



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

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- 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.

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?

- *Imperfect Implementation*: Can result from poorly constructed work flows, 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.