI to give medical consultation](#) based on personal medical history and common medical knowledge. Users report their symptoms into the app, which uses speech recognition to compare against a database of illnesses. Babylon then offers a recommended action, taking into account the user’s medical history.

5. Virtual Nurses

The startup [Sense.ly has developed Molly](#), a digital nurse to help people monitor patient’s condition and follow up with treatments, between doctor visits. The program uses machine learning to support patients, specializing in chronic illnesses.

In 2016, [Boston Children’s Hospital developed an app for Amazon Alexa](#) that gives basic health information and advice for parents of ill children. The app answers asked questions about medications and whether symptoms require a doctor visit.

6. Medication Management

The National Institutes of Health have created the [AiCure app](#) to monitor the use of medication by a patient. A smartphone's webcam is partnered with AI to autonomously confirm that patients are taking their prescriptions and helps them manage their condition. Most common users could be people with serious medical conditions, patients who tend to go against doctor advice, and participants in clinical trials.

7. Drug Creation

Developing pharmaceuticals through clinical trials can take more than a decade and cost billions of dollars. Making this process faster and cheaper could change the world. Amidst the recent Ebola virus scare, [a program powered by AI](#) was used to scan existing medicines that could be redesigned to fight the disease.

The program found two medications that may reduce Ebola infectivity in one day, when analysis of this type generally takes months or years – a difference that could mean saving thousands of lives.

8. Precision Medicine

Genetics and genomics look for mutations and links to disease from the information in DNA. With the help of AI, body scans can spot cancer and vascular diseases early and predict the health issues people might face based on their genetics.

9. Health Monitoring

Wearable health trackers – like those from FitBit, Apple, Garmin and others – monitors heart rate and activity levels. They can send alerts to the user to get more exercise and can share this information to doctors (and AI systems) for additional data points on the needs and habits of patients.

10. Healthcare System Analysis

In the Netherlands, 97% of healthcare invoices are digital. [A Dutch company](#) uses AI to sift through the data to highlight mistakes in treatments, workflow inefficiencies, and helps area healthcare systems avoid unnecessary patient hospitalizations.

These are just a sample of the solutions AI is offering the healthcare industry. As innovation pushes the capabilities of automation and digital workforces, from providers like Novatio, more solutions to save time, lower costs, and increase accuracy will be possible.

The fear is  that

AI in an unregulated environment will lead to a loss of human supervisory control and unfortunate outcomes.



Hence

There is a need to develop regulation for AI in Healthcare

1. What are the key considerations for AI policy making in India

Democratize AI technologies and data: Clean, accurate, and appropriately curated data is essential for training algorithms. Importantly, large quantities of data alone do not translate into better results. Accuracy and curation of data should be as important as quantity of data.

Re-thinking Intellectual Property Regimes: Going forward it will be important for the government to develop an intellectual property framework that encourages innovation. AI systems are trained by reading, viewing, and listening to copies of human-created works. These resources such as books, articles, photographs, films, videos, and audio recordings are all key subjects of copyright protection. Copyright law grants exclusive rights to copyright owners, including the right to reproduce their works in copies, and one who violates one of those exclusive rights “is an infringer of copyright.

AI Data Storage:

Capacity needs to increase as the volume of data that needs to be processed in India increases. The data storage should also be made secure from hacking

AI Networking Infrastructure

Organizations will need to upgrade their networks in a bid to upgrade and optimize efficiencies of scale. Scalability must be undertaken on a high priority which will require a high-bandwidth, low latency and creative architecture, which requires appropriate last mile data curation enforcement.

2. What are the key points to be considered for AI regulation?

Transparency: Algorithms will need to be constructed so an engineer/computer scientist can evaluate that the algorithm is doing what it purports to do, and this needs to be rendered in a clinically interpretable fashion for clinical pathologies...to the extent possible but not as a rule.

Accountability or Liability: It ensures that the benefits and harms are distributed among stakeholders. This is because AI is considered to be inanimate, and therefore a strict liability scheme that holds the producer or manufacturer of the product liable for harm.

Fairness: Benefits of the AI based tool should also reach the data source on which the AI was trained

3. What are the guidelines to be maintained for algorithm design for AI in Healthcare?

- (1) **Advisory**: Algorithms must retain an advisory capacity that augments existing human capability rather than replacing human discretion outright;
- (2) **Lawful**: Algorithm's proposed function, application, individual effect and use of datasets should be considered in symbiosis with necessity, proportionality and data minimisation principles;
- (3) **Granularity**: Data analysis issues such as meaning of data, challenges stemming from disparate tracts of data, omitted data and inferences should be key points in the implementation process;
- (4) **Data Ownership**: Due regard should be given to intellectual property ownership but in the case of algorithms used for governance, it may be better to have open source algorithms at the default. Regardless of the sector, the developer must ensure that the algorithm works in a manner that enables a third party to investigate the workings of the algorithm in an adversarial judicial context.
- (5) **Challengeable**: The results of algorithmic analysis should be applied with regard to professional codes and regulations and be challengeable. In a report evaluating the NITI AAYOG Discussion Paper, CIS has argued that AI that is used for governance, must be made auditable in the public domain, if not under Free and Open Source Software (FOSS)-particularly in the case of AI that has implications for fundamental rights.
- (6) **Accuracy**: The design of the algorithm should be checked for accuracy, properly validated clinically before public use
- (7) **Responsible**: Should consider a wider set of ethical and moral principles and the foundations of human rights as a guarantor of human dignity at all levels and
- (8) **Explainable**: Machine Learning should be interpretable and accountable.

4. Should regulation of products be based upon the process for development, such as minimum dataset standards and clinician involvement, or on the quality of the output?

Ans. Regulators need to focus on two broad issues in tandem – is the process correct and is the content correct? Both aspects will bring fresh challenges as AI, by its very nature, is dynamic. Additional aspects are the dissemination of the results and manner of housing the data.

5. Artificial intelligence will need high quality labelled data from electronic health records. Is it clinicians' responsibility to make sure all data is recorded in a standardized machine-readable way?

Ans. it is programmers responsibility to handle the data and standardize it, train a machine with the data collected by clinician as per their finer knowledge of their patients.

6. Algorithms using neural networks have been developed for the detection of melanoma, using publicly available images of melanoma, which is more prevalent in white skin. The technology is therefore more effective at detecting melanoma in white skin than black. However, even though melanoma is rarer in individuals with black skin, those with black skin have higher rates of mortality. This is not only due to the type of melanoma, but also because of poor detection rates and identification by physicians. Will this type of technology therefore promote bias and unfairness?

Ans. Machine learning is data dependent, so this can be one of its drawbacks.

7. On whom will the accountability and liability would be affixed in case of AI -related breach?

Ans: Generally on the algorithm developer or the companies providing the service. But depending on the nature of the process, other stakeholders can also become answerable.

8. Can the developers of AI seek protection of their work against copyright infringement?

Ans: Unless a creator had an extensive role in the AI machine's work, they can't seek copyright protection in the work.

9. Are the laws and their implementation sophisticated enough to ensure adequate comfort to consumers where AI is involved?

Ans: While data privacy laws provide protection against misuse of data, these laws and their implementation may not be sophisticated *enough to ensure adequate comfort to consumers where AI is involved.*

10. Should AI be notified as a medical device in the future?

Ans: Yes. The softwares that are currently using AI, like FitBits and smartwatches, can analyse data to alert users and their healthcare professionals on potential health issues and risks.

Hospitals and healthcare professionals are seeing the benefits in using AI in technology and storing patient's data on private clouds, like the Google Cloud Platform. AI allows doctors and patients to more easily access health records and assess patient's health data that is recorded over a period of time via AI-infused technology.

11. What type Govt. intervention is required to stop miss use of AI in Healthcare

Ans. Appropriate certification for AI driven health system and technology needs to be created by the govt.

Because for data collection and its management, there is a need to have widespread expertise – which will also contribute in research, innovation and responses.

12. As we know that Health is a State subject and deployment of AI in State will be a great challenge. How to increase the trust of the people in AI in Healthcare?

Ans. (1) Allied subject on the Co-ordination and determination of standards in institutions for higher education or research and scientific and technical institutions falls under the Union-list.

(2) Enacting a data protection law for our Country so that making algorithms that are used by public bodies etc. should have minimum standards and creating positive social attitude will play a driving force behind optimal proliferations of the AI.

13. The WHO has classified the radiation emitted from Cell Phone and Cell Phone Tower as 2B Carcinogen i.e. Possibly carcinogenic to humans (302) or agents for which there is limited evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals. Debates are going on to categorized these radiation as 2A Carcinogen, i.e. Probably carcinogenic to humans (82). Under present situation how we will be able to protect the AI users from any adverse health effects from such type of radiation?

Ans.

Thanks