Understanding the Potential of AI in Clinical Testing: Opportunities and Considerations

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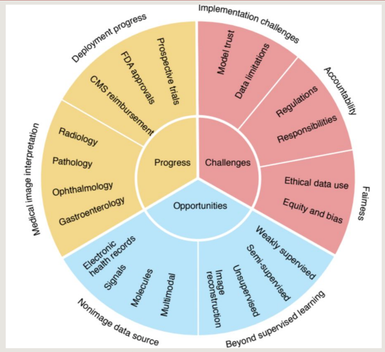
Introduction



An overview of the current progress, challenges, and opportunities that AI in healthcare presents.[1]

Progress:
Machine learning (ML) models can detect, diagnose, and analyze images with increasing accuracy. The push for FDA approval and increased number of clinical trials demonstrates receptiveness to AI systems and a shift from testing to deployment.

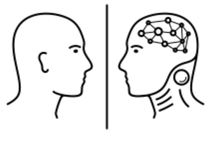
Opportunities:
The development of ML systems that can train off unlabeled data and/or analyze non-image data sources (eg: signals and audio) reflects increased opportunities for A2I collaboration and autonomy.

Challenges:
Addressing concerns related to privacy, data security, and ensuring medical professionals' trust in AI-enabled solutions is paramount to successful deployment and integration of AI technologies into existing healthcare systems.

Collaboration Between AI and Humans

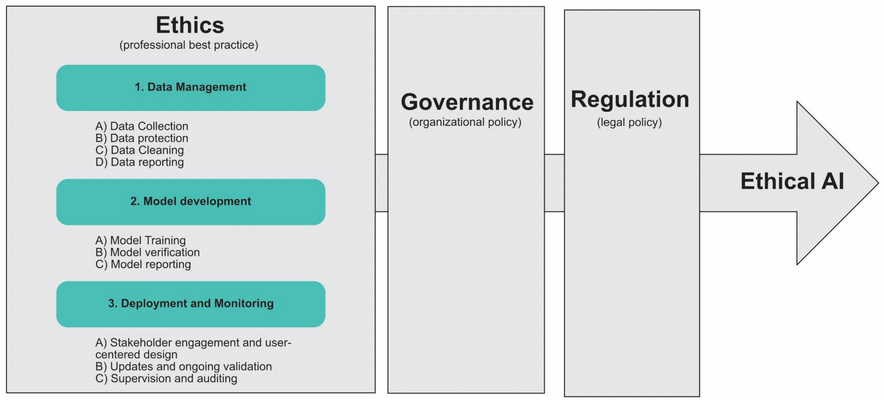
Role of Molecular Geneticists at CHLA (for brain tumor cases):
- Goal: make a molecular diagnosis
- Review test results (from somatic next-generation sequencing panel, DNA methylation profile, RNA-seq, etc.)
- Look for DNA sequencing variants, RNA fusions, gene amplifications, etc.
- Discuss results with neuropathologists & neuro-oncologists before making diagnosis
- Write and sign out reports

Role of DKFZ Heidelberg Random Forest Classifier for CNS Tumors at CHLA:
- Goal: accurately classify and distinguish different types of Central Nervous System (CNS) tumors
- Uses the random forest algorithm to classify and distinguish CNS tumors based on the distinct features and characteristics of the tumor
- Aids Molecular Geneticists in diagnosing the patient



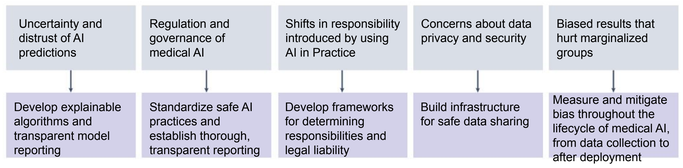
Conventional Workflow vs New Opportunities:
Making diagnoses and interpreting brain tumor cases is a nuanced, time-consuming process. ML models have the potential to aid molecular geneticists in diagnosing patients more accurately and efficiently.
- The current workflow reflects low levels of collaboration: a classifier is fed data and gives the human an output for them to interpret. The molecular geneticist then interprets the classifier's results, writes a report, and signs out the case.
- When using current algorithms, such as the DKFZ classifier, humans are **retrospectively analyzing results rather than producing real-time, actionable insights** that encourage collaboration
- ML models are capable of handling growing data sets and operating off of fully/partially unlabeled data sets, a skill that should be taken advantage of

Ethical Considerations and Challenges



An outline of the procedures and levels of regulations that AI models must follow in order to deploy an ethical AI system.[3]

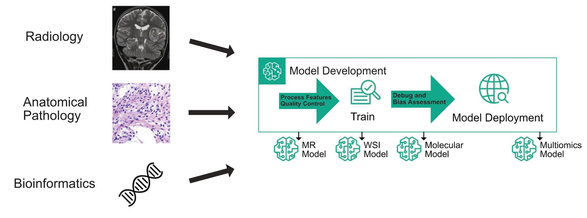
Ethical Challenges for AI in Medicine



Overview of the various ethical challenges and concerns that prevent AI models from being implemented, along with a proposed solution to combat each challenge. [1]

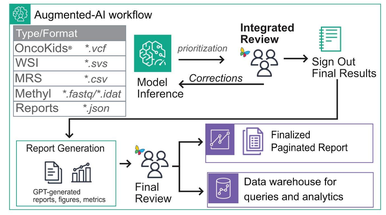
Augmented AI Approach for CHLA Molecular Diagnostics

Patient data is processed for machine-learning operations



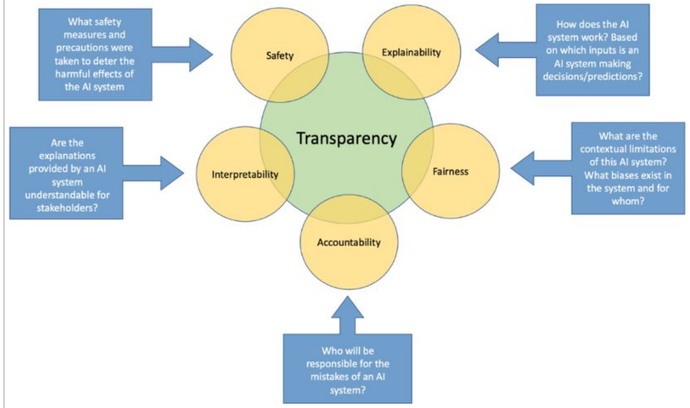
Patient data from radiology, histology, and bioinformatics in the development of machine learning models to accurately predict patient diagnoses. The incorporation of diverse datasets offers a comprehensive and promising approach towards revolutionizing medical diagnostics and advancing personalized patient care.

Human review clinical workflow for AI-predicted diagnostics



Augmented-AI framework utilizing machine-learning (ML) models to prioritize cases for review, followed by GPT-drafted results. ML classifier will prioritize cases based on OncoKids® variant calls, VGG16-transformed whole-slide images (WSI), and quantized MRS spectra for an integrated expert-review. Expert review will provide annotations, and if necessary, correct model inference to benefit future predictions. Final paginated report with clinical annotations and multi-omic results will be warehoused in a public data server.

Transparency in Augmented AI Model at CHLA



Transparency in CHLA's Augmented Workflow[4]

1. **Safety:**
   - All predictions made by model will undergo expert review to prevent misdiagnosis
   - Clinicians can accept, reject, or modify predictions to train the model
   - Clinical Laboratory director always has final say for diagnosis
1. **Explainability:**
   - Clinicians understand that CHLA's model will be trained off large sets of patient data.
   - System works by making brain tumor predictions based off its training
   - Confidence score will be given along with prediction
1. **Fairness:**
   - Model will be trained for use at CHLA, and should thus be trained off data representative of the population who may visit CHLA
   - CHLA's greater population of Hispanic individuals creates biases
   - debugging & bias assessments in place so that model does not perpetuate racism
   - Costs to run the model must not interfere with its accessibility to patients
1. **Accountability:**
   - Clinicians and laboratory directors are responsible for ensuring that mistakes are caught before the final report is signed out, thus taking liability
1. **Interpretability:**
   - Explanations should be understandable to humans
   - System should clearly outline its design, purposes, intentions, and procedures
   - Limitations should be explicitly communicated to patients, stakeholders, and directors

Reflection

Two Concerns:

1. **Monopolization of Software:** Large tech-companies have much more money and manpower to implement AI technology at a large scale. How do we keep trained medical professionals at the forefront of AI development in healthcare? Is preventing tech-companies from developing monopolies feasible? Are monopolies an advantage or disadvantage?

1. **Equality:** Is it *possible* for technology to be "equal" or accessible to all? How will the release of ML models impact disadvantaged or marginalized communities? Will shareholders find ways to make novel technology more accessible to the wealthy to increase profit margins?

I worry about the inherently individualistic nature of our society. There is no doubt that one will profit and another will suffer. While I hope that artificial intelligence will help bridge inequalities, I don't know if its implementation actually will.

CONTACT US

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