Evolving Role of Artificial Intelligence in Radiological Imaging

No-Human-in-the-Loop AI-enabled Healthcare: Risk, Rewards, and Regulation

Anthony E. Samir, MD MPH
Laura Brattain, PhD
Masoud Baikpour, MD
Massachusetts General Hospital
Disclosures

Consulting:
• Astra Zeneca
• Bracco Diagnostics
• Bristol Myers Squibb
• Founder Collective
• General Electric
• Gerson Lehman Group
• Supersonic Imagine
• Novartis
• Pfizer
• Philips
• Parexel Informatics
• WorldCare Clinical

Advisory or Scientific Board Memberships:
• General Electric
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Research Funding:
• Allergan
• Analogic Corporation
• Boehringer Ingelheim
• Department of Defense
• Echosens
• FNIH
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• Intercept
• Medimmune
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• NIH
• Partners Healthcare
• Philips
• Supersonic Imagine
• Takeda
• Toshiba Medical Systems
• Siemens

Research Support:
• Analogic Corporation
• General Electric
• Hitachi
• Philips
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• Toshiba Medical Systems
• Siemens
Outline

• What is No-Human-in-the-Loop AI?
• Process of Ultrasound Imaging and Machine Learning
• Examples From CURT
• FDA Regulations
Key Points

• No-Human-in-the-Loop AI will be ubiquitous
• The risk profile of No-Human-in-the-Loop AI is fundamentally different to conventionally engineered systems
• Post-market surveillance will be a key element of successful regulation
What is No-Human-in-the-Loop AI?

• **Assist and Guide:**
  - A human cannot practically be involved in the decision making:
    • Image reconstruction
  - Happening now!
  - Very common

• **Complete replacement:**
  - A considerable distance away!
  - May happen for select applications
Process of Ultrasound Imaging

Machine Intelligence
Assist, Guide

Desired State

https://www.vicc.org/cancer-info/childhood-liver-cancer
Ultrasound Imaging

Urinary Bladder

Gallbladder
Process of Ultrasound Imaging

[Diagram showing the process with labels: Analytic, Intervention, Diagnostics, Desired State]
Shear Wave Elastography Assist (SWE-Assist):

- Selection of appropriate imagery
- Discarding SWE images of poor quality
- Performing computational diagnostics using algorithms
Shear Wave Elastography Assist (SWE-Assist)
Analytic

Hepatorenal index:
- Automatically detecting liver and kidney
- Selecting appropriate regions of interest
- Comparing the echogenicity of the two organs
Diagnostics

Ascites Detection:
- Automatically segmenting free abdominal fluid
Ascites Detection

Case 1

Case 2

Case 3
Ascites Detection

(A)

(B)
CATH-AI:

- Enhance image interpretation
- Provide procedure guidance
- Reduce need for specialized training

AFSOC Field Equipment Demonstration

AFSOC: US Air Force Special Operations Command

Brattain et al, Method For Objective, Noninvasive Staging of Diffuse Liver Disease From Ultrasound Shear Wave Elastography. US Provisional Patent 2019

CFA: Common femoral artery
CFV: Common femoral vein

Porcine data acquired using Terason Ultrasound. Study was approved by the IACUC from Massachusetts General Hospital

Gjestebj et al, CATH-AI: Ultrasound-Guided Semi-Automated Vascular Cannulation System MHSRS 2019

Example Femoral Artery and Vein Tracking
AI in Healthcare - Rewards

- Pushing boundaries of human performance
- Democratizing medical knowledge and excellence
- Automating drudgery out of medical practice
- Managing patients and medical resources
Risk Management – Core Concepts

• Deterministic vs. stochastic systems, knowns vs. unknowns

Reports that say that something hasn’t happened are always interesting to me, because as we know, there are known knowns; there are things we know we know. We also know there are known unknowns; that is to say we know there are some things we do not know. But there are also unknown unknowns—the ones we don’t know we don’t know. And if one looks throughout the history of our country and other free countries, it is the latter category that tend to be the difficult ones.

https://en.wikipedia.org/wiki/There_are_known_knowns#cite_note-defense.gov-transcript-1
Risks in Deterministic vs. Stochastic Systems

Easier to anticipate risks

Inferior model performance

Harder to anticipate risks

AI/ML

Known Knowns
Known Unknowns

Unknown Unknowns

Superior model performance
Dealing with the unknown unknowns

• Recognize the limitations of premarket regulatory processes
• Increased importance of post-market surveillance, expeditious reporting of problems, and error resolution processes
Key Points

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• Post-market surveillance will be a key element of successful regulation
Thank you for your attention!

Any Questions?