The Legal And Ethical Concerns That Arise From Using Complex Predictive Analytics In Health Care

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One Hypothetical Use Case

• Physician decision on whether to send a patient with moderate organ dysfunction to ICU.

• Evaluation for risk of arrest or adverse event would take hours, limited accuracy.

• The Future: predictive analytics model might ascertain the instantaneous risk for cardiopulmonary arrest of every one of a thousand patients in a given hospital at every second and determine which patients would most benefit from ICU admission.
Lifecycle of Predictive Analytics Model

Phase 1: Acquiring Data

• Consent and Privacy: Should we require explicit consent? Is de-identification possible? Should patients be given notice?
• Equitable Representation: The importance of community engagement.

Phase 2: Building and Validating Model

• Patient-Centered Perspectives: How to ensure patient role in governance? Trust models? Analogy to biobanks.
• Validation: How rigorous? Who decides?
• Transparency: Key variables and relative contribution disclosed? Will doctors trust a “black box”? Intellectual property protection.
Phase 3: Testing Model in Real World Settings

*Consent*: Do patients need to consent to have the model used “on them”? Notification when they enter hospital?

*Liability*: Integration with decision support software may lead to new liability risks. Vicarious liability for health systems?

*Choice Architecture*: Should the model trigger default care intervention (opt out)?

Phase 4: Broader Dissemination of Model

*Equitable Access*: Can all health systems that contribute to the model development afford to implement? Graduated licensing fees?
Lifecycle of Predictive Analytics Model

- **Imperfect Implementation**: Can result from poorly constructed workflows, insufficient consideration of patients' preferences, inadequate checks and balances. Who has liability for “off label” use?

- **The Role of the Physician**: New training requirements and communication challenges. Shift to team-based care. Frequent hand-offs and problem of lack of awareness of patient preferences? Importance of maintaining physician override.