



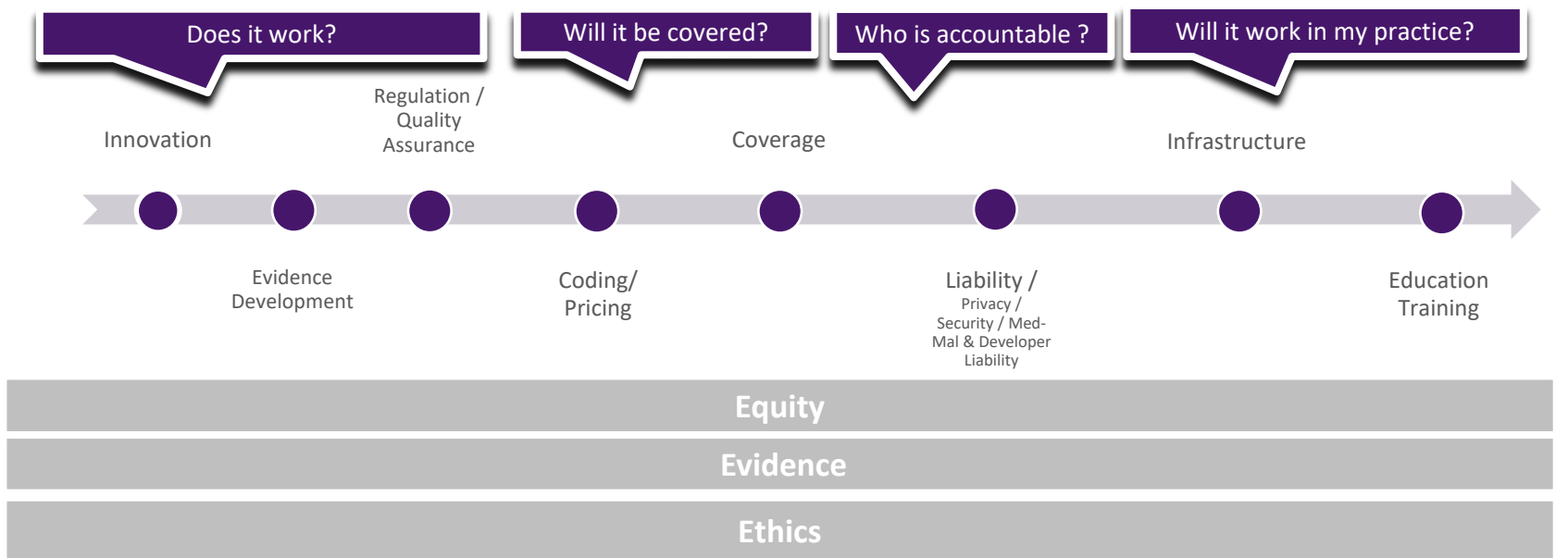
Physician Perspectives on Transparency in Augmented Intelligence

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Transparency: A Precondition for Clinical Integration

From innovation to clinical integration . . . AI considerations



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



Physicians' powerful ally in patient care