Real-World Validation of Health Innovation: A systematic review

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Background

- ✓ Real-World Data (RWD) and Real-World Evidence (RWE) are playing an increasing role in health care decisions. This data holds the potential to allow us to better design and conduct studies in the health care setting.

- ✓ Randomized Controlled Trials (RCT) are time and resource-intensive, lack of generalizability and typically restricted to evaluating specific interventions one at a time.

Aim of the review

✓ To assess the literature to establish a clearer definition of Real World Validation (RWV) including a better understanding of the associated methods, determining in how and in which contexts RWV has been used.

Searches

Cochrane library, PubMed, MedLine (EBSCO), Web-of-Science (BIOSIS Citation Index, BIOSIS Previews, KCI-Korean journal database, Russian Science Citation Index, SciELO Citation Index), SCOPUS, and grey literature

Published: 1st January 1984 – 1st February 2020

Exclusion Criteria: Human, English Language

Methods

Double title and abstract screening (full text screening ongoing) on Endnote

Double extraction with document bases (ongoing)

Quality Assessment (ongoing)

1,153 records identified

254 T&A screened

43 full text included for extraction

… with agreement of 96.45%

Preliminary Findings

✓ RCTs are being challenged by health care providers since they are looking for RWE to validate innovative interventions.

✓ RWV generates insight, foresight, and explorative findings to bring a product to the healthcare market and to ensure its significance in clinical practice, grasping up with the principles of health economics and outcome research, thereby exhibiting the value of real-world insights in healthcare decision.

Hypothesis / Definition

Real-World Validation is a cost-effective, and adaptable mix-method user inclusive methodology to assess the impact and benefits to patients, staff and the health economy, in a non-controlled environment by using RWD and RWE, of an innovation that has already undergone a pilot process.

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