New England Regional Healthcare Risk Management Conference
Best Practices for Risk Managing Artificial Intelligence

Pat Folcarelli, BIDLH
Christine Vaz, Coverys
Anthony Abeln, Morrison Mahoney
Bill McDonough, Integro, Moderator

April 29 2019

Materials were created for presentation at the 2019 New England Regional Conference. Reproduction or reuse without written permission from the Moderator is prohibited.
Our Agenda Today...

- Introductions
- Definitions
- What is AI in Healthcare?
- AI and Patient Care, Patient Safety
- AI and the Underwriters Dilemma
- AI and Legal Challenges, Defense of a Claim
- Insurance and Coverage Scenarios
- Case Studies
- Questions
Artificial Intelligence: What is it?

- **Artificial Intelligence (AI) in healthcare** is the use of algorithms, software and other platforms to approximate human cognition in the analysis of complex medical data.

- The primary aim of health related AI applications is to analyze relationships between prevention or treatment techniques and patient outcomes.

\[ \text{AI} = \text{Risk?} \]
Examples: What is AI?

- Machine Learning
  - Digital Assist Healthcare Delivery
    - Care in Place
  - Acute Care Predictive Analytics
  - Intensive Ambulatory Care Analytics
  - Population Health Prediction Models
    - Aging In Place Analytics
  - Genomics / Oncology
  - Radiographic Image Evaluation
    - Physician Workflow
  - “Internet of Things”/ Use / Optimization
    - Image Integration (Different sources)
  - Tissue Evaluation (Quantitative Morphology)
Personal health tracking
Medical imaging
Patient Monitoring
Home monitoring
Medication adherence
Pathology
Quantification
Genomics
Analytics
AI AND THE PATIENT
SAFETY CHALLENGES

Pat Folcarelli
"If you want a second opinion, I'll ask my computer."
Data Infrastructure

Data Acquisition

BIG DATA

ARTIFICIAL INTELLIGENCE

Data Characteristics

Variability
Variety
Veracity
Velocity
Volume

Statistics

Data Clustering
Hypothesis Testing
Inference
Regression Analysis
Risk and Uncertainty

Modeling

Data Mining
Optimization
Simulation
Virtual Reality
Visualization

AI Models

Machine learning
Expert Systems
Neural Networks
Intelligent Agents
Pattern Recognition

Broadband
Cloud Service
Internet of Things
Connectivity

Adapted from J. Environ. Res. Public Health 2018, 15, 2796
The AI health market is seeing explosive growth

**HEALTH AI MARKET SIZE 2014-2021**

- Acquisitions of AI startups are rapidly increasing while the health AI market is set to register an explosive CAGR of 40% through 2021

2014: $600M  
2021: $6.6B  
11x

Source: Accenture analysis
# Top 10 AI Applications

<table>
<thead>
<tr>
<th>APPLICATION</th>
<th>VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robot-Assisted Surgery*</td>
<td>$40B</td>
</tr>
<tr>
<td>Virtual Nursing Assistants</td>
<td>$20B</td>
</tr>
<tr>
<td>Administrative Workflow Assistance</td>
<td>$18B</td>
</tr>
<tr>
<td>Fraud Detection</td>
<td>$17B</td>
</tr>
<tr>
<td>Dosage Error Reduction</td>
<td>$16B</td>
</tr>
<tr>
<td>Connected Machines</td>
<td>$14B</td>
</tr>
<tr>
<td>Clinical Trial Participant Identifier</td>
<td>$13B</td>
</tr>
<tr>
<td>Preliminary Diagnosis</td>
<td>$5B</td>
</tr>
<tr>
<td>Automated Image Diagnosis</td>
<td>$3B</td>
</tr>
<tr>
<td>Cybersecurity</td>
<td>$2B</td>
</tr>
</tbody>
</table>

**TOTAL = ** $150B

Source: Accenture analysis

* "Value" is the estimated potential annual savings for each application by 2026.

\* Orthopedic surgery specific.
AI is changing Healthcare...

- Venture capital firm Rock Health reports that 121 AI machine learning companies raised $2.7 Billion between 2011-2017.
- Accenture study reports that the 10 most promising AI interventions could create $150 billion in annual savings.
- Digital Healthcare organizations continue to emerge including:
  - Patient generated data and customized services (wearables)
  - Network utilization and management (scheduling, confirming etc.)
  - Referral management and in-network retention (logic based tools - right doctor/patient)
  - Social community support (public health, care coordination)
  - Convenient patient access (telemedicine, virtual exams)
Examples

- Amazon has partnered with Merck to explore how Alexa can help people with diabetes better manage their condition.

- Hospitals around the country are using Alexa for helping surgeons create checklists, or sharing discharge information with patients at home.

- University of Chicago and Google have used machine learning to develop a predictive model for patient risk of death. Named eCART, the tool has been layered into technology at the hospital so that a computer pages a nurse to respond to patients deemed high risk.

- Northwell Health [New York’s largest healthcare provider] is able to calculate the likelihood of readmission in real time using large data.
Advantages of AI - Radiology

- Automatic Detection of Diseases while minimizing human error
- Creating Study Protocols
- Improving image quality and decreasing radiation doses
- Decreasing time in MRI scanners
- Optimizing staff utilization and reducing costs
- Tele medicine - world health implications
  - Specific Examples:
    - Mammography for Breast Cancer
    - CT for colon cancer
    - Pulmonary Nodules
    - MRI Brain Tumor Segmentation
    - Neurological disorders such as Alzheimer’s Disease
Challenges and Considerations...

- Algorithms may mirror human biases in decision making
- Ethnical biases could be built into models
- Are AI applications considered to be medical devices?
- Accountability:
  - “As AI starts making autonomous decision about diagnoses and treatments, moving beyond its role as merely a support tool, a problem arises as to whether its developer can be held accountable for its decisions. The first question is: who will be sued if an AI-based decision makes a mistake?”
  - (Insights Imaging (2018) 9:745-753)
- Legislation
- Explainability and Interpretability
- Privacy and Anonymity
- Ethics and Fairness
We always overestimate the change that will occur in the next two years and underestimate the change that will occur in the next ten.

-Bill Gates
AI AND UNDERWRITING - HOW DO WE DEFINE THIS RISK?

Christine Vaz
Information Gathering

**Who**
- Who is using the technology?
- Who is teaching the technology?
- Who is securing the data?

**What**
- What AI technology are they using?
- What are their plans to implement this technology?

**When**
- When are they using the AI technology and how often?
- When and to whom are they sharing the data?

**Where**
- Where is the technology being utilized in the organization?
- Where is the data and the evaluation of the data being stored?

**How**
- How are they harvesting the data?
- How long has the AI technology been around?
Underwriting the Risk

• It is a balancing act of good vs. bad risk characteristics
• Determine what you are not comfortable with
• Stay informed of changes in market standards as it relates to security and use of patient data analytics

• Utilize risk management protocols and evaluations.
• Implement predicative modeling once is data available
• Continue to ask questions at each renewal
AI AND CLAIMS
HOW DO WE DEFEND THIS NEW CARE MODEL
Tony Abeln
What Might Potential Advanced AI Claims/Lawsuits Look Like?

- Hospital based Negligence/Vicarious Liability
- Physician Negligence
- Cyber/Privacy
- Product Liability/Learned Intermediary
- Underlying question to all: Who or What Is Responsible?
Why Artificial Intelligence?
Global Challenges...

- A Growing Total World Population
- 13+ Million Provider Shortfall
- An Aging Developed World Population
- Chronic and Preventable Disease Epidemic
Is the Input Accurate?

- Is the AI’s algorithm reliable?

Concern: Incomplete data informing algorithms:

- Data not representative of the population (e.g. ethnic minorities are usually under-represented in the medical studies)

- May lead to some conditions which affect some under-represented populations more (e.g. sickle cell anemia) being similarly under-represented in AI technology

- AI system output inappropriate/inapplicable to a member of an under-represented population.
Is the Output Accurate?

- What happens when there is systemic error? 
  *(i.e. January 1, cannot properly review tests performed the day before)*

- What happens when there is interpretive error? 
  *(i.e. unusual presentation of a melanoma that AI reads as within normal limits)*

- When providers pursue improper treatment as the result of an algorithm error
  *Respondeat superior (vicarious liability): liability on employers for the negligent acts of employees acting within the scope of their employment.*

- AI personhood for purposes of malpractice? ????
Independent Institutional Negligence

- Hospitals and other health care providers may be held separately negligent for failing to exercise due care in hiring, training, or supervising employees, or for failing to maintain adequate facilities and equipment.

- What if hospital administration does not know the inner workings of the tool? Is that itself negligent?

- Is AI like this any different than the robotics used during surgery?

- For the hospital? For the provider?
Provider negligence

How does the provider use the AI?
Diagnostic AI as “resident”

- Attestation by AI Attending?
  - “I have reviewed the results of Radiology AI Machine Vision evaluation of Chest X-ray on April 10, 2019 and I agree with the interpretation.”

- Diagnostic AI as “overread”? When done? Different than ECG?
- Diagnostic AI as “curbside consultation” with an “expert”

Would a reasonably prudent provider rely on an AI interpretation or recommendation?
Standard of Care?

When does particularized AI become standard of care? Considerations:

- Availability
- Effectiveness
- Prevalence
- Usage in provider community (primary care/community hospital/tertiary care)
- Professional organizations/governmental agencies
- Is it a scalpel or is it an expert?
Is it a product liability case?

- Flawed algorithm?
- Flawed learning?
- “Learned Intermediary Doctrine”
- What if the doctor simply relies on the output of “expert AI”? 
In Conclusion…

Artificial intelligence will…

• Enable preventive and precision medicine
• Improve patient experience, access and outcomes
• Augment the intelligence of the clinician, and remove non-value added work
• Create increasing opportunities for corporate – clinical co-creation and innovation
• Answer global healthcare challenges
• Create the Perpetual Global Clinical Trial Platform
• Allow us to “know” our patients like never before

BUT…
Appendix
Artificial Intelligence
New England Regional:  April 29, 2019
Virtual care, predictive analytics, prevention, self-care, precision medicine, health promotion, workforce impact, 3rd world impact.
Patterns of the Past, Current

Demography
Words
General Appearance
Sounds
Physical Signs, Symptoms
Smell
Touch / Feel
Xray Images
Fluids
Tissues

+…”What Has Happened Before”

+... “What I Have Seen Before”
<table>
<thead>
<tr>
<th>AI Risks &amp; Challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large quantities of data with appropriate patient privacy protection</td>
</tr>
<tr>
<td>Curated clean databases</td>
</tr>
<tr>
<td>Trust &amp; transparency</td>
</tr>
<tr>
<td>Combining data and knowledge driven learning</td>
</tr>
<tr>
<td>The last mile: understanding of the (local) clinical context</td>
</tr>
<tr>
<td>Clinical Cycles</td>
</tr>
<tr>
<td>Inclusion</td>
</tr>
<tr>
<td>Fragmented Healthcare IT infrastructure</td>
</tr>
</tbody>
</table>