



When Therapeutic Evidence Meets Patient Reality: Reframing the Value of Medicines Beyond the Prescription

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Abstract

The value of a medicine is often defined primarily through evidence of efficacy and safety generated during clinical development. However, the experience of patients after a medicine reaches routine healthcare can differ considerably from the controlled circumstances of clinical trials. Treatment adherence, accessibility, affordability, health literacy, comorbidities, patient preferences, treatment burden, and healthcare-system factors can all influence whether a theoretically effective medicine produces meaningful benefit in practice. Consequently, evaluating medicines solely according to conventional efficacy and safety endpoints may provide an incomplete picture of therapeutic value. Patient-entered evidence, real-world data, patient-reported outcomes, and longitudinal treatment information can provide complementary perspectives on how medicines perform in everyday healthcare.

Keywords: Therapeutic Value; Medicines; Patient-Centred Care; Clinical Evidence; Real-World Evidence; Treatment Adherence; Patient-Reported Outcomes; Precision Medicine; Healthcare Delivery

Abbreviations

Real-World Evidence (RWE); Real-World Data (RWD); Patient-Reported Outcomes (PROs); Randomized Controlled Trial (RCT); Artificial Intelligence (AI).

Introduction

Modern medicine relies heavily on clinical evidence to determine whether a therapeutic intervention should be approved and incorporated into clinical practice. Randomized controlled trials provide a rigorous framework for assessing efficacy and safety under predefined conditions. They remain essential for establishing whether a medicine can produce a beneficial effect. However, the circumstances of a clinical

trial are not identical to those encountered by patients in everyday healthcare [1].

Patients receiving medicines outside clinical trials may have multiple chronic conditions, take several medications simultaneously, experience different levels of healthcare access, and have treatment preferences that influence their decisions. They may also face financial, geographical, social, or logistical barriers that affect whether treatment is initiated and maintained. As a result, the difference between what a medicine can achieve under controlled conditions and what a patient experience can be substantial.

The prescription itself represents only one point in the therapeutic journey. After prescribing, a patient must

obtain the medicine, understand how to use it, tolerate it, remain able or willing to continue treatment, and ultimately experience an outcome that is meaningful to them. A medicine with demonstrated efficacy may therefore have limited real-world value if treatment burden is excessive, adherence is difficult, access is inconsistent, or adverse effects interfere with continued use.

Efficacy and effectiveness should not be regarded as interchangeable concepts. Efficacy generally describes the effect of an intervention under controlled research conditions, whereas effectiveness concerns how that intervention performs within routine healthcare. The distinction is important because real-world circumstances introduce variables that cannot always be fully controlled within conventional trials.

Real-world evidence can provide complementary information regarding treatment utilization, effectiveness, safety, adherence, and longer-term outcomes. Electronic health records, registries, insurance claims, pharmacy information, and patient-generated data can contribute to understanding how medicines perform across broader

populations [2].

However, real-world evidence must be interpreted carefully. Large datasets do not automatically produce reliable conclusions. Confounding, missing data, selection bias, measurement differences, and variations in clinical practice can affect observational findings. The goal should therefore not be to replace randomized evidence with real-world data, but to integrate different evidence sources to produce a more complete understanding of therapeutic performance.

References

1. Oehrlein EM, Schoch S, Burcu M (2023) Developing Patient-Centered Real-World Evidence: Emerging Methods Recommendations from a Consensus Process. *Value Health* 26(1): 28-38.
2. Corneli A, Hanlen-Rosado E, McKenna K (2023) Enhancing Diversity and Inclusion in Clinical Trials. *Clin Pharmacol Ther* 113(3): 489-499.