



Real World Evidence (RWE) in Behavioral Health: Its History and Its Future

Kenneth Park, MD

Disclosure

- Kenneth Park is currently employed by Clarify Health Solutions which provides software, analytic, and data solutions to payers, providers, and life science customers including pharmaceutical manufacturers, diagnostics companies, and medical device manufacturers

What will be covered today

- History of Real World Evidence (RWE) over the past ~30 years and where it's going
- Snapshots in time every ~12 years
- Early efforts to use electronic data
- Earliest days of RWE as an industry term
- Current use of RWE including most recent developments
- What the future needs to solve for

My first exposure to RWE

1996



**Massachusetts
General Hospital**



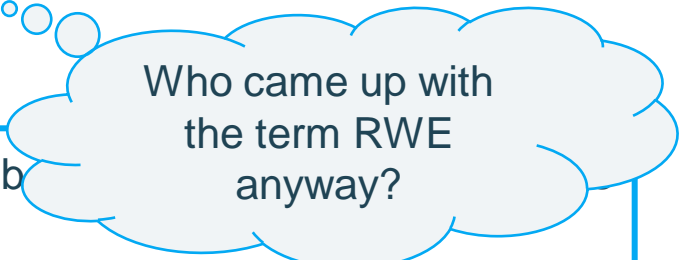
McLean Hospital

- Manually curated database of >8,000 individuals
- Full DICA or SCID provided for Axis I disorders
- Neuropsychological batteries conducted
- DICA/SCID results catalogued symptom by symptom
- Neuropsychological results captured
- GAF scores recorded
- Periodically updated for patients to help track change in symptomology over time
- Served as both clinical and research database

The introduction of Real World Evidence (RWE) to pharma

2008

- Original concept – use data created outside of a controlled, experimental environment to be used outside of a controlled, experimental environment
- Expansion and significant growth of investment into the fields of epidemiology, Health Economics & Outcomes Research (HEOR), and clinical informatics



Who came up with the term RWE anyway?

Value demonstration to payers

- Payers skeptical of clinical trial data
- What if RWE could prove that drugs had the same effect in the 'real world' that they did in a trial?
- Greater, proven value to payers = higher negotiated price points for pharma = higher profits

Pharmacovigilance

- Academic researchers already starting to use EMR data to look for safety issues with drugs
- Concerns on research quality and ability to respond
- What if RWE could answer safety questions much more quickly and accurately?
 - Protect patients from unsafe drugs
 - Ensure continued access to safe drugs

RWE applications and current use

2023

Who uses it?

- Academics
- Government agencies (e.g., FDA, state agencies, CMS)
- Pharmaceutical, medical device, and diagnostics companies
- Patients
- Financial institutions

What are they using it for?

- Epidemiology
- Pharmacovigilance
- Cost effectiveness
- Comparative effectiveness
- Clinical trial planning and design
- Drug discovery
- Genomic research
- Financial forecasting

Newer applications

- Pragmatic studies
- Enriched studies
- Synthetic control arms
- Clinical trial recruitment

Challenges to future adoption and value creation

2024 - ?

Data Granularity



Data Collection



Data Longitudinality

- Structured symptom level data
- Severity
- Frequency
- Aligned with DSM diagnostic criteria

- Routine collection in electronic format
- Can be facilitated by psychometricians or collected organically

- Eliminate gaps in time
- Eliminate gaps in data completeness
- Connect data across multiple providers, payers, episodes