Please share your comments/suggestions on this task force separately on an individual page by 20th June 2024 on email Id: umeshkapil@gmail.com.

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DRAFT

NATIONAL ACADEMY OF MEDICAL SCIENCES (INDIA)

DIRECTORATE GENERAL OF HEALTH SERVICES

MINISTRY OF HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA

REPORT OF TASK FORCE

ON

ARTIFICIAL INTELLIGENCE (AI) IN HEALTH CARE IN INDIA

2023

NAMS – DGHS – Govt. of India – Task Force Series No. 07

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Acknowledgement

Deliberations of the Executive Council of the National Academy of Medical Sciences in Apr 2022, resulted in the establishment of Task Force(s) to focus on various critical aspects of medical care including Artificial Intelligence (AI) in Healthcare. This expressed need for guidelines in suggesting actionable recommendations to improve the usability of AI in healthcare in Indian context has been fulfilled vide this document. We are grateful for the encouragement and support provided by the President NAMS, Prof SK Sarin and Prof Umesh Kapil, Secretary NAMS and his Secretariat team, through the duration of the Task Force.
We are grateful to the tireless guidance and inspirational leadership provided by Prof. Chetan Arora, Chairperson of the AI Task Force in identifying, perusing, distilling and developing a multitude of international guidelines focused on various aspects of AI, into actionable and up to date guidance for the Indian context.
We profusely thank Dr. Ketan Paranjape, Dr. Kash Patel, Dr. Avneesh Khare, Prof. Kolin Paul and all other task force members for their invaluable contribution to the various sections.
The Task Force Secretariat undertook extensive reviews of literature and evidence, and collated them with an overarching view to present an easy to refer format for clinicians in the Indian context. The public health and health systems focus and orientation was maintained consistently through the proceedings of the Task Force and the resultant document by the efforts of the Co-Chairs, Prof. S N Sarbadhikari and Dr. Ketan Paranjape,

Preface

Artificial Intelligence (AI) is intelligence displayed by machines, in contrast with human intelligence. AI attempts to approximate or translate human behavior and thought processes into algorithms or computer processes and embody them into computers or machines so that outputs of those mimic outputs which humans may produce on similar inputs. AI therefore makes it possible for machines to learn from experience, adjust to new inputs and perform human-like tasks.

AI is becoming an increasingly advanced, sophisticated, and meaningful field, and its uses and implications are far reaching. AI's value proposition is the ability to process vast amounts of data, and then act on that data through computing abilities. In contrast to the human mind, computers are scalable and tireless. By processing data, the computer algorithms (algorithm is defined as a set of rules for calculations or other problem-solving processes or operations) can 'learn' much faster than any human and develop what we understand as AI.

India should envision a healthcare system, both in the public sector and the private health care system, in which a collaborative, multidisciplinary approach will ensure a digital technology-adoptive population and an AI-enabled healthcare system, through standardised, evolving, evidence based guidelines, to deliver sustainable, high quality, affordable and patient focused care.

An extensive review of up-to-date published literature and consensus statements / guidelines was undertaken by this Task Force of the NAMS specifically focusing on the application of AI in Healthcare. These guidelines have emerged from there.

The Task Force has recommended that consensus be achieved amongst the various stakeholders in the health of the people of India, towards a national Vision i.e., an open attitude towards judiciously using AI for healthcare.

List of abbreviations

ABDM	Ayushman Bharat Digital Mission
AI	Artificial Intelligence
BIS	Bureau of Indian Standards
DPDP	Digital Personal Data Protection
EMR	Electronic Medical Record
GDPR	General Data Protection Regulation
HIPAA	Health Insurance Portability and Accountability Act
IRDAI	Insurance Regulatory and Development Authority
MoHEF	Ministry of Health and Family Welfare
MelTy	Ministry of Electronics and Information Technology
NAMS	National Academy of Medical Sciences
NCD	Non-Communicable Disease
PHI	Protected Health Information / Personally Identifiable Information
PICO	Population, Intervention, Comparator, and Outcome
PII	Personally Identifiable Information / Protected Health Information
PM-JAY	Prime Minister’s Jan Arogya Yojana
TNeGA	Tamil Nadu e-Governance Agency
TNSBCS	Tamil Nadu State Blind Control Society

Operational definition of terms used in the report

Artificial Intelligence (AI) refers to the ability of machines to perform cognitive tasks like thinking, perceiving, learning, problem solving and decision making.

Privacy means an individual's interest in limiting who has access to personal health care information. Specific patient authorization is required for use and disclosure of clinical notes. As per Fernando & Dawson, 2009, privacy is control of access to private information avoiding certain kinds of embarrassment and can be shared or not shared with others; Only authorized (by the patient) people can view the recorded data or part thereof.

Protected Health Information (PHI) / Personally Identifiable Information (PII): Any individually identifiable information whether oral or recorded in any form or medium that is created, or received by a health care provider, health plan or health care Healthcare provider and relates to past, present, or future physical or mental health conditions of an individual; the provision of health care to the individual; or past, present, or future payment for health care to an individual.

Executive summary

Artificial Intelligence (AI) refers to the ability of machines to perform cognitive tasks like thinking, perceiving, learning, problem solving and decision making. It can help in significant improvement of healthcare outcomes.

An extensive review of up-to-date published literature and consensus statements / guidelines was undertaken by a Task Force of the NAMS specifically focusing on the application of AI in Healthcare. These guidelines have emerged from there.

The Task Force has recommended that consensus be achieved amongst the various stakeholders in the health of the people of India, towards a national Vision i.e., an open attitude towards judiciously using AI for healthcare.

The National Academy of Medical Sciences envisions a healthcare system in India, both in the public sector and the private health care system, in which a collaborative, multidisciplinary approach will ensure a digital technology-adoptive population and an AI-enabled healthcare system, through standardised, evolving, evidence based guidelines, to deliver sustainable, high quality, affordable and patient focused care.

The key issues identified by the Task Force include Privacy issues, Accountability, Transparency, and Explainability, Bias and Inequalities, Security (including Cybersecurity), Training and Standardization issues.

Recommendations have been made to bridge critical gaps / deficiencies as identified, including capacity building. Presently there is no formal system for upgradation and verification of skill sets of healthcare professionals in applying AI in healthcare. Recommendations have been made by the Task Force to address this suitably. The measures required to be taken call for stakeholders to take effective action to create a future for India, where:

1. The health professionals are knowledgeable about the risk factors, beneficial outcomes, and overall risk-benefit ratio of AI in healthcare, and individuals feel empowered to talk with their healthcare providers about AI-enabled healthcare whenever appropriate.

2. Evidence-based practices for the development, deployment, and use of AI / ML in healthcare are clearly understood and routinely applied by all medical professionals in all settings.
3. New scientific evidence is constantly being uncovered to fill gaps in knowledge, and these findings are quickly and easily disseminated to the healthcare professional educators and put into practice by healthcare professionals.

There needs to be concerted efforts by policy makers and medical professional bodies, to focus attention on the policy gaps, and also India specific recommendations on awareness and training for application of AI in healthcare.

Thus, there is a need for budgetary allocation of funds and policy initiatives, for assigning research priorities, and a need for convergence of medical specialities, to better serve the Indian population.

A community based strategy is recommended to create awareness periodically. This is recommended to be steered by a special Committee or Cell that may be established by Ministry of Health and Family Welfare (MoHFW), with the cooperation of the National Academy of Medical Sciences (NAMS), in coordination with the NITI Aayog and Ministry of Electronics and Information technology (MeITy).

After due deliberations on the need for current evidence about AI-enabled healthcare practices, has proposed the conduct of a rapid multicentric cross sectional study on a pan India basis, to ascertain a representative view of the real world (non AI-enabled healthcare) practices. This is intended to be undertaken to develop indigenous digital health interventions that improve the health outcomes of the population and also reduce the cost and time of healthcare delivery.

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1. Introduction

Artificial Intelligence (AI) is intelligence displayed by machines, in contrast with human intelligence. AI attempts to approximate or translate human behavior and thought processes into algorithms or computer processes and embody them into computers or machines so that outputs of those mimic outputs which humans may produce on similar inputs. AI therefore makes it possible for machines to learn from experience, adjust to new inputs and perform human-like tasks.

AI is becoming an increasingly advanced, sophisticated, and meaningful field, and its uses and implications are far reaching. AI's value proposition is the ability to process vast amounts of data, and then act on that data through computing abilities. In contrast to the human mind, computers are scalable and tireless. By processing data, the computer algorithms (algorithm is defined as a set of rules for calculations or other problem-solving processes or operations) can 'learn' much faster than any human and develop what we understand as AI. AI can, for example, learn to identify potential diseases, treatment plans, and trends based on sifting through information and analyzing patient history, and provide recommendations to support, inform, and enable physician decision-making or make decisions on which human's act. Given these diverse use cases, AI is also referred to as Automated Intelligence or Augmented Intelligence.

1.1.Need for AI in healthcare

We need to understand the state of healthcare today to truly appreciate what will drive AI. In many developed countries, mature but aged national healthcare services are being burdened with a growing aging population, accessibility to healthcare, changes in payment reforms, need for better diagnostics and treatments, worker shortage and rising costs of delivering care(*2020 Global Health Care Sector Outlook*, 2017; Vogenberg & Santilli, 2018; Wolff et al., 2020). Combined with a sudden surge in innovative technologies such as AI which can help with automating medical records to provide a more accurate diagnosis and tailored treatments, today's healthcare systems are ready for change (Davenport & Kalakota, 2019).

1.2.AI Applications in Health and Medicine

Now with an understanding of AI technologies, let us consider how AI is being used in the patient and physicians' health journey. We live in a world of episodic care, where following an early or routine diagnosis, a physician develops a treatment plan based on a clinical decision support protocol. Then with the help of the health system, the physician gets paid for their services. Given the burdens we discussed earlier to all the healthcare stakeholders, we need to start focusing on wellness or preventative care and look at new options such as virtual assistants for triaging patients before they enter the hospital system. Finally, there are health conditions that go untreated resulting in an added burden to the health system.

Table- 1 List of AI applications in certain healthcare disciplines

Key Focus Area		
Patient Care	Assisted or automated diagnosis and participation	Chatbots can help patients self-diagnose or assist doctors in diagnosis (Y. Wang & Neff, 2013)
	Prescription auditing	AI audit systems can help minimize prescription errors (Corny et al., 2020)
	Pregnancy Management	Monitor mother and fetus to reduce mother's worries and enable early diagnosis (Iftikhar et al., 2020)
	Real-time prioritization and triage	Prescriptive analytics on patient data to enable accurate real-time case prioritization and triage (M. Wang et al., 2020)
	Personalized medication and care	Find the best treatment plans according to patient data reducing cost and increasing effectiveness of care (Freedman, 2019)
	Patient data analytics	Analyze patient and/or 3rd party data to discover insights and suggest actions. AI allows the institution to analyze clinical data and generate deep insights into patient health. It provides an opportunity to reduce cost of care, use resources efficiently, and manage population health easily (Mehta et al., 2019)
	Wellness	AI can be used to learn from almost unlimited data from healthy individuals to provide detailed analytics on wellness management that is tailored to the individual (Tran et al., 2019)

	Surgical robots	Robot-assisted surgeries combines AI and collaborative robots. These robots perform repetitive tasks. AI can identify patterns within surgical procedures to improve best practices and to improve a surgical robots' control accuracy to sub-millimeter precision (Guo & Li, 2018)
	Preventative Care	Using data analysis to predict potential health outcomes, AI technology can help with diagnosis, recommend options for preventive care and improve accuracy.
Clinical Decision Support, Medical Imaging and Diagnostics	Clinical Decision Support	Feeding well managed and curated health data to Machine Learning algorithms can enable efficient clinical decision support. This data can further be mined and cross-referenced with medical journals, data from other patients, and case studies to provide predictive analytics on the patient's health (Baron et al., 2019)
	Early diagnosis	Analyze chronic conditions leveraging lab data and other medical data to enable early diagnosis (Schinkel et al., 2019)
	Medical imaging analytics	Advanced medical imaging to analyze and transform images and model possible situations (Erickson et al., 2017)
Research and Development	Drug discovery	Find new drugs based on previous data and medical intelligence (Vamathevan et al., 2019)
	Clinical trial participation	Address concerns with patent cliff, analyzing real-world data and evidence, enabling outcome -driven approaches for treating conditions (Harrer et al., 2019)
	Gene analysis and editing	Understand genes and their components. Predict the impact of gene edits (Chen & Ishwaran, 2013)

	Device and drug comparative effectiveness	Applying AI to extract meaningful, actionable information from images and videos for experiment design (Park et al., 2020)
Healthcare Management	Brand management and marketing	Create an optimal marketing strategy for the brand based on market perception and target segment
	Pricing and risk	Determine the optimal price for treatment and other service according to competition and other market conditions (Wolff et al., 2020)
	Market research	Prepare hospital competitive intelligence.
	Operations	Process automation technologies such as intelligent automation and RPA help hospitals automate routine front office and back office operations such as reporting
	Customer service chatbots	Customer service chatbots allow patients to ask questions regarding bill payment, appointments, or medication refills (Y. Wang & Neff, 2013)
	Fraud detection	Patients may make false claims. Leveraging AI-powered fraud detection tools can help hospital managers to identify fraudsters (*McKinsey Global Institute*, n.d.)
	Cybersecurity	Ability to prevent breaches to protect patient data (Anderson, 2020)

Table 2 – Summary of AI applications in healthcare

Disease Type	*Clinical Management*	*AI Capability*
Diabetic retinopathy (Gulshan et al., 2016)	Detection of early changes in fundi of patients with diabetes	Reading the retina and blood vessels to identify patients at risk of developing complicated diabetic retinal disease
Breast cancer (Rodríguez-Ruiz et al., 2019)	Diagnosis of early breast cancer based on mammography	Reading mammographic pictures to detect early malignant transformation in breast cancer screening
Skin cancer (Esteva et al., 2017)	Diagnosis of skin cancer by its clinical morphology	Identification of skin cancer by pictures and classification of types of skin neoplasia
Cerebrovascular disease (Zihni et al., 2020)	Predicting outcome after a cerebrovascular accident	Predicting outcomes such as mortality of events such as stroke
Non-communicable chronic diseases (Ciccone et al., 2010)	Monitoring of diabetes and heart failure in primary care setting	Assisting patients monitoring of blood pressure and blood glucose at home and transmitting information to family medicine clinics
Heart Failures (Kwon et al., 2019)	Predicting the clinical outcome of patients with heart failure	Predicting in-hospital mortality among patients with heart disease based on echocardiography
Sepsis (Schinkel et al., 2019)	Prediction models to diagnose sepsis	Assistance with treatment of sepsis, where the use of AI is associated with reducing mortality rates
Neurology (Belić et al., 2019)	Monitoring and management of neurodegenerative movement disorders	Detection and management of neurology conditions such as Parkinson's, Alzheimer's and Traumatic Brain Injury
Nephrology (Niel & Bastard, 2019)	Patient management around prescriptions and transplants	Improve clinical care, hemodialysis prescriptions, and follow-up of transplant recipients

1.3. AI Applications in Digital Pathology

Diagnostic Applications - The majority of ML/AI use cases in pathology application cases fall into one of three categories:

- Tools that can improve accuracy, efficacy for safer and better patient care
- Tools to increase the productivity
- New digital biomarker discovery tools can also assist them gain new insights into data that they haven't been able to classify or quantify using current tools.

Pathologists can use machine learning models to help with tasks including detection, classification, segmentation, and quantification. Pathologists can utilize slide coverage maps to help verify all tissue or levels of a given slide have been examined, or they can use clinical grade ML models as an aid to prevent small/minor tumour foci from being missed.

- **Independent reporting algorithms** - There is a need for the creation of new tools to help pathologists with the reporting process as traditional pathology gives way to digital pathology. Strong WSI analysis software solutions that are user-friendly and brimming with therapeutically useful technologies have recently been developed (Bankhead et al., 2017). These software programs provide interactive sketching tools for annotation and are capable of handling huge WSIs and metadata produced by many device manufacturers. Additionally, they have features that can extract features and detect cells whereby automated examination of a large number of specimens may enhance accessibility and lower the cost of diagnosis and therapy.
- **Diagnosis-aided tools -** These tools contain algorithms that evaluate several aspects of the slides, such as the grade, kind, and extent of the tumour. Pathologists frequently evaluate several features and combine them all to make a diagnosis. The integration of such single- feature diagnostic algorithms into the diagnostic workflow and the pathologists' capacity to use such tools should be given careful consideration by those who develop them. Such AI algorithms' additional value will depend on a number of factors, including the attributes to be evaluated, how quickly findings will be available, and how usable the integrated algorithms are. Although recent studies have shown that AI algorithms have the ability to perform as well as or better than physicians at a variety of therapeutic tasks, it is crucial to take into account the context of the intended clinical use case. For instance, the AI solution could have a sub optimal performance in

a stand alone mode but can do substantially better when acting as an assistive tool for the pathologist (e.g lymph node metastasis detection (Steiner et al., 2018)).

- **Automated quantification of specific features -** There have been reported successes in increasing the efficiency and accuracy in the quantification of mitoses in breast cancer (Pantanowitz et al., 2020), prostatic adenocarcinoma (Raciti et al., 2020), automated pre-screening of acid fast bacilli (Pantanowitz et al., 2021), lymph nodes with micrometastases (Steiner et al., 2018) etc. Liquid Cytology, urine cytology and Liquid Biopsy (Lone et al., 2022) have also shown promise as a WSI modality driven by advances in AI/ML to help the analysis (*Comparison of the Hologic Genius Digital Diagnostics System With the Liquid-Based Cytology (LBC) Manual Microscopy*, n.d.).

- **Prognostic and predictive applications -** The ability to forecast a patient's prognosis and responsiveness to a particular medication based on morphological traits is one of the most significant potential uses of AI in pathology (Wulczyn et al., 2020). Currently, pathologists only employ a small number of morphological findings on tissue sections to identify the kind and grade of tumours. Multiple criteria, such as environmental patterns and distinct morphological patterns, must be combined into a single predictive score or index.

- **Integration with patient genomic and genetic profiles** - New digital biomarkers have been the focus of extensive cutting-edge research. A biomarker is a quantifiable sign of the progression of a disease. Predictive, diagnostic, risk-related, safe, monitoring, therapeutic response prediction, and prognostic biomarkers are some of the biomarker discovery categories. In this area, there is a lot of research being done, and there are some early clinical applications that will probably change how pathology is practised in the future. Digital biomarkers that predict the genotype and/or symptoms of usable mutations are being actively researched. Studies have demonstrated the ability to predict molecular aberrations and PD-L1 status solely from digital H&E slides (Coudray et al., 2018). In a similar vein, machine learning techniques that infer disease mutations have their roots in molecular pathology pipelines analysing next-generation sequencing data. It is also becoming more common to predict the protein phenotype of cells using virtual labelling of hematoxylin and eosin (H&E) slides. A detection, quantification, and spatial orientation tool that scores the quantity of certain immune cells at the invasive margin and at the centre of a tumour to provide a risk of relapse score can be used to develop cutting-edge digital biomarker tools to forecast patient outcomes (Galon & Lanzi, 2020). This can help create a model that predicts the likelihood that a patient will respond to treatment and researchers can examine the spatial distribution of the tumour microenvironment and link it with patient outcomes.

- **Pathology workflow efficiency** - Many locations that have already experienced a digital transformation have altered their processes by allowing more access to pathology slides from prior patients or by bringing in digital consultations from other locations (Hanna et al., 2019) (Schüffler et al., 2021). The potential for pathologists to analyse their cases with deeper underlying insights of what might be present in their assigned cases is increasing thanks to workflow abelledation technologies. Platforms equipped with tools for workflow abelledation can make it easier for pathologists to review highlighted cases. In order to speed up the pathologist's slide assessment, clinical decision support technologies can computationally run on the relevant input data (such as machine instrument outputs or pixels from digital images) and locate areas of interest.

1.4. Challenges with AI in Healthcare

- **Privacy Issues** - Patient data contains highly sensitive personally identifiable information (PII) (e.g., medical histories, identity information, payment information), which is protected by international regulations such as General Data Protection Regulation (GDPR) in the European Union and Health Insurance Portability and Accountability Act (HIPAA) in the United States of America. The large data requirements of most AI models and hospitals concerns over the possibility of data leakages reduce the adoption of healthcare AI technologies. For example, an AI system might be able to identify that a person has Parkinson's disease based on the trembling of a computer mouse, even if the person had never revealed that information to anyone else (or did not know). Patients might consider this a violation of their privacy, especially if the AI system's inference were available to third parties, such as banks or life insurance companies.

- **Accountability, Transparency, and Explainability** - Due to the lack of transparency and explainability associated with machine learning, it might be difficult or impossible to understand why an algorithm made a certain conclusion. There is also the issue of who has access to critical algorithms and how well they're understood, which is compounded by the usage of proprietary algorithms. Because AI systems are taking over decision-making, there are no clear criteria for who will be held responsible for any negative consequences.
- **Bias and Inequality** - There are risks involving bias and inequality in healthcare AI. AI systems learn from the data on which they are trained, and they can incorporate biases from those data. For instance, if the data available for AI are principally gathered in academic medical centers, the resulting AI systems will know less about—and therefore will treat less effectively—patients from populations that do not typically frequent academic medical centers. Similarly, if speech-recognition AI systems are used to transcribe encounter notes, such AI may perform worse when the provider is of a race or gender underrepresented in training data (Bajorek, 2019).
- **Security and cyber security** - As AI becomes increasingly used to assist in the execution of cyber-attacks, AI software could be hacked, and the data it uses can be changed or manipulated. Algorithms have been shown to be susceptible to risk of adversarial attack. Although somewhat theoretical at present, an adversarial attack (Finlayson et al., 2019) describes an otherwise-effective model that is susceptible to manipulation by inputs explicitly designed to fool them. For example, in one study, images of benign moles were misdiagnosed as malignant by adding adversarial noise or even just rotation.
- **Training** - As healthcare is getting digitized, the medical curriculum has not kept pace with introducing medical students or residents to new technologies such as AI, mobile healthcare applications, and telemedicine. There is a need to establish a framework where digital concepts are tested as part of the entrance examinations and training on the use of technologies is part of the clinical program.
- **Standardization** - Use of AI in healthcare is impacted by the liability for the predictions of an algorithm. For example, electronic health record (EHR)–derived data

from oncology patients typically exhibits wide interpatient variability in terms of available data elements. This interpatient variability leads to missing data and can present critical challenges in developing and implementing predictive models to underlie clinical decision support for patient-specific oncology care (Baron et al., 2021). It is unclear who is liable when a patient experiences serious harm because of an inaccurate prediction. One could argue for any of the involved parties: the physician, the hospital, the company that developed the software, the person who developed the software, or even the person who delivered the data. Standards for use of AI in healthcare are still being developed (Evans & Zweig, 2018) (Center for Devices & Radiological Health, n.d.). New standards for clinical care, quality, safety, malpractice, and communication guidelines have to be developed to allow for greater use of AI.

1.5. Challenges with AI in Digital Pathology

- **Access to large well-annotated data sets -** Histopathology data annotation is the most cumbersome step. Hence, acquiring labeled data is the main hurdle. Obtaining within image annotations from pathologists is difficult as this is a very tedious, eye-straining, mundane work which requires an exponential amount of time and expenses. In addition, when used on other sites from under served geographical areas, the same ML model trained although using these clinical grade data of expert quality, high volume and diversity may not generalise well (Campanella et al., 2019).

  A structured initiation of a facility for labeled dataset in a country requires a central large-scale annotated pathology dataset effort to move forward; this is possible by creating a common resource pool by all the medical institutions together. Crowd-sourcing, grand challenges and involvement of post-graduate Pathology students through interesting contests can partially solve this issue. Since, laboratory processing variability is another huge obstacle in implementing and further applications of AI solutions that are generated, it is all the more essential to have ML solutions created on data sets from different regions and different standards of labs across India. This will take care of all the pre-analytical, analytical, and post-analytical variabilities in Pathology labs. Thus, similar to the radiology DICOM, pathology formats are a must. There are several other major differences including presence of colour information in pathology images, no apparent anatomical orientation, availability of information at multiple levels so z-stacks are important, and findings have high variability with pathology image or patch interpretation always done in the context of rest of the image features, clinical information, and lab context. In contrast to the simple “yes” or “no” for binary understanding, pathology images have infinite variability and pathology diagnosis employs several processes including cognition, understanding clinical context, perception, and empirical experience. Implementation of computational pathology itself may require a significant investment in IT infrastructure. Pathology images are commonly larger than 50 000 by 50 000 pixels, translating into estimated file sizes ranging from 0.5 to 4GB. The large multi-giga byte size of these images presents a problem for evaluation, storage, and inventory management.

- **Algorithms are slow to run -** Other computing obstacles that users face are processor speed and memory requirements of local workstations, data storage requirements, and limitations of the network. Additional considerations when running deep learning algorithms include, but are not limited to, the number of intended users, flexibility of the server or cloud configuration to accommodate new algorithms or case-loads, cyber-security, and associated costs. The large size of whole slide images presents a potential hurdle for efficient processing in environments that lack sufficient bandwidth. Deep learning is best performed using graphics processing units (GPUs), which can provide significant performance enhancement over central processing units (CPUs). Most computers are designed to perform computations on their CPU and use the GPU simply to render graphics. It may be necessary to purchase a more powerful GPU designed for deep learning; these are generally more expensive and tend to generate more heat. Some laboratories may therefore elect to dedicate high-performance workstations strictly for deep learning. Whole slide imaging by the automated scanners for both brightfield and fluorescent microscopes is possible, but the cost of such imaging systems is so high (usually 1-2 crores) with additional expenses for image analysis software making them beyond reach for the majority of the Pathology labs across India.
- **Algorithms require Manual (local) Tweaking** - Quality assessment, regulatory, ethical, and cyber-security concerns are the major obstacles all over the world. In India, initiating the process for augmenting pathology rather than replacing it will be a wise step forward. This would mean AI implementation in prognostication, biomarker development, patient treatment decisions but not directly in the diagnosis, as a first step of AI Pathology. Even for these indications, the issue of patient data sharing versus

confidentiality needs clear regulations. Without sharing data with data scientists, AI cannot be implemented, and as AI has black-box effect to assess the validity of AI results, patient information would have to be shared in the public domain. These issues and appropriate consents are to be decided before starting this venture.

- **Pathology training and education -** The next generation of pathologists can benefit from the use of AI tools, which can give automatic annotations and other interactive features to create a dynamic learning environment. Additionally, pathology students and biomedical scientists can apply diagnostic AI techniques to complement primary reporting. In the early stages of the transition, these educational models will be a helpful addition to the traditional educational methods offered by the experts and will complement them. The inclusion of AI tools in the reporting workflow can give trainees access to extra data, such as lists of differential diagnoses and potential auxiliary tests that can be ordered, the difficulty and subjectivity of the lesion's diagnosis, and the pertinent educational resources, all of which could help them learn more effectively. For this to happen, properly defined protocols for training and evaluation need to be in place.
- **Algorithms are not properly validated -** The assurance that AI will soon be included into standard clinical care has increased interest in and investment in AI medical applications among governmental agencies and technical firms. Concern has been raised regarding the legal and moral implications of using AI to healthcare, though. These worries include the potential for biases, the lack of openness surrounding some AI algorithms, privacy issues surrounding the data used to train AI models, and safety and liability concerns with the use of AI in clinical settings. Hence there is a growing awareness of the fact that Algorithms must meet regulatory standards for testing and use in clinical settings and clearly the legal oversight of AI's capabilities in the healthcare industry is still in its infancy. Laptev et. al. present a state of art review to "to define the legal personality of AI and circumscribe the scope of its competencies" and present some suggestions to adequately formulate the approaches for legal regulation of AI in healthcare (Laptev et al., 2021). The rise in "Grand Challenges" is one factor that has fueled progress in computational pathology which also works in favor of improving the quality of algorithms and standardizing datasets. These are open, public competitions with a focus on key use cases in the field of computational pathology, and

they frequently offer data sets and annotations to participants so they can create algorithms, as well as test data and evaluation standards so those algorithms can be compared and benchmarked (*Ethics and Governance of Artificial Intelligence for Health*, 2021).

- **Lack of health economics** - The usability and additional value of the suggested AI technologies, as well as the possible disturbance to the current workflow, are issues that need to be taken into account. Only if AI tools are developed to function in the most necessary areas, such as screening normal cases or identifying cases that require double reporting, or in aspects where multiple components need to be assessed at once, rather than in the measurement of one or a few components, can they add value to clinical practice. Such programs will aid in making this technology as useful and efficient as possible. The cost benefit ratio as well as the clinical relevance of the integration of the AI tools in the pathology workflow and patient pathways has to be considered. Since WSIs consume hundreds of terabytes of space, long-term storage costs are high and put a strain on the majority of hospitals. The long-term storage of glass slides is required by current regulations, which doubles the expense of storing diagnostic materials. Additionally, for the multimodal use case, AI systems will have to access radiology images, WSIs images, genomic data, and in situ hybridization data, which adds another layer of complexity to the integration process.

2. Background

In this section we will highlight the various healthcare challenges, AI use cases, technology initiatives, government policy and privacy initiatives in India.

2.1.Healthcare Challenges

- There is a shortage of qualified healthcare professionals, services and infrastructure.
- The accessibility to healthcare is non-uniform, with a glaring disparity between rural and urban India. This problem is further accentuated by lack of consistent quality in healthcare across the country.
- With private spending making up the majority of healthcare costs and the majority of these being out-of-pocket spending, which is one of the highest in the world, affordability continues to be an issue.

- The majority of patients only visit a hospital or doctor when their disease has progressed to an advanced stage, increasing the cost of treatment and decreasing the likelihood of a full recovery. This reactive approach to essential healthcare is largely the result of lack of awareness, access to services, and behavioral factors.
- The Covid-19 outbreak exposed the broken state of the current healthcare system, which works inefficiently by healthcare professionals, payers, and patients operating in silos.
- Only a small number of hospitals in India have either an HIS or an EMR that has digitalized patient records. The majority of records are still on paper. Even though India has an electronic health record (EHR) policy in place, sharing data between different hospital chains is still a work in progress because different chains have varied definitions of what "digitizing" information means.
- Due to its slow adoption rate, lack of enabling data ecosystems, inadequate availability of experienced workers and skilled personnel, high initial cost, unclear regulations, unattractive intellectual property regimes and deficiencies in its large-scale and extensive dissemination throughout the healthcare industry, there is still a sizable gap in the full utilization of artificial intelligence.
- Cost reduction will provide a significant challenge for hospitals as India transitions to a value-based healthcare ecosystem. Effective care management will be required, which means hospitals must actively manage their patients in order to enhance patient health outcomes. This will be crucial for both their reputation and the money and incentives they receive from insurance companies.

2.2.AI use cases creating impact

In order to screen for diseases like diabetic retinopathy, cancer and cardiovascular disease, AI is already being incorporated into diagnostic algorithms.

- With increasing cases of diabetes, the prevalence of **diabetic retinopathy** is increasing in India. Early detection and rapid treatment of the illness can decrease the burden of sight-threatening retinopathy.

  As a pilot project, the NITI Aayog is collaborating with Microsoft and Forus Health to introduce a technology for the early identification of diabetic retinopathy (Awasthi, n.d.). A portable screening tool for common eye issues, 3Nethra was created by Forus Health. Utilizing Microsoft's retinal imaging APIs to integrate AI capabilities, 3Nethra's operators may now get AI-powered insights while working at eye checkup clinics in remote locations with spotty or nonexistent cloud connectivity. The resulting technological solution also addresses problems with image capture quality and provides system checks that assess the usefulness of the obtained image. However, due to the range of populations examined, generalizability is an issue.

- **Cataract** is a major cause of preventable blindness in India. To overcome the resource limitations associated with screening a large number of people for cataracts, the Tamil Nadu e-Governance Agency (TNeGA) has created a smartphone app based on artificial intelligence (AI) called ePaarwai (*AI-Based Cataract Screening App Developed by TNeGA*, n.d.). The app may be used to perform a quick eye screening by just clicking a photo. Additionally, macular disintegration can be found using the application. The software was introduced with the assistance of the Tamil Nadu State Blind Control Society (TNSBCS), and is currently undergoing testing in a few districts. The outcomes of the field experiments are quite positive. If these initiatives are successful, it will prevent the loss of vision in millions of old people living in low-income communities in cities and rural areas.
- **Breast cancer** is the most common cancer for women in India. A constantly improving, scalable breast cancer detection service (thermography, non-contact, non-invasive, and non-radiation-based) is being provided by NIRAMAI Health Analytix using TensorFlow machine learning models and containerization with Google Kubernetes Engine. NIRAMAI is harnessing AI and ML to enable early identification of breast cancer and subsequently to increase survival rates from the disease (*NIRAMAI Health Analytix Case Study*, n.d.). The core concept of Niramai is a portable, low-cost, automated, and accurate cancer screening device that may be used in any clinic. In the future, it plans to increase the model's or method's capacity for a full body study.
- Due to shortage of expertise in **cardiovascular diseases** at the peripheral centres, often there is a delay in the diagnosis of cardiac conditions, which leads to increased morbidity and mortality. One of the startups working to solve this problem is Tricog, which has leveraged existing IoT networks aided by cloud connected ECG and Echo machines (**InstaECG and InstaEcho**) and in-built algorithms that receive, interpret and send back analysis (*Accelerating Cardiac Care*, 2022).

Table 3 – List of other possible use cases in Indian scenario

Patient Journey	• Health detection and monitoring using speech signals • Automated chatbots for scheduling appointments, collecting basic details and symptoms, post intervention followup, etc. • Prediction of patient waiting times in various departments, especially emergency • Prevention and early detection of patient fall in hospital • Generating insights from patient feedback
Physician Journey	• Optimisation of workflow by use of electronic emergency triage and patient priority systems • Speech based entry of notes • Prediction of avoidable readmissions or hospital length of stay • Prediction of adverse surgical outcomes • Prediction, prevention, or early detection of adverse drug events, decompensation, and diagnostic errors
Administrative	• Demand prediction e.g., forecasting outpatient visits, prediction of ambulance demand, predicting peak demand days of cardiovascular admissions, predicting patient punctuality in ambulatory care centres, etc. • Optimisation of hospital bed management, planning and usage • Prediction of healthcare costs • Optimisation of revenue cycle management and billing • Optical character-reading systems to scan prescriptions and check prescribed medications against the inventory. • Identification of fraud in provider claims data

https://www.researchgate.net/publication/358897338_Artificial_Intelligence_in_Healthcare_2021_Year_in_Review
https://www.researchgate.net/publication/349570341_Artificial_Intelligence_in_Healthcare_2020_Year_in_Review)

2.3. Technology Initiatives

- **The Ayushman Bharat Digital Mission (ABDM)** aims to establish a national digital health ecosystem that supports universal health coverage while being effective, affordable, accessible, inclusive, and safe. It also provides a wide range of data, information, and infrastructure services while appropriately utilising open, interoperable, federated, standards-based digital systems and ensuring the security, confidentiality, and privacy of health-related personal information.

  The current robust public digital infrastructure, which includes that connected to Aadhaar, Unified Payments Interface, and the extensive use of the Internet and mobile phones, offers a solid foundation for developing the foundation of the Ayushman Bharat Digital Mission (ABDM). The current ability to digitally identify individuals, physicians, and healthcare facilities, enable electronic signatures, guarantee non-repudiable contracts, make paperless payments, securely store digital records, and make contact with people, opens up possibilities for streamlining healthcare information through digital management.

  https://ndhm.gov.in/abdm
- **5G services have been launched in India on 1st October, 2022.** 5G technology can improve quality and access to healthcare facilities by ensuring medical aid in remote areas, tele-health, specialised healthcare at primary care centres and connecting them to speciality hospitals.
- **The 04 pillars of Digital India**

  (https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1864246)

  1. **Cost of Devices –** With *AatmaNirbhar Bharat* the cost of devices can be reduced to a large extent. In the year 2014 there were 02 mobile manufacturing units in the country, whereas presently there are 200 manufacturing units. India is now at second position in the world for manufacturing of mobile and is also a large exporter of mobiles.
  2. **Digital Connectivity –** Country has made a huge progress; in 2014 there were 6 cr Broadband users which has now increased to 80 crore users. Approx 100 GPs were connected with OFC in the country and now more than 1,70,000 GPs in the country are connected with OFC. Internet users in the rural areas of the country are growing at a faster rate than the urban area.

3. **Cost of Data –** The cost of data has reduced from Rs. 300 per GB in 2014 to Rs. 10 per GB in 2022. Average Data used per person is 14 GB per month, and reduction in cost of data has brought considerable savings per month for citizens.
4. **Idea of Digital First –** Many people carried the opinion that the rural poor of this country will not be able to adopt digital technology, but the citizens, particularly the rural people, have made these assumptions wrong. Rural India is fast adopting the digital technologies and internet in their daily lives.

2.4. Policy and Regulation around AI

Here is a summary of the various AI standardization, policy and regulation activities being pursued by multiple agencies in India .

Table 4 – Summary of AI and technology related policy and regulation in India

	Committee/Ministry	*Summary*
1.	INDIAai (The National AI Portal of India) (*The National AI Portal of India*, n.d.)	A joint venture by Ministry of Electronics and Information Technology (MeitY), National e-Governance Division (NeGD) and National Association of Software and Service Companies (NASSCOM), has been set up to prepare the nation for an AI future. It is the single central knowledge hub on artificial intelligence and allied fields for aspiring entrepreneurs, students, professionals, academics, and everyone else. The portal focuses on creating and nurturing a unified AI ecosystem for driving excellence and leadership in India's AI journey, to foster economic growth and improve lives through it.
2.	NITI Aayog's National Strategy for AI - #AIForAll, 2018 (*National Strategy for Artificial Intelligence*, n.d.)	Policy focuses on how AI may be used for both economic growth and social inclusion. The plan intends to: 2. Enhance and empower Indians with the skills to find quality jobs. 3. Invest in research and sectors that can maximize economic growth and social impact. 4. Scale Indian-made AI solutions to the rest of the developing world. The approach aims to use AI to drive economic, social, and inclusive growth, as well as serve as a "Garage" for rising and developing economies. Sectors include - Healthcare, Agriculture, Education, Smart Cities, and Infrastructure, and Smart Mobility and Transportation.
3.	Ministry of Electronics and IT (MeITy), 2019	Focus on the impact of AI on the economy and society. Created 4 committees -

	(*Artificial Intelligence Committees Reports*, n.d.)	• Platforms and data on AI • Leveraging AI for identifying national missions in key sectors • Mapping technological capabilities, key policy enablers required across sectors, skilling, and reskill • Cyber security, safety, legal and ethical issues
4.	Ministry of Commerce and Industry, 2017 (*Artificial Intelligence Task Force*, n.d.)	Goal to embed AI in our Economic, Political and Legal thought processes so that it is the systematic capability to support the goal of India becoming one of the leaders of AI-rich Economies
5.	Department of Telecom (DOT), 2019 (Anjali, n.d.)	Established a group in 2019 to standardize AI technology by combining the knowledge of many stakeholders. The Committee has requested papers on Artificial Intelligence from all interested parties. These original publications aimed to cover a wide range of AI topics, including functional network architecture, AI architecture, data structures necessary etc.,
6.	Bureau of Indian Standards (BIS), 2017 (*Standards National Action Plan*, 2019)	The council includes professionals from top research institutions, academia, government entities, and technological businesses. The group would concentrate on the standardization of projects involving cyber security, legal and ethical challenges in the IT sector, technological mapping, and the use of AI for national missions.
7.	Indian Council of Medical Research (ICMR) (*Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare*, n.d.)	Ethical guidelines for application of AI in biomedical research and healthcare.

2.5. Privacy

- In addition to the rights afforded by the Indian Constitution**, NITI Aayog's National Strategy for AI** prioritizes principles of privacy, ethics, security, fairness, transparency and accountability.
  https://indiaai.gov.in/news/niti-aayog-launches-first-of-two-part-approach-paper-on-responsible-ai-adoption
- **The Ayushman Bharat Digital Mission (ABDM)** takes a citizen centric approach, and identifies citizens as the owner of data. It defines that all the data is to be federated and stored close to the point of generation (Federated Architecture). Also, security and privacy is to be built into the design and development of the APIs, which should be audited for security and privacy before deployment.
  https://ndhm.gov.in/abdm
- Data access must be subject to **accountability and informed consent**. Patients need to be made fully aware of how their data may be used to train AI models and of the specific circumstances that led a doctor to recommend a particular course of therapy. In the Indian context, where doctors typically spend relatively little time with each patient, this is very crucial.

3. Terms of Reference (TORs) for the Task Force

The terms of reference for the Task force were as follows:

- To identify the current status of Artificial Intelligence in Healthcare in the country
- To identify the deficiencies/issues which need to be addressed
- To suggest measures to improve the use of Artificial Intelligence in Health Care

4. Methodology

On receipt of the Terms of Reference from the NAMS Executive Council, the Task Force (TF) was convened under the Chairmanship of Dr. Chetan Arora, with membership from a cross section of domain experts (list at Annexure 1).

Through a process of discussions in the virtual mode, a consensus was reached amongst the Members of the TF, on the methodology to be adopted for developing the guidelines. The task at hand was divided into sections and members allocated the sections based on their specific domain expertise.

An extensive literature review was undertaken using the websites PubMed and Google Scholar using the search terms “Artificial Intelligence” AND “Healthcare” for English language documents, with a preference for Review articles, Clinical Trials , Consensus Statements and Guidelines. Professional Society websites were browsed for latest guidelines and consensus statements. Thus, almost all published work from India was reviewed along with all similar international work on AI for Healthcare. A synthesis of the obtained literature was prepared and deliberated upon by the Task Force.

A series of weekly meetings were conducted in virtual mode for reviewing the progress being made, and to discuss the allocated sections of the White Paper.Minutes of the Meetings were prepared and circulated within the TF for information and guidance.

While developing the document, the PICO framework was relied upon to define the various stakeholders and recommend the interventions required.

Iterations of the document developed with the contributions of the members were circulated and discussed sequentially over the term of the TF. This modification of the Delphi technique was essential for the process of eventual consensus, as the guidelines required reference to the latest evidence and conformity with professional Society guidelines, keeping in view the requirements of the country and the best interests of the patient population.

5. Observation /Critical review

5.1. Current situation in the country

- There is a shortage of qualified healthcare professionals, services and infrastructure.
- The accessibility to healthcare is non-uniform, with a glaring disparity between rural and urban India. This problem is further accentuated by lack of consistent quality in healthcare across the country.
- With private spending making up the majority of healthcare costs and the majority of these being out-of-pocket spending, which is one of the highest in the world, affordability continues to be an issue.
- The majority of patients only visit a hospital or doctor when their disease has progressed to an advanced stage, increasing the cost of treatment and decreasing the

likelihood of a full recovery. This reactive approach to essential healthcare is largely the result of lack of awareness, access to services, and behavioral factors.

- The Covid-19 outbreak exposed the broken state of the current healthcare system, which works inefficiently by healthcare professionals, payers, and patients operating in silos.
- Only a small number of hospitals in India have either an HIS or an EMR that has digitalized patient records. The majority of records are still on paper. Even though India has an electronic health record (EHR) policy in place, sharing data between different hospital chains is still a work in progress because different chains have varied definitions of what "digitizing" information means.
- Due to its slow adoption rate, lack of enabling data ecosystems, inadequate availability of experienced workers and skilled personnel, high initial cost, unclear regulations, unattractive intellectual property regimes and deficiencies in its large-scale and extensive dissemination throughout the healthcare industry, there is still a sizable gap in the full utilization of artificial intelligence.
- Cost reduction will provide a significant challenge for hospitals as India transitions to a value-based healthcare ecosystem. Effective care management will be required, which means hospitals must actively manage their patients in order to enhance patient health outcomes. This will be crucial for both their reputation and the money and incentives they receive from insurance companies.

5.2. Implementation status & challenges in context of the AI

In order to screen for diseases like diabetic retinopathy, cancer and cardiovascular disease, AI is already being incorporated into diagnostic algorithms.

5.2.1.Implementing AI Technology

AI technologies, such as machine learning and natural language processing, have the potential to provide new insights into complex health data (Morrow et al., 2022). AI methods are becoming increasingly implemented in healthcare as decision support tools, business intelligence tools & diagnostic tools. This is a constantly evolving field, and there is much interest in collecting and mining big data using standardized methods and AI modeling.

Data is often referred to as the lifeblood of AI, and powerful algorithms generated by AI are steadily entering and transforming the decision-making processes in all areas of health care, public health, and medical research. Lessons learned from the pandemic and exponential growth of data in the Indian healthcare system warrant the use of AI for gathering evidence-based-insights with agility and ease in real world medicine. Digitization in India took a rapid pace during the pandemic, replacing the conventional systems with advanced technology to connect people and provide them with real time public health information by the central, state and local governments. But the country faces significant gaps, delays and challenges in data management and governance at enterprise levels of the healthcare system. India's massive wealth of data and insights is trapped in silos within the legacy core that must be freed to create a data-driven healthcare system. Government legislation to facilitate data collection and sharing will create the foundation for adopting and implementing AI technologies in the vast healthcare system.

5.2.2.Main challenges

The main challenges are (i) **Lack of data** in ready-to-use form (ii) **Inadequate infrastructure and connectivity** , particularly in rural areas (iii) Lack of **regulation and governance** about how these technologies will be used, who will be responsible for deployment, and how data privacy and security will be protected (iv) Lack of skills due to the **shortage of skilled personnel** to build and deploy AI solutions (v) Adequate and timely **funding and investment** that can limit or halt the development and deployment (vi) **Ethical and societal concerns** about implications of AI, particularly in terms of the impact on jobs, privacy and equality.

5.2.3.Potential of AI technology

Despite these challenges there is a growing recognition of the need to overcome these challenges, which requires political will and vision, to fully realize the potential of this technology.

1. **Healthcare Data Collection and Management:** The government of India has already proven to the world its remarkable potential of digitization by implementing the largest 21st century system of Unique Identification (UID) to over a billion Indian residents. The UID system of India has laid the cornerstone of the largest demographic data in the world. Utilizing this UID system for planning and developing state-of-the-art healthcare data exchange systems and storage across the country can improve the functioning of the health care system in India. India's capabilities in health information technology (HIT) have been tested and recognized in other countries like, USA, UK, and Europe. Well-

developed health information systems with data exchange capabilities are necessary in both public and private sectors of healthcare to enable robust data-driven AI technologies.

2. **Data Sharing and Data Federation:** Central and State level Health Information Exchanges (HIEs) can help share patient-care data while protecting the privacy of citizens. Data privacy and portability can be ensured using technology and government policies. Upgrading current state databases and state disease registries can bring data from disparate and fragmented data sources in public and private sectors. Building a public-private coalition to ensure data collection has proven effective during the Covid 19 pandemic. Data collected from state level databases can be integrated into a federated data storage system governed by the central government of India. Framing legislative acts and rules to govern data collection and to enforce them in a fair, transparent and accountable manner are key characteristics of a well-functioning data driven health system.
3. **Data Quality and Types of Data:** The Ministry of Health and Family Welfare (MoHFW) may take the leadership to expand and integrate the existing fragmented systems. Currently the MoHFW uses a Health Management Information System (HMIS) to monitor the performance of programs across states through a large network of rural and urban health facilities. Official records state that 179,000 facilities report data every month. However, this information is often not fed back into the system or to the facilities from which the data is collected (*India Health System Review*, n.d.). Setting data quality standards and integrating disparate healthcare sources of data can lay a strong foundation for implementing AI technologies. Automatic information retrieval from unstructured text in medical records is greatly aided by Natural Language Processing (NLP), the primary approach taken in this field to gather more insights (Malden et al., 2022).
4. **Standardization of Data:** Guidelines for health care data standards are required at national level to align with international standards and quality. Implementing the international coding systems and terminologies for gathering and analyzing clinical data (ICD 10), pharmacy data (RxNorm), lab data (LOINC) and

administrative data (Revenue Codes) are required for ensuring standardization of data. The Insurance Regulatory and Development Authority of India (IRDAI) through its data analytics arm regularly collects and publishes information on the number of health insurance policyholders, total premiums collected, claims paid out and by schemes (Wiersinga & Prescott, 2020). The deficiencies of this system could be mitigated by expanding the Prime Minister's Jan Arogya Yojana (PM-JAY) that has a national database storing data from all transactions across the country. The government should take measures to collect, use and disseminate information and data from the private sector, which remains a challenge. Upgrading the PM-JAY infrastructure can help gather strong and reliable data.

5. **AI based Automation and Opportunities:** Deployment of AI and automation technologies can improve the quality of healthcare delivery, lift the economy, and increase the prosperity of India in healthcare and other industries. While India's contribution to global pharmaceutical production is well-known, using AI technologies in medical research can open avenues for new discoveries and innovation. India is growing as a hub for international medical tourism and receives large numbers of patients from developed and developing countries. Establishing data standards and deploying AI tools can bring in more revenues, more growth, and opportunities for medical tourism as well as the quality of care. Medical AI has been widely adopted and applied in western countries despite some ethical and legal challenges narrated in this document. Studies show that the public acknowledges the unique advantages and convenience of medical AI. The standard application and reasonable supervision of medical AI is key to ensuring its effective utilization. Using AI to analyze real world data can improve real time health care services to protect and save lives. Implementing and applying medical AI, while ensuring safety in healthcare practice, can help India to set up an intelligent public health monitoring system and diagnosis system for early detection and prevention of communicable and non-communicable diseases. This in turn will help build a healthy nation, reduce per capita expenditure for healthcare and improve productivity.

6. **AI Pragmatic Framework** This section is intended as a framework for Ai implementation. Several of the already discussed topics are addressed in this example and can be used to develop a richer standard,

Rationale: Non-Communicable Diseases (NCDs) such as cardiovascular disease, cancer, and chronic respiratory disease, are a major source of preventable illness, disability and mortality worldwide. Furthermore, chronically ill patients often suffer from multimorbidity, which can be defined as the co-occurrence of several chronic conditions within one person. NCDs place a significant burden on health systems, presenting a challenge to universal health coverage. The World Economic Forum estimated that the world would lose $47 trillion USD, during 2011–2030, due to NCDs and mental illness. In Europe it is estimated that NCDs account for 550 000 premature deaths of people of working age with an estimated €115 billion economic loss per year (0.8% of GDP). These costs are spent on the treatment of such diseases that to a large extent are preventable. Furthermore, only around 3% of the health care budgets are currently spent on preventive measures although there is a huge potential for prevention using high quality data and Artificial Intelligence (AI) tools at the point of care for diagnostics (e.g., cancer identification, cirrhosis), automated risk assessments, treatment, care workflows and surveillance. In addition, AI can help spot high risk populations (over very large data sets, not humanly manageable) with risk factors related to poor nutrition, prior conditions, prior acute visits and harmful use of substances.

The global AI market for healthcare is poised to be over $150 billion USD over the next 5 years. The technologies include massively large data quality analyses, automated tools for interoperability, unstructured and unnatural language elements in data, image, video and omics classifications to enable accurate identification of patients at-risk, disease progression, right level of service, optimal care and the right destination (e.g., Hospital stay, ICU, HDU or another emergency service or home health or discharge to the home). Preventing unnecessary Emergency room visits (or frequent attenders) can reduce costs per patient, optimize the use of Emergency room capacity, enable capacity planning for hospital bed-use, and reduce burden on the clinicians, while improving patient outcomes and quality of care.

Adoptability: For AI tools to be used and adopted by clinicians' validation has to be done on the algorithms on retrospective and prospective ER data to identify at-risk patient-cohorts (e.g., Pneumonia, Liver or Kidney or Cardiac patients). The outcomes include high ER utilization and likely unplanned repeat ER visits in the future. The machine-driven algorithms can ingest multiple years' worth of Emergency room records (**de-identified**) from an EMR system covering 100s of the thousands of unique patients, The hypothesis is that patients with "rising and acute" cardiovascular (including Liver) conditions will likely be at high-risk of future Emergency Visits within 7, 14, 21 and 28 days of discharge from the Emergency room. In addition, AI can help detect the likely at-risk population that would meet criteria for hospitalization (and hospital bed utilization), and a further subset are likely to be "steered" to the ICU to treat critical Liver patients. Several factors contribute to ER visits, and they include GI Bleed, Fever, Hepatic Encephalopathy, Cirrhosis, Trauma, Pneumonia and other infection conditions. In addition, we anticipate that the AI algorithms will identify further factors that could be contributing to an ER visit, repeat ER visit and utilization.

Validation to build trust: modeling and validation AI driven algorithms can help transform and drive new pathways and clinical decisions for patients admitted to the ER. The study leverages prior work done on a range of validation methods for Emergency room visit risk, utilization risk and repeat admissions to the ER. Prior studies include applying AI methods and tools over very large data sets to extract relevant risk factors for predictive modeling, clinical decision tools and outcomes improvement.

a. **AI System:** Identifying at-risk patients through ER records using automated and AI driven tools is novel and challenging. In addition, identifying patients at-risk of unplanned and repeat ER visits is of great challenge as patient cases have to be monitored either at the hospital with appropriate treatments or discharged home with specific medication therapy. Across the world there is interest in examining value-based care models to reduce costs, improve quality of care and outcomes for patient populations. Value-based models with support from AI driven tools are being investigated and promoted by CMS (e.g., Bundled Payment

Initiative-Advanced) in the US, the Dutch healthcare and UK health systems, and lately the Indian Government (NHA).

Big and High Quality Data Challenges: Sound medical diagnosis and follow-up care are crucial for a patient's quality of life and survival. Equally important is the ability of the clinicians to identify the patient's risk accurately for the right level of care. Any misdiagnoses can change the clinical paths, and can increase costs of care, and lead to adverse outcomes, and drive hospitalization costs as high as 500 Crores across India annually. In the following, we present the study design, population characteristics, adaptive NLP, machine learning models and accuracy of our adaptive NLP system on identifying factors from the ER visit notes (discharge notes) such as current symptoms, chief complaint, current medications, health status, Liver condition, vitals and other critical information.

b. **Design requirements** This section illustrates methods to glean risk-factors from text written in patient-visit records, demographics, labs, vitals, call-center records and surveys, and identify patients at risk. The primary aim is to glean patient risk factor information embedded (leading indicators or signals) in the discharge notes These nuggets can provide valuable early warnings on which patients to support and the level of service to be provided to the patients. Even though clinicians document nearly every patient encounter, detecting the patient conditions, past history and attributing that to the patient can be difficult. Clinical documentation is diverse and can include images, audio and multimedia, but a vast fraction of clinical information is semi-structured and unstructured text. Key objectives are as follows:

OB1: Identify and integrate (using secure ETLs and workflows into NIC-Cloud) symptoms, medications, vitals and conditions from unstructured discharge notes (e.g., NLP[1] based) using AI driven NLP tools.

OB2: Extract and Analyze text written in the discharge notes, intake summaries, surveys and related records, which can the feed into a larger Artificial Intelligence (AI) algorithm to identify patients-at-risk.

OB3: Analyze millions of discharge notes using ontology driven NLP tools, and identify high-risk patients based on clinical and social conditions written in the body of the discharge notes.

OB4: Apply dictionaries on analyzing clinical notes to extract the phenotype attributes for each patient. The dictionary terms and sub-terms include the following (e.g., fatigue, fever, GI bleed, medication counts, medication details, and more).

OB5: Double blinded comparison of automated versus manual analyses of clinical factors with clinicians.

OB6: AI driven algorithm development, refinement and validation based on the data (text and NLP driven) collected from the patients.

OB7: Validate visually, manually and through automated methods patients at risk and help with planning and support to reduce the risk of patient admissions to Emergency rooms.

Increasingly this heterogeneously structured clinical documentation is in digital form (EMR), growing 63% from 2001 to 2020 among clinical practices in many western countries. The volume of documentation is so great that it is impractical to sift through a large number of patient charts to determine non-adherent activity. Semantic differences, variation in documentation styles, and heterogeneous documentation traditions (e.g., physicians vs other clinicians) make for difficult manual evaluation. Automated decision tools are needed to enable the following:

Identification of modifiable risk factors for NCDs (e.g., diet, exercise, smoking, alcohol consumption, comorbidities) with the insights leading to interventions to ameliorate these factors and improve health: through identifying correlations between risk factors and disease can be identified by applying analytics on datasets that include information about health outcomes as well as about potential risk factors. Input can come from EHRs, data collection tools such as sensors of patient disease symptoms, real-time monitors of behavior, etc. Machine learning can lead to novelty in the measurement, prevention, and treatment of NCD by creating individualized risk profiles that are linked to a customized intervention plan.

Monitoring & measuring health behaviors: Patient generated data can originate from IoT sensors, connected devices, wearable devices, like smart watches and exercise trackers and can be tracked and assessed. AI systems can employ monitoring devices that apply advanced analytics and AI to derive insights on diseases and identify patients who are at risk of decline, whether in the hospital or home, so that providers can proactively intervene, AI-features like early warning score systems, whose algorithms are built upon big data sets, help detect potential deterioration early allowing clinicians to take preventative action to improve patient outcomes.

Algorithms that provide personalized feedback & treatment to patients: In addition to monitoring, AI systems can provide personalized feedback to assist with behavior modification at key moments of decision making (e.g., encouraging exercise at the end of the workday, or giving a personalized warning about location based environmental triggers). Transformative technologies such as big data interoperability and management, AI and machine learning have the potential to expand the capacity for digital health management and clinicians to provide integrated, accessible care that channels expertise and personalized treatment to the individual patient.

c. **Design and Validation** The AI system needs millions of records, terms and sub-terms to allow for constructing a phenotype for risk and point of care workflows. The table below captures the structure and characteristics needed for validation and trust building amongst clinicians prior to use.

Table 5 – Study design and patient characteristics for the analyses of patient Clinical Factors

Patient Characteristics and Risk Factors Characteristics	Learning set (Derivation)	Validation set
Gender: M/F	M/F (48%/52%)	M/F (48%/52%)
Ages: 65 to 100 (all inpatients) 28,000+ patients	All patients	All Patients
Dx: All conditions	All conditions	All conditions
Methods: Neural Networks, Tensor flows and Decision trees	70% on training and cross validation (10-fold)	30% on validation/test (and cross validation, 10-fold)

Data	EMR, Discharge, Admissions, Demographics, Labs and Vitals	EMR, Discharge, Admissions, Demographics, Labs and Vitals
Outcome variable	ER Visits, Repeat ER visits and High Utilization Risk	ED Visits
Predictor variables pruned from 150+ · Age, marital status · Medication count · BMI · Comorbidities · Substance abuse status · Symptoms · AMA · Prior history of ER and Hosp visits · Liver panel test results · Blood panel test results · Chemistry panel test results	• 70% • Cross Validation P value <0.01	• 30% • Cross Validation P value < 0.01

Data sets for our analyses of the patient Clinical Factors, we considered real-time (multiple times a day access to) clinical notes, call center records and patient surveys (conducted daily). The data sets were as follows for our analyses, machine learning and clinical (and manual) validation.

Table 6 – Data Sources

Data Source	*From*	*Type*	*Key areas*	*Years*
HIS – Emergency Room discharge notes, Labs, Vitals and demographics. Notes includes medications, vitals, symptoms and conditions		Hospital reported performance measures	· Access · Intake notes	2022
Prior Benchmark data on populations (Emergency Room Risk)		·Survey questions · Utilization ·Diagnoses · Labs ·Comorbidities	·Clinical Factors ·Exposure	2021-2022

We developed a methodology for analyzing unstructured and structured elements in patient records in order to develop actionable information for clinicians to improve care on a daily basis for both patient and other vulnerable patient populations by monitoring closely their daily Clinical Factors, conditions and health status at their homes. The monitoring was done through patient surveys conducted on high-risk patients.

e. **Validation Methods** We consider the following groups for validation: a) a derivative group, consisting of patients who are monitored; b) validation group, where the identification models are applied to compare manual versus automated methods. Calibration is needed post validation to ensure the models don't deviate from the specification with respect to accuracy of identification or forecasting.

Table-7, Validation steps and calibration

Validation Models	*Process for validation*	*Description and duration*
Multi-Year model using recent claims (similar to prospective methods)	Model using 2019 and 2020 data, and test/validate using 2021 EMR data sets	Performance of the models based on past history
Ten-fold cross validation	10-fold cross validation is a foundational model for evaluating the performance of the AI models.	Model validation based on 10-fold cross validation.
Gold Standard Test using Human Review of Identified Patients	Clinicians to review a pool of high-risk populations identified by the AI algorithms. This is a cumbersome process, but enables review	Compare the ranking of human review and the machine intelligent
Random selection of test and validation	Perform validation millions of claim records randomly selected	Validate across different test sets (selected randomly)
Prospective models	Validate predicted risk scores (and probabilities) using prospective data sets (on a monthly basis).	Perform analysis of outcomes and validate hypothesis based on future months of data

6. Recommendations

6.1. Vision

It is recommended that consensus be achieved amongst the various stakeholders in the health of the people of India, towards a national Vision *i.e.,* an open attitude towards judiciously using AI for healthcare.

The National Academy of Medical Sciences envisions a healthcare system in India, both in the public sector and the private health care system, in which a collaborative, multidisciplinary approach will ensure a digital technology-adoptive population and an AI-enabled healthcare system, through standardised, evolving, evidence based guidelines, to deliver sustainable, high quality, affordable and patient focused care.

Further to National Health Policy 2017, the goal of a AI-enabled healthcare system and digital technology-adoptive population, being proposed by the National Academy of Medical Sciences, is for attainment of the highest possible level of health and wellbeing for all, at all ages, through a preventive and promotive health care orientation, and universal access to good quality health care services without anyone having to face financial hardship as a consequence, by adding AI-enabled healthcare amongst other initiatives of the Govt of India.

6.2. Key issues / gaps identified in the current situation in the country in context of the problem/health issue

- **Privacy Issues** - Patient data contains highly sensitive personally identifiable information (PII) (e.g., medical histories, identity information, payment information), which is protected by international regulations such as GDPR and HIPAA. The large data requirements of most AI models and hospitals concerns over the possibility of data leakages reduce the adoption of healthcare AI technologies. For example, an AI system might be able to identify that a person has Parkinson's disease based on the trembling of a computer mouse, even if the person had never revealed that information to anyone else (or did not know). Patients might consider this a violation of their privacy, especially if the AI system's inference were available to third parties, such as banks or life insurance companies. It is to be noted that the Digital Personal Data Protection (DPDP) Bill 2022 is currently under consideration by the Parliament of India (*Ministry of Electronics and Information Technology, Government of India*, n.d.).

- **Accountability, Transparency, and Explainability** - Due to the lack of transparency and explainability associated with machine learning, it might be difficult or impossible to understand why an algorithm made a certain conclusion. There is also the issue of who has access to critical algorithms and how well they're understood, which is compounded by the usage of proprietary algorithms. Because AI systems are taking over decision-making, there are no clear criteria for who will be held responsible for any negative consequences.
- **Bias and Inequality** - There are risks involving bias and inequality in healthcare AI. AI systems learn from the data on which they are trained, and they can incorporate biases from those data. For instance, if the data available for AI are principally gathered in academic medical centers, the resulting AI systems will know less about—and therefore will treat less effectively—patients from populations that do not typically frequent academic medical centers. Similarly, if speech-recognition AI systems are used to transcribe encounter notes, such AI may perform worse when the provider is of a race or gender underrepresented in training data (Bajorek, 2019).
- **Security and cybersecurity** - As AI becomes increasingly used to assist in the execution of cyber-attacks, AI software could be hacked, and the data it uses can be changed or manipulated. Algorithms have been shown to be susceptible to risk of adversarial attack. Although somewhat theoretical at present, an adversarial attack (Finlayson et al., 2019) describes an otherwise-effective model that is susceptible to manipulation by inputs explicitly designed to fool them. For example, in one study, images of benign moles were misdiagnosed as malignant by adding adversarial noise or even just rotation.
- **Training** - As healthcare is getting digitized, the medical curriculum has not kept pace with introducing medical students or residents to new technologies such as AI, mobile healthcare applications, and telemedicine. There is a need to establish a framework where digital concepts are tested as part of the entrance examinations and training on the use of technologies is part of the clinical program.
- **Standardization** - Use of AI in healthcare is impacted by the liability for the predictions of an algorithm. It is unclear who is liable when a patient experiences serious harm because of an inaccurate prediction. One could argue for any of the involved parties: the physician, the hospital, the company that developed the software,

the person who developed the software, or even the person who delivered the data. Standards for use of AI in healthcare are still being developed (Evans & Zweig, 2018) (Center for Devices & Radiological Health, n.d.). New standards for clinical care, quality, safety, malpractice, and communication guidelines have to be developed to allow for greater use of AI.

6.2.1.Recommendations made to bridge the critical gaps/ deficiencies in this aspect

The measures required to be taken call for stakeholders to take effective action to create a future for India, where:

(a) The health professionals are knowledgeable about the risk factors, beneficial outcomes, and overall risk-benefit ratio of AI in healthcare, and individuals feel empowered to talk with their healthcare providers about AI-enabled healthcare whenever appropriate.

(b) Evidence-based practices for the development, deployment, and use of AI / ML in healthcare are clearly understood and routinely applied by all medical professionals in all settings.

(c) New scientific evidence is constantly being uncovered to fill gaps in knowledge, and these findings are quickly and easily disseminated to the healthcare professional educators and put into practice by healthcare professionals.

6.2. Key issues/ gaps identified in the current infrastructure, facilities, technologies, policies, programs etc. in the country in context of the problem/health issue

Data is often referred to as the lifeblood of AI, and powerful algorithms generated by AI are steadily entering and transforming the decision-making processes in all areas of health care, public health, and medical research. Lessons learned from the pandemic and exponential growth of data in the Indian healthcare system warrant the use of AI for gathering evidence-based-insights with agility and ease in real world medicine. Digitization in India took a rapid pace during the pandemic, replacing the conventional systems with advanced technology to connect people and provide them with real time public health information by the central, state and local governments. But the country faces significant gaps, delays and challenges in data management and governance at enterprise levels of the healthcare system. India's massive wealth of data and insights is trapped in silos within the legacy core that must be freed to create a data-driven healthcare system. Government legislation to facilitate data collection and sharing will create the foundation for adopting and implementing AI technologies in the vast healthcare system.

https://www.researchgate.net/publication/368983262_Artificial_Intelligence_in_Healthcare_2022_Year_in_Review;https://www.researchgate.net/publication/358897338_Artificial_Intelligence_in_Healthcare_2021_Year_in_Review
https://www.researchgate.net/publication/349570341_Artificial_Intelligence_in_Healthcare_2020_Year_in_Review)

7. Way forward

The NAMS Task Force after due deliberations on the need for current evidence about AI-enabled healthcare practices, has proposed the conduct of a rapid multi centric cross sectional study on a pan India basis, to ascertain a representative view of the real world (non AI-enabled healthcare) practices. This is intended to be undertaken to develop indigenous digital health interventions that improve the health outcomes of the population and also reduce the cost and time of healthcare delivery.

7.1.Short Term

- We need to identify the areas within healthcare where current strategies are not effective, and integration and complex analysis of novel, unstructured data are necessary to make accurate predictions.
- Automation of routine administrative tasks to enhance workflow and save costs.
- We need to identify the existing challenges, and explore solutions for enhanced assessment and adoption of technology in the real world environment.
- Different stakeholders have adopted different interpretations of 'digitizing' records. Hence, there needs to be a guiding document that erases ambiguity from these terminologies.
- There is an urgent need for an integrated technology solution that is Interoperable, Scalable, and Affordable.
- Adoption of a cloud-based health management system can reduce the challenges arising from bureaucracy and red-tapism, and operational costs.
- Investment should be made in the training of healthcare leadership and workforce. A comprehensive understanding of AI in national curricula for students studying medicine and public health is also necessary for integration of AI into healthcare systems.

- Entry of startups should be encouraged by facilitative infrastructural government initiatives.
- The principle of ART – Accountability, Responsibility and Transparency should be embedded in all AI applications. Focus should be on human-in-the-loop and human-centric designs that enable healthcare personnel to comprehend how a decision is made and how to apply this information to therapy.

7.2.Medium Term

- Data entry into Electronic Medical Record (EMR) systems can be automated by use of technologies like ambient AI, IoT and 5G.
- In order to promote coordination between academia, government, industry, NGOs, and patient advocacy groups, the government must also invest in and create public-private partnerships across the healthcare sector.
- Evidence generation, adoption and full integration of solutions need to be incentivised.
- Scaling up governance and regulatory frameworks will ensure adequate protection of privacy, equity, and openness.
- Critical investments should be made on sustainable data pipelines and infrastructure, design and processes, as well as innovative business models.

7.3.Long Term

- Having an entire department dedicated towards clinical artificial intelligence (in each health facility or in each region) may be considered in future.
- As an option instead of working in silos, a multidisciplinary group involving all stakeholders such as administration, technology, and clinical staff, is recommended.
- Data stewardship is essential to build trust and long-term integration of AI into India's healthcare system.
- Implement new AI tools alongside existing tools, so that practitioners can feel comfortable with the new tools and /workflows and experience their added value in practice firsthand while awaiting further research studies on the clinical evidence, implementation, and benefits of AI (Paranjape, Schinkel, Hammer, et al., 2021).

- Long-term success depends on a controlled approach that scales up AI in healthcare while ensuring meaningful human control and informed consent.

7.4. Digital Pathology

- Creation of five centers of excellence in Computational Pathology. This could be done along the lines of the Swiss Digital Pathology Infrastructure (SDPI) to "organically facilitate (a) multi-site clinical trials and (b) implementation of tools for increased diagnostic accuracy, quality and patient safety, while simultaneously unlocking the hidden value of DP images by (c) advancing the utilization of artificial intelligence (AI) towards improved patient-level diagnosis, prognosis and therapy response prediction"(Janowczyk et al., 2022).
- Mandate progressive digitalization of physical slide collections and the use of digital tools in the analytical phase of diagnosis
- Initiate India Specific Grand Challenges for Annotation and Diagnosis. Large country level data base collection for various cancers and non-cancer conditions must be created. The huge patient load in India can make this generation a fast process. Grand challenges and crowdsourcing with incentive based approach to attract postgraduate Pathology students to participate in such gaming competitions should be one of the immediate activities that can be started under the aegis of NAMS.
- Central regulations and guidelines for maintenance of medical records and best practices in Pathology lab. This is the most important step for the future when we are looking forward to acquiring AI based solutions for health problems and when we are implementing AI over expected similar standards of pathology tissue handling. ICMR can spearhead this activity.
- Wide scale support for purchase of equipment (e.g. digital microscopes) and software must be initiated by the Government quickly. An ecosystem for multi Institution collaboration to create a Country repository of digitized slides (including WSI) must be initiated by the government at the earliest. Such a facility can be meaningfully used only with a proactive role of NAMS and the government by Training and teaching Data Science basics and holding webinars

demonstrating the importance and applications of AI in Pathology in various medical colleges across India.

- Given the bias in datasets and the difficulty in creating datasets which are properly annotated and of the desired quality, emphasis has to be on the development of Unsupervised, Weakly supervised and Transfer Learning based models for effective use of AI in Pathology.
- Health Grid to be created which can allow access to datasets and (some) compute and storage resources.
- India specific Regulatory and Ethics recommendations for use of AI in clinical diagnosis must be defined.

7.5. Suggested Policy activities and advocacy for policy makers

AI systems are poised to drastically alter the way businesses and governments operate on a global scale, with significant changes already under way. This technology has manifested itself in multiple forms including natural language processing, machine learning, and autonomous systems, but with the proper inputs can be leveraged to make predictions, recommendations, and even decisions.

As sectors such as healthcare invest significant resources into AI, it is critical to understand the current and proposed legal frameworks regulating this novel technology (Paranjape et al., 2020). Specifically for multinational enterprises operating globally or international collaboration on healthcare innovation, the task of ensuring that their AI technology complies with applicable regulations will be complicated by the differing standards that are emerging from around the world.

We systematically searched for work going on in governments, academia, international consortiums and organizations and technology companies where policy guidelines and recommendations are being identified to address both the data and algorithm components of AI (Paranjape, Schinkel, Nanayakkara, et al., 2021). Subject matter experts in these groups include members from science, engineering, economics, ethics, regulation and policy. It must be noted that the majority of these recommendations do not directly address the healthcare industry, however, the suggested recommendations could be applicable to the use of AI in healthcare.

In the following table we briefly summarize activities that have gained significant momentum based on their impact and highlight if these are guidelines and recommendations to drive policy or enacted into legislation. We also call out if these recommendations apply to healthcare.

Table 8 – Summary of global initiatives developing AI policy and guidelines

	Initiative/Country	*Summary*

1.	General Data Protection Regulation (2016; GDPR), European Union (*EUR-Lex - 32016R0679 - EN - EUR-Lex*, n.d.)	• GDPR explicitly addresses algorithmic discrimination by –
		  ○ "Data Sanitization" – removing special categories from data sets used in automated decision making.
		  ○ "Right to Explanation" whereby data subjects are entitled to" meaningful information about the logic involved, as well as the significance and the envisaged consequences" when automated decision making or profiling takes place
		• Enacted into legislation

2.	EU AI Act (2021), European Union (*The Act*, 2021)	• RIsk-based approach - Create a process for self-certification and government oversight of many categories of high-risk AI systems, transparency requirements for AI systems that interact with people, and attempt to ban a few "unacceptable" qualities of AI systems.
3.	Internet Information Service Algorithmic Recommendation (2022), China (Creemers et al., 2022)	• Governing use of algorithms in online recommendation systems, requiring that such services are moral, ethical, accountable, transparent, and "disseminate positive energy." • Mandated companies notify users when an AI algorithm is playing a role in determining which information to display to them and give users the option to opt out of being targeted. • Prohibits algorithms that use personal data to offer different prices to consumers.

4.	National AI Initiative Act (2021), US - https://www.congress.gov/116/crpt/hrpt617/CRPT-116hrpt617.pdf#page=1210	• An overarching framework to strengthen and coordinate AI research, development, demonstration, and education activities across all U.S. Departments and Agencies.
5.	Algorithmic Accountability Act (2022), US (Algorithmic Accountability Act of 2022, 2022)	• With focus on challenges with biases and discriminatory outcomes, Act would direct the Federal Trade Commission (FTC) to create regulations that mandate "covered entities", including businesses meeting certain criteria, to perform impact assessments when using automated decision-making processes. This would specifically include those derived from AI or machine learning.
6.	U.S. Equal Employment Opportunity Commission (EEOC) (2022), US (*The Americans with Disabilities Act and the Use of Software, Algorithms, and Artificial Intelligence to Assess Job Applicants and Employees*, n.d.)	• Potential liabilities if use of algorithmic decision-making tools to assess job applicants and employees violates the Americans with Disabilities Act by, in part, intentionally or unintentionally screening out individuals with disabilities.
7.	National Science and Technology Council (2016), US - https://www.nitrd.gov/pubs/AI-Research-and-Development-Progress-	• NTSC subcommittee on Machine Learning and Artificial Intelligence • Strategy to coordinate all US government activities in AI. • Seven-point strategy with recommendations specific to healthcare (explain-ability and transparency)

	Report-2016-2019.pdf	
8.	Royal Statistical Society (RSS) (2017), UK - http://www.rss.org.uk/Images/PDF/influencing-change/2017/RSS	• RSS's recommendations to the House of Commons Science and Technology Select Committee inquiry around the use of algorithms in decision making • Recommendations include setting up an independent data ethics council to provide advice to government, public and private sector on the use of algorithms
9.	Association of Computing Machinery (ACM) (2017) US, Europe https://www.acm.org/binaries/content/assets/public-policy/final-joint-ai-statement-update.pdf	• Developed by ACM's US Public Policy Council and Europe Council Policy Committee • Seven-principles to address potential harmful biases generated by algorithms such as transparency, accountability, auditability, explanation, accountability and validation
10.	Organisation of Economic Co-Operation and Development (2017), Global (*[No Title]*, n.d.)	• OECD's report on Algorithms and Collusion recommended that policy approaches should be developed in cooperation with competition law enforcers, consumer protection authorities, data protection agencies, relevant sectoral regulators and organizations of computer sciences with expertise in deep learning.
11.	AMA Guidance for Healthcare Stakeholders (2018), US (*AMA Passes First Policy Recommendations on Augmented Intelligence*, n.d.)	• First policy on healthcare Augmented Intelligence • Report provided that the overarching goal of AI in health care is to be human-centered and augment human intelligence and advance the quadruple aim: improve population health; improve health outcomes and patient satisfaction; increase value; and improve healthcare team satisfaction.
12.	International	• Recently started a focus group to identify

	Telecommunications Union (ITU) and World Health Organization (WHO) Joint Focus Group on Artificial Intelligence for Health (2020), Global (*Artificial Intelligence*, n.d.)	opportunities for international standardization of AI for Health-relevant data, information, algorithms, and processes, which will foster the application of AI to health issues on a global scale. The goal is to establish a standardized assessment framework with open benchmarks for the evaluation of AI-based methods for health, such as AI-based diagnosis, triage or treatment decisions.

7.6. Recommendations for health/Medical professionals

Given the promise of AI for impacting the practice of medicine, there are multiple perspectives on how it may impact medical education. Since health professionals in training or junior health professionals are likely to see significant adoption of AI during their careers, it is of interest to teach how AI may be used to augment clinical workflows. There is also interest in using AI as a tool for quantitative assessment of trainees, particularly in the context of medical procedures. Finally, given the likely role AI will play in many specialties of medicine, there is a question of the appropriate level of training a clinician should have with this technology. There is a role for educational research to guide how AI can be incorporated into medical education.

In the context of augmenting clinical workflows, AI has the potential to serve as an instructional and learning tool for triaging cases, particularly those involving image and video analysis. Specifically, AI-based tools may be used to confidently identify cases for which the diagnosis is straightforward or clear (e.g., of echocardiograms), so that the clinician may focus on the challenging cases. Such integration of AI technology into medical workflows is likely to occur across all specialties for which image and video analysis is central.

AI also has potential as a quantitative assessment tool, particularly in the context of training implementation of procedures. For example, in the context of training and evaluating surgeons videos may be taken of a procedure, and AI may be used to segment the video into a series of underlying steps or tasks. One may use AI to evaluate the quality of each step as performed by a trainee, relative to a skilled surgeon, and may identify areas for trainee improvement.

Given the impact that AI is likely to have in many aspects of medicine, there is a question of how much training a clinician should have in the underlying technology. It is unlikely that most clinicians will need expertise in the methodology of AI, but they likely should understand the fundamentals of how it works, to appreciate opportunities for its use, as well as to recognize its limitations to translate its meaning when interacting with other health professionals and with patients.

7.6.1 Framework

The traditional medical curriculum, which is mostly memorization based, must follow the transition from the information age to the age of AI (Paranjape et al., 2019). Future physicians have to be taught competence in the effective integration and utilization of information from a growing array of sources (Wartman & Combs, 2018). To embed this knowledge into medicine, it is of the essence to start introducing these concepts from the beginning of training. In many countries, a Medical College Admission Test (MCAT) has to be taken to be admitted into medical school. The current United States MCAT exam, for example, focuses on biology, chemistry, physics, psychology, sociology and reasoning. These exams could start testing on mathematical concepts such as the basis of linear algebra and calculus. These concepts are vital to the elementary understanding of AI and will set the tone for the rest of the curriculum. In the core phase of preclinical didactics, time should be devoted to working with health data curation and quality, provenance, integration and governance, working with EHR's, AI fundamentals, and ethics and legal issues with AI. Course work in critical appraisal and statistical interpretation of AI and robotic technologies is also important. First, these subjects could be taught in self-contained courses, to teach about the fundamentals of these subjects that can be used even after current applications become outdated (Shortliffe, 2010). These self-contained courses could potentially replace and augment courses on medical informatics and statistics in the current curriculum. Second, they should also recur in clinical courses to familiarize students with the clinical applications of AI and work with EHR's in diverse settings. An approach to introducing AI could be to incorporate this technology during courses such as Evidence Based Medicine. As the student is taught to appraise evidence through databases such as PubMed or diagnostic tests or systematic reviews, this process could be augmented by applying concepts from data sciences, applying AI technologies such as NLP and analyzing scenarios to test them on questions of ethics and liability (Beam & Kohane, 2016). In addition, the students should also be trained in the fundamentals of computer and software engineering to understand the semantics behind real-world AI applications. For example, the basics of hardware and software development and user experience design may also be valuable.

During clinical rotations and residency, focus should shift towards relevant applications of AI in practice. With advancements in digital biomarkers(Coravos et al., 2019) and digital therapeutics (Sverdlov et al., 2018) students should also be trained in these technologies as they rely on AI. They have the potential to enable large-scale diagnostics and treatments in in-home environments in the near future (Alami et al., 2017). At the end of training, the university should include a substantial number of questions on data science and AI fundamentals in their final exams. Attendance of conferences on health care AI could be incentivized, so that health care professionals stay up-to-date with the latest developments. For attending physicians, extensive courses on AI and data science should be part of Continuous Medical Education (CME). See Table 2 for more details.

AI skills must also be balanced with non-analytics and person-centered aspects of medicine to develop a more rounded doctor of the future. Other skills such as communications, empathy, shared decision making, leadership, team building and creativity are all skills that will continue to gain importance for physicians. At the Dell Medical School at the University of Texas, Austin, the curriculum in basic sciences has been reduced in duration to accommodate training in soft skills such as leadership, creativity, and communication (Johnston, 2018).

To enable clinicians to think innovatively and create technology-enabled care models, multi-disciplinary training is needed in implementation science, operations and clinical informatics. The Stanford medical school has created such a program to train clinician-innovators for the digital future by introducing a human-centered design approach to graduate medical education (Carter et al., 2018). At the Health care Transformation Laboratory at Massachusetts General Hospital in Boston, a 1-year fellowship is offered in health care innovation exposing resident trainees to topics in data sciences, machine learning, health care operations, services, design thinking, intellectual property, and entrepreneurship (*Healthcare Transformation Lab*, n.d.).

These projects are new developments and are the first steps taken in order to introduce AI in medical education.

7.6.2 First steps

As not all of these interventions can be introduced simultaneously, we suggest a few first steps that will lay the foundation for the upcoming years. We suggest starting off by introducing questions on mathematical concepts into the MCAT. High quality web-based courses on data sciences and AI fundamentals should be freely offered in the core phase of medical education. This might lead to students focusing on applications of these subjects more naturally in following years of training.

For residents and medical students who have already finished this phase of training, courses on the fundamental subjects should be available and mandatory throughout the remaining part of their medical education. For students interested in creating new technology-enabled care models, dedicated training in health care innovation during a gap year during the clinical years or after residency should be encouraged. For attending physicians, introductory courses and refresher courses should also be made available. Extensive training is especially necessary for this group so that they can partly take back the task of educating medical students and residents on these subjects in the future. Table 1 lists suggested content that can be added to the various phases of medical education. Table 2 lists a small subset of rapidly evolving AI in healthcare conferences that physicians and trainees can attend to learn more about this technology and its applications in health care.

Table 9 – Recommendations per stage of Medical Education

Medical Education Stage	*Suggested Recommendations*	*Suggested Content*
Entrance Exams (NEET, JPIMER, AIIMS-MBBS, CMSE, CMC, MH-CET etc.	Introduce questions on linear algebra (vectors, linear transformations, matrix, solutions for linear systems), calculus (limits. Differential calculus, integral calculus), probability (joint, conditional, distribution)	Education Testing Services'(ETS) Graduate Record Examination (GRE) mathematics test
Medical School – Core Phase	Working with medical data sets (curation, quality, provenance, integration, governance), EHRs, AI fundamentals, Ethics and Legal	Data sets examples • India primary healthcare data - Kaggle (Web Access, 2018) • HealthData.gov (*HealthData.Gov*, n.d.) • Public datasets in health care (*Public Datasets: Descriptions*, n.d.) AI fundamentals • AI 101 course from MIT (Nathan, 2023) Ethics, Law • Teaching AI, Ethics, Law and Policy (Wilk, 2019) • AI Law (*Frontier AI & Robotics: Law & Ethics*, n.d.) EHR Training ("Training Courses," 1996)

Medical School – Clinical Phase	Familiarize with AI based clinical applications, Expand knowledge beyond basic principles of data/AI	Clinical Utility • Overview of Clinical applications of AI (Busnatu et al., 2022) • AI for Health and Health Care (US Department of Health and Human Services) (Aftergood, n.d.) Center for AI in Medicine and Imaging (*Center for Artificial Intelligence in Medicine & Imaging*, n.d.) AI in Healthcare Accelerated Program (*Program Info – My CMS*, n.d.)
Medical licensure exam - National Exit Test (NExT) by National Medical Commission (NMC) (Desk, n.d.)	Introduce questions on data sciences, AI, working with EHRs	Data Science Courses (*Data Science Training Course: Data Scientist Bootcamp*, n.d.) (*Data Science*, n.d.)
Residents	Detailed knowledge on clinical applications, Attend conference in health care AI	Table 9
Specialist	Stay up to date on Data/AI through CME[f] credits, Attend conference in health care AI	Table 9, Table 10

[a]MCAT: Medical College Admission Test.

[b]EHRs: electronic health records.

[c]AI: artificial intelligence.

[d]MIT: Massachusetts Institute of Technology

[f]CME: Continuing Medical Education.

Table 10– List of Artificial Intelligence in Healthcare conferences

Name of Conference	*Topics*
Ai4 Artificial Intelligence Healthcare Conference (*Ai4 2023*, 2020)	Exploring top use cases of AI and Machine Learning (ML) in health care
AI in Healthcare (*AI in Healthcare - AI World Conference & Expo*, n.d.)	Business value outcomes of AI, Experience in clinical care and hospital operations
Machine Learning and AI forum (Health care Information and Management Systems Society - HIMSS)	Data, Analytics, Real-world applications of ML and AI
AI in Healthcare @ JP Morgan Healthcare Conference (Dove et al., 2017)	AI applications - drug discovery, secure data exchange, insurer coordination, medical imaging, risk prediction, at-home patient care, and medical billing
Radiology in the age of AI (*RSNA Spotlight Course*, n.d.)	AI in medical imaging
American Medical Informatics Association (AMIA) Clinical Informatics Conference (*AMIA 2019 Clinical Informatics Conference*, n.d.)	AI in medical informatics
Association for the Advancement of Artificial Intelligence (*AAAI Association for the Advancement of Artificial Intelligence*, 2022)	"Increase public understanding of AI, improve the teaching and training of AI practitioners, and provide guidance for research planners and funders concerning the importance and potential of current AI developments and future directions"

Table 11– List of Continuing Medical Education programs on artificial intelligence in healthcare

Program	Faculty; *Organization*	Number of Continuing Medical Education credits
Artificial Intelligence and the Future of Clinical Practice (*Artificial Intelligence and the Future of Clinical Practice*, n.d.)	Computational biologist, Business economist; *Massachusetts Medical Society*	2.0
Intro to AI and Machine Learning: Why All the Buzz	Medical Informatics, Radiology; *The Radiological Society of North America*	1.0
Current Applications and Future of Cardiology (*eMedEvents*, n.d.)	Health care Technologists, Bioinformatics, Cardiology; *Mayo Clinic*	10.0
Artificial Intelligence and Machine Learning: Application in the Care of Children	Pediatric Medicine; *University of Pittsburgh School of Medicine*	1.0
Artificial Intelligence in Health care: The Hope, The Hype, The Promise, The Peril (*Artificial Intelligence in Healthcare: The Hope, The Hype, The Promise, The Peril*, n.d.)	Medical Informatics, Business Administration; *Stanford University School of Medicine*	6.0

8. Annexure

Annexure-8.1 Details of Task force members

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