Artificial Intelligence for Real Wellness

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- -Understand various ways the AI is integrating in healthcare.
- -Understand the AI's negative sides and learn to manage them.
- -Understand the AI's positive aspects and integrate them in medical practice to reduce administrative burden on physicians.
- -Leverage the contribution of AI to Physician Wellness

Artificial Intelligence



• Definition

- A machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments.
- AI systems use machine- and humanbased inputs
- AI includes machine learning

U.S. Department of Health and Human Services

Enhancing the health and well-being of all Americans

Office of the Chief Information Officer (OCIO)

- AI adoption
- enable HHS-wide familiarity, comfort, and fluency with artificial intelligence (AI) technology and its potential
- promote AI scaling with the application of best practices and lessons learned from piloting and implementing AI capabilities to additional domains and use cases across HHS
- spark AI acceleration by increasing the speed at which HHS adopts and scales AI and ML



• <u>https://www.hhs.gov/sites/default/files/hhs-ai-use-cases-2023-public-inventory.csv</u>

• More than 150



- Artificial Intelligence (AI) and Machine Learning (ML) can be described as a branch of computer science, statistics, and engineering that uses algorithms or models to perform tasks and exhibit behaviors such as learning, making decisions, and making predictions.
- ML is considered a subset of AI that allows models to be developed by training algorithms through analysis of data, without models being explicitly programmed.



- The increased use of AI/ML throughout the drug development life cycle and across a range of therapeutic areas.
- A significant increase in the number of drug and biologic application submissions using AI/ML components over the past few years, with more than 100 submissions reported in 2021 and 175 submissions in 2022.
- These submissions traverse the landscape of drug development from drug discovery and clinical research to post-market safety surveillance and advanced pharmaceutical manufacturing.
- AI/ML is increasingly integrated in areas where FDA is actively engaged, including <u>Digital Health</u> <u>Technologies (DHTs)</u>, and <u>Real-World Data (RWD)</u> analytics.

Potential Improvement

- automation and learning of medical devices
- the efficiency of diagnostic/therapeutic development and commercial manufacturing
- regulatory assessment
- post market surveillance

AI/ML devices

- Data augmentation, transferring learning, and other novel approaches to enhance AI/ML training/testing for small clinical datasets.
- Study design and analysis methods for AI/ML-based computer-aided triage (CADt).
- Non-clinical phantoms and test methods for assessing specific imaging performance claims for DL-based denoising and image reconstruction algorithms.
- Imaging phantoms and computational models to support QI and radiomics assessment.
- Assessment techniques for evaluating the reliability of adaptive AI/ML algorithms to support non-clinical test method development.
- Assessment approaches to estimate and report the robustness of AI/ML to variation in data acquisition factors.
- Technical factors influencing AI reproducibility for digital pathology applications.
- Methods for assessing the generalizability of AI performance in digital pathology applications

Advantages

- clinical trial results analysis
- Pharmacometrics
- precision medicine
- foodborne pathogen WGS data integration, analysis, and visualization.
- use of genomic data to predict the mean inhibitory concentration (MIC) for pathogens and antimicrobials
- mammographic computer-aided diagnostic (CAD) devices
- <u>software as a medical device (SaMD)</u>
- improve quality decision making.

Artificial Intelligence Program Activities

• The Artificial Intelligence Program focuses on regulatory science research in these areas:

- Data augmentation and synthetic data
- Methods regarding algorithmic bias, performance difference, and generalizability
- Study designs and analysis methods for AI/ML-based computer-aided triage (CADt)
- New evaluation frameworks
- Training regarding machine learning algorithms
- Reliability assessments of adaptive AI/ML.
- Estimating and reporting data acquisition factors.

Practical Use

- Precise Diagnosis
- Al algorithms analyze medical imaging data, such as X-rays, MRIs, and CT scans, to assist healthcare professionals in accurate and swift diagnoses. Al-based diagnostic tools can also speed up the interpretation of complex images and improve early detection of disease.

Practical Use

- Drug discovery
- AI can help humans predict toxicity, bioactivity, and other characteristics of molecules. AI-based systems can also reduce the need to test potential drug compounds physically, which can be a costsavings.

Practical Use

- Communication
- AI can improve communication between physicians and patients. Automatic Speech Recognition (ASR) technology uses advanced algorithms and machine learning models to convert spoken language into written text.



• AI-based image processing can facilitate personalized treatment plans, thereby optimizing healthcare delivery

Current Landscape

- Medical artificial intelligence (AI) can perform with expert-level accuracy and deliver cost-effective care at scale.
 - IBM's <u>Watson</u> for heart disease
 - <u>Chatbots</u> for the United Kingdom's National Health Service
 - <u>Smartphone</u> apps and skin cancer with expert accuracy.
 - <u>Algorithms for eye diseases</u>
 - Medical AI will <u>pervade 90% of hospitals</u> and replace as much as <u>80% of what doctors currently</u> <u>do</u>.

Current Landscape

- ChatGPT and USMLE
- Med-PaLM language model

Potential quick turnarounds

- Provide advice on the diagnosis and treatment for these symptoms.
- Create a personalized treatment plan based on the patient's age and lifestyle.
- Analyze this X-ray to detect abnormalities.
- Identify risk factors from this patient's EHR.
- Write a letter explaining the medical necessity of this treatment.

Physician-Machine Collaboration

 The human aspects of care, including <u>empathy</u>, compassion, critical thinking, and complex decision-making, are invaluable in providing holistic patient care beyond diagnosis and treatment decisions.

Wellness

- AI and physician burnout
- AI and access to care
- AI and physician workforce shortages

Considerations of AI in Health Care

- Despite the potential benefits of AI in health care, there are significant safety, privacy, reliability and ethical considerations. Furthermore, without appropriate precautions, AI may perpetuate inherent biases in diagnosis and treatment.
- Physicians will likely continue to play a critical role in ensuring that the ethical and moral implications of medical decisions are carefully considered and that patients receive the highest quality of care.
- To achieve this, physicians must be prepared to take on new roles and responsibilities in the era of AI, including expanded opportunities in medical informatics. Physicians can also guide patients on how to use AI to obtain reliable health information and receive appropriate care

Enhancing Medicine with AI

- AI has the potential to transform health care for the better. It's a powerful tool that can lead to better patient outcomes when complemented with physician expertise. AI can also facilitate scientific discovery and breakthroughs in disease prevention and treatment through vast data analytics.
- Integrating AI into routine clinical practice will require careful validation, training and ongoing monitoring to ensure its accuracy, safety and effectiveness in supporting physicians to deliver care.
- While AI can be a valuable asset in the medical field, it cannot replace the human element. However, AI can and should be used to enhance the practice of medicine, empowering doctors with the latest technological tools to serve our patients better.

AI and People

- Resistance to medical AI
 - Lack of Context
 - Lack of Individualization
 - Inflexible
 - Standardize

Integrative approach

- For purely AI-based health care services (e.g., chatbot diagnoses, algorithm-based predictive modeling, app-based treatments, feedback from wearable devices), providers could emphasize the information gathered about patients to generate their unique profile, including their lifestyle, family history, genetic and genomic profiles, and details about their environment.
- Patients might then feel that the AI provider will take into account the kind of information that would be considered by a human provider such as their general practitioner who has access to their history. This information could be used to better explain to patients how the care would be <u>tailored</u> to their unique profile.

Mastering The Machine

- Get informed.
- Get involved.
- Stay current.
- Leverage the technology.

Get On the Board

