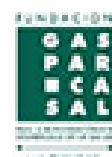


REAL WORLD DATA (RWD), AS AN EVIDENCE SOURCE TO FACILITATE A MORE EFFECTIVE AND EFFICIENT HEALTHCARE

JL García- López, J.E.del Llano Señaris*, Jorge del Diego Salas, Juan A. Recalde Manrique on behalf of "Gaspar Casal" Foundation



Background



- Decision makers have a constant need of information about real world data in healthcare.
- Randomized and controlled clinical trials, the gold standard to define the efficacy and the safety of interventions, are focused on selected groups of patients and are conducted with a high consumption of resources.
- We need to determine the effectiveness and the safety of interventions in our real clinical practice.

Background



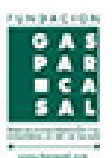
- Real world data (RWD) include all those studies that supplement the best evidence provided with randomized clinical trials, not only from selected patients, but also from real patients in our clinical practice.
- Different designs of studies can be considered as RWD: observational registries, data from electronic health records, health surveys and pragmatic clinical trials.

Objective



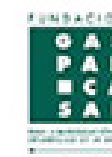
- The aim of this study is to identify the contributions of RWD, to improve the resources consumption and the clinical practice.

Methods



- A three-stage design has been performed:
 - Review of scientific literature.
 - A survey about RWD was sent to regional health institutions, scientific societies and academia, with the main objective of identifying unpublished studies.
 - Analysis of contributions from a focus group, constituted by experts and decision-makers at the National and Regional Healthcare Systems in Spain:
 - the aim of this third step was to incorporate qualitative evaluations to our conclusions in previous steps, based on opinions of all included stakeholders.

Results



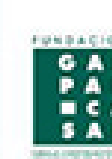
- Throughout observational and registries studies, we have detected different applications of RWD in healthcare:
 - Research projects: clinical, epidemiological, adverse events surveillance, etc...
 - Evaluation of Health Services: planning improvements in healthcare
 - Teaching projects with RWD: Image Databases, ECG, etc...
- A cultural shift is necessary to take advantage of the information from RWD.

Conclusions



- RWD based studies have been conducted for many years in Spain, but they have been called with different names: post-authorization studies, observational studies, etc...
- Our study shows that, even though different institutions have demonstrated a great experience collecting and conducting RWD based studies, mainly observational registries of diseases and treatments, these types of research have a limited dissemination through scientific literature.
- After the qualitative evaluation based on the focus group, we detect needs of a cultural shift to take RWD into account for making decisions in healthcare.

Conclusions



- According to these results, we propose a roadmap to endow us with the needed resources to obtain high quality RWD, what will be able to impact on the clinical practice and on the efficient use of healthcare resources:

Roadmap

