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Closing the Treatment-to-Outcome Gap: Emerging Evidence on How Medicines Perform in Everyday Care

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Short Communication

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Abstract

The effectiveness of a medicine in routine healthcare can differ from the efficacy demonstrated under the controlled conditions of clinical trials. This treatment-to-outcome gap may arise from differences in patient characteristics, comorbidities, adherence, treatment duration, healthcare access, prescribing practices, and patterns of medicine use. As medicines move from clinical research into everyday care, understanding their performance across broader and more diverse populations becomes increasingly important. Real-world data generated from electronic health records, registries, claims databases, pharmacy records, and patient-generated information provide opportunities to evaluate treatment effectiveness and safety beyond conventional trial settings. Real-world evidence can complement randomized clinical-trial findings by providing information about treatment utilization, persistence, long-term outcomes, and effectiveness in populations that may be underrepresented in controlled studies.

Keywords: Real-World Evidence; Real-World Data; Drug Effectiveness; Clinical Trials; Medicine Evaluation; Treatment Outcomes; Patient-Centred Care; Healthcare Data; Pharmacovigilance

Introduction

Clinical trials provide the foundation for evaluating the efficacy and safety of medicines before regulatory approval. Randomized controlled trials are particularly valuable because randomization and controlled study conditions can reduce several forms of bias and allow researchers to estimate treatment effects under predefined circumstances.

However, the patients who receive medicines after approval may differ substantially from participants enrolled in clinical trials. Routine clinical populations can include individuals with multiple comorbidities, polypharmacy, different levels of adherence, advanced age, varying socioeconomic circumstances, and diverse healthcare needs.

Consequently, there may be a gap between the results observed in clinical trials and the outcomes achieved during everyday treatment. This does not necessarily indicate that clinical-trial evidence is inadequate. Rather, it reflects the fact that efficacy and effectiveness answer related but different questions [1].

From Efficacy to Everyday Effectiveness

Efficacy generally describes how well a medicine performs under controlled research conditions, whereas effectiveness concerns how well the medicine performs

within routine clinical practice. In clinical trials, participants receive predefined interventions and are usually monitored according to standardized protocols. In everyday healthcare, treatment decisions are influenced by clinical judgment, patient preferences, adherence, healthcare access, concomitant treatments, and changing disease conditions.

The Growing Role of Real-World Data

Real-world data are increasingly available through multiple healthcare and patient-related sources. Electronic health records can provide information regarding diagnoses, prescriptions, laboratory findings, clinical encounters, and treatment outcomes. Registries can offer longitudinal information for specific diseases or patient groups, while claims and pharmacy databases can provide information regarding healthcare utilization and medication dispensing.

Patient-generated information may provide an additional perspective by capturing symptoms, treatment experiences, and outcomes that are not always available through conventional clinical records.When appropriately analysed, these sources can contribute to real-world evidence concerning the effectiveness and safety of medicines. They may also help identify treatment patterns and outcomes across populations that are less represented in traditional trials [2].

Conclusion

The treatment-to-outcome gap represents an important consideration in contemporary medicine evaluation. A medicine that demonstrates efficacy in controlled clinical trials may encounter different conditions when introduced into routine healthcare. Patient characteristics, adherence, treatment persistence, comorbidities, healthcare access, and clinical practice can all influence real-world outcomes.

Real-world evidence provides an important complementary perspective by helping researchers understand how medicines perform across broader populations and longer periods. Nevertheless, its value depends on rigorous study design, reliable data, appropriate analytical methods, and careful interpretation.

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