Physician Perspectives on Transparency in Augmented Intelligence

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Transparency: A Precondition for Clinical Integration

From innovation to clinical integration . . . AI considerations

- **Does it work?**
  - Innovation
  - Evidence Development

- **Will it be covered?**
  - Regulation / Quality Assurance
  - Coding / Pricing

- **Who is accountable?**
  - Coverage
  - Liability / Security / Medical & Developer Liability

- **Will it work in my practice?**
  - Infrastructure
  - Education Training

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Equity

Evidence

Ethics

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Physician Perspectives: AI Transparency

• AMA convened experts from across the Federation of Medicine to better understand the profession’s perspectives and concerns related to augmented intelligence (AI) product transparency and explainability
  • Radiology, cardiology, ophthalmology, pathology, surgery, dermatology, internal medicine

• Perspective: AI done right can improve outcomes

• Concern: Lack of transparency threatens trust
  • Development – how were tools designed, validated and in which populations?
  • Data Quality - Inaccurate or mislabeled data threaten performance and trust
  • Bias – Do the data sets used to develop, test and validate the AI span diverse ethnic and racial populations? How limited or generalizable are the AI outputs?
Clinical Validation of AI Products

• Strong physician consensus that FDA should require clinical validation before AI products are marketed

• Physicians across all specialties are concerned about what, if any, clinical evidence has been generated to support the use of an AI product
Transparency — Explainability

• Explainability is a key element of physician trust in AI products
  • Additional transparency may be required to ensure black box algorithms are explainable
• Physicians need to be able to answer key questions:
  • How does it learn?
  • What decisions is it making?
  • What does the result mean?
  • How will I know when it’s “gone wrong?”
Data Quality and Data Bias

• Data Quality Impacts AI product performance:
  • AI products trained on a certain data set in a specific environment or population may not work in other settings or populations when differences are meaningful or the devices producing the data are different (i.e., different imaging platforms)
  • Product performance measured using test data cannot always be relied upon in the clinic
  • Transparency about how data is collected, how the system is trained, data limitations, and populations included or excluded is essential

• Robust data sets across ethnic and racial populations are essential to ensure the AI tool is generalizable

• Robust privacy protections and disclosures about the potential use of a patient’s data by an AI product are necessary
AI Product Labeling

• Product labeling for AI products should be robust and require new product disclosures to help build physician trust and understanding of the product
• FDA and stakeholder communities need to work to develop a list of required disclosures
  • Required disclosures should include information about:
    • What safety and efficacy data has shown about the product in question and whether clinical studies have been conducted
    • The populations for which the product has been validated
    • The potential limitations of the data sets used in developing AI products
    • Elements helping explain algorithm decision making/logic (explainability)
    • Information on the use of an individual's data to develop and/or train AI
• Post-market surveillance requirements are critical
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