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Ravneet Singh Sangha, Bachelor of Science 2026
The University of Cincinnati, College of Medicine.
Cincinnati, Ohio, USA
Email – ravneetss02@gmail.com

THE ROLE OF REAL-WORLD EVIDENCE BASED RESEARCH IN ADVANCING GLOBAL HEALTH OUTCOMES

Introduction

Real world evidence (RWE) research is an essential part of modern medicine. Disparities in wealth, access to healthcare and health outcomes are widespread in global health. Randomized clinical trials (RCTs) are recognized as the gold standard in advancing modern therapies. Gaye B recently wrote about bias in medical research and how African populations are missing from medical research[1]. He wrote how Africa accounts for about 25% of the global disease burden and 19% of the global population. In his review of five prestigious medical journals only 3.9% of clinical trials were conducted exclusively in Africa. He describes how the risk of severe adverse effects with the use of angiotensin converting enzyme inhibitor medications (ACE-i) in people of African descent is three to four-fold higher than other populations. There is evidence that genetics, environment and diet all play a role in how people respond to medications. Without African populations being represented in randomized clinical trials the external validity of trials performed in non-African populations is thus limited.

Real world evidence is the systematic use of data collected from patients and populations to study diseases, treatments and interventions. This data is collected from organized electronic health records, digital technology, medical claims and registries. Registries are organized and systematically collected patient information. In contrast to randomized clinical trials, registries examine very diverse populations over long periods of time. This allows for a greater understanding of both acute and chronic conditions.

Much of the research conducted in low-income countries (LICs) has been in acute conditions like infectious diseases. But, with increasing lifespans worldwide the incidence of chronic disease is increasing globally as well[2]. In Africa chronic diseases like cardiovascular-heart disease, diabetes and stroke now account for a larger proportion of deaths than ever before[3]. The prevalence of multiple sclerosis (MS) has traditionally been associated with latitude and vitamin D exposure[4]. However, traditional research examining MS prevalence has typically been done with data obtained from developed countries. With the use of RWE, Hwang et al. showed that health care access significantly contributes to the global variations in MS prevalence[5]. Especially since national wealth rises with latitude this likely results in significant underestimation of MS prevalence in countries with lower health expenditures. MSBase is one source of RWE that can be used to further global health outcomes. MSBase is a global registry dedicated to tracking information for Multiple Sclerosis and other neuro-immunologic disorders. Currently, the registry includes 200 clinics in 45 countries compromising over 125,000 patient records[6]. The only African country with over 5000 patients enrolled in the MSBase registry is Egypt[6].

Registries cannot solve problems of health care structures or access to medication alone

however; they can help to improve the quality of care. Naehrlich wrote about how documentation of each person with Cystic Fibrosis (CF) via CF registries worldwide can identify individual challenges, gaps, and the room for diagnostic and therapeutic improvements[7]. This can be part of quality control. Analysis of a cohort at the center and country level gives the opportunity to see a broader picture regarding age distribution, age at diagnosis, disease progression, and the burden of therapy. This helps to identify opportunities for improvement in the structure and diagnostic/therapeutic strategy over time. Data from a CF registry in South Africa documented gaps in access to an innovative cystic fibrosis transmembrane conductance regulator (CFTR) medication. This was used by the South African CF Association to advocate for expanded access to the CFTR medication for more patients[8].

Regulatory authorities like the U.S. Food and Drug Administration (FDA) have recently provided updated guidance for the use of RWE data to support regulatory decision making[9]. Recently, the FDA has issued new guidance for certain types of medical device submissions and will soon expand this to drug and biologic submissions. The FDA will accept RWE without requiring that identifiable individual patient data always be included in a marketing submission[9]. The use of RWE for regulatory approvals under current pathways of the FDA will continue to increase further for drugs and devices[10]. The FDA Commissioner Marty Makary, M.D., M.P.H. stated "We're removing unnecessary barriers that have prevented us from using powerful real-world evidence to get life-changing treatments to patients faster. This common-sense reform will unlock access to vast databases like cancer and cystic fibrosis registries that contain critical insights into how treatments work in the real world."

Rare and ultra rare diseases already have difficulties in getting approved therapies from regulatory authorities. The economic and practical aspects of conducting RCTs in rare disease patients make them generally unfeasible. With traditional RCTs being economically not practical, the chance of getting approved therapies is minimal. Real world evidence offers another pathway for rare / ultra rare disease therapy approvals.

Conclusion

Real-World Evidence (RWE) data is being increasingly utilized to provide data for improving health care worldwide. Traditional RCTs have significantly underrepresented populations from LICs which carry significant disease burdens. With ageing populations worldwide, the prevalence of chronic diseases like MS have been shown to be associated with wealth and health disparities in epidemiological research. Regulatory bodies like the U.S. FDA have increasingly embraced the potential for use of RWE in advancing the safety and efficacy of products it regulates. Global health outcomes can be impacted by use of RWE data to support health systems and countries.

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