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Commentary

# Real-World Evidence and Pharmacovigilance: The Key to Safer Medicines

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## ABOUT THE STUDY

Real World Evidence (RWE) is data collected from real-world settings, such as Electronic Health Records (EHRs), patient registries, and claims data. This data can be used to study the safety and effectiveness of medications in a way that traditional clinical trials.

Pharmacovigilance (PV) is the science and practice of monitoring the safety of medicines after they are marketed. PV activities include identifying, assessing, and mitigating risks associated with medicines [1-3].

RWE and PV are complementary approaches to ensuring the safety of medicines. RWE can be used to identify safety signals that may not be detected in clinical trials, and PV can be used to confirm or refute these signals.

### Benefits of using RWE for pharmacovigilance

There are several benefits to using RWE for pharmacovigilance. First, RWE can be used to study a much larger population of patients than is possible in clinical trials. This is important because rare side effects may not be detected in clinical trials, which typically involve a small number of participants.

Second, RWE can be used to study the safety of medications in real-world settings. This is important because the way that medications are used in the real world may differ from the way that they are used in clinical trials. For example, patients may not always take medications as prescribed, and they may be taking other medications that could interact with the medication being studied [4,5].

Third, RWE can be used to study the safety of medications over a longer period of time than is possible in clinical trials. Clinical trials typically last for only a few months, but patients may take medications for years. RWE can be used to identify side effects that may only occur after a long period of time.

Examples of how RWE and PV have been used to improve drug safety:

- In 2004, the FDA approved the drug Vioxx for the treatment of arthritis. However, within a few years, it became clear that Vioxx was associated with an increased risk of heart attack and stroke. This was identified through the use of RWE, specifically data from EHRs. The FDA subsequently withdrew Vioxx from the market [6].
- In 2009, the FDA approved the drug Avandia for the treatment of diabetes. However, in 2010, a study published in the New England Journal of Medicine found that Avandia was associated with an increased risk of heart failure. This was identified through the use of RWE, specifically data from claims data. The FDA subsequently required Avandia to carry a black box warning, the most serious warning that the FDA can issue [7].
- In 2013, the FDA approved the drug Seroquel XR for the treatment of schizophrenia. However, in 2015, a study published in the Journal of the American Medical Association found that Seroquel XR was associated with an increased risk of diabetes. This was identified through the use of RWE, specifically data from claims data. The FDA subsequently required Seroquel XR to carry a black box warning [8].

These are just a few examples of how RWE and PV have been used to improve drug safety. As the use of these approaches continues to grow, we can expect to see even more benefits for patients.

### Challenges of using RWE for pharmacovigilance

There are also some challenges to using RWE for pharmacovigilance. First, RWE can be difficult to collect and analyze. EHR data can be messy and incomplete, and claims data may not be accurate.

Second, RWE can be difficult to interpret. There are many factors that can affect the safety of a medication, and it can be difficult to determine which factors are associated with a particular side effect [9].

Third, RWE can be expensive to collect and analyze. The cost of

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collecting and analyzing RWE can be prohibitive for some organizations.

## Future of RWE and pharmacovigilance

The use of RWE for pharmacovigilance is growing. As the cost of collecting and analyzing RWE decreases, and as the technology for collecting and analyzing RWE improves, RWE will become an increasingly important tool for ensuring the safety of medicines.

In the future, RWE is likely to be used in conjunction with traditional clinical trials to study the safety of new medications. RWE will also be used to monitor the safety of existing medications, and to identify and mitigate new safety risks [10].

The use of RWE for pharmacovigilance has the potential to make medicines safer for patients. By using RWE, we can identify and mitigate risks associated with medicines more quickly and efficiently. This will help to ensure that patients can benefit from the safe and effective use of medicines.

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