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How “real” is the real world?

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Over the past few years, the term *real world* has become firmly established in the biomedical literature. Its widespread adoption has paralleled the growing interest in *real-world data* (RWD) and *real-world evidence* (RWE), concepts with well-established methodological definitions: information collected outside the setting of randomized clinical trials, derived from routine clinical practice, patient registries, electronic health records, or administrative databases.[1,2] However, what began as a precise methodological term has increasingly become a convenient label, appearing with growing frequency in titles, abstracts, and discussion sections, often functioning more as a buzzword than as an accurate methodological description.

Today, expressions such as *real-world study*, *real-world experience*, and *real-world setting* are commonplace. Yet one may reasonably ask what information this label actually adds. What distinguishes a “real-world” study from an observational study? Is there a specific methodological characteristic that justifies this designation, or is it simply a new way of describing study designs that have existed for decades? In many instances, the latter appears to be true.

Furthermore, one may question whether merely incorporating the expression real world confers additional value on a study. Its use seems to imply greater clinical relevance, broader applicability of the findings, or a more faithful representation of routine clinical practice. However, none of these qualities depends on what the study is called.[3] External validity, population representativeness, and the generalizability of findings are determined by the methodological design, patient selection, data quality, and statistical analysis—not by a label added to the title.

Paradoxically, many studies presented as “real-world” investigations fall well short of reproducing the complexity of everyday clinical practice. They frequently employ strict inclusion and exclusion criteria, define carefully delimited observation periods, analyze selected patient populations, exclude individuals with incomplete data, or evaluate interventions delivered under highly standardized conditions. All of these methodological decisions are reasonable—and often necessary—to answer a specific research question. Yet by controlling sources of variability and minimizing bias, such studies move closer to the experimental model and, at least in part, further away from the very “real world” they claim to represent.

This contradiction becomes even more evident when the label is applied to small case series from a single institution or clinical service. In

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these situations, representativeness is inherently limited, raising the question of how "real" a study can be when its findings reflect the experience of a relatively small group of patients treated within a highly specific healthcare setting. Such experience can hardly be considered representative of routine clinical practice. Nevertheless, it is not uncommon to find small single-center case series or cohort studies presented as "real-world" research, as though the use of this expression could somehow compensate for their inherent limitations in representativeness and external validity.

Fundamentally, all clinical research involves a balance between control and representativeness. Experimental studies deliberately seek to control as many conditions as possible in order to evaluate the relationship between predictors and outcomes while minimizing the influence of confounding factors. Observational studies relinquish part of that control to describe or analyze phenomena in routine healthcare settings, typically at substantially lower cost and with greater feasibility. Neither approach captures reality in its entirety; both construct a methodological framework tailored to the research question they seek to answer.

For this reason, the dichotomy between experimental studies and "real-world" studies may not be as clear-cut as it is often portrayed. Observational studies also carefully define their study populations, eligibility criteria, exposure and outcome definitions, and analytical strategies. Conversely, many pragmatic clinical trials are intentionally designed to approximate routine clinical practice. In many cases, the boundary between these two approaches is far less distinct than the terminology suggests.

There is also an additional conceptual risk. As noted earlier, the growing popularity of the expression *real world* may create the impression that it represents a superior methodological category or an implicit guarantee of quality, as though the use of this qualifier obviated the need for confirmation through appropriately controlled studies. Such an interpretation would be misguided. Real-world data are invaluable for assessing effectiveness, safety, healthcare resource utilization, and outcomes in large populations, and real-world evidence has become an increasingly important complement to the existing body of evidence. Nevertheless, these approaches do not eliminate the inherent limitations of observational research, nor do they replace the role of randomized clinical trials when the objective is to establish causal relationships.

The indiscriminate use of this terminology inevitably creates confusion. For this reason, precise methodological descriptions should be preferred. Readers learn far more when an article is described as a retrospective cohort study, a prospective registry, a multicenter observational study, or an analysis of population-based databases than when it is simply presented as a real-world study. The former explains how the evidence was generated; the latter, all too often, serves merely as a fashionable expression.

Biomedical research depends on clear concepts and rigorous terminology. Real-world data and real-world evidence are valuable and complementary tools within the contemporary methodological arsenal. Precisely because of their importance, their specific meanings should be preserved, and their indiscriminate use should be avoided lest these concepts gradually lose their content. No study becomes better simply by calling itself a "real-world" study; its quality will continue to depend, as it always has, on the rigor with which it was designed, conducted, and reported.

Methodology establishes validity; labels merely create expectations. ■

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