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Real-World Mental Health Data: Unveiling Opportunities and Ethical Challenges

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Background

REAL-WORLD MENTAL HEALTH DATA

An estimated 20% of adults in the US live with mental illness.[1] Across disorders and treatments, pharmacotherapies often have small effect sizes for their target symptoms. In light of the growing need for improved treatment efficacy and reduced adverse effects in the treatment of mental disorders, the use of Real-World Mental Health Data (RWMHD) in clinical and pharmaceutical settings has risen. Real-World Data (RWD) encompasses information collected from routine clinical practice (ie. Electronic Health Records—EHRs) and other sources outside of controlled research settings including biobanks, claims data, registries, and wearables to offer a more comprehensive view of patient outcomes in their demographic and clinical contexts.

The reliance on Randomized Controlled Tests (RCTs) has been criticized for its focus on standardized treatments, which may not account for individual differences in response to therapy.[2] As a result, there is a growing recognition of the need to complement traditional research methods with innovative approaches that can provide a more nuanced understanding of mental health disorders. By leveraging RWD, researchers can gain a deeper understanding of the epidemiology of mental health disorders, identify patterns and predictors of treatment response, and evaluate the effectiveness of interventions in diverse populations.

Unfortunately, with the rise in digital technologies, HIPAA has not kept pace in ensuring the protection of digital patient health information. The most pressing gap facing policy makers and regulators is the lack of ethical frameworks to address issues.
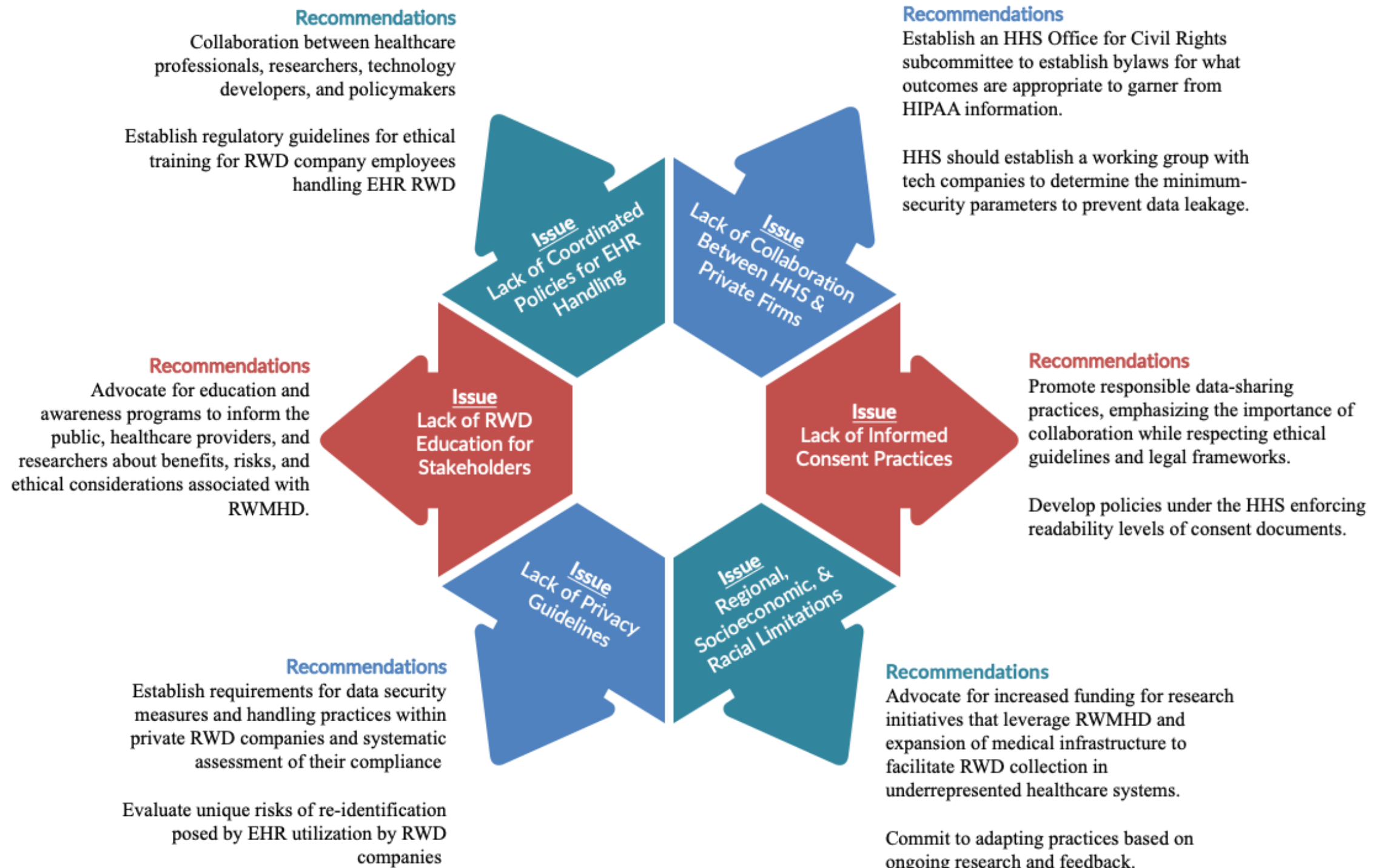
Case Study

When considering privacy implications, informed consent becomes blurred as informed consent equates to user's comprehensive of consent. The case study below explores how Meta used user data to suicide interventions based on their analysis of potential suicidality.

When Meta, formerly known as Facebook, began running AI to detect suicide prevention there was a variety of media responses to this experiment. Tineke Broer published an article "The Googlization of Health: Invasiveness and Corporate Responsibility in Media Discourses on Facebook's Algorithm Program for Suicide Prevention" that categorized how the media felt.[3] The question is if Facebook is ethically making medical decisions or disrespecting people's right to privacy?

In 2017, Facebook used AI to determine the risk of suicide for its members. Facebook would utilize natural language processing, to flag comments that could pose a suicide risk. According to NPR, Facebook stated they conducted 3,500 wellness checks in the first year. The overall intent of the company was to help combat the increasing number of suicides facing people in the United States.

The problem is should Facebook be able to make this determination if a person is mentally unstable and requires a wellness check? *Sector Creep* is when an industry operates outside its perceived boundaries, such as a company making health decisions without any license to operate. The overall media view was that Facebook was being invasive of privacy. While there is an understanding that what is posted on that site is public domain, it doesn't necessarily mean that users consent for their posts to be turned into actionable items for their safety.[4] Of note, the EU does not allow Facebook to utilize data the same way, and therefore there were no "wellness checks" in the EU. Users of Facebook may choose to consent to Facebook's methods of monitoring, but with constantly evolving terms of service, it is difficult for users to know how their data is being used.

Recommendations

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Collaboration between healthcare professionals, researchers, technology developers, and policymakers

Establish regulatory guidelines for ethical training for RWD company employees handling EHR RWD

Issue
Lack of Coordinated Policies for EHR Handling

Issue
Lack of Collaboration Between HHS & Private Firms

Recommendations
Establish an HHS Office for Civil Rights subcommittee to establish bylaws for what outcomes are appropriate to garner from HIPAA information.

HHS should establish a working group with tech companies to determine the minimum-security parameters to prevent data leakage.

Recommendations
Advocate for education and awareness programs to inform the public, healthcare providers, and researchers about benefits, risks, and ethical considerations associated with RWMHD.

Issue
Lack of RWD Education for Stakeholders

Issue
Lack of Informed Consent Practices

Recommendations
Promote responsible data-sharing practices, emphasizing the importance of collaboration while respecting ethical guidelines and legal frameworks.

Develop policies under the HHS enforcing readability levels of consent documents.

Issue
Lack of Privacy Guidelines

Issue
Regional, Socioeconomic, & Racial Limitations

Recommendations
Establish requirements for data security measures and handling practices within private RWD companies and systematic assessment of their compliance

Evaluate unique risks of re-identification posed by EHR utilization by RWD companies

Recommendations
Advocate for increased funding for research initiatives that leverage RWMHD and expansion of medical infrastructure to facilitate RWD collection in underrepresented healthcare systems.

Commit to adapting practices based on ongoing research and feedback.

Challenges and Considerations

Data Standardization

The development of sophisticated algorithms and treatment plans hinges on the quality of data. Efforts to standardize mental health data creates a unified criteria for assessment and treatment are imperative.

This standardization is not only technical but also clinical, necessitating consensus among practitioners on diagnostic criteria and treatment outcomes.

Equity

Access to the latest technologies is often skewed by socioeconomic status, geography, and education, potentially exacerbating existing disparities in mental health care.

Strategies must be developed to ensure that innovations in are accessible and beneficial to all segments of the population.

Future Directions

The most pressing gap facing policy makers and regulators is the lack of ethical frameworks to address issues. Examples of ethical issues include informed consent and equity and concerns to guide safe use of this data in large public or private data sets. An ethical framework would allow both research and companies a better system to evaluate data collection and ensure ethical adhere to those handling that data. A new ethical framework would require constant monitoring and updates to ensure that the recommendations remain current with the rapidly changing ecosystem surrounding RWMHD. Various stakeholders include hospitals who collect data and industry partners who de-identify and analyze data. Such cross-disciplinary collaboration requires every partner to be involved in the knowledge acquisition and policymaking process. This collaboration ensures that ethical standards and policies created in this field are robust enough to anticipate the ethical dilemmas that may arise in the future.

References

[1] National Institute of Mental Health. Mental illness. National Institute of Mental Health. Published March 2023. Accessed February 4, 2024. https://www.nimh.nih.gov/health/statistics/mental-illness

[2] Clay RA. Trials and tribulations. Monitor on Psychology. 2010;41(8). Accessed April 2, 2024. https://www.apa.org/monitor/2010/09/trials.

[3] Broer T. The Googlization of Health: Invasiveness and corporate responsibility in media discourses on Facebook's algorithmic programme for suicide prevention. Social Science & Medicine. 2022;306doi:10.1016. Accessed October 14, 2024. https://doi-org.proxy.lib.duke.edu/10.1016/j.socscimed.2022.115131

[4] Sharon T. From hostile worlds to multiple spheres: towards a normative pragmatics of justice for the Googlization of health. Medicine, Health Care and Philosophy. 15 March 2021 2021;24:315-327. doi:10.1007.Accessed February 2, 2024. https://link.springer.com/article/10.1007/s11019-021-10006-7