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| **Abstract:** | Driven by growth of big data and the machine learning techniques, Artificial intelligence (AI) is rapidly moving to change the healthcare system. Tools based on AI are being developed to improve the process of diagnosis, clinical care, to advance medical research, and to improve efficiency. These tools rely on algorithms, programs created from healthcare data that can make predictions or recommendations. Big data enables AI algorithms to uncover more fine-grained patterns and make more timely and accurate predictions than ever before. However, these developments are posing new challenges that require new regulatory frameworks to be put in place. |

# Introduction

Medical Science, like many other fields, is experiencing a confluence of two recent developments: the rise of big data, and the growth of sophisticated machine learning (ML)/artificial intelligence (AI) techniques that can be used to find complex patterns in big data. Big data has been ascribed a number of definitions and characteristics. The most popular definition of big data was put forth in a report by Meta (now Gartner)[[1]](#footnote-1) in 2001, which looks at it in terms of the three 3V’s—***volume, velocity and variety***. Besides 3V’s- *volume, velocity and variety*, other defining characteristics of big data articulated by different commentators are— *veracity[[2]](#footnote-2), value[[3]](#footnote-3), complexity[[4]](#footnote-4)* and *variability[[5]](#footnote-5)*. Big data is thus not just a collection of data but also a term encompassing the use of techniques to capture, process, analyse and visualize huge chunk of data in a reasonable time frame. It therefore, decodes the untouched data to derive new insight by analysts, researchers and business people thereby facilitating breakthroughs in many fields.

In medicine, the data can come from many sources: electronic health records, test reports following use of different diagnostic tools, medical literature, clinical trials, insurance claims data, pharmacy records, information entered by patients into their smartphones for tracking their health and fitness levels etc.

The increase in ML/AI is driven by simultaneous evolution of computational power and statistical methods to handle exponential collation and manipulation of data. Whenever an algorithm transforms itself into new actionable intelligence based on data, machine learning takes place.

# Discussion

So far as medical data is concerned, algorithms can make predictions based on data on —how long is a patient expected to live given his collection of symptoms, and does that picture of a patch of skin look like a benign or a cancerous lesion? — but typically, these techniques cannot explain why or how they reach the conclusion they do. Presently most AI solutions suffer from what is commonly known as the “black box phenomena”, with little or no understanding of what happens in between and only the input data and results being the known factors. This is equally applicable in the case of AI applications in health too.

Also, there are questions on: to what degree can doctors delegate the task of diagnosing medical conditions to intelligent scanning systems without exposing themselves to increased liability for malpractice if the system makes an error?

Current medical devices also include software inside them. Hence, the extant medical devices regulation includes software within their scope, depending upon the intended use. This software can be stand alone or incorporated into an existing device. Standards covering the application of traditional software as a medical device (SAMD) have been developed over recent years. However, AI solutions have introduced new set of challenges that have not been considered previously and some important ones are:

(i) **Ethical and privacy concerns largely on collection and inappropriate use of data:** AI models, solutions and other applications depend on generation, collection and processing of large amount of data on individual entity and community behaviour. Data collection without proper consent, privacy of personal data, inherent collection biases and resilient risk of privacy and discrimination are some of the issues requiring deliberation and proper recourse.

(ii) Issues of security arising from the implication and the consequent accountability of any AI system

(iii) Level of autonomy introduced by AI technologies

(iv) Ability of continuous learning systems to change their output overtime in response to new data

(v) Ability to expand and understand how the output has been reached

(vi) Transparency with regard to design of algorithms

(vii) Quality of data input

# Conclusion

All these emerging challenges in the use of AI in health challenges are met with a regulatory vacuum. It is therefore, important that a comprehensive study is conducted on identifying regulatory challenges and opportunities of AI in health, which is also the mandate of the Working Group on “regulatory consideration of AI on health” of the FGAI4Health. This would be useful while framing regulatory frameworks for AI on health.

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1. <http://www.gartner.com/it-glossary/big-data/> [↑](#footnote-ref-1)
2. Added by IBM [↑](#footnote-ref-2)
3. Added by Oracle [↑](#footnote-ref-3)
4. Added by SAS [↑](#footnote-ref-4)
5. ibid [↑](#footnote-ref-5)