A systematic literature review of Real-World Evidence (RWE) on post-market assessment of medical devices

Stefania Manetti (stefania.manetti@santannapisa.it)
Scuola Superiore Sant'Anna
Elisa Guidotti
Scuola Superiore Sant'Anna
Federico Vola Vola
Scuola Superiore Sant'Anna
Milena Vainieri
Scuola Superiore Sant'Anna

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Abstract

The increasing use of real-world evidence (RWE) and real-world data (RWD) to assess post-market Medical Devices (MDs) might satisfy the urgent need for data sharing and traceability. This study sought to i) get an overview of current practice in post-market assessments of MDs reporting on RWE/RWD; ii) draw policy recommendations for governments and health organizations and identify a research agenda for scholars.

A systematic review was undertaken until July 2020 following the PRISMA guidelines. Original peer-reviewed articles in English and incorporating RWE/RWD into any sort of post-market assessment strategy for an MD were included and their reference lists manually checked. A narrative synthesis was employed to describe evidence retrieved.

Totally, 103 research articles were identified. Administrative databases were mostly utilised; clinical and/or economic evidence gathered in a short/medium time horizon the most frequently reported; other evidence types (e.g., organizational) underreported; patient perspectives rarely incorporated; the innovation complexity of MDs relatively low.

To our knowledge, this study is the first in its kind to provide a comprehensive picture of how non-randomized evidence has been used when assessing MDs working in real-life conditions. The implications of this review might help policy-makers to better understand the risks and benefits of medium and long-term use of MDs alongside clinical practice and make more informed decisions about adoption and use.

1. Introduction

The role of evidence in healthcare, and the way evidence is used to inform decisions on technology introduction and adoption, differs from other industries (1). This is because new technologies are taken-up within a complex environment made of: intertwined policies and regulations at both institutional and organisational level, multiple professional cultures, and different stakeholders who take part in the decision-making process (1–4). The importance of evidence is partly related to how decisions on adoption and diffusion of technology innovations are made within the healthcare ecosystem, and partly to the methods used for assessing innovations, aspect intrinsically linked to the basis of that evidence (1,5,6). Evidence generation, interpretation, and validity are complex and controversial, as each step needs to be judged both pertinent and sufficient from a variety of professional groups operating within the healthcare ecosystem, including representatives of a wide range of organizations and institutions (7–10). In this complex system, each decision about the introduction and spread of an innovation needs to engage and persuade all active stakeholders on board. Nevertheless, (i) the techniques for evidence generation may be underdeveloped and positivist scientific methods, such as Randomized Controlled Trial (RCTs), may be not appropriate when assessing complex innovations like Medical Devices (MDs); (ii) different stakeholders may have different expectations on what constitutes evidence and the evidence basis, as well as contest its interpretation; (iii) there may be no agreed criteria to assess evidence validity (1).

Health Technology Assessment (HTA) has been adopted worldwide as a cross-disciplinary and multidimensional measurement framework for judging the performance of a medical technology at different time points of its lifecycle (11). In a broader term, HTA is the systematic evaluation of the clinical, health economic, societal, legal, and ethical issues related to the introduction, dissemination, and use of a medical technology (12). It aims to generate and synthesise multi-disciplinary evidence to inform health policy, resource allocation, and clinical decision-making (13,14). The concept of HTA is intrinsically embedded with the approach of evidence-based to medicine and management, being an integral component of healthcare governance to set guidelines and standards, provide feedback and forwards actions on delivery of care, and improve quality and performance of health services alongside clinical practice (1,15–18).

Historically, the object of HTA has been restricted to pharmaceuticals, rather than MDs, and evidence on clinical efficacy/effectiveness (i.e., can it work/does it work) and/or cost-effectiveness (i.e., is it worth it) has formed a key part of the formal assessment, taking over other relevant evidence types (e.g., human factor) when assessing the impact of a healthcare innovation (1,19,20). In terms of evidence generation, HTA has been traditionally based on positive scientific methods, such as systematic reviews and randomized controlled trials (RCTs), which have been preferred due to their lower risk of bias by design compared to real-world studies (21). However, traditional methods for evidence generation, such as RCTs, raise general concerns about generalisability and external validity (18,22–24). Moreover, such methods assume or imply that useful data on an innovation can be gathered according to study design, and this assumption is no longer appropriate when assessing complex healthcare innovations, like MDs, whose key features differ from other medical technologies and demand “a more pluralist approach to gather evidence on their impact” (1,18). In terms of efficacy/effectiveness, MDs are performance dependent on user skills and training, have a learning curve, may be used to treat different conditions in different clinical settings and present a faster product lifecycle (18,22,25). In this sense, MDs represent a ‘dynamic’ innovation, whose attributes are not well-defined and specified, making trial results difficult to compare and quickly outdated (26,27). This aspect has, in turn, a negative incentive on clinical evidence generation that is usually limited at each stage of an MD lifecycle and less stringent in terms of market approval than pharmaceuticals. Finally, MDs may bring together elements of new technology (i.e., physical innovation) and organizational process changes (i.e., service, staff, professional role) and, in this sense, are more complex to assess than traditional innovations (1,26).

In recent years, there has been a growing interest in the use of non-randomized studies, which are becoming the main source of evidence for assessing MDs (21,26). Real-World Data (RWD) are data related to patient health and/or the delivery of routine clinical practice collected by multiple sources, such as registries, observational studies, health surveys, claims and administrative datasets, electronic health records (EHR), social media, mobile and wearable technologies to which MDs are connected (28–31). The related concept of Real-World Evidence (RWE), i.e., evidence obtained from the analysis of RWD, and the increased conduction of studies using RWE/RWD might satisfy the urgent need for data sharing, traceability, and help to understand the risks and benefits derived from medium and long-term use of MDs in routine clinical practice and current applications (32). Uncertainties and limitations concerning evidence on safety, efficacy/effectiveness, and cost-effectiveness, as well as rate of innovation uptake, are intrinsically linked to the special characteristics of MDs. Only limited and fragmented information is available on real-world performance of new or novel MDs, making challenging understanding what happens in real-life

at different time points of the post-market phase (i.e., adoption, diffusion/monitoring, and obsolescence). Recent public scandals involving MDs after their successful introduction into routine clinical practice have raised medium-term safety concerns about public health showing the urgent need for evidence generation and monitoring (32).

The aim of this study was to provide a detailed overview of published and peer-reviewed practice in post-market assessment of MDs using RWE/RWD. Specifically, we conducted a Systematic Review (SR) and set the following objectives: i) to select application papers reporting on RWE/RWD when assessing post-market MDs; ii) to map the use of RWE/RWD (i.e., evidence type, source, observation time horizon, and aggregation level) throughout MD maturity and type.

2. Materials And Methods

2.1 Literature search

A SR was performed using Ovid MEDLINE (1946–2020, July Week 4), EMBASE (1974–2020, July Week 4), and Scopus (2004–2020, July Week 4) databases. We supplemented this search by performing i) a check on the reference list of the included studies; ii) a search on Google and Google Scholar in the same date of the original search (July 2020, Week 4).

Initial searches were carried out in May 2019 and updated in July 2020 to identify the most up-to-date published research. A search strategy was developed using both subject headings and free-text terms to capture three main concepts: (i) RWE/RWD; (ii) MD or biomedical technology; (iii) post-market assessment strategy, with a special attention to HTA and health economics analyses. Full details of the search strategy, which was developed in consultation with an expert medical librarian at Oxford University, are provided in the **Supplementary file**.

2.2 Inclusion and exclusion criteria

For inclusion, studies were required to be full-text publications of peer-reviewed original research published in English and incorporating RWE/RWD into any sort of post-market assessment strategy for an MD working in real-life conditions. Given the exploratory aim of this research, the authors did not apply restrictions in terms of MD types, clinical specialties, comparators, outcomes, or assessment dimensions. Moreover, studies were retained for further analyses irrespective of whether they assessed post-market performance using one-dimensional or multidimensional evaluation strategies, as well as whether they incorporated RWE/RWD alone or in combination with other data sources. As intended in this SR, one-dimensional evaluation studies were defined as studies focusing on a single assessment dimension (e.g., clinical) among those traditionally included into an HTA strategy. Additionally, RWE/RWD were defined as data collected outside the traditional RCT setting (24,30,33). We subsequently excluded studies designed as RCTs and/or controlled clinical trials, which were categorized as ‘non-RWE’ studies.

2.3 Data extraction

A pilot screening of the first 600 articles was independently undertaken by two pairs of authors (EG and FV) and (MV and SM) to develop a common assessment strategy. A first-round screening of titles and abstracts was followed by a second-round screening of full-text articles. The two rounds of screening were independently conducted by two reviewers (SM and EG), and possible discrepancies over the eligibility were resolved by consensus or through discussions with the senior reviewer (MV) until consensus was reached.

Data extraction was undertaken using a pre-designed data extraction form developed in Microsoft Excel (Excel 2016 for Windows, Microsoft Corporation, Redmond, WA) and iteratively refined to capture the key features of the retrieved publications. More specifically, data extracted from each article included: country, MD type and maturity (i.e., adoption/monitoring), MD risk class, innovation complexity, clinical specialty, funding, evidence aggregation level (i.e., monocentric/multicentric study), comparator (if any), population to be treated, patient sample size, time horizon, evidence generation (i.e., source), methodology, and evidence type(s) incorporated into the evaluation strategy. To classify MDs retrieved from literature, the authors were consistent with (i) the updated European risk classification (34); (ii) the classification of healthcare innovations according to their complexity into ‘discrete or simple innovations’, which may not require new training or redesign of organisational process to be used straightway, and ‘fuzzy or complex innovations’, which bring together elements of new technology and organisational (or service) model changes (1,35). Moreover, the parameters of benefit (param) for which the post-market assessment exercise was undertaken, as well as strengths, limitations, key findings, and study outcomes were extracted and categorised. More specifically, the item ‘study outcome’ was codified according to the following algorithm: i) positive, i.e., statement identifying recommendations to use (or continue to use) the target MD (e.g., cost-effectiveness achieved); (ii) neutral, i.e., statement identifying recommendations to use (or not to use) the target MD, as equal benefits are achieved (e.g., equal costs) versus comparator (e.g., usual care); (iii) negative, i.e., statement identifying recommendations to prefer not to use (or stop the use of) the target MD; (iv) unknown, if recommendations could not be clearly identified as positive/neutral/negative; (v) not identified, if no statement regarding recommendations could be found.

2.4 Data analysis

We employed narrative synthesis to illustrate evidence retrieved from literature. Narrative synthesis, which is based on the application of texts and words to describe literature findings into an appropriate textual narrative, is particularly suitable in cases where a high level of heterogeneity from multiple studies prevents the use of meta-analysis to synthesize evidence (36).

This SR was conducted in line with the Preferred Reporting Items for Systematic reviews and Meta-Analyses Protocols (PRISMA) guidelines in an effort to limit any risk of bias and error (37). Information about internal validity and study quality of the included studies was extracted and assessed using the Quality Appraisal Checklist (38) developed by NICE to review HTA evidence on innovative MDs. The QAC checklist is constituted by 14 items measured on a 3-point

Likert scale. Moreover, a reduced version of the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) guidelines (39) was employed to extract and appraise economic and/or health economic evidence. Finally, an overall score (i.e., “plus plus”, “plus”, “minus”) was recorded for each study considering the fulfilment of the checklist criteria.

3. Results

The literature search identified a total of 6,500 hits, of which 2,011 were duplicates (Fig. 1). A further 3,989 hits were excluded at title and abstract review stage for specific reasons, as outlined in Fig. 1. Overall, 500 articles were assessed for eligibility. A detailed review at the full article review stage further excluded 397 articles, primarily because the articles employed non-RWE sources, assessed non-medical device interventions, and focused on different phases of an MD lifecycle than post-market. Finally, a total of 103 primary research articles were included in the SR.

The temporal trend of the included articles (Fig. 2) highlights, in recent years, the increased interest paid by scientific community to measure post-market performance of new or novel MDs using RWE/RWD sources. Indeed, research articles incorporating RWE sources seem to have kept growing since 2013.

3.1 Types of post-market assessment methods

Quantitative methodologies (n = 84/103 [82%]) represented the most common methods used to assess evidence gathered. Only a limited number of quantitative studies reported decision-analytic models (n = 5/84 [6%]) with any form of sensitivity analyses (i.e., PSA vs deterministic). The remaining selected articles employed mixed (n = 10/103 [11%]) or qualitative methods alone (n = 9/103 [7%]).

3.2 Study recommendations

Only four publications (40–45) reported no statement concerning study recommendations, which were classified as ‘not identified’ (n = 4/103 [4%]). The majority of the selected application papers reported a clear positive recommendation to use or continue to use the MD in routine clinical practice (n = 66/103 [64%]), whereas 18 articles included a study outcome categorised as ‘unknown’, which could not be clearly identified as positive/neutral/negative recommendation (n = 18/103 [17%]). The remaining studies reported negative outcomes (i.e., not use or stop to use the device) (n = 10/103 [10%]) or neutral recommendations on the use of the MD in clinical practice (n = 5/103 [5%]).

3.3 Study characteristics

The use of RWE/RWD (i.e., evidence type, source, time of observation, and aggregation level) was mapped throughout MD maturity and types in each of the included studies (Table 1).

Evidence generated by each study was grouped into i) clinical (88/103 [85%]), which was the most frequently reported; ii) economic (31/103 [30%]); iii) social (31/103 [30%]); iv) organizational (10/103 [10%]); v) human factor (9/103 [9%]); vi) ethical (8/103 [8%]). Frequency of reporting performance indicators specifically for each type of evidence (e.g., efficacy/effectiveness for clinical evidence) is shown in Fig. 3.

The frequencies of using RWE/RWD sources among the selected studies (Fig. 4) showed that observational prospective/retrospective studies were the most frequently reported (n = 53/103 [51%]), followed by claim/administrative databases (n = 26/103 [25%]).

Among the selected publications, the total use of each RWE/RWD source increased over time; for instance, the use of claim/administrative databases tripled from 2010 to 2020. Studies were also grouped into those including a time horizon less than or equal to 1 year (n = 34/103 [33%]), between 1 and 5 years (n = 25/103 [24%]), and greater than or equal to 5 years (n = 34/103 [33%]). In terms of aggregation level, studies mostly reported evidence aggregated at national (n = 44/103 [42%]) or hospital (n = 45/103 [44%]) level. Only few studies were conducted at international (n = 11/103 [11%]), regional level (n = 3/103 [3%]). Among the studies that reported patient samples, samples greater than 300 patients (n = 38/103 [37%]) and samples ranging from 100 to 300 patients (n = 31/103 [30%]) were the most utilized. Publications informed by registries (n = 21/103 [20%]) reported more detailed information of the populations to be treated (e.g., age, gender, comorbidities, habits); however, among these, only few studies (46–50) focused on clinically complex populations and elderly patients.

Studies were grouped according to the MD type into i) therapeutic, - mainly implantable devices -, (n = 62/103 [60%]); ii) diagnostic (n = 21/103 [20%]), and iii) surgical (n = 16/103 [16%]) and monitoring (n = 4/103 [4%]. Of the 16 studies assessing surgical devices, 14 reported general surgical procedures involving the specific MD. The most frequently reported clinical specialty was cardio-vascular (n = 41/103 [40%]), while only a small number of studies were identified for the other specialties (e.g., orthopaedics n = 10/103 [10%]). In terms of MD maturity, the monitoring stage was the most frequently reported (n = 79/103 [77%]). A single MD intervention was assessed by the majority of the selected studies (n = 69/103 [67%]), whereas the remaining studies evaluated two (n = 24/103) [23%]) or three MDs (n = 5/103 [5%]). Only half of the studies were comparative analysis (n = 56/103 [54%]) that mostly utilized a non-MD intervention (i.e., clinical procedures). Only 19 studies employed another MD as comparator, 5 papers no intervention and 1 publication a pharmaceutical intervention. **Table 1** shows a narrative synthesis of the included studies.

Table 1. **The table shows a narrative synthesis of the 103 included studies**

#	Author (s)	Year	Country of focus	Medical Device(s)	Device class	Maturity	Innovation complexity	Evidence source	Evidence type	T c
1	Webb, S. M. et al. (45)	1990	Australia	In vitro-fertilization devices	II	Monitoring	Discrete	Observational studies Electronic Health Records (EHR)	Clinical Economical	5
2	Scott, T. E. et al. (51)	1992	USA	Intraoperative cholangiography (IOC)	II	Monitoring	Discrete	Administrative data Health Surveys Systematic review Expert opinion	Clinical Economical	N r
3	Lawrence, W. F. et al. (52)	1995	USA	Magnetic resonance angiography	II	Monitoring	Discrete	Administrative data Systematic review	Clinical Economical	1
4	Human, D. G. et al. (53)	1995	Canada	Device for nonsurgical closure of patent ductus arteriosus (PDA)	III	Monitoring	Discrete	Observational studies Health Surveys Electronic Health Records (EHR)	Clinical Economical Societal	6
5	Andersson, L. (54)	1996	Sweden	Radiotherapy machines	II	Monitoring	Discrete	Health Surveys Systematic review	Clinical Economical	N r
6	Taylor, R. E. (55)	1997	United Kingdom	Radiotherapy machines	II	Monitoring	Discrete	Observational studies	Clinical	6
7	Givon, U et al. (56)	1998	Israel	Cemented Total Hip Arthroplasty Hybrid Total Hip Arthroplasty HA coated Total Hip Arthroplasty	III	Monitoring	Discrete	Health Surveys Narrative review	Clinical Societal	9
8	Fleisher, L.A. et al. (57)	1988	USA	Intraoperative air warming (FAW)	II	Monitoring	Discrete	Observational studies Health surveys	Clinical Economical Societal	5
9	Pelletier-Fleury, N. et al. (58)	1999	France	Telemonitoring polysomnography device	II	Adoption	Fuzzy	Observational studies	Clinical Organizational	1
10	Ihnat, D. M. et al. (59)	1999	USA	Duplex scan	II	Monitoring	Discrete	Observational studies	Clinical	1
11	Klein, E. E. et al. (60)	1999	USA	Elekta multileaf collimation Siemens multileaf collimation Varian 52-leaf, 80-leaf	III	Monitoring	Discrete	Health surveys	Clinical Societal	5
12	Houbouyan-Reveillard, L. L. et al. (61)	2000	France	Automated immunoturbidimetric D-dimer assays, MDA® D-dimer and STA® Liatest® D-dimer	II	Adoption	Discrete	Observational studies	Clinical Human factor	3

Note: *Public funding; **Mixed funding

#	Author (s)	Year	Country of focus	Medical Device(s)	Device class	Maturity	Innovation complexity	Evidence source	Evidence type	T c
13	Mousiama, T. et al. (62)	2001	Greece	Mammography screening, Prostate Specific Antigen screening Ultrasonography	II	Monitoring	Discrete	Registries Health surveys Systematic review	Clinical	1
14	Bodai, B. I et al. (63)	2001	USA	Vacuum-assisted biopsy (VAB) needle-wire-localized open surgical biopsy	II	Monitoring	Discrete	Administrative data Health Surveys Electronic Health Records (EHR)	Economical	N r
15	Chevallier, J. M. et al. (64)	2002	France	Laparoscopic application of an adjustable gastric band (LAGB)	II	Monitoring	Discrete	Observational studies	Clinical Societal	3
16	Cook, C. H. et al. (65)	2002	USA	Transthoracic echocardiography	III	Monitoring	Discrete	Observational studies	Clinical Economical	4
17**	Ekstein, S. et al. (66)	2002	Israel	Balloon angioplasty Bypass grafting	III	Monitoring	Discrete	Observational studies Electronic Health Records (EHR) Administrative data	Clinical Economical Societal	1
18**	Allen, C. S. et al. (67)	2002	USA	Frequency Double Technology C20-I screening algorithm Humphrey Field Analyser II 24 – 2 SITA-FAST	II	Monitoring	Discrete	Observational studies	Clinical	1
19*	Peiser, J. G. et al. (68)	2002	Israel	Laparoscopic appendectomy	II	Monitoring	Discrete	Observational studies Electronic Health Records (EHR) Administrative data	Clinical	1
20	Napoleone, C. P. et al. (69)	2003	Italy	Aortic coarctation with prosthetic material (Dacron, polytetrafluorethylene or heterologous pericardium)	II	Monitoring	Discrete	Observational studies	Clinical	2
21	Shames, M. L. et al. (70)	2003	USA	Endovascular repair with the AneuRx stent-graft	II	Monitoring	Discrete	Observational studies	Clinical	2
#	Author (s)	Year	Country of focus	Medical Device(s)	Device class	Maturity	Innovation complexity	Evidence source	Evidence type	T c
22**	Briggs, A. et al. (71)	2004	United Kingdom	Charnley and Spectron hip prostheses	III	Adoption	Discrete	Registries Health surveys Observational studies	Clinical Economical Societal	6

Note: *Public funding; **Mixed funding

#	Author (s)	Year	Country of focus	Medical Device(s)	Device class	Maturity	Innovation complexity	Evidence source	Evidence type	T c
23	Rigberg, D. A et al. (72)	2004	USA	Endovascular repair (EVAR)	III	Monitoring	Discrete	Electronic Health Records (EHR)	Clinical	2
24	Taplin, S. H. et al. (73)	2004	USA	Test for cancer screening	II	Monitoring	Discrete	Registries	Clinical	1
25	Kaitelidou, D. et al. (74)	2005	Greece	Hemodialysis machine	III	Monitoring	Discrete	Observational studies Systematic review Expert opinion	Clinical Economical	1
26*	Østensjø, S. et al. (75)	2005	Norway	Assistive devices refer to any item, piece of equipment, or product system that is used to increase, maintain, or improve functioning in people with disabilities (e.g., Orthotic walking systems, manual wheelchair)	II	Monitoring	Discrete	Health surveys	Clinical Economical	1
27	Sheehan, J. J. et al. (76)	2007	United Kingdom	FDG PET	II	Adoption	Discrete	Observational studies	Clinical Human factor	1
28	Burns, L. R. et al. (77)	2007	USA	Clip appliers Internal mechanical and endoscopic-mechanical staplers Trocars (bladed and nonbladed) Sutures and needles Endoscopic specimen retrieval devices	III	Adoption	Discrete	Health surveys	Clinical Human factor	1
29*	Nijdam, W. et al. (78)	2007	The Netherlands	Robotic radiosurgery	II	Monitoring	Fuzzy	Observational studies	Clinical Economical Societal	5
30*	Giansanti, D. et al. (79)	2008	Italy	Wearable device for Parkinson disease	II	Adoption	Fuzzy	Observational studies	Clinical Ethical Societal	2
31	Passerini, R. et al. (80)	2009	Italy	Laboratory-based automated surveillance system	II	Monitoring	Discrete	Observational studies	Clinical Organizational	N r
32*	Kelso, R. L. et al. (81)	2009	USA	Endovascular repair (EVAR)	III	Monitoring	Discrete	Observational studies Registries	Clinical	8
33	Zachrisson, S. et al. (82)	2009	Sweden	CT (Computed tomography) scan	II	Monitoring	Discrete	Observational studies	Clinical Organizational	2
34	Bailey, N. O. et al. (83)	2010	USA	Codman-Hakim Programmable Valve	III	Adoption	Discrete	Observational studies	Clinical Economical	3
35	Hibino, N. et al. (84)	2010	USA	Tissue-engineered vascular grafts	III	Adoption	Discrete	Observational studies	Clinical Societal	5
36	Nelissen, R. G. et al. (85)	2011	The Netherlands	RSA-tested total knee replacements	III	Adoption	Discrete	Administrative data Registries	Clinical Economical	2

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#	Author (s)	Year	Country of focus	Medical Device(s)	Device class	Maturity	Innovation complexity	Evidence source	Evidence type	T c
37	Hong, Y. J. et al. (86)	2011	South Korea	Cypher Select Cypher Select Plus sirolimus-eluting stent (SES)	III	Monitoring	Discrete	Registries	Clinical Societal Human factor	1
38*	Urban, P. et al. (87)	2011	Switzerland	Sirolimus-eluting stents (SES)	III	Monitoring	Discrete	Observational studies Registries	Clinical Societal Human factor	1
39	Grube, E. et al. (88)	2011	The Netherlands	XIENCE V Everolimus-Eluting Coronary Stent	III	Monitoring	Discrete	Observational studies Administrative data	Clinical	1
40*	Weatherly, H. L. et al. (89)	2011	United Kingdom	Continuous positive airway pressure (CPAP) device	II	Monitoring	Discrete	Administrative data Expert opinion Systematic review	Clinical Economical Societal	1
41	Barbaro, S. et al. (90)	2012	Italy	Robot-assisted radical prostatectomy	II	Monitoring	Fuzzy	Observational studies Electronic Health Records (EHR) Systematic review	Clinical Economical Organizational	1
42	Bleyer, A. et al. (91)	2012	USA	Screening mammography	II	Monitoring	Discrete	Registries Health Surveys	Clinical	3
#	Author (s)	Year	Country of focus	Medical Device(s)	Device class	Maturity	Innovation complexity	Evidence source	Evidence type	T c
43*	Gagnon, M. P. et al. (92)	2012	Spain	Home telemonitoring system	II	Adoption	Fuzzy	Health surveys	Organizational Human factor	1
44	Abizaid, A. et al. (46)	2012	USA	Sirolimus-Eluting Cypher SelectCoronary Stent	III	Monitoring	Discrete	Registries	Clinical	1
45	Wu, T. et al. (93)	2013	Taiwan	excimer laser assisted angiography with spot stent excimer laser assisted angiography with primary stenting	III	Monitoring	Discrete	Observational studies	Clinical	2
46	Seth, A. et al. (49)	2013	India	Biolimus (A9) eluting stent	III	Adoption	Discrete	Registries	Clinical	2
47	Lucchini, R. et al. (94)	2013	Italy	Ultrasonic focus dissector	II	Adoption	Discrete	Administrative data	Economical	1
48	Wiegering, A. et al. (95)	2013	Germany	Composix Kugel implantations	III	Adoption	Discrete	Observational studies Administrative data Health surveys	Clinical	5

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#	Author (s)	Year	Country of focus	Medical Device(s)	Device class	Maturity	Innovation complexity	Evidence source	Evidence type	T c
49*	Close, A. et al. (96)	2013	United Kingdom	Robot-assisted laparoscopic prostatectomy	II	Monitoring	Fuzzy	Administrative data Systematic review Other commercial sources	Clinical Economical Societal	1
50	Okura, H. et al. (97)	2013	Japan	Paclitaxel-Eluting Stent	III	Monitoring	Discrete	Observational studies Registries	Clinical Societal	1
51*	Galach, M. et al. (98)	2013	Peritoneal equilibration test	II	Adoption	Discrete	Observational studies	Clinical	1 year	H
52	Mauri, G. et al. (99)	2014	Italy	Intraprocedural contrast-enhanced ultrasound (CEUS)	III	Adoption	Discrete	Observational studies	Clinical Economical Ethical Societal Organizational Human factor	1
53	Grosso, A. et al. (100)	2014	Italy	23 gauge vitrectomy 25 gauge vitrectomy	II	Monitoring	Discrete	Observational studies Administrative data	Clinical Economical	1
54	Löve, A. et al. (101)	2014	Sweden	CT (Computed tomography) scan	II	Monitoring	Discrete	Observational studies	Clinical	N r
55	Ohashi, K. Et al. (102)	2014	USA	3D color volume-rendered (VR) cross-sectional computed tomography (CT)	II	Monitoring	Discrete	Observational studies	Clinical	4
56	Damonti, A. et al. (103)	2015	Italy	Laparoscopy	II	Adoption	Discrete	Administrative data Expert opinion	Clinical Economical Ethical Societal Organizational	1
57	Smedira, N. G. et al. (104)	2015	USA	Hearthmate pump II	III	Monitoring	Discrete	Registries	Clinical	6
58	Brodano, G. B. et al. (105)	2015	Italy	Hydroxyapatite-derived products Bone graft extenders Substitutes for spine fusion	III	Monitoring	Discrete	Observational studies	Clinical	5
59	Patel, R. et al. (106)	2015	USA	Duplex scan	II	Monitoring	Discrete	Observational studies	Clinical	1
60	De Waure, C. et al. (107)	2015	Italy	Therokos online extracorporeal photopheresis	III	Adoption	Discrete	Administrative data Health surveys Systematic review	Clinical Economical	7

Note: *Public funding; **Mixed funding

#	Author (s)	Year	Country of focus	Medical Device(s)	Device class	Maturity	Innovation complexity	Evidence source	Evidence type	T c
61	Tremaine, A. M. et al. (108)	2015	USA	Alexandrite, Cryolipolysis;diode, Focused ultrasound, fractional resurfacing, intense pulsed light, laser hair removal, pulsed dye laser;microwave technology, Nd:YAG, radiofrequency	II	Monitoring	Discrete	Administrative data	Clinical	1
62	Brügger, U. et al. (109)	2015	Switzerland	Hand prothesis	III	Adoption	Discrete	Administrative data Registries Expert opinion Systematic review	Clinical Economical Ethical Societal Organizational	N r
63	Tsilimparis, N. et al. (44)	2015	USA	Zenith endograft	III	Monitoring	Discrete	Observational studies	Clinical	5
64	Luchetti, M. et al. (110)	2015	Italy	New “handwrist system” Michelangelo, hand prothesis	III	Monitoring	Discrete	Health surveys	Clinical Societal	1
65	Pillay, B et al. (111)	2016	South Africa	Stent graft Covered stent	III	Monitoring	Discrete	Electronic Health Records (EHR)	Clinical	N r
#	Author (s)	Year	Country of focus	Medical Device(s)	Device class	Maturity	Innovation complexity	Evidence source	Evidence type	T c
66	Okumura, K. et al. (112)	2016	Japan	Cryoballoon Ablation	III	Monitoring	Discrete	Observational studies	Clinical	1
67	Good, E. D. et al. (48)	2016	USA	Linox ICD (Implantable Cardioverter-defibrillator) Linox Smart ICD	III	Monitoring	Discrete	Registries	Clinical	5
68	Yokoi, Y. et al. (113)	2016	Japan	Paclitaxel-coated Zilver PTX stent	III	Monitoring	Discrete	Observational studies	Clinical	1
69	Kahn, J. et al. (114)	2016	Germany	CT (Computed tomography) scan	II	Monitoring	Discrete	Observational studies	Clinical	2
70	Sorajja, P. et al. (115)	2017	USA	Transcatheter Mitral Valve Repair	III	Monitoring	Discrete	Registries Administrative data	Clinical Societal	1
71	Radziszewski, M. et al. (116)	2017	Poland	Hemiarthroplasty devices	III	Adoption	Discrete	Electronic Health Records (EHR)	Clinical Societal	2
72	Ogawa, Y. et al. (117)	2017	Japan	Paclitaxel-coated Zilver PTX stent	III	Monitoring	Discrete	Observational studies	Clinical Societal	2
73	Kwon, Y. et al. (118)	2017	South Korea	Endoscopic submucosal dissection (ESD)	II	Monitoring	Discrete	Observational studies Expert opinion	Clinical	3
74	Beck, A. W. et al. (119)	2017	USA	Thoracic endovascular aortic repair (TEVAR)	III	Monitoring	Discrete	Observational studies	Clinical	5
75*	Varabyova, Y. et al. (120)	2017	Germany	Endovascular aneurysm repairs (EVAR)	III	Monitoring	Discrete	Administrative data Systematic review	Clinical Economical Societal	7

Note: *Public funding; **Mixed funding

#	Author (s)	Year	Country of focus	Medical Device(s)	Device class	Maturity	Innovation complexity	Evidence source	Evidence type	T c
76	Ryan, M. et al. (121)	2017	United Kingdom	Stent grafts	III	Adoption	Discrete	Health surveys Expert opinion	Clinical Economical Human factor	N r
77*	Turchetti, G. et al. (122)	2017	Italy	Robotic surgical system (RSS)	II	Monitoring	Fuzzy	Observational studies Health surveys Systematic review	Economical Societal Organizational	3
78	Seo, M. et al. (123)	2017	South Korea	Endoscopic surgery	II	Monitoring	Discrete	Electronic Health Records (EHR)	Clinical	N r
79**	Gregori, N. Z. et al. (41)	2018	USA	Argus II Implantation	III	Monitoring	Discrete	Observational studies	Clinical	1
80	Cipollari, S. et al. (124)	2018	Japan	Zilver PTX Drug-Eluting Stent	III	Monitoring	Discrete	Observational studies	Clinical	2
81	Yu, W. et al. (125)	2018	USA	Stent grafts	III	Monitoring	Discrete	Observational studies Registries	Clinical	3
82	Young, C. et al. (126)	2018	United Kingdom	Aortic valve replacement	III	Monitoring	Discrete	Observational studies	Clinical	2
83*	Dinesh, T. A. at al. (127)	2018	India	Robotic surgical system (RSS)	II	Monitoring	Fuzzy	Observational studies	Clinical Economical	2
84	McElhinney, D. B. et al. (128)	2018	USA	Transcatheter pulmonary valve replacement (TPVR)	III	Adoption	Discrete	Observational studies	Clinical	5
85	Shemesh, S. S. et al. (129)	2019	USA	Bone treated with intralesional currettage (IC)	III	Monitoring	Discrete	Electronic Health Records (EHR)	Clinical	2
86	Setford, S. et al. (130)	2019	United Kingdom	Haematocrit-intensive blood glucose test strip	II	Monitoring	Discrete	Administrative data	Clinical	3
87	Alexander, M. J. et al. (131)	2019	USA	Wingspan stent system	III	Monitoring	Discrete	Registries	Clinical	6
88	Tasca, G. et al. (50)	2019	Italy	CARDIOROOT vascular graft	III	Monitoring	Discrete	Registries	Clinical	4
89	Lambers, A. et al. (40)	2019	Australia	TFNA Proximal Femoral Nailing System	III	Monitoring	Discrete	Administrative data	Clinical	2
90	Mckee, J. L. et al. (132)	2019	Canada	iTClamp, bleeding control device	II	Monitoring	Discrete	Administrative data Case report	Clinical	3
91	Kichikawa, K. et al. (133)	2019	Japan	Zilver PTX Drug-Eluting Stent	III	Monitoring	Discrete	Observational studies	Clinical	1
92	Thygesen, M. K. et al. (134)	2019	Denmark	Colonoscopy Colon capsule endoscopy	II	Adoption	Discrete	Health surveys	Clinical Ethical Societal	1
93	Pelt, C. E. et al. (135)	2019	USA	Bicruciate retainig TKA	III	Monitoring	Discrete	Observational studies	Clinical Societal	3
#	Author (s)	Year	Country of focus	Medical Device(s)	Device class	Maturity	Innovation complexity	Evidence source	Evidence type	T c
94	Latz, C. A. et al. (136)	2019	USA	Stent graft	II	Monitoring	Discrete	Observational studies	Clinical	2

Note: *Public funding; **Mixed funding

#	Author (s)	Year	Country of focus	Medical Device(s)	Device class	Maturity	Innovation complexity	Evidence source	Evidence type	T c
95**	Sieniewicz, B. J. et al. (137)	2020	United Kingdom	WISE-CRT system	II	Monitoring	Discrete	Registries	Clinical	1
96**	Oliveira-Pinto, J. et al. (138)	2020	The Netherlands	Endurant (Medtronic) device, Endovascular aneurysm repair (EVAR)	III	Monitoring	Discrete	Observational studies	Clinical	1
97	Bauser-Heaton, H. et al. (139)	2020	USA	PDA stenting	III	Monitoring	Discrete	Observational studies	Clinical	9
98	Dake, M. D. et al. (47)	2020	USA	Zilver PTX Drug-Eluting Stent	III	Monitoring	Discrete	Registries	Clinical	3
99	Xu, Z. et al. (140)	2020	USA	HeartWare Ventricular Assist Device HearthMate II	III	Monitoring	Discrete	Administrative data	Clinical	1
100	White, A. B. et al. (141)	2020	USA	Single-incision Solyx Obtryx II	II	Monitoring	Discrete	Observational studies	Clinical Societal	3
101	Inoue, S. et al. (142)	2020	Japan	Transcatheter Aortic Valve Implantation	III	Monitoring	Discrete	Administrative data Systematic review Expert opinion	Clinical Economical Societal	N r
102	Vettoretto, N. et al. (143)	2020	Italy	Fluorescence-guided surgery	II	Adoption	Discrete	Health Surveys	Clinical Economical Ethical Societal Organizational	1
103	Horup, M. B. et al. (144)	2020	Denmark	Alternating-air mattresses	II	Adoption	Discrete	Health Surveys	Clinical Ethical Societal Organizational	1

Note: *Public funding; **Mixed funding

3.5 Appraisal of the included studies

Quality assessment revealed considerable heterogeneity. More than half of the selected studies (n = 73/103 [70%]) were rated “minus” (low study quality) because few or no checklist criteria were fulfilled. Some of the checklist criteria were fulfilled by 27% (n = 28/103 [27%]) of the selected publications, which were classified as good quality studies (“plus”). Only two of the included studies (71,96) met all or most of the checklist criteria and were classified as excellent quality studies (“plus plus”). A synthesis of the quality assessment is shown in the **Supplementary file**.

4. Discussion

In this review, we described the incorporation of RWE/RWD into post-market assessment of MDs, and we identified limits, opportunities, and implications of current practices for RWE/RWD generation to guide future research.

Multisource evidence based on non-randomized evidence is increasingly being utilised to inform decisions on the introduction and use of healthcare innovations (21,145,146). The review confirmed the increasing reporting of RWE/RWD as the main source of evidence for MDs while highlighting differences in non-randomized evidence generation across time. Claim and/or administrative databases were mostly utilized in the setting of observational studies, associated with multidimensional post-market assessment strategies, and their use tripled between 2010 and 2019, whereas registries were mostly reported by mono-dimensional clinical studies and their use was limited while keeping growing since 2013.

The review also revealed that all publications were ‘one shot’ and ‘ad hoc’ studies, as no study was part of a continuous nor periodical post-market monitoring strategy. Moreover, the key limitations identified across all the retrieved publications included: i) adoption of a narrow approach to the post-market assessment with a focus on a limited number of evidence types, i.e., two dimensions at maximum (n = 81/103 [79%]); ii) stress on clinical and/or economic evidence gathered in a short/medium time horizon (between 1 and 5 years); iii) little attention to other relevant evidence dimensions for an MD working in real-life

conditions, such as contextual influence and organizational impact; iv) very limited incorporation of patient perspectives and preference; v) focus on MDs with a relatively low innovation complexity.

Even though in recent years there has been an increasing understanding of the need to seek a broader approach by considering additional parameters of benefit to the traditional ones (i.e., clinical and/or economic), only few publications assessed organizational requirements and/or human factors, which were reduced to usability and/or acceptability excluding a considerable contribution to the assessment in terms of human efficacy and effectiveness (19,147–150). Moreover, the majority of the retrieved studies investigated short (up to 1 year) and/or medium-term (between 1 and 5 years) impact, which may be insufficient to observe longer events related with the MD usage alongside current applications and clinical pathways. Recent public scandals of MDs after their successful introduction into clinical routine practice raised concerns about public health and hopes are addressed to the new European Directive of MDs that should come into force by March 2020 leading to more stringent requirements of evidence generation, including a continuous and systematic life cycle assessment of the devices to overcome limitations of “one-shot” and short-term studies (151–153). This review showed that there has been an overemphasis on researching and assessing well-defined, clearly bounded innovations (i.e., relative ‘discrete’ or simple MDs) being adopted by a single organizational unit (i.e., single hospital or team) rather than complex innovations, which bring together technology and organizational or service changes.

This SR further revealed substantial heterogeneity in terms of study quality. Firstly, all the 40 publications classified as observational studies did not mention the type(s) of RWE source employed to conduct the study. This may lead to confusion between two separate concepts: data source (e.g., registry) and study design (e.g., observational study), as previously highlighted by Makady and colleagues (154). Second, of the 94 retrieved publications including the health economic dimension, only 50 studies specified the decision analytic model used and/or conducted sensitivity analysis. Third, 25 publications did not report the patient sample size. Overall, we documented a general lack of conformity with good practices and little attention to manage decision-making uncertainty.

It should be stressed a general lack of inclusion of patient characteristics, preferences, and other relevant user perspectives. Only 21% of the retrieved publications included Patient Reported Outcome Measures (PROMs) in the form of quality-of-life and/or pain assessment data, mainly assessed using standardised generic questionnaires, such as EuroQoL five dimensions (EQ-5D). Few publications (7%) included Patient Reported Experience Measures (PREMs), mostly evaluated through open interviews.

To our knowledge, this review is one of the first attempt to systematize key features, empirical uses, and quality of RWE/RWD studies across time in response to the increasing attention paid by scientific community when assessing post-market MDs. A strength of this study is that it is consistent with the PRISMA guidelines and followed its checklist to pilot reporting extracted features from the included studies. This SR also revealed that all publications were ‘one shot’ studies and there was huge heterogeneity in terms of evidence generation, MD type and clinical application, as well as study quality. Potential limitations include the English language, which affected the geographical distribution of the results, as most of the included studies come from English speaking countries (e.g., UK and Canada). The grey literature encompassing non-peer-reviewed publications, such HTA reports, was also excluded, which may limit the comprehensiveness of the review. Therefore, for some innovations regional and/or national bodies act as “gatekeepers” to the health system by gathering evidence and produce HTA reports written in local languages (e.g., French, German etc.). In addition to this, the authors faced with substantial publication biases. The review confirmed that almost all post-market studies funded by private bodies reported a clear positive outcome of the study. Health economic analyses are generally not reported by HTA bodies and come from private funders (155). The authors expect that such analyses are only published when the outcome is positive (i.e., publication bias). The previous limitations prevent the authors to take a definitive picture of the current practices in post-market assessment of MDs and make comparisons across regions.

5. Conclusions

The use of non-randomized evidence is growing steadily when assessing post-market MDs (21,26). Indeed, RWE/RWD are particularly relevant for MDs because of their peculiarities, such as user-dependency. In fact, uncertainties and limitations concerning evidence on safety, efficacy/effectiveness, and cost-effectiveness, as well as the rate of innovation uptake, are intrinsically linked to the unique challenges of MDs compared to traditional health technologies, such as drugs and pharmaceuticals. To the best of our knowledge, despite the large use of non-randomized evidence when assessing MDs, empirical studies and reviews focusing on a specific device and/or a target clinical area have already been published, however a comprehensive picture on the current practice and the implications of using real-world evidence to inform policy decisions is currently lacking. In this sense, our study is the first in its kind to provide a holistic picture of how non-randomized evidence has been used when assessing MDs working in real-life conditions. This review seeks to provide an empirical-based foundation for the use of RWE/RWD in adopting, monitoring, and assessing post-market performance of new or novel MDs alongside clinical routine practice. Our findings led the authors to draw some policy implications addressed to governments and healthcare organizations.

Firstly, the review highlighted the need for a shift from “ad hoc” and “one-shot” studies to monitoring systems that allow the continuous performance assessment of post-market MDs. Indeed, the variability in the quality of care, access, equity, and the financial aspects related to the use of MDs across countries, regions or hospitals and health organizations can be observed and reduced if the monitoring system is continuous and systematic using a benchmarking approach. This can lead to a continuous RWE/RWD generation alongside clinical routine practice, prevent public safety scandals, as well as ensure a fairer allocation of health resources. Hence, we recommend to include MD performance indicators with a population-based perspective into wider performance evaluation systems at healthcare pathway level (see, for instance, the Italian experience of measuring the performance path (156)).

Secondly, the review highlighted that at maximum one third of the included studies deals with a medium-long time horizon (i.e., greater than 5 years). It should be stressed that the adoption of a short time window may be insufficient to observe longer events related with the MD usage alongside current applications, especially for implantable devices, whose side effects on safety and effectiveness are little known during adoption. For specific types of MDs (e.g., TAVI), healthcare organizations activated devices’ registries and traceability systems, however no evidence in terms of iterative or periodical assessment has been found in the literature retrieved.

Thirdly, health managers and policy-makers might finance more multidimensional assessment studies, focus on more innovative MDs (e.g., telemedicine) that require significant organizational changes into current frameworks, as well as promote more publicly funded RWE/RWD studies. Encouraging public research on post-market assessment/monitoring is desirable not only to increase knowledge into MDs' routinary use and applications but also to generate independent evidence that ensure more transparency of the results obtained. Indeed, studies funded by public bodies can contribute to generating evidence for MDs' "non-use", which is currently lacking.

Furthermore, a research agenda has been identified for research scholars aiming to increase efficacy and quality of evidence generation in post-market phases with a population-based approach. Future research is needed to close the gaps highlighted by this review. In particular, scholars are asked to i) close the evidence gap between RCT and real-world by continue to conduct real-life assessment studies; ii) shift their research efforts on more complex or fuzzy boundaries innovations involving multiple changes to healthcare practices and targeted at service and/or professional role redesign; iii) incorporate the personal value in future RWE/RWD studies, i.e., the value determined by the fit between the study outcome and the individual user including patient value (156–160); iv) generate more multidimensional evidence on both MDs' use and "non-use"; v) consider also to provide evidence on the last stage of MDs maturity, such as obsolescence and replacement, which are under-investigated by scientific literature. Although it might be an issue covered by grey literature and reports, it could be relevant to have an overview of the MDs that are disinvested, replaced, or re-adopted/re-allocated in other clinical settings.

Declarations

Ethics approval and consent to participate. All the methods were in accordance with the declaration of Helsinki/ relevant national/institutional guidelines.

Consent for publication. Not required.

Availability of data and materials. The datasets analyzed are available from the corresponding author upon reasonable request.

Competing interests. None declared.

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Authors' contributions. Stefania Manetti (SM) designed the paper with the supervision of Milena Vainieri (MV). SM and Elisa Guidotti (EG) performed data selection and screening. EG performed the quantitative analyses. EG and SM drafted the manuscript. All the authors contributed to the interpretation of results. Federico Vola (FV) and MV critically revised the whole work. All the authors gave the final approval of the version to be published.

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Figures

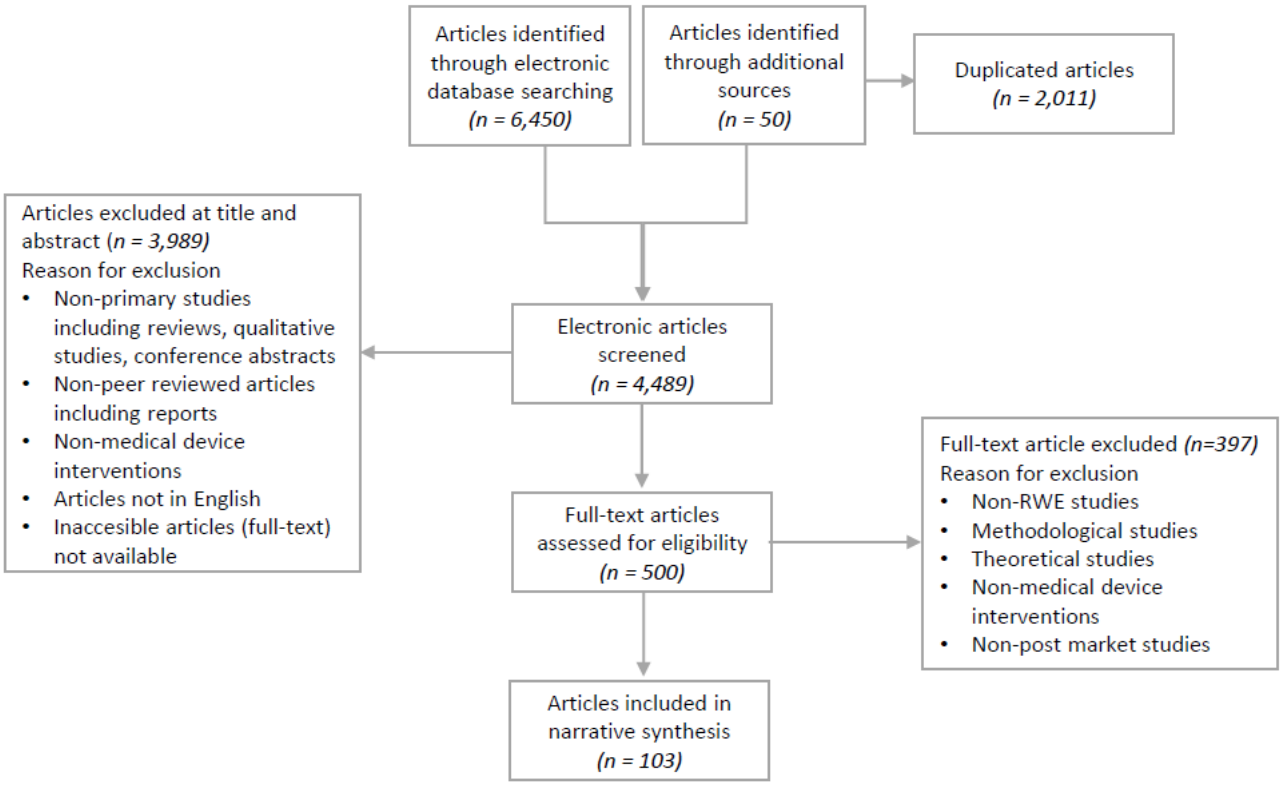

Figure 1

PRISMA flow chart showing the process of paper screening for this review.

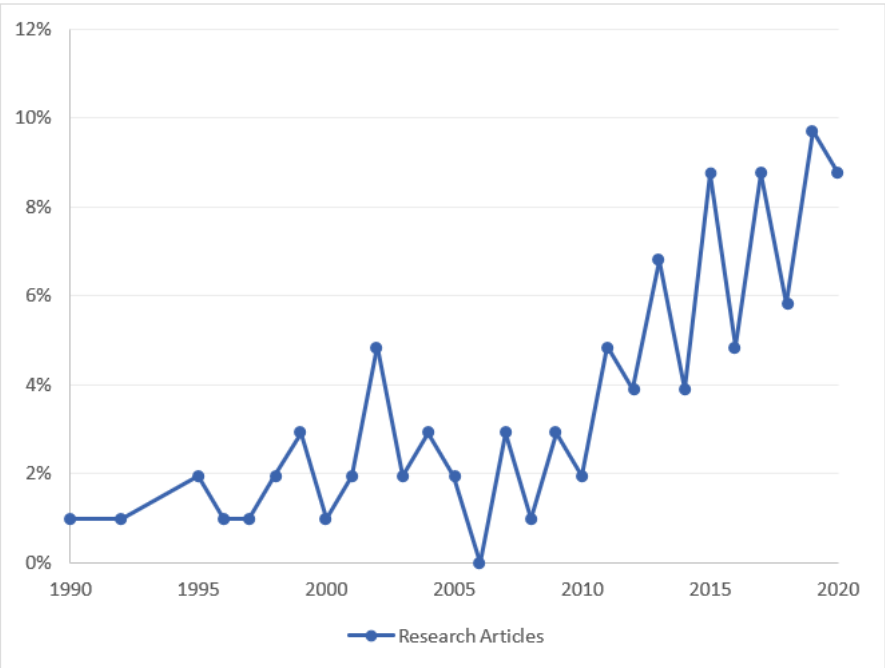

Figure 2

Temporal trend of the included articles identified from the Ovid Medline, Scopus, and Embase databases for each year between January 1990 and July 2020.

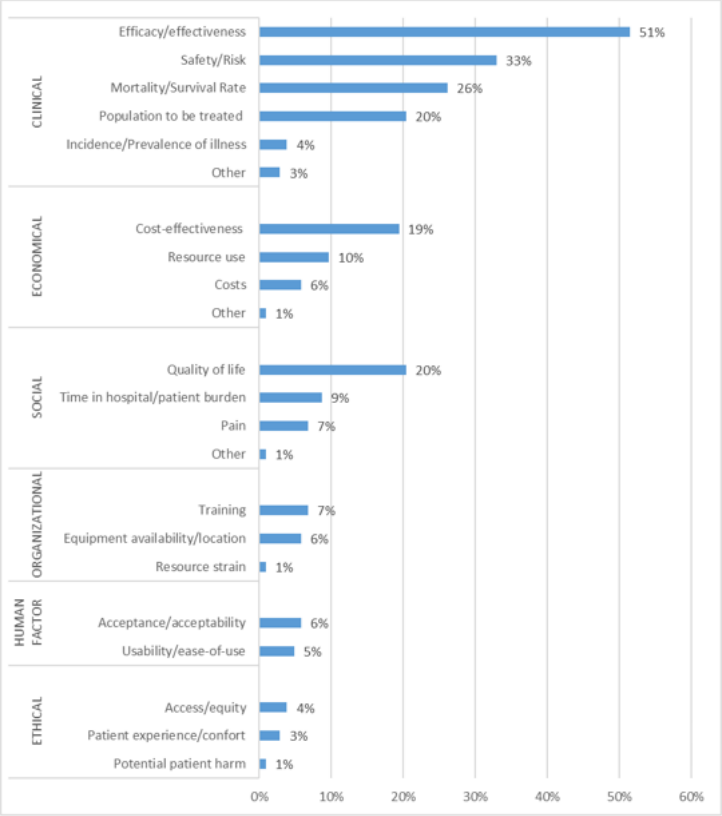

Figure 3

Performance indicators analysed for each HTA dimension incorporated in the included studies

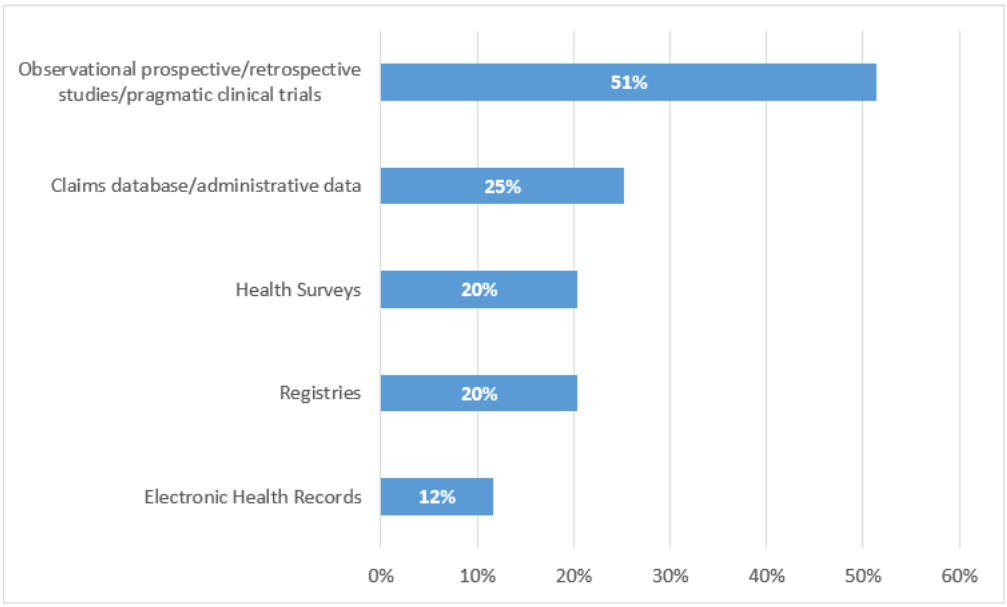

Figure 4

RWE sources employed by the included studies

Supplementary Files

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