Health & Research Journal

Vol 11, No 1 (2025)

Volume 11 Issue 1 January - March 2025

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doi: 10.12681/healthresj.39915

To cite this article:

Apostolakis, I. (2025). Unlocking the power of Real-World Data: Transforming practice for Healthcare Professionals. *Health & Research Journal*, *11*(1), 1–6. https://doi.org/10.12681/healthresj.39915

HEALTH AND RESEARCH JOURNAL
E-ISSN:2459-3192
(2025), Volume 11, Issue 1

EDITORIAL ARTICLE

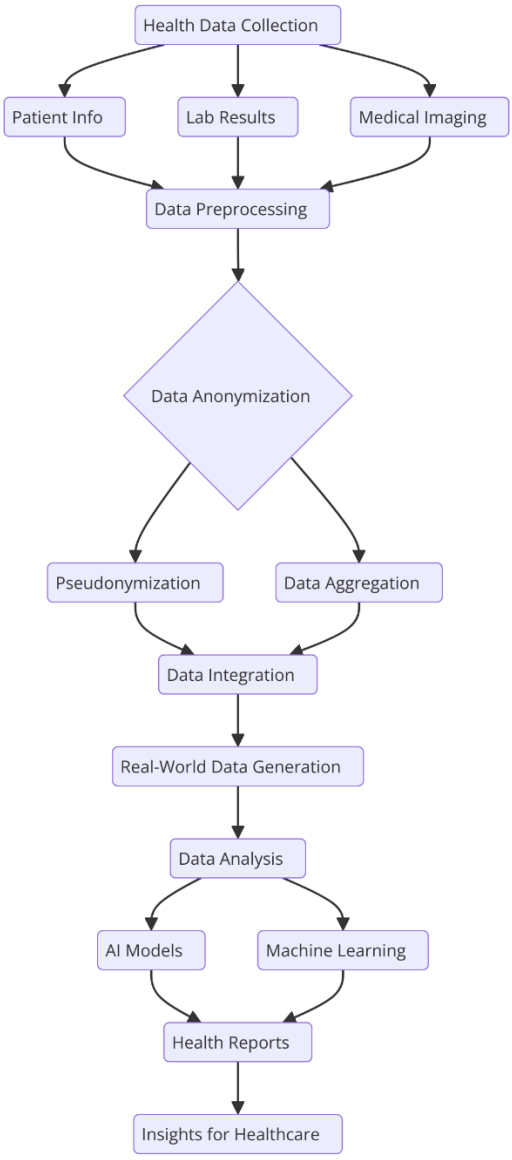
UNLOCKING THE POWER OF REAL-WORLD DATA: TRANSFORMING PRACTICE FOR HEALTHCARE PROFESSIONALS

Real-world data (RWD) refers to information and data acquired from real-time and uncontrolled healthcare settings. Unlike data generated from traditional clinical trials, RWD involves diversity and variability. RWD comes from various sources such as diagnosis, treatment, and patient electronic health records (EHR), health insurance billing data and claims, wearables, patient virtual communities, social media, the literature and the Internet. The importance of RWD lies in their heterogeneity, spanning different sectors and reflecting the complexity of real-world scenarios in healthcare. The FDA emphasises the potential of RWD and RWE (Real-world evidence) to complement traditional clinical trial data, by providing valuable insights on the safety and efficacy of medical products in real-world settings.[1,2]

In the journey towards the digital transformation of healthcare, RWD provides credible evidence to empower healthcare professionals (HCPs), researchers, and policymakers. To achieve this, acquiring health data is essential, making the technological upgrade of healthcare organisations imperative.[3] Information and Communication Technologies (ICT) play a key role in establishing a digital health ecosystem, which will facilitate the acquisition of health data. They encompass various digital tools including information systems, EHRs, telemedicine networks, wearable devices, and artificial intelligence (AI) algorithms. The digitisation of health and medical data, alongside data from electronic services such as e-prescription and EHRs, can improve evidence-based clinical decision-making, encourage patient involvement, support preventive care, and facilitate the creation of personalised treatments. In Greece, there are several organizations, such as the National Organization for Health Care Services (EOPYY), the National Public Health Organization (EODY), the Agency for Quality Assurance in Health (ODIPY), the Electronic Government Centre for Social Security (IDIKA), the Hellenic Institute for DRGs, the National Organization for Medicines (EOF) and the Hellenic Statistical Authority (ELSTAT), generating and collecting health data, which can yield RWD. In addition, hospitals generate large amounts of imprinted and digital health data.

Transforming health datasets into RWD involves a series of crucial and necessary steps, starting with acquiring data from all available sources. Data anonymisation, standardisation, refinement, unification and security will ensure data quality, accuracy and reliability. The application of advanced statistical methods and machine learning can extract trends, patterns and correlations between data, invisible to the human eye. Ultimately, the output of this transformation can enhance our understanding of health trends, diseases and treatment outcomes, while providing the foundations for informed decision-making in the various facets of healthcare (**Figure**).[4,5]

Figure 1. Generation of RWD from health data



The literature highlights the value of RWD in healthcare, emphasizing its potential to assist HCPs in making informed decisions. Koch et al. emphasize the importance of using RWD in combination with biobanks and research data to develop and test prediction models for treatment outcomes in mental disorders, with the goal of bringing precision medicine interventions to psychiatry.[6] AlQattan et al. conclude in their review that leveraging digital health technologies and RWD can

help HCPs identify and assess adverse drug effects in elderly individuals, promoting patient safety and evidence-based pharmacovigilance.[7] Liao points out that utilising RWD for drug repurposing offers an effective alternative to traditional clinical trials. This approach addresses challenges such as costly and long-term planning, participant shortages and health crises like pandemics.[8,9] Other articles highlight the use of RWD for clinical evaluation and post-market surveillance of medical products to accelerate approval and market access, and document post-approval product safety.[10,11] In brief, integrating RWD into HCPs practices can enhance:

- **Data-driven clinical decision-support** of HCPs through providing access to data from real-world cases for the quality and safety of medical products and practices. The literature provides several paradigms of successful implementation of clinical decision-support systems (CDSS) in healthcare, which are digital tools integrated in clinical workflows and aim to assist HCPs in decision-making.[12]
- **Patient-centred care** and **patient safety** through establishing evidence-based clinical decision-making and pharmacovigilance. This approach ensures that therapeutic interventions are tailored to individual patient needs, while continuously monitoring drug safety and efficacy to prevent adverse effects, improve patient outcomes, and promote accountability and trust in healthcare delivery.[13]
- **Personalised** or **individualised precision medicine** through employing genetic data, biobanks and biomarkers to develop targeted and precise treatment plans. The integration of genetic information into RWD analysis could lead discovering new and implementing effective treatments for individual genetic profiles.[14]
- **Research** and **development** of new treatments through drug repurposing, development of new drugs and enrichment of clinical trials with data. RWD from patient monitoring, EHRs, e-prescriptions, and adverse event documentation alongside AI can help researchers, HCPs and the medical industry understand treatment responses, repurpose existing medication for other diseases, and optimize medication doses.[15]
- **Public health** and **epidemiology** through population health monitoring and disease surveillance, timely and updated health policies, and immediate response to health crises. As the recent COVID-19 pandemic demonstrated, RWD can play a key role in detecting and monitoring the spread of diseases and the effectiveness of public health measures. In such cases, RWD provides immediate and updated health data for planning and implementing effective public health policies.[16]
- **Effective resource allocation** through understanding diverse people needs for specific health services and continuously monitoring and evaluating health services effectiveness. RWD can provide valuable insights into disease prevalence and health conditions, enabling policymakers to plan and implement timely and effective interventions and allocate necessary resources.[17]
- **Education** and **practice enhancement** of HCPs. Information from EHRs, claims, and clinical data, as well as patient outcomes, can be summarised using large-language models (LLMs). This can facilitate the development of purpose-built systems for evidence summarisation and new evidence generation for medical education.[18]

In this context, it is important to note the challenges that could hinder or undermine the generation of RWD. The hetero-

geneous data landscape poses a significant obstacle in the acquisition and processing of health data generated from different sources and systems in healthcare organisations.[1] Data privacy and security are also concerns, requiring strict measures and clear regulations to protect patients' sensitive information.[19] Moreover, ensuring data accuracy and quality remains a persistent challenge, requiring thorough standardisation processes.[20] The need for skilled personnel, implementation of EHR, advanced infrastructure and interoperability for data acquisition, storage and sharing add further complexity.[21] Overcoming these challenges requires strategic investments in ICT, clear data governance frameworks, HCPs training and collaboration between stakeholders (HCPs, healthcare managers, government bodies, regulatory authorities, healthcare industry).

RWD can transform healthcare by offering a rich canvas of knowledge and evidence. While the added value of RWD in improving the quality of healthcare, research, resource allocation and decision-making is evident, several challenges still need to be addressed. On the one hand, organisations have to address issues related to systems interoperability, data management and security, requiring investments in modern technological solutions of both software and hardware. On the other hand, HCPs have concerns on data management and security, which require ongoing training and collaboration. Collectively addressing these challenges requires a holistic approach, combining skills, technological advances, regulations and individual policies to unlock the full potential of RWD.

References

1. Liu F, Panagiotakos D. Real-world data: a brief review of the methods, applications, challenges and opportunities. BMC Med Res Methodol. 2022;22(1):287. https://doi.org/10.1186/s12874-022-01768-6
2. Dang A. Real-World Evidence: A Primer. Pharm Med. 2023;37(1):25–36. https://doi.org/10.1007/s40290-022-00456-6
3. Rudrapatna VA, Butte AJ. Opportunities and challenges in using real-world data for health care. J Clin Invest. 2020;130(2):565–74. https://doi.org/10.1172/JCI129197
4. Zhang J, Symons J, Agapow P, Teo JT, Paxton CA, Abdi J, et al. Best practices in the real-world data life cycle. PLOS Digit Health. 2022;1(1):e0000003. https://doi.org/10.1371/journal.pdig.0000003
5. Sun F, Bedenkov A, Liu BC, Yang J, Xu J fu, Ji L, et al. Maximizing the Value of Real-World Data and Real-World Evidence to Accelerate Healthcare Transformation in China: Summary of External Advisory Committee Meetings. Pharm Med. 2024;38(3):157–66. https://doi.org/10.1007/s40290-024-00520-3
6. Koch E, Pardiñas AF, O'Connell KS, Selvaggi P, Camacho Collados J, Babic A, et al. How Real-World Data Can Facilitate the Development of Precision Medicine Treatment in Psychiatry. Biol Psychiatry. 2024. https://doi.org/10.1016/j.biopsych.2024.01.001

7. AlQattan KM, AlQahtani MA, Almahboub MS, Alruwaili ES, Almermish AH, AlGhanim WI. Pharmacovigilance and Patient Safety: the Interplay of Nursing, Diagnosis, and Medical Records. Int J Health Sci. 2024;8(S1):924–37. https://doi.org/10.53730/ijhs.v8nS1.15002
8. Furtner D, Shinde SP, Singh M, Wong CH, Setia S. Digital Transformation in Medical Affairs Sparked by the Pandemic: Insights and Learnings from COVID-19 Era and Beyond. Pharm Med. 2022 Feb 1;36(1):1–10. https://doi.org/10.1007/s40290-021-00412-w
9. Liao Y. Identification of potential new COVID-19 treatments via RWD-driven drug repurposing. Sci Rep. 2023;13(1):14586. https://doi.org/10.1038/s41598-023-40033-8
10. Mofid S, Bolislis WR, Kühler TC. Real-World Data in the Postapproval Setting as Applied by the EMA and the US FDA. Clin Ther. 2022;44(2):306–22. https://doi.org/10.1016/j.clinthera.2021.12.010
11. Li J, Liu L, Cao H, Yang M, Sun X. Use of real-world evidence to support regulatory decisions on medical devices in China and a unique opportunity to gain accelerated approval in “Boao Lecheng Pilot Zone”. Cost Eff Resour Alloc. 2023;21(1):7. https://doi.org/10.1186/s12962-022-00412-w
12. Sutton RT, Pincock D, Baumgart DC, Sadowski DC, Fedorak RN, Kroeker KI. An overview of clinical decision support systems: benefits, risks, and strategies for success. Npj Digit Med. 2020;3(1):1–10. https://doi.org/10.1038/s41746-020-0221-y
13. Monteleone P, Ahern R, Banerjee S, Desai KR, Kadian-Dodov D, Webber E, et al. Modern Treatment of Pulmonary Embolism (USCDT vs MT): Results From a Real-World, Big Data Analysis (REAL-PE). J Soc Cardiovasc Angiogr Interv. 2024;3(1):101192. https://doi.org/10.1016/j.jscai.2023.101192
14. Kalra D. The importance of real-world data to precision medicine. Pers Med. 2019;16(2):79–82. https://doi.org/10.2217/pme-2018-0120
15. Behr M, Burghaus R, Diedrich C, Lippert J. Opportunities and Challenges for AI-Based Analysis of RWD in Pharmaceutical R&D: A Practical Perspective. KI - Künstl Intell. 2023. https://doi.org/10.1007/s13218-023-00809-6
16. Donelle L, Comer L, Hiebert B, Hall J, Shelley JJ, Smith MJ, et al. Use of digital technologies for public health surveillance during the COVID-19 pandemic: A scoping review. Digit Health. 2023;9:20552076231173220. https://doi.org/10.1177/20552076231173220
17. Lazebnik T. Data-driven hospitals staff and resources allocation using agent-based simulation and deep reinforcement learning. Eng Appl Artif Intell. 2023;126:106783. https://doi.org/10.1016/j.engappai.2023.106783
18. Low YS, Jackson ML, Hyde RJ, Brown RE, Sanghavi NM, Baldwin JD, et al. Answering real-world clinical questions using large language model based systems. arXiv; 2024. https://doi.org/10.48550/arXiv.2407.00541

19. Keshta I, Odeh A. Security and privacy of electronic health records: Concerns and challenges. Egypt Inform J. 2021;22(2):177–83. https://doi.org/10.1016/j.eij.2020.07.003
20. Ueno S, Komiyama Y, Doi M, Hoshi K. Need for Data Standardization and Infrastructure of Research Data Management to Promote Using Real-world Data. J Soc Clin Data Manag. 2024;5(2). https://doi.org/10.47912/jscdm.210
21. Grimberg F, Asprion PM, Schneider B, Miho E, Babrak L, Habbabeh A. The Real-World Data Challenges Radar: A Review on the Challenges and Risks regarding the Use of Real-World Data. Digit Biomark. 2021;5(2):148–57. https://doi.org/10.1159/000516178

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