

OBJECTIVES

The use of medico-administrative databases (MADB) to carry out real-life studies on health products is now widespread. Linkage with data from other sources (e.g., registry, medical records) is a major lever for enriching the MADBs and broadening research perspectives. The role and use of studies on linked databases have already been described for drugs in several therapeutic areas but are still poorly understood in the medical devices (MD) industry.

Our objective was therefore to clarify the role and use of data linkage in studies that aim at evaluating MDs, through a systematic review.

METHODS

A systematic review of the literature was conducted using PubMed up to February 2023. The following search terms were used: observational study OR epidemiological study OR clinical study OR data linkage study AND data linkage OR database linkage OR record linkage AND Equipment and Supplies [Mesh]. Articles were selected on title and abstract, then on full text by two authors, independently. Inclusion criteria were: (1) studies using data linkage; (2) evaluating medical device (3) using epidemiological or clinical approaches ; (4) published in English.

Two independent researchers extracted the data using a standardized form. Extracted data included study information (authors, year of publication, etc.), linkage characteristics (type, direct or indirect, etc.), information related to MD (Assessment, type of medical device, etc.).

The following statistics were calculated: (i) for quantitative variables mean, standard deviation, median, minimum and maximum, 1st and 3rd quartiles (ii) for qualitative variables, frequency and percentage for each category.

RESULTS

(i) Studies selection

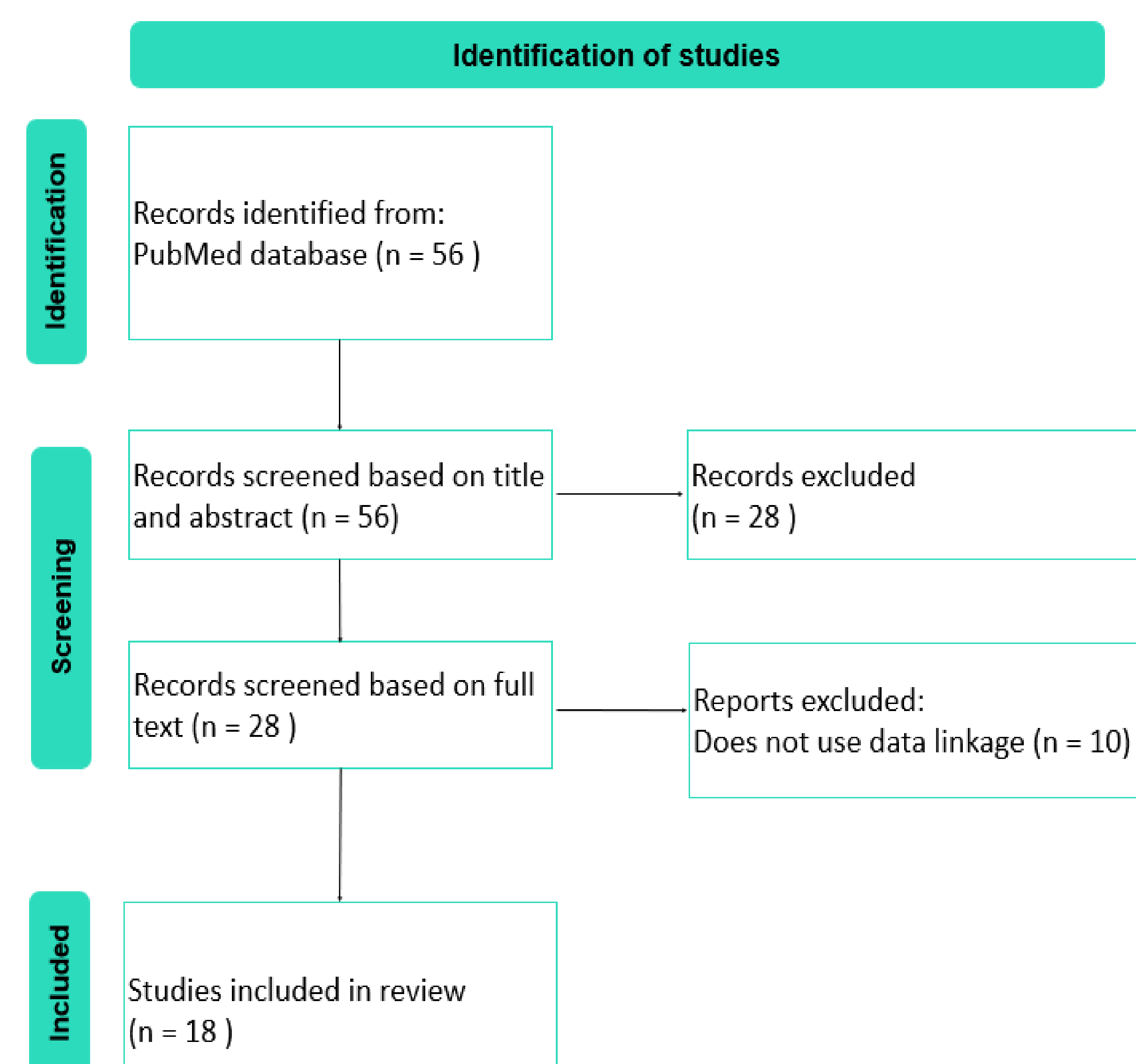


Figure I : Flow chart of studies selection

RESULTS (continued)

(ii) Study characteristics

The identified studies countries: USA were conducted in the following (n=7), Sweden (n=3), England, Canada, Finland (n=2) and the Netherlands, Scotland (n=1).

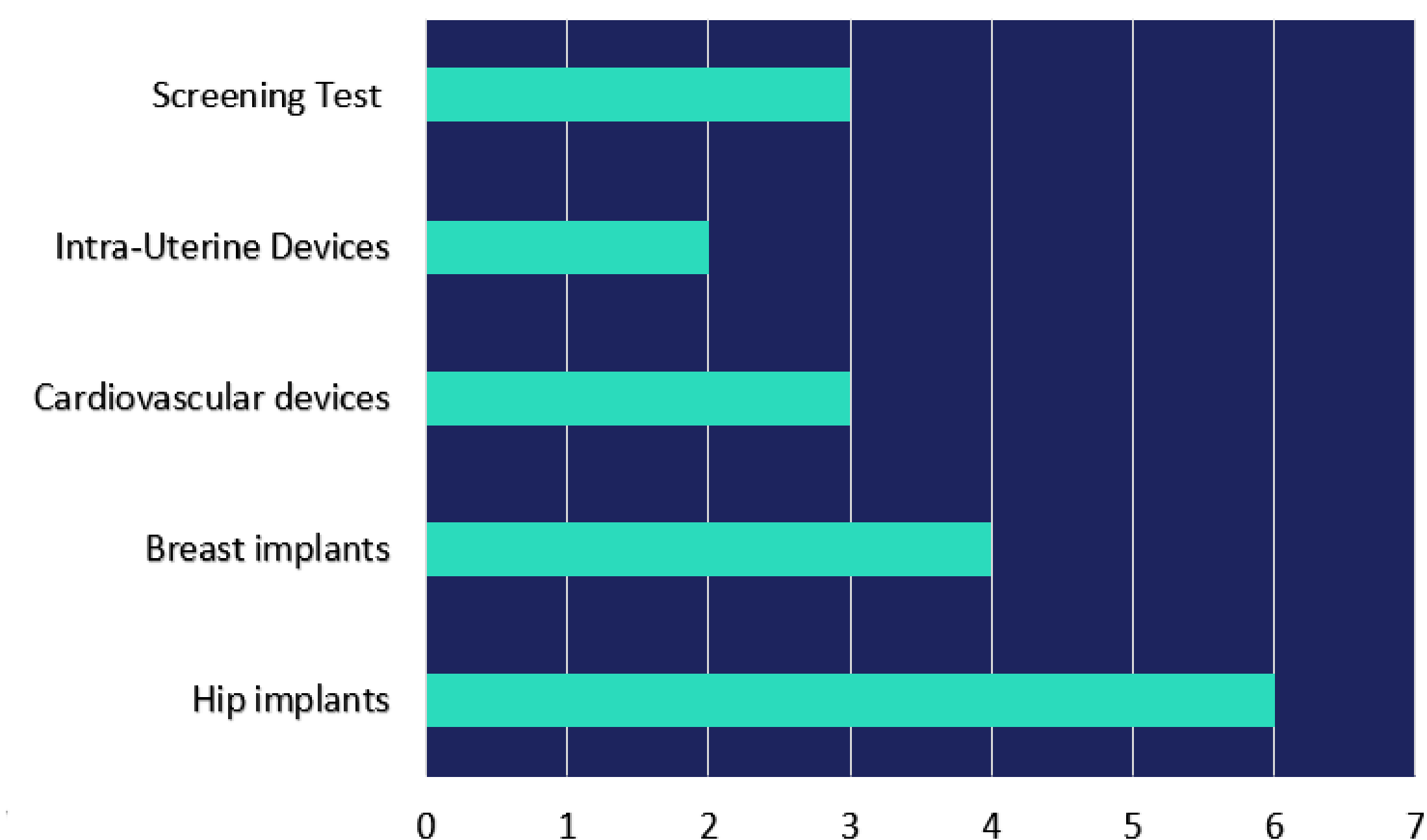
Table I : Typical data linkage study included

Typical data linkage study	Included studies representativeness
USA	39 % conducted in United states of America (USA)
National	100 % are national studies
Academic	89 % are academic studies
Safety	89 % assess the safety
Cancer	44 % focus on cancer

These studies are mainly comparative, evaluating the safety of a MD (n=16) in terms of cancer risk (n=8) or cardiovascular risk (n=4). With an average follow-up of 18.7 years, they included between 147 and 322,898 patients.

(ii) Medical devices evaluation

Regarding the type of MD, the majority are implantable devices (n=15), particularly represented by hip implants (n=5), breast implants (n=4) and cardiovascular devices (n=3).



(iii) Data linkage

Less than half of linkages involved MADB. The other linkages involved registries (linked to each others or to medical records). The linkage was direct for 11 studies (using a common unique identifier between the linked databases) and indirect for the other linkages (based on common variables).

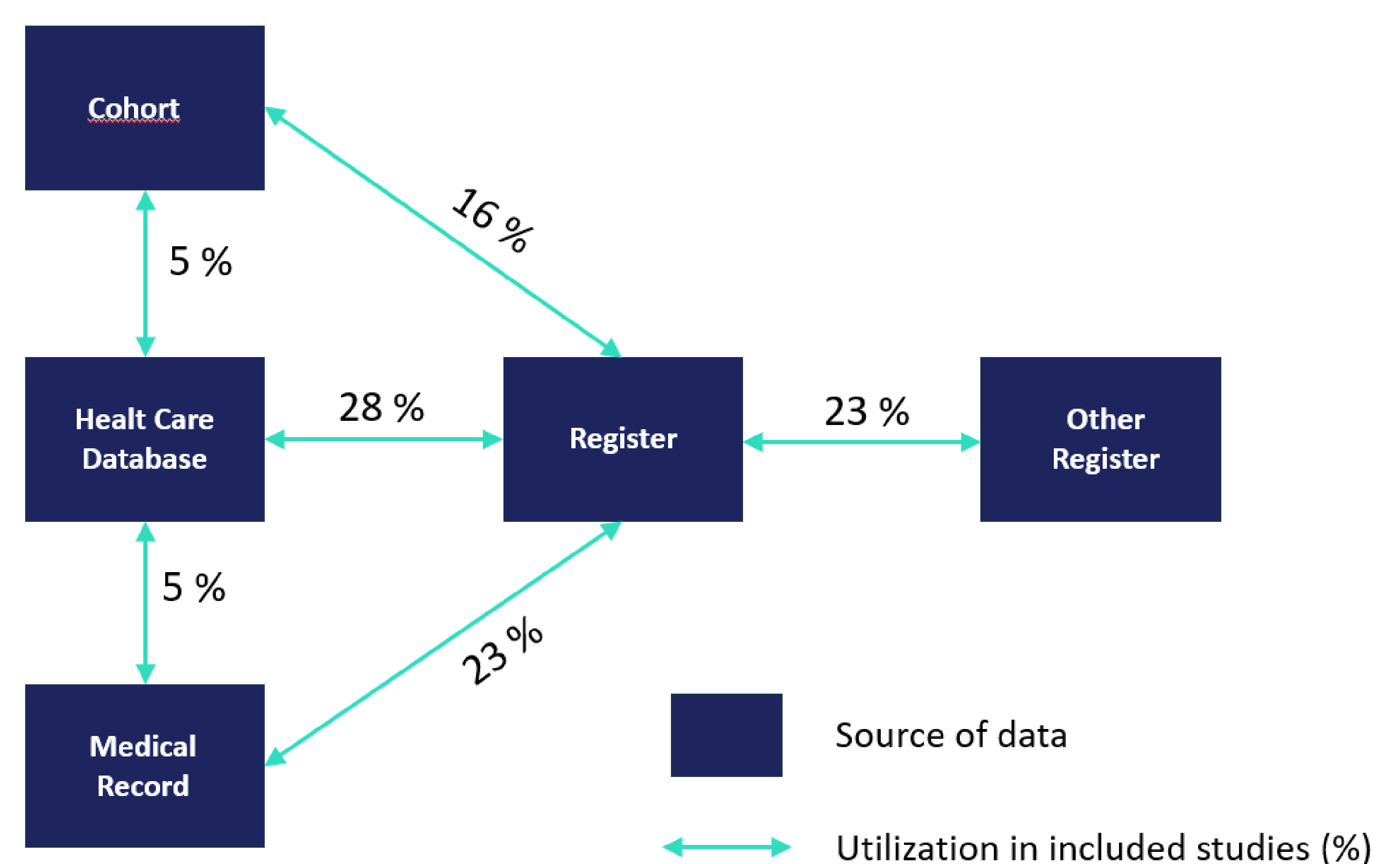


Figure III : Use of data linkage in included studies

CONCLUSIONS

This systematic review focused on references available on PubMed, which is the main limit of this review.

In conclusion, most linkages were made directly, showing the strength of using a unique identification number to facilitate data enrichment. These results suggest that the logistical, regulatory, and analytical difficulties make it a solution that is still little used to date, and the lack of standardization of the data linkage methods make their validation and interpretation difficult. This lack of standardization may also explain why these studies are not listed in PubMed.