

## Real World Data: Methodology, Challenges and Opportunities

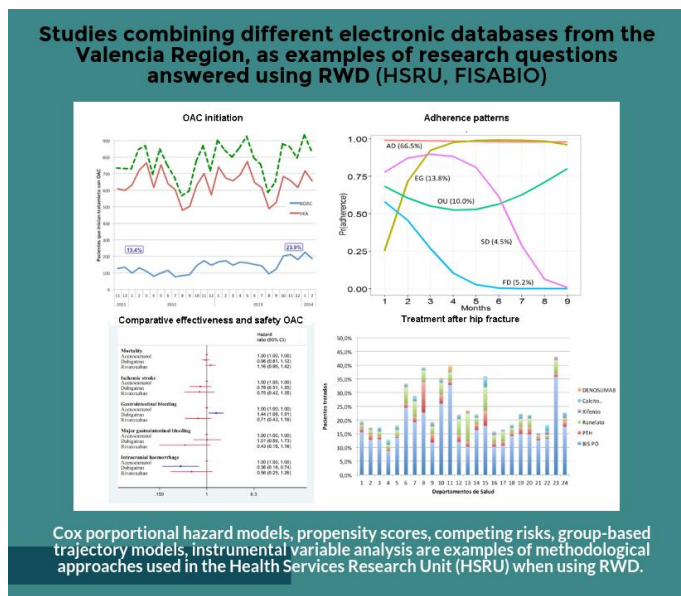
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**Background:** The increase in the volume of electronic data (quantity and quality) generated during routine healthcare provision and the availability of analysis of population-based information systems (covering millions of patients) provides the opportunity to combine different information systems through a unique personal identifier to build retrospective cohorts with long follow-up periods and the possibility to assess a wide range of health outcomes.

It is widely acknowledged that there is great potential for using these data to obtain information about

Figure1.



utilization patterns, adherence, and clinical outcomes (positive and adverse events) in a real-life setting of medication use. Furthermore, this information is essential to evaluate and direct the quality and efficiency of healthcare organizations. This ultimately allows stakeholders and healthcare providers to make informed decisions on ways to improve patient care and health outcomes.

### Challenges and opportunities:

There is some reluctance on the part of many health professionals to use observational data to support healthcare decisions. However, the performance of medications in real-world settings might differ from that shown in randomized

controlled trials, as the conditions of routine clinical practice include greater variability regarding patients, healthcare professionals and delivery systems. The impact of such variability has an important potential to influence the benefits and risks of medications or other interventions in individual patients. Challenges in conducting observational studies based on electronic databases include concern about methods to reduce the impact of misclassification and confounding (decisions regarding study designs, analytic methods, data sources, comparison groups, endpoints, etc.) that will necessarily have tradeoffs with respect to important features such as validity, feasibility, generalizability, clinical relevance, etc. Therefore, additional to the knowledge needed to conduct studies based on real-world data, transparency in reporting, and caution in interpreting results are required.

**Approaches to the use of RWD (methodology and results of studies used as examples):** To enhance the understanding of challenges, the potential and scope of using real world data, examples regarding different research questions using routine electronic healthcare data from the Valencia region (covering

5 million of inhabitants) will be given along with methods to minimize outcome and exposure misclassifications (sensitivity analysis, different data sources...) as well as several techniques to control both measured and unmeasured confounders (restriction, specific designs, stratification, proxy measures, propensity scores, instrumental variables and sensitivity analyses), *Fig 1*.