

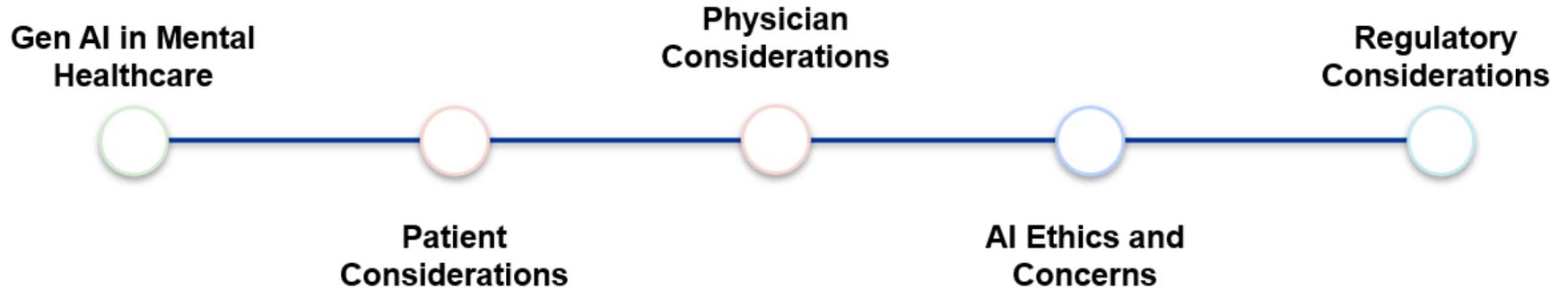


# PATIENT-PROVIDER CONSIDERATIONS IN THE USE OF GEN AI-ENABLED DIGITAL MENTAL HEALTH MEDICAL DEVICES

Brooke Trainum, November 6, 2025



# USE OF GEN-AI IN MENTAL HEALTH CARE – ROADMAP





Diagnosis



Clinical Support



Direct Therapy



- **Patient-Provider Relationship**
- **Informed Consent & Understanding**
- **Privacy & Emotional Safety**
- **Cultural and Clinical Appropriateness**
- **Accessibility**
- **Immediacy**
- **Cost**
- **Parasocial Relationships**



**Clinical Oversight and Responsibility**



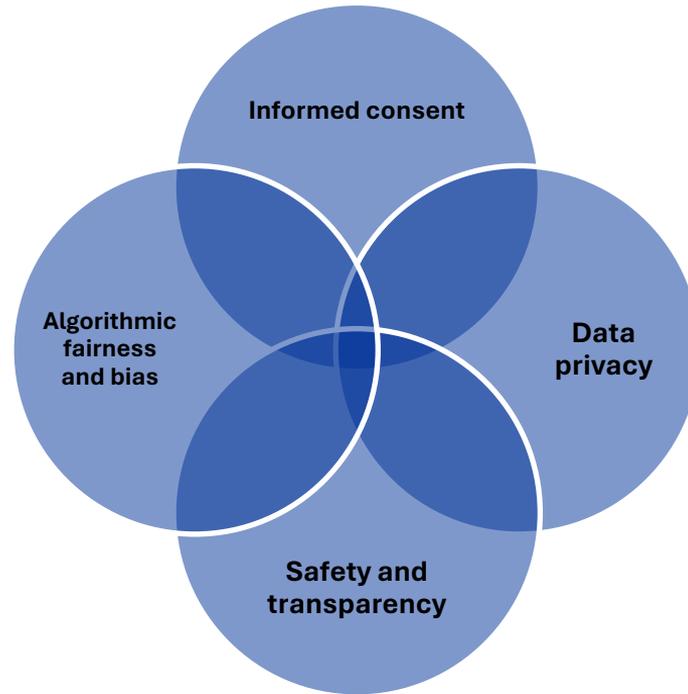
**Workflow Integration**



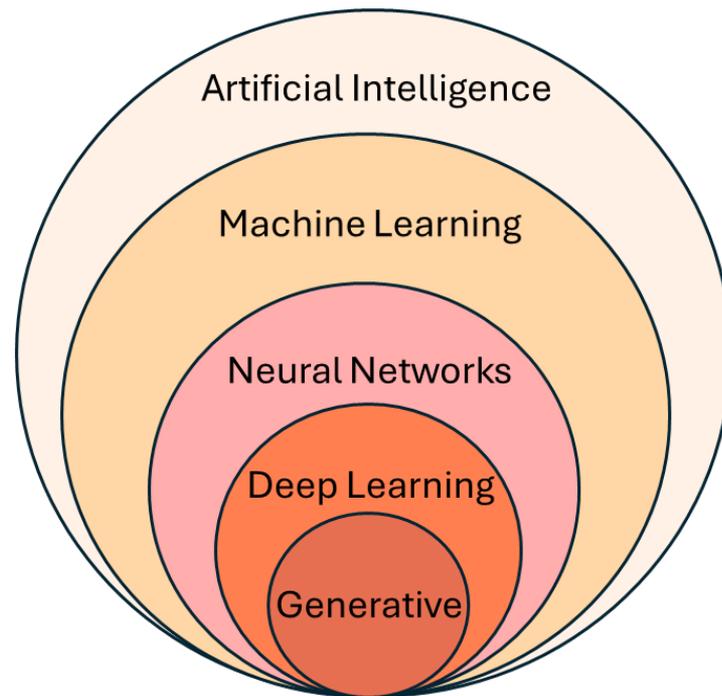
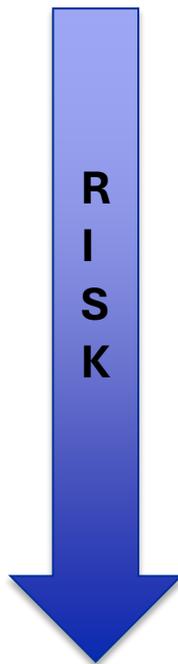
**Liability and Documentation**



**Cost**



- More Complex
- Less Transparency or Explainability
- Heavily dependent on data: Large, high-quality datasets
- Biased data can perpetuate or amplify bias
- Potential for unexpected failure modes



Florida teen dies by suicide after AI chatbot convinced him Game of Thrones Daenerys Targaryen loved him

## People Blindly Trust AI Even When It's Clearly Wrong, Study Shows

Science in Poland

PRESS RELEASE

Founder/CEO and Clinical President of Digital Health Company Arrested for \$100M Adderall Distribution and Health Care Fraud Scheme

Thursday, June 13, 2024

DOJ

For Immediate Release

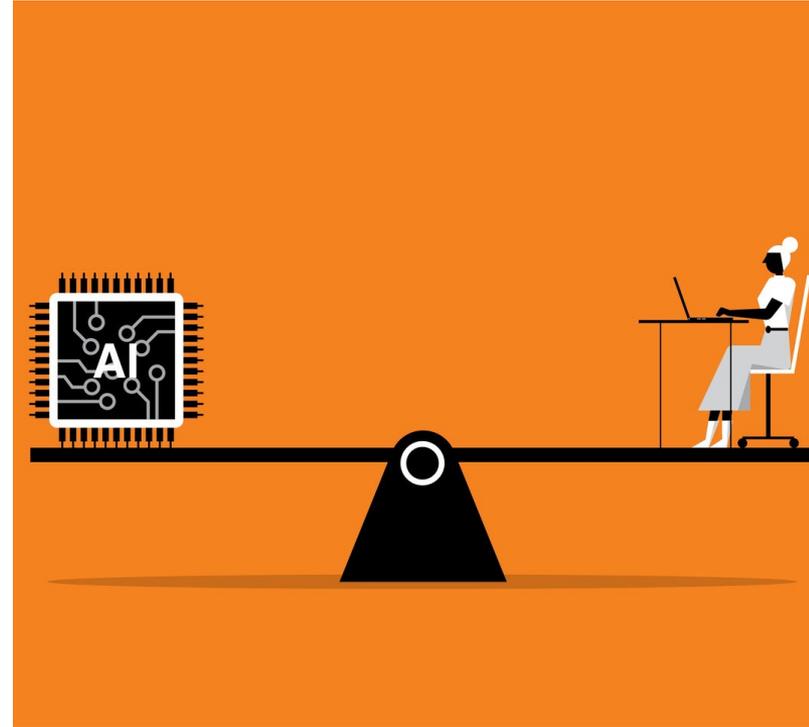


“Clinically, AI Psychosis is a complex clinical syndrome in which psychotic symptoms overlap with mood changes, limited insight, poor judgment, neurovegetative symptoms, and behavioral changes. The psychotic symptoms include changes in thought content, such as delusions and auditory hallucinations, and changes in thought process, ranging from tangential or circumstantial thinking to overly disorganized thinking. Paranoid delusions, reference delusions, and grandiose delusions have been reported.”



Preda, A. (2025). Special Report: AI-Induced Psychosis: A New Frontier in Mental Health. *Psychiatric News*, 60(10).  
<https://doi.org/10.1176/appi.pn.2025.10.10.5>

- Issue: Cannot generalize current research
- Components:
  - Technical Development
  - Clinical and Ethical
  - Legal and Regulatory
- Need: larger sample studies with appropriate controls and standardized metrics to properly determine the efficacy of Gen AI applications in mental healthcare



- Define intended use clearly: Wellness vs medical treatment
  - Wellness products still collect sensitive vital and health information from consumers, and this data is not protected by HIPAA or HITECH
- Consumers are confiding in non-confidential chatbots and mis-using them for therapeutic purposes which has resulted in harm
- Regulation is needed to govern any technology that handles sensitive health data
- Ongoing post-market surveillance, especially for unintended consequences
- Consider frameworks for:
  - **Transparency** (Explainability to patient + provider)
  - **Human-in-the-loop** requirements
  - **Risk stratification** based on patient population and clinical use

# IS IT READY FOR CLINICAL CARE?

**Regulation must reflect the human realities of therapeutic relationships**

**With the right guardrails, it may be able to enhance access, administrative burdens, and quality**



1. The need to standardize foundational information about AI tools in the form of labeling requirements AI facts label
2. Prioritize patient-centered design and evaluation
3. Encourage co-development with mental health experts and diverse patient groups
4. Mandate clinical involvement in high-risk contexts
5. Support continued research on efficacy and safety focusing on clinical rigor
6. Post Market surveillance