Background
The MediVerse: Governance To Enable AI-Driven Health

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ROPES & GRAY

Terminology and Related Technologies

Web 1.0, 2.0, 3.0	▪ Web 1.0: The original, “read-only” web ▪ Web 2.0: The “read-write” web ▪ Web 3.0: The “read-write-execute” web
Artificial Intelligence (AI)	▪ The theory and development of computer systems able to perform tasks that normally require human intelligence, such as visual perception, speech recognition, decision-making, and translation between languages.
Machine Learning (ML)	▪ A branch of AI and computer science; enables a computer system to continue learning and improving on its own, based on experience (imitating human learning).

Terminology and Related Technologies

Extended Reality	▪ Any technology that alters reality by adding digital elements; umbrella term
Augmented Reality	▪ Modification of a real-life environment by the integration of digital elements in real time; creates an experience that enhances the real world with an overlay of computer-generated content
Mixed Reality	▪ Blend of the physical or real-world with digital or virtual elements where physical and digital elements can interact; user can interact with both physical and digital environment
Virtual Reality	▪ Use of computer technology to create fully simulated or artificial 3-D environments

Terminology and Related Technologies

Blockchain	▪ A system of records, where multiple exact copies of data are stored across computers in the network; a type of database capable of recording/storing data ▪ Used for validating, settling, tracking, and recording transactions; create “trust” or “consensus” based on mathematics and encryption
Digital Twin	▪ A digital representation, or virtual model, of a real-world entity, system, or object

Potential Pitfalls

- **Ethical concerns**
  - AI-related biases
  - Creating or exacerbating inequalities
- **Accessibility**
  - Certain technologies needed to participate in meaningful manner
  - Accommodations for persons with disabilities or impairments
- **Increase in digital engagement**
  - Erosion of social fabric and norms
  - Increased screen time
- Impact on **physical health, mental health, and development**
- **Privacy and security** concerns (*more to come later!*)

Potential Benefits

- Increase **access to information**, as metaverse allows synthesis of large swaths of information in an easy-to-digest format
- Promote **active user participation**
- New opportunities for **shared experiences** and **collaboration**
- Potential for **increased access to experiences** that may otherwise be out of reach for users
- In health space, many of the same benefits as telehealth—expanded **access to care**, better **care coordination**, focus on **prevention**, potential to **reduce biases** found in traditional care systems
- Potential for **different interface** with AI
- **One to many** interactions
- Large-scale **population assessments**

Health Care Issues

Potential applications:

- **Improved diagnostics and diagnoses**
  - Application of AI/ML to various sources of information, including patient information collected through VR/AR and other wearables
  - *e.g.,* predict how an individual may recover after surgery based on AI/ML review of their movements and certain health data points
- **Immersive patient therapies and experiences**
  - Aid to various health/mental health treatments
  - Potential to encourage patient compliance and patient empowerment, and improve outcomes
  - Patients' ability to better imagine and experiment with other realities may be useful for some treatments
  - *e.g.,* mental health sessions involving exposure therapy (a form of cognitive-behavioral therapy) to address PTSD or eating disorder
  - *e.g.*, physical and rehabilitative therapies

Applications

Potential applications:

- **Education for patients, caregivers, and providers**
  - Prepare patients for procedures and provide interactive trainings (*e.g.*, how to use a medical device at home, diabetes management techniques, experience surgery in the metaverse before real-world procedure)
  - Teach caregivers needed skills to support their loved ones at home
  - Prepare providers for surgery via simulations, and use real-time AR to bring up patient charts, scans, etc. during surgery
  - Reinforce providers' procedural skills, such as airway and IV placement
  - Provide provider re-training for certain rare (but critical) events, like a mass casualty event or a novel virus pandemic

Applications

Potential applications:

- **Health care payments**
  - Use of digital currency or property to cover cost of care
  - Use of micropayments to incentivize specific patient behavior
- **Managing patient identity and records**
  - Creation of a patient's virtual identity via virtual ID "card"
  - Management of patient health records
  - Patient health record interoperability and portability

General Legal Challenges

The rise of the metaverse raises many general legal questions:

- **Who or what will govern?**
  - Will a central body or individual jurisdictions monitor the metaverse?
  - What are the monitoring obligations of metaverse operators?
  - Will the government regulate, or will development and management be left to private companies?
  - How will laws be enforced as related to metaverse activities?
- **What laws will apply and where?**
  - What are the geographic boundaries? How will conflicts of law be resolved?
  - Will existing laws apply to online activities or will a unique legal framework be implemented?
  - Do rights afforded to individual's extend to their avatar/digital twin?
- **Some legal precedent** related to virtual property (IP issues)

Data Privacy and Information Security

Privacy and security concerns are both new and old:

- The metaverse has the potential to create, store, track, and expose **large swaths of information** on a scale never seen before, and **data sharing** required for the metaverse to function could be unprecedented
  - Information collected during a metaverse experience will include **data not typically collected** from patients at present, *e.g.*:
    - Data from sensors within headsets and other AR/VR wearables that track retinal movements, gait, body temperature, brain activity, pupil dilation, facial expression, other biometric information, and precise location
  - 20 minutes of VR activity reportedly can generate 2 million unique data elements
- **Consent paradigm difficult in dynamic, immersive environment**

Data Privacy and Information Security

- **Heightened protections already required for health care data**
  - (Extra) heightened protections for mental health, substance use, infectious diseases
  - Increasing regulation of **telehealth interactions**, **biometric data**, and **use of AI/ML** in health care decision-making

- The metaverse will present novel scenarios and raise questions regarding the **adequacy and applicability of existing privacy laws** that often arise in the health care context, including HIPAA, CCPA/CPRA, CMIA, other state laws, FTC, and GDPR
  - Digital interactions may implicate privacy laws of multiple jurisdictions; may not be clear which should apply
  - Patchwork of laws could make it difficult to implement appropriate compliance measures

- **Regulators unlikely to get ahead of technology, and could derail**

Data Privacy and Information Security

- **Patient reidentification is getting easier**
  - The size and complexity of individual datasets makes de-identification and other protection measures more difficult
  - AI/ML algorithm able to correctly identify user with 95% accuracy when given just 5 minutes of VR data, even with all personally identifiable information stripped

- **Challenges of secure data storage**
  - Increase in volume of patient data and interoperability requirements in the metaverse will make secure data storage and management difficult
  - At present, electronic medical records systems often are siloed
  - Potential use of blockchain and similar technologies to store sensitive patient information, manage patient identity, and manage health care transactions

Data Privacy and Information Security

- **Potential for novel cyber attacks**
  - Real-time tracking of VR/AR device to compromise location privacy
  - Psychological attacks; next-level gaslighting
  - Inducing cybersickness and user disorientation, and other direct attacks on users' health and well-being via cyber tools

- **Interoperability challenges**
  - Interoperability (*i.e.*, the ability of two or more systems to exchange health information and use the information once it is received) is a challenge with existing technology platforms and networks
    - At present, information often is inconsistent across sources, and protocols for sending, receiving, and managing information often varies between different health systems and providers
  - Without collaboration across metaverse creators, the metaverse likely will only exacerbate these interoperability issues

Looking Forward

- **Everyone needs a seat at the table**—regulators, public and private companies, and end users
  - Public-private partnerships
  - Blockchain governance structures
  - Patient engagement in development process
  - Multidisciplinary approach
  - *Don't just leave it to the engineers!*
- **Ensure "privacy by design" in metaverse-related technologies**
- **Encourage transparency**
  - In the process of developing metaverse-related technologies
  - In the regulatory development process
  - In the patient engagement process (*e.g.*, informed consent)
- **Develop industry codes of conduct, policies, and other means of self-governance**

Ethics and Governance

- **Determining data ownership**
- **Laws will trail technological development**
  - Regulation may deter technological experimentation
  - Laws will enforce societal expectations, but the technologies may set those expectations
  - Institutional experimentation may be necessary to respond to technological experimentation
    - AI regulation of AI?
- **Development of Articulable Ethical Principles**
  - Ethical Design / Ethical by Design
  - Designation of Data Fiduciaries
- **Governance of processes**