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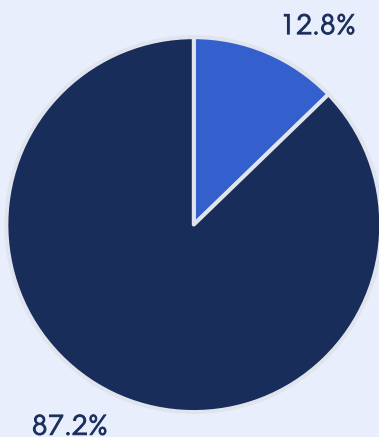
The Need for Real-World Evidence to Close the Behavioral Health Evidence Gap

December 2021

An Introduction to Real-World Evidence

Real-world evidence is critical for the development and approval of new medical treatments.

More than 10% of the global population lives with a mental health condition.[1]

12.8%

87.2%

Real-world evidence (RWE) is critical for the development and approval of new medical treatments—and has become increasingly important over the last several years.

Real-world data (RWD) are patient health status or health care delivery information collected as a part of routine clinical care and can be derived from sources such as electronic health records (EHRs), insurance claims and billing, and wearable monitoring devices. RWE is generated from the analysis of RWD, and it is used both by pharmaceutical companies to develop new treatments and by regulatory bodies to support decision making regarding these new treatments' safety and efficacy. The landscape surrounding the use of RWE and the frequency with which it is used is rapidly evolving.

1. OWID. (August 6, 2019). Number of people globally that suffered from select mental health or substance use disorders as of 2017 (in millions) [Graph]. In *Statista*. Retrieved December 03, 2021, from https://auth.lib.unc.edu/ezproxy_auth.php?url=https://www.statista.com/statistics/979869/number-of-people-with-mental-health-disorders-globally/

The FDA recognizes the potential of RWE.

The U.S. Food and Drug Administration (FDA) has recognized the potential of RWE, releasing guidance on its use as part of the agency's implementation of the 21st Century Cures Act, which was enacted by Congress in 2016 to "accelerate medical product development and bring innovations faster and more efficiently to the patients who need them." Now, Congress is building on the momentum generated by this legislation and has introduced Cures 2.0, which calls for "approaches to maximize and expand the use of RWE" and is expected to become law later this year or early next.

> **Behavioral disorders are the leading causes of disability worldwide, representing about 10% of the global disease burden.[2]**

Although RWE has been helpful in advancing discovery and treatment development in therapeutic areas such as oncology and neurodegenerative disorders, its application in behavioral health—which includes both mental health and substance use disorders—has lagged behind. The impact of behavioral health challenges worldwide is staggering and has only increased during the COVID-19 pandemic.
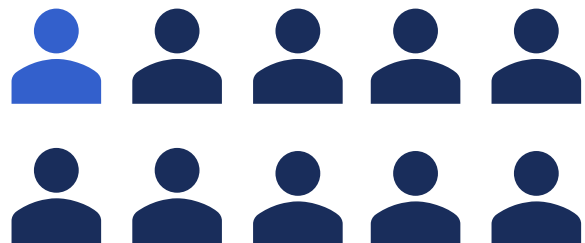
The relatively slow adoption of RWE in behavioral health can be attributed to many factors. First, there is a substantial disconnect between the kinds of outcomes we measure in clinical trials for the development of new treatments and the kinds of outcomes we measure in routine clinical care. Similarly, in clinical care, there are obstacles to how data and evidence are used to inform day-to-day practice. These disconnects in both clinical trials and clinical practice represent what we refer to as the **behavioral health evidence gap**, which significantly limits the degree to which RWE can be used effectively to improve treatment development and clinical care.

2. (n.d.). Grand Challenges in Global Mental Health. National Institute of Mental Health.
https://www.nimh.nih.gov/about/organization/cgmhr/grandchallenges

At Holmusk, we are working to address this gap by building the world's largest RWE platform for behavioral health.

The challenges are many, and we provide a high level outline of some of them below. But we are committed to addressing these challenges and highlight steps we can and are taking to do so. We call on our colleagues in the field to join us in leveraging the opportunities that accompany these challenges. Together, we can close the behavioral health evidence gap and use RWE to improve research and care for behavioral health.

Challenges

There has been slow uptake of EHR systems in behavioral health care.

Routinely collected behavioral health data are highly variable and subjective across patients and settings.

Existing data have great potential — which is difficult to fulfill.

Clinical trials that generate evidence are not representative of the real world.

RWE in Behavioral Health:
Large Challenges, Larger Opportunities

Challenge:

There has been slow uptake of EHR systems in behavioral health care.

The Health Information Technology for Economic and Clinical Health (HITECH) Act, which incentivized adoption of electronic health records among health care providers, was enacted in 2009—but behavioral health was not included in this federal legislation due, in part, to other existing laws regarding privacy for mental health and substance use disorder treatment.

Opportunity:

We must continue to increase the adoption of EHRs in settings and systems that provide behavioral health care.

Our approaches for managing data and protecting privacy have improved significantly since the passage of the HITECH Act, and we should seek to standardize the manner in which electronic data can be collected and aggregated for behavioral health conditions.

Challenge:

Routinely collected behavioral health data are highly variable and subjective across patients and settings.

The behavioral health field does not yet have objective markers for diagnosis, disease progression, or outcomes. Beyond data that are collected for billing purposes, there is generally not consensus about what information should be gathered for any given indication or condition. Most clinical visits are documented via patient report and clinician judgment, and even these measures are not consistently measured and recorded in a patient chart.

Opportunity:

We must advocate for better standards and processes in documentation when it comes to patient care.

Clinicians will only use standardized approaches for measuring and documenting behavioral health outcomes if they can be shown to meaningfully improve quality of care and outcomes, and if these approaches do not add additional complexity to clinical workflows. We must seek ways to demonstrate these quality improvements and address implementation barriers.
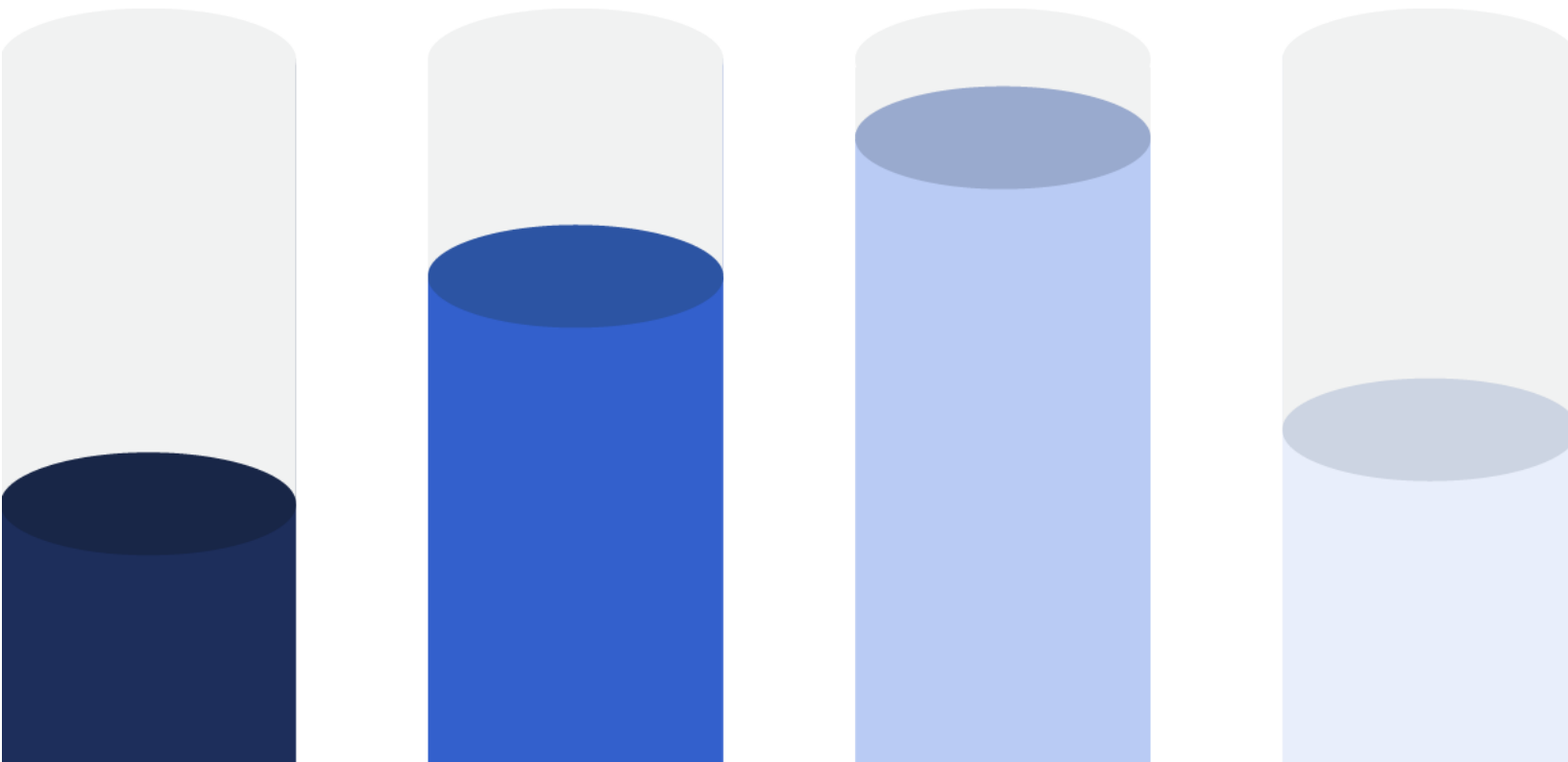
Challenge:

Existing data have great potential — which is difficult to fulfill.

Clinician notes are rich with meaningful data points, including descriptions of mental status, treatment response, stressors, and other important information that could help derive new insights. However, because these data often lie within subjective free text within the clinical chart, they are difficult to aggregate, and their potential remains unfulfilled.

Opportunity:

We must deploy a multifaceted approach for improving the quality of routinely collected behavioral health clinical data in order to better draw insights from the rich information gathered during care.

We should leverage both technology (eg., improvements in EHR user experience and the use of novel tools for gathering patient-generated health data) and advances in data science (eg., applying machine learning and artificial intelligence methods to pull "signal" out of the "noise" of otherwise complex and multidimensional data). Taken together, these approaches will help advance the generation of true RWE for behavioral health.

Challenge:

Clinical trials that generate evidence are not representative of the real world.

Both trial outcomes and patient populations for clinical trials are misaligned from what is actually used and seen in practices that provide behavioral health care. While clinical trials in many other therapeutic areas measure outcomes that are routinely assessed in clinical practice, this is not the case in clinical trials for behavioral health, making it difficult to apply clinical trial results to real world care, and vice-versa. In addition, restrictive eligibility requirements to participate in clinical trials lead to patient populations for trials that do not mirror patient populations seen in the real world. This lack of representativeness impacts generalizability of trial results and makes it challenging to improve patient care for all.

Opportunity:

We must seek to align outcomes in clinical trials with those collected in clinical care and work to ensure that RWE studies are representative of real patient populations.

SAMPLE CLINICIAN NOTE

ANALYSIS

1. Mental Status

2. External stressors

3. Outcomes

4. Side Effects

This means considering new and innovative outcomes in trials, along with better collection of high-quality data in clinical practice. Once these outcomes are better aligned, it will be easier to promote representativeness in RWE studies by easing eligibility requirements and enabling more people to participate. This will require an iterative process with input from clinicians, sponsors, regulators, and patients, but will lead to better clinical evidence generation and improve behavioral health care in meaningful ways for a larger proportion of those who need it most.

Our Role in Building a Better RWE Future for Behavioral Health

At Holmusk, we're pairing clinical expertise with powerful data science applications to address these challenges and build upon their accompanying opportunities. Our resources and capabilities include:
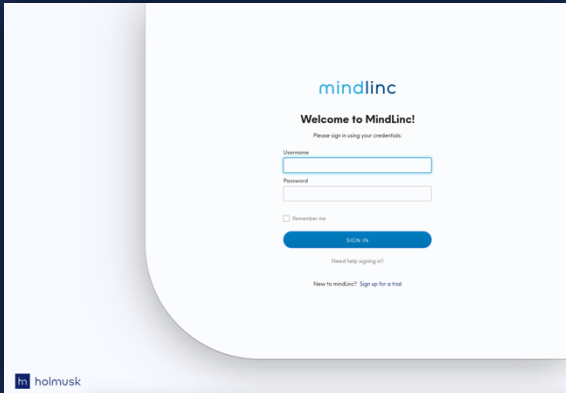
MINDLINC 2.0

Our EHR system is specifically designed for behavioral health, improving data quality by helping clinicians capture important points of the patient experience, such as disease severity, through structured fields. High-quality input leads to better output—data that are structured and standardized. MindLinc also offers predictive analytics and a suite of decision-making tools that enables clinicians to deliver improved care in real time.

DATA SCIENCE, DEPLOYED

Data science applications such as Holmusk's proprietary natural language processing models aid in processing and gaining meaning from unstructured data, transforming messy and widely variable clinician notes into structured data elements that can unlock new insights. Additionally, sophisticated predictive modeling approaches, such as NeuralODE and semi-mechanistic quantitative systems pharmacology can be used to inform research and clinical care decisions.

NEUROBLU

We're aggregating the EHR and other data to build the world's largest RWE platform for behavioral health and create a common data model for previously disparate data. NeuroBlu, our data analytics platform—which currently contains over 50 million rows of data and is growing rapidly—is poised to address the toughest challenges in behavioral health.

Learn more at www.holmusk.com.