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# Artificial Intelligence in Health Care: Legal and Practical Considerations

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# AI AND ITS USE IN HEALTHCARE

# *Health Care's Holy Grail:*

IMPROVED INDIVIDUAL PATIENT EXPERIENCE

*AND*

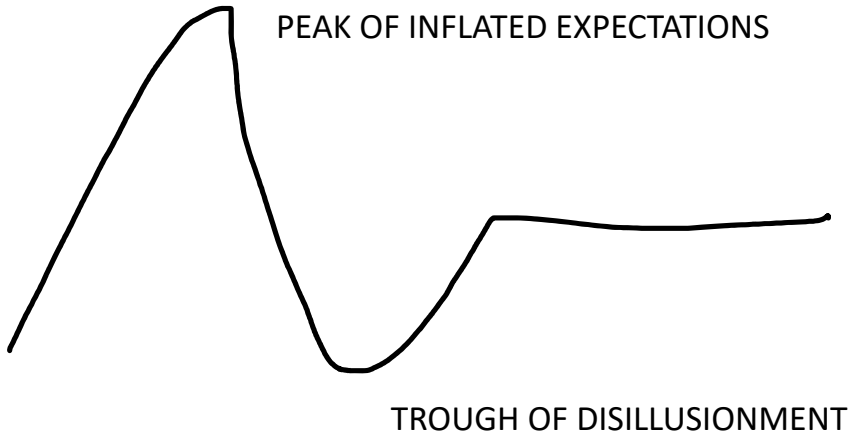
IMPROVED POPULATION HEALTH

*AND*

REDUCED COSTS

# *AI and the Potential of Achieving the Holy Grail*

The Gartner Hype Curve:



# *Artificial Intelligence: Why Do We Care?*

"Demographically, aging populations in most developed countries will require more medical services even as the health care workforce shrinks. ***Meanwhile, millennials who were raised in a digital world are demanding a health care system that is as simple to navigate, predictive, and interactive as Amazon***."

*Big Data, Analytics & Artificial Intelligence,* GE and UCSF, 2016

# *Artificial Intelligence: What Is It?*

- AI is a tool that powers systems and applications; it is not itself a system

- Algorithms that learn from experience, that develop neural connectivity and robotic functions that self-improve over time/experience - ***JUST LIKE PEOPLE***

# *No, Really – What Is It?*

- AI uses data – a lot of data – Big Data - to drive predictive analytics, clinical and non-clinical functions, and precision medicine, among other things

- Luckily, health care has a surreal amount of data; 2013 estimates have it at 153 exabytes. One exabyte equals one quintillion ($10^{18}$) bytes or one billion gigabytes

*All the words ever spoken by humans could be stored in 5 exabytes (allegedly)*

# *No, Really – What Is It?*

ACCORDING TO ACCENTURE, THE TOP 5 AI APPLICATIONS IN HEALTH CARE (BY VALUE) ARE/WILL BE:

- Orthopedic Robot-Assisted Surgery - $40B
- Virtual Nursing Assistants - $20B
- Administrative Workflow Assistance - $18B
- Fraud Detection - $17B
- Dosage Error Reduction - $16B

*"Value" is the estimated potential annual benefits by 2026*

# *Food for Thought*

"Cognitive robotics can integrate information from pre-op medical records with real-time operating metrics to physically guide and enhance the physician's instrument precision. ***The technology incorporates data from actual surgical experiences to inform new, improved techniques and insights."***

***Artificial Intelligence: Healthcare's New Nervous System,*** **Accenture, 2017**

# *AI: It's Already Here*

- 85% of Americans already use at least one AI powered device regularly
  - *Google Maps*
  - *Alexa/Siri/Google Home*
  - *Smart appliances*
  - *Streaming content (Netflix, etc.)*

- Chatbots – the same AI technology that helps you pick out just the right shoes online can also help you find the correct health information

# *…But it Freaks People Out*

AI may be embraced in our personal/consumer lives, but health care adoption has been slower.

- Losing the “human touch” / lack of human oversight
- Job security
- “Black box”

# *More Food for Thought*

***"Through 2020, 80% of AI projects remain alchemy, run by wizards whose talents will not scale in the organization…Change is outpacing the production of competent professionals…"***

*Gartner Top Strategic Predictions for 2019 and Beyond,* Oct. 16, 2018

# *Familiar Healthcare AI*

- Diagnoses and Reduced Errors
  - Symptom checking chatbot guides patients to correct care
  - Diabetic retinopathy detection
  - Microscopes scan for harmful bacteria faster than humans – 95% accuracy
  - AI-enabled radiology assistants
  - Deep learning network had 100% accuracy in detecting certain breast cancers in pathology images (2017 Case Western study)
- Drug Development
  - AI enabled systems help identify patient characteristics for clinical trials
  - Identifying new medicines and new applications for existing ones

# *More Food for Thought*

***"A 2016 study of 35,000 physician reviews revealed 96% of patient complaints are about lack of customer service, confusion over paperwork and negative front desk experiences."***

*Journal of Medical Practice Management,* cited in *Surgical Robots, New Medicines and Better Care: 32 Examples of AI in Healthcare,* www.builtin.com

# *Familiar Healthcare AI*

- Improved patient experience
  - Nurse avatars answer questions 24x7, automate data collection
  - AI platforms that automate eligibility checks, claims, data collection
  - Patient flow optimization and predictive analysis
  - Personalized health plans - Cleveland Clinic uses IBM's Watson and big data to create an individual's treatment plan

# *More Food for Thought*

The McKinsey Global Institute estimates that applying big-data strategies to better inform decision making could generate up to ***$100 billion in value*** annually across the US health-care system, by optimizing innovation, improving the efficiency of research and clinical trials, and building new tools for physicians, consumers, insurers, and regulators to meet the promise of more individualized approaches.

McKinsey & Company, *How big data can revolutionize pharmaceutical R&D,* 2013

# *Familiar Healthcare AI*

- Mining/managing health data to recover some of that $100 billion
  - AI-enabled system sifts through enormous amounts of data to personalize treatments
  - Risk prediction to predict clinical, financial and operational risks
  - AI analyzed data to predict ICU transfers and hospital-acquired infection in a particular patient; predict and detect sepsis

# *The Future Is Now – Command Centers*

- Johns Hopkins Hospital created a command center powered by AI technology for predictive analytics; it helps command center staff to know, among other things, how to reduce wait times by predicting room turns and patient discharges.
- Humber River Hospital is all-digital, employing tracking devices, robots and automating 75% of its non-clinical operations.

*The command center "will be equivalent to adding 45 new beds, enabling us to serve 4,000 more patients per year*."

# *The Future Is Now*

- Robots even add a “human touch” at some hospitals:

https://commons.wikimedia.org/wiki/File:SoftBank_pepper.JPG#/media/File:SoftBank_pepper.JPG

Pepper, at Humber River Hospital, uses AI to determine your mood via facial recognition functionality and then behaves appropriately. It even does yoga and dances.

# *The Future Is Now*

- Univ of Toronto working on “emotional modeling” – AI in Pepper being designed to do automated data intake to reduce ER wait times, monitor patients and provide interactive companionship.
- Pepper already holds the hands of pediatric patients while they are waiting for surgery.

# *Not Quite Here Yet*

- *Predicting certain adverse health events in individual patients* (system under development by Penn Medicine and University of Pennsylvania): algorithms that can predict in-surgical and post-discharge complications in individual patients

# *More Food for Thought*

"It might be easiest if people stop viewing AI technology as "a collection of circuits in a console" and start viewing it as "an army of fellowship-trained radiologists with photographic memories, IQs of 500 and no need for food or sleep."

Robert Schier, MD, *Commentary, Journal of the American College of Radiology,* quoted in *Radiology Business,* May 14, 2018

# *Practical Considerations - Challenges*

- Tapping the potential of AI to achieve the Holy Grail has practical challenges:
  - Concerns about inherently biased data (lawyers can't "fix" this, but may be able to help allocate the risk appropriately)
  - Skeptical users – "it's the digital snake oil of the early 21st century", according to AMA CEO James Madara, MD (2016)
  - Payer acceptance – who gets paid if a robot delivers care? If a robot chooses a treatment plan?

# *Practical Considerations: Biased Data*

- If the data consumed by an AI application is biased, then the result it generates is questionable.
- Users may not know the data is biased
- Lawyers can help allocate risk by asking a vendor where the data comes from, its quality and diversity; representations and warranties

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# *Practical Considerations: Skeptical Users*

- Users/providers have been burned before
- Lack of case studies
- Unwillingness to learn another technology
- Distrust of results
- Lawyers can help alleviate this by ensuring training in robust service agreements

## *Practical Considerations: Payer Acceptance*

- Increased efficiencies on the back end (*e.g.*, improved claims accuracy, less fraud) may encourage reimbursement rates for AI assisted care that reflect the value of that care, without consideration of who/what is delivering it

- Other possibilities?

# LEGAL AND PRACTICAL CONSIDERATIONS IN USING AI IN HEALTHCARE

# Regulation and Licensing

**FDA**

- FDA is considering a new regulatory framework for AI
- FDA's traditional paradigm not designed for AI and machine learning technologies
  - April 2019 – Commissioner statement
  - release of discussion paper
  - feedback will direct guidance to be issued
  - acknowledgment of great potential of AI and ML to transform healthcare
- AI/ML Based Software as a medical device (SaMD)
  - FDA solicited comments on pre-market approach for review of AI and ML software modifications

# Regulation and Licensing

**State Boards and Other Licensing Bodies**

- Standards of state medical boards and other licensing and accreditation bodies continue to evolve and have made little inroads into AI.

- Summer 2018 – AMA passed first policy addressing augmented intelligence

  Per the AMA, the term augmented intelligence (AI) conceptualizes artificial intelligence by focusing on AI's assistive role, emphasizing that its design enhances human intelligence rather than replacing it.

# Regulation and Licensing

**More interesting question is…**
**how can physicians use AI and what are the limitations based on their licensure?**

- Limitations will vary on a state by state basis depending on license practice act requirements

- By way of example, Illinois Medical Practice Act prohibits the following:
  - Making a false or misleading statement regarding skill or **the efficacy or value of the medicine, treatment, or remedy prescribed…at** their direction in the treatment of any disease or other condition of the body or mind. (emphasis added)

# Regulation and Licensing

**More interesting question is…**
**how can physicians use AI and what are the limitations based on their licensure?**

- Illinois Medical Patient Rights Act (410 ILCS 50/1 et seq.)
  - Right to be informed of treatment
  - Right to care consistent with sounds nursing and medical practices
  - Right to privacy/confidentiality
  - Right not to be discriminated against
    - How do you manage bias that it is implicit in AI?

# Informed Consent & Transparency

AMA Principles of Medical Ethics

- Code of Medical Ethics Opinion 1.1.1 – Physician has responsibility to use sound medical judgment
- Code of Medical Ethics Opinion 1.1.3 - Patient Rights
  - an opportunity to discuss benefits, risks and costs appropriate to treatment alternatives
  - an opportunity to ask questions about treatment
  - a right to privacy and confidentiality
- Code of Medical Ethics Opinion – 1.1.6 – Quality
  - A physician shall "actively engage in efforts to improve quality of health care" by keeping current with best practices and maintaining professional competence
  - 1.1.7 – Exercise of Conscience
    - Take care that their actions do not discriminate
    - Uphold standards of informed consent

# Informed Consent & Transparency

- Code of Medical Ethics Opinion 2.1.3
  - "Truthful and open communication between physician and patient is essential for trust in the relationship and for respect for autonomy. Withholding pertinent medical information from patients in the belief that disclosure is medically contraindicated creates a conflict between the physician's obligations to promote patient welfare and to respect patient autonomy."

- Code of Medical Ethics Opinion 1.2.11 - Ethically Sound Innovation in medical practice
  - Innovate based on sound scientific evidence
  - Refrain from offering until have developed appropriate knowledge and skills
  - Recognize need for informed consent (disclosure of known risks, benefits and burdens)
  - Provide meaningful professional oversight

# Informed Consent & Transparency

Providers using AI should be:

- Informed and understand the role of AI and risks/benefits
- Competent to use AI
- Able to communicate clearly and effectively about
  - Role of AI and role of provider
  - Risks and benefits
  - Liability

# Privacy and Security

AI involves MASSIVE amounts of personal data, which invokes data protection laws.

AI does not reconcile with long-standing data protection principles.

- collection limitation
- purpose specification
- use limitation
- fairness principle

Who owns the data generated?

Does the developer have rights to use and process the data collected, create derivative works using the data and re-disclose it?

Does the developer (or licensing entity) have rights to use the original data?

Potential Privacy frameworks implicated:

- HIPAA
- GDPR (other international)
- State laws (CCPA, among others)

# Privacy and Security

## HIPAA

- Analysis of HIPAA relationships among provider (covered entity) and AI developer, manufacturer and/or licensor.
    - How is the PHI flowing?
    - Is there a business associate relationship?
    - If not, is authorization required?

# Privacy and Security

GDPR

Article 22 – “The data subject shall have the right not to be subject to a decision based solely on automated processing, including profiling, which produces legal effects concerning him or her or similarly significantly affects him or her.”

Except:

- where the processing is necessary for performance of a contract

OR

- where separately authorized by another law which includes suitable measures to safeguard data subject’s rights and freedoms and legitimate interests

OR

- with explicit consent of the data subject.

# Privacy and Security

Providers need to consider:

- Compliance with HIPAA (and other privacy/security frameworks such as GDPR, as applicable)
- Compliance with FTC, FDA and state privacy laws (i.e. CCPA).
- How to prevent a breach? Allocation of liability

- Retaining service providers that can maintain reasonable security and oversight (vendor management)

# Liability

Who is responsible? It may be difficult to determine.

Developer
Manufacturer
Distributor
User

Liability management – how to allocate liability?

- Indemnification
- Limitations of Liability
- Insurance

# Practical Take-Aways

For Individual providers:

- Review applicable license practice act and regulations to determine whether it addresses limitations on use of AI
- Review any relevant state laws that address patient rights
- Consider responsibilities and duties under medical code of ethics

- Understand the AI
  - Receive proper training
  - Understand its limitations, risks and benefits
- Clear communication about the role of AI and benefits/risks

# Practical Take-Aways

For provider entities:

- Consider clear and transparent documentation and informed consent in patient care

- In exploring AI, consider:

    - Intellectual property
    - Liability
    - Data privacy/security
    - Licensure/registration

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