Artificial Intelligence in Real-World Evidence Generation: Systematic Review of Applications and Challenges

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INTRODUCTION

- RWE is increasingly vital in healthcare for clinical decisions, regulatory approvals, and assessments. It uses data from sources like electronic health records and claims to offer insights beyond clinical trials.
- AI, especially through machine learning and natural language processing, transforms RWE by identifying patterns, predicting outcomes, and automating data processing, improving efficiency and accuracy.

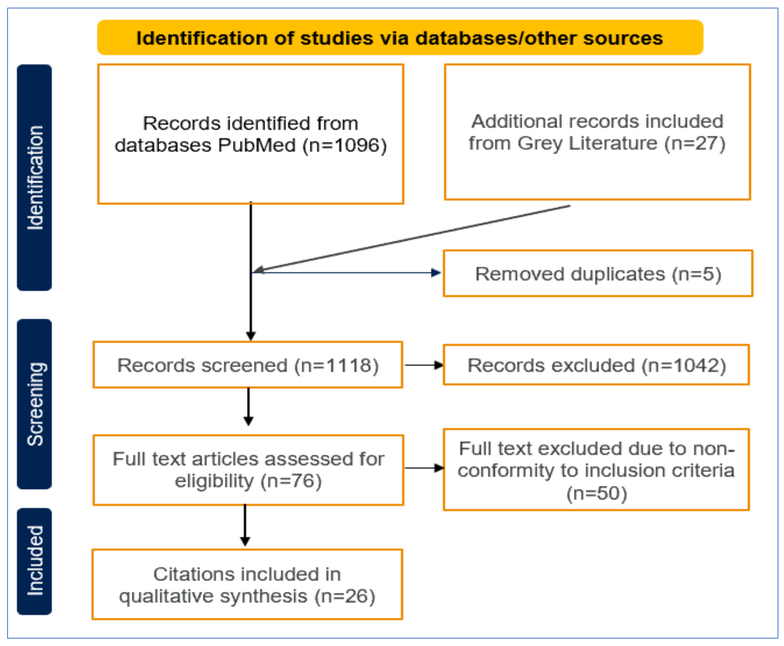
OBJECTIVE

- This systematic review evaluates the diverse applications of Artificial Intelligence (AI) ingenerating real-world evidence (RWE) within healthcare.
- The aim is to synthesize findings, assess methodologies, and identify challenges in AI's application for robust RWE.

METHOD

- A comprehensive literature search was conducted across PubMed/MEDLINE, Google Scholar, and Web of Science, focusing on studies published from 2014 to 2024 that employed AI techniques to generate RWE.
- Key search terms included "Artificial Intelligence," "Real-World Evidence," "Health Data," and "Machine Learning."
- The review adhered to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, emphasizing the methodologies and outcomes of the selected studies (Figure 1).

Figure 1: PRISMA checklist



RESULTS

- From a pool of 1123 initially identified studies, including database and grey literature sources,76 underwent full-text review, with 26 meeting final inclusion criteria (Figure 1).
- The review showcased a global distribution of studies, with a notable concentration in the United States (n=12), followed by Europe (n=8),and Asia (n=6).
- AI applications in generating RWE were diverse, spanning cardiovascular and respiratory(n=6), neurological Conditions (n=5), endocrine conditions (n=5), general and Miscellaneous Conditions(n=10) as outlined in Table 1.
- Methodologies included machine learning algorithms (n=15), natural language processing (NLP) (n=7), deep learning techniques (n=3), and Random Forest, XGBoost (n=1).
- These approaches were applied across various data sources such as electronic health records (EHRs), claims data, and patient-reported outcomes, demonstrating AI's potential to enhance RWE accuracy in data extraction, disease prediction, and treatment outcomes.
- Challenges identified included data quality, integration issues across healthcare systems, and the need for more extensive long-term validation studies to ensure reliability.

Table 1: Summary of studies using machine learning and type of real-world evidence data used

Author	Year of publication	Therapeutic Area	Type of Real-World Evidence Data Used	Applications of AI in the Study
Maddali et al	2022	Acute Respiratory Distress Syndrome	Clinical Data	Validation and utility of ARDS sub-phenotypes
Alemi et al	2024	Depression	Database	Identify factors affecting remission rate and clinicians' selection
Sax et al	2021	Intimate Partner Violence (IPV)	Clinical Notes	Extract and screen for situational terms related to IPV
Nguyen et al	2023	Emergency Department Admissions	Patient Encounter Data	Predict admission from ED to inpatient and ICU
Fenn et al	2021	Dysphagia and Aspiration Pneumonia	Hospital Information System Data	Predict dysphagia risk and stratify patients
Jauk et al	2023	Antimicrobial Use	Electronic Health Records	Identify inpatient antimicrobial use
Brom et al	2020	ICU Readmission	Electronic Health Records	Predict ICU readmission
Moehring et al	2021	Radiology Report Annotation	Radiology Reports	Annotate and extract report contents
Rojas et al	2018	Metastatic Cancer	Clinical Data	Predict patient life expectancy
Hassanpour et al	2016	Abdominal Aortic Aneurysms (AAA)	Imaging Study Reports	Identify and measure AAA from imaging data
Gensheimer et al	2021	Coronary Artery Disease (CAD)	Clinical Data	Predict patient mortality
Steele et al	2018	Intracerebral Hemorrhage (ICH)	Claims Data	Assign ICD-10 medical codes to disease

CONCLUSIONS

- AI offers promise in advancing RWE, supporting informed healthcare decisions and personalized care.
- Addressing data integration, ethical considerations, and validating AI-generated RWE are crucial for maximizing AI's impact in healthcare.
- Continued advancements and rigorous evaluations are essential for effective AI integration into the healthcare landscape

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