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ETHICAL GUIDELINES FOR APPLICATION OF ARTIFICIAL INTELLIGENCE IN BIOMEDICAL RESEARCH AND HEALTHCARE

DHR-ICMR AI CELL, NEW DELHI, INDIA

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Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare

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ISBN: 978-93-5811-343-3

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Published by:

Indian Council of Medical Research
V. Ramalingaswami Bhawan, P.O. Box No. 4911
Ph: 91-26588895 Fax: 91-11-26588662
Email: icmrhqds@sansad.nic.in
www.icmr.gov.in

Designed & Printed at M/s Aravali Printers & Publishers (P) Ltd., W-30, Okhla Industrial Area, Phase-II, New Delhi-110020, Phone: 47173300, 26388830-32

These guidelines may be followed by all stakeholder, including innovators, developers, technologists, researchers, healthcare professional, Ethics Committees (ECs), Institutions, sponsors, and funding agencies involved in research related to artificial intelligence in biomedical research and healthcare.

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FOREWORD

Artificial intelligence (AI) is one of the most promising technologies in the coming decade and healthcare sector is the one to benefit the most by integrating with AI. Medical AI has enormous potential to overcome some of the major challenges in healthcare, such as lack of medical professionals and infrastructure, rising healthcare costs, and difficulties in the implementation of new technology due to the complex healthcare system.

The adoption of AI technology in healthcare is growing in India. However, AI as data-driven technology has many potential ethical challenges which include algorithmic transparency and explainability, clarity on liability, accountability and oversight, bias and discrimination.

I am happy that the DHR-ICMR AI Cell has identified the need to develop these guiding ethical principles concerning AI/ML-based tools. These guidelines will provide the ethical framework for development of AI based tools which will benefit all stakeholders, including innovators, developers, patients, technologists, researchers, healthcare professionals, ethics committees (ECs), sponsors and funding agencies involved in research related to AI in biomedical research and healthcare.

I hope that this document will contribute in the adoption of ethical standards during development of AI based tools in India.

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THE INCLEN TRUST INTERNATIONAL

RESEARCH AND TRAINING FOR IMPROVING
EQUITY, EFFICIENCY AND QUALITY IN HEALTH CARE

PREFACE

Artificial Intelligence (AI) and Machine Learning (ML) are certainly the game-changer in the space of healthcare. A wide variety of exciting and future-looking applications of AI/ML techniques and platforms are available now. Identification of disease, screening, making diagnosis, medical imaging, intelligent health operations management, personalized medicine to digital surveillance for public health, outbreak prediction, and drug discovery are only some of the emerging uses of AI/ML. The central goal for such systems should be to make the AI-assisted platforms available **for the benefit of largest section of common people with safety and highest precision possible.** Human beings are the target and that makes the goal complex and demanding. Data quality, data ownership, usability, trust of the patient-doctor duo on AI software's effectiveness, risk acceptance by the doctor and the patient and ethics are among the various challenges that should be taken up as medical profession increasingly applies AI based solutions.

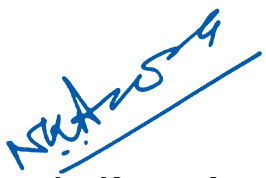
Patient privacy, confidentiality and ethics are of paramount concerns for this emerging field of biomedical research and its application. ICMR is the apex body for conduct of biomedical research and has been at the forefront to set

the standards on ethics in biomedical and health research. The ICMR ethical guidelines are highly regarded not only in India but in a number of other nations.

The purpose of the Guideline is to provide an ethics framework which can assist in the development, deployment, and adoption of AI-based solutions for biomedical research and healthcare delivery. The guidelines are intended for all stakeholders involved in research on artificial intelligence in healthcare, including creators, developers, technicians, researchers, clinicians, ethics committees, institutions, sponsors, and funding organizations. The document includes separate sections addressing ethical principles for AI in health, guiding principles for stakeholders, ethics review process, governance of AI use for healthcare and research, and informed consent process involving human participants and their data. The guideline has been formulated after extensive discussions with subject experts, researchers and ethicists.

We expect the ICMR "Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare, 2023" to guide the stakeholders in ethical conduct of research that provides AI solutions in healthcare and will help in identifying and negotiating emerging ethical challenges and concerns. Similar to the basic field, ethics for AI/ML is also a rapidly evolving area and therefore the document is a live document and will be updated as and when the need arises.

Warm wishes,



Prof (Dr) Narendra Kumar Arora
Executive Director
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ACKNOWLEDGEMENTS

This document entitled 'Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare' is the result of continuous efforts of the member of the Drafting Committee of ethical guidelines of AI in biomedical research and healthcare. I thank each one of them for their valuable direction and advice during the formulation of this guidelines. In particular, I wish to express my profound sense of reverence and gratitude to Prof. (Dr.) Narendra Kumar Arora, Chairman, for his guidance, supervision and leadership.

I would like to express my gratitude to Dr. Rajiv Bahl, Secretary, Department of Health Research and Director General, Indian Council of Medical Research, New Delhi, for his support.

I express my sincere thanks to Prof. (Dr.) Balram Bhargava, Former Secretary, Department of Health Research and Director General, Indian Council of Medical Research, New Delhi, for his encouragement and keen interest in publishing this document.

The publication of this document would not have been possible without the commitment and contribution of a team of scientists from the Indian Council of Medical Research and ICMR-National Institute of Medical Statistics, New Delhi.

Last but not the least, I would like to thank the project staff from the ICMR AI Cell for their valuable support at different stages of the preparation and finalization of this document.

(M. Vishnu Vardhana Rao)

Preamble

Artificial intelligence(AI) is defined as “a system’s ability to correctly interpret external data and to use those learnings to achieve specific goal and tasks through flexible adaption”[1]. AI uses complex computer algorithms to emulate human cognition albeit with far reaching capabilities of analyzing large datasets. The field of AI is rapidly expanding and has made significant inroads in almost all aspects of human life, including healthcare. The incorporation of AI-based tools and techniques is expected to improve healthcare delivery by making healthcare accessible and affordable and improving the quality of care provided. For example, Computed Tomography (CT) scans can be automatically read by AI as well as radiologists[2]. Tuberculosis screening can be done by AI using Chest X-Rays with comparable performance as molecular testing[3], and mammography scans can be used to predict the onset of breast cancer before visual signs appear[4]. As a result, AI for health has been recognized as one of the core areas by researchers as well as the governments.

An ethically sound policy frame work is essential to guide the AI technologies development and its application in healthcare. Further, as AI technologies get further developed and applied in clinical decision making, it is important to have processes that discuss accountability in case of errors for safeguarding and protection. Just like any other diagnostic tool, AI-based solutions themselves cannot be held accountable for its decisions and judgments. It is therefore important to have assignment of accountability and responsibility at all stages of development and deployment of AI for health.

Despite all the potential benefits, adopting AI for health brings to the fore several ethical, legal, and social concerns, especially as it pertains to its development and deployment. The field can be broadly guided by well-established

principles of health research but the development, as well as deployment of AI-based solutions in healthcare, has to deal with several issues, including those related to data safety, data sharing, data privacy, etc. For example, AI-based solutions can empower the masses by permitting easy and early diagnosis and access to health facilities but unsupervised use of such tools and techniques is potentially risky. It is therefore mandatory to have ethical and regulatory framework before AI for Health becomes part of health research and delivery of healthcare. While the general principles related to biomedical research and healthcare delivery are applicable to AI for health, the field also has some unique ethical considerations.

The Indian Council of Medical Research (ICMR) has formulated ethical guidance documents from time to time for promoting ethical and high quality research in India. The most recent version of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants, was released in 2017[5]. In 2019, Central Drugs Standard Control Organization (CDSCO) also brought out guidelines for evaluation of new drugs and conduct clinical trials[6]. India has given these guidelines legal status under the new drugs and clinical trials rules.

In developing AI technology for application in healthcare, broadly same ethical principles can be followed. However, since AI technology has several unique methodological and interpretation challenges and in the context of rapidly evolving healthcare scenario, the guidelines have been formulated in consultation with experts from these two fields. The purpose of these guidelines is not to limit innovation or recommend any disease-specific diagnostic or therapeutic approach but to guide effective yet safe development, deployment and adoption of AI based technologies in biomedical research and healthcare delivery. These guidelines are to be used by experts and ethics committees reviewing research proposals involving use of AI based tools and technologies.

There is no standard and commonly accepted term and therefore the term AI technology has been used to refer to AI technologies, AI applications, AI models, AI products, AI-driven solutions, or AI-based solutions in the entire document.

Scope

These guidelines apply to AI based tools created for all biomedical and health research and applications involving human participants and/or their biological data. Considering the far-reaching implications of AI-based technologies in healthcare, these guidelines are applicable to health professionals, technology developers, researchers, entrepreneurs, hospitals, research institutions, organization(s), and laypersons who want to utilize health data for biomedical research and healthcare delivery using AI technology and techniques.

Both healthcare and AI technologies are rapidly advancing and so shall the associated ethical dimensions. The document therefore shall remain a living document and undergo refinement periodically.

Applications of AI in Healthcare

The induction of AI into healthcare has the potential to be the solution for significant challenges faced in the field of healthcare like diagnosis and screening, therapeutics, preventive treatments, clinical decision making, public health surveillance, complex data analysis, and predicting disease outcomes. This list is likely to grow continuously in future.

Diagnostics and Screening

AI technologies provides an edge in diagnosing diseases. AI provides the hope to tackle the diagnosis and screening burden on the healthcare system.

As per the National Academies of Sciences, Engineering, and Medicine report, "Postmortem studies have shown that around 10 percent of patient deaths can be attributed to diagnostic errors. They also reported that the diagnostic errors account for 6-17 percent of adverse events as per the review of medical records[7].

AI-based technologies might help reduce human error in healthcare and have the potential of enhancing known methods of screening and diagnosis of disease, improving diagnostic accuracy, and guiding evidence based treatment algorithms, predicting outcomes, identifying health system gaps, with an overall impact on human health and wellness. AI technology has recently been used to predict genetic makeup based on body phenotypes.

Therapeutics, Drug Discovery and Development

AI technology such as Machine learning (ML) is being used in the field of drug discovery and epitope identification for vaccine development and has the potential to accelerate the process and make it more cost effective.

Precision medicine as the word suggests explores the possibility of delivering personalized treatments based upon individual's unique characteristics such as age, gender, race, family history and genomic variation. ML algorithms utilizing large datasets such as genomic, socio-demographic, and electronic medical records for predicting disease outcomes[8]. Genetic based analysis and personalized drugs to target specific health conditions using AI technology can guide treatment plans.

Clinical Care

Healthcare demand is ever rising and countries are facing a shortage of skilled workforce. Advances in AI have opened up new opportunities to tackle this shortage. Telemedicine and self-care via interactive chatbots,

digital monitoring devices like wearable is one of the areas which have shown significant development in the recent years. This also provides an alternative for remote monitoring and identifying early signs of disease by healthcare workers[9].

Natural Language Processing (NLP) is being utilized to analyze unstructured data like physician clinical notes to facilitate clinical decision making[10]. Google Deep Mind and IBM Watson Analytics have developed AI powered tools including mobile based medical assistant, diagnostics, clinical decision-making tools and prognostic prediction tools for improving overall patient outcomes [11][12]. AI technology can assist in self-monitoring of personal health-related parameters such as intake of nutrition, physical activity, blood pressure, glucose, lipids for identifying high risk group. AI based health coaching systems and smartphone apps using neural network and ML methods could provide solutions for medication adherence, motivation, reminders and building a care network[13]. Chatbots and robotic assistants can empower patients in self-management of Non-Communicable Diseases (NCDs) and improve decision making.

Epidemiology and Prevention of Disease

Epidemiology is the cornerstone of public health that guides policy decisions and evidence-based practice. The science involves identification of the factors and determinants of the diseases and the trends, patterns and prediction of diseases. Conventional methods of data collection involve one or two sources but AI methods have the potential to integrate data from several sources viz., surveillance, administrative, hospital data, registries and General Practitioner clinics to provide meaningful evidence. AI and ML tools allow handling large and diverse datasets efficiently with a high accuracy and offer data driven solutions for predicting the risk and strategies to mitigate them. For example

during the initial times of the COVID-19 pandemic many countries used AI based methods for early detection and tracing of contacts to monitor the spread of the disease[14].

AI solutions through medical image interpretation, scrutinizing societal, behavioural and health data, and medical records can provide decision support system both at an individual level and for large-scale preventive intervention planning. It can help in reducing risk factors and hazardous exposures in places using *Geographic Information System* (GIS) based sources and automation services.

Behavioral and Mental Healthcare

Medical AI model provides significant possibilities in behavioural and mental health treatment. Medical AI may improve psychology and psychiatric procedures in a variety of ways, including assisting patients in receiving a diagnosis, actively managing their symptoms between in-person consults, predicting and preventing probable flare-ups, and more.

Individuals with several mental and behavioural conditions exhibit distinguishable symptoms that may be diagnosed by verbal output (written or spoken), facial expressions, tone of voice, body language, and various other factors. AI psychology and psychiatry models will assist patients stay active in their self-care to assure better treatment of their illness and optimal mental and behavioural health.

Chatbots are one of potential use of AI in mental health. While mental disorders continue to carry significant social stigma, and many people struggle to express their thoughts and feelings directly, mental health chatbots provide an opportunity for individuals who are inhibited to seek direct professional psychological and psychiatric help to take their first step towards self-care.

In this approach, AI chatbots on mental health can give initial assistance for people who are not ready for professional or non-professional care, as well as augment that support in between interactions with psychologists, psychiatrists, and peers.

Health Management Systems using AI

AI has the potential of improving and optimizing operational functions in a healthcare setup or healthcare organization. Healthcare management involves scheduling, admission, Electronic Medical Records (EMR), accounting, billing, claim settling that involves repetitive task and high level of scrutiny. By leveraging AI powered tools and automated processes, the productivity could be enhanced, operational and clinical workflows could be improved and operating costs for healthcare practices could be reduced. Robotic process automation (RPA) is capable of advanced financial accounting, medical billing and claims. NLP can automate clinical documentation thus reducing the turnaround time. AI healthcare administration tools can help in in-patient and out-patient scheduling, interdepartmental coordination and patient alerts for optimizing the functionality. Thus AI technology could be useful both in patient care and in back-office operations thereby boosting productivity in health sector.

***Medical AI Software for Clinic Management Systems*:** Medical AI has the potential to make Clinic Management System (CMS) more autonomous, efficient and functional. Custom ML is rapidly being used to accomplish tasks that were previously completed by employees. Task scheduling and appointment may be automatically modified to meet changing conditions, with assignments and time-tables adjusted on the fly and notifications provided to relevant physicians and other staff to match the redirected processes. CMS model also makes it easier for clinicians to store EMR and patients to access

it, providing for quick access and preservation of health and treatment history for speedier decision-making based on a more comprehensive understanding of the patient's unique health profile.

Medical AI can assure the accuracy of recorded medical data by promoting follow-up queries when certain symptoms are reported. These models can also assist in locating a qualified specialist in the patient's insurance network and share pertinent information for future diagnosis, consultation, and treatment. CMS model may also employ to check that medical billing and claims verification, and that any prescriptions given are appropriate for the insurance benefit of the patient's individual plan and pharmacy. These AI models may also provide advanced financial accounting parameters to CMS, allowing administrators to better balance expenses and identify new potential for efficiency improvement in their firm.

Medical AI Software for Hospital Management Systems: Medical AI can enhance Hospital Management Systems (HMS) in the same manner that CMS could. Hospitals have unique issues that may provide greater potential for better functioning using AI technology. Medical AI may aid in the administration of in-patient and out-patient scheduling, where decisions on patient rotation can be made based on a range of parameters such as prognosis, prior health history, treatment response, available personnel and more. AI HMS systems can facilitate interdepartmental communication and coordination to make sure the optimal use of resources and time for best results for all patients, with alerts issued when specific areas are stressed to give direction a heads up on finding alternative solutions as needed.

SECTION 1

ETHICAL PRINCIPLES FOR AI IN HEALTHCARE

General Ethical Principles for Healthcare Research

At the outset, all health and biomedical research, whether AI-based or conventional methods, should adhere to the basic ethical principles of respect for persons (autonomy), do good (beneficence), do no harm (non-malfeasance), and distributive justice, to ensure the protection of the dignity, rights, safety, and well-being of the community and the participants. These four basic principles have been expanded into 12 general principles in the ICMR National Ethical guidelines, 2017.

These general ethical principles address most of the ethical aspects of any biomedical and health research. Nevertheless, AI for health to a large extent depends on data obtained from human participants and invokes additional concerns related to potential biases, data handling, interpretation, autonomy, risk minimization, professional competence, data sharing, and confidentiality. It is therefore imperative to have an ethical framework that addresses issues specific to AI for biomedical research and healthcare.

Responsible AI

Inclusiveness, fair, secure, and transparency are core elements of widely asserted responsible AI frameworks, but how they are operationalized and interpreted by each domain can vary. Furthermore, there is significant dispute about whether responsible AI frameworks can address the explicit and implicit biases contained within systems to assure equality in prediction judgments, particularly when applied to biomedical applications. Secure, responsible and ethical AI deployment necessitates a collaborative, multidisciplinary,

and informed approach. However, a lack of consensus on how to employ AI technology ethically has left many medical decision-makers seeking for guidance.

1. Ethical Principles for AI Technology in Healthcare

The development and application of AI technology in healthcare has to be guided by the values and principle of ethics adhered and practiced by all relevant stakeholders. AI technology uses various types of data sets and algorithms such as, supervised, semi-supervised and unsupervised learning. Although promising, the complex nature of such "machine-driven" analytical processes has prompted caution among health professionals and researchers. Unlike other fields of AI, AI for Health directly affects human life and can potentially have grave implications on all aspects of patients. Therefore, a cautious but non-obtrusive and ethical approach is mandated before these algorithms can become part of routine health sector. The issues related to safety and confidentiality of patients' health data are equally important and must be dealt with caution at all stages of development and deployment of AI for health.

Fig.1: Ethical principles in AI for Health.

The ten ethical principles in Fig 1 addresses issues specific to AI for health. These principles are patient-centric and are expected to guide all the stakeholders in the development and deployment of responsible and reliable AI for health. These principles are as follows –

1.1 *Autonomy*

When AI technologies are used in healthcare, there is a possibility that the system can function independently and undermine human autonomy. The application of AI technology into healthcare may transfer the responsibility of decision-making into the hands of machines. Humans should have complete control of the AI based healthcare system and medical decision-making. The AI technology should not interfere with patient autonomy under any circumstances.

The 'Human in The Loop' (HITL)[15] model of AI technologies gives room for humans to oversight the functioning and performance of the system. Clinical decisions made by the AI technology and the physician may be different and such disparity causes confusion to the user/patient, whether to trust the clinician or the AI technology. In such cases, the patient should be provided with both the options. Before introducing any AI technology in healthcare, consent process is must for all research projects and evaluation programs patients should be fully informed about the use of AI technologies benefits and associated physical, psychological and social risks. Patients must have complete autonomy to choose or reject AI technologies. There should be effective and transparent monitoring of human values and moral consideration at all stages of AI development and deployment.

The patient/ participant has the right to refuse consent. There should not be any coercion from the government/sponsor/researcher/healthcare professional and all other stakeholders for using such AI technologies. Over-dependency

on AI system for diagnosis and treatment may negatively affect the patient clinician relationship and autonomy of the patient. Therefore developers, institutions, hospitals, health systems and linked stakeholders should develop policies and guidelines to strengthen the autonomy of the participants.

1.2 *Safety and Risk Minimization*

Before an AI technology based system is put into widespread use, affirmation is required that the system will operate safely in a reliable manner. The responsibility of ensuring the safety of participant's lies with all the stakeholders involved in the development and deployment of the AI technology. Protection of dignity, rights, safety, and well-being of patients/ participants must have the highest priority. The risk involved with the deployment of AI technology and techniques in clinical research or patient care will differ based on the type of use case and subsequent deployment methodology used. For example, the risk involved with models running in an unsupervised way, i.e. without a human in the loop, will be more than those deployed under the supervision of AI researchers and healthcare professionals. The risk of using AI-enabled tools in areas with a high potential for harm to patients will be much higher than in other areas. Some of the risk minimization and safety points are mentioned below:

i. A robust set of control mechanisms is necessary to prevent unintended or deliberate misuse.

ii. The paramount and essential requirement is to have secure systems and software because of the sensitive nature of data in the healthcare sector.

iii. It is essential that AI technologies be designed with a pre-emptive approach to risks in such a way that they perform consistently while minimizing unintended consequences and results.

iv. AI technologies are prone to cyber-attacks and can be exploited to get access to sensitive and private information, thus threatening the security and confidentiality of patients and their data. It must be ensured that the data is completely anonymized and offline/delinked or from the global technology for its final use.

v. All AI technologies/algorithms must be tested with scientific rigor in the settings where it is intended to be used. The performance of the algorithm must be evaluated in different races, ethnic groups, age groups, social classes, and other relevant human characteristics. The researcher has to ensure that the AI technology performance is satisfactory in varied conditions.

vi. The Ethical Committee (EC) and other stakeholders must ensure that there is a favorable benefit-risk assessment. The benefit should outweigh the risk involved. The risk must be justifiable when the social and scientific value of AI technology is considered.

vii. All possible measures for participant/patient protection must be undertaken by the researcher. The measure should be reviewed by the EC and other regulatory bodies.

viii. AI technologies should be built in line with legal and data protection requirement of the country and with strict adherence to the basic principles of ethics.

ix. A robust explicitly stated mechanism should be in place to continuously monitor the performance, vulnerabilities and safety standards of the AI technology.

x. AI technologies must adhere to the highest security standard with regard to patient data. The manufacturer and all other stakeholders

must ensure timely upgradation of security standards. The security measures taken to protect the patient data must be publicized so that it can undergo rigorous scrutiny and gain public trust.

xi. Measures must be in place to protect and safeguard patients/ participants from stigmatization or discrimination due to their health status that may be revealed by the use of AI technologies. The EC and relevant authorities must scrutinize these measures before deploying AI technologies in healthcare.

xii. Similar to trials for new drugs and products, if new evidence of unintended harm associated with using an AI technology comes to light, then the researcher/ manufacturer and all other relevant stakeholders must inform the concerned ethics committee and data safety monitoring board. Post introduction also, like phase 4 trials, rare and new technology related unintended harm is to be monitored and documented. The patient/ participant must be informed about the increased risk of harm. They must have the freedom to withdraw or continue in the study/treatment.

xiii. AI technologies that have the potential to cause physical/ mental harm should have additional security measures. Additional security measures will be reviewed by the relevant regulatory bodies and shared with ethics committees.

xiv. At any stage of AI technology development, if vulnerable groups are involved, additional security measures must be in place to protect the rights and security of such groups. The researcher must be able to justify their inclusion.

xv. Special care must be given to ensure the safety and security of the vulnerable population. The composition and quality of training

datasets may not adequately represent the population in which the AI is intended to be used. The marginalized communities and vulnerable groups may be underrepresented in the training data sets. It may lead to distorted or poor performance of AI technologies. The EC, sponsors, and all other stakeholders must ensure the adequate representation of the population in the data. Exposing patients to unnecessary risk is unethical.

xvi. AI technologies that are used for predicting the possibility of acquiring a disease may predispose the patient/participant to emotional and psychological stress. This may potentially lead to the stigmatization of individuals or communities. The researcher and EC must explore methods for mitigating such harm. The patients/participants must be fully informed about the probable outcomes of using AI technology and the chances of stigmatization and harm.

xvii. The assessment of AI technology and techniques should address risks posed by the use of technology derived information, which may cause discomfort or unanticipated physical, psychological, social, economic, or legal harm.

xviii. Depending upon the risk assessment of the situation, appropriate oversight bodies/committees may be included to ensure the fairness during the development or deployment of AI technology.

xix. Risk minimization is a continuous process; all stakeholders must ensure that the objective and impact of the technology are in line with the expected performance. External audits for accessing potential risks must be encouraged. The reports of such audits have to be submitted before respective stakeholders and relevant regulatory authorities.

xx. The potential and the extent to which an AI technology can cause harm must be assessed before the deployment of AI technology for widespread use. AI technologies must not cause severe bodily injury or serious emotional distress.

xxi. AI developers, EC, and concerned regulatory bodies must review the measures taken for risk minimization. EC and other regulatory bodies can advise regarding risk minimization strategies.

1.3 *Trustworthiness*

Trustworthiness is the most desirable quality of any diagnostic or prognostic tool to be used in AI healthcare. Clinicians need to build confidence in the tools that they use and the same applies to AI technologies. In order to effectively use AI, clinicians and healthcare providers need to have a simple, systematic and trustworthy way to test the validity and reliability of AI technologies. In addition to providing accurate analysis of health data, a trustworthy AI-based solution should also be:

i. Lawful, i.e., it must adhere to all applicable laws and regulations.

ii. Ethical, to ensure adherence to ethical principles and values cherished by the community. Agencies involved in developing and deployment of AI should cultivate trust in the general public by adopting ethical principles at all stages of development.

iii. Reliable and valid, both from technical and social perspectives, to ensure predictability in the results and outcomes of AI-based solutions when applied in variety of clinical settings. The results thus obtained also should be in sync with standard assessment tools.

iv. Explainable, i.e., the results and interpretations provided by AI-based algorithms should be explainable based on scientific plausibility. It should be possible to understand the logic behind the results obtained so that AI technology is valid, reliable and responsible. The lack of information about the decision-making by AI algorithms has prompted some to label it as a "black box" which can prove a deterrent to its wider adoption. A well explainable AI-based solution is expected to improve the confidence of both the patient and the health professionals.

v. A diagnostic AI technology may produce results that are not in line with the physicians' views/ decision on disease. Such situations may question the credibility of the system as well as the doctor. In such cases, the physician may seek the help of their colleagues or may consult with AI developers. The patient should be informed about the recommendation from both the doctor(s) and the AI technology. The patient must have the ultimate autonomy to choose over whether to accept or reject the AI technology-generated decision.

vi. Transparent, i.e., details about the development and deployment must be easily available to all the stakeholders to enable them to make an informed decision. AI developers should ensure transparency in every step so that consumers can make informed choices about sharing their data and using AI. The end-user must be provided with adequate information in a language they can understand to ensure that they are not being manipulated by the AI technologies. The end-user must be informed about the intention, outcome and limitation of using AI technologies. In absence of transparent information about the processes involved it is difficult to expect large scale adoption of AI for health. This is also important for legal and regulatory

purposes in cases where undesirable clinical outcomes may arise out of the inaccurate interpretation and or recommendation by AI-technologies. Therefore, for the regulation, acceptance, and deployment of AI technologies transparency, explainability and functional understanding is necessary. Limitation in transparency of the system impairs validation, clinical recommendations, and make it difficult to identify errors and biases.

vii. Sufficient information must be published widely before deploying AI technologies in the healthcare sector. An adequate platform must be there to ensure the input of public consultation and debate regarding design, usage, safety security, etc. such information must be published regularly and must be documented.

viii. All AI technologies must comply with legal norms. Developers must be able to demonstrate and interpret how the AI technology complies with data and privacy laws. All software/ privacy policy updates in an already established AI technology must comply with legal norms.

ix. AI technologies developed outside India must have the ethical responsibility to be explicitly transparent like an indigenously developed AI technology and comply with the law. Evaluation will include all the steps as for any indigenously developed AI technology.

x. Conflict of interest arising at any stage of development must be disclosed and available on public platforms.

1.4 *Data Privacy*

AI-based technology should ensure privacy and personal data protection at all stages of development and deployment. Maintaining the trust of all the stakeholders including the recipient of healthcare over the safe and secure

use of their data is of prime importance to the successful and widespread deployment of AI. Data privacy must aim to prevent unauthorized access, modification, and/ or loss of personal data. The application of AI to personal data must not unreasonably curtail people's real or perceived liberty [16]. These practices are crucial in the healthcare sector where medical information represents sensitive data that, if misused, could harm patients or subject them to discrimination even if it is unintended. Individual patients' data should preferably be anonymized unless keeping it in an identifiable format is essential for clinical or research purposes. All algorithms handling data related to patients must ensure appropriate anonymization before any form of data sharing. It is important to know that patient identifiers can be present as "Metadata" and as "on-image" data and both need to be effectively anonymized. The issues related to the ownership of the data are complex and vary based on the national or regional laws and regulations. It also depends on the degree of data anonymization. Since often data for building AI applications is gathered from multiple diverse sources (e.g., medical and insurance records, pharmaceutical data, genetic data, social media, GPS data, etc.), it can potentially become easier to trace that data to patient and (intentionally or unintentionally) defeat the goals of privacy. Current Data Protection Act available in India is the IT Act, 2000. According to section 43A, corporate bodies possessing, dealing with or handling any sensitive personal data, or information in a computer resource owned, controlled, or operated by it would be liable to pay damages as compensation to affected persons if they are negligent in implementing and maintaining reasonable security practices and procedures to protect sensitive personal data or information[17]. To ensure privacy and security of health data, the Indian government is bringing a new healthcare data protection law - Digital Information Security in Healthcare Act (DISHA) Bill and Personal Data Protection (PDP); these will have binding on AI technology ethical guidelines[18]. Some of the salient point on data privacy are mentions below:

i Users should have control over the data that has been collected from them for the purpose of developing and designing AI technologies for healthcare. Users should be provided with the provision to access, modify, or remove such data from AI technology at any point in time.

ii. End-users must be explicitly explained about the safeguards designed for the protection of privacy. They must be well informed about the type of data collected and how it will be used using either for developing the AI algorithms or interpretation or storage.

iii. Predictive algorithms of AI technologies may produce inappropriate results, which may harm the privacy of the patient. Consent must be mandatory before running a predictive algorithm in participants/ patients.

iv. AI technologies requiring human biometric data should have additional security measures to safeguard the data. Approval from EC and regulatory bodies should be mandatory for using such data. An accidental leak of such data can have unprecedented consequences.

v. Impact assessment must be carried out by relevant authorities before deploying AI for widespread use. It should focus on key areas like human rights, privacy, and ethical principles.

vi. The manufacturer has the responsibility to prevent re-identification from datasets and the prevention of leakage of identifiable information.

vii. Data sharing may expose patients/ participants to privacy threats. Additional consent from patients is required for data sharing if not

taken previously. The consent must contain the nature of data, to what extent it is being shared, and possible harm that can occur from sharing data.

viii. Excess data collected contributes to data surplus. It is unethical to repurpose data surplus without proper consent from the patient/ participants. Storing surplus data for future uses may require additional consent, if not taken earlier.

1.5 *Accountability and Liability*

Accountability is described as the obligation of an individual or organization to account for its activities, accept responsibility for their actions, and to disclose the results in a transparent manner. AI technologies intended to be deployed in the health sector must be ready to undergo scrutiny by concerned authorities at any point in time. AI technologies must undergo regular internal and external audits to ensure their optimum functioning. These audit reports must be made publicly available. AI developers must allow independent analysis and review of their systems, some of them are mention below

i. Innovators in the field of AI may be unfamiliar with medical ethics, research regulations, and regulatory guidelines applicable to this area. It is therefore important to have representatives from health sector at all stages of development and deployment of AI based tools and technologies.

ii. The most direct benefit of AI-based solutions is automation. Machine-assisted decision algorithms are coming into use in clinical medicine. Nevertheless, inherent risks of misinterpretation in the clinical setting with full automation mandates caution. Therefore, unlike other fields of AI technologies where unsupervised deployment is common, AI

for health should always be appropriately supervised. Open source software must also follow best ethical practices so as to ensure that ethical consideration are not compromised at any point of time in the name of innovation.

iii. The concept 'Human In The Loop' (HITL) places human beings in a supervisory role and is more relevant for healthcare purposes. This will ensure an individualized decision making by the health professionals keeping the interest of the patient in the center. Adoption of the HITL principle throughout the development and deployment of AI for Health also helps in optimal sharing of accountability by the team involved in development and deployment of AI-based algorithms.

iv. It is critical to ensure that the entity(s) seeking such responsibility have proper legal and technical credentials in the area of AI technologies for health.

v. The AI-based solutions may malfunction, underperform, or make erroneous decisions with a potential of harm to the recipient especially if it is left unsupervised. The health professional who will use the technology, will assign responsibility. Like other diagnostic and decision-making tools used in clinical practice the responsibility of optimal utilization of the technology is on the health professional using AI-based solutions for delivering healthcare.

vii. During the deployment of AI technology based tools, the legal responsibility of its usage needs to be defined before adopting it into clinical or public use.

viii. The responsibility of harm caused by AI technology malfunction depends on the nature of the cause of harm. If the malfunction is

primarily due to flaws in functionality, then the designer, developer, or manufacturer may be held responsible. If the harm is caused due to defective implementation of technology, then the end-user or organization may be held accountable. There should be a clear understanding and allocation of responsibility before the deployment of AI technology.

ix. If AI technology has caused harm, then there should be an appropriate mechanism to identify the relative roles of stakeholders in damage, extending from the manufacturer to the user and their legal liability. All stakeholders engaged in conceptualization to implementation chain must associate and work together to minimize harm.

1.6 *Optimization of Data Quality*

AI is a data driven technology, the outcomes of which largely depend upon the data used for training and testing the AI. This is of particular importance in the field of AI for health as a dataset which is skewed and is not sufficiently large can produce issues related to data bias, errors, discrimination etc. Data bias is considered to be the greatest threat to data driven technology like AI for health [29]. Due diligence is necessary to ensure that the "training data" is free from known biases and represents large sections of the target population.

One major concern it raises is the pre-existing prejudice that arises in AI models when making decisions against a specific group of people, which is primarily attributed to the human involved in training those data, clouding the AI judgment. Challenges inherent in ML science, logistical difficulties in implementation, and consideration of adoption barriers as well as necessary socio-cultural or pathway changes. Following measure may be taken for medicating the challenges related to data quality:

i. Before deploying AI technologies, the possibilities of biases must be considered, identified and thoroughly scrutinized. Training data must not have any sampling bias. Such sampling bias may interfere with data quality and accuracy. Researchers must ensure data quality.

ii. Data sets used in AI technologies should adequately represent the population in which the technologies are intended to be used. Data of ethnic minorities, marginalized and remotely located population should be adequately represented, or oversampling may be required to obtain the same quality of results observed with populations that are better represented.

iii. The existence of bias in the data set can potentially affect the functioning of AI technology. If there is any allegation of discrimination or indication of bias in an AI technology, the operation of such a system must be temporarily discontinued. The manufacturer has the responsibility to eliminate the bias. Demonstration of a bias-free AI technology with the optimum function before a competent authority is mandatory for resuming operations.

iv. The process of data collection and development of AI algorithms has various challenges and tradeoffs and developers and researchers need to ensure that the best possible data is used for their specific use-case.

v. These inherent problems related to data can be minimized by rigorous clinical validation before any AI-based technology is used in healthcare.

vi. All emerging technologies including AI must pass through a well-established process of scrutiny applicable to all areas of biomedical

research and clinical care. In fact, it is prudent to implement a 'pre-deployment testing' process at every new site were AI is being deployed so that the AI's performance can be ensured at a local level. There should be a robust mechanism to oversee data collection methods, it should be able to check the fairness and inclusiveness of data collection and should be able to point out inadequacies and misrepresentations.

vii. Poor data quality, inappropriate and inadequate data representations may lead to biases, discrimination, errors and suboptimal functioning of the AI technology.

1.7 *Accessibility, Equity and Inclusiveness*

The use of computers for development as well as the deployment of AI technologies in healthcare presupposes wider availability of infrastructure. The digital divide is known to exist in almost all countries and is more prominent in low- and middle-income countries (LMICs). The heavy reliance on technology may therefore interfere with the wider application of promising tools in areas where it is expected to make a greater difference. It can be accomplished in the following ways:

i. AI developers and concerned authorities have to make sure of fairness in the distribution of AI technology. Organizations should endeavour to provide equal opportunity and access to AI technology among different user groups. Special consideration must be given to those groups who are underprivileged or lack the infrastructure to access such technology. Priority must be given to such groups. Government and other regulatory bodies must encourage such potential end user groups to access AI technologies.

ii. AI technologies might lead to discrimination in ways that may be hidden or which may not align with the fundamental rights of humans.

iii. AI developers and other stakeholders should focus on the accessibility of such technologies to socially and economically disadvantaged classes.

iv. Social, cultural and economic background shape the patient perspective towards AI technologies. AI technologies must be designed to be used in a wide range of variations in user with regards to gender, race, ethnicity, income classes, other characteristics, etc.

v. AI developers should pay special attention to employing people from different strata of society with diverse cultural backgrounds. They should have sufficient opportunity to actively participate in designing and developing AI technologies. It would reduce the bias associated with the AI technologies.

vi. AI technologies may include local languages in their user interface to overcome the language barrier associated with the accessibility of technology. It increases AI technology acceptance and more comprehensive user compliance.

vii. Some AI technologies may need internet connectivity, technical expertise, electricity, and other infrastructure. Relevant stakeholders of AI technology should ensure that adequate infrastructure is available for the smooth and optimum functioning of an AI technology that is intended to be used in a low-resource setting.

viii. Digital divide refers to uneven distribution of access to, use of or effect of information and communication technologies among any

number of distinct groups. The government and other relevant stakeholders have to eliminate the already existing digital divide in society for universal acceptance and usage of newer technologies. The introduction of newer AI technology should not cause or worsen digital divide among populations/groups.

ix. Each and every person involved in the development of AI technologies, including those who have given data for AI development, is ethically eligible to access the technology. Access to AI technologies must be granted to all individuals or groups from which the data for AI development is collected.

ix. The interoperability of AI software must be considered whenever it is possible so that different applications can work seamlessly over different platforms. It promotes wider accessibility option for user groups.

x. The user interface of AI technology may enable multiple language settings so as to overcome language barrier and narrow the digital divide.

1.8 *Collaboration*

The field of AI for health is data-driven. A large collection of well-curated datasets is mandatory for any meaningful use of AI for health. This can only be achieved by fostering collaboration at every level. Considering the rapidly changing landscape of AI technology, it is imperative to collaborate among AI experts at the time of research and development so that the most appropriate techniques and algorithms are used to address any healthcare problem. Needless to say, the collaboration among AI researchers and health professionals throughout the process of development and adoption of AI-

based solutions is likely to improve the yield from this promising technology. As a result, stronger collaborations must be achieved with the following principles:

i. While inter-disciplinary collaboration should be encouraged, it is important to ensure that no ill effect comes on the patients whose data may be used to build or test the algorithms during prospective trials of AI technologies.

ii. Motivation for collaborations, and potential conflicts of interest, should be explicitly stated and examined deeply if required to ensure avoidance of harm to any stakeholders.

iii. All international collaborations or assistance related to biomedical and health research with regard to data collection, sharing of biological samples, and intellectual property must be submitted to the Health Ministry's Screening Committee (HMSC) for approval before initiation.

iv. Data sharing for any national or international collaboration while safeguarding privacy and security is very critical in the case of using healthcare data in an AI technology's research and development as it might contain very sensitive information about a participant. Indian laws and guidelines (DISHA & PDP guidelines) are to be adhered to. Appropriate MoU and/or MTA to safeguard the interests of participants and ensure compliance (addressing issues of confidentiality, sharing of data, joint publications) must be in ensured. Actively involving those whom the data is intended to serve is important for effective use of data. Stakeholder engagement and involvement of diverse interest groups helps in better communication of the technology, ensuring that the AI technology meets the user need.

1.9 *Non Discrimination and Fairness Principles*

In order to refrain from biases and inaccuracies in the algorithms and ensure quality, the following principles should be followed:

i. The data set used for the training algorithm must be accurate and representative of the population in which it is used. The researcher has the responsibility to ensure data quality.

ii. Inaccuracy and biases can cause suboptimal or malfunctioning of AI technologies external independent algorithmic audits and continuous end-user feedback analysis should be performed to minimize inaccuracies and biases. The AI developers/researchers must acknowledge any biases involved and should take the necessary steps to rectify it.

iii. AI should never be used as a tool for exclusion. Special attention must be given to under-represented and vulnerable groups like children, ethnic minorities, persons with disabilities, etc. The AI developers should promote the active inclusion of women and minority groups.

iv. Developers should give special attention to promoting and protecting the equality of individuals. Freedom, rights and dignity, should be treated with equality and justice.

v. AI technologies should be designed for universal usage. Discrimination of individuals or groups on the grounds of race, age, caste, religion, social status is unethical.

vi. The reversibility of decisions made by the AI technology should be considered; if harm has occurred to any patient/ participant. Before

implementing the technology, the option for reversibility of decision must be integrated with the AI design.

vii. In case of any unfortunate events arise from the malfunctioning of the AI technology occurs, then there should be an appropriate redressal mechanism for the victim. The manufacturer must ensure that there is a provision for proper grievance redressal.

viii. There must be a safe mechanism to raise concerns pertaining to the AI technology the issues can be technical, functional, ethical, or misuse of technology. There should be a proper mechanism for protecting the whistleblower.

1.10 *Validity*

AI technology in healthcare must undergo rigorous clinical and field validation before application on patients/participants. These are necessary to ensure safety and efficacy. The divergence of AI-based algorithms may be amplified due to differences in the datasets used for training of AI algorithms. Like any other diagnostic tool, such discordance in the diagnostic abilities of different solutions is expected to confuse the end-users, both health professionals as well as the recipient of AI healthcare. There has to be an internal mechanism to monitor such issues and convey appropriate feedback to the developers while keeping in view the clinical context. When an AI technology impacts an individual or healthcare system there must be an efficient feedback mechanism for bringing in necessary updates. Application of AI based decisions for clinical applications can lead to clinical mismanagement or a potential health hazard. Therefore, any AI-based tool needs to be validated based on the principles described under section 2.1.

SECTION 2

GUIDING PRINCIPLES FOR STAKEHOLDERS INVOLVED IN DEVELOPMENT, VALIDATION AND DEPLOYMENT

The development, validation/ testing, and utilization of AI-based solutions for healthcare is a multistep process and involves partners from different areas of expertise. Each of these steps must follow standard practices to make the AI-based solutions technically sound, ethically justified and applicable to a large number of individuals with equity and fairness. All the stakeholders should adhere to these guiding principles to make the technology more useful and acceptable to the users and beneficiaries of the technology. Furthermore, stakeholders have a role right from conceptualisation, design, development, implementation, monitoring, feedback, accountability, ongoing education, training, and advocacy. Public engagement can play an important role in improving acceptability and building public trust.

A brief can be provided on the roles and responsibility of stakeholders such as the following:

a. Academic/ Researchers

b. Industry/ Sponsors

c. Clinicians/ Hospitals/Public health system

d. Public/ Patients/ Community

e. Ethics Committees

f. Government/ Regulators

2.1 *Guiding principles during Development phase*

The whole process of concept design and product development should be based on the inputs from all the stakeholders including health professionals so that the final product performs as intended. The data collection should consider the following:

i. The purpose and end goal of data collection by developers of AI technologies should be known to hospitals/institutes, technicians, and developers of the AI technology.

ii. Pre-consent should be taken if applicable. Informed consent, confidentiality, privacy, and re-consent are largely influenced by the degree of identifiability, whether the biomedical material and data are anonymized or not.

iii. The data should not be used to inflict harm or discrimination on anyone. AI technology developers should use techniques such as data encryption and data anonymization to serve the purpose of protecting individuals' privacy. Highest standards of data security and privacy protection policies has to be followed.

iv. There should be an established mechanism to ensure delivery of information back to the patient/healthcare professional/health authority in case of any findings of significance.

v. There should be a feedback mechanism for which the user/physician can communicate concerns and suggestions with the developers.

vi. The organizations or the researchers must be truthful to the participants as to how their health data will be used.

vii. The data collection should be limited to only what is necessary, with defined time limits of storage of the protected data. Surplus data if collect should be destroyed or can be stored after obtaining proper informed consent from the participant /patient.

viii. Existing data sets (e.g., hospital record, EMR, EHR, administrative sources, research data) can be used with due diligence as already mentioned and following ethical guidelines and safety, security and confidentiality measure mentioned before and also referred in the 2017 ICMR ethical guidelines[5].

ix. The provision of removing/modifying the data from the databases also must be ensured in case a patient opts out at a later time. The user must have the right to exercise the right to be forgotten.

x. There should be appropriate provisions for disciplinary (legal or financial) actions in case the providers fail to comply with these regulations. The relevant stakeholders should be made liable to pay compensation to the users in case of any harm or injury arising from the use of AI technologies.

xi. The source of both the training as well testing data should be properly documented and reviewed by organizational ECs. In case there is a difference between the actual purpose for data collection and the objective of the AI technology being developed using this data, the same should be documented and reviewed. The population on which the AI technology is intended to be used should be part of the testing and validation data sets.

xii. Data should include person from wide range of geographical areas representing different race, ethnicity, gender, socio economic class and age to reduce bias in training data.

xiii. Consent waiver can be obtained in case of anonymized data for retrospective studies.

xiv. AI technologies have a dynamic learning process and the performance of the tool improves with the addition of more data ECs should consider the issue of enhancing the quality of these additional training datasets appropriately. While the inclusion of more datasets is likely to improve the generalizability of the algorithm the developers should develop a mechanism to maintain both audit trail and the quality of datasets used for ongoing training of the algorithm. In absence of such a mechanism, the AI-technologies may prove to be less accurate than claimed in earlier validation studies.

2.2 *Guiding principles for Validation Phase*

The objective of conducting a clinical validation is to establish the safety and accuracy of AI-based solutions throughout its life cycle and especially after deployment, and to evaluate whether the AI-based solution will live up to its claimed performance when deployed in the real world. In order to validate the performance of an AI technology, independently collected datasets other than the training dataset should be used[19]. Auditing of algorithms has also been proposed as a possible approach for deep validation of AI technologies[20]. A robust process of clinical validation minimizes systemic biases and can uncover various limitations that might have remained unnoticed in the preclinical stages of the development of AI-based solution(s).

i. Clinical validation verifies the clinical accuracy of the AI-based solutions for a specific clinical condition. Similarly, for public health applications, screening, surveillance, and performance of health system are to be assessed using AI technologies. The process typically compares the performance and efficacy of the AI-based algorithm in the designated setting to the levels claimed by the

developers of the AI in comparison to gold standard. The process must also aim at determining whether or not the proposed AI-based solution is fit-for-purpose.

ii. Performing robust validation of an AI technology requires a multi-dimensional multi-sectoral team comprising of clinical, data science, statistical, engineering, public health and epidemiological experts.

iii. In case of validation using retrospective data, all segments of population where the AI-based solution is intended to be used should be included. However, the entire AI related data should be made available for audit, if required.

iv. The validation should be preferably done prospectively which could be hospital, laboratory, community based or both depending upon the need. There may be a mechanism for real-time communication of false positive / false negative cases, as the case maybe.

v. The validation should be objective and based on principles of both, biomedical research and medical practice.

vi. In addition to the assessment of accuracy, the validation should also include usability and user experience results. It should also include an assessment of any potential risks to the healthcare providers and recipients of healthcare.

vii. SPIRIT-AI[20] and CONSORT–AI[21] may be used as frameworks for designing and running assessment trials related to AI.

viii. The whole process of AI-technology based analysis and decision support must have mechanisms of audit both at the level of pilot studies and implementation in the clinical scenario. This is extremely

important to retain the faith of both the healthcare providers and recipients.

ix. AI-technology output should be explainable, and the mechanism for explaining the outputs as well.

The validation of AI technology is constantly evolving with newer and more complex statistical metrics coming up to evaluate the performance of AI for health purposes. Appropriate and update analytics should be applied for validation studies such as AUCROC, Sensitivity, Specificity, F1 Score, Mathew's Correlation Coefficient [22][23].

2.3 *Guiding principles for clinical and other health related deployment*

Deployment of AI technology is the last and most important step in the journey of the development of these tools and technologies. It must be dealt with utmost care since poorly designed healthcare deployment of AI can have significant negative impact on patients and healthcare providers.

i. Health professionals are the most important contact person for the recipient of healthcare. Irrespective of whether the data is used for research or patient management or public health decision making, concerned health professionals should be aware as to how the data collected from the participants will be used. They also should be aware of the processes used for data safety and privacy while it is being used to train or validate various AI-technology algorithms. Proper training should be provided to the healthcare providers regarding the appropriate and safe use of AI technology.

ii. Health deployment of AI technology should be preceded by relevant validation of the tools at a local level to determine whether the AI

technology is performing optimally or as expected on the target population.

iii. During the initial deployment phase the AI technologies should be evaluated in variety of rigorous situations to ensure its optimum functioning.

iv. Prior to deployment, health professionals should have a fair idea about the functional basis of the AI-technology. This should also include strength, weakness, opportunity, and threats (SWOT) analysis of the proposed solution.

v. The usability of any diagnostic or prognostic tool should be based on the risk profile of the area of healthcare it belongs to. The perceived risk assessment will also guide the level of involvement of health professionals at different levels of development and deployment of AI for health.

vi. Health professionals using AI-based solutions for biomedical research and or in the clinical/public health setting may be responsible and accountable for the consequences arising out of their use. However if the adverse consequences are arising due to inherent defect in the development of the AI technology, then all relevant stakeholders have their own shared responsibilities.

vii. If any adverse event or injury occurs due to the use of AI technology, then the user/participant has the right to receive appropriate compensation. The onus of providing the compensation lies with all stakeholders.

viii. Health professionals should be aware of potential lacunae and limitations of the AI technology prior to clinical/research/public health deployment. Such limitations must be communicated with the patient/participant.

ix. Prior to clinical deployment, the user of the AI-technology should be educated about various forms of bias that might creep in once the tool is used [24].

x. Individuals and organizations responsible for the development of AI-technology should be accountable for the quality of the algorithm. They should also be responsible for any deviations in the performance of the AI technology in the research, clinical and public health settings. There should be an inbuilt mechanism of switching over to alternative mode of health provision in case the AI technology falters in providing optimal support for which it is intended.

xi. Appropriate security protocols and processes should be in place that accounts for the use of AI technologies.

xii. The AI technology should neither exaggerate nor underestimate the seriousness of the clinical condition of the patient. The output of the AI technology should be aligned with the capabilities and understanding of the user of the technology, and appropriately the "Human-in-the-loop" concept may be adhered to. Human oversight and manual override mechanisms must be made compulsory for all AI technologies that have the capability to cause severe or bodily injuries.

xiii. The information about the use of AI-based technology should be shared with the healthcare recipient or their legal representative. A

disclaimer in this regard must be included in the resultant document highlighting to what extent and for what purpose the said AI tool was used during biomedical research or clinical decision making. The terms of service need to include pointers to guide end users that it is an AI technology and the results/diagnosis/interpretations are not done by humans. A statement of disclaimer in this regard should be explicitly conveyed to the health professional and the subject for whom the technology has been employed.

xiv. The information on cost effectiveness and operational cost should be mentioned when available to improve adoption of the AI technology.

xv. The terms of service should clearly mention the technology used behind the solution is an AI technology, validations/certifications if acquired any and underlying assumptions and disclaimers.

SECTION 3

ETHICAL REVIEW PROCEDURES IN MEDICAL AI

The EC is responsible for assessing both the scientific rigor and ethical aspects of all health research and should ensure that the proposal is scientifically sound and weigh all potential risks and benefits for the population where the research is being carried out. ECs should check the proposals for data source, quality, safety, anonymization, and/or data piracy, data selection biases, participant protection, payment of compensation, possibility of stigmatization and others.

A. Composition of an EC–Apart from guidelines mentioned in the National Ethical Guidelines for Biomedical and Health Research involving human participants (2017), ECs that frequently deal with AI-technology projects should consider including legal experts who have experience in IT and medical law, data scientists and computer scientists with expertise in AI technology. Subject experts may also be invited if AI related proposals are to be reviewed occasionally.

B. Training - Members should be occasionally trained in emerging AI technologies such as big data, DL, internet of things (IoT), so that they are informed about these subjects to an appropriate level before they start evaluating proposals for the same.

C. Roles and responsibilities of the EC - The EC reviews research proposal, progress and final reports as well as reporting of adverse events and provides suggestions for minimizing the risk to the study. Recommendations regarding appropriate compensation for research related injury should be made by the EC, wherever it is required. Monitoring visits at study sites should be carried out by the EC as and when needed. In case

of conflicts in ethical requirements during implementation of key ethical requirements, decisions on the tradeoff should be evaluated regularly.

D. Types of review: As provided in the ICMR Ethical guidelines the type of review will be based on the type and degree of risk involved and can be exempt, expedited or full committee review as the case may be.

E. Ethical issues related to reviewing a protocol. All research proposals require scientific and ethical review by the EC. While in general all issues specified in the National ethical guidelines should be followed while reviewing a protocol based on AI technologies, there are certain specific additional requirements to be examined by the committee before taking the decision.

3.1 *Ethical Issues Related to Reviewing A Protocol*

Table 1: Ethical Issues Related To Reviewing A Protocol

Routine issues	Special issues for AI related protocols
1. Essentiality of the study	1. Essentiality and appropriateness of the system
2. Disclosure or declaration of potential COI	2. Alternates available and opportunity/cost comparison
3. Scientific design and conduct of study	3. Qualifications of researchers/ developers
4. Benefit-risk assessment	4. Training for Data collection procedures

5. Recruitment of research participants (Retrospective/ Prospective study)	5. Selection of Training and Testing populations
6. Informed consent process	6. Possible Technology malfunctions / glitches / failures and the redressal mechanisms Stakeholder responsibility and accountability to different aspects of AI technology malfunction / injury
7. Payment for participation (Prospective study)	7. Adequacy assessment of study sites
8. Protection of privacy and confidentiality including data privacy (both retrospective and prospective)	8. Informed Refusal process 9. Data source, participant selection process and quality assessment 10. Opportunity to constantly upgrade AI technology with additional data and technology and its influence on participants 11. Quality check of the AI technology. 12. Participants 'right-to-be-forgotten' 13. Data storage and sharing policies

	14. Community considerations
	15. Compensation for study related injury including medical management

For further details refer the National Ethical Guidelines for Biomedical and Health Research involving Biomedical and Health Research, 2017.

SECTION 4

INFORMED CONSENT PROCESS

The researcher must obtain written informed consent from the study participant for any health research involving human participants and their data. This requirement is based on the principle that competent individuals are entitled to choose freely whether or not to participate or continue to participate in the research and development. Informed consent is a process which primarily involves three major components providing relevant information to prospective participants, ensuring the individual's competence, ensuring the information is easily understood by the participants and ensuring the voluntariness of participation.

4.1 Requisites

The document must inform that this is a "research". The participant must be able to comprehend the proposed research or system to be developed, be able to make an informed decision about whether or not to participate in the study and communicate her/his decision to the researcher in order to give consent. The consent should be freely given and not obtained through duress or coercion of any kind, or by offering undue inducements. In case the participant is not competent (medically or legally) to give consent, the consent must be taken from a legally authorized representative. Before beginning any study-related procedures involving the participant, a researcher must obtain consent. At all stages, participants' privacy and confidentiality must be protected. The potential consequences of breech in privacy should also be mentioned in the informed consent document.

4.2 Essential information for prospective research participants/ Responsibility of researchers

i. The Researcher must make sure that the research participants understands the alternatives available (including traditional methods) for the AI technology in question, including doing nothing. Also, the comparable benefits and risks involved should be discussed.

ii. The Researcher must ensure that the patient/research subject has understood the process and must evaluate the research subject by "teach-back", or "show-me" or any other evaluation technique. The patient/research participant education is a very important step for an ongoing process which would be required including if consent obtaining is required multiple times to reduce patient drop-outs. This should also be documented.

iii. The Researcher/End-user of the product should be able to distinguish between the role of human caregivers and technology during each part of the procedure. This should be explained clear to the research subject/patient.

iv. The Researcher/End-user of the product should clearly explain the possibility of missteps at each level of the procedure and the risk attached to it.

v. Without prior consent, AI technologies informing significant decisions should not attempt to make value judgments on people's behalf. When informing an AI subject about important decisions they will make, AI technologies should not unreasonably limit the available options or otherwise attempt to influence their value judgements without the AI subject's consent. The standard procedure for documentation of

informed consent process, electronic consent and specific issues in clinical trials may be followed as per the National Ethical Guidelines for bio-medical and health research, 2017.

vi. IEC approval is required for the use of retrospective data for developing and validating the AI technology.

vii. Waiver of consent - The researcher may apply to the EC for a waiver of consent if the research involves less than minimal risk to participants and the waiver will not jeopardize the participants' rights and welfare. (As per the National Ethical Guidelines for Biomedical and Health Research, 2017).

SECTION 5

GOVERNANCE OF AI TECHNOLOGY USE FOR HEALTHCARE AND RESEARCH

Healthcare AI technologies also known as Software as a Medical Device (SaMD) has immense potential to improve health outcomes which also carries along with it, immense challenges for regulatory bodies and related stakeholders. The regulation of AI technologies in healthcare is still in the nascent stage even in developed countries like US and EU who have taken steps towards building a regulatory framework for such a complex technology. The AI Act proposed by the European Commission (EC) intends to build the first legal frame work which aims to "guarantee the safety and fundamental rights of people and businesses, while strengthening uptake, investment and innovation across the EU"[25].

The Indian Government has made efforts to streamline AI technologies in various sectors including healthcare. The National Health Policy (2017) focuses on the integration of digital health and establishment of National Digital Health Authority for leveraging Digital health Technologies[26]. The National Digital Health Blueprint (NDHB 2019) further builds on developing a system of Electronic health records based on international standards and establishment of data ownership pathways with integrated ethical principles of data anonymization and de-identification[27].

The Digital Information Security in Healthcare Act (DISHA) 2018 proposed by the MOHFW, Government of India is a step towards providing "electronic health data privacy confidentiality, security and standardization and provide for establishment of National Data Health Authority and Health Information Exchanges". The Act intends to provide for "establishment of National and

State eHealth Authorities and Health Information Exchanges to standardize and regulate the processes related to collection, storing, transmission and use of digital health data; and to ensure reliability, data privacy, confidentiality and security of digital health data"[28].

Regulatory frameworks lay guidelines to assess the product's probable benefits and risk as well as provide an enabling environment. The Medical Device Rules, 2017 and its amendments in 2020 have expanded the definition of medical device and includes any software or an accessory intended to be used for a medical purpose[29]. However, there is a need to further develop and establish norms for testing and validating SaMD in India.

Ethics Checklist of AI for Biomedical Research and Healthcare

Table 2: Ethics checklist of AI for biomedical research and healthcare[30]

S. No.	Index	Description
1.	Objectives	The project's objectives and functioning of the AI tool.
2.	Technology	Describe the broad principles of AI technology used and its application (e.g., supervised or unsupervised)
3.	Funding & conflict of interest	Notify all sources of funding and who would possibly have an interest or benefit from the AI technology
4.	Credentials	Description of Team and individual expertise in AI technology for healthcare or any other field of AI domain. And also describe how these participants will assist in the design, development and validation of AI tool.
5.	Type of participants	Describe the participants (Healthy volunteers, Patients, Vulnerable persons/ Special groups)
6.	Participant recruitment methods used	The recruiter name (person, organization, etc.) and the recruitment methods considering equity, fairness, representativeness, geographic distribution, and ethnic minorities

7.	Risks involved and management strategy	The anticipated physical/social/psychological discomforts/ risk to participants if any may be mentioned and risk management strategy.
8.	Treatment of research related injuries	Describe the provision for free treatment/ management for AI technology research related injuries.
9.	Potential benefits of AI tool	Describe the potential benefits of AI tool (e.g., for the participants, medical/clinical science, health system, society/community, enhancement of science)
10.	Evidence	Provide justification and evidence regarding AI technology in terms of accuracy, validity, efficacy, and performance. Sources of scientific publication, if any, may be added.
11.	Validation	Provide details of the validation strategy or methodology run on the AI technology and outcomes of testing under different scenarios/ contexts.
12.	Accountability	Describe the complaint redressal procedure and the names of the persons/institutions who will be accountable for the AI tool related actions and associated consequences
13.	Monitoring	Process of monitoring unintended consequences and adverse events with the use of AI technology

14.	Data collection, storage, sharing and access to data	Describe the source of data, data collection method and storage, data access procedures, and data security
15.	Informed consent	Describe the type of consent (Signed consent, Verbal/Oral consent, Witnessed consent and Audio-Video (AV) consent). Ethical approval from an Ethics Committee! Who will obtain the informed consent (PI/Co-PI, Nurse/Counselor, Research Staff or Other.)? And mechanism for consent withdrawal.
16.	Right to be forgotten	Can a person retrieve and erase all their records or not? And if yes then how? Describe the process.
17.	Moderation (human in the loop)	Does the AI technology require human intervention/ moderation? If yes give proper details for instance, who will control the access to AI technology

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Abbreviations:

AI	- Artificial Intelligence
CDSCO	- Central Drugs Standard Control Organization
CMS	- Clinic Management System
COI	- Conflict of Interest
CSR	- Clinical Study Report
DL	- Deep Learning
EC	- Ethics Committee
EPSRC	- Engineering and Physical Sciences Research Council
GCP	- Good Clinical Practice
HCP	- Healthcare Professional
HITL	- Humans in the loop
HMS	- Hospital Management Systems
HMSC	- Health Ministry's Screening Committee
HTA	- Health Technology Assessment
ICD	- Informed Consent Document
ICF	- Informed Consent Form
ICMR	- Indian Council of Medical Research
IEEE	- Institute of Electrical and Electronics Engineers
ITU	- International Telecommunication Union
LAR	- Legally Authorized Representative
ML	- Machine Learning

MoU	- Memorandum of Understanding
MTA	- Material Transfer Agreement
NGO	- Non-Governmental Organization
NLP	- Natural Language Processing
PIS	- Participant Information Sheet
SAE	- Serious Adverse Event
SOP	- Standard Operating Procedures
WHO	- World Health Organization

Glossary:

1. **Algorithms:** Algorithm refers to a set of rules/instructions that step-by-step define how a work is to be executed upon in order to get the expected results.

2. **Artificial Intelligence (AI):** The simulation of human intelligence processes by machines, especially computer systems. These processes include learning (the acquisition of information and rules for using the information), reasoning (using rules to reach approximate or definite conclusions) and self-correction.

3. **Black-box:** In science, computing, and engineering, a black box is a device, system or object which can be viewed in terms of its inputs and outputs (or transfer characteristics), without any knowledge of its internal workings. Its implementation is 'opaque' and is therefore referred to as 'black box'.

4. **Data Anonymization/ De-identification:** Data Anonymization is the process of protecting private or sensitive information by erasing or encrypting identifiers that connect an individual to stored data. The process of de-identification mitigates privacy risks to individuals and thereby supports the secondary use of data for comparative effectiveness studies, policy assessment, life sciences research, and other endeavors.

5. **Deep Learning (DL):** DL is a subset of machine learning based on artificial neural networks in which multiple processing layers are used to extract higher level features from the data. It can be supervised, semi-supervised or unsupervised.

6. **Homomorphic Encryption:** Homomorphic Encryptions is a technique which allows computational encryption on data enabling AI functions without the need to transfer personal information. It includes key generation, encryption, decryption and evaluation algorithms.

7. **Human in the Loop (HITL):** Human-in-the-loop (HITL) is a branch of artificial intelligence that leverages both human and machine intelligence to create machine learning models. In this people are involved in a virtuous circle where they train, tune, and test a particular algorithm.

8. **Informed Consent:** Informed Consent is the process by which a patient learns about and understands the purpose, benefits, and potential risks of a medical or surgical intervention, including clinical trials, and then agrees to receive the treatment or participate in the trial.

9. **Informed Refusal:** Informed refusal is where a person has refused a recommended medical treatment based upon an understanding of the facts and implications of not following the treatment. It is linked to the informed consent process, as a patient has a right to consent, but also may choose to refuse.

10. **Intellectual Property Rights (IPR):** Intellectual Property Rights (IPRs) are legal rights that protect creations and/or inventions resulting from intellectual activity in the industrial, scientific, literary or artistic fields. The most common IPRs include patents, copyrights, marks and trade secrets.

11. **Machine Learning (ML):** Machine learning is an application of Artificial Intelligence (AI) that provides systems the ability to automatically learn and improve from experience without being explicitly programmed.

12. **Teach-back /Show-me Technique:** The teach-back also called the show-me is a communication confirmation technique used by healthcare providers to confirm whether a patient/ care taker understands what is being explained to them. If a patient understands, they are able to "teach-back" the information accurately.

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The Indian Council of Medical Research (ICMR), New Delhi, the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest medical research bodies in the world.

DHR-ICMR Artificial Intelligence (AI) Cell is an overarching body to coordinate and supervise all AI-related activities of different divisions and institutes of ICMR.

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