**EXECUTIVE INSIGHT**

**REAL-WORLD EVIDENCE: PRESENT AND FUTURE**
Implications for Patients, Providers, and Healthcare

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**WHAT DOES REAL-WORLD EVIDENCE MEAN FOR PATIENT CARE?**

**SB:** Most providers would agree on two critical imperatives driving healthcare transformation: controlling costs and improving quality. Real world evidence (RWE) is part of the solution. Clinical trials are crucial to examine the safety, ethics and efficacy of new therapies. Equally important are best practice clinical interventions, which can offer improved means to prevent, screen for, diagnose or treat a disease. However, understanding effectiveness, or how existing clinical interventions and therapies ultimately impact outcomes when used on the frontlines of healthcare rather than within the confines of a carefully controlled clinical trial, is key to implementing standardized protocols that drive total cost and quality improvement.

In most cases, controlled trials have strict eligibility requirements that eliminate pools of possible participants for a number of reasons including age and co-morbid conditions. RWE, however, represents a paradigm shift in how research is conducted by using data from actual events in heterogeneous populations that occur in clinical practice. RWE research can include pragmatic trials in diverse clinical practice settings with everyday patients and clinicians. However, most RWE research is observational, gaining insights from medical records, prescriptions, registries, apps, surveys (including patient reported outcomes), chart reviews, and administrative data, such as claims and charge masters. RWE is derived from examining several factors when testing how FDA-approved interventions affect targeted patient populations, particularly those with unmet medical needs, to create best practices for existing and new treatments.

**WHY SHOULD PROVIDERS CARE ABOUT REAL-WORLD EVIDENCE?**

**SB:** Most providers have participated in some sort of clinical trial – which looks narrowly at the effect of a therapy, usually a drug, with a homogeneous population that is being treated in a controlled setting with specialized personnel. Clinicians are the ones truly driving these therapies forward across a diverse range of healthcare settings. Outcomes can vary widely depending on if the therapy was used in a hospital, outpatient clinic or nursing home or – as frequently the case, on patients unlike those included in clinical trials (e.g., the elderly are often excluded).

RWE research is focused on short- and long-term outcomes, efficiency, cost implications, patient reported outcomes and other data. At the end of the day, this work helps hospitals and health systems enhance clinical practices and drive greater value around targeted medical approaches – examining efficiency and the quality of these interventions and how they impact short- and long-term patient outcomes.

For example, a real-world retrospective observational research study led by Premier and bioMerieux examined the effect of testing with the biomarker procalcitonin in thousands of U.S. patients admitted to an intensive care unit (ICU) with sepsis. Procalcitonin exhibits greater sensitivity and specificity than other markers in ruling-out and ruling-in sepsis and other serious bacterial infections. The results showed that patients in the procalcitonin testing group spent less time in the hospital (reduced length-of-stay up to 1.3 days) and reduced hospitalization costs by nearly $2,800 per patient.

Another real-world research study conducted by Premier Applied Sciences and Janssen Pharmaceuticals focuses on patients with atrial fibrillation who are at risk for stroke. Despite numerous effective and safe treatment options that are aligned with national guidelines, approximately half of these patients are not receiving an oral therapy that can help prevent it. This first of its kind study is evaluating the effects of targeted real-world interventions that can improve the utilization of evidence-based practices for these patients, reduce the occurrence of stroke and improve outcomes.

**HOW IS REAL-WORLD EVIDENCE CHANGING HEALTHCARE?**

**WHAT IS THE FUTURE FOR THIS WORK?**

**SB:** RWE is a science and data-driven best practice that drives true effectiveness analyses of treatments, practices and IT systems. It provides a meaningful assessment of costs when delivering new and innovate treatments. RWE can also lay the foundation in establishing effective risk-sharing agreements between manufacturers, payers and providers based on patient outcomes.

Growth in the prevalence and breadth of electronic health records was a step in the right direction for RWE. As mergers and acquisitions continue to be a force within the healthcare marketplace – and the disparate systems which come along with this type of activity that fosters lack of interoperability and siloed data – both providers and Life Sciences companies should seek out partners with robust clinical and financial healthcare databases to provide easier and quicker access to insights derived from RWE.

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