An Integrative Systematic Review of Patient Reported Outcome Measures (PROMs) Used to Evaluate Orthopedic, Cardiovascular and Diabetes High Risk Implantable Medical Devices.

Citation

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Review question

Question: How are Patient Reported Outcome measures (PROMS) being used in the assessment of the utility of high-risk medical devices (class III). Does the use of PROMS generate evidence that could be used to improve regulatory oversight of new high-risk medical devices.

Framing our research question within PECO: The searches will be conducted with the populations of orthopedic, cardiovascular and diabetes patients. The exposure/intervention to be targeted will be the surgical procedure or implant of a device. The comparator will the medical condition and life situation before surgery or without surgery. The outcomes will be PROM dimensions.

Searches

MEDLINE, CINAHL, Cochrane trials database and trial registries will be searched for publications between January 2000 and July, 2022. Limitation included be studies on humans with full-text availability in English.

Search strategy

https://www.crd.york.ac.uk/PROSPEROFILES/344424_STRATEGY_20220706.pdf

Types of study to be included

Inclusion: randomised controlled trials; clinical outcomes; methodological studies, pre- and post market surveillance,

Exclusion: Editorial, Case reports, Opinion pieces, and Commentaries.

Condition or domain being studied

The disease areas will be orthopedics, cardiovascular and diabetes conditions requiring implant of a high-risk, class III, medical devices. These devices will include knee and hip replacement, cardiovascular stent and valves, Insulin pump and artificial pancreas.

Participants/population

Inclusion: surgical patients receiving orthopedic, cardiovascular or diabetes class III implantable medical devices.

Exclusion: populations where the follow-up is less than 3 months

Intervention(s), exposure(s)

Inclusion: surgical treatment to implant a high-risk medical devices (class III). These interventions are limited to knee and hip replacement, cardiovascular stent and valves, Insulin pump and artificial pancreas.

Exclusion: exposure to rehabilitation or care processes related to the acceptability of a device or follow-up treatment; pre-operative procedures.

Comparator(s)/control

The comparator will be symptom/ life situation prior to surgery or non-exposure.

Context

Medical devices marketed in Europe require a CE mark to indicate standards of quality. This review will examine PROM data before and after the CE mark date.

Main outcome(s)

PROMs used, domains examined, methods of administration, timing of data collections follow-ups, reported use of PROM data, responsiveness and sensitivity. Patient acceptability (response rate) of the PROMS.

Measures of effect

Not applicable

Additional outcome(s)

Not applicable

Measures of effect

Not applicable

Data extraction (selection and coding)

Phase 1: Records will be identified through database searching and will then be exported to Endnote reference manager

(Endnote X9, 2019), where duplicates based on title and author will be removed. The remaining references will then be exported to Rayyan, a software program that allows the manageable screening of citations (Rayyan, 2019) where further duplication will be removed that are assessed by the program to be at least 85% duplication.

Phase 2: Titles and abstracts will be screened by at least two independent researchers and records excluded based on inclusion and exclusion criteria. Disagreement will be resolved by group discussion. Articles will be excluded for the following reasons: 1. wrong implementation focus 2. PROMS not used 3. wrong study design.

Phase 3: Articles that then go forward to full text screening will also be assessed in Rayyan. Further exclusion criteria will be applied during the full text screening process and documented in Rayyan.

Phase 4: Reference lists of the included studies will be hand screened for potential study inclusion and added to Rayyan.

Senior authors of publications will be contacted for further information if required. Where studies report on the same cohort, the studies will be merged, however where studies report on separate aspects they will remain as separate studies.

Risk of bias (quality) assessment

Risk of bias assessment will be represented in table format showing each included study and its strength across the quality criteria for that particular study type. Studies including PROMS are likely to be mostly of a mixed methods design and therefore Mixed Methods Appraisal Tool (MMAT) will be used. The MMAT is designed for reviews that include qualitative, quantitative and mixed methods studies.

Strategy for data synthesis

We will describe the data in narrative form using Popay et al.'s (2006) four main elements for narrative synthesis (i.e., develop a theoretical model, preliminary synthesis, relationship, and assess robustness).

Analysis of subgroups or subsets

no subgroup analysis planned

Contact details for further information

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Organisational affiliation of the review

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Type and method of review

Intervention, Narrative synthesis, Systematic review

Anticipated or actual start date

01 July 2022

Anticipated completion date

31 December 2022

Funding sources/sponsors

European Horizon 2020 project

Grant number(s)

State the funder, grant or award number and the date of award

European Horizon project: H2020-SC1-BHC-2018-2020 ID: SC1-HCO-18-2020

Conflicts of interest

Language

English

Country

Belgium, Denmark, Norway, Sweden

Stage of review

Review Ongoing

Subject index terms status

Subject indexing assigned by CRD

Subject index terms

Diabetes Mellitus; Humans; Patient Reported Outcome Measures; Prostheses and Implants; Surveys and Questionnaires

Date of registration in PROSPERO

19 July 2022

Date of first submission

08 July 2022

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

none

Stage of review at time of this submission

Stage	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	Yes	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.

The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.

Versions

19 July 2022

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