

I Live in the Real World. My Patients Do, Too

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The term “evidence-based practice” is supposed to mean the use of the best available evidence when making patient care decisions. Typically, however, this “best evidence” is obtained from randomized controlled trials (RCTs), the patients are recruited from a homogenous group, and the data are closely controlled and monitored. Evidence gathered in such a research setting does not reflect real-world clinical practice. That is where more pragmatic real-world evidence (RWE) studies come in. If the results of RCTs represent what is possible, RWE represents what is probable, and don't we want to rely more heavily on evidence of the probable?

We strive to make health care more effective and personalized. To do this, we must understand the difference between evidence from RCTs and RWE. RCTs have strict inclusion and exclusion criteria; include extensive, regimented monitoring; usually offer substantial patient support and education; and are designed with relatively short follow-up periods (i.e., weeks, months, or 1–2 years) (1). In contrast, RWE studies include estimates of effectiveness in a variety of typical practice settings; allow for multiple alternative interventions (e.g., older vs. newer drugs) or comparisons between different clinical strategies beyond a placebo condition; enable estimates of the risk-benefit profile of a given intervention; facilitate the collection of clinical outcomes from a diverse study population; and incorporate

information that includes adherence to therapy (2).

RWE encompasses clinical, genomic, and socioeconomic data and thus yields a better picture of individual patient characteristics, improving our ability to treat individual patient needs. Increasingly, even insurers are requesting RWE so they can evaluate the benefits of therapies they are covering to the patients actually receiving them.

We care for heterogeneous patients in our real-world practice settings. Living in the real world can be challenging for ourselves and for our patients. The increasing availability of RWE—data derived from large databases reflecting hundreds of thousands of patient experiences in real-world settings outside of RCTs—allows us to make health care more effective for our real-world patients.

Duality of Interest

No potential conflicts of interest relevant to this article were reported.

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