REVIEW PROTOCOL

1. Review title

Economic evaluations informed exclusively by real world data: a systematic review

2. Actual start date

21/08/2018

3. Anticipated completion date

28/02/2019

4. Stage of review at time of this submission

Preliminary searches – Started and completed

Piloting of the study selection process – Started

Formal screening of search results – Not started

Data extraction – Not started

Risk of bias – Not started

Data analysis – Not started

5. Name and email contact

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6. Name contact address and phone number

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7. Organizational affiliation of review and web adress

Institut de Recerca Sant Joan de Déu

http://www.fsjd.org/es/grupos-de-investigaci%C3%B3n_125025/8124/line#main-line-menu

8. Review team members and organizational affiliations

Dr. Ignacio Aznar-Lou - Institut de Recerca Sant Joan de Déu

Dr. Maria Rubio-Valera - Institut de Recerca Sant Joan de Déu

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Dr César Augusto Guevara-Cuellar – Universidad ICESI

Mr. Edward Burn – NDORMS – University of Oxford

9. Funding Sources and conflicts of interest

None.

10. Collaborators

Dr. Antoni Serrano-Blanco

11. Review question

This systematic literature review aims to evaluate the adequate use of Real World Data (RWD) in developing complete economic evaluations. These economic evaluations have to be performed using patient data exclusively. All patients do not have to have been recorded about cost and effects but the information must not have been recorded exclusively for a trial; extrapolations are considered if the same patients reported cost and effects in RWD methodology.

More specifically, this review will assess the quality of economic evaluations exclusively based on RWD. This goal will be split into two: quality of conduct (i.e. were appropriate methods used) and quality of reporting (i.e. were the methods used appropriate detailed).

12. Searches

The following electronic databases will be searched: PubMed, Ovid EMBASE, Web of Science and Centre for Reviews and Dissemination databases (University of York).

The searches will be conducted by using two main concepts: RWD and Economic Evaluations. An example of PubMed Search is provided below.

Time frame: Beginning of databaseses - August 21st, 2018.

Language: English and Spanish

All the references in those papers initially selected will be also reviewed.

URL to search strategy will be publicly available when the review is complete.

13. Condition or domain being studied

All conditions will be studied.

14. Participants/population

No restriction for participants or populations if information was RWD.

15. Intervention(s), exposure(s)

Any intervention reported in economic evaluations performed by using RWD.

16. Comparator(s)/control

Any comparator reported in economic evaluations performed by using RWD.

17. Types of study to be included

Inclusion criteria:

-Complete economic evaluations (cost-benefit, cost-utility or cost-effectiveness).

-Including humans

-Language: English or Spanish

Exclusion critera:

-Economic models

-Not health related

-Grey literature

-Study protocol

18. Context

Any context

19. Main outcome(s)

Quality of conduct and quality of reporting. No additional outcomes

20. Data extraction

Selection of studies:

Five researchers will participate in the selection of studies. The selection process will be conducted in duplicate. In case of discrepancy, a third reviewer will evaluate the paper.

First, titles and abstracts will be review independently by each peer reviewers using Rayyan QCRI platform.

Finally, those articles that are considered to be potentially eligible will be full-text reviewed.

Data extraction and coding:

Extracted information will include: study setting; study population; details of the intervention and control conditions; study methodology; RWD source; economic outcomes; clinical outcomes; time horizon; potential risk of bias and methods applied to control for bias.

Five researchers will participate in the extraction and coding of information. The selection process will be conducted in duplicate. In case of discrepancy, a third reviewer will be consulted.

21. Risk of bias (quality) assessment.

Two review authors will assess each article using the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement and the items recommended by the "Good practices for real-world data studies of treatment and/or comparative effectiveness: Recommendations from the joint ISPOR-ISPE Special Task Force on real-world evidence in health care decision making".

22. Strategy for data synthesis

A narrative synthesis of results is planned with the goal of discussing the performance of economic evaluations using RWD.

23. Analysis of subgroups or subsets

The synthesis of results will take into account the type of economic evaluation (cost-benefit, cost-utility or cost-effectiveness).

24. Type and method of review

Cost effectiveness, methodology, narrative synthesis and systematic review

25. Health area

General interest

26. Language

English and Spanish

27. Country

Colombia, United Kingdom and Spain

28. Dissemination plans

The goal of this review is to develop a paper which will be submitted to a leading journal in this field

29. Keywords

Real World Data; Economic evaluation; Individual patient data

30. Details of any existing review of the same topic by the same authors

No similar systematic reviews have been published by the same authors. However, Gansen FM has recently published a similar review with a narrower scope (only Germany).

Health economic evaluations based on routine data in Germany: a systematic review. BMC Health Serv Res. 2018 Apr 10;18(1):268.

31. Current review status

Ongoing.