Real-world evidence and real-world data in contemporary healthcare: A critical overview

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Abstract

The utilisation of real-world data (RWD) and real-world evidence (RWE) is transforming healthcare research and decision-making. As an alternative to traditional clinical trials, RWD encompasses data from everyday clinical settings, while RWE represents the actionable insights generated from analysing these data. The integration of RWD and RWE offers critical benefits for healthcare delivery, clinical decision-making, pharmaceutical development, and policy formulation. This article delves into the definitions of RWD and RWE, outlines their distinctions, explores their sources, and discusses their broad applications in modern healthcare. In doing so, it highlights the evolving role of RWD in shaping personalised, evidence-based care and the future of healthcare systems globally.

Introduction

In the last few decades, healthcare research has witnessed a transformative shift. While controlled clinical trials have historically been the gold standard for evaluating medical interventions, they are limited in their ability to reflect the complexity of real-world patient care. Real-world data (RWD) and real-world evidence (RWE) offer a solution by providing insights into healthcare practices, patient outcomes, and treatment effectiveness outside the highly controlled environments of clinical trials.[1] These data elements, when harnessed effectively, provide a more comprehensive understanding of healthcare delivery, driving better clinical decisions, more accurate policymaking, and more effective pharmaceutical development.[2]

RWD is the raw data collected from diverse sources, such as electronic health records (EHRs), insurance claims, patient registries, and wearable devices. RWE, on the other hand, refers to the actionable insights derived from systematically analysing RWD. Together, these tools are reshaping how the healthcare system makes decisions, implements treatments, and designs policies. This article explores the distinction between RWD and RWE, their sources, transformation processes, and their applications in improving healthcare outcomes.

Understanding real-world data (RWD)

RWD is defined as data collected from a variety of healthcare environments outside the scope of clinical trials. Unlike the carefully controlled settings of randomised controlled trials (RCTs), RWD captures the complexity of patient experiences in everyday clinical practice. It includes data from routine clinical care, patient registries, electronic health records, insurance claims, mobile health apps, wearable devices, and more. This data is valuable because it reflects how medical treatments, interventions, and healthcare systems work in real-world settings, as opposed to the idealised environments of clinical trials.

Key sources of RWD

RWD is collected from several diverse and interconnected sources (see Table 1). These data sources offer a comprehensive view of patient care and provide a wealth of information that can be used to evaluate healthcare trends and outcomes.[3]

Real-world evidence (RWE): From data to insight

RWE is the actionable insight that is derived from the analysis of RWD. While RWD represents the raw data collected from various sources, RWE is the end result of analysing this data in order to generate evidence that can inform clinical decision-making, healthcare policies, and pharmaceutical development (see Table 2).[4] The process of transforming RWD into RWE involves sophisticated methodologies that account for the inherent complexities and variability of RWD.

The process of converting RWD into RWE involves several stages. Each stage plays a crucial role in ensuring that the data is not only reliable but also actionable for clinical and policy decisions.[6] These stages are:

1. **Data collection**: The first step in generating RWE is the collection of data from multiple sources. This data includes not only clinical records but also information related to patient behaviour, socio-economic status, treatment adherence, and more.[1] The broad scope of data collected in real-world settings ensures that RWE captures the diversity and complexity of patient experiences.
2. **Data integration**: After data collection, the next step is to integrate and harmonise the various datasets. RWD often comes from disparate sources, and these sources may use different formats and standards.[3] The integration process ensures that all data are standardised and compatible, creating a unified dataset that can be analysed effectively.
3. **Data analysis and interpretation**: Once the data is integrated, it is analysed using advanced statistical techniques. Researchers apply machine learning models, regression analysis, and other methodologies to uncover patterns, trends, and relationships within the data.[6] The goal of this analysis is to extract meaningful insights that can guide clinical decisions, shape healthcare policies, and influence drug development strategies.
4. **Application of results**: The insights generated through RWE analysis are then applied in real-world healthcare settings. These insights can inform individual clinical decisions, enhance the design of healthcare policies, and improve the safety and efficacy of treatments.[5] By applying RWE, healthcare providers can better tailor treatment plans to individual patients, ensuring more personalised and effective care.

Table 1. Primary sources of RWD

Primary source	Details
Electronic health records (EHRs)	EHRs are digital versions of patients' medical records and are maintained by healthcare providers. These records include comprehensive data about patients' demographics, diagnoses, treatment histories, lab results, and prescriptions. EHRs provide a continuous, longitudinal view of patient care, making them one of the most valuable sources of RWD.[4] By analysing EHR data, researchers can track disease progression, evaluate treatment efficacy, and monitor patient outcomes across different healthcare settings.
Health insurance claims data	Health insurance claims data offers a wealth of information regarding healthcare service utilisation. This includes records of medical services such as hospitalisations, doctor visits, prescriptions, and diagnostic procedures, as well as reimbursement details.[1] Claims data is instrumental in studying healthcare patterns, understanding the cost of care, and assessing the impact of different treatment strategies on patient outcomes.
Patient registries	Patient registries are specialised databases that collect detailed information about individuals diagnosed with specific diseases or conditions. These registries serve as critical tools for tracking disease prevalence, monitoring treatment patterns, and conducting long-term outcomes research.[3] They are particularly valuable in understanding rare diseases or conditions that may not be adequately represented in clinical trials.
Wearable devices and mobile health applications	With the rise of digital health technologies, wearable devices (e.g., fitness trackers, smartwatches) and mobile health apps have become popular sources of real-time health data. These devices can measure physical activity, heart rate, sleep patterns, blood pressure, and more.[2] The data generated by wearables and apps provide continuous monitoring, offering valuable insights into patient behaviours and health outcomes in the real world.
Pharmacy records	Pharmacy records contain information about medications that are prescribed, dispensed, and used by patients. These records offer insights into medication adherence, treatment patterns, and therapeutic outcomes.[5] Analysing pharmacy data can help assess the effectiveness of drug therapies, identify trends in medication usage, and improve strategies for managing chronic diseases.

Image: Freepik

Table 2. Key difference in the data's stage of processing and its application[4]

	RWD	RWE
Raw data vs. analysed evidence	RWD refers to the raw, unprocessed data that is collected from various healthcare settings. It represents the factual information about healthcare practices and patient experiences.	RWE is the analysed, interpreted evidence derived from this raw data.[2] RWE provides insights that are actionable and can be used to inform clinical decision-making and policy formulation.
Data vs. insight	RWD consists of diverse, unstructured, and often complex datasets. It can be difficult to extract meaningful information from this raw data without appropriate analysis.	RWE, on the other hand, simplifies this complexity by distilling the data into actionable insights that healthcare professionals, policymakers, and researchers can use to improve care and outcomes.[1]
Purpose and application	The purpose of RWD is to collect comprehensive data about real-world healthcare practices, patient behaviours, and treatment outcomes.	The goal of RWE is to apply this data to improve clinical outcomes, guide policy decisions, and inform pharmaceutical development.
Complexity	RWD is inherently more complex due to its heterogeneity. It comes from various sources with varying formats and standards.	RWE simplifies this complexity by providing evidence that is directly applicable to real-world healthcare situations, making it easier for stakeholders to interpret and use in decision-making.[5]

Image: Freepik

5. **Continuous feedback loop**: One of the distinguishing features of RWE is that it is not static. As new data is continuously collected and analysed, the evidence base evolves.[7] This ongoing process allows healthcare systems to refine their practices, adapt to emerging trends, and improve patient care over time.

Real-world applications of RWD and RWE

The applications of RWD and RWE are diverse and far-reaching. They have the potential to revolutionise many aspects of healthcare delivery, from improving patient outcomes to guiding public health policy. Below are some key areas where RWD and RWE are making an impact:[3]

1. **Medication safety**: RWD, such as health insurance claims data and EHRs, can be used to identify potential adverse drug reactions (ADRs). This type of data provides a comprehensive view of patient treatment patterns and outcomes, helping researchers detect safety signals that may not be evident in controlled clinical trials.[1] RWE derived from this data can confirm the safety profile of medications, guide safety monitoring, and influence regulatory decisions regarding drug approval and use.
2. **Chronic disease management**: Chronic diseases such as diabetes, heart disease, and asthma are prevalent worldwide, and managing these conditions effectively requires ongoing monitoring and tailored treatment plans. RWD collected from EHRs and patient registries allows healthcare providers to track the long-term outcomes of patients with chronic diseases.[4] RWE generated from this data can help assess the effectiveness of various treatment regimens, refine clinical guidelines, and improve care management strategies.
3. **Pharmaceutical development**: RWD plays a critical role in pharmaceutical development by providing insights into disease prevalence, patient demographics, and treatment patterns. This information can be used to inform the design of clinical trials, making them more reflective of the real-world patient population.[6] Additionally, RWE is used in post-marketing surveillance to monitor the long-term safety and efficacy of drugs once they are available to the public.
4. **Healthcare policy and disparities**: RWD is also a powerful tool for identifying disparities in healthcare access and outcomes. By analysing data from different populations, policymakers can gain insights into the social, economic, and geographic factors that contribute to health inequities.[3] RWE can be used to shape policies aimed at reducing healthcare disparities, improving access to care, and promoting health equity.

Discussion and conclusion

The integration of RWD and RWE into healthcare practice is a monumental shift that holds the potential to transform how healthcare systems operate.[1] RWD provides a comprehensive view of real-world patient care, while RWE offers actionable insights that can guide decision-making at every level of the healthcare system. Together, these tools enable a more personalised, data-driven approach to healthcare, with the ability to improve patient outcomes, streamline clinical practices, and inform policy decisions.[2]

As healthcare continues to evolve, the role of RWD and RWE will become increasingly central in optimising patient care and shaping evidence-based healthcare policies. By continually collecting and analysing RWD, healthcare providers, researchers, and policymakers can ensure that healthcare practices are aligned with the realities of patient care, ultimately leading to better health outcomes on a global scale. The future of healthcare is one that integrates RWD and RWE into every aspect of decision-making, driving innovation, improving efficiency, and promoting health equity.

Disclosures and conflicts of interest

The author declares no conflicts of interest.

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Andrew Balkin has been a medical writer for more than 20 years, and recently co-founded Ambermed Medical Writing and Consulting.