Journal of Law and Legal Research Development
ISSN: 3048-5045

Regulation of Artificial Intelligence in India: Difficulties and Factors to be Considered

Ariffa K

Assistant Professor, Department of Law, S. Thangapazam Law College, Vasudevanallur, Tamilnadu, India

Article History

Received: Sep-2024
Revised: Sep-2024
Accepted: Oct-2024
Published: Oct-2024

Keywords

Artificial Intelligence
Health focus
disease detection
public health
AI

Abstract

Artificial Intelligence (AI) is revolutionizing various sectors, particularly healthcare, by improving processes, enhancing efficiency, and driving economic growth. In India, the healthcare system faces significant challenges, including inadequate access to quality care, especially in rural areas, and a severe shortage of skilled medical professionals. Despite having world-class hospitals that bolster medical tourism, India struggles with disparities in healthcare access and affordability. AI has the potential to address these issues by improving access to high-quality care, reducing the burden on healthcare professionals, and enabling personalized treatments on a large scale. The Indian government is actively working to integrate AI into the healthcare system, as demonstrated by initiatives like the National Health Stack and the National Digital Health Blueprint. These policies aim to create a digital infrastructure that facilitates data sharing and supports innovation in the private sector. Additionally, collaborations between government bodies, technology companies, and healthcare providers are accelerating the development and implementation of AI-driven solutions. For example, NITI Aayog's partnerships with Microsoft and Forus Health focus on early disease detection, while the Maharashtra government is working with Wadhwani AI to enhance rural healthcare. These efforts highlight AI's potential to transform India's healthcare system, making it more efficient, accessible, and affordable, ultimately improving public health outcomes and reducing poverty related to healthcare costs.

Corresponding Author:

K. Ariffa

Assistant Professor, Department of Law, S. Thangapazam Law College, Vasudevanallur, Tamilnadu, India

ariffanoorkasim@gmail.com

1. INTRODUCTION

Artificial intelligence (AI) has made substantial progress in several industries by transforming procedures, enhancing productivity, and improving decision-making. AI's growing prominence may be attributed to its substantial capacity to stimulate economic expansion. AI has made prominent growth in almost every sectors of life from banking, life sciences to health care industry. AI is mostly used in medical imaging, diagnostics, personalized therapies, and predictive analysis. Artificial intelligence (AI) has the ability to improve the quality of patient care and reduce healthcare costs. As the population continues to grow, the need for health care, particularly in emerging nations like India, will also continue to rise. India's healthcare system requires innovative strategies to improve its efficacy and efficiency in order to accommodate the expanding population. Artificial intelligence has the potential to greatly enhance the healthcare industry[1].

1 Indo-Asian News Service (2017), 'India is now among fastest-growing medical tourism destinations', India Today, 13 October 2017

Fitness systems in India have significant issues in rapports of excellence, accessibility, cost, and disparity. India has world-class hospitals, which have led to the development of a thriving medical tourism industry However, there is a severe scarcity of skilled medical practitioners. Based on an availability rate of 80 percent, the ratio of physicians to population may be roughly approximated at 1:1,596, as computed by the Central Bureau of Health Intelligence in 2018[2]. The ratio is especially deficient in rural regions, necessitating patients to undertake extensive journeys in order to get even rudimentary healthcare. In addition, India's allocation of government funds for healthcare in 2016-17 was just 1.4% of its GDP, which is among the lowest in the world. A majority of Indians, namely 79% of urban families and 73% of rural households, depend on isolated healthcare providers, as reported by the National Sample Survey Office in 2014[3]. However, the private healthcare sector in India is characterized by fragmentation and lack of regulation, with just about 1 percent of private hospitals being officially certified. The issue of healthcare affordability is also a cause for worry. The public sector covers 30 percent of the overall health cost, while the remaining 70 percent is paid by individuals directly. The exorbitant expenses associated with private healthcare significantly contribute to the ongoing prevalence of poverty. In 2011, a staggering 55 million individuals in India were forced into poverty as a result of healthcare expenditures, with 39 million of them specifically dropping below the insufficiency line owing to the exorbitant prices of medicine[4]. AI technologies have the potential to tackle several challenges in healthcare. They can enhance access to high-quality healthcare, especially in rural and low-income areas. AI can also help address the imbalance between the number of skilled doctors and patients. Furthermore, it can improve the preparation and effectiveness of doctors and nurses, mainly in complex medical measures. Additionally, AI can enable the provision of personalized healthcare on a large scale.

The rapid progress in technology, together with the growing interest and involvement of entrepreneurs, presents India with a chance to address its persistent healthcare issues in serving a significant portion of its people. The government is actively trying to establish a digital healthcare system throughout the whole nation, as outlined in the latest policy papers for the National Health Stack and the National Digital Health Blueprint (2019) (NDHB) (Ministry of Health and Family Welfare, 2019). The key components of this digital structure consist of the Health locker, a nationwide health database and cloud-based data storage solution that consolidates health details for the entire country; a decentralized personal health records (PHR) system that enables citizens and medical researchers to utilize data easily; a platform for insurance coverage and claims that facilitates thorough wellness programs; a national health analytics structure; and a distinct digital health ID for each individual[5]. The government has implemented Ayushman Bharat (Healthy India), commonly referred to as the National Health Protection Scheme (2018), in order to provide health insurance coverage to households with incomes falling below the poverty threshold. These efforts are derived from the preceding National Health Policy (2017), which sought to develop an integrated health information system linked to the Aadhaar system, and enhance public health outcomes via the use of big data analytics. These policies advocate for the establishment of a digital infrastructure supported or facilitated by the government for the purpose of exchanging data. This infrastructure is made available to the private sector to encourage further innovation. It is built on open application programming interfaces (APIs) and national data portability[6]. The emphasis on AI in healthcare has spurred more cooperation among government entities, technological firms, and conventional healthcare providers. As an instance, NITI Aayog, the main policy think-tank of the government, is collaborating with Microsoft and the medical technology start-up Forus Health to create a preliminary version for the early identification of DR.3 The Maharashtra state government has entered into a formal agreement with NITI Aayog and the Wadhwani AI firm to establish the International Centre for Transformational Artificial Intelligence (ICTAI). The centre will specifically concentrate on improving healthcare services in rural areas. In a similar manner, the government of Telangana has implemented the Microsoft Intelligent Network for Eyecare, a technology created in collaboration with the LV Prasad Eye Institute situated in Hyderabad.

2. AI IN HEALTH CARE

Health care is one of the most dynamic and challenging sectors in India, it has been facing many problems such as shortage of qualified Doctors, Nurses, technicians as well as non-uniform accessibility of health care services. Artificial intelligence for health encompasses various technologies such as machine learning (ML), natural language processing (NLP), speech recognition (text-to-speech and speech-to-text), image recognition and machine vision, expert systems (computer systems that mimic human decision-making), robotics, and systems for planning, scheduling, and optimization. Machine learning is an essential element of artificial intelligence that enables systems to acquire knowledge and enhance their performance without the need for explicit programming. AI is inherently dependent on ML. Computer programs autonomously acquire and use data in order to learn and adapt their operations without any human involvement or support. Deep learning, a subfield of machine learning, draws inspiration from the structure and functioning of the human brain. It employs neural networks with several layers to identify intricate patterns and correlations in extensive datasets that conventional machine learning methods would overlook. Natural Language Processing (NLP) is a specialized branch of AI that enables computers to comprehend, interpret, and modify human language. The field relies upon several fields such as computational linguistics, information engineering, linguistics, and computer science. Its objective is to bridge the gap between human communication and machine comprehension. Speech recognition refers to the capacity of a

[2] *Central Bureau of Health Intelligence (2018), 'National Health Profile 2018', Ministry of Health and Family Welfare*

[3] *Rao, N. (2018), 'Who Is Paying for India's Healthcare?', The Wire, 14 April 2018*

[4] *Selvaraj, S., Farooqui, H. H. and Karan, A. (2018), 'Quantifying the financial burden of households' out-of-pocket payments on medicines in India: a repeated cross-sectional analysis of National Sample Survey data, 1994–2014', BMJ Open, 8(5), doi:10.1136/bmjopen-2017-018020*

[5] *NITI Aayog (2018b), National Health Stack: Strategy and Approach, Delhi: NITI Aayog*

[6] *India.gov.in (2018), 'Ayushman Bharat: National Health Protection Mission',*

computer or program, which combines software and hardware, to recognize and convert spoken words and phrases into a format that can be understood by a machine. It may also transform machine-readable language back into spoken language. It is also referred to as automated voice recognition (AVR) or voice-to-text[7].

The use of AI in various field of health care is creating a change in various stages of health care such as

- Artificial Intelligence in Medical Diagnosis – which helps to forecast and identify diseases at a quicker pace compared to the majority of medical experts.
- Artificial Intelligence in the arena of Drug Discovery - artificial intelligence (AI) is expediting this process by assisting in medication design, forecasting potential adverse effects, and pinpointing optimal candidates for clinical trials.
- Artificial Intelligence in the context of patient experience. Efficiently ensuring a smooth patient experience enables hospitals, clinics, and doctors to attend to a greater number of patients each day.
- Artificial Intelligence in the management of healthcare data - Implementing this may lead to decreased duration and expenses associated with healthcare administrative procedures, hence enhancing the overall efficiency of daily operations and improving patient satisfaction.
- Artificial intelligence (AI) and robotics - The use of robot-assisted operations has resulted in a reduction in surgery-related problems, less discomfort, and a faster recovery period.

The companies which are paving the way for AI enabled health care services are mentioned as

Sl. No.	Companies	Use of AI
1.	HealthifyMe	An Indian digital health and wellness company offers an application that includes services like calorie monitoring and guidance on nutrition and fitness.
2.	Niramai Health Analytix	A portable AI-powered device for early detection of breast cancer.
3.	PharmEasy	AI-based app connects users with pharmacies and provides seamless medical deliveries.
4.	*Diagnostic assistance*	AI systems have been used to analyze medical images, such as those collected via X-rays or MRI scans.
5.	*Tricog*	AI-powered platform provides quick and accurate ECG interpretations.
6.	Aravind Eye Hospital & Google	AI is used to screen for diabetic retinopathy by analyzing retinal images.
7.	Qure.ai	Qure.ai uses AI algorithms to interpret radiology images, such as X-rays and CT scans.
8.	Strand Life Sciences	AI analyzes genomic data for personalized cancer treatment.
9.	Practo and 1mg	AI chatbots and virtual assistants for initial consultations and symptom checks.

The incorporation of AI hooked on the healthcare sector has given rise to several notable obstacles and concerns. Here are few concrete instances that illustrate these issues:

2.1 Inaccurate Treatment Recommendations by IBM Watson for Oncology

IBM's Watson for Oncology was designed to aid oncologists by offering AI-powered therapy suggestions. Nevertheless, it received backlash for providing hazardous and inaccurate recommendations for therapy. The AI system was discovered to have been trained on a restricted dataset only from Memorial Sloan Kettering Cancer Center, resulting in a deficiency in its capacity to generalize outside that specific institution. This resulted in a decrease in confidence and restricted implementation in clinical practice as medical practitioners were skeptical about the system's dependability[8].

2.2 Bias and Disparities in Accuracy by Google Health's AI for Breast Cancer Detection

Google Health developed an AI system to detect breast cancer from mammograms. While the AI showed high accuracy overall, studies revealed that its performance varied across different demographic groups. The system was less accurate for certain racial and ethnic groups compared to others. These disparities raised concerns about the fairness and inclusivity of AI in healthcare, highlighting the need for diverse training data and rigorous testing across varied populations[9].

2.3 Over prediction and Alarm Fatigue by Epic Systems' Sepsis Prediction Model

Epic Systems developed an AI model to predict sepsis in hospitalized patients. Reports indicated that the model often over predicted sepsis, leading to numerous false positives. This caused alarm fatigue among healthcare providers, who were overwhelmed by constant alerts. Over prediction not only

[7] *World Wide Web Foundation (2017), 'Artificial Intelligence: The Road Ahead in Low- and Middle-Income Countries'*

[8] *Ross C, Swetlitz I: IBM's Watson supercomputer recommended "unsafe and incorrect" cancer treatments, internal documents show. STAT. July 25, 2018. Available at www.statnews.com/wp-content/uploads/2018/09/IBMs-Watson-recommended-unsafe-and-incorrect-cancer-treatments-STAT.pdf.*

[9] *Istasy, P., Lee, W. S., Iansavichene, A., Upshur, R., Gyawali, B., Burkell, J., Sadikovic, B., Lazo-Langner, A., & Chin-Yee, B. (2022). The Impact of Artificial Intelligence on Health Equity in Oncology: Scoping Review. Journal of medical Internet research, 24(11), e39748. https://doi.org/10.2196/39748*

strained healthcare resources but also potentially diverted attention from patients who genuinely needed urgent care[10].

2.4 Privacy and Ethical Concerns by Amazon's Rekognition for Health Monitoring

Amazon's facial recognition technology, Rekognition, has been explored for various healthcare applications, including patient monitoring. However, its deployment raised significant privacy and ethical concerns, especially regarding the surveillance of patients without their explicit consent. The potential for misuse of biometric data and the erosion of patient privacy led to public backlash and calls for stricter regulations[11].

2.5 Inconsistent Medical Advice by Babylon Health's Chatbot

Babylon Health developed an AI-powered chatbot to provide medical advice and triage symptoms. Investigations revealed that the chatbot sometimes offered inconsistent or incorrect medical advice compared to human doctors. This inconsistency posed risks to patient safety and highlighted the limitations of relying solely on AI for medical decision-making[12].

2.6 Data Privacy Violations by Microsoft's AI for Medical Research

Microsoft's AI initiatives in healthcare, including data analysis for medical research, have occasionally faced scrutiny over data privacy issues. Instances of inadequate de-identification of patient data and insufficient consent protocols were reported. Such privacy violations undermine public trust in AI applications in healthcare and can lead to legal repercussions for companies[13].

2.7 Exaggerated Claims and Lack of Transparency by Theranos

Although not strictly an AI issue, Theranos' scandal serves as a cautionary tale about the dangers of overhyping technology. The company falsely claimed its technology could perform numerous tests with a single drop of blood, leading to widespread misinformation and public deception. The fallout resulted in severe legal consequences, loss of investor trust, and harm to patients who received inaccurate test results[14]. The integration of AI into healthcare holds immense promise but also presents significant challenges. These examples underscore the importance of robust data practices, addressing biases, ensuring transparency, and maintaining ethical standards to mitigate risks and maximize the benefits of AI in healthcare. Addressing these issues requires collaboration between technology developers, healthcare providers, regulators, and patients to build trust and ensure the safe and effective use of AI. While AI in healthcare presents numerous opportunities for improving patient care and outcomes in India, it also brings several challenges that need to be addressed. Successful examples like Qure.ai, Niramai, Tricog Health, Practo, 1mg, and Strand Life Sciences highlight the potential of AI to transform healthcare delivery. However, companies must focus on addressing data privacy, bias, accountability, integration, regulatory, cost, and reliability issues to fully realize the benefits of AI in healthcare. Collaborative efforts between technology developers, healthcare providers, regulators, and policymakers are essential to navigate these challenges and ensure the ethical and effective use of AI in healthcare.

3. LEGAL FRAMEWORK FOR AI IN HEALTH CARE – A GLOBAL APPROACH

3.1 United States of America

- At now, the United States lacks dedicated regulatory paths for AI based tools. However, the FDA assesses these innovations using the current governing agenda designed for medical expedients. In Apr-2019, the FDA introduced the "Proposed Regulatory Framework for Modifications to AI/ML-based SaMD." This framework holds designers responsible for the actual concert of their AI systems in real-world settings. Developers are required to inform the FDA about any changes in performance and input. The suggestion also highlighted the need of restarting the clearance procedure in the event of a modification in the anticipated use of the AI system. In response to this idea, the FDA released the "AI/ML-based SaMD Action Plan" in Jan-2021. The plan included five measures that would be taken to oversee AI-MDs over their entire life cycle, using the Total Product Life Cycle (TPLC) methodology.
- A precise regulatory framework has been established through the release of draft guidance on the "Predetermined Change Control Plan";
- Implementation of effective practices for machine learning,
- Adoption of a patient-centric approach, ensuring limpidity of devices to users;
- Development of methods to eliminate bias in machine learning algorithms and enhance their performance;
- Conducting pilots to monitor the real-world performance of devices.

The purpose of "Predetermined Change Control Plan" is to provide a structure for making modifications to AI-MDs. This plan would outline the specific types of changes that are expected, referred to as "SaMD pre-specifications" (SPSs), as well as the procedures used to appliance these changes in a controlled manner to minimize risks to patients. This controlled implementation process is known as the "algorithm change protocol" (ACP). The TPLC strategy for AI-MD developers used good machine learning principles (GMLPs). GMLP concerns for

[10] *Cull, J., Brevetta, R., Gerac, J., Kothari, S., & Blackhurst, D. (2023). Epic Sepsis Model Inpatient Predictive Analytic Tool: A Validation Study. Critical care explorations, 5(7), e0941. https://doi.org/10.1097/CCE.0000000000000941*

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[12] *Magalhaes Azevedo, D., & Kieffer, S. (2021). User reception of AI-enabled mHealth Apps: The case of Babylon health.*

[13] *Murdoch, B. (2021). Privacy and artificial intelligence: challenges for protecting health information in a new era. BMC Medical Ethics, 22, 1-5.*

[14] *Griffin III, O. H. (2022). Promises, deceit and white-collar criminality within the Theranos scandal. Journal of White Collar and Corporate Crime, 3(2), 109-121.*

SaMDs pertain to the implementation of sound software-engineering performs or excellence system practices, which include the following characteristics[15]:

- The data available is highly pertinent to the clinical issue and aligns with current clinical practice.
- The collection of data is consistent and adheres to the intended purpose of the SaMD.
- There is a predetermined process for making adjustments to the SaMD.
- The datasets used to train, fine-tune, and test the AI algorithms have suitable limitations.
- The AI algorithms and their results are transparent to users.

3.2 United Kingdom

In 2019, the National Institute for Health and Care Excellence (NICE) collaborated with the National Health Service (NHS) England to publish the "Evidence Standards Framework for Digital Health Technologies." This document establishes the criteria for a range of goods, such as applications, software, and online platforms, that may function alone or be combined with other health-related items. In Nov-2022, the UK's Regulatory Horizons Council, a body that provides professional guidance to the government on technology advancements, released a publication titled "The Regulation of AI as a Medical Device." This paper aims to improve communication clarity among regulators, manufacturers, and users by addressing the complete lifecycle of AI-MDs and enhancing patient and public participation. The "Software and AI as a Medical Device Change Programme" was initiated by the Medicines and Healthcare Products Regulatory Agency (MHRA) in Sep-2021. Its purpose is to provide a complete regulatory framework, including guidelines, for the oversight of AI-MDs (Artificial Intelligence Medical Devices). This program consists of two primary workstreams. The first workstream focuses on implementing essential reforms at every stage of Software as a Medical Device (SaMD) development, including addressing cybersecurity, data privacy threats, and conducting post-market reviews of the medical device. The second work stream specifically addresses the extra problems presented by artificial intelligence in the medical field.[16].

3.3 Europe

In 2019, the European Union (EU) established its strategy for dealing with AI by issuing non-binding recommendations, which included the "Ethics Guidelines for Trustworthy AI" and the "Policy and Investment Recommendations." In May-2021, the EU implemented the "European Medical Device Regulation," which established a regulatory stance by categorizing the risk levels of SaMDs according to their diagnostic and therapeutic functions. In Apr-2021, the EU introduced the AI Act, which implemented a comprehensive legal structure for AI goods and services, including all stages from creation to implementation. Within this context, this change represents the European Union's progression from a non-binding approach to a legally binding framework for regulating artificial intelligence. The AI Act utilizes a risk-based approach to govern AI systems. High-risk AI systems in the healthcare industry include biometric identification, patient sorting based on medical history, and software for administering public healthcare services and electronic health data. Data governance and risk management are the essential criteria for high-risk AI systems under the AI Act, and it is the responsibility of the manufacturer to satisfy these requirements. A voluntary code of behavior is advocated for low- and minimal-risk AI systems, such as chatbots used in healthcare services to communicate with people, in order to provide safe and trustworthy service. Critics contend that the AI Act is inflexible, since it now does not include mechanisms for categorizing novel AI applications as "high-risk" in the event that they arise in unanticipated industries and present hazards.[17].

3.4 India

The Central Drugs Standard Control Organization (CDSCO) is an authoritative body responsible for regulating drugs and ensuring their quality and safety. The CDSCO serves as the principal regulatory authority responsible for supervising medical devices in India. Medical devices that use artificial intelligence are classified as medical devices and are required to adhere to the regulations outlined in the Medical Devices Rules of 2017. The Medical Devices Rules of 2017 - The classification of medical devices into four categories (A, B, C, and D) is determined by these guidelines, which are based on the level of risk associated with each item. AI-based gadgets are often categorized into higher risk categories, namely categories C or D. Manufacturers must get appropriate permits, establish quality management systems, and perform clinical assessments in accordance with the regulations. Software as a Medical Device (SaMD) - Software designed for medical use is classified as SaMD, which stands for Software as a Medical Device. The gadget must adhere to the same rules as conventional medical devices, including criteria for safety, effectiveness, and performance[18].

4. OTHER GLOBAL INITIATIVES

The World Health Organization (WHO) provides comprehensive guidance on the ethical and responsible use of artificial intelligence (AI) in healthcare. The key principles emphasized by the WHO include equity, transparency, accountability, ethical considerations and inclusiveness and participation[19].

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[15] *FDA . Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning-Based Software as a Medical Device 2019. FDA; Silver Spring, MD, USA: 2019. [(accessed on 27 February 2023)]. Available online: https://www.fda.gov/files/medical%20devices/published/US-FDA-Artificial-Intelligence-and-Machine-Learning-Discussion-Paper.pdf*

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[18] *Bajpai, N., & Wadhwa, M. (2021). Artificial Intelligence and Healthcare in India (No. 43). ICT India Working Paper.*

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4.1 International Medical Device Regulators Forum (IMDRF) on AI

The International Medical Device Regulators Forum (IMDRF) is an organization that aims to harmonize the regulatory processes for medical devices, including those incorporating AI technologies, across different countries. The IMDRF's work includes harmonization of regulations, guidance development, stakeholder engagement and providing guidelines. The IMDRF's efforts in harmonizing regulatory approaches help ensure that AI technologies in medical devices are developed and used in a way that maximizes their benefits while minimizing risks[20].

5. CONCLUSION

The governance of artificial intelligence (AI) in India poses a difficult task that calls for a strategy that is well-balanced and considers a variety of technological, ethical, legal, and social aspects. There are a number of important factors that need to be addressed as India goes towards using AI for the purpose of fostering economic development and social benefits. In order to guarantee justice, accountability, and transparency, the development and deployment of artificial intelligence (AI) must comply to ethical norms. Among them are the elimination of biases in artificial intelligence systems and the prevention of their exploitation. Stable data protection regulations are very necessary in order to safeguard personal information and preserve the confidence of the general public. It is imperative that the rule ensures that artificial intelligence systems adhere to data privacy standards and put in place strict security measures to avoid data breaches. It is vital to improve the skill set of the workforce in order to respond to changes brought about by artificial intelligence. This involves making investments in educational and training programs that provide people with the skills they need to flourish in an economy that is highly integrated with artificial intelligence. It is of the utmost importance to have a comprehensive regulatory framework that is capable of simultaneously keeping up with the fast improvements in technology. This entails the creation of flexible regulations that are able to adapt to the ever-evolving environment of artificial intelligence while still providing developers and consumers with clear instructions. In order to achieve effective regulation, it is necessary for many stakeholders, such as government agencies, industry specialists, academic institutions, and civil society organizations, to work cohesively together. When this is done, a holistic strategy that takes into account the many effects of AI is ensured. The process of aligning India's artificial intelligence rules with international norms and practices has the potential to make international collaborations easier and to guarantee that India maintains its competitive position within the global ecosystem of artificial intelligence. Therefore, in order to regulate artificial intelligence in India, a complex approach that takes into consideration ethical, legal, and societal elements is required. India is able to exploit the promise of artificial intelligence (AI) while limiting its hazards by cultivating a regulatory framework that is both inclusive and adaptable. This will eventually contribute to India's contribution to sustainable development and technological growth.

6. FUNDING

This article did not get any explicit financial support from any public, private or non-profit funding sectors.

7. CONFLICT OF INTEREST

Conflict of interest declared none.

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